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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	Position of the Council at first reading with a view to the adoption of a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006 – Adopted by the Council on 28 September 2026

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REGULATION (EU) 2026/…
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of …

laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[2],

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[1] OJ C, C/2024/879, 6.2.2024, ELI: http://data.europa.eu/eli/C/2024/879/oj.

[2] Position of the European Parliament of 10 April 2024 (OJ C, C/2025/1329, 13.3.2025, ELI: http://data.europa.eu/eli/C/2025/1329/oj) and position of the Council at first reading of 28 September 2026 (not yet published in the Official Journal). Position of the European Parliament of … (not yet published in the Official Journal).

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Whereas:

(1) The Union pharmaceutical legislation for centrally authorised medicinal products, laid down in, inter alia, Regulations (EC) No 141/2000[3], (EC) No 726/2004[4] and (EC) No 1901/2006[5] of the European Parliament and of the Council, has enabled the authorisation of high-quality, safe and efficacious medicinal products in the Union, contributing to a high level of public health and the smooth functioning of the internal market for those products.

(2) The 'Pharmaceutical Strategy for Europe' adopted by the Commission in its communication of 25 November 2020 marks a turning point, with the addition of further key objectives. It aims to create an attractive environment for research, development and production of medicinal products in the Union, together with a modern framework that makes innovative and established medicinal products available to patients and healthcare systems at affordable prices. It also aims to strengthen the fight against shortages of medicinal products, ensure security of supply and address environmental concerns.

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[3] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1, ELI: http://data.europa.eu/eli/reg/2000/141/oj).

[4] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj).

[5] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1901/oj).

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(3) Ensuring that patients receive the medicinal products they need, when they need them, regardless of where they live in the Union, is a central objective of the Commission's approach as set out in its communication of 22 May 2024 entitled 'The European Health Union: acting together for people's health'. Ensuring the competitiveness of the European pharmaceutical industry, whilst providing better availability of medicinal products and more equal and timely access for patients, is a key objective of the Union pharmaceutical reform, as proposed by the Commission in April 2023.

(4) Commission communication of 24 October 2023 entitled 'Addressing medicine shortages in the EU' outlined key measures aimed at addressing critical shortages of medicinal products and strengthening security of supply in the Union in anticipation of the measures provided for in a revised pharmaceutical regulation. Among other things, that communication envisaged a first informal Union list of critical medicinal products and the launch of a European voluntary solidarity mechanism for medicinal products allowing Member States to request support from another Member State and redistribution of available stocks in the event of shortage.

(5) Addressing unequal patient access to medicinal products has become a key priority of the Pharmaceutical Strategy for Europe as has been highlighted by the Council and the European Parliament. Member States and the European Parliament have called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring a transparent process, patient access to medicinal products, and availability as well as affordability of medicinal products in all Member States.

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(6) Previous amendments to the Union pharmaceutical legislation have addressed access to medicinal products by providing for accelerated assessment of marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products to meet unmet medical needs. While these measures accelerated the authorisation of innovative and promising therapies in some areas, the medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicinal products. In addition, many unaddressed public health priorities remain.

(7) The COVID-19 pandemic further underlined critical issues, which require a reform of the Union pharmaceutical legislation to strengthen its resilience, while improving the availability of medicinal products and ensuring that it contributes to public health needs and serves the people under all circumstances.

(8) For the sake of legal clarity and simplification, and having regard to the need to reform the Union pharmaceutical legislation, the legal provisions applicable to centrally authorised medicinal products should be integrated into a new Regulation.

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(9) Veterinary medicinal products are governed by Regulation (EU) 2019/6 of the European Parliament and of the Council[6]. Those medicinal products fall outside the scope of this Regulation, except for certain provisions on the governance and general tasks of the European Medicines Agency (the 'Agency') set out in this Regulation that still apply to them. The Agency's specific tasks concerning veterinary medicinal products are laid down in Regulation (EU) 2019/6 and Regulation (EC) No 470/2009 of the European Parliament and of the Council[7].

(10) Without prejudice to the provisions laid down in Regulation (EU) 2019/6, which remain applicable for veterinary medicinal products, in order to create greater legal certainty, this Regulation should set certain conditions for placing on the market medicinal products authorised by the Union, confer on the Agency powers to monitor the distribution of medicinal products authorised by the Union, define the responsibilities regarding the transparency rules for the Agency's work and, in the event of failure to observe this Regulation and the conditions contained in the marketing authorisations granted under the procedures it establishes, specify the sanctions and the procedures for implementing them.

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6 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/oj).

7 Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11, ELI: http://data.europa.eu/eli/reg/2009/470/oj).

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(11) It is necessary to provide for the coordinated implementation of Union procedures for the marketing authorisation of medicinal products, and of Member States procedures for the marketing authorisation which have already been harmonised to a considerable degree by Directive (EU) 2026/… of the European Parliament and of the Council[8+].

(12) The scope of this Regulation with regard to centrally authorised medicinal products needs to be adapted to the realities of the market and technological development as well as to the need to ensure a centralised evaluation of certain categories of medicinal products. In the light of the Commission's report of 31 August 2021, addressed to the European Parliament and the Council, on the experience acquired with the procedures for authorising and supervising medicinal products for human use, it has proved necessary to improve the functioning of the marketing authorisation procedures for the placing of medicinal products on the internal market and to amend certain administrative aspects of the Agency. In addition, the regulatory framework should be adapted to the current market conditions and economic reality, while continuing to safeguard a high level of protection of public health and the environment. It emerges from the report that certain operating procedures need to be corrected and adapted in order to take account of scientific and technological development. It also emerges from the report that the previously established general principles which govern the centralised marketing authorisation procedure ('centralised procedure') should be maintained.

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8 Directive (EU) 2026/… of the European Parliament and of the Council of … on the Union code relating to medicinal products for human use, and repealing Directives 2001/83/EC and 2009/35/EC (OJ L, …, ELI: …).

+ OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Directive, including its ELI number.

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(13) As regards the scope of this Regulation, the authorisation of antimicrobials at Union level is in the interest of patients' health and therefore it should be made possible to authorise them through the centralised procedure.

(14) Medicinal products for rare diseases and for children should be subject to the same provisions as any other medicinal product concerning their quality, safety and efficacy, for example as regards the marketing authorisation procedures and the pharmacovigilance, quality and environmental risk assessment requirements. However, specific requirements also apply to them. Such requirements, which are currently laid down in separate legislative acts, should be integrated into this Regulation in order to ensure the clarity and coherence of all the measures applicable to such medicinal products.

(15) With a view to maintaining a high level of scientific evaluation for new medicinal products and medicinal products that will serve the entire Union population, the centralised procedure should be mandatory for high-technological medicinal products, particularly those resulting from biotechnological processes, and for advanced therapy medicinal products, priority antimicrobials, orphan medicinal products, medicinal products authorised in accordance with paediatric use marketing authorisation and any medicinal product containing a new active substance. In addition, the mandatory scope of the centralised procedure should be aligned with that provided for in Regulation (EC) No 726/2004. Accordingly, it should continue to apply to medicinal products containing a new active substance authorised between 20 May 2004 and the date of application of this Regulation, for the indications listed in Annex I to this Regulation.

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(16) For medicinal products for human use, optional access to the centralised procedure should also be provided for where a single procedure offers added value for patients. The centralised procedure should remain optional for medicinal products that do not fall within categories subject to centralised marketing authorisation but are nonetheless therapeutically innovative. It is appropriate to extend access to that procedure to medicinal products that, while not necessarily innovative, could still provide benefits to society or to patients, including paediatric patients, especially if they are authorised at Union level from the outset, such as certain medicinal products which can be dispensed without a medical prescription. This option could be extended to generic medicinal products and biosimilar medicinal products authorised by the Union, provided that this does not undermine harmonisation achieved when the reference medicinal product was evaluated nor the results of that evaluation. At the same time, to ensure wide availability of generic medicinal products, it is possible for those medicinal products to be authorised by the competent authorities of the Member States, even if they are based on a centrally authorised reference medicinal product.

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(17) The Court of Justice of the European Union (hereafter ‘the Court’) has on numerous occasions held that the health and life of humans rank foremost among the assets and interests protected by the Treaties. According to the Charter of Fundamental Rights of the European Union (the ‘Charter’), a high level of human health protection is to be ensured in the definition and implementation of all the Union’s policies and activities. The centralised procedure ensures a high standard of scientific evaluation and delivers significant benefits to the Union’s patient population, particularly regarding innovative medicinal products that can improve prevention, diagnosis and treatment of diseases and patients’ lives. In addition to its objective of guaranteeing a high level of protection of public health at Union level, the centralised procedure also brings greater clarity and efficiency to the Union’s authorisation system. This allows the marketing authorisation applicant (the ‘applicant’) of such medicinal products to benefit from easier and harmonised access to the internal market. However, these innovative medicinal products are often unevenly available across the Union. This results in different levels of patient access depending on the Member State in which patients live. While fully respecting fundamental rights and without prejudice to the provisions of the Treaties, including provisions on the free movement of goods and common rules on competition, it is essential that marketing authorisation holders who obtain a centralised marketing authorisation for such medicinal products make every effort to place them on the market in all Member States.

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In light of the fact that medicinal products are key for a broad and good therapeutic offer to patients in the Union, this is necessary to maintain a high level of public health protection across the Union, remove obstacles within the internal market and to strengthen Union-wide access to these products. Marketing authorisation holders should, in addition to complying with national legislation and procedures aiming at placing on the market and supplying medicinal products at national level, also make their best efforts in complying with the specific requirements on placing on the market and supplying a medicinal product in a Member State provided for by Directive (EU) 2026/…[+] that allow Member States to signal directly to companies their interest to have supply of a specific new medicinal product. Accordingly, a marketing authorisation holder for a medicinal product authorised through the centralised procedure which is subject to regulatory protection or intellectual property rights, should ensure that the medicinal product is placed on the market and supplied in accordance with the needs of patient populations across all Member States. This obligation, however, is neither to compromise the financial viability of the company nor to be considered breached where external factors beyond the company's control make supply in all Member States impossible.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(18) The establishment of the Agency by means of Council Regulation (EEC) No 2309/93[9], which was repealed by Regulation (EC) No 726/2004, has made it possible to reinforce the scientific evaluation and monitoring of medicinal products in the Union, in particular through its scientific bodies and committees for which competent authorities of the Member States provide experts and expertise, ensuring a high quality and independent assessment. As this Regulation serves to replace Regulation (EC) No 726/2004, the Agency, previously established under Regulation (EC) No 726/2004, should continue to function under this Regulation.

(19) Experience with the functioning of the regulatory system has shown that the existing Agency multi-scientific committee structure often creates complexity in the scientific assessment process among committees, duplication of work and non-optimised use of expertise and resources. In addition, the Agency and the competent authorities of the Member States are confronted with challenges related to limited capacity and appropriate expertise to deal with increasing number of procedures related to existing medicinal products and assessment of new ones, in particular cutting edge innovative and complex medicinal products.

(20) Scientific committees, such as the Committee for Advanced Therapies, have been instrumental to ensure expertise and capacity building in an emerging technological field. However, after more than 15 years, advanced therapy medicinal products are now more common. The integration of their assessment in the work of the Committee for Medicinal Products for Human Use will facilitate the scientific evaluation of medicinal products within the same therapeutic class, regardless of the technology on which they are based.

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[9] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medic inal Products (OJ L 214, 24.8.1993, p. 1, ELI: http://data.europa.eu/eli/reg/1993/2309/oj).

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(21) To optimise the functioning and efficiency of the regulatory system, the structure of the Agency's scientific committees is simplified and reduced to two main committees for medicinal products for human use, namely the Committee for Medicinal Products for Human Use and Pharmacovigilance Risk Assessment Committee.

(22) The simplification of procedures should not have an impact on standards or the quality of scientific evaluation of the medicinal products to guarantee the quality, safety and efficacy of medicinal products. It should also allow for the reduction of the scientific evaluation period from 210 days to 180 days.

(23) The Agency's scientific committees should be supported, in relation to their evaluation duties, by working parties, whilst retaining complete responsibility for the scientific opinions issued by them. Those working parties should be open to experts from the scientific world appointed for that purpose.

(24) The Agency and its committees should, where necessary, establish the appropriate working parties to ensure the appropriate expertise for the evaluation of medicinal products, including an Environmental Risk Assessment working party. That working party should have the scientific expertise necessary to characterise and assess the environmental risks, and the mitigation measures for such risks, related to the use and disposal of medicinal products.

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(25) The expertise of the Committee for Advanced Therapies, the Committee for Orphan Medicinal Products, the Paediatric Committee and Committee for Herbal Medicinal Products is retained through working groups, working parties, advisory groups, and a pool of experts who are organised based on different areas of expertise and who are giving input to the Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee. This structure gives the possibility for the Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee to call upon additional scientific experts to provide specific input and advice on specific aspects raised during the evaluation. In addition, patients and healthcare professionals can be part of the pool of experts based on their expertise. The Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee consist of experts from all Member States while working parties and expert groups consist in majority of experts appointed by the Member States, based on their expertise, and, if necessary, of external experts. The model of rapporteurs remains unchanged. The efficiency gain, involvement of appropriate scientific expertise and broad geographic representation of experts in the scientific committees, working parties and working groups will be ensured as part of the strategy for the organisational management and internal control systems. Representation of patients and health-care professionals, with expertise in a wide range of areas, including rare and paediatric diseases, is assured at the Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee, in addition to the dedicated working groups representing patients and health-care professionals. Information regarding the composition and work of the committees, working parties and working groups, should be publicly available.

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(26) It is crucial not only that the expertise of experts be preserved within working groups, working parties and a pool of experts, but also that the relevant expertise be expanded to cover emerging technologies, incorporate expertise from a broader range of Member States and enable the Agency to continue fulfilling its obligations at the highest scientific level. It is also essential for experts to be able to share knowledge, expand their skills through training programmes, such as those offered by the EU Network Training Centre, and engage in on-the-job learning activities, including through shadowing rapporteurs, mentoring, and participating in discussions on topics of interest in working parties, European scientific expert groups, and other relevant fora.

(27) The Agency's scientific committees field of activity should be enlarged and their operating methods and composition modernised. Therefore it is important to ensure patient and healthcare professional representation in the Committee for Medicinal Products for Human Use as it is the main evaluation committee of the Agency.

(28) The Committee for Medicinal Products for Human Use should be exclusively responsible for preparing the Agency's opinions on all questions concerning medicinal products for human use.

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(29) The patients and healthcare professionals representatives, for both the Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee, should be selected by the Commission, based on a public call for expressions of interest. Healthcare professionals can be represented by doctors and pharmacists. The appointment of such representatives should ensure there is a well-balanced representation of medical specialties and diseases amongst appointed members and alternates, and there are robust rules on the prevention of conflicts of interest including financial or other interests in the pharmaceutical or medical devices industry which could affect their impartiality.

(30) The structure and functioning of the Agency's various bodies should be designed in such a way as to ensure the continuous renewal of scientific expertise, foster cooperation between Union and national bodies and ensure the adequate involvement of civil society, as well as to be able to accommodate a future enlargement of the Union. The Agency's various bodies should establish and develop appropriate contacts with the parties concerned, in particular with representatives of patients, consumers and healthcare professionals.

(31) The Agency's primary task should be to provide Member States and Union institutions with the best possible scientific opinions, enabling them to exercise the powers of authorisation and supervision of medicinal products conferred on them by Union legal acts in this field. Marketing authorisation should be granted by the Commission after completion of a single scientific evaluation procedure, conducted by the Agency, applying the highest possible standards, addressing the quality, safety and efficacy of high-technology medicinal products.

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(32) When examining the marketing authorisation application of the medicinal product, the Agency should draw up the European public assessment report (EPAR) on the quality, safety, efficacy, and the environmental risk assessment of the medicinal product and state the reasons for its opinion. The Agency should make publicly available a summary of the EPAR and a summary of the environmental risk assessment, after the deletion of any information of a commercially confidential nature and written in a manner that is understandable to the public.

(33) To ensure close cooperation between the Agency and the experts operating in Member States, the composition of the Management Board should be such as to guarantee that the competent authorities of the Member States are closely involved in the overall management of the system for authorising medicinal products in the Union.

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(34) The independence and impartiality of the members of the Management Board, the committees, rapporteurs and experts who participate in meetings or working groups of the Agency is crucial to avoid any conflict of interest and to preserve the scientific integrity of the work and activities of the Agency. In implementing this objective, the Agency faces the challenge of balancing the need for specific expert input within tight time -limits with the necessity of safeguarding the credibility of its decisions from being compromised by conflicts of interest. In certain fields, such as rare diseases, special populations, niche therapeutic indications and highly innovative technologies, the pool of experts is limited, and many are involved in clinical research on medicinal products. In situations where specific expertise is required and can be provided only by individuals with competing interests, which would normally disqualify or limit their involvement in the Agency's activities as a member or expert, it might still be in the interest of public health to allow such individuals to provide observations before a scientific evaluation is finalised, while excluding them from direct involvement in discussions or decision-making.

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(35) The Agency's budget should be transparent and composed of fees and charges paid by the private sector and contributions from the Union budget to implement Union policies as well as contributions paid from third countries, and comply, where applicable, with Regulation (EU) 2024/568 of the European Parliament and of the Council[10]. Although the majority of its funding comes from fees, the Agency is a public authority. It is of utmost importance to safeguard Agency's integrity and impartiality in order to maintain public trust in its work and the Union regulatory framework.

(36) It is important that Member States ensure adequate funding of competent authorities to carry out their tasks under this Regulation and under Directive (EU) 2026/…[+]. In addition, in line with the Joint Statement of the European Parliament, the Council and the Commission on decentralised agencies of 19 July 2012, Member States ensure that adequate resources are assigned by the competent authorities of the Member States for the purposes of their contributions to the work of the Agency, taking into account the cost-based remuneration they receive from the Agency.

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[10] Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L, 2024/568, 14.2.2024, ELI: http://data.europa.eu/eli/reg/2024/568/oj).

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(37) The staff of the Agency, including the Executive Director and the Deputy Executive Director of the Agency, as officials or other servants of the Union, are bound by the principles of independence, impartiality, integrity, as well as by the obligations provided for in the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the Union laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68[11] ('the Staff Regulations' and 'Conditions of Employment of Other Servants') and the rules agreed upon by the Union's institutions. These obligations should continue after leaving the service such as engaging in lobbying or advocacy vis-à-vis staff of their former institution for their business, clients or employers on matters for which they were responsible. The Staff Regulations also lay down rules for those intending to engage in an occupational activity, whether gainful or not, after leaving the service and provides for the possibility for the Agency, having regard to the interests of the service, either forbid them from undertaking it or give its approval subject to any conditions it thinks fit.

[11] OJ L 56, 4.3.1968, p. 1, ELI: http://data.europa.eu/eli/reg/1968/259(1)/oj.

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(38) Scientific advice for future applicants seeking a marketing authorisation should be provided more generally and in greater depth and should be adapted to the specificities of the medicinal product concerned. Similarly, structures allowing the development of advice for companies, in particular micro, small and medium-sized enterprises ('SMEs') within the meaning of Commission Recommendation 2003/361/EC[12], and for not-for-profit entities, should be put in place. The Agency should also promote open and public exchanges about the latest scientific developments and updates of scientific guidelines.

[12] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

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(39) In order to allow for scientific advice for future applicants that is more informative and an exchange of information between different bodies, scientific advice provided by the Agency should sometimes take place in parallel to scientific advice provided by other bodies. This should be the case for the joint scientific consultation carried out by the Member State Coordination Group on Health Technology Assessment established by Regulation (EU) 2021/2282 of the European Parliament and of the Council[13] and for the consultation of the expert panels, in cases of medicinal products involving a medical device, as provided for in Regulation (EU) 2017/745 of the European Parliament and of the Council[14]. Where parallel scientific advice consultation mechanisms are established under other relevant Union legal acts, a similar mechanism should apply.

(40) Promising medicinal products that have the potential to significantly address patients' unmet medical needs and are expected to be of major public health interest, particularly regarding their level of therapeutical innovation, or are priority antimicrobials or are likely to target a neglected tropical disease, should benefit from early and enhanced scientific support. Such support will ultimately help patients benefit from new therapies as early as possible.

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[13] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/2282/oj).

[14] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

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(41) It is important to recognise that unmet medical needs also exist in the area of mental health, and that promising medicinal products to address such unmet medical needs should also benefit from early and enhanced scientific support.

(42) The Agency should deliver on request scientific recommendations on whether a product under development, which could potentially fall under the mandatory scope of the centralised procedure, meets the scientific criteria to be a medicinal product. Such an advisory mechanism would address, as early as possible, questions related to borderline cases with other areas, such as substances of human origin, cosmetics or medical devices, which could arise as science develops. To ensure that recommendations given by the Agency take into account the views of equivalent advisory mechanisms in other legal frameworks, the Agency should consult the relevant advisory or regulatory bodies.

(43) Pharmaceutical research plays a decisive role in the continuing improvement in public health and in ensuring the Union's competitiveness. Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research. While such rules can contribute to the attractiveness of the internal market, they are however agnostic to the medicinal products' geographical origin and medicinal products from third countries authorised in the Union are equally eligible to receive Union incentives.

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(44) To promote innovation and the development of new medicinal products by SMEs and to reduce the cost of the placing on the market of medicinal products for human use authorised via the centralised procedure, these undertakings should benefit from a support scheme from the Agency.

(45) The support scheme should be composed of regulatory, procedural and administrative support, and of a reduction, deferral or waiver of fees. The scheme should cover the various steps involved in pre-authorisation procedures, such as scientific advice, the submission of the marketing authorisation application, and post-authorisation procedures.

(46) Not-for-profit entities, such as universities, public bodies, research centres or not-for-profit organisations, represent an important source of research in the area of unmet medical needs, research in different subpopulations, repurposing and treatment optimisation and should also benefit from this support scheme. Whereas it should be possible to take account of the particular situation of these entities on an individual basis, such support can best be achieved by means of a dedicated support scheme, including administrative support and through the reduction, deferral and waiver of fees.

(47) To increase transparency of scientific assessments and all other activities, a European medicines web-portal should be created and maintained by the Agency.

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(48) The Union Register of Medicinal Products lists all medicinal products for human use as well as orphan medicinal products that have been granted a marketing authorisation by the Commission through the centralised procedure. The information provided in the Union Register can be used to search for pertinent information on the medicinal product in question, including the active substance, and any post-authorisation requirements as well as applicable prolongations to regulatory protection periods.

(49) To allow for more informative advice on clinical trial applications and therefore a more integrated development advice in view of future data requirements for marketing authorisation applications, the Agency can engage in consultation with representatives from Member States having clinical trial expertise. Nevertheless, decisions on clinical trial applications should remain within the competence of the Member States, in accordance with Regulation (EU) No 536/2014 of the European Parliament and of the Council[15].

[15] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).

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(50) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities or bodies could be, as appropriate, representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the substances of human origin (SoHO) Coordination Board, the Coordination Group on Health Technology Assessment, the Medical Devices Coordination Group, medical devices competent authorities of Member States, competent authorities of Member States for pricing and reimbursement of medicinal products, national insurance funds or healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients, healthcare professionals, industry, associations representing payers, or other stakeholders, as relevant.

(51) It is also necessary to reinforce the role of the Agency's scientific committees in such a way as to enable it to participate actively in international scientific dialogue and to develop certain activities that will be necessary, in particular regarding international scientific harmonisation and technical cooperation with the World Health Organization ('WHO').

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(52) In the context of cooperation with international organisations to support global public health, it is important to leverage the scientific assessment performed by the Union and to promote reliance by third-country regulatory authorities based on the use of certificates of medicinal products for authorised medicinal products in the Union. An applicant should be able to request independently or as part of an application under the centralised procedure a scientific opinion from the Agency for the use of the medicinal product for markets outside the Union. The Agency should cooperate with the WHO and relevant third-country regulatory authorities and bodies to issue such scientific opinions.

(53) The Agency should be able to cooperate with competent authorities of third countries in the context of performing its tasks. Such regulatory cooperation should be consistent with the broader economic relationship of the Union with the third country concerned, taking account of the relevant international agreements between the Union and that third country.

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(54) The Union is required, pursuant to Article 208 of the Treaty on the Functioning of the European Union (TFEU), to take account of the objectives of development cooperation in the policies that it implements which are likely to have an impact on low- and middle-income countries. Union pharmaceutical legislation has a role to play in the realisation of global public health objectives by promoting the development of efficacious, safe, accessible, and affordable innovations for antimicrobial resistance, poverty-related, emerging and re-emerging health threats, and neglected diseases, and other conditions of global public health interest. For example, as part of its Priority Medicines scheme, the Agency will offer dedicated support to medicinal product developments in the area of neglected tropical diseases. The Commission needs to continue encouraging research, development and innovation in areas of major global health interest, in line with its international commitments.

(55) In the interest of public health, marketing authorisation decisions under the centralised procedure should be taken on the basis of the scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations. However, Member States should be able, exceptionally and temporarily, to prohibit the use in their territory of certain medicinal products. Member States should provide justification for such prohibition of use to the Commission and the Agency.

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(56) The quality, safety and efficacy principles of Directive (EU) 2026/…[+] should apply to medicinal products authorised by the Union under the centralised procedure. The benefit-risk balance of all medicinal products should be assessed when they are placed on the market, and at any other time the competent authority deems appropriate.

(57) To avoid unnecessary administrative and financial burden both for the pharmaceutical industry and the competent authorities of the Member States or the Agency, certain streamlining measures should be introduced. Marketing authorisation applications, like any other application submitted to the Agency, should follow the 'digital by default' principle and hence be sent to the Agency in electronic form. Electronic applications for marketing authorisations and for variations to the terms of the marketing authorisation should be made possible.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(58) Applications should be examined on the basis of the file submitted by the applicant in accordance with the provisions of Directive (EU) 2026/…[+] on different types of applications. At the same time, the Agency and its relevant committees should be able to take into account any information that is in their possession. Applicants should be requested to generally submit raw data, in particular with regard to the clinical trials conducted by the applicant in order to ensure a full scientific evaluation of the quality, safety and efficacy of the medicinal product. However, the obligation to submit raw data should not be construed as obliging the Agency and the relevant committees to examine or make use of all such data during their scientific assessment. They should retain the discretion to determine in which cases such data are relevant and necessary for the purpose of examining the application.

(59) To optimise the use of resources for both applicants and competent authorities of the Member States or the Agency assessing such applications, a single assessment of an active substance master file should be introduced. The outcome of the single assessment should be issued through a certificate. To avoid duplication of assessment, the use of an active substance master file certificate should be mandatory for subsequent applications for marketing authorisations for medicinal products for human use containing that active substance from an active substance master file certification holder.

(60) In the context of the development and authorisation of medicinal products, it is crucial that particular attention be given to the composition of clinical trials in order to ensure comprehensive clinical data and, where appropriate, gender-based equity.

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(61) Directive 2010/63/EU of the European Parliament and of the Council[16] lays down provisions on the protection of animals used for scientific purposes based on the principle of replacement, reduction and refinement. Any study involving the use of live animals, which provides essential information on the quality, safety and efficacy of a medicinal product, should take into account that principle of replacement, reduction and refinement, where it concerns the care and use of live animals for scientific purposes, and should be optimised in order to provide the most satisfactory results whilst using the minimum number of animals. The procedures of such testing should be only used where necessary and be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available guidelines of the Agency and of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. In particular, the applicant and the marketing authorisation holder should take into account the principle of replacement, reduction and refinement laid down in Directive 2010/63/EU, giving priority to new approach methodologies in place of animal testing. These can include: *in vitro* models, such as microphysiological systems including organ-on-chips, (2D and 3D-) cell culture models, organoids and human stem cells-based models; *in silico* tools, in chemico technologies and any combination thereof or read-across models. Ultimately, efforts should be made to fully replace procedures on live animals for scientific purposes.

[16] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33, ELI: http://data.europa.eu/eli/dir/2010/63/oj).

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(62) This Regulation contributes to the implementation of the One Health Approach, stressing the well-established interconnectedness between human, animal and ecosystem health, and the need to include those three dimensions when addressing public health threats. Environmental stress and degradation, including biodiversity loss, contribute to the transmission of diseases between, and the disease burden of, humans and animals. In addition, pollution from active pharmaceutical ingredients negatively affects the quality of waters and ecosystems, causes antimicrobial resistance to increase rapidly, posing risks to public health globally.

(63) Procedures are to be in place to facilitate joint animal testing, wherever possible, in order to avoid unnecessary testing using live animals covered by Directive 2010/63/EU. Applicants and marketing authorisation holders should make all efforts to reuse animal study results and make the results obtained from animal studies publicly available. In line with Directive (EU) 2026/…[+], abridged applications are to refer to the relevant studies conducted for the reference medicinal product.

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(64) The summary of product characteristics and the package leaflet should reflect the scientific evaluation of the Agency and be part of its scientific opinion. The opinion could recommend certain conditions that should be part of the marketing authorisation, for example on the safe and efficacious use of the medicinal product or on post-authorisation obligations that have to be complied with by the marketing authorisation holder. Those conditions could include the requirement to conduct post-authorisation safety or efficacy studies or other studies that are considered necessary to optimise the treatment, for example where the dose scheme proposed by the applicant, whilst acceptable and justifying a favourable benefit-risk balance, could be further optimised after the authorisation has been granted. Where the applicant disagrees with parts of the opinion, the applicant should be able to submit a request for its re-examination.

(65) Due to the need to reduce overall approval times for medicinal products, the time between the opinion of the Committee for Medicinal Products for Human Use and the final decision on the application for a marketing authorisation should in principle be no longer than 46 days.

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(66) On the basis of the opinion of the Agency, the Commission should adopt a decision on the application for a marketing authorisation by means of implementing acts. In justified cases, the Commission should be able to refer back the opinion for further examination or deviate in its decision from the opinion of the Agency. Taking into account the need to make medicinal products swiftly available to patients, it should be acknowledged that the chairperson of the Standing Committee on Medicinal Products for Human Use will use the available mechanisms under Regulation (EU) No 182/2011 of the European Parliament and of the Council[17] and in particular the possibility to obtain the committee's opinion by written procedure and within expeditious time limits which, in principle, will not exceed 10 calendar days.

(67) As a general rule, a marketing authorisation should be granted for an unlimited time. However, one renewal may be decided only on justified grounds related to the safety of the medicinal product.

[17] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

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(68) There is a need to ensure that the ethical requirements of Regulation (EU) No 536/2014 apply to medicinal products authorised by the Union. In particular, with respect to clinical trials conducted outside the Union on medicinal products to be authorised within the Union, at the time of the examination of the application for authorisation, it should be verified that those trials were conducted in accordance with the principles of good clinical practice and the ethical requirements that are equivalent to those set out in Regulation (EU) No 536/2014 as regards the rights and safety of the subject and the reliability and robustness of the data generated in the clinical trial.

(69) Environmental risks can arise from medicinal products consisting of, or containing, genetically modified organisms (GMOs). It is thus necessary to subject such medicinal products to an environmental risk-assessment procedure similar to the procedure under Directive 2001/18/EC of the European Parliament and of the Council[18], to be conducted in parallel with the evaluation, under a single Union procedure, of the quality, safety and efficacy of the medicinal product concerned. The environmental risk-assessment should be conducted in accordance with the requirements laid down in this Regulation and in Directive (EU) 2026/…[+] which are based on the principles set out in Directive 2001/18/EC but taking into account the specificities of medicinal products.

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[18] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj).

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(70) Directive (EU) 2026/…[+] permits Member States to temporarily allow the use and supply of unauthorised medicinal products for public health reasons or individual patient needs and that includes medicinal products to be authorised under this Regulation. It is also necessary, that Member States are allowed under this Regulation to make a medicinal product available for compassionate use prior to its marketing authorisation. In those exceptional and urgent situations, where there is a lack of a suitable authorised medicinal product, the need to protect public health or the health of individual patients must prevail over other considerations, in particular the need to obtain a marketing authorisation and consequently, to have available complete information about the risks posed by the medicinal product, including any risks to the environment from medicinal products consisting of, or containing, GMOs. To avoid delays in making these products available or uncertainties as regards their status in certain Member States, it is appropriate, in those exceptional and urgent situations, that for a medicinal product consisting of, or containing, GMOs, an environmental risk assessment or consent in accordance with Directive 2001/18/EC or Directive 2009/41/EC of the European Parliament and of the Council[19] should not be a prerequisite. Nevertheless, in those cases, Member States should implement appropriate measures in line with the precautionary principle to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the medicinal products consisting of, or containing, GMOs into the environment.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

[19] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75, ELI: http://data.europa.eu/eli/dir/2009/41/oj).

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(71) For medicinal products, the period for protection of data relating to non-clinical tests and clinical trials should be the same as that provided for in Directive (EU) 2026/…[+].

(72) In order to meet, in particular, the legitimate expectations of patients and to take account of the increasingly rapid progress of science and therapies, accelerated assessment procedures should be set up, reserved for medicinal products of major therapeutic interest, and procedures for obtaining conditional marketing authorisations subject to certain regularly reviewable conditions.

(73) Compassionate use programmes allow for an early access to medicinal products. Existing provisions should be reinforced to ensure that a common approach is followed, whenever possible, regarding the criteria and conditions for the compassionate use of new medicinal products under national law. Moreover, it is important to allow for data on such use to be collected to inform decisions regarding the benefit-risk balance of the medicinal products concerned.

(74) It should be recognised that unmet medical needs also exist in the area of mental health. Promising medicinal products to address serious mental health conditions should therefore also be considered for compassionate use.

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(75) There is the possibility under certain circumstances for marketing authorisations to be granted, subject to specific obligations or conditions, on a conditional basis or under exceptional circumstances. The legislation should allow under similar circumstances for medicinal products with a standard marketing authorisation for new indications to be authorised on a conditional basis or under exceptional circumstances. The medicinal products authorised on a conditional basis or under exceptional circumstances should in principle satisfy the requirements for a standard marketing authorisation, with the exception of the specific derogations or conditions outlined in the relevant conditional or exceptional marketing authorisation, and should be subject to specific review of the fulfilment of the imposed specific conditions or obligations. The grounds for refusal of a marketing authorisation should apply *mutatis mutandis* for such cases.

(76) Before a medicinal product for human use is authorised for placing on the market of one or more Member States, it generally has to undergo extensive studies to ensure that it is of high quality, safe and effective for use in the target population. However, in the case of certain categories of medicinal products for human use, in order to meet unmet medical needs of patients and in the interest of public health, it might be necessary to grant marketing authorisation on the basis of less complete data than is normally the case. Such marketing authorisation should be granted subject to specific obligations. The categories of medicinal products for human use concerned should be the medicinal products that aim at the prevention, diagnosis or treatment of seriously debilitating or life-threatening diseases, or that are intended to be used in emergency situations in response to public health threats.

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(77) In principle, it should not be possible for more than one marketing authorisation to be granted to an applicant for a medicinal product. Duplicate marketing authorisations should be granted only in exceptional circumstances. When those exceptional circumstances are no longer present, in particular as regards the protection by a patent or a supplementary protection certificate in one or more Member States, any potentially negative effects on markets from the existence of duplicate marketing authorisations should be minimised through a withdrawal of the initial or the duplicate marketing authorisation.

(78) Regulatory decision-making on the development, authorisation and supervision of medicinal products can be supported by access and analysis of health data, including real-world data, where appropriate, i.e. health data generated outside of clinical studies, and data generated via *in silico* methods, such as computational modelling and simulation, digital molecular representation and mechanistic modelling, digital twin technology and artificial intelligence (AI). The Agency should be able to use such data, including via the Data Analysis and Real World Interrogation Network and the European Health Data Space interoperable infrastructure. Through the use of those possibilities, the Agency can take advantage of all the potential of supercomputing, AI and big-data science to fulfil its mandate, without compromising privacy rights. The Agency should put in place sufficient, effective and specific technical and organisational measures to safeguard the fundamental rights and interests of data subjects in accordance with Union law. It is appropriate for the Agency to cooperate with the competent authorities of the Member States, where necessary, with a view to achieving that objective.

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(79) The handling of health data requires a high level of protection against cyber attacks. It is necessary for the Agency to be equipped with a high level of security controls and processes against cyber attacks to ensure that the Agency operates normally at all times. To that end, the Agency should establish a plan to prevent, detect, mitigate and respond to cyber attacks so that its operations are secure at all times, while preventing any illegal access to documentation held by the Agency.

(80) Due to the sensitive nature of health data, the Agency should safeguard its processing operations and ensure that they respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. Where the processing of personal data is necessary for the purposes of this Regulation, such processing should be done in accordance with Union law on the protection of personal data. Any processing of personal data under this Regulation should take place in accordance with Regulations (EU) 2016/679[20] and (EU) 2018/1725[21] of the European Parliament and of the Council.

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[20] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

[21] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).

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(81) Access to individual patient data from clinical studies in structured format allowing for statistical analyses is valuable to assist regulators in understanding the submitted evidence and to inform regulatory decision-making on the benefit-risk balance of a medicinal product. The introduction of such possibility in the legislation is important to further enable data-driven benefit-risk assessments at all stages of the life cycle of a medicinal product. This Regulation therefore empowers the Agency to receive and use such data as part of the assessment of initial and post-authorisation applications.

(82) In a situation of public health emergency, it is of major interest for the Union that safe and efficacious medicinal products can be developed and made available within the Union as soon as possible. Agile, fast and streamlined processes are of the essence. A range of measures already exists at Union level to facilitate, support and speed up the development of and granting marketing authorisations for treatments and vaccines during a public health emergency.

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(83) It is also considered appropriate for the Commission to have the possibility to grant temporary emergency marketing authorisations to address public health emergencies. Temporary emergency marketing authorisations can be granted provided that, having regard to the circumstances of the public health emergency, the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent to the fact that additional comprehensive quality, non-clinical and clinical data might still be required. A temporary emergency marketing authorisation should be valid only during the public health emergency. The Commission should be given the possibility to vary, suspend or revoke such marketing authorisations in order to protect public health or when the marketing authorisation holder has not complied with the conditions and obligations laid down in the temporary emergency marketing authorisation.

(84) It is appropriate to have in place transparency measures and standards regarding the Agency's regulatory activities in relation to medicinal products, in particular those that are granted a temporary emergency marketing authorisation. Those measures should include the timely publication of all relevant information on centrally approved medicinal products.

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(85) In the event of a risk to public health, the marketing authorisation holder or the competent authorities of the Member States or the Agency should be able to implement urgent safety or efficacy restrictions on their own initiative to ensure a swift adaption of the marketing authorisation to maintain the safe and efficacious use of the medicinal product by healthcare professionals and patients. If a review is launched by a competent authority regarding the same safety or efficacy concern as one which has been covered by urgent restrictions, any written observations by the marketing authorisation holder should be considered in that review to avoid duplication of assessment.

(86) The terms of a marketing authorisation for a medicinal product for human use can be varied. While the core elements of a variation to the marketing authorisation are laid down in this Regulation, the Commission should be empowered by means of delegated acts to complement those core elements by laying down further necessary elements, to adapt the system to technical and scientific progress, and to employ digitalisation measures to ensure that unnecessary administrative burden is avoided for marketing authorisation holders and competent authorities of the Member States or the Agency.

(87) Competent authorities of the Member States or the Agency should have the power to evaluate additional evidence that could affect the benefit-risk balance of medicinal products, beyond the evidence provided by marketing authorisation holders. Where justified, competent authorities of the Member States or the Agency should be able to recommend that the marketing authorisation holder vary the terms of its marketing authorisation.

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(88) For generic medicinal products and biosimilar medicinal products, as a general rule, risk management plans should not be developed and submitted, also considering that the reference medicinal product has such a plan. However, in specific cases, a risk management plan for generic medicinal products and biosimilar medicinal products should be developed and submitted to the competent authorities of the Member States or the Agency.

(89) It is appropriate to entrust the Commission, in close cooperation with the Agency and after consultations with the Member States, with the task of coordinating the execution of the various supervisory responsibilities vested in the Member States, and in particular with the tasks of providing information on medicinal products and of checking the observance of good manufacturing, laboratory and clinical practices.

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(90) Without prejudice to the powers of the competent authorities of Member States and without undermining their national inspection resources, the Agency should be provided with the targeted inspection capacity to contribute to the strengthening of the supervision of the manufacturing of the medicinal products worldwide, in the interest of the Union. This could be the case in situations where, to ensure faster access to medicinal products, challenges with inspection capacities at national level have to be addressed in a timely manner or where a response to a public health emergency or a major event requires immediate action. Therefore, the Agency should be empowered and given the capacity to support Member States with regard to carrying out inspections in third countries. In particular, where the competent authorities of the Member States request support in carrying out their tasks under Directive (EU) 2026/…[+], the Agency should be able to participate in inspections. Where the competent authority of a Member State cannot carry out an inspection, the Agency should facilitate the delegation of the inspection to another competent authority of a Member State. As a last resort, where no other competent authority of a Member State is able to accept the delegation to carry out an inspection, the competent authority concerned should be able to request the Agency to carry out the inspection.

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(91) To ensure consistency in supervision of inspected activities and enforcement of good manufacturing and distribution practices in the Union, harmonised inspection standards should be ensured through the establishment of a joint audit programme ('JAP') within the Agency. This JAP will also further harmonise the interpretation of good manufacturing and distribution practices on the basis of Union legislative requirements. As regards the implementation of the JAP by the competent authorities of the Member States or the Agency, this Regulation takes into account the specific constitutional and administrative structures of each Member State pursuant to Article 4(2) of the Treaty on the European Union (TEU), while ensuring the effectiveness of such implementation, in accordance with Article 4(3) TEU. Moreover, it will support further mutual recognition of inspection outcomes between Member States and with strategic partners. Within the JAP, the competent authorities of the Member States or the Agency are subject to regular audits conducted by other Member States to maintain an equivalent and harmonised quality system and to ensure an appropriate implementation of relevant good manufacturing and distribution practices in national law and their equivalence with those of other Member States.

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(92) The inspection working groups, which provide input and recommendations on all matters relating, directly or indirectly, to good clinical practice, good manufacturing practice, good distribution practice and good pharmacovigilance practice, irrespective of the marketing authorisation procedure through different reporting lines, should be established within the Agency. In particular, the working group in charge of good manufacturing and good distribution practices should be responsible for the establishment, development and overall supervision of the JAP.

(93) The Union should have the means to carry out a scientific assessment of a medicinal product authorised in accordance with the decentralised marketing authorisation procedures. Moreover, with a view to ensuring the effective harmonisation of administrative decisions taken by Member States with regard to a medicinal product authorised in accordance with decentralised marketing authorisation procedures, it is necessary to endow the Union with the means to resolve disagreements between Member States concerning the quality, safety and efficacy of medicinal products in accordance with the referral procedure.

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(94) The development of antimicrobial resistance is a growing concern. However, antimicrobial research and development is being hampered by the low commercial value of the antimicrobial medicinal product market. It is therefore necessary to maintain the efficacy of existing antimicrobials for as long as possible and to consider a number of new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support companies, often SMEs, and not-for-profit entities which choose to invest in this area. It is equally necessary to support research and development of novel antimicrobials including through the establishment of subscription models. Such models delink the volume of antimicrobial sales from the reward received, in particular through voluntary joint procurement and can help overcome such market failures. Such measures should facilitate the development of alternative treatments, such as bacteriophages, which can be effective against multi-drug resistant bacteria and can be used as an alternative treatment or together with antibiotics.

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(95) Reluctance to invest in the development of antimicrobials exists in part because the development of antimicrobials is costly and many developers, often SMEs, cannot afford to proceed to the next stage of development. Additionally, when an antimicrobial is developed, there is a limited market for it by virtue of the inherent need to use antimicrobials prudently, which typically limits the sales of such products. Therefore, it is necessary to consider further Union level action to support the development of antimicrobials and address existing market failures. Accordingly, a voluntary subscription model for the joint procurement of antimicrobials should be developed to ensure that a market exists for developers that delinks volumes sold from payment received.

(96) To be considered a 'priority antimicrobial', a medicinal product should represent a real advancement against antimicrobial resistance and therefore its developer should provide non-clinical and clinical data that underpin a significant clinical benefit with respect to antimicrobial resistance. When assessing the conditions for antimicrobials, the Agency should take into account the prioritisation of pathogens as regards the risk of antimicrobial resistance set out in the 'WHO Bacterial Priority Pathogens List: Bacterial pathogens of public health importance to guide research, development and strategies to prevent and control antimicrobial resistance' ('WHO bacterial priority pathogens list'), specifically those listed in the 'critical group' or in the 'high group'. Where there is an equivalent list of priority pathogens established at Union level, it would be appropriate for the Agency to give precedence to that Union list.

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(97) The creation of a transferable data exclusivity voucher (‘data exclusivity voucher’) as an incentive rewarding the development of priority antimicrobials through an additional year of regulatory data protection has the capacity to provide the needed financial support to developers of priority antimicrobials. However, in order to ensure that the financial reward which is ultimately borne by health systems is mostly absorbed by the developer of the priority antimicrobial and not the buyer of the data exclusivity voucher, the number of available data exclusivity vouchers on the market should be kept to a minimum. It is therefore necessary to establish strict conditions of granting, transfer and use of the data exclusivity voucher and to further give the possibility to the Commission to revoke the data exclusivity voucher under certain circumstances.

(98) A data exclusivity voucher should only be available to those antimicrobials that bring a significant clinical benefit with respect to antimicrobial resistance, and which have the characteristics described in this Regulation. It is also necessary to ensure that an undertaking which receives this incentive is in turn capable to supply the antimicrobial to patients across the Union in sufficient quantities and to provide information on all funding received for research related to its development in order to provide a full account of the direct financial support given to those antimicrobials.

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(99) To ensure a high level of transparency and complete information on the economic effect of a data exclusivity voucher, in particular as regards the risk of overcompensation of investment, a developer of a priority antimicrobial is required to provide in a declaration information on all direct financial support received for research related to the development of the priority antimicrobial. The declaration should include direct financial support received from any source worldwide.

(100) It should be possible for the transfer of a data exclusivity voucher for a priority antimicrobial to be conducted by sale. It should not be possible for such a voucher to be transferred more than once. The value of the transaction, which can be monetary or otherwise agreed between the buyer and the seller, should be made public so as to inform regulators and the public. The identity of the holder of a data exclusivity voucher that has been granted and not yet used should be publicly known at all times so as to ensure a maximum level of transparency and trust.

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(101) The provisions related to data exclusivity vouchers should be applicable for a specified period from the entry into force of this Regulation or until a maximum number of those vouchers are granted by the Commission in order to limit the total cost of the measure to Member State health systems. The limited application of the measure will also provide the possibility to assess the effect of the measure in addressing the market failure in the development of new antimicrobials tackling antimicrobial resistance and assess the cost on national health systems. That assessment will provide the knowledge necessary to decide whether to extend the application of the measure. On the basis of that assessment, the Commission should, where appropriate, submit a proposal to the European Parliament and to the Council to extend the period of application of the provisions on data exclusivity vouchers for priority antimicrobials and the total number of those vouchers.

(102) Through the Priority Medicines (PRIME) scheme, the Agency has gained experience of the provision of early scientific and regulatory support to developers of certain medicinal products that, based on preliminary evidence, are likely to address an unmet medical need and are considered promising at an early stage of development. It is appropriate to recognise this early support mechanism for medicinal products that have the potential to significantly address patients' unmet medical needs and are expected to be of major interest from the point of view of public health, in particular as regards therapeutic innovation, or are antimicrobials addressing antimicrobial resistance or target a neglected tropical disease when they fulfil the criteria for the scheme. The Agency, in consultation with the Member States and the Commission, should establish selection criteria for promising medicinal products.

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(103) The Agency, in consultation with the Member States and the Commission, should set the scientific selection criteria for medicinal products that receive pre-authorisation support with priority to be given to the most promising developments in therapies. In the case of medicinal products for unmet medical needs, based on the scientific selection criteria set by the Agency, any interested developer can submit preliminary evidence to demonstrate that the medicinal product has the potential to address an identified unmet medical need and be of major public health interest particularly regarding its therapeutic innovation.

(104) In the preparation of scientific advice and in duly justified cases, the Agency should also be able to consult authorities established in other relevant Union legal acts or other public bodies established in the Union, as applicable. These could include experts in clinical trials, medical devices, substances of human origin or any other as required for the provision of the scientific advice in question.

(105) Some conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition cannot be recovered by the expected sales of the medicinal product. However, patients suffering from such rare conditions should be entitled to the same quality of treatment as other patients. It is therefore necessary to stimulate the research, development and placing on the market of appropriate medicinal products by the pharmaceutical industry.

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(106) Regulation (EC) No 141/2000 has proved to be successful in boosting developments of orphan medicinal products in the Union, although more progress is needed, as a majority of rare diseases are still without an authorised treatment. Action at Union level therefore remains preferable to uncoordinated measures by the Member States, which could result in distortions of competition and barriers to intra-Union trade.

(107) The open and transparent centralised procedure for the designation of potential medicinal products as orphan medicinal products established by Regulation (EC) No 141/2000 should be maintained. To increase legal clarity and simplification, the specific legal provisions applicable to those medicinal products should be integrated in this Regulation.

(108) Objective criteria for the orphan designation based on the prevalence of the life-threatening or chronically debilitating condition for which prevention, diagnosis, or treatment is sought and the existence of no satisfactory method of prevention, diagnosis or treatment of the condition in question that has been authorised in the Union should be maintained. A prevalence of not more than five affected persons per 10 000 is generally regarded as appropriate for orphan designation. The orphan designation criterion on the basis of return on investment has been abolished, since it has never been used.

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(109) The criterion for orphan designation based on prevalence of a disease might not be appropriate to identify rare diseases in all cases. For example, for conditions which have a short duration and high mortality, measuring the number of people that acquired the disease during a specific time period would better reflect if it is rare within the meaning of this Regulation than measuring the number of people who are ‘affected by it’ in a specific moment of time.

(110) With the aim to better identify only those diseases which are rare, the Commission should be empowered to supplement the designation criteria by a delegated act if they are not appropriate for certain conditions due to scientific reasons and on the recommendation of the Agency. In addition, the designation criteria require implementing acts to be adopted by the Commission.

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(111) If a satisfactory method of prevention, diagnosis or treatment of the condition in question has already been authorised in the Union, the orphan medicinal product will have to be of significant benefit to those affected by that condition. In this context, a medicinal product authorised in one Member State is generally deemed as being authorised in the Union. It is not necessary for it to have Union authorisation or to be authorised in all Member States to be considered a satisfactory method. In addition, commonly used methods of prevention, diagnosis, or treatment that are not subject to a marketing authorisation can be considered to be satisfactory if there is scientific evidence of their safety and efficacy. In certain cases, medicinal products prepared for an individual patient in a pharmacy according to a medical prescription, or according to the prescriptions of a pharmacopoeia and intended to be supplied directly to patients served by the pharmacy, may be considered to be satisfactory treatment if they are well known and safe and this is a general practice for the relevant patient population in the Union.

(112) The competence to designate a medicinal product as an orphan medicinal product, in the form of a decision, is accorded to the Agency. This is expected to facilitate and expedite the designation procedure, while ensuring high level of scientific expertise.

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(113) In order to incite faster authorisation of designated orphan medicinal products, the validity of orphan designation has been set at seven years, with the possibility of extension by the Agency under certain specified conditions. The orphan designation can be withdrawn at the request of the orphan medicinal product sponsor, who provides a reasoned justification for the withdrawal request. The Agency should make the reasoned justification for the withdrawal request publicly available, when that justification is provided by the orphan medicinal product sponsor.

(114) The Agency is responsible for designation of an orphan medicinal product as well as for the setting up and management of a register of designated orphan medicinal products. That register should be publicly available. The minimum data which should be included in the register have been specified in this Regulation and the Commission is empowered to amend or supplement those minimum data by a delegated act.

(115) Sponsors of orphan medicinal products designated under this Regulation should be entitled to the full benefit of incentives granted by the Union or by the Member States to support the research and development of medicinal products for the prevention, diagnosis or treatment of orphan conditions, including rare diseases.

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(116) Patients suffering from rare diseases deserve medicinal products of the same quality, safety and efficacy as other patients. Designated orphan medicinal products should therefore be submitted to the normal evaluation process carried out by the Committee of Medicinal Products for Human Use for the applicant to obtain a marketing authorisation for those indications which meet the criteria for orphan designation, while a separate marketing authorisation can be granted for indications not meeting the criteria of an orphan medicinal product. Those marketing authorisations should be considered as belonging to the same global marketing authorisation.

(117) A vast percentage of rare diseases remains without treatment with research and development clustered in the areas where profit is better assured. Therefore, there is a need to target those areas where research is mostly needed and where investments are most risky.

(118) Orphan medicinal products are considered to be breakthrough orphan medicinal products if they prevent, diagnose or treat conditions where no other method of prevention, diagnosis or treatment exists and they result in a clinically relevant reduction in disease morbidity or mortality for the relevant patient population.

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(119) Experience since the adoption of Regulation (EC) No 141/2000 shows that the strongest incentive for industry to invest in the development and making available of orphan medicinal products is where there is a prospect of obtaining market exclusivity for a certain number of years during which part of the investment might be recovered. In addition to the periods of market exclusivity, orphan medicinal products will benefit from the periods of regulatory data and market protection set out in Directive (EU) 2026/…[+], as well as from one additional year of regulatory data protection provided for in this Regulation by using a data exclusivity voucher. However, where an orphan medicinal product obtains an additional therapeutic indication, it should only benefit from the prolongation of market exclusivity in accordance with this Regulation.

(120) In order to incentivise research and development of breakthrough orphan medicinal products, to ensure market predictability and to ensure a fair distribution of incentives, a modulation of market exclusivity has been introduced. Breakthrough orphan medicinal products benefit from the longest market exclusivity, while market exclusivity for well-established-use orphan medicinal products, requiring less investment, is the shortest. In order to ensure increased predictability for developers, the possibility to review the eligibility criteria for market exclusivity six years after the marketing authorisation has been abolished.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(121) To maximise the potential benefit of clinical research, continued exploration of new therapeutic indications for orphan medicinal products should be encouraged. To reward research into and development of new therapeutic indications, an additional period of one year of market exclusivity is provided for a new therapeutic indication (with a maximum of two indications).

(122) This Regulation aims to avoid unjustified benefits being derived from market exclusivity and to improve the accessibility of medicinal products by ensuring faster entry on the market of generic medicinal products, biosimilar medicinal products and similar medicinal products. It also clarifies the concurrence of market exclusivity with regulatory data protection periods and sets out situations in which a similar medicinal product can be granted a marketing authorisation despite ongoing market exclusivity.

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(123) The EU Health Strategy developed by the Commission has identified rare diseases as a priority for action with the aim to improve patient access to diagnosis, information and care. Programmes for Union action in this field build on a supportive policy framework at Union level that encourages national plans and collaborative efforts among Member States. Under Directive 2011/24/EU of the European Parliament and of the Council[22], the Commission has supported the continued development of European Reference Networks connecting healthcare providers across the Union to share expertise and provide consultations for patients suffering from rare diseases. Funding is provided through programmes like Horizon Europe to support research on rare diseases. Moreover, efforts are made to enhance patient registries and data collection to support research and improve knowledge on rare diseases. Additionally, the European Health Data Space is set to have a transformative impact on research, particularly for rare diseases. It will draw on the work of the European Platform on Rare Diseases Registration, to address the issue of fragmentation of patient data across the Union. In 2024 the Commission launched a new 7-year research partnership, the European Rare Diseases Research Alliance for better prevention, better diagnosis, and better treatment of rare diseases. With these comprehensive set of actions, the Union aims to improve diagnosis, treatment, and quality of life and to better meet the unmet needs of people living with rare diseases and their carers.

[22] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45, ELI: http://data.europa.eu/eli/dir/2011/24/oj).

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(124) Before a medicinal product for human use is placed on the market in one or more Member States, it has to have undergone extensive studies, including non-clinical tests and clinical trials, to ensure that it is safe, of high quality and effective for use in the target population. It is important that such studies are undertaken also in the paediatric population in order to ensure that medicinal products are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric population. It is also important that medicinal products be presented in dosages and formulations that are suitable for children.

(125) Therefore, the development of medicinal products that could potentially be used for the paediatric population should become an integral part of the development of medicinal products, integrated into the development programme for adults. Thus, paediatric investigation plans should be submitted early during medicinal product development, in time for studies to be conducted in the paediatric population, where appropriate, before marketing authorisation applications are submitted.

(126) As the development of medicinal products is a dynamic process dependent on the result of ongoing studies, in certain cases, for example when limited information on the medicinal products are available because the medicinal products are tested for the first time in the paediatric population, a specific procedure allowing to progressively build up a paediatric investigation plan should be put in place.

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(127) During public health emergencies, in order not to delay a prompt authorisation of a medicinal product intended for the prevention or treatment of a condition related to the public health emergency, there should be a possibility to temporarily waive the requirements concerning paediatric studies to be submitted at the moment of marketing authorisation.

(128) In order to not endanger the health of children and to avoid exposing them to unnecessary clinical trials, the obligation to agree and conduct studies in children should be waived when the medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, the specific medicinal product does not represent a significant therapeutic benefit over existing methods of prevention, diagnosis or treatment for children or the disease for which the medicinal product is intended occurs only in the adult population. Nevertheless, if on the basis of existing scientific evidence, the medicinal product due to its mechanism of action is relevant for a different disease or condition in children in the same therapeutic area, the obligation should be maintained.

(129) To ensure that research in the paediatric population is only conducted to meet their therapeutic needs, the Agency should agree and make public lists of waivers for specific medicinal products or for classes or part of classes of medicinal products. As knowledge of science and medicine evolves over time, provision should be made for the lists of waivers to be amended. However, if a waiver is revoked, the requirement for a paediatric investigation plan should not apply for a given period in order to allow time for such a plan to be agreed and for studies in the paediatric population to be initiated before an application for marketing authorisation is submitted.

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(130) With a view to ensuring that research is conducted only when safe and ethical and that the requirement for study data in the paediatric population does not block or delay the authorisation of medicinal products for other populations, the Agency should be able to defer, on scientific or technical grounds or on the basis of considerations related to public health, the initiation or completion of some or all of the measures contained in a paediatric investigation plan for a limited period. Such deferral should be extended only in duly justified cases.

(131) The possibility to modify an agreed paediatric investigation plan should be provided for in cases where the applicant encounters such difficulties with its implementation as to render the plan unworkable or no longer appropriate.

(132) The Agency, after consultation of the Commission and of interested parties, should draw up the details of the content of an application for agreement of a paediatric investigation plan, for its modification, for waivers and for deferral requests.

(133) Where it is intended to develop medicinal products for use only in children, simplified details of the paediatric investigation plan should be sufficient.

(134) To ensure that the data supporting the marketing authorisation concerning the use of a medicinal product in children to be authorised under this Regulation have been correctly developed, the Committee for Medicinal Products for Human Use should check compliance with the agreed paediatric investigation plan and any waivers and deferrals at the validation step for marketing authorisation applications.

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(135) Scientific advice, free of charge, should be provided by the Agency as an incentive to sponsors developing medicinal products for the paediatric population.

(136) To provide healthcare professionals and patients with information on the safe and efficacious use of medicinal products in the paediatric population, the results of the studies conducted in compliance with an agreed paediatric investigation plan, independently from the fact that they support or not the use of the medicinal product in children, should be included in the summary of product characteristics and, if appropriate, in the package leaflet.

(137) To sustain the development of novel, paediatric only indications from authorised medicinal products no longer covered by intellectual property rights, it is necessary to establish a specific type of marketing authorisation, the paediatric use marketing authorisation. A paediatric use marketing authorisation should be granted through existing marketing authorisation procedures but should apply specifically for medicinal products developed exclusively for use in the paediatric population. It should be possible for the name of the medicinal product that has been granted a paediatric use marketing authorisation to retain the existing name of the corresponding medicinal product authorised for adults, in order to capitalise on existing brand recognition, while benefiting from the regulatory protection associated with a new marketing authorisation.

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(138) An application for a paediatric use marketing authorisation should include the submission of data concerning use of the medicinal product in the paediatric population, collected in accordance with an agreed paediatric investigation plan. Such data could be derived from the published literature or from new studies. An application for a paediatric use marketing authorisation should also be able to refer to data contained in the dossier of a medicinal product which is or has been authorised in the Union. This is intended to provide an additional incentive to encourage SMEs, including companies manufacturing generic medicinal products, to develop off-patent medicinal products for the paediatric population.

(139) Some paediatric investigation plans might be discontinued for various reasons despite possible positive results for the treatment of children obtained from the studies already conducted. The information of such discontinuations and their reasons should be collected by the Agency and made public in order to inform eventual third parties who might be interested in continuing those studies.

(140) To increase the transparency on clinical trials conducted in children in third countries and referred to in a paediatric investigation plan or conducted from a marketing authorisation holder independently from a paediatric investigation plan, information on these clinical trials should be included in the European clinical trial database ('EU database') created pursuant to Regulation (EU) No 536/2014.

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(141) The summary of the results of all the paediatric clinical trials included in the EU database created by Regulation (EU) No 536/2014 should be made publicly available within six months of the end of the clinical trials unless this is not possible for justified scientific reasons.

(142) To discuss priority in medicinal product development, in particular in areas of unmet medical need for children and to coordinate studies relating to paediatric medicinal products, the Agency should set up a European network for paediatric research composed of patient representatives, academics, medicinal products developers, investigators and research centres based in the Union or in the European Economic Area.

(143) Union funding should be provided to cover all aspects of the work of the Agency resulting from paediatric related activities, such as the assessment of paediatric investigation plans, fee waivers for scientific advice, and information and transparency measures, including the database of paediatric studies and the European network for paediatric research.

(144) It is necessary to take measures for the supervision of medicinal products authorised by the Union, and in particular for the intensive supervision of undesirable effects of these medicinal products, and the collection of real-world data within the framework of Union pharmacovigilance activities, so as to ensure the rapid withdrawal from the market of any medicinal product presenting a negative benefit-risk balance under normal conditions of use.

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(145) The main tasks of the Agency in the area of pharmacovigilance laid down in Regulation (EC) No 726/2004 should be maintained. They include the management of the Union pharmacovigilance database and data-processing network (the ‘Eudravigilance database’), the coordination of safety announcements by the Member States and the provision to the public of information regarding safety issues. The Eudravigilance database should be the single point of receipt of pharmacovigilance information. Member States should therefore not impose any additional reporting requirements on marketing authorisation holders. The database should be fully and permanently accessible to the Member States, the Agency and the Commission, and accessible to an appropriate extent to marketing authorisation holders and the public.

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(146) Member States and marketing authorisation holders should operate a pharmacovigilance system to collect information that is useful for the monitoring of medicinal products, including information on suspected adverse reactions arising from use of a medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including off-label use, overdose, misuse, abuse and medication errors by patients and healthcare professionals. Mistakes in the prescribing, dispensing, storing, preparation and administration of medicinal products are common types of medication errors. Suspected adverse reactions should be recorded and reported by Member States and marketing authorisations holders to the Eudravigilance database for the monitoring of safety of medicinal products. The reports should be part of the continuous evaluation of the benefit-risk balance of the medicinal products. Summaries of data relevant to the benefit-risk balance should be included in periodic safety update reports. Marketing authorisation holders should also record and report information on adverse reactions occurring in the context of post-authorisation studies, including post authorisation studies in specific populations such as children, for evaluation of the benefit-risk balance.

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(147) Where the Commission considers that there are reasons to believe that a medicinal product could present a potential serious risk to human health, a scientific evaluation of the medicinal product should be undertaken by the Agency, leading to a decision whether to maintain, vary, suspend or revoke the marketing authorisation, and taken on the basis of an overall evaluation of the benefit-risk balance. It should also be possible for the Commission to act on a centralised marketing authorisation where the conditions attached to it are not complied with.

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(148) It is recognised that improved access to information contributes to public awareness and increases public trust, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. The general public should therefore have access to information in the Union Register of Medicinal Products, the Eudravigilance database and the Union database referred to in Article 191(15) of Directive (EU) 2026/…[+], after the deletion of any commercially confidential information by the competent authority, unless there is an overriding public interest in disclosure, in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council[23]. Regulation (EC) No 1049/2001 gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The Agency should therefore give the widest possible access to the documents while carefully balancing the right to information with existing data protection requirements. Certain public and private interests, such as personal data and commercially confidential information, should be protected by way of exception in accordance with Regulation (EC) No 1049/2001.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

[23] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43, ELI: http://data.europa.eu/eli/reg/2001/1049/oj).

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(149) To enhance the efficiency of market surveillance, the Agency should be responsible for coordinating Member States' pharmacovigilance activities. A number of provisions are required to put in place stringent and efficient pharmacovigilance procedures, to allow the competent authority of the Member State to take provisional emergency measures, including the introduction of amendments to the marketing authorisation and, finally, to permit a reassessment to be made at any time of the benefit-risk balance of a medicinal product.

(150) Scientific and technological progresses in data analytics and data infrastructure are essential for the development, authorisation and supervision of medicinal products. The digital transformation has affected regulatory decision-making, making it more data-driven and multiplying the possibilities to access evidence and real-world data, across the life cycle of a medicinal product. This Regulation recognises the Agency's experience and capacity to access and analyse data submitted independently from the applicant or marketing authorisation holder. On this basis, the Agency should take the initiative to recommend the marketing authorisation holder to vary the summary of product characteristics in cases where new safety or efficacy data have an impact on the benefit-risk balance of a medicinal product, without excluding other actions that the competent authority might take.

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(151) The Union and Member States have developed an evidence-based scientific evaluation process that allows competent authorities of the Member States to determine the relative effectiveness of new or existing medicinal products. This process focuses specifically on the added value of a medicinal product in comparison with other new or existing medicinal products and health technologies. However, such process should not be conducted in the context of a marketing authorisation for which it is agreed that the fundamental criteria of quality, safety and efficacy should be retained. It is useful in this respect to allow the Agency for the possibility of gathering information on the methods used by the Member States to determine the therapeutic benefit obtained by each new medicinal product.

(152) In the area of medicinal products, a high level of protection of health of, inter alia, citizens and consumers, as well as legal certainty and a level playing field and fair competition, always need to be ensured and existing levels of protection need to be respected.

(153) Regulatory sandboxes can provide a structured context for experimentation under a controlled framework, to enable where appropriate in a real-world environment the testing of innovative technologies, products, services or approaches – at the moment especially in the context of digitalisation or the use of AI and machine learning in the life cycle of medicinal products from drug discovery, through the development to the administration of medicinal products – for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place. In particular, SMEs and startups should have the possibility to participate in regulatory sandboxes to which they can, as relevant contribute with their knowhow and experience.

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(154) Implementing powers should be conferred on the Commission to establish a regulatory sandbox, based on the recommendation of the Agency, when the development and authorisation of an innovative medicinal product or innovative category of medicinal products cannot be achieved under the requirements applicable to medicinal products, due to methods related to those innovative medicinal products or innovative categories of medicinal products or their inherent scientific or technical characteristics. A regulatory sandbox facilitates the development, validation and testing of the innovative element of the medicinal products or categories of medicinal products under the supervision of the Agency and national regulators while allowing, where necessary and justified, the adaptation of the regulatory requirements for those medicinal products or categories of medicinal products. However, such adaptation should ensure that the principles of quality, safety and efficacy of medicinal products laid down in Union legislation are respected. Regulatory sandboxes can also benefit patients' access to groundbreaking new therapies without compromising the standards of quality, safety and efficacy. The outcome of regulatory sandboxes should guide the Commission in assessing if an adapted framework for the medicinal products in question is appropriate and should be pursued.

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(155) The establishment of a regulatory sandbox by means of a Commission implementing Decision, following a recommendation of the Agency, should be based on a detailed and comprehensive plan outlining the particularities of the sandbox as well as describing the products to be covered. A regulatory sandbox should be limited in duration and could be terminated at any time based on public health considerations. The learnings stemming from a regulatory sandbox are capable of informing future changes to the legal framework to fully integrate the particular innovative aspects into the medicinal product regulation. Where appropriate, adapted frameworks could be developed by the Commission on the basis of the results of a regulatory sandbox. Marketing authorisations under a sandbox should ensure that the principles of quality, safety and efficacy under this Regulation and Directive (EU) 2026/…[+] are respected. The regulatory sandbox should not affect the supervisory and corrective powers of the competent authorities of the Member States or the Agency and the liability of the participants, such as clinical trial sponsors, marketing authorisation holders, applicants, or any entities involved in the lifecycle of the medicinal product.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(156) Shortages of medicinal products represent a growing threat to public health, with potential serious risks to the smooth functioning of the internal market, as well as the health of patients in the Union and impacts on their right to access appropriate medical treatment, including longer delays or interruptions in care or therapy, longer periods of hospitalisation, increased risks of exposure to falsified medicinal products, medication errors, adverse events following the substitution of unavailable medicinal products with alternative ones, significant psychological distress for patients and increased costs for healthcare systems. The root causes of shortages are multifactorial, with challenges identified along the entire pharmaceutical value chain, and can range from quality to manufacturing problems. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. Member States, depending on their situation, have addressed this in different ways. Due to a lack of coordination of measures taken at national level, these efforts have resulted in a fragmented response jeopardising the availability of medicinal products across the Union. Increased coordination is therefore required at Union level.

(157) More often than in the past, Member States experience critical shortages of various medicinal products, including certain antimicrobials, endangering the health of patients and risking the development of antimicrobial resistance. Those critical shortages of antimicrobials are the result of a multiplicity of factors, including changing infection patterns, which strongly increases demand. On the supply side, the long lead times needed to boost production make it difficult to respond quickly. This experience underlines the need for a dedicated effort from all actors to address the issue of critical shortages.

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(158) To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on reporting of supply disruptions and monitoring of expected or actual shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted in the Union. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection within the Union.

(159) A Member State should be able to decide to exempt a marketing authorisation holder from complying with certain obligations under Chapter X where the medicinal product is authorised by that Member State based on public health grounds.

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(160) Without prejudice to this Regulation, Member States remain the sole responsible for their own national security. They are responsible for defending their essential state functions, including ensuring their territorial integrity and safeguarding national security. In particular, under Article 346 TFEU, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security. For this reason, Member States should be able to exempt marketing authorisation holders and other relevant actors from some of the obligations applicable to them only when the medicinal products are manufactured for military and defence purposes and insofar as the application of such requirements imply a risk to national security and defence. For medicinal products that are supplied for military and defence purposes but also to cover the needs of patients, such exemptions should only target the specific batches that are supplied for military and defence purposes. Furthermore, Member States should be able to also exempt national authorities from communicating information where such a requirement would imply a risk to national security and defence.

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(161) To prevent or mitigate future shortages of medicinal products, marketing authorisation holders should notify the concerned competent authorities of the Member States and, where applicable, the Agency of any future withdrawal of a marketing authorisation, permanent market cessation or temporary suspension of the marketing of a medicinal product and any supply disruption exceeding two weeks. Supply disruptions should be notified as soon as the marketing authorisation holder becomes aware of the situation, and at the latest six months in advance of the interruption, unless there are duly justified exceptional circumstances, to allow competent authorities of the Member States or the Agency to engage with relevant stakeholders and take the necessary mitigation measures. Furthermore, shortage prevention plans are key tools for the prevention of shortages given that they require marketing authorisation holders to identify risks in their supply chains and take the necessary mitigation measures to avoid shortages. Therefore, marketing authorisation holders should have shortage prevention plans in place for medicinal products subject to medical prescription and, where applicable, additional medicinal products identified by the Commission, taking into account recommendations from the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), to prevent or mitigate shortages. The Agency should provide guidance to marketing authorisation holders on approaches to streamline the implementation of those plans. A documented risk assessment of supply chain risks should be required for other medicinal products. The Commission should be able to request the information of the shortage prevention plans of medical countermeasures in the context of crisis preparedness.

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(162) To ensure continuity of supply and availability of medicinal products identified as critical at national level and other specific medicinal products on the market of any Member State where the medicinal product is authorised, rules for the transfer of the marketing authorisation or for the offer of a letter of access prior to the withdrawal of the marketing authorisation or the permanent market cessation, respectively, in Member States where the marketing authorisation is valid, should be laid down. Such transfer should not be considered to be a variation. Rules on wholesale distribution of medicinal products, marketed as a result of a marketing authorisation, whose data have been shared via a letter of access, do not affect the contractual arrangements between the marketing authorisation holders or wholesalers concerned.

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(163) The competent authorities of the Member States should monitor shortages of medicinal products that are authorised through both national and centralised procedures, based on notifications of marketing authorisation holders. The Agency should monitor shortages of centrally authorised medicinal products, also based on notifications of marketing authorisation holders. When critical shortages of Union concern are identified, both competent authorities of the Member States and the Agency should work in a coordinated manner to manage those critical shortages, whether the medicinal product concerned by the critical shortage is covered by a centralised marketing authorisation or a national marketing authorisation and communicate the necessary information to patients, consumers and healthcare professionals. Marketing authorisation holders and other relevant entities should provide the relevant information to inform the monitoring. Wholesale distributors and other entities, including natural and legal persons, such as patient organisations or health-care professionals, should also be able to report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority. The Agency, with the support of MSSG already established within the Agency pursuant to Regulation (EU) 2022/123 of the European Parliament and of the Council[24], should establish and, where necessary, update a list of critical shortages of Union concern. The Agency, in coordination with the competent authority of the Member State concerned should ensure monitoring of those shortages.

[24] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).

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(164) Parallel trade of medicinal products concerns medicinal products traded from one Member State to another Member State. Parallel trade facilitates the free movement of medicinal products due to the fact that the medicinal products are authorised in more Member States on the basis of the Union legislation. This situation is different from export, where the harmonised system of authorising and making medicinal products available on the market does not exist. While the Court has ruled that parallel trade fosters the free movement of medicinal products and is therefore beneficial to the internal market, it has also recognised the need to ensure that a Member State has reliable supplies for essential medical purposes, in particular a supply of medicinal products to the public that is reliable and of good quality. Therefore, it should be possible for a Member State to require, for certain medicinal products, wholesale distributors to inform it whenever such a product leaves the Member State in question to be distributed in another Member State.

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On the basis of that information and other information at its disposal, including shortage prevention plans, the Member State should be able to take measures to prevent or mitigate shortages and should notify them to the Agency. Those measures should also be appropriate and proportionate to such objectives and take into account that the principle of the free movement of goods is restricted only for the purpose of safeguarding public health, thus respecting the case law of the Court and the Treaties, in particular the provisions on free movement of goods and competition. The information requirements laid down in this Regulation do not affect existing obligations under Union law for the notification of technical regulations and technical barriers to the internal market, including those laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council[25]. It is important to recognise that parallel import can contribute to the objective of access to medicinal products, especially in smaller or vulnerable markets.

[25] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1, ELI: http://data.europa.eu/eli/dir/2015/1535/oj).

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(165) A voluntary mechanism can foster solidarity between Member States in the context of critical shortages that require urgent collective action. The voluntary solidarity mechanism for medicinal products can be activated as a last resort mechanism and should aim to support Member States experiencing critical shortages that cannot be resolved at national level despite exhaustive short-term measures. Activation of that Mechanism should be contingent upon specific conditions, including the lack of therapeutic alternatives and insufficient quantities to cover critical indications and an imminent risk of stockout which underline the urgency of the situation. The Agency should facilitate communication and coordinate support responses, thereby also offering assistance in liaising with marketing authorisation holders when necessary. The MSSG should be responsible for establishing procedural rules to ensure the efficient operationalisation of that Mechanism.

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(166) Competent authorities of the Member States should identify, on the basis of a common Union methodology, medicinal products they consider to be critical at national level. The resulting list of critical medicinal products identified by Member States ('Union long list') should be adopted and published by the Commission. The MSSG should also propose a Union list of critical medicinal products authorised in accordance with Directive (EU) 2026/…[+] or in accordance with this Regulation to ensure monitoring of the supply of those products, to be adopted by the Commission. The MSSG, supported by the Agency, should undertake the vulnerability evaluation of critical medicinal products on the Union list of critical medicinal products following a defined prioritisation. The Commission should gradually, taking into account the outcome of the vulnerability evaluation, specify the critical medicinal product for which a vulnerability is established. Among those medicinal products the Commission should also specify those critical medicinal products, including their active substances, which are vulnerable due to a high level of dependency on a single or limited number of countries outside the Union. The MSSG should be able to provide recommendations on measures to be taken by marketing authorisation holders, the Member States, the Commission and other entities to resolve any critical shortage or to ensure the security of supply of those critical medicinal products to the market. Where appropriate, those security of supply measures should also comprise the use of regulatory flexibilities such as on packaging and labelling requirements. However, such flexibility should not undermine the quality, safety, and efficacy standards.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(167) Monitoring and prevention activities, together with targeted actions at national level, have at times proven to be insufficient to prevent disruption of supply within the Union of critical medicinal products. Experience has shown that difficulties in the supply chain have led to uncoordinated approaches at company and governmental level, such as imposing contingency stocks requirements on actors in the supply chain, which led to restrictions in the internal market. Such restrictions are also likely to result in a suboptimal level of availability of critical medicinal products, due to the fact that a fragmented approach is jeopardising the availability throughout the Union. It is necessary to ensure that tools for a Union approach are available to address such situations which are likely to lead to such restrictions, in specific circumstances, to ensure the free movement of medicinal products by safeguarding security of a safe and stable supply of them at Union level. The Commission should therefore be able to draw up recommendations on national measures, after having duly identified a serious risk of disruptions, to improve security of supply within the Union.

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(168) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal products for human use granted in accordance with this Regulation, the Commission should be able to impose financial penalties. When assessing the responsibility for failures to comply with those obligations and imposing such penalties, it is important that means exist to address the fact that marketing authorisation holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties. The penalties imposed should be effective, proportionate and dissuasive, having regard to the circumstances of the specific case. For the purpose of ensuring legal certainty in the conduct of the infringement procedure, it is necessary to set maximum amounts for penalties. Those maximum amounts should not be linked to the turnover of a particular medicinal product but the economic entity involved.

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(169) To supplement or amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of determining the situations in which post-authorisation efficacy studies could be required; specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal; specifying exemptions to variation and the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations as well as specifying conditions and procedures for cooperation with third countries and international organisations for examination of applications for such variations; establishing procedures for the examination of applications for the transfer of marketing authorisations; laying down the procedure and rules for the imposition of fines or periodic penalty payments for a failure to comply with the obligations under this Regulation as well as the conditions and methods for their collection. The Commission should be empowered to adopt supplementary measures laying down the situations in which post-authorisation efficacy studies could be required.

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It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission of 13 April 2016 on Better Law-Making[26]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

[26] OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

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(170) In order to ensure uniform conditions for the implementation of this Regulation in relation to marketing authorisations for medicinal products for human use, implementing powers should be conferred on the Commission. The implementing powers related to the granting of centralised marketing authorisations and for suspending, revoking or withdrawing those authorisations, for granting data exclusivity vouchers, establishing and modifying regulatory sandboxes and adopting decisions on the regulatory status of medicinal products should be exercised in accordance with Regulation (EU) No 182/2011.

(171) Article 91 of Regulation (EU) No 536/2014 currently stipulates, amongst others, that it applies without prejudice to Directives 2001/18/EC and 2009/41/EC.

(172) Experience shows that, in clinical trials with investigational medicinal products consisting of, or containing, GMOs, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.

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(173) The complexity of that procedure increases greatly in the case of multi-centre clinical trials conducted in several Member States, as sponsors of clinical trials need to submit multiple requests for authorisation to multiple competent authorities in different Member States in parallel. In addition, national requirements and procedures for the environmental risk assessment (ERA) and written consent by competent authorities under GMO legislation vary greatly from one Member State to another as some Member States apply Directive 2001/18/EC, others apply Directive 2009/41/EC and there are Member States that apply either Directive 2009/41/EC or 2001/18/EC depending on the specific circumstances of a clinical trial. It is therefore not possible to determine a priori the national procedure that is to be followed.

(174) Consequently, it is particularly difficult to conduct multi-centre clinical trials with investigational medicinal products that consist of, or contain, GMOs involving several Member States.

(175) One of the objectives of Regulation (EU) No 536/2014 is that there will be a single coordinated and harmonised assessment of the clinical trial application between the involved Member States, with one country leading the coordination of the assessment (the ‘reporting Member State’).

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(176) It is therefore appropriate to envisage a centralised assessment of the ERA involving experts from the competent authorities of the Member States and where relevant the Environmental Risk Assessment working party.

(177) Article 5 of Directive 2001/18/EC provides that the authorisation procedures for the deliberate release into the environment of GMOs for any other purpose than for placing on the market and related provisions in Articles 6 to 11 do not apply to medicinal substances and compounds for human use if such release is authorised by Union legal acts that meet the requirements listed in that Article.

(178) The requirement for the holding of authorisation of manufacturing and import of investigational medicinal products in the Union in accordance with Article 61(2), point (a), of Regulation (EU) No 536/2014 should be extended to investigational medicinal products consisting of, or containing, GMOs in Directive 2009/41/EC.

(179) It is thus judicious, in order to ensure an efficient functioning of Regulation (EU) No 536/2014, to define a specific authorisation procedure for the deliberate release of medicinal substances and compounds for human use consisting of, or containing, GMOs that meet requirements of Article 5 of Directive 2001/18/EC and taking into account the specific characteristics of medicinal substances and compounds.

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(180) Detailed rules concerning financial penalties for failure to comply with certain obligations laid down in this Regulation are specified in Commission Regulation (EC) No 658/2007[27]. Those rules should be maintained, but it is appropriate to consolidate them by moving their core elements and the list specifying those obligations into this Regulation, while maintaining a delegation of powers that allows the Commission to supplement this Regulation by laying down procedures for imposing such financial penalties. It is appropriate, in order to provide for legal certainty, to clarify that Commission Regulation (EC) No 2141/96[28] remains in force and continues to apply unless and until repealed. For the same reason, it should be clarified that Commission Regulations (EC) No 2049/2005[29], (EC) No 507/2006[30], (EC) No 658/2007 and (EC) No 1234/2008[31] remain in force and continue to apply unless and until repealed.

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27 Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 155, 15.6.2007, p. 10, ELI: http://data.europa.eu/eli/reg/2007/658/oj).

28 Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93 (OJ L 286, 8.11.1996, p. 6, ELI: http://data.europa.eu/eli/reg/1996/2141/oj).

29 Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (OJ L 329, 16.12.2005, p. 4, ELI: http://data.europa.eu/eli/reg/2005/2049/oj).

30 Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 92, 30.3.2006, p. 6, ELI: http://data.europa.eu/eli/reg/2006/507/oj).

31 Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use (OJ L 334, 12.12.2008, p. 7, ELI: http://data.europa.eu/eli/reg/2008/1234/oj).

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(181) This Regulation is based on the double legal basis of Article 114 and Article 168(4), point (c), TFEU. It aims at achieving an internal market as regards medicinal products for human use, based on a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medicinal products in order to meet common safety concerns as regards those products. Both objectives are being pursued simultaneously. Those two objectives are inseparably linked and one is not secondary to another. Regarding Article 114 TFEU, this Regulation establishes a European Medicines Agency and provides specific provision with regard to the central authorisation of medicinal products, therefore ensuring the functioning of the internal market and the free movement of medicinal products. Regarding Article 168(4), point (c), TFEU, this Regulation sets high standards of quality and safety for medicinal products.

(182) Since provisions on the centralised procedure for the authorisation and supervision of medicinal products for human use, including orphan medicinal products and paediatric medicinal products, and on the European Medicines Agency, are integrated into this Regulation, it is necessary to repeal Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006.

(183) This Regulation respects the fundamental rights and observes the principles recognised by the Charter and in particular human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science. Similarly this regulation integrates a high level of protection of the environment.

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(184) Since the objective of this Regulation, namely to ensure the authorisation of high quality medicinal products, including for paediatric patients and patients suffering from rare diseases throughout the Union, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale of the action needed, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(185) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on 19 June 2023[32],

HAVE ADOPTED THIS REGULATION:

[32] OJ C, C/2023/712, 14.11.2023, ELI: http://data.europa.eu/eli/C/2023/712/oj.

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Chapter I
Subject matter, scope and definitions

Article 1

Subject matter and scope

1. This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level.

2. This Regulation also establishes rules and procedures, at both Union and Member State level, relating to the monitoring and management of shortages and critical shortages and the security of supply of medicinal products.

3. Furthermore, this Regulation establishes the European Medicines Agency (the 'Agency'), previously established by Regulation (EC) No 726/2004, and lays down provisions concerning its governance, as well as provisions concerning its tasks relating to medicinal products for human use laid down in this Regulation, and concerning other tasks laid down in Regulation (EU) 2019/6 and in other relevant Union legal acts.

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4. This Regulation shall not affect the powers of Member States' authorities as regards setting the prices of medicinal products for human use, or the inclusion of medicinal products within national health systems or social security schemes on the basis of health, economic and social conditions. Member States may choose from the particulars contained in the marketing authorisation those therapeutic indications and pack sizes which will be covered by their social security bodies.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medicinal product' or 'medicinal product for human use' means a medicinal product as defined in Article 5(1), point (1), of Directive (EU) 2026/…[+];

(2) 'antimicrobial' means an antimicrobial as defined in Article 5(1), point (23), of Directive (EU) 2026/…[+];

(3) 'antimicrobial resistance' means antimicrobial resistance as defined in Article 5(1), point (24), of Directive (EU) 2026/…[+];

(4) 'substance' means a substance as defined in Article 5(1), point (2), of Directive (EU) 2026/…[+];

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(5) ‘active substance’ means an active substance as defined in Article 5(1), point (3), of Directive (EU) 2026/…[+];

(6) ‘active substance master file’ means an active substance master file as defined in Article 5(1), point (42), of Directive (EU) 2026/…[+];

(7) ‘radiopharmaceutical’ means radiopharmaceutical as defined in Article 5(1), point (19), of Directive (EU) 2026/…[+];

(8) ‘reference medicinal product’ means a reference medicinal product as defined in Article 5(1), point (12), of Directive (EU) 2026/…[+];

(9) ‘homeopathic medicinal product’ means a homeopathic medicinal product as defined in Article 5(1), point (67), of Directive (EU) 2026/…[+];

(10) ‘package leaflet’ means package leaflet as defined in Article 5(1), point (49), of Directive (EU) 2026/…[+];

(11) ‘labelling’ means labelling as defined in Article 5(1), point (52), of Directive (EU) 2026/…[+];

(12) ‘environmental risk assessment’ or ‘ERA’ means an environmental risk assessment as defined in Article 5(1), point (40), of Directive (EU) 2026/…[+];

(13) ‘starting material’ means starting material as defined in Article 5(1), point (4), of Directive (EU) 2026/…[+];

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(14) ‘intermediate product’ means an intermediate product as defined in Article 5(1), point (5), of Directive (EU) 2026/…[+];

(15) ‘excipient’ means an excipient as defined in Article 5(1), point (6), of Directive (EU) 2026/…[+];

(16) ‘post-authorisation safety study’ means a post-authorisation safety study as defined in Article 5(1), point (61), of Directive (EU) 2026/…[+];

(17) ‘adverse reaction’ means an adverse reaction as defined in Article 5(1), point (64), of Directive (EU) 2026/…[+];

(18) ‘non-clinical’, with respect to a study or test, means non-clinical as defined in Article 5(1), point (11), of Directive (EU) 2026/…[+];

(19) ‘benefit-risk balance’ means benefit-risk balance as defined in Article 5(1), point (47), of Directive (EU) 2026/…[+];

(20) ‘risk management plan’ means a risk management plan as defined in Article 5(1), point (38), of Directive (EU) 2026/…[+];

(21) ‘risk management system’ means a risk management system as defined in Article 5(1), point (39), of Directive (EU) 2026/…[+];

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(22) ‘pharmacovigilance system’ means a pharmacovigilance system as defined in Article 5(1), point (62), of Directive (EU) 2026/…[+];

(23) ‘pharmacovigilance system master file’ means a pharmacovigilance system master file as defined in Article 5(1), point (63), of Directive (EU) 2026/…[+];

(24) ‘medical prescription’ means a medical prescription as defined in Article 5(1), point (45), of Directive (EU) 2026/…[+];

(25) ‘variation’ or ‘variation of the terms of a marketing authorisation’ means a variation or a variation of the terms of a marketing authorisation as defined in Article 5(1), point (60), of Directive (EU) 2026/…[+];

(26) ‘critical medicinal product’ means a medicinal product whose insufficient supply would result in serious harm or risk of serious harm to patients, and identified using the methodology set out in Article 136(1), point (a);

(27) ‘not-for-profit entity’ means a not-for-profit entity as defined in Article 5(1), point (58), of Directive (EU) 2026/…[+];

(28) ‘micro, small and medium-sized enterprise’ means a micro, small and medium-sized enterprise as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC;

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(29) ‘medical device’ means a medical device as defined in Article 2, point (1), of Regulation (EU) 2017/745;

(30) ‘*in vitro* diagnostic medical device’ means an *in vitro* diagnostic medical device as defined in Article 2, point (2), of Regulation (EU) 2017/746;

(31) ‘advanced therapy medicinal product’ means an advanced therapy medicinal product as defined in Article 2(1), point (a), of Regulation (EC) No 1394/2007 of the European Parliament and of the Council[33];

(32) ‘allergen medicinal product’ means an allergen medicinal product as defined in Article 5(1), point (10), of Directive (EU) 2026/…[+];

(33) ‘substance of human origin’ or ‘SoHO’ means a substance of human origin as defined in Article 3, point (1), of Regulation (EU) 2024/1938 of the European Parliament and of the Council[34];

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[33] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121, ELI: http://data.europa.eu/eli/reg/2007/1394/oj).

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

[34] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).

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(34) ‘orphan condition’ means a life-threatening or chronically debilitating condition that meets the rarity criteria set out in Article 65(1), point (a), and Article 65(2);

(35) ‘designated orphan medicinal product’ means a medicinal product under development which has been granted an orphan designation by a decision pursuant to Article 66(4);

(36) ‘orphan medicinal product’ means a medicinal product which has been granted an orphan marketing authorisation pursuant to Article 71;

(37) ‘orphan medicinal product sponsor’ means any legal or natural person, established in the Union, who has submitted an application for or been granted an orphan designation for a medicinal product by a decision pursuant to Article 66(4);

(38) ‘significant benefit’ means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product if such an advantage or contribution benefits the relevant part of the target population;

(39) ‘clinically superior’, with respect to a medicinal product, means that a medicinal product is shown to provide a significant therapeutic or diagnostic advantage above that provided by an orphan medicinal product in one or more of the following ways:

(a) greater efficacy in the relevant part of the target population than an orphan medicinal product which has market exclusivity;

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(b) greater safety in the relevant part of the target population than an orphan medicinal product which has market exclusivity;

(c) in exceptional cases, where neither greater safety nor greater efficacy as referred to in points (a) and (b) has been shown, demonstration that the medicinal product otherwise makes a major contribution to diagnosis or to patient care;

(40) ‘similar active substance’ means an identical active substance, or an active substance, which has the same principal molecular structural features (but not necessarily all of the same molecular structural features) and which acts via the same mechanism; for advanced therapy medicinal products, for which the principal molecular structural features cannot be fully determined, the similarity between two active substances shall be assessed based on the biological and functional characteristics;

(41) ‘similar medicinal product’ means a medicinal product which contains a similar active substance or similar active substances as contained in an orphan medicinal product for the same therapeutic indication;

(42) ‘generic medicinal product’ means a generic medicinal product as defined in Article 5(1), point (13), of Directive (EU) 2026/…[+];

(43) ‘biosimilar medicinal product’ means a biosimilar medicinal product as defined in Article 5(1), point (15), of Directive (EU) 2026/…[+];

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(44) ‘paediatric investigation plan’ means a paediatric investigation plan as defined in Article 5(1), point (43), of Directive (EU) 2026/…[+];

(45) ‘paediatric population’ means paediatric population as defined in Article 5(1), point (44), of Directive (EU) 2026/…[+];

(46) ‘strength’ as regards a medicinal product means strength as defined in Article 5(1), point (55), of Directive (EU) 2026/…[+];

(47) ‘paediatric use marketing authorisation’ means a marketing authorisation granted for a medicinal product for human use which is not protected by a supplementary protection certificate under Regulation (EC) No 469/2009 of the European Parliament and of the Council[35] or by a patent which qualifies for the granting of the supplementary protection certificate, and which covers exclusively therapeutic indications which are relevant for use in the paediatric population, or subsets thereof, including the appropriate strength, pharmaceutical form or route of administration for that product;

(48) ‘public health emergency’ means a public health emergency as defined in Article 5(1), point (57), of Directive (EU) 2026/…[+];

(49) ‘vaccine’ means a vaccine as defined in Article 5(1), point (31), of Directive (EU) 2026/…[+];

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

[35] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/469/oj).

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(50) ‘name of the medicinal product’ means the name of the medicinal product as defined in Article 5(1), point (53), of Directive (EU) 2026/…[+];

(51) ‘abuse of medicinal products’ means abuse of medicinal products as defined in Article 5(1), point (46), of Directive (EU) 2026/…[+];

(52) ‘regulatory sandbox’ means a regulatory framework within which it is possible to develop, validate and test innovative or adapted regulatory solutions in a controlled environment, thereby facilitating the development and authorisation of innovative medicinal products which are likely to fall within the scope of this Regulation, according to a specific plan and for a limited time under regulatory supervision;

(53) ‘letter of access’ means a letter of access as defined in Article 5(1), point (16), of Directive (EU) 2026/…[+];

(54) ‘shortage’ means a situation in which the supply (as defined in Annex IV) of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand (as defined in Annex IV) for that medicinal product in that Member State whatever the cause;

(55) ‘critical shortage in the Member State’ means a shortage of a medicinal product for which there is no appropriate alternative medicinal product available in sufficient quantities on the market in a Member State and which could result in a significant impact on the healthcare system of that Member State, or result in harm or risk of harm to patients;

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(56) ‘critical shortage of Union concern’ means a critical shortage in the Member State that cannot be resolved at Member State level and for which coordinated Union level action is necessary to resolve it in accordance with this Regulation;

(57) ‘wholesale distribution’, with respect to medicinal products, means wholesale distribution as defined in Article 5(1), point (76), of Directive (EU) 2026/…[+];

(58) ‘falsified medicinal product’ means a falsified medicinal product as defined in Article 5(1), point (56), of Directive (EU) 2026/…[+];

(59) ‘veterinary medicinal product’ means a medicinal product as defined in Article 4, point (1), of Regulation (EU) 2019/6;

(60) ‘herbal medicinal product’ means a herbal medicinal product as defined in Article 5(1), point (69), of Directive (EU) 2026/…[+];

(61) ‘biological medicinal product’ means a biological medicinal product as defined in Article 5(1), point (14), of Directive (EU) 2026/…[+];

(62) ‘manufacture of medicinal products’ means manufacture of medicinal products as defined in Article 5(1), point (73), of Directive (EU) 2026/…[+];

(63) ‘decentralised manufacturing’ means decentralised manufacturing as defined in Article 5(1), point (74), of Directive (EU) 2026/…[+].

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Article 3

Centrally authorised medicinal products

1. A medicinal product listed in Annex I shall be placed on the market in the Union only if it has been granted a marketing authorisation by the Union in accordance with this Regulation (‘centralised marketing authorisation’ or ’marketing authorisation’).

2. A medicinal product not listed in Annex I may be granted a centralised marketing authorisation, if it meets at least one of the following requirements:

   (a) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of a centralised marketing authorisation is in the interest of patients’ health at Union level, including in relation to antimicrobial resistance and medicinal products for public health emergencies;

   (b) it is a medicinal product intended solely for paediatric use;

   (c) the applicant refers in the marketing authorisation application to a reference medicinal product that has been authorised through the centralised marketing authorisation procedure (‘centralised procedure’);

   (d) the medicinal product contains a new active substance which, on 20 May 2004, was not authorised in the Union.

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3. Homeopathic medicinal products shall not be granted a centralised marketing authorisation.

4. The Commission shall grant and supervise centralised marketing authorisations for medicinal products for human use in accordance with Chapter II.

5. The Commission is empowered to adopt delegated acts in accordance with Article 181 to amend Annex I, in order to adapt it to scientific and technological progress. When preparing and drawing up a delegated act, the Commission shall:

(a) justify the appropriateness of updating the description of the biotechnological processes referred to in point 1 of Annex I on the basis of scientific and technological evidence;

(b) base the delegated act on an up-to-date scientific literature review as regards the types and extent of developments that have occurred, including, where applicable, international guidelines and comparative standards;

(c) where applicable, take into account any relevant new or updated scientific opinions from the WHO or medicines agencies.

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Article 4

National marketing authorisation of medicinal products

that refer to centrally authorised reference medicinal products

By way of derogation from Article 3 of this Regulation, the competent authorities of the Member States may authorise, in accordance with Directive (EU) 2026/…[+], a medicinal product that refers to a centrally authorised reference medicinal product where the following conditions are met:

(a) the application for marketing authorisation is submitted in accordance with Article 10 or 12 of Directive (EU) 2026/…[+] or, in duly justified cases, in accordance with Article 11 or 13 of that Directive;

(b) the summary of product characteristics and the package leaflet are in all relevant respects consistent with that of the medicinal product authorised by the Union, including its indications;

(c) the reference medicinal product is not a medicinal product referred to in Annex I, point 1 or 2.

Where the application for marketing authorisation is submitted in accordance with Article 11 or 13 of Directive (EU) 2026/…[+], the applicant shall demonstrate that all the indications covered by the application have been centrally authorised for the active substance concerned.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Point (b) of the first paragraph shall not apply to those parts of the summary of product characteristics or the package leaflet that refer to indications, posologies, pharmaceutical forms, methods or routes of administration or any other ways in which the medicinal product can be used that were protected by a patent or a supplementary protection certificate for medicinal products at the time of the placing on the market of the medicinal product for which a marketing authorisation has been applied for under this Article where the applicant has requested not to include that information in the marketing authorisation.

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Chapter II

General provisions and rules on applications

SECTION 1

APPLICATION FOR CENTRALISED MARKETING AUTHORISATIONS

Article 5

Submission of applications for centralised marketing authorisations

1. The marketing authorisation holder for medicinal products covered by this Regulation shall be established in the Union. The marketing authorisation holder shall be responsible for the placing on the market of those medicinal products, whether done by that marketing authorisation holder or by one or more persons designated to that effect.

2. The marketing authorisation applicant (the ‘applicant’) and the Agency shall agree on the submission date for a marketing authorisation application.

3. The applicant shall submit an application for a marketing authorisation electronically to the Agency, using the format made available by the Agency.

4. The applicant shall be responsible for the accuracy and completeness of the information and documents submitted with respect to its application.

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5. Within 20 days of receipt of an application, the Agency shall check whether all particulars and documents required under Article 7 have been submitted and whether the application contains any critical deficiencies that might prevent the evaluation of the medicinal product. The Agency shall then decide on the validity of the application.

6. If the Agency considers that the application is incomplete, or contains critical deficiencies that may prevent the evaluation of the medicinal product, it shall notify the applicant accordingly and set a time limit for submitting the missing information and documents. The Agency may extend that time limit once.

   Upon receiving the applicant's responses to the request for missing information and documents, the Agency shall determine whether the application can be considered valid. If the Agency refuses to validate an application, it shall notify the applicant and provide the reasons for such a refusal.

   If the applicant fails to provide the missing information and documents within the time limit referred to in the first subparagraph, the application shall be considered to have been withdrawn.

7. The Agency shall draw up scientific guidelines for the identification of critical deficiencies that might prevent the evaluation of a medicinal product, in consultation with the Commission and the Member States.

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Article 6

Requirements to place on the market and supply centrally authorised medicinal products

1. With a view to facilitating access to a centrally authorised medicinal product, and where such product is subject, as applicable, to regulatory data protection or regulatory market protection pursuant to Article 83 of Directive (EU) 2026/…[+], market exclusivity pursuant to Article 73 of this Regulation, patent or a supplementary protection certificate, a Member State may request the marketing authorisation holder to place that medicinal product on the market of that Member State and to supply it, either in accordance with the requirements laid down in Article 59 of Directive (EU) 2026/…[+], including the requirements referred to in paragraph 2 of that Article, or independently from the provisions of that Article. The marketing authorisation holder shall ensure, upon agreement with the respective Member State and within the limits of its responsibility, that such medicinal product is placed on the market and supplied so that the needs of patients in that Member State are met.

The practical arrangements between the marketing authorisation holder and the respective Member State to implement the requirements laid down in the first subparagraph shall be proportionate to the objective pursued.

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A marketing authorisation holder shall comply with the requirements laid down in the first subparagraph, unless there are exceptional and unforeseeable circumstances, including those related to disruptions of supply, or other circumstances fully outside the marketing authorisation holder's control, the consequences of which could not have been avoided even if all best reasonable measures had been taken. In such a case, the marketing authorisation holder shall provide an explanation of the circumstances of the case and provide duly justified reasons for non-compliance.

2. Where a Member State considers that a marketing authorisation holder has consistently failed to place on the market and supply a medicinal product to meet the needs of patients in that Member State, it may inform the Commission. The Member State shall provide the Commission with a detailed description of the facts of the case and substantiate the marketing authorisation holder's failure to place on the market and supply a medicinal product.

Prior to informing the Commission, the Member State shall notify the marketing authorisation holder concerned and invite it to provide written observations within four weeks of the notification. This period may be extended once. The written observations shall be attached to the information provided to the Commission in accordance with the first subparagraph. When informing the Commission, the Member State shall duly consider the explanations provided by the marketing authorisation holder in its written observations.

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3. Whenever more than one Member State invokes non-compliance pursuant to the first subparagraph of paragraph 2 in relation to the same medicinal product, the Commission shall require the marketing authorisation holder to enter into negotiations in good faith with those Member States and make best efforts to ensure supply in order to meet the needs of patients in those Member States.

4. By … [four years from the date of application of this Regulation], the Commission shall present a report to the European Parliament and the Council on the application of this Article. That report shall be based on, inter alia, information provided by Member States, and it shall include an assessment of whether the rules provided for in this Article ensure that the medicinal products concerned are placed on the market and supplied for use in patients in all Member States that have applied this Article. The Commission shall, where appropriate, submit legislative proposals based on that assessment, in particular with regard to remedial actions in the case of non-compliance, including the possibility to impose penalties in accordance with Article 178.

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Article 7

Centralised marketing authorisation applications

1. Applications for a centralised marketing authorisation of a medicinal product for human use, submitted to the Agency in accordance with Article 5 of this Regulation, shall specifically and completely include the particulars and documents required pursuant to Chapter II of Directive (EU) 2026/…[+]. In the case of applications in accordance with Article 7(2) and Articles 11 and 13 of Directive (EU) 2026/…[+], those particulars and documents shall be accompanied by raw data submitted electronically, in accordance with Annex II to that Directive.

The particulars and documents referred to in the first subparagraph of this paragraph shall include a declaration to the effect that clinical trials carried out outside the Union meet the ethical requirements of Regulation (EU) No 536/2014. Those particulars and documents shall take account of the Union nature of the authorisation requested and, in cases other than exceptional cases relating to the application of the law on trademarks pursuant to Regulation (EU) 2017/1001 of the European Parliament and of the Council[36], shall include the use of a single name for the medicinal product. The use of a single name shall not exclude the use of additional qualifiers where necessary to identify different presentations of the medicinal product concerned.

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[36] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/1001/oj).

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2. The Agency may offer to the applicant a phased review of complete data packages for individual modules of particulars and documents as referred to in paragraph 1 for medicinal products which:

(a) are likely to address an unmet medical need as referred to in Article 85(1) of Directive (EU) 2026/…[+] and are expected to be of major interest from the point of view of public health, particularly regarding its therapeutic innovation;

(b) are antimicrobials with any of the characteristics mentioned in Article 41(3) or are antimicrobials targeting pathogens included in the 'WHO bacterial priority pathogens list', specifically those listed in the 'critical group' or 'high group', or included in any equivalent list of priority pathogens established at Union level; or

(c) are intended to be used in relation to a potential or recognised public health emergency.

The Agency shall apply the first subparagraph following the advice of the Committee for Medicinal Products for Human Use regarding the fulfilment of the criteria listed in points (a) to (c) of the first subparagraph, and the maturity of the data concerning the development of those medicinal products.

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The Agency may at any stage suspend or cancel the phased review, where the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient maturity or where it considers that the medicinal product no longer fulfils the criteria set out in the first subparagraph. The Agency shall inform the applicant accordingly.

3. A fee shall apply for a centralised marketing authorisation application and shall be payable to the Agency for the examination of the application.

4. Where appropriate, the application for a centralised marketing authorisation may include summary documents, certificates, protocols or master files in accordance with Chapter II, Section 4, and Annex II to Directive (EU) 2026/…[+].

5. The applicant shall demonstrate that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied in accordance with Directive 2010/63/EU with regard to any animal study conducted in support of the application.

The applicant shall not carry out animal testing where scientifically satisfactory non-animal testing methods are available.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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6. The Agency shall ensure that the opinion of the Committee for Medicinal Products for Human Use is issued within 180 days of receipt of a valid application. In the case of a medicinal product for human use that consists of, or contains, genetically modified organisms (GMOs) the opinion of that Committee shall take into account the evaluation of the environmental risk assessment in accordance with Article 8(1).

On the basis of a duly justified request, the Committee for Medicinal Products for Human Use may extend the duration of the analysis of the scientific data related to an application for a centralised marketing authorisation.

7. When an application for a centralised marketing authorisation is submitted for a medicinal product for human use which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure. That shall also apply to medicinal products referred to in Article 62. The request shall be duly substantiated.

If the Committee for Medicinal Products for Human Use accepts the request referred to in the first subparagraph of this paragraph, the time limit specified in paragraph 6, first subparagraph, shall be reduced to 150 days.

8. The adapted frameworks established in accordance with Article 31 of Directive (EU) 2026/…[+] may also apply for the purpose of obtaining a centralised marketing authorisation in accordance with this Regulation.

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Article 8

Environmental risk assessment for medicinal products consisting of, or containing, GMOs

1. Without prejudice to Article 23 of Directive (EU) 2026/…[+], the marketing authorisation application of a medicinal product for human use consisting of, or containing, GMOs as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the GMOs on human or animal health, and the environment.

2. The environmental risk assessment for the medicinal products referred to in paragraph 1 of this Article shall be conducted in accordance with the elements listed in Article 9 of this Regulation and the specific requirements set out in Annex II to Directive (EU) 2026/…[+] which are based on the principles laid down in Annex II to Directive 2001/18/EC taking into account the specificities of medicinal products.

3. Articles 13 to 24 of Directive 2001/18/EC shall not apply to medicinal products for human use consisting of, or containing, GMOs.

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4. Articles 6 to 11 of Directive 2001/18/EC as well as Articles 4 to 13 of Directive 2009/41/EC shall not apply to operations related to the supply and clinical use, including the packaging and labelling, distribution, storage, transport, preparation for administration, administration, destruction or disposal of medicinal products consisting of, or containing, GMOs, with the exception of their manufacture, in any of the following cases:

(a) where such medicinal products have been exempted from the requirements of Directive (EU) 2026/…[+] by a Member State pursuant to Article 4(1) of that Directive;

(b) where the use and distribution of such medicinal products have been temporarily authorised by a Member State pursuant to Article 4(4) of Directive (EU) 2026/…[+]; or

(c) where such medicinal products are made available by a Member State pursuant to Article 27(1).

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5. In the cases referred to in paragraph 4, Member States shall implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the medicinal products consisting of, or containing, GMOs into the environment.

The competent authorities of the Member States shall ensure that information related to the use of medicinal products referred to in paragraph 4 of this Article is available and provided to the competent authorities under Directive 2009/41/EC, when necessary and in particular in the event of an accident referred to in Articles 14 and 15 of Directive 2009/41/EC.

Article 9

Content of the environmental risk assessment for medicinal products consisting of, or containing, GMOs

The environmental risk assessment referred to in Article 8(2) shall contain the following elements:

(a) a description of the GMO and the modifications introduced as well as characterisation of the finished product;

(b) an identification and characterisation of hazards for the environment, animals and human health;

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(c) an exposure characterisation, which assesses the likelihood or probability that the identified hazards materialise;

(d) a risk characterisation, which takes into account the magnitude of each possible hazard and the likelihood or probability that an adverse effect occurs;

(e) risk minimisation and mitigation strategies proposed to address identified risks including specific containment measures to limit contact of the medicinal product with human beings other than the intended patient and its dissemination in the environment;

(f) an overall risk evaluation and conclusions.

Article 10

Procedure for the environmental risk assessment for medicinal products consisting of, or containing, GMOs

1. The applicant shall submit an environmental risk assessment as provided for in Article 8(1) to the Agency.

The Committee for Medicinal Products for Human Use shall assess the environmental risk assessment.

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2. In the case of first-in-class medicinal products or when a novel question is raised during the assessment of the submitted environmental risk assessment, the Committee for Medicinal Products for Human Use, or the rapporteur appointed by that Committee, shall, as necessary, carry out consultations with bodies established by Member States in accordance with Directive 2001/18/EC. They shall, as necessary, consult the relevant Union bodies. Details on the consultation procedure shall be published by the Agency at the latest by … [12 months from the date of entry into force of this Regulation].

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Article 11

Assessment by the Committee for Medicinal Products for Human Use of applications for marketing authorisation

1. When preparing its opinion pursuant to Article 13, the Committee for Medicinal Products for Human Use shall verify that the particulars and documents submitted in accordance with Article 7 comply with the requirements of Directive (EU) 2026/…[+], and shall assess whether the conditions specified in this Regulation for granting a centralised marketing authorisation are satisfied. When preparing its opinion, the Committee for Medicinal Products for Human Use may request:

   (a) that an official medicines control laboratory or a laboratory that a Member State has designated for that purpose tests the medicinal product for human use, its starting materials, ingredients and, where necessary, its intermediate products or other constituents in order to ensure that the control methods employed by the manufacturer and described in the particulars and documents accompanying the centralised marketing authorisation application are satisfactory;

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(b) that the applicant supplements the particulars and documents accompanying the application within a specific time -limit; in the event of such a request, the time limit specified in Article 7(6), first subparagraph, shall be suspended until the supplementary information requested is provided; likewise, this time limit shall be suspended for the time allowed for the applicant to prepare oral or written explanations.

2. Where within 90 days of the date of validation of the centralised marketing authorisation application and during its assessment, the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient quality or maturity to complete the assessment, the assessment may be terminated. Prior to the termination, the Committee for Medicinal Products for Human Use shall summarise the deficiencies in writing. On that basis, the Agency shall inform the applicant accordingly and set a time limit for the applicant to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the Agency, the assessment shall be terminated and the application shall be considered to have been withdrawn.

3. The Committee for Medicinal Products for Human Use may consider additional evidence that is available to the Agency, independently from the data submitted by the applicant, and adopt its opinion pursuant to Article 13 based on that evidence.

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Article 12

Certification of manufacturer and importer and inspection of the manufacturing site

1. Upon receipt of a written request from the Committee for Medicinal Products for Human Use, a Member State shall provide the information demonstrating that the manufacturer of a medicinal product or the importer from a third country is able to manufacture the medicinal product concerned or carry out the necessary control tests, or both, in accordance with the particulars and documents submitted by the applicant pursuant to Article 7.

2. The Committee for Medicinal Products for Human Use may, if it considers it necessary in order to complete its assessment, require the applicant to undergo a specific inspection of the manufacturing site of the medicinal product concerned.

   The inspection shall be carried out within the time limit specified in Article 7(6), first subparagraph, by inspectors from the Member State holding the appropriate qualifications. Those inspectors may be accompanied by a rapporteur or an expert appointed by the Committee for Medicinal Products for Human Use, or by one or more inspectors of the Agency. The inspection may be carried out unannounced.

   For manufacturing sites located in third countries, the inspection may be carried out by the Agency, following a request by the Member States and based on the procedure laid down in Article 54.

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Article 13

Committee for Medicinal Products for Human Use opinion

1. The Agency shall without undue delay inform the applicant if the opinion of the Committee for Medicinal Products for Human Use is that the application:

   (a) does not satisfy the criteria for centralised marketing authorisation set out in this Regulation;

   (b) satisfies the criteria set out in this Regulation provided that changes required by the Agency to the summary of product characteristics are made;

   (c) satisfies the criteria set out in this Regulation provided that changes required by the Agency to the labelling or package leaflet of the medicinal product are made to ensure compliance with Chapter VI of Directive (EU) 2026/…[+]; or

   (d) where applicable, satisfies the criteria set out in Articles 19 and 20 subject to specific conditions set out in those Articles.

2. Within 12 days of receipt of the opinion referred to in paragraph 1, the applicant may request by written notice to the Agency a re-examination of the opinion. In that case, the applicant shall provide the Agency with the detailed grounds for the request within 60 days of receipt of the opinion.

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The re-examination procedure shall address only the points of the opinion initially identified by the applicant and shall be based only on the scientific data available at the time the Committee for Medicinal Products for Human Use adopted its initial opinion.

Within 60 days of receipt of the grounds for the request, the Committee for Medicinal Products for Human Use shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the final opinion.

3. Within 12 days of the adoption of the final opinion of the Committee for Medicinal Products for Human Use, the Agency shall send it to the Commission, to the Member States and to the applicant, together with a report describing the assessment of the medicinal product by the Committee for Medicinal Products for Human Use and stating the reasons for its conclusions (the 'assessment report').

4. If an opinion is favourable to the granting of the relevant marketing authorisation, the following documents shall be annexed to the opinion:

(a) a summary of product characteristics referred to in Article 65 of Directive (EU) 2026/…[+] which corresponds to the assessment of the medicinal product and to the opinion referred to in paragraph 1;

(b) a recommendation on the frequency of submission of periodic safety update reports;

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(c) details of any conditions or restrictions to be imposed on the supply or use of the medicinal product concerned, including the conditions under which the medicinal product may be made available to patients, in accordance with the criteria set out in Chapter XII of Directive (EU) 2026/…[+];

(d) details of any recommended conditions or restrictions with regard to the safe and effective use of the medicinal product;

(e) details of any recommended measures for ensuring the safe use of the medicinal product to be included in the risk management system;

(f) where appropriate, details of any recommended obligation to conduct post-authorisation safety studies or to comply with obligations on the recording or reporting of suspected adverse reactions which are stricter than those referred to in Chapter VIII of this Regulation;

(g) where appropriate, details of any recommended obligation to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been placed on the market. Such an obligation to conduct such studies shall be based on the delegated acts adopted pursuant to Article 22 of this Regulation while taking into account the scientific guidance referred to in Article 127 of Directive (EU) 2026/…[+];

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(h) where appropriate, details of any recommended obligation to conduct any other post-authorisation studies to improve the safe and effective use of the medicinal product, including treatment optimisation studies;

(i) in the case of medicinal products for which there is substantial uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, details of any post-authorisation obligation to substantiate the clinical benefit;

(j) where appropriate, details of any recommended obligation to conduct additional post-authorisation environmental risk assessment studies or the collection of monitoring data or information on use, or to implement appropriate risk mitigation measures, where concerns about risks to the environment or public health, including antimicrobial resistance, need to be further investigated or mitigated after the medicinal product has been placed on the market;

(k) the text of the labelling and package leaflet, presented in accordance with Chapter VI of Directive (EU) 2026/…[+];

(l) the assessment report as regards the results of the pharmaceutical and non-clinical tests and of the clinical trials, and as regards the risk management system and the pharmacovigilance system for the medicinal product concerned;

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(m) where appropriate, details of any recommended obligations to carry out medicinal product-specific validation studies to replace animal-based control methods with non-animal-based control methods;

(n) where applicable, reasoning as to whether the medicinal product satisfies the criteria of Article 85 of Directive (EU) 2026/…[+] regarding medicinal products addressing an unmet medical need.

5. When adopting its opinion, the Committee for Medicinal Products for Human Use shall include the criteria for the medical prescription or for use of the medicinal product, in accordance with Article 53 of Directive (EU) 2026/…[+].

SECTION 2

CENTRALISED MARKETING AUTHORISATION DECISIONS

Article 14

Commission decision on the marketing authorisation

1. Within 12 days of receipt of the opinion of the Committee for Medicinal products for Human Use, the Commission shall submit to the Standing Committee on Medicinal Products for Human Use referred to in Article 179(1) a draft decision on the application for centralised marketing authorisation (‘draft decision’).

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In duly justified cases, the Commission may refer the opinion of the Committee for Medicinal Products for Human Use back to the Agency for further consideration.

Where a draft decision envisages the granting of a centralised marketing authorisation, it shall include or make reference to the documents referred to in Article 13(4).

Where a draft decision envisages the granting of a centralised marketing authorisation subject to the conditions referred to in Article 13(4), points (c) to (j), it shall lay down deadlines for the fulfilment of the conditions, where necessary.

Where the draft decision differs from the opinion of the Agency, the Commission shall provide a detailed explanation of the reasons for the differences.

The Commission shall send the draft decision to the Member States and the applicant.

2. The Commission shall, by means of implementing acts, take a final decision within 12 days of obtaining the opinion of the Standing Committee on Medicinal Products for Human Use. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 179(2) and (3).

3. Where a Member State raises, within the Standing Committee on Medicinal Products for Human Use, important new questions of a scientific or technical nature that have not been addressed in the opinion issued by the Agency, the Commission may refer the application back to the Agency for further consideration. In that case, the procedures laid down in paragraphs 1 and 2 shall start again upon receipt of the reply of the Agency.

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4. The Agency shall publish the documents referred to in Article 13(4), points (a) to (e), and, where relevant, the documents referred to in Article 13(4), points (f) to (n), together with any deadlines laid down pursuant to paragraph 1, first subparagraph of this Article.

Article 15

Withdrawal of a centralised marketing authorisation application

If an applicant withdraws an application for a marketing authorisation submitted to the Agency before an opinion has been issued by the Committee for Medicinal Products for Human Use on the application, the applicant shall communicate its reasons for doing so to the Agency. The Agency shall make this information publicly available and shall publish the assessment report, if available, after deletion of all information of a commercially confidential nature.

After the opinion has been issued on the application, the applicant is no longer in the position to withdraw an application on its own initiative.

Article 16

Refusal to grant a centralised marketing authorisation

1. The Commission shall refuse to grant the centralised marketing authorisation where, after verification of the particulars and documents submitted by the applicant in accordance with Article 7, it appears that:

   (a) the benefit-risk balance of the medicinal product is not favourable;

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(b) the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product;

(c) the qualitative and quantitative composition of the medicinal product is not as declared;

(d) the environmental risk assessment is incomplete or insufficiently substantiated, or the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant, including through risk mitigation measures, unless the applicant has duly justified and substantiated the reasons for the incomplete or insufficiently substantiated environmental risk assessment and the Agency considers that the marketing authorisation can be granted subject to the condition that post-authorisation environmental risk assessment studies be conducted or risk mitigation measures be implemented, as referred to in Article 13(4), point (j);

(e) particulars or documents provided by the applicant in accordance with Article 7(1) to (4) are incorrect;

(f) the labelling and package leaflet proposed by the applicant are not in accordance with Chapter VI of Directive (EU) 2026/…[+].

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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2. The Commission decision to refuse to grant a centralised marketing authorisation shall constitute a prohibition on the placing on the market of the medicinal product concerned throughout the Union.

3. Information about all refusals and the reasons for them shall be made publicly available.

Article 17

Marketing authorisations

1. Without prejudice to Article 1(7) and (8) of Directive (EU) 2026/…[+], a marketing authorisation which has been granted in accordance with this Regulation shall be valid throughout the Union. It shall confer to the marketing authorisation holder the same rights and obligations in each of the Member States as a marketing authorisation granted by that Member State in accordance with Article 6 of Directive (EU) 2026/…[+].

   The Commission shall ensure that authorised medicinal products for human use are added to the Union Register of Medicinal Products and that they are given a number, which shall appear on the packaging.

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2. A summary table of decisions on marketing authorisation shall be published in the *Official Journal of the European Union*, quoting the date of notification of the marketing authorisation and the registration number in the Union Register of Medicinal Products, any International Non-proprietary Name of the active substance of the medicinal product, its pharmaceutical form, and any Anatomical Therapeutic Chemical Code.

3. The Agency shall immediately publish the European public assessment report (EPAR) on the medicinal product for human use and the reasons for its opinion in favour of granting marketing authorisation, after deletion of any information of a commercially confidential nature. The justification for a marketing authorisation granted under Articles 19, 20 and 31 shall be included in the assessment report.

The EPAR shall include:

(a) a summary of the assessment report written in a manner that is understandable to the public. The summary shall contain in particular a section relating to the conditions of use of the medicinal product;

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(b) a summary of environmental risk assessment studies and their results as submitted by the marketing authorisation holder and the evaluation of the environmental risk assessment and of the information submitted on the basis of the scientific guidelines referred to in Article 23(5) of Directive (EU) 2026/…[+] by the Agency;

(c) for antimicrobials, the information referred to in Article 18(1), point (a), of Directive (EU) 2026/…[+] and paragraph 21, point (a), of Annex I to that Directive, as well as any other obligations imposed on the marketing authorisation holder.

4. After a marketing authorisation has been granted, the marketing authorisation holder shall inform the Agency of the dates of placing on the market of the medicinal product for human use in the Member States, taking into account the various presentations authorised.

Upon request by the Agency, particularly in the context of pharmacovigilance under Chapter VIII, the marketing authorisation holder shall provide the Agency with all data relating to the volume of sales of the medicinal product at Union level, broken down by Member State, and any data in the marketing authorisation holder's possession relating to the volume of medical prescriptions in the Union and its Member States.

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Article 18

Validity and renewal of marketing authorisations

1. Without prejudice to paragraph 2, a marketing authorisation for a medicinal product shall be valid for an unlimited period.

2. By way of derogation from paragraph 1, the Commission may decide when granting an authorisation, on the basis of a scientific opinion by the Agency concerning the safety of the medicinal product, to limit the validity of the marketing authorisation to five years.

   Where the validity of the marketing authorisation is limited to five years, the marketing authorisation holder shall apply to the Agency for a renewal of the marketing authorisation at least nine months before the marketing authorisation ceases to be valid.

   Where a renewal application has been submitted in accordance with the second subparagraph of this paragraph, the marketing authorisation shall remain valid until a decision is adopted by the Commission in accordance with Article 14.

   The marketing authorisation may be renewed on the basis of a re-evaluation by the Agency of the benefit-risk balance. Once renewed, the marketing authorisation shall be valid for an unlimited period.

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Article 19

Marketing authorisation granted in exceptional circumstances

1. In exceptional circumstances where, in an application under Article 7 of Directive (EU) 2026/…[+] for a marketing authorisation of a medicinal product or a new therapeutic indication of an existing marketing authorisation under this Regulation, an applicant is unable to provide comprehensive data on the safety and efficacy of the medicinal product under normal conditions of use, the Commission may, by way of derogation from Article 7 of this Regulation, grant an authorisation under Article 14 of this Regulation, subject to specific conditions, where the following requirements are met:

   (a) the applicant has demonstrated, in the application file, that there are objective and verifiable reasons not to be able to submit comprehensive data on the safety and efficacy of the medicinal product under normal conditions of use based on one of the grounds set out in Annex II to Directive (EU) 2026/…[+];

   (b) except for the data referred to in point (a), the application file is complete and satisfies all the requirements of this Regulation.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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The specific conditions referred to in the first subparagraph shall be included in the Commission decision granting the marketing authorisation, in particular to ensure the safety of the medicinal product as well as to ensure that the marketing authorisation holder notifies to the competent authorities of the Member States and the Agency any incident relating to its use and takes appropriate action where necessary.

2. The maintenance of the authorised new therapeutic indication and the validity of the marketing authorisation granted in accordance with paragraph 1 shall be linked to the reassessment by the Agency of the conditions referred to in paragraph 1 after two years, or a shorter period as set out in the marketing authorisation, from the date when the new therapeutic indication was authorised or the marketing authorisation was granted, and thereafter at a risk-based frequency to be determined by the Agency and specified by the Commission in the marketing authorisation.

This reassessment shall be conducted on the basis of an application by the marketing authorisation holder to maintain the authorised new therapeutic indication or renew the marketing authorisation under exceptional circumstances.

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Article 20

Conditional marketing authorisation

1. In duly justified cases, to meet an unmet medical need of patients, a conditional marketing authorisation or a new conditional therapeutic indication in an existing marketing authorisation granted in accordance with Article 14 of this Regulation may be granted by the Commission to a medicinal product that is likely to address the unmet medical need in accordance with Article 85(1), of Directive (EU) 2026/…[+], prior to the submission of comprehensive clinical data, provided that the benefit of the immediate availability on the market of that medicinal product outweighs the risk inherent in the fact that additional data are still required.

   In emergency situations, a conditional marketing authorisation or a new conditional therapeutic indication referred to in the first subparagraph may be granted also where comprehensive non-clinical or pharmaceutical data have not been supplied.

2. Conditional marketing authorisations or a new conditional therapeutic indication referred to in paragraph 1 may be granted only if the benefit-risk balance of the medicinal product is favourable and the applicant is likely to be able to provide comprehensive data.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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3. Conditional marketing authorisations or a new conditional therapeutic indication granted pursuant to this Article shall be subject to specific obligations. Those specific obligations and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation. Those specific obligations shall be reviewed annually by the Agency.

4. As part of the specific obligations referred to in paragraph 3, the marketing authorisation holder of a conditional marketing authorisation granted pursuant to this Article shall be required to complete ongoing studies, or to conduct new studies, with a view to confirming that the benefit-risk balance is favourable.

5. The summary of product characteristics and the package leaflet shall clearly mention that the conditional marketing authorisation for the medicinal product has been granted subject to specific obligations as referred to in paragraph 3.

6. By way of derogation from Article 18(1), an initial conditional marketing authorisation granted pursuant to this Article shall be valid for one year on a renewable basis.

7. When the specific obligations referred to in paragraph 3 of this Article have been fulfilled for a conditional marketing authorisation granted pursuant to this Article, the Commission may, following an application by the marketing authorisation holder pursuant to Article 7, and after having received a favourable opinion from the Agency, grant a marketing authorisation pursuant to Article 14.

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8. The Commission is empowered to adopt delegated acts in accordance with Article 181 to supplement this Regulation by establishing the following:

(a) the categories of medicinal products to which paragraph 1 of this Article applies;

(b) the procedures and requirements for granting a conditional marketing authorisation, for its renewal, and for adding a new conditional therapeutic indication to an existing marketing authorisation.

Article 21

Imposed post-authorisation studies

1. After the granting of a marketing authorisation, the Agency may consider that it is necessary that the marketing authorisation holder:

(a) conduct a post-authorisation safety study if there are concerns about the risks of an authorised medicinal product. If the same concerns apply to more than one medicinal product, the Agency shall, following consultation with the Pharmacovigilance Risk Assessment Committee, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation safety study;

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(b) conduct a post-authorisation efficacy study when the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly. The obligation to conduct the post-authorisation efficacy study shall be based on the delegated acts adopted pursuant to Article 22 of this Regulation while taking into account the scientific guidance referred to in Article 127 of Directive (EU) 2026/…[+];

(c) conduct any other post-authorisation studies to improve the safe and effective use of the medicinal product, including treatment optimisation based on clinical experience;

(d) conduct a post-authorisation environmental risk assessment study to further investigate the risks to the environment or public health, including antimicrobial resistance, due to the release of the medicinal product in the environment, if new concerns emerge on the authorised medicinal product, or other medicinal products containing the same active substance.

If the same concerns apply to several medicinal products, the Agency shall encourage the marketing authorisation holders concerned to conduct a joint post-authorisation environmental risk assessment study.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Where the Agency considers that any of the post-authorisation studies referred to in points (a) to (d), of the first subparagraph is necessary, it shall inform the marketing authorisation holder of its opinion in writing, stating the grounds for its assessment and shall include the objectives and time limit for submission and conduct of the relevant study.

2. The Agency shall provide the marketing authorisation holder with an opportunity to present written observations in response to its opinion within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the opinion.

3. On the basis of the written observations presented by the marketing authorisation holder, the Agency shall review its opinion.

4. Where the opinion of the Agency confirms the need for any of the post-authorisation studies referred to in paragraph 1, first subparagraph, points (a) to (d), of this Article, to be carried out, the Commission shall vary the marketing authorisation, by means of implementing acts, adopted pursuant to Article 14 to include the obligation to conduct such a study as a condition of the marketing authorisation unless the Commission refers the opinion back to the Agency for further consideration. For obligations under paragraph 1, first subparagraph, points (a), (b) and (c), of this Article, the marketing authorisation holder shall update the risk management system accordingly.

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Article 22

Delegated acts on post authorisation efficacy studies

The Commission is empowered to adopt delegated acts in accordance with Article 181 to supplement this Regulation by determining the situations in which post-authorisation efficacy studies may be required under Article 13(4), point (g), and Article 21(1), first subparagraph, point (b).

Article 23

Risk management system

The marketing authorisation holder shall incorporate any condition of authorisation reflecting the elements referred to in Article 13(4), points (d) to (i), Article 21(1), first subparagraph, points (a), (b) and (c), or in Article 19(1) and Article 20, in their risk management system.

Article 24

Liability of the marketing authorisation holder

The granting of a marketing authorisation shall not affect the civil or criminal liability of the manufacturer or of the marketing authorisation holder pursuant to the applicable national law in Member States.

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Article 25

Suspension of marketing, withdrawal from the market of a medicinal product, withdrawal of a marketing authorisation by the marketing authorisation holder

1. The marketing authorisation holder shall notify the Agency without undue delay of any action they take to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with a detailed reasoning for such action.

   The marketing authorisation holder shall declare if such action is based on the following grounds:

   (a) the medicinal product is harmful;

   (b) it lacks therapeutic efficacy;

   (c) the benefit-risk balance is not favourable;

   (d) its qualitative and quantitative composition is not as declared;

   (e) the controls on the medicinal product or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out, or any other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled;

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(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder; or

(g) commercial reasons.

Where the action notified pursuant to the first subparagraph is to withdraw a medicinal product from the market, the marketing authorisation holder shall provide information on the impact of such withdrawal on patients who are already being treated.

The marketing authorisation holder shall make the notification electronically and in the formats made available by the Agency. The Agency shall consult the Member States when drawing up the formats.

2. The marketing authorisation holder shall make the notification pursuant to paragraph 1 if the action is taken in a third country and such action is based on any of the grounds set out in paragraph 1, second subparagraph, points (a) to (f).

3. In the cases referred to in paragraphs 1 and 2, the Agency shall forward the marketing authorisation holder's notification to the competent authorities of the Member States without undue delay.

4. In the case referred to in paragraph 1, second subparagraph, point (f), the Agency shall immediately inform the Commission, and the marketing authorisation holder shall inform the relevant national and Union authorities without delay.

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Article 26

Duplicate marketing authorisations

1. Only one marketing authorisation may be granted to an applicant for a specific medicinal product.

By way of derogation from the first subparagraph, the Commission shall authorise the same applicant to submit more than one application to the Agency for that medicinal product in either of the following cases:

(a) if one of its indications or pharmaceutical forms, posologies, methods or routes of administration or any other way in which the medicinal product may be used is protected by a patent or a supplementary protection certificate in one or more Member States;

(b) for reasons of co-marketing with a different undertaking not belonging to the same group as the marketing authorisation holder of the medicinal product for which a duplicate marketing authorisation is requested.

As soon as the relevant patent or supplementary protection certificate referred to in the second subparagraph, point (a), expires, the marketing authorisation holder shall withdraw the initial or duplicate marketing authorisation as soon as possible.

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2. As regards medicinal products for human use, Article 190(3) of Directive (EU) 2026/…[+] shall apply to medicinal products authorised under this Regulation.

3. Without prejudice to the Union nature of the content of the documents referred to in Article 13(4), points (a) to (k), this Regulation shall not prohibit the use of two or more commercial designs for a given medicinal product for human use covered by a single marketing authorisation.

Article 27

Medicinal products for compassionate use

1. Member States may make available a medicinal product for human use belonging to the categories referred to in Article 3(1) and (2) for compassionate use. Making available a medicinal product for compassionate use may include new therapeutic uses of an authorised medicinal product.

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2. For the purposes of this Article, ‘compassionate use’ shall mean making a medicinal product belonging to the categories referred to in Article 3(1) and (2) available for compassionate reasons to a single patient or group of patients with a chronically or seriously debilitating disease, or whose disease is considered to be life-threatening, or is impacting their mental health with severe psychological or emotional distress, leading to worsening of clinical symptoms and severely compromising the ability to function in daily life, and who cannot be treated satisfactorily by an authorised medicinal product. The medicinal product for compassionate use shall either be the subject of an application for a marketing authorisation that has been submitted in accordance with Article 7 or whose submission is imminent, or be undergoing clinical trials for the same proposed therapeutic indication.

3. When applying paragraph 1, Member States shall notify the Agency, which shall make that notification publicly available.

4. When compassionate use is envisaged by a Member State, the Committee for Medicinal Products for Human Use, after consulting the manufacturer or the applicant, may adopt an opinion on the conditions for use, the conditions for distribution, the patients targeted and the conditions of monitoring. The opinion shall be updated where necessary.

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In the preparation of its opinion, the Committee for Medicinal Products for Human Use may request information and data from the marketing authorisation holder and from the medicinal product developer and may engage with them in preliminary discussions. The Committee for Medicinal Products for Human Use may also make use of health data generated outside of clinical studies, including real-world data, where available, taking into account the reliability of those data.

The Agency may also liaise with third-country agencies for medicinal products with respect to additional information and data exchanges.

In the preparation of its opinion, the Committee for Medicinal Products for Human Use may consult the Member State concerned and request it to provide any available information or data that the Member State has in its possession relating to the medicinal product concerned.

5. When applying paragraph 1, Member States shall take account of any available opinion and notify the Agency of the making available of medicinal products on the basis of the opinion in their territory. Member States shall ensure that pharmacovigilance requirements as regards the recording and reporting of suspected adverse reactions and the submission of safety reports are applied for those medicinal products.

6. The Agency shall keep an up-to-date list of the opinions adopted in accordance with paragraph 4 and shall publish it on its website.

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7. The opinions referred to in paragraph 4 shall not affect the civil or criminal liability of the manufacturer or of the applicant.

8. In cases where a Member State has a compassionate use programme in place, the applicant shall ensure the supply of the medicinal product to patients taking part in that programme, if necessary for the entire period, after the marketing authorisation has been granted, and until the medicinal product is made available on the market of the Member State concerned.

9. This Article shall be without prejudice to Regulation (EU) No 536/2014 and to Article 4 of Directive (EU) 2026/…[+].

10. The Agency shall adopt detailed guidelines laying down the format and content of notifications referred to in paragraphs 3 and 5, and of any data exchange under this Article.

Article 28

Request for opinion on scientific matters

At the request of the Executive Director of the Agency or the Commission, the Committee for Medicinal Products for Human Use shall draw up an opinion on any scientific matter concerning the evaluation of medicinal products for human use. That Committee shall take due account of any requests by Member States for such an opinion.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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The Agency shall publish the opinion referred to in the first paragraph after deletion of any information of a commercially confidential nature.

Article 29

Regulatory scope concerning decisions on marketing authorisations

An authorisation to place on the market a medicinal product covered by this Regulation shall not be granted, refused, varied, suspended, withdrawn or revoked except through the procedures and on the grounds set out in this Regulation.

Article 30

Regulatory protection periods

Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with this Regulation shall benefit from the periods of regulatory protection set out in Chapter VII of Directive (EU) 2026/…[+].

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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SECTION 3

TEMPORARY EMERGENCY MARKETING AUTHORISATION

Article 31

Temporary emergency marketing authorisation

During a public health emergency recognised at Union level, the Commission may grant a temporary emergency marketing authorisation for medicinal products intended for prevention, diagnosis or treatment of a serious or life-threatening disease or condition which is directly related to that public health emergency, prior to the submission of the complete quality, non-clinical, clinical and environmental data and information.

Where medicinal products consisting of, or containing, GMOs as defined in Article 2(2) of Directive 2001/18/EC are concerned, Articles 13 to 24 of that Directive shall not apply.

An application for a temporary emergency marketing authorisation shall be submitted to the Agency in accordance with Articles 5 and 7.

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Article 32

Requirements for granting a temporary emergency marketing authorisation

A temporary emergency marketing authorisation may be granted only after the recognition of a public health emergency at Union level in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council[37] and where the following requirements are met:

(a) there is no other satisfactory method of prevention, diagnosis or treatment authorised or sufficiently available in the Union or, if such method is already available, the temporary emergency marketing authorisation of the medicinal product will contribute to address the public health emergency;

(b) based on the scientific evidence available, the Agency issues an opinion concluding that the medicinal product could be effective in preventing, diagnosing or treating the disease or condition directly related to the public health emergency, and the known and potential benefits of the product outweigh the known and potential risks of the product, taking into consideration the threat posed by the public health emergency.

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[37] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

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Article 33

Scientific opinion of the Agency

1. The Agency shall ensure that the Committee for Medicinal Products for Human Use prepares a scientific opinion without undue delay, taking into account the recommendation of the Emergency Task Force referred to in Article 39(1), second subparagraph. For the purpose of issuing its opinion, the Agency may consider any relevant data on the medicinal product concerned.

2. The Agency shall without undue delay review any new evidence provided by the medicinal product developer, the Member States or the Commission, or any other evidence that comes to its attention, in particular evidence that might influence the benefit-risk balance of the medicinal product concerned.

   The Agency shall update its scientific opinion as necessary.

3. The Agency shall transmit without undue delay to the Commission the scientific opinion and its updates and any recommendations on the temporary emergency marketing authorisation.

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Article 34

Commission decision for a temporary emergency marketing authorisation

1. On the basis of the scientific opinion of the Agency or its updates referred to in Article 33(1) and (2), the Commission shall, by means of an implementing act, take a decision without undue delay on the granting of a temporary emergency marketing authorisation of the medicinal product subject to the specific conditions set in accordance with paragraphs 2 and 3 of this Article. Such implementing act shall be adopted in accordance with the examination procedure referred to in Article 179(2).

2. On the basis of the scientific opinion of the Agency referred to in paragraph 1, the Commission shall set specific conditions with respect to the temporary emergency marketing authorisation, in particular the conditions for manufacturing, use, supply and safety monitoring and the compliance with related good manufacturing and pharmacovigilance practices. Where necessary, those conditions may specify the batches of the medicinal product concerned by the temporary emergency marketing authorisation.

3. Specific conditions may be set to require the completion of ongoing studies or to conduct new studies to ensure the safe and effective use of the medicinal product or minimise its impact on the environment. A time limit for the submission of those studies shall be set.

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4. The specific conditions set in accordance with paragraphs 2 and 3 and, where appropriate, the time limit for the submission of the results of the studies referred to in paragraph 3 shall be specified in the conditions to the temporary emergency marketing authorisation and shall be reviewed annually by the Agency.

5. The Agency shall immediately publish the assessment report on the medicinal product for human use and the reasons for its opinion in favour of granting the temporary emergency marketing authorisation, after deletion of any information of a commercially confidential nature.

Article 35

Validity of a temporary emergency marketing authorisation

The temporary emergency marketing authorisation shall cease to be valid when the Commission terminates the recognition of a public health emergency in accordance with Article 23(2) and (4) of Regulation (EU) 2022/2371.

Article 36

Variation, suspension or revocation of a temporary emergency marketing authorisation

The Commission may vary, suspend or revoke the temporary emergency marketing authorisation by means of implementing acts at any time in any of the following cases:

(a) the criteria set out in Article 32 are no longer met;

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(b) it is appropriate to protect public health;

(c) the marketing authorisation holder of a temporary emergency marketing authorisation has not complied with the conditions and obligations laid down in the temporary emergency marketing authorisation;

(d) the marketing authorisation holder of a temporary emergency marketing authorisation has not complied with the specific conditions laid down in accordance with Article 34.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 179(2).

Article 37

Granting of a marketing authorisation or a conditional marketing authorisation after a temporary emergency marketing authorisation

As soon as sufficient data have been generated, the marketing authorisation holder of a temporary emergency marketing authorisation in accordance with Article 34 shall submit an application in accordance with Articles 5 and 7 in order to replace the temporary emergency marketing authorisation by a marketing authorisation granted in accordance with Article 14, 19 or 20.

For the purposes of regulatory data protection, the temporary emergency marketing authorisation and any subsequent marketing authorisation as referred to in the first paragraph shall be considered to be part of the same global marketing authorisation.

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Article 38

Transitional period

Where a temporary emergency marketing authorisation of a medicinal product is suspended or revoked for reasons other than the safety of the medicinal product, or if that temporary emergency marketing authorisation ceases to be valid, Member States may, in exceptional circumstances, for a transitional period, allow the supply of the medicinal product to patients who are already being treated with it. In such cases, the Member State concerned shall inform the Agency about the application of the transitional period. Conditions for manufacturing, use, supply and safety monitoring and the compliance with the related good manufacturing and pharmacovigilance practices shall continue to apply during that period.

Article 39

Relation with Article 18 of Regulation (EU) 2022/123

1. For medicinal products for which a temporary emergency marketing authorisation is being considered by the Agency, Article 18(1) and (2) of Regulation (EU) 2022/123 shall apply.

   The Emergency Task Force established pursuant to Article 15 of Regulation (EU) 2022/123 shall provide a recommendation for a temporary emergency marketing authorisation to the Committee for Medicinal Products for Human Use for an opinion in accordance with Article 33 of this Regulation. To this purpose, the Emergency Task Force may, where appropriate, perform the activities referred to in Article 18(2) of Regulation (EU) 2022/123 prior to the recognition of a public health emergency.

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2. Where a request referred to in Article 18(3) of Regulation (EU) 2022/123 for a recommendation has been made and there is an application for a temporary emergency marketing authorisation for the medicinal product concerned, the procedure for a recommendation under Article 18(3) of Regulation (EU) 2022/123 shall be stopped and the procedure for a temporary emergency marketing authorisation shall prevail. Any available data shall be considered under the temporary emergency marketing authorisation application.

Article 40

Withdrawal of authorisations granted

in accordance with Article 4(4) of Directive (EU) 2026/...[+]

When the Commission has granted a temporary emergency marketing authorisation in accordance with Article 34 of this Regulation, Member States shall, where possible and within a reasonable time limit, withdraw any authorisation granted in accordance with Article 4(4) of Directive (EU) 2026/…[+] for the use of medicinal products containing the same active substance for any therapeutic indications covered by the temporary marketing authorisation.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Chapter III

Incentives for the development of antimicrobials

SECTION 1

TRANSFERABLE DATA EXCLUSIVITY VOUCHERS FOR PRIORITY ANTIMICROBIALS

Article 41

Granting of a transferable data exclusivity voucher

1. Following a request by the applicant when applying for a marketing authorisation, the Commission may, by means of an implementing act, grant a transferable data exclusivity voucher (‘data exclusivity voucher’) to a ‘priority antimicrobial’ referred to in paragraph 3, under the conditions referred to in paragraph 4, based on a scientific assessment by the Agency.

2. The data exclusivity voucher referred to in paragraph 1 shall give the right to its holder to extend by 12 months the regulatory data protection period referred to in Article 83(1) of Directive (EU) 2026/…[+] for one authorised medicinal product.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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3. An antimicrobial shall be considered a ‘priority antimicrobial’ if it addresses a multi-drug resistant organism, if the preclinical and clinical data demonstrate a significant clinical benefit with respect to antimicrobial resistance and if it has at least one of the following characteristics:

(a) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;

(b) it contains a new active substance that, when used either alone or in combination with other active substances, addresses a serious or life threatening infection.

In the scientific assessment of the criteria referred to in the first subparagraph, the Agency shall take into account the ‘WHO bacterial priority pathogens list’, or an equivalent list of priority pathogens established at Union level.

4. To be granted the data exclusivity voucher referred to in paragraph 1 by the Commission, the applicant shall:

(a) demonstrate capacity to supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market;

(b) provide information on all direct financial support received for research related to the development of the priority antimicrobial;

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(c) demonstrate that the application for a marketing authorisation of the priority antimicrobial has been first submitted to the Agency or has been submitted no later than 180 days after the submission of the application for the first marketing authorisation outside the Union.

Within 30 days of the granting of the marketing authorisation, the marketing authorisation holder shall make the information referred to in point (b) of the first subparagraph publicly available via a dedicated webpage and shall communicate to the Agency, in a timely manner, the electronic link to that webpage.

5. Once the marketing authorisation is granted, the Agency shall inform the Executive Steering Group on Shortages and Safety of Medicinal Products ('MSSG') without undue delay with a view to proposing the potential inclusion of the priority antimicrobial on the Union list of critical medicinal products in accordance with Article 137(2).

6. A priority antimicrobial shall be reserved for exclusive use for the treatment of humans for a period of 10 years to preserve the efficacy of those antimicrobials.

The period referred to in the first subparagraph may be prolonged based on an assessment by the Agency on the basis of the criteria set in the Commission Delegated Regulation (EU) 2021/1760[38].

[38] Commission Delegated Regulation (EU) 2021/1760 of 26 May 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans (OJ L 353, 6.10.2021, p. 1, ELI: http://data.europa.eu/eli/reg_del/2021/1760/oj).

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7. The Commission shall inform the Member States of the granting of the marketing authorisation and include a recommendation inviting Member States to make use of the possibility of a voluntary subscription model for joint procurement referred to in Article 45.

Article 42

Transfer and use of the data exclusivity voucher

1. A data exclusivity voucher referred to in Article 41 of this Regulation may be used to extend by 12 months the regulatory data protection period referred to in Article 83(1) of Directive (EU) 2026/…[+] of the priority antimicrobial or of another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.

A data exclusivity voucher may be used once and in relation to a single centrally authorised medicinal product.

In the case of a medicinal product other than the priority antimicrobial concerned, the use of the data exclusivity voucher shall take place only in the fifth or sixth year of the regulatory data protection period and only if the marketing authorisation holder demonstrates that the annual gross sales of that medicinal product in the Union during any of the first four years after the granting of the marketing authorisation have not exceeded EUR 490 000 000.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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2. The marketing authorisation holder shall demonstrate that information about the annual gross sales referred to in paragraph 1 is accurate and complete and that it has been audited by an independent external auditor.

A data exclusivity voucher may only be used if the marketing authorisation of the priority antimicrobial for which the right was initially granted has not been withdrawn.

3. To use the data exclusivity voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 49 to extend the regulatory data protection period.

4. A data exclusivity voucher may be transferred to another marketing authorisation holder and shall not be transferred further.

5. A marketing authorisation holder to whom a data exclusivity voucher is transferred shall notify the Agency of the transfer within 30 days, stating the value of the transaction between the two parties. The Agency shall make this information publicly available on its webpage.

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Article 43

Validity of the data exclusivity voucher

1. A data exclusivity voucher shall cease to be valid in the following cases:

   (a) where the Commission has adopted a decision in accordance with Article 49 to extend the regulatory data protection period of the medicinal product in respect of which the regulatory data protection extension was granted;

   (b) where it is not used in accordance with Article 42(3) within five years of the date on which it was granted.

2. The Commission may revoke the data exclusivity voucher prior to its transfer as referred to in Article 42(4) if a request for supply by any Member State or the Commission, for procurement or for purchase of the priority antimicrobial in the Union has not been fulfilled.

3. Without prejudice to patent rights, or supplementary protection certificates, if a priority antimicrobial is withdrawn from the internal market prior to the expiry of the periods of regulatory data protection and regulatory market protection laid down in Articles 83 and 84 of Directive (EU) 2026/…[+], those periods shall not prevent the validation of an application for a marketing authorisation for a medicinal product that uses the priority antimicrobial as a reference medicinal product, or the authorisation or placing on the market of such a medicinal product, in accordance with Chapter II, Section 2, of Directive (EU) 2026/…[+].

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Article 44

Duration of application of Section 1 of this Chapter

Section 1 shall apply, taking into account the outcome of the evaluation referred to in Article 176(6), until … [15 years from the date of entry into force of this Regulation] or until the date when the Commission has granted a total of five data exclusivity vouchers in accordance with this Chapter, whichever date is the earliest.

SECTION 2

VOLUNTARY SUBSCRIPTION MODEL FOR ANTIMICROBIALS

Article 45

Voluntary subscription model for the joint procurement of antimicrobials

1. Contracting authorities from different Member States may act jointly in the award of public contracts pursuant to Article 39 of Directive 2014/24/EU of the European Parliament and of the Council[39] with a view to purchasing antimicrobials.

2. For the purposes of paragraph 1, in addition to the elements set out in Article 39(4) of Directive 2014/24/EU, the agreement between contracting authorities from different Member States shall determine the practical arrangements governing the conditions for a subscription model and other procedures, including the duration of the public contract to be awarded and whether parallel procurement is allowed.

[39] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65, ELI: http://data.europa.eu/eli/dir/2014/24/oj).

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3. The public contract to be awarded shall take the form of a multi-year subscription and include at least the following conditions:

(a) delinkage or partial delinkage of funding from the volume of sales of the antimicrobial;

(b) arrangements regarding criteria to support continuous and sufficient supply in pre-agreed quantities.

4. For the purpose of paragraphs 2 and 3, the Commission shall, in consultation with Member States and relevant parties, draw up guidelines to identify the relevant components for a subscription model, including the methodology for valuing and remunerating medicinal products to ensure economic viability of their supply, and incentives to encourage investment in the development of priority antimicrobials. Member States may take such guidelines into account when they establish a subscription model under this Article.

5. The Commission shall upon request support Member States in the application of this Article. Member States may, where necessary, request the Commission to organise joint meetings between the competent authorities of the Member States, the Agency, and any other relevant parties, as appropriate, including bodies responsible for pricing and reimbursement, to discuss issues related to the practical application of this Article. Member States shall notify the Commission when applying this Article.

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Chapter IV
Post-marketing authorisation measures

Article 46

Urgent safety or efficacy restrictions

1. If the marketing authorisation holder, in the event of a risk to public health, applies urgent safety or efficacy restrictions on its own initiative, it shall immediately inform the Agency and the competent authorities of the Member States in which the medicinal product is placed on the market.

   If the Agency has not raised objections within 24 hours of receipt of the information referred to in first subparagraph, the urgent safety or efficacy restrictions shall be deemed temporarily accepted. The marketing authorisation holder shall submit the corresponding application for variation, in accordance with Article 49, within 12 days of the initiation of the urgent safety or efficacy restriction.

2. In the event of a risk to public health, the Commission may vary the marketing authorisation to impose urgent safety or efficacy restrictions on the marketing authorisation holder.

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Where the Commission decision in accordance with this Article imposes restrictions with regard to the safe and effective use of the medicinal product, the Commission may also adopt a decision addressed to the Member States for the implementation of those restrictions pursuant to Article 59.

Where the marketing authorisation holder disagrees with the Commission decision, it may provide to the Agency written observations on the variation within 12 days of the receipt of the Commission decision. The Agency shall, based on the written observations, issue an opinion on whether an amendment of the variation is required.

If an amendment of the variation is required, the Commission shall take a final decision in accordance with the examination procedure referred to in Article 179(2).

If a referral procedure under Article 57 of this Regulation or under Article 98 or 118 of Directive (EU) 2026/…[+] is launched on the same safety or efficacy concern covered by this variation, any written observation provided by the marketing authorisation holder shall be considered in that referral procedure.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Article 47

Marketing authorisation update related to scientific and technological developments

1. After a marketing authorisation has been granted in accordance with this Regulation, the marketing authorisation holder shall, in respect of the methods of manufacture and control provided for in points (6) and (10) of Annex I to Directive (EU) 2026/…[+], take account of scientific and technical progress and introduce any changes that might be required to enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods. The marketing authorisation holder shall apply for approval of corresponding variations in accordance with Article 49 of this Regulation.

2. The marketing authorisation holder shall, without undue delay, provide the Agency, the Commission and the Member States with any new information which might entail the amendment of the particulars or documents referred to in Articles 12 and 31, Article 44(5) or Article 65 of Directive (EU) 2026/…[+], in Annex I or II to that Directive, or in Article 13(4) of this Regulation.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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The marketing authorisation holder shall, without undue delay, inform the Agency, the Commission and the competent authorities of the Member States of:

(a) any prohibition or restriction imposed on the marketing authorisation holder or any entity in contractual relationship with the marketing authorisation holder by the competent authorities of any Member State or any third country in which the medicinal product is made available on the market; and

(b) any other new information which might influence the evaluation of the benefits and risks of the medicinal product concerned.

The information referred to in this paragraph shall include both positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the marketing authorisation, as well as data on the use of the medicinal product where such use is outside the terms of the marketing authorisation.

3. The marketing authorisation holder shall ensure that the terms of the marketing authorisation, including the summary of product characteristics, the labelling and package leaflet, are kept up to date with the current scientific knowledge, including the conclusions of the assessments and recommendations made public by means of the European medicines web portal set up in accordance with Article 106.

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4. The Agency may at any time request the marketing authorisation holder to submit data demonstrating that the benefit-risk balance remains favourable. The marketing authorisation holder shall answer fully and within the time limit set for any such request. The marketing authorisation holder shall also respond fully and within the time limit set to any such request of a competent authority regarding the implementation of any measures previously imposed, including risk minimisation measures.

The Agency may at any time ask the marketing authorisation holder to submit a copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit that copy at the latest seven days after receipt of the request.

The marketing authorisation holder shall also respond fully and within the time limit set to any request of a competent authority regarding the implementation of any measures previously imposed with regard to risks to the environment or public health, including antimicrobial resistance.

5. The Agency, through its scientific committees referred to in Article 148, points (d) and (e), may consider additional evidence available, independently from the data submitted by the marketing authorisation holder. If the additional evidence has an impact on the benefit-risk balance of a medicinal product, the Agency may recommend that the summary of product characteristics be updated, without excluding other actions that may be taken. In this case the marketing authorisation holder shall submit to the Agency an appropriate application for a variation, including an updated summary of product characteristics.

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Article 48

Update of risk management plans

1. The marketing authorisation holder for a medicinal product referred to in Articles 10 and 12 of Directive (EU) 2026/…[+] who did not submit a risk management plan in accordance with Article 22 of Directive (EU) 2026/…[+] shall submit to the Agency a risk management plan and a summary thereof, where the marketing authorisation for the reference medicinal product is withdrawn but the marketing authorisation for the medicinal product referred to in Articles 10 and 12 of Directive (EU) 2026/…[+] is maintained.

   The risk management plan and the summary thereof shall be submitted to the Agency within 60 days of the withdrawal of the marketing authorisation for the reference medicinal product by means of a variation in accordance with Article 49.

2. The Agency may impose an obligation on the marketing authorisation holder for a medicinal product referred to in Articles 10 and 12 of Directive (EU) 2026/…[+] to submit a risk management plan and summary thereof where:

   (a) additional risk minimisation measures have been imposed concerning the reference medicinal product; or

   (b) it is justified on pharmacovigilance grounds.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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3. In the cases referred to in paragraph 1 and paragraph 2, point (a), the marketing authorisation holder shall align the risk management plan referred to in paragraph 2 with the risk management plan for the reference medicinal product.

4. The imposition of the obligation referred to in paragraph 2 of this Article shall be duly justified in writing, notified to the marketing authorisation holder and shall include the deadline for submission of the risk management plan and the summary by means of a variation in accordance with Article 49.

Article 49

Variation of a centralised marketing authorisation

1. An application for variation of a centralised marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing authorisation holder of the information held in the database referred to in point (b) of paragraph 5.

2. Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to the terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product to changes that have no or minimal impact thereon and to administrative changes.

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3. The procedures for examination of applications for variations shall be proportionate to the risk and impact as referred to in paragraph 2. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation of the variation and subsequent notification by the marketing authorisation holder to the Agency. Such procedures may also allow updates by the marketing authorisation holder of the information held in the database referred to in point (b) of paragraph 5.

4. Where necessary, depending on the category of variation as referred to in paragraph 2 and the type of procedure as referred to in paragraph 3, the Commission shall take a decision to vary the centralised marketing authorisation by means of an implementing act.

5. The Commission is empowered to adopt delegated acts in accordance with Article 181 to supplement this Article by:

(a) establishing the categories referred to in paragraph 2 in which variations shall be classified;

(b) establishing the procedures for the examination of applications for variations to the terms of marketing authorisations, including procedures for updates of information, through a database, by the marketing authorisation holder;

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(c) establishing the conditions for submission of a single application for more than one change to the terms of the same marketing authorisation and for the same change to the terms of several marketing authorisations;

(d) specifying exemptions to the variation procedures where the update of information in the marketing authorisation referred to in Annex I to the Directive (EU) 2026/…[+] may be directly implemented;

(e) establishing the conditions and procedures for cooperation with competent authorities of third countries or international organisations on examination of applications for variations to the terms of marketing authorisation.

Article 50

Scientific opinion on data submitted by not-for-profit entities for repurposing of an authorised medicinal product

1. A not-for-profit entity may submit to the Agency or to a competent authority of the Member State substantive non-clinical or clinical evidence for a new therapeutic indication of an authorised medicinal product that is expected to fulfil an unmet medical need.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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The Agency may, at the request of a Member State, the Commission, or on its own initiative and on the basis of all available evidence, including any additional evidence that may be submitted by the marketing authorisation holder for the medicinal product concerned, make a scientific evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication and deliver a scientific opinion. The Agency shall draw up guidance on the consultation process.

The scientific opinion of the Agency shall be made publicly available and the competent authorities of the Member States and the marketing authorisation holder shall be informed thereof.

2. In cases where the scientific opinion is favourable and the new therapeutic indication addresses an unmet medical need, at the request of the Agency, the marketing authorisation holder of the medicinal product concerned shall submit an application for a variation to update the product information with the new therapeutic indication.

3. Articles 84(2) and 86(1) of Directive (EU) 2026/…[+] shall not apply for variations required under paragraph 2 of this Article.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Article 51

Transfer of a marketing authorisation

1. A marketing authorisation may be transferred to a new marketing authorisation holder. Such a transfer shall not be considered to be a variation. The transfer shall be subject to prior approval by the Commission, by means of an implementing act, following the submission of an application to the Agency for the transfer of a marketing authorisation.

2. The Commission is empowered to adopt delegated acts in accordance with Article 181 to supplement this Regulation by establishing procedures for the examination of an application to the Agency for the transfer of a marketing authorisation.

Article 52

Supervisory authorities

1. In the case of medicinal products manufactured within the Union, the supervisory authorities for manufacturing shall be the competent authorities of the Member State or Member States which granted the manufacturing authorisation referred to in Article 146(1) of Directive (EU) 2026/…[+] in respect of the medicinal product concerned.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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2. In the case of medicinal products imported from third countries, the supervisory authorities for imports shall be the competent authorities of the Member State or Member States that granted the manufacturing authorisation to the holder responsible for certification of the batches of the medicinal product concerned in accordance with Article 157(3) of Directive (EU) 2026/…[+].

A Member State may request assistance from another Member State or from the Agency.

3. The supervisory authority for pharmacovigilance shall be the competent authority of the Member State in which the pharmacovigilance system master file is located.

Article 53

Responsibilities of the supervisory authorities

1. The supervisory authorities for manufacturing and import shall be responsible for verifying on behalf of the Union that the marketing authorisation holder for the medicinal product or the manufacturer or importer established within the Union satisfies the requirements concerning manufacturing and import laid down in Chapters XI and XV of Directive (EU) 2026/…[+].

When carrying out the verification referred to in the first subparagraph, the supervisory authorities may request to be accompanied by a rapporteur or expert appointed by the Committee for Medicinal Products for Human Use or by an inspector of the Agency.

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The supervisory authorities for pharmacovigilance shall be responsible for verifying on behalf of the Union that the marketing authorisation holder for the medicinal product satisfies the pharmacovigilance requirements laid down in Chapters IX and XV of Directive (EU) 2026/…[+].

The supervisory authorities for pharmacovigilance may, if necessary, conduct pre-authorisation inspections to verify the accuracy and successful implementation of the pharmacovigilance system as it has been described by the applicant in support of the application.

2. Where, in accordance with Article 205 of Directive (EU) 2026/…[+], the Commission is informed of serious differences of opinion between Member States as to whether the marketing authorisation holder for the medicinal product for human use or a manufacturer or importer established within the Union satisfies the requirements referred to in paragraph 1, the Commission may, after consultation with the Member States concerned, request an inspector from the supervisory authority to undertake a new inspection of the marketing authorisation holder, the manufacturer or the importer.

The inspector in question may be accompanied by up to two inspectors from Member States which are not party to the dispute or by two experts nominated by the Committee for Medicinal Products for Human Use.

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3. Without prejudice to any agreements which may have been concluded between the Union and third countries, the Commission may, following a request from a Member State or from the Committee for Medicinal Products for Human Use, or on its own initiative, require a manufacturer established in a third country to undergo an inspection.

The inspection shall be requested from the supervisory authority referred to in Article 52(2). The inspection shall be carried out by appropriately qualified inspectors from the Member States or, when requested, from the Agency. Inspectors may request to be accompanied by a rapporteur or an expert appointed by the Committee for Medicinal Products for Human Use or by an inspector from the Agency. The inspections reports shall be made available electronically to the Commission, the Member States and the Agency.

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Article 54

Cooperation between competent authorities of the Member States and the Agency for inspections in third countries

1. Without prejudice to the responsibilities of the competent authorities of Member States under Article 191(1) of Directive (EU) 2026/…[+], when an inspection is needed under Article 191(1), second subparagraph, point (a) of Directive (EU) 2026/…[+] or requested, as referred to in Article 12(2) of this Regulation, for a site located in a third country, the competent authority of the Member State concerned may:

   (a) request the Agency to participate in the inspection; the Agency may provide its assistance by participating in a joint inspection of the site with the requesting competent authority of the Member State concerned; in that case the requesting competent authority of the Member State shall lead the inspection and the follow-up thereof; or

   (b) request the Agency to facilitate cooperation among competent authorities of Member States when a competent authority of a Member State intends to delegate the inspection to a competent authority of another Member State as referred to in Article 192(6) of Directive (EU) 2026/…[+]; or

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(c) if no competent authority of a Member State accepts the delegation to carry out the inspection as referred to in point (b) of this paragraph, request the Agency to carry out the inspection and the follow-up thereof; if the inspection is in the interest of the Union as defined in Annex III to this Regulation, the Agency shall accept the delegation and carry out the inspection; if the outcome of that inspection shows that the inspected entity complies with the principles of good manufacturing practice (GMP), the Agency shall issue the relevant GMP certificate and shall enter that certificate in the Union database referred to in Article 191(15) of Directive (EU) 2026/…[+].

Where the Agency carries out the inspection, the Agency may request the competent authorities of Member States to participate in the inspection. Article 192 of Directive (EU) 2026/…[+] concerning joint inspections shall apply to any such request.

The Agency may also request to be accompanied by a rapporteur or expert appointed by the Committee for Medicinal Products for Human Use.

Where the Agency has issued a GMP non-compliance statement and a follow-up inspection is required, the Agency shall accept a request of a competent authority of a Member State to perform that follow-up inspection.

2. Article 191(6) and Article 191(8) to (17) of Directive (EU) 2026/…[+] shall apply *mutatis mutandis* to the inspections referred to in paragraph 1, first subparagraph, point (c), of this Article.

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3. Following a request by a competent authority of a Member State, the inspectors of the Agency may provide support to that competent authority of a Member State when it performs inspections under Regulation (EU) No 536/2014.

4. The Agency shall:

(a) ensure that appropriate resources are made available for the performance of inspection tasks in accordance with paragraphs 1 and 3;

(b) ensure that the inspectors of the Agency possess expertise, technical knowledge, and formal qualifications equivalent to those of the national inspectors as detailed in the compilation, published by the Commission of Union procedures on inspections and exchange of information;

(c) implement a quality system in accordance with the principles referred to in Article 193(1), point (a), of Directive (EU) 2026/…[+], to the extent applicable, and participate as an inspectorate in the joint audit programme ('JAP') referred to in Article 56 of this Regulation, which includes periodic audits;

(d) review its inspectorate regularly to ensure that its resources are providing appropriate additional capacity to competent authorities of the Member States without undermining their inspection resources and, where needed, take actions for improvement.

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5. The cooperation between competent authorities of the Member States and the Agency for the inspections in the interest of the Union shall be facilitated by the inspection working group referred to in Article 148, point (k).

Article 55

International inspection programmes

1. The Agency shall, in consultation with the Commission and Member States, coordinate a structured cooperation on inspections in third countries between Member States and, as relevant, the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe, the World Health Organisation and trusted international authorities, by means of international inspection programmes.

2. The Agency, in particular through its inspection working group referred to in Article 148, point (k), in agreement with the Commission, shall draw up detailed guidelines laying down the principles applicable to those international inspection programmes.

Article 56

Joint audit programme

1. The inspection working group referred to in Article 148, point (k), shall ensure the following:

   (a) the establishment and development of the JAP and the supervision thereof;

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(b) the monitoring of any measure taken by the Member State concerned or by the Agency pursuant and limited to paragraph 4 of this Article, in cooperation with that Member State or the Agency;

(c) cooperation with relevant international and Union level bodies to facilitate the work of the JAP and to facilitate the recognition by international partners of the inspections carried out by the competent authorities of the Member States or the Agency.

For the purposes of the first subparagraph, the inspection working group may establish an operational subgroup.

2. For the purposes of paragraph 1, first subparagraph, point (a), each Member State shall:

(a) provide trained auditors;

(b) accept that the competent authorities of Member States in charge of the implementation of good manufacturing and good distribution practices and related surveillance and enforcement activities applicable to medicinal products and active substances are audited, regularly and where appropriate, in accordance with the JAP.

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3. The JAP shall be considered an integral part of the quality system of the inspectorates of competent authorities of Members States and the Agency in accordance with the principles referred to in Article 193(1), point (a), of Directive (EU) 2026/…[+] and ensure that adequate and equivalent quality standards are maintained within the Union network of competent authorities.

4. Under the JAP, the auditors shall issue an audit report after each audit. The audit report shall include, where relevant, appropriate recommendations on measures that the Member State concerned or the Agency shall consider taking to ensure that its relevant quality system and its enforcement activities are consistent with Union quality standards.

   At the request of the Member State concerned, the Commission or the Agency may support that Member State in taking the appropriate measures pursuant to the first subparagraph.

5. For the purposes of paragraph 4 of this Article, the Agency in particular through its inspection working group referred to in Article 148, point (k), shall:

   (a) ensure the harmonisation of the assessments during the JAP's audits, and the quality and consistency of audit reports;

   (b) establish the criteria for the provision of the JAP's recommendations.

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6. The Agency, in particular through its inspection working group referred to in Article 148, point (k) of this Regulation, shall update the compilation of Union procedures on inspections and exchange of information referred to in Article 3(1) of Commission Directive (EU) 2017/1572[40] to cover rules applicable to the functioning, structure and tasks of the JAP.

7. The Union shall provide the financing for activities that support the work of the JAP.

Article 57

Referral procedure

1. Where the supervisory authorities or the competent authorities of any other Member State are of the opinion that the manufacturer or importer established within the Union territory is no longer fulfilling the obligations laid down in Chapter XI of Directive (EU) 2026/…[+], they shall without undue delay inform the Agency and the Commission, stating their reasons in detail and indicating the course of action proposed.

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[40] Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use (OJ L 238, 16.9.2017, p. 44, ELI: http://data.europa.eu/eli/dir/2017/1572/oj).

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Similarly, where a Member State or the Commission considers that one of the measures envisaged in Chapters IX, XIV and XV of Directive (EU) 2026/…[+] is to be applied in respect of the medicinal product concerned or where the Committee for Medicinal Products for Human Use has issued an opinion to that effect, they shall without undue delay inform each other, as well as the Committee for Medicinal Products for Human Use, stating their reasons in detail and indicating the course of action proposed.

2. In each of the situations referred to in paragraph 1, the Commission shall request the opinion of the Agency within a time limit which it shall specify having regard to the urgency of the matter, in order to examine the reasons advanced. Whenever practicable, the marketing authorisation holder for placing the medicinal product for human use on the market shall be invited to provide oral or written explanations.

3. At any stage of the procedure laid down in this Article, following appropriate consultation of the Agency, the Commission may take temporary measures, by means of implementing acts. Those temporary measures shall be applied immediately.

Without undue delay, the Commission shall, by means of implementing acts, adopt a final decision concerning the measures to be taken in respect of the medicinal product concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 179(2).

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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The Commission may also, pursuant to Article 59, adopt a decision addressed to the Member States.

4. Where urgent action is essential to protect public health or the environment, a Member State may, on its own initiative or at the Commission's request, suspend the use in its territory of a medicinal product for human use which has been authorised in accordance with this Regulation.

When a Member State takes suspensive measures on its own initiative, it shall inform the Commission and the Agency of the reasons for its action at the latest on the next working day following the suspension. The Agency shall inform thereon the other Member States without delay. The Commission shall immediately initiate the procedure laid down in paragraphs 2 and 3.

5. In cases referred to in paragraph 4, the Member State shall ensure that healthcare professionals are rapidly informed of the action taken and the reasons for it. Networks set up by professional associations may be used to this effect. The Member States shall inform the Commission and the Agency of actions taken for this purpose.

6. The suspensive measures referred to in paragraph 4 may be maintained in force until such time as a final decision has been adopted by the Commission in accordance with paragraph 3.

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7. The Agency shall, upon request, inform any person concerned of the final decision and make the decision publicly available immediately after it has been taken.

8. Where the procedure is initiated as a result of the evaluation of data relating to pharmacovigilance, the opinion of the Agency, in accordance with paragraph 2 of this Article, shall be adopted by the Committee for Medicinal Products for Human Use on the basis of a recommendation from the Pharmacovigilance Risk Assessment Committee and Article 119(2) of Directive (EU) 2026/…[+] shall apply.

9. By way of derogation from paragraphs 1 to 7 of this Article, where a procedure under Article 98 or Articles 118, 119 and 120 of Directive (EU) 2026/…[+] concerns a range of medicinal products or a therapeutic class, medicinal products that are authorised in accordance with this Regulation and that belong to that range or class shall only be included in the procedure under Article 98, or Articles 118, 119 and 120 of that Directive.

Article 58

Action on conditional marketing authorisation

and on marketing authorisations granted under exceptional circumstances

Where the Agency concludes that a holder of a marketing authorisation granted in accordance with Articles 19 and 20, including a new therapeutic indication granted referred to Articles 19 and 20, failed to comply with the conditions or obligations laid down in the marketing authorisation, the Agency shall inform the Commission accordingly.

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The Commission shall adopt a decision to vary, suspend or revoke that marketing authorisation in accordance with the procedure laid down in Article 14.

Article 59

Member States implementation of conditions or restrictions on a centralised marketing authorisation

Where the Committee for Medicinal Products for Human Use refers in its opinion to recommended conditions or restrictions as provided for in Article 13(4), points (d) to (g), the Commission may adopt a decision addressed to the Member States, in accordance with Article 14, for the implementation of those conditions or restrictions.

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Chapter V

Pre-authorisation regulatory support

Article 60

Scientific advice

1. Undertakings or, as relevant, not-for-profit entities may request scientific advice as referred to in Article 144(1), second subparagraph, point (q), from the Agency.

   Such an advice can also be requested for medicinal products referred to in Articles 85 and 86 of Directive (EU) 2026/…[+].

2. In preparing the scientific advice referred to in paragraph 1 and upon request by undertakings or, as relevant, not-for-profit entities that requested the scientific advice, the Agency may consult experts of the Member States with clinical trials or medical devices expertise or the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745.

3. In preparing the scientific advice referred to in paragraph 1 the Agency may consult authorities established under other Union legal acts, as relevant, for the provision of the scientific advice in question, other public bodies established in the Union, as applicable, and in duly justified cases public bodies established in third countries.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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4. The Agency shall include in the EPAR the key areas of the scientific advice once the Commission has taken the corresponding marketing authorisation decision in relation to the medicinal product concerned, after deletion of any information of a commercially confidential nature. For priority medicinal products the EPAR shall include the key areas of enhanced scientific and regulatory support provided by the Agency in accordance with Article 62, together with explanations on how the conditions for that enhanced support have been fulfilled and, if applicable, the reasons for stopping the enhanced support prior to the granting of the marketing authorisation.

5. To support undertakings or, as relevant, not-for-profit entities, the Agency shall develop guidelines on the design of studies in support of marketing authorisation applications. When developing such guidelines, it shall use, where relevant, the consultation process referred to in Article 169.

Article 61

Parallel scientific advice

1. Undertakings or, as relevant, not-for-profit entities established in the Union may request that the scientific advice referred to in Article 60(1) of this Regulation takes place in parallel to the joint scientific consultation carried out by the Member State Coordination Group on Health Technology Assessment, in accordance with Article 16(5) of Regulation (EU) 2021/2282.

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2. In the case of medicinal products involving a medical device or an *in vitro* diagnostic medical device, undertakings or, as relevant, not-for profit entities may request scientific advice as referred to in Article 60(1) of this Regulation in parallel to the consultation of the expert panels referred to in Article 61(2) of Regulation (EU) 2017/745 and Article 48(6) of Regulation (EU) 2017/746.

3. In the case of paragraph 2 of this Article, the scientific advice, as referred to in Article 60(1), shall involve exchanges of information between the respective authorities or bodies and, where applicable, have synchronised timing, while preserving the separation of their respective remits.

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Article 62

Enhanced scientific and regulatory support for priority medicinal products (PRIME)

1. The Agency may offer enhanced scientific and regulatory support, including as applicable consultation with other bodies as referred to in Articles 60 and 61 and accelerated assessment mechanisms, for certain medicinal products that, based on preliminary evidence submitted by the medicinal product developer, fulfil at least one of the following conditions:

   (a) are likely to address an unmet medical need as referred to in Article 85(1) of Directive (EU) 2026/…[+] and are expected to be of major interest from the point of view of public health, in particular as regards therapeutic innovation, taking into account the early stage of their development;

   (b) are antimicrobials with any of the characteristics mentioned in Article 41(3), are antimicrobials targeting pathogens included in the 'WHO bacterial priority pathogens list', specifically those listed as 'critical group' or 'high group', or are antimicrobials targeting pathogens included in any equivalent list of priority pathogens established at Union level; or

   (c) are likely to target a neglected tropical disease.

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2. The Agency, at the request of the Commission and after consulting the EMA Emergency Task Force, may offer enhanced scientific and regulatory support to developers of a medicinal product preventing, diagnosing or treating a disease resulting from serious cross border threats to health if access to such product is considered necessary to ensure a high level of Union preparedness and response to such health threats.

3. The Agency may stop the enhanced support if it is established that the medicinal product is no longer a priority medicinal product in accordance with paragraphs 1 and 2, including where it does not address the identified unmet medical need, or does not have the potential to ensure a high level of Union preparedness and response to serious cross border health threats to the anticipated extent.

4. The compliance of a medicinal product with the criteria set out in Article 85 of Directive (EU) 2026/…[+] to be considered as addressing an unmet medical need shall be assessed on the basis of the relevant criteria, independently of whether it has received enhanced support for priority medicinal products under this Article.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Article 63

Scientific recommendation on regulatory status

1. For products under development which may fall within the categories of medicinal products to be authorised by the Union listed in Annex I, a developer, a competent authority of the Member States or the Commission on its own initiative may submit a duly substantiated request to the Agency for a scientific recommendation with a view to determining on scientific grounds whether the concerned product is potentially a ‘medicinal product’, including an ‘advanced therapy medicinal product’. The Agency may rely on the relevant expertise of working parties and pools of experts when making its recommendation.

   The Agency shall deliver its recommendation within 60 days of receiving such a request, which shall be extended by an additional 30 days where a consultation in accordance with paragraph 2 is required.

2. When preparing the recommendation referred to in paragraph 1 of this Article, the Agency shall consult, where appropriate and where there is a doubt as to the regulatory status of a product under development, relevant advisory or regulatory bodies established under other Union legal acts in related fields. In particular, in the case of products which are based on substances of human origin, the Agency shall consult the substances of human origin (SoHO) Coordination Board as established in Regulation (EU) 2024/1938.

   The advisory or regulatory bodies consulted shall reply to the consultation within 30 days of receipt of the request.

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The Agency shall annex to its scientific recommendations the opinions received from the relevant advisory or regulatory bodies referred to in the first subparagraph and shall publish summaries of the recommendations delivered in accordance with paragraph 1, after deletion of all information of a commercially confidential nature.

Article 64

Decision on regulatory status

1. In the case of duly substantiated disagreement with the Agency's scientific recommendation, in accordance with Article 63(2), a Member State may request the Commission to initiate a procedure in order to decide whether the product is a medicinal product referred to in Article 63(1).

   The Commission may initiate the procedure referred to in the first subparagraph on its own initiative.

2. The Commission may ask the Agency for clarifications or refer the recommendation back to the Agency for further consideration where a Member State's substantiated request raises new questions of a scientific or technical nature or on its own initiative.

3. The decision of the Commission referred to in paragraph 1 shall be adopted by means of implementing acts, in accordance with the examination procedure referred to in Article 179(2), taking into account the scientific recommendation of the Agency.

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Chapter VI
Orphan medicinal products

Article 65

Criteria for orphan designation

1. A medicinal product that is intended for the prevention, diagnosis or treatment of a life-threatening or chronically debilitating condition shall be granted the status of designated orphan medicinal product (‘orphan designation’) where the orphan medicinal product sponsor can demonstrate that the following criteria are met:

   (a) the condition affects not more than five in 10 000 persons in the Union when the application for an orphan designation is submitted; and

   (b) no satisfactory method of prevention, diagnosis or treatment of the condition has been authorised in the Union or, if there is such a method of, prevention, diagnosis, or treatment, the medicinal product would be of significant benefit to those affected by that condition.

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2. On the basis of a recommendation from the Agency concluding that the criteria set out in paragraph 1, point (a), of this Article are not appropriate to identify certain conditions as being an orphan condition within the scope of rarity in paragraph 1, point (a), of this Article due to the specific characteristics of those conditions or any other scientific reasons, the Commission is empowered to adopt delegated acts in accordance with Article 181 in order to supplement paragraph 1, point (a), of this Article, by setting specific criteria for certain conditions.

3. The Commission shall adopt the necessary provisions for implementing this Article by means of implementing acts in accordance with the procedure laid down in Article 179(2) in order to further specify the criteria set out in paragraph 1 of this Article.

Article 66

Decision granting a medicinal product an orphan designation

1. The orphan medicinal product sponsor shall submit to the Agency an application for the orphan designation of a medicinal product (‘application for an orphan designation’) at any stage of the development of the medicinal product before the application for marketing authorisation referred to in Articles 5 and 7 is submitted.

2. The application for an orphan designation shall be accompanied by the following particulars and documents:

(a) the name or company name and permanent address of the orphan medicinal product sponsor;

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(b) the information on the active substances of the medicinal product;

(c) proposed condition for which the medicinal product is intended or its proposed therapeutic indication;

(d) justification that the criteria set out in Article 65(1) or in the relevant delegated acts adopted in accordance with Article 65(2) are fulfilled and a description of the stage of development of the medicinal product, including its expected therapeutic indication.

The orphan medicinal product sponsor shall be responsible for the accuracy of the particulars and documents submitted pursuant to the first subparagraph.

3. The Agency shall, in consultation with the Member States, the Commission and interested parties, draw up detailed guidelines on the procedure, format and content of applications for an orphan designation and for the transfer of the orphan designation pursuant to Article 67.

4. Within 90 days of receipt of a valid application, the Agency shall adopt a decision granting or refusing the orphan designation based on the criteria set out in Article 65(1) or in the relevant delegated acts adopted in accordance with Article 65(2). The Agency shall verify the validity of the application. The application shall be considered valid if it includes all the particulars and documents referred to in paragraph 2 of this Article.

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For the purpose of establishing whether the orphan designation criteria set out in Article 65(1) or in the relevant delegated acts adopted in accordance with Article 65(2) are fulfilled, the Agency may ask the orphan medicinal product sponsor to provide supplementary information, within the time limit set by the Agency.

For the purpose of establishing whether the orphan designation criteria are fulfilled, the Agency shall consult the Committee for Medicinal Products for Human Use. The Committee for Medicinal Products for Human Use shall ensure the appropriate involvement of the relevant scientific expertise through the scientific working parties referred to in Article 157 or may delegate this task to one of those working parties. The outcome of such consultations, including information on the involvement of relevant scientific expertise, shall be annexed to the Agency's decision granting or refusing the orphan designation, as part of the scientific conclusions of the Agency which justify the decision.

The decision together with the Annexes referred to in the third subparagraph shall be notified to the applicant.

By way of derogation from the third subparagraph, the Committee for Medicinal Products for Human Use shall establish scientific principles to determine the situations where consultation of that Committee is not required.

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5. When the scientific conclusions referred to in the third subparagraph of paragraph 4 of this Article state that the application does not fulfil the criteria set out in Article 65(1), they shall be transmitted without delay by the Agency to the orphan medicinal product sponsor before the adoption of the decision referred to in paragraph 4 of this Article.

Within 15 days of receipt of the scientific conclusions, the orphan medicinal product sponsor may submit to the Agency a duly reasoned request, in writing, for a re-examination of the scientific conclusions.

Within 30 days of receipt of the request for re-examination referred to in second subparagraph of this paragraph, the Agency shall reexamine its scientific conclusions. The reasons for the conclusion reached following that re-examination shall be part of the final scientific conclusions. The time limit referred to in paragraph 4 of this Article shall be suspended until the scientific conclusions become final. For the purposes of this paragraph, the Agency shall consult the Committee for Medicinal Products for Human Use.

If the orphan medicinal product sponsor does not submit a written justified request for re-examination within 15 days of receipt of the scientific conclusions, they shall become final.

6. Decisions of the Agency on granting or refusing the orphan designation shall be made public after deletion of any information of a commercially confidential nature.

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Article 67

Transfer of an orphan designation

1. The orphan designation may be transferred from one orphan medicinal product sponsor (the ‘current orphan medicinal product sponsor’) to another orphan medicinal product sponsor (the ‘new orphan medicinal product sponsor’). Such transfers shall be subject to prior approval by the Agency, following the submission of an application for transfer by the current orphan medicinal product sponsor to the Agency.

2. The application for transfer of an orphan designation by the current orphan medicinal product sponsor shall be accompanied by the following particulars and documents:

   (a) name or company name and permanent address of the current and new orphan medicinal product sponsor;

   (b) decision of the Agency granting the orphan designation pursuant to Article 66(4);

   (c) designation number as referred to in Article 69(1), point (e);

   (d) reasons for the transfer of the orphan designation.

3. The Agency shall adopt a decision granting or refusing the transfer of the orphan designation within 30 days of receipt of a valid application by the current orphan medicinal product sponsor. The application shall be considered valid if it includes all the particulars and documents referred to in paragraph 2. The Agency shall address its decision to the current and new orphan medicinal product sponsor.

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Article 68

Validity of an orphan designation

1. An orphan designation shall be valid for seven years. During that period, the orphan medicinal product sponsor shall be eligible for incentives referred to in Article 70.

2. By way of derogation from paragraph 1, on the basis of a reasoned request by the orphan medicinal product sponsor, the Agency may extend the validity of the orphan designation, where the orphan medicinal product sponsor provides evidence that the relevant studies supporting the use of the designated orphan medicinal product to prevent, diagnose or treat the condition specified in the application for an orphan designation are ongoing and promising with regard to the filing of a future application. Any extension shall be limited in time, taking into account the expected time remaining needed to file an application for marketing authorisation.

3. By way of derogation from paragraph 1 of this Article, where an orphan designation is valid at the time when a marketing authorisation application for an orphan medicinal product has been submitted in accordance with Article 5, the orphan designation shall remain valid until a decision is adopted by the Commission in accordance with Article 14(2).

4. An orphan designation shall cease to be valid once an orphan medicinal product sponsor has obtained a marketing authorisation for a therapeutic indication covered under the orphan designation in accordance with Article 14(2).

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5. An orphan designation may be withdrawn at any time, at the request of the orphan medicinal product sponsor. The orphan medicinal product sponsor shall provide the Agency with the reasons for such request. The Agency shall make this information publicly available.

Article 69

Register of designated orphan medicinal products

1. The Agency shall set up and manage a register of designated orphan medicinal products and make it publicly available. The register of designated orphan medicinal products shall list all designated orphan medicinal products and shall include at least the following particulars and documents:

(a) the information on the active substance;

(b) the name or company name and permanent address of the orphan medicinal product sponsor;

(c) the proposed condition for which the medicinal product is intended or its proposed therapeutic indication;

(d) the designation date;

(e) the designation number;

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(f) the decision on granting the orphan designation;

(g) the decision on transfer of the orphan designation; and

(h) where applicable, the decision extending the validity of the orphan designation in accordance with Article 68(2).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 181 in order to amend the information to be included in the register of designated orphan medicinal products referred to in paragraph 1 of this Article to ensure that users of the register are sufficiently informed.

3. Where an orphan designation ceases to be valid or is withdrawn pursuant to Article 68, the Agency shall make an entry in the register of designated orphan medicinal products.

Article 70

Protocol assistance and research support for designated orphan medicinal products

1. Prior to the submission of an application for marketing authorisation, the orphan medicinal product sponsor may request advice from the Agency on the following:

(a) the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of the medicinal product, as referred to Article 144(1), second subparagraph, point (q);

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(b) the conduct of the various tests and trials necessary for the environmental risk assessment of the medicinal product;

(c) the demonstration of significant benefit within the scope of the orphan condition as set out in Article 65(1);

(d) the demonstration of similarity to, or clinical superiority over, other medicinal products, which have market exclusivity for the same therapeutic indication.

2. Medicinal products designated as orphan medicinal products under this Regulation shall be eligible for incentives made available by the Union and by the Member States to support research into, and the development and availability of, orphan medicinal products and in particular aid for research for SMEs and entities not engaged in economic activity provided for in framework programmes for research and technological development.

Article 71

Marketing authorisation as an orphan medicinal product

1. An application for marketing authorisation as an orphan medicinal product shall be submitted in accordance with Articles 5 and 7 and the related marketing authorisation shall be obtained in accordance with Article 14(2).

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2. In addition, the applicant shall demonstrate that the medicinal product has been granted an orphan designation and that the criteria set out in Article 65(1) or in the relevant delegated acts adopted in accordance with Article 65(2) are fulfilled for the therapeutic indication sought.

Where appropriate, the applicant shall provide relevant evidence to demonstrate that the medicinal product meets the criteria laid down in Article 72(1).

3. The Committee for Medicinal Products for Human Use shall assess whether the medicinal product fulfils the criteria set out in Article 65(1) or in the relevant delegated acts adopted in accordance with Article 65(2). In the situation referred to in paragraph 2, second subparagraph, of this Article that Committee shall also assess whether the medicinal product is considered a breakthrough orphan medicinal product as provided for in Article 72(1). The Committee for Medicinal Products for Human Use shall ensure the appropriate involvement of scientific expertise regarding orphan medicinal products.

The assessment pursuant to the first subparagraph shall be subject to the same time limit as the application for the marketing authorisation itself. The assessment and its detailed conclusions shall be part of the opinion referred to in Article 13(1) and, where relevant, the final opinion referred to in Article 13(3).

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4. The orphan marketing authorisation shall cover only those therapeutic indications which fulfil the criteria set out in Article 65(1) or in the relevant delegated acts adopted in accordance with Article 65(2) at the time when the orphan marketing authorisation is granted.

5. If after the submission of an application for the orphan marketing authorisation and prior to the opinion of the Committee for Medicinal Products for Human Use the orphan designation is withdrawn pursuant to Article 68(5), the application for the orphan marketing authorisation shall be treated as the application for a marketing authorisation in accordance with Article 7.

6. An applicant may submit an application for a separate marketing authorisation for other therapeutic indications which do not fulfil the criteria set out in Article 65(1) or in the relevant delegated acts adopted in accordance with Article 65(2).

Article 72

Breakthrough orphan medicinal products

1. A medicinal product which meets the criteria referred to in Article 65 shall be considered a breakthrough orphan medicinal product if it meets the following additional criteria:

(a) there is no medicinal product authorised in the Union for the orphan condition; and

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(b) the use of the medicinal product results in a clinically relevant reduction in disease morbidity or mortality for the relevant patient population.

2. A medicinal product for which an application has been submitted in accordance with Article 14 of Directive (EU) 2026/…[+] shall not be considered to meet the criteria laid down in paragraph 1 of this Article.

Article 73

Market exclusivity of orphan medicinal products

1. Where an orphan marketing authorisation is granted and without prejudice to intellectual property law, the Union and the Member States shall not grant a centralised or national marketing authorisation or extend an existing centralised or national marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product for the duration of market exclusivity set out in paragraph 2.

2. The duration of market exclusivity shall be as follows:

(a) nine years for orphan medicinal products other than those referred to in points (b) and (c);

(b) eleven years for breakthrough orphan medicinal products referred to in Article 72;

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(c) four years for orphan medicinal products which have been authorised in accordance with Article 14 of Directive (EU) 2026/…[+].

3. Where a marketing authorisation holder holds more than one orphan marketing authorisation for the same active substance, those authorisations shall not benefit from separate market exclusivity periods. The duration of the market exclusivity shall start from the date when the first orphan marketing authorisation was granted in the Union.

4. By way of derogation from paragraph 1, and without prejudice to intellectual property law, the centralised or national marketing authorisation may be granted, for the same therapeutic indication, to a similar medicinal product if:

(a) the marketing authorisation holder for the original orphan medicinal product has given consent to the second applicant;

(b) the marketing authorisation holder for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product; or

(c) the second applicant can establish in the application that the second medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior.

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5. The submission, validation and assessment of the application for the centralised or national marketing authorisation and the granting of the centralised or national marketing authorisation for a generic medicinal product or biosimilar medicinal product to the reference medicinal product, shall not be prevented by the market exclusivity of a similar product to the reference medicinal product.

6. The market exclusivity of the orphan medicinal product shall not prevent the submission, validation and assessment of an application for a centralised or national marketing authorisation, including to extend an existing centralised or national marketing authorisation for a new therapeutic indication, of a similar medicinal product, including generic medicinal products and biosimilar medicinal products, where the remainder of the duration of the market exclusivity is less than two years. This may include the adoption of the corresponding decision provided that the decision granting or extending the centralised or national marketing authorisation does not enter into force prior to the expiry of the market exclusivity period.

7. Where the Agency adopts scientific guidelines for the application of paragraphs 1 and 4, it shall consult the Commission.

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Article 74

Extension of market exclusivity

1. The period of market exclusivity shall be extended by an additional period of 12 months for orphan medicinal products referred to in Article 73(2), points (a) and (b), if, at least two years before the end of the exclusivity period, the orphan marketing authorisation holder obtains a marketing authorisation for one or more new therapeutic indications for a different orphan condition.

   Such an extension may be granted twice, provided that each new therapeutic indication concerns a different orphan condition.

2. The orphan medicinal products which benefit from the extension of market exclusivity referred to in paragraph 1 of this Article shall not benefit from the additional period of market protection referred to in Article 84(2) of Directive (EU) 2026/…[+].

3. Article 73(3) equally applies to the extension of market exclusivity referred to in paragraph 1 of this Article.

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Article 75

Union financial contribution related to orphan medicinal products

The working arrangements referred to in Article 8 of Regulation (EU) 2024/568 shall set out total or partial reductions for the applicable fees and charges payable to the Agency as laid down in that Regulation. Such reductions shall be covered by the Union contribution provided for in Article 161(3), first subparagraph, point (a) of this Regulation.

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Chapter VII
Paediatric medicinal products

Article 76

Paediatric investigation plan

1. A paediatric investigation plan shall specify the timing and all the measures proposed to evaluate the quality, safety and efficacy of the medicinal product in all subsets of the paediatric population that might be concerned. In addition, the paediatric investigation plan shall describe any measures to adapt the pharmaceutical form, the strength, route of administration and any administration device for the medicinal product so as to make its use more acceptable, easier, safer or more effective for different subsets of the paediatric population.

2. By way of derogation from paragraph 1, an applicant may submit only an initial paediatric investigation plan in the following cases:

   (a) where the active substance is not yet authorised in any medicinal product in the Union and is intended for diagnosis, prevention or treatment of a novel paediatric condition or for the diagnosis, prevention or treatment of an existing paediatric condition by means of a new mechanism of action; or

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(b) where the Agency has accepted a duly justified request from an applicant in accordance with paragraph 3.

An initial paediatric investigation plan shall specify only the details and the timing of the measures proposed to assess the quality, safety and efficacy of the medicinal product in all subsets of the paediatric population that might be concerned, that are known at the moment of the submission of the request for agreement referred to in Article 78(1).

The initial paediatric investigation plan shall also specify the timing for the submission to the Agency of updated versions of that paediatric investigation plan and for the submission of a final paediatric investigation plan complying with paragraph 1.

3. When it is not possible, on the basis of scientifically justified reasons, to have a complete paediatric investigation plan in accordance with the timing referred to in Article 76(1) an applicant may submit a duly justified request to the Agency to use the procedure mentioned in paragraph 2 of this Article. The Agency has 20 days to accept or refuse the request and shall immediately inform the applicant and state the reasons for refusal.

4. On the basis of the experience acquired as a result of the application of this Article or of scientific knowledge, the Commission is empowered to adopt delegated acts in accordance with Article 181 to amend the grounds for granting the possibility to derogate from paragraph 1 of this Article pursuant to paragraph 2 of this Article.

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Article 77

Class or product-specific waivers

1. In accordance with the procedure laid down in Article 80 of this Regulation, the Agency may decide that the production of the information referred to in Article 7(5), first subparagraph, point (a), of Directive (EU) 2026/…[+] shall be waived for specific medicinal products or for classes of medicinal products, if there is evidence showing any of the following:

   (a) that the specific medicinal product or class of medicinal products is likely to be ineffective or unsafe in part or all of the paediatric population;

   (b) that the disease or condition for which the specific medicinal product or class of medicinal products is intended occurs only in the adult population, except when the specific medicinal product displays a mechanism of action, including where its action is directed at a specific molecular target or biological pathway that, on the basis of existing scientific data, is relevant for a different disease or condition in children in the same therapeutic area as the one for which the specific medicinal product or class of medicinal products is intended for in the adult population;

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(c) that the specific medicinal product is likely to not represent a significant therapeutic benefit over existing methods of diagnosis, prevention or treatment for paediatric patients, except when the specific medicinal product displays a mechanism of action, including where its action is directed at a specific molecular target or biological pathway that, on the basis of existing scientific data, is relevant for a different disease or condition in children in the same therapeutic area as the one for which the specific medicinal product or class of medicinal products is intended for in the adult population.

2. The waiver provided for in paragraph 1 may be granted with reference to one or more specified subsets of the paediatric population, or to one or more specified therapeutic indications, or to a combination of both.

3. On the basis of the experience acquired as a result of the application of this Article or of scientific knowledge, the Commission is empowered to adopt delegated acts in accordance with Article 181 to amend the grounds for granting a waiver provided for in paragraph 1 of this Article.

4. The Agency shall, in consultation with the Commission, the competent authorities of the Member States and relevant interested parties, draw up guidelines for the application of this Article.

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Article 78

Validation of a proposed paediatric investigation plan or of a waiver

1. A paediatric investigation plan pursuant to Article 76 or an application for a product-specific waiver pursuant to Article 77 shall be submitted to the Agency together with a request for agreement, except in duly justified cases, before the initiation of safety and efficacy clinical studies so as to ensure that a decision on use in the paediatric population of the medicinal product concerned can be taken at the time of the marketing authorisation or other application concerned.

2. Within 30 days of receipt of the request referred to in paragraph 1, the Agency shall verify the validity of the request and inform the applicant of the result of that verification.

3. Where appropriate, the Agency may ask the applicant to submit additional particulars and documents, in which case the time limit of 30 days referred to in paragraph 2 shall be suspended until the supplementary information has been provided.

4. In consultation with the Commission, the competent authorities of the Member States and with interested parties, the Agency shall draw up and publish guidelines for the practical application of this Article.

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Article 79

Decisions agreeing a paediatric investigation plan

1. Within 90 days of the validation of the proposed paediatric investigation plan referred to in Article 76(1) in accordance with Article 78(2), the Agency shall adopt a decision as to whether the studies proposed will ensure the generation of the data necessary to determine the conditions in which the medicinal product may be used to treat the paediatric population or subsets of that population, and as to whether the expected therapeutic benefits, where appropriate, including as compared to existing treatments, justify the studies proposed. When adopting its decision, the Agency shall consider whether the measures proposed to adapt the pharmaceutical form, the strength, route of administration and any administration device for the medicinal product for use in different subsets of the paediatric population are appropriate.

2. The Agency shall adopt a decision within 70 days of the validation of the proposed initial paediatric investigation plan referred to in Article 76(2), first subparagraph, in accordance with Article 78(2), as to whether the paediatric investigation plan is expected to ensure the generation of the data necessary to determine the conditions in which the medicinal product may be used to treat the paediatric population or subsets of that population, and as to whether the expected therapeutic benefits, where relevant, including as compared to existing treatments, justify the studies proposed.

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3. After receiving an updated version of the paediatric investigation plan referred to in Article 76(2), third subparagraph, the Agency shall review it within 60 days.

After the expiry of the time limit specified in the first subparagraph of this paragraph, and in the absence of any request from the Agency in accordance with paragraph 5, the updated version of the paediatric investigation plan shall be considered to be agreed.

4. Within 60 days of receipt of the final paediatric investigation plan referred to in Article 76(2), third subparagraph, the Agency shall adopt a final decision on the paediatric investigation plan, considering the initial decision and any updated reviews conducted in accordance with paragraphs 2 and 3 of this Article.

5. Within the time limits referred to in paragraph 1, 2, 3 or 4, the Agency may request the applicant to propose modifications to the paediatric investigation plan or ask for supplementary information, in which case the time limits referred to in paragraphs 1, 2, 3 and 4 shall be extended for a maximum of the same number of days. Those time limits shall be suspended until the supplementary information has been provided.

6. The procedure laid down in Article 89 shall apply for the adoption of decisions by the Agency under this Article.

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Article 80

Decisions granting, refusing, reviewing or revoking a class or product-specific waiver

1. An applicant may apply to the Agency for a product-specific waiver, on the grounds set out in Article 77(1).

2. Within 90 days of receipt of a valid application, the Agency shall adopt a decision granting or refusing a product-specific waiver.

   Where appropriate, the Agency may request the applicant to supplement the particulars and documents submitted. Where the Agency avails itself of this option, the 90-day time limit shall be suspended until the supplementary information has been provided.

3. Where appropriate, the Agency may on its own motion adopt decisions, on the basis of the grounds set out in Article 77(1), to the effect that a class or a product-specific waiver, as referred to in Article 77(2), is granted.

4. The Agency may at any time adopt a decision reviewing a class or product-specific waiver.

5. If a particular class or product-specific waiver is revoked, the requirement laid down in Article 7(5) of Directive (EU) 2026/…[+] shall not apply for 36 months from the date of its removal from the list of waivers referred to in Article 81 of this Regulation.

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6. The procedure laid down in Article 89 shall apply for the adoption of decisions by the Agency under this Article.

7. In consultation with the Commission, the competent authorities of the Member States and interested parties, the Agency shall draw up and publish guidelines for the practical application of this Article.

Article 81

List of waivers

The Agency shall maintain a list of waivers. The list shall be updated regularly and publicly available.

Article 82

Waivers granted following a negative decision on a paediatric investigation plan

If, having assessed a paediatric investigation plan, the Agency concludes that Article 77(1), point (a), (b) or (c), applies to the medicinal product, it shall adopt, simultaneously:

(a) a negative decision under Article 79(1), (2) or (4); and

(b) a decision granting a class or a product-specific waiver under Article 80(3).

The procedure laid down in Article 89 shall apply for the adoption of decisions by the Agency under this Article.

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Article 83

Decisions granting or refusing deferrals

1. At the same time as the request for agreement of a paediatric investigation plan is submitted to the Agency pursuant Article 78(1) or during the assessment for a paediatric investigation plan, the applicant may also make a request to the Agency for deferral of the initiation or completion of some or all of the measures set out in that plan. Such deferral shall be justified on scientific or technical grounds or on grounds related to public health.

   In any event, a deferral shall be granted when it is appropriate to conduct studies in adults prior to initiating studies in the paediatric population or when studies in the paediatric population will take longer to conduct than studies in adults.

2. The Agency shall adopt a decision granting or refusing the deferral and inform the applicant thereof. The Agency shall adopt that decision at the same time as it adopts a positive decision under Article 79(1) or (2).

   A decision granting the deferral shall specify the time limits for initiating or completing the measures concerned.

3. The length of the deferral shall be specified in the decision of the Agency and shall be substantiated by scientific or technical grounds or by considerations pertaining to public health and shall not exceed five years.

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4. On the basis of the experience acquired as a result of the application of this Article, the Commission is empowered to adopt delegated acts in accordance with Article 181 to amend the grounds for granting a deferral referred to in paragraph 1 of this Article.

Article 84

Decisions on extension of deferrals

1. In duly justified cases, a request for an extension of the deferral, may be submitted, at least six months before the expiry of the deferral period. An extension of the deferral shall not exceed the duration of the deferral period given under Article 83(3).

   The Agency shall decide on the extension within 60 days.

2. Where appropriate, the Agency may ask the applicant to submit, within the time limit specified by the Agency, additional particulars and documents, in which case the time limit of 60 days shall be suspended until the supplementary information has been provided.

3. The procedure laid down in Article 89 shall apply for the adoption of decisions by the Agency under this Article.

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Article 85

Derogation during a public health emergency

1. The decision by the Agency referred to in Article 7(5), first subparagraph, point (e), of Directive (EU) 2026/…[+] shall concern only medicinal products intended for prevention, diagnosis or treatment of a serious or life-threatening disease or condition which is directly related to the public health emergency.

2. The decision referred to in paragraph 1 shall include the grounds for providing such derogation and its duration.

3. At the latest at the date of expiry of the derogation referred to in paragraph 2 of this Article, the applicant shall submit to the Agency a paediatric investigation plan or an application for a waiver with a request for agreement in accordance with Article 78(1).

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Article 86

Modification of a paediatric investigation plan

1. If, following the decision agreeing the paediatric investigation plan, the applicant encounters such difficulties with its implementation as to render the plan unworkable or no longer appropriate, the applicant may propose modifications to the plan or request the Agency to grant a deferral in accordance with Article 83 or a waiver in accordance with Article 77. The Agency shall, within 90 days, adopt a decision on the basis of the procedure laid down in Article 89. If appropriate, the Agency may request the applicant to supplement the particulars and documents submitted. Where the Agency avails itself of this option, the time limit shall be suspended until such supplementary information has been provided.

2. If, following the decision agreeing the paediatric investigation plan referred to in Article 79(1), (2) and (4), or on the basis of the updated paediatric investigation plan received in accordance with Article 79(3), the Agency, on the base of new scientific information available, considers that the agreed plan or any of its elements are no longer appropriate, it shall request, based on scientific grounds, that the applicant propose modifications to the paediatric investigation plan.

   The applicant shall submit the modifications requested within 60 days.

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Within 30 days, the Agency shall review those modifications and adopt a decision on their refusal or acceptance.

3. Within the time limit referred to in paragraph 2, third subparagraph, the Agency may request the applicant for additional modifications to the submitted modifications or to provide supplementary information. In that case, the time limit referred to in that subparagraph shall be extended by another 30 days. This time limit shall be suspended until the additional modifications or the supplementary information have been provided.

4. The procedure laid down in Article 89 shall apply for the adoption of decisions by the Agency under this Article.

Article 87

Detailed arrangements for applications

in relation to paediatric investigation plans, waivers and deferrals

1. In consultation with the Member States, the Commission and interested parties, the Agency shall draw up the detailed arrangements concerning the format and content for applications for agreement or modification of a paediatric investigation plan, and requests for waivers or deferrals in order to be considered valid as well as concerning the operation of the compliance verification referred to in Article 51 and Article 52(2) of Directive (EU) 2026/…[+], and Article 88 and Article 92(2) of this Regulation.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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2. The detailed arrangement concerning the format and content of applications for agreement of a paediatric investigation plan mentioned in paragraph 1 shall:

(a) specify which information is to be included in an application for agreement or modification of a paediatric investigation plan or requests for a waiver in the cases referred to in Article 77(1);

(b) be adapted to take into account the specificities of:

(i) the adapted procedure for paediatric investigation plans as referred to in Article 76(2);

(ii) products intended to be developed only for paediatric use;

(iii) products intended to be submitted under the procedure referred to in Article 94.

Article 88

Compliance with the paediatric investigation plan

Where an application for marketing authorisation or variation is submitted in accordance with this Regulation, the Committee for Medicinal Products for Human Use shall verify whether the application complies with the requirements laid down in Article 7(5) of Directive (EU) 2026/…[+].

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Article 89

Procedure for adopting a decision

in relation to paediatric investigation plans, a waiver or a deferral

1. Decisions of the Agency adopted pursuant to Articles 79, 80, 82, 83, 84 and 86 shall be supported by scientific conclusions which shall be annexed to those decisions.

2. The Agency shall consult the Committee for Medicinal Products for Human Use when preparing the scientific conclusions referred to in paragraph 1 of this Article. The Committee for Medicinal Products for Human Use shall ensure, as necessary, the appropriate involvement of the relevant scientific expertise through at least one of the working parties established under Article 157 or may delegate this task to one of those working parties. The outcome of such consultations shall be annexed to the decisions referred to in paragraph 1 of this Article, as part of the scientific conclusions of the Agency which justify the relevant decision.

3. By way of derogation from paragraph 2, the Committee for Medicinal Products for Human Use shall establish scientific principles to determine the situations where consultation of that Committee is not required.

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4. The Agency shall transmit its scientific conclusions referred to in paragraph 1 of this Article to the applicant without delay before the adoption of the decisions pursuant to Articles 79, 80, 82, 83, 84 and 86. Within 15 days of receipt of the scientific conclusions, the applicant may submit to the Agency a duly justified request, in writing, for the re-examination of the scientific conclusions. Within 30 days of receipt of a request the Agency shall reexamine its scientific conclusions. The reasons for the conclusion reached following that re-examination shall be part of final scientific conclusions. The time limit referred to in Articles 79, 80, 84 and 86 will be suspended until the scientific conclusions become definitive. For the purposes of this paragraph, the Agency shall consult the Committee for Medicinal Products for Human Use.

If the applicant does not submit a justified request for re-examination in writing within 15 days of receipt of the scientific conclusions, they shall become definitive.

5. Decisions of the Agency pursuant to Articles 79, 80, 82, 83, 84 and 86 shall be made public after deletion of any information of a commercially confidential nature.

Article 90

Discontinuation of a paediatric investigation plan

Where an applicant intends to discontinue a paediatric investigation plan that has been agreed in accordance with Article 79(1), (2) and (4), the applicant shall notify its intention to the Agency. The notification shall be sent without undue delay and in any case at least six months before the intended discontinuation and shall include the reasons for discontinuation.

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The Agency shall publish the information contained in the notification after deleting any personal or commercially sensitive information.

Article 91

Scientific advice for paediatric developments

Any legal or natural person who develops a medicinal product intended for paediatric use or in utero treatment may, prior to the submission of a paediatric investigation plan and during its implementation, request advice from the Agency on the design and conduct of the various tests and studies necessary to demonstrate the quality, safety and efficacy of the medicinal product in the paediatric population in accordance with Article 144(1), second subparagraph, point (zb).

The Agency shall provide advice under this Article free of charge.

Article 92

Data deriving from a paediatric investigation plan

1. Where a marketing authorisation or a variation of a marketing authorisation, is granted under this Regulation:

   (a) the results of all studies conducted in compliance with an agreed paediatric investigation plan as referred to in Article 7(5), first subparagraph, point (a), of Directive (EU) 2026/…[+] shall be included in the summary of product characteristics and, if appropriate, in the package leaflet; or

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(b) any class or product-specific waiver granted as referred to in Article 7(5), first subparagraph, points (b) and (c) of Directive (EU) 2026/…[+] shall be recorded in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

2. The Commission shall include a statement in the marketing authorisation indicating that the application complies with the agreed paediatric investigation plan if the following conditions are met:

(a) the application complies with all the measures contained in the agreed completed paediatric investigation plan; and

(b) the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan.

Article 93

Variation of marketing authorisations on the basis of paediatric studies

1. Any clinical study which involves the use in the paediatric population of a medicinal product covered by a centralised or national marketing authorisation and is sponsored by the marketing authorisation holder, whether or not it is conducted in compliance with an agreed paediatric investigation plan, shall be submitted to the Agency or to the Member States in which the medicinal product is authorised within six months of completion of the studies concerned.

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2. Paragraph 1 shall apply irrespective of whether the marketing authorisation holder intends to apply for a marketing authorisation of a paediatric indication.

3. When products are authorised in accordance with this Regulation, the Commission may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly.

Article 94

Paediatric use marketing authorisation

1. An application for a paediatric use marketing authorisation shall be submitted in accordance with Articles 5 and 7 and shall be accompanied by the particulars and documents necessary to establish quality, safety and efficacy in the paediatric population, including any specific data needed to support an appropriate formulation, pharmaceutical form, strength, route of administration and eventual administration device for the medicinal product, in accordance with the agreed paediatric investigation plan. The application shall also include the decision of the Agency agreeing the paediatric investigation plan concerned.

2. Where a medicinal product is or has been authorised in a Member State or in the Union, data contained in the dossier on that product may, where appropriate, be referred to, in accordance with Article 30 of this Regulation or Articles 10 and 12 of Directive (EU) 2026/…[+], in an application for a paediatric use marketing authorisation.

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3. The medicinal product in respect of which a paediatric use marketing authorisation is granted may retain the name of any medicinal product which contains the same active substance and in respect of which the same marketing authorisation holder has been granted authorisation for use in adults.

4. Submission of an application for a paediatric use marketing authorisation shall in no way preclude the right to apply for a marketing authorisation for other therapeutic indications.

Article 95

Rewards for products authorised under the paediatric use marketing authorisation procedure

Where a paediatric use marketing authorisation referred to in Article 94 of this Regulation is granted and includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the medicinal product shall benefit from independent regulatory data protection and regulatory market protection periods referred to in Articles 83 and 84 of Directive (EU) 2026/…[+].

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Article 96

Paediatric clinical trials

1. The EU database set up pursuant to Article 81 of Regulation (EU) No 536/2014 (the 'EU database') shall include clinical trials that are conducted in third countries and that are:

   (a) contained in an agreed paediatric investigation plan;

   (b) submitted in accordance with Article 93.

2. For the clinical trials referred to in paragraph 1 of this Article which are conducted in third countries, the description of the following elements shall be entered into the EU database referred to in paragraph 1 of this Article prior to the start of the trial by the clinical trial sponsor, the addressee of the Agency's decision on a paediatric investigation plan referred to in Article 79, or by the marketing authorisation holder, as appropriate:

   (a) the clinical trial protocol;

   (b) the investigational medicinal products used;

   (c) the therapeutic indications covered;

   (d) details of the clinical trial population.

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Within six months of the end of the clinical trial, irrespective of the outcome thereof, the clinical trial sponsor, the addressee of the Agency's decision on a paediatric investigation plan or the marketing authorisation holder, as appropriate, shall submit a summary of the results of the clinical trial to the EU database. That summary shall be entered into the EU database.

If for scientific reasons, it is not possible to submit the summary of the result of the clinical trial within six months, it shall be submitted to the EU database at the latest within 12 months of the end of the clinical trial, together with the reasons for the delay.

3. In consultation with the Commission, Member States and interested parties, the Agency shall draw up guidance on the nature of the information referred to in paragraph 2.

4. On the basis of the experience acquired as a result of the application of this Article, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 179(2) to amend the details concerning clinical trials conducted in third countries to be submitted to the EU database pursuant to this Article.

Article 97

European network for paediatric research

1. The Agency shall develop a European network of patient representatives, academics, medicinal product developers, investigators and centres with expertise in the performance of studies in the paediatric population ('European network for paediatric research').

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2. The objectives of the European network for paediatric research shall be, inter alia, to discuss priorities in the clinical development of medicinal products for children, in particular in areas of unmet medical need, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at Union level, and to avoid unnecessary duplication of studies or testing in the paediatric population.

Article 98

Incentives for research in medicinal products for children

Paediatric medicinal products shall be eligible for incentives made available by the Union and by the Member States to support research into, and the development and availability of, paediatric medicinal products.

Article 99

Fees and Union contribution for paediatric activities

1. Where an application for a paediatric use marketing authorisation is submitted in accordance with the procedure laid down in Article 94 of this Regulation, the amount of the reduced fees for the assessment of the application and the maintenance of the marketing authorisation shall be set in accordance with Article 6 of Regulation (EU) 2024/568.

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2. The following assessments by the Agency shall be free of charge:

(a) applications for waivers;

(b) applications for deferrals;

(c) applications for paediatric investigation plans;

(d) compliance with the agreed paediatric investigation plan.

3. The Union contribution provided for in Article 161 shall cover the work of the Agency, including the assessment of paediatric investigation plans, scientific advice and any fee waivers provided for in this Chapter, and shall support the Agency's activities under Articles 96 and 97.

Article 100

Yearly reporting on paediatric activities

At least on an annual basis, the Agency shall make public:

(a) a list of the entities and of the medicinal products that have benefited from any of the rewards and incentives in this Chapter;

(b) the entities that have failed to comply with any of the obligations in this Chapter;

(c) the number of paediatric investigation plans agreed in accordance with Article 76;

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(d) the number of waivers granted, providing also a summary of their reasons;

(e) a list of deferrals granted;

(f) the number of paediatric investigation plans completed;

(g) the prolongations of the deferrals beyond five years and the detailed reasons provided referred to in Article 84;

(h) the scientific advice provided for the development of medicinal products intended for paediatric use, requested in accordance with Article 91.

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Chapter VIII
Pharmacovigilance

Article 101

Pharmacovigilance

1. The obligations of marketing authorisation holders laid down in Article 102 and Article 103(1), of Directive (EU) 2026/…[+] shall apply to marketing authorisation holders for medicinal products for human use centrally authorised in accordance with this Regulation.

2. The Agency may impose an obligation on a holder of a centralised marketing authorisation to operate a risk management system, as referred to in Article 102(4), point (c) of Directive (EU) 2026/…[+], if there are concerns about the risks affecting the benefit-risk balance of an authorised medicinal product. In that context, the Agency shall also oblige the marketing authorisation holder to submit a risk management plan for the risk-management system that they intend to introduce for the medicinal product concerned.

   The obligation shall be duly justified, notified in writing, and shall include the timeframe for submission of the risk-management plan.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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3. The Agency shall provide the marketing authorisation holder with an opportunity to submit written observations in response to the imposition of the obligation referred to in paragraph 2 within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.

On the basis of the written observations submitted by the marketing authorisation holder, the Agency shall review its opinion.

4. Where the opinion of the Agency confirms the obligation referred to in paragraph 2 of this Article, and unless the Commission refers the opinion back to the Agency for further consideration, the Commission shall vary the marketing authorisation in accordance with the procedure laid down in Article 14, to include:

(a) that obligation as a condition of the marketing authorisation;

(b) the measures to be taken as part of the risk management system as a condition of the marketing authorisation referred to in Article 13(4), point (e).

In the case of point (a) of the first subparagraph, the marketing authorisation holder shall update the risk management system accordingly.

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Article 102

Safety announcements

The obligations of marketing authorisation holders laid down in Article 107(1) and (2) of Directive (EU) 2026/…[+], and the obligations of the Member States, the Agency and the Commission laid down in paragraphs 3 and 4 of that Article shall apply to the safety announcements referred to in Article 144(1), second subparagraph, point (g), of this Regulation concerning medicinal products for human use authorised in accordance with this Regulation.

Article 103

Eudravigilance database

1. The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a database and data processing network (‘Eudravigilance database’) to collate pharmacovigilance information regarding medicinal products authorised in the Union and to allow competent authorities of the Member States or the Agency to access that information simultaneously and to share it.

   The Eudravigilance database shall include pharmacovigilance information with regard to medicinal products made available for compassionate use as referred to in Article 27 or through early access schemes.

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The Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation, as well as from uses outside the terms of the marketing authorisation, and on suspected adverse reactions occurring in the course of post-authorisation studies relating to the medicinal product or to occupational exposure to that medicinal product.

2. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the Eudravigilance database, together with a timeframe for their implementation.

The Agency shall prepare an annual report on the Eudravigilance database and send it to the European Parliament, the Council and the Commission.

Any substantial change to the Eudravigilance database and the functional specifications shall take into account the recommendations of the Pharmacovigilance Risk Assessment Committee.

The Eudravigilance database shall be fully accessible to the competent authorities of the Member States and to the Agency and the Commission. It shall also be accessible to marketing authorisation holders and applicants to the extent necessary for them to comply with their pharmacovigilance obligations.

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The Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the Eudravigilance database, and that personal data are protected in accordance with Union law. The Agency shall work together with all stakeholders, including research institutions, healthcare professionals, as well as patient and consumer organisations in order to define the 'appropriate level of access' for healthcare professionals and the public to the Eudravigilance database.

The data held on the Eudravigilance database shall be made publicly available in an aggregated and anonymised format together with an explanation of how to interpret the data.

3. The Agency shall, in collaboration either with the marketing authorisation holder or with the Member State that submitted an individual suspected adverse reaction report to the Eudravigilance database, be responsible for operating procedures that ensure the quality and integrity of the information collected in the Eudravigilance database.

4. Individual suspected adverse reaction reports and follow-ups submitted to the Eudravigilance database by marketing authorisation holders and applicants shall be transmitted electronically, upon receipt, to the competent authority of the Member State where the reaction occurred.

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Article 104

Forms for reporting suspected adverse reactions

The Agency shall, in collaboration with the Member States, develop standard web-based structured forms for the reporting of suspected adverse reactions by healthcare professionals and patients in accordance with Article 110 of Directive (EU) 2026/…[+].

Article 105

Periodic safety update reports repository

The Agency shall, in collaboration with the competent authorities of the Member States and the Commission, set up and maintain a repository for periodic safety update reports (the 'repository') and the corresponding assessment reports regarding medicinal products authorised in the Union so that they are fully and permanently accessible to the Commission, the competent authorities of the Member States, the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use and the coordination group for decentralised and mutual recognition procedures referred to in Article 40 of Directive (EU) 2026/…[+] (the 'coordination group referred to in Article 40 of Directive (EU) 2026/…[+]').

The Agency shall, in collaboration with the competent authorities of the Member States and the Commission, and after consultation with the Pharmacovigilance Risk Assessment Committee, draw up the functional specifications for the repository.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Any substantial change to the repository and the functional specifications shall always take into account the recommendations of the Pharmacovigilance Risk Assessment Committee.

Article 106

European medicines web-portal

1. The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised or to be authorised in the Union. That web-portal shall be easily accessible and user-friendly. By means of that portal, the Agency shall make public the following:

   (a) the names of members of the committees referred to in Article 148, points (d) and (e), of this Regulation, and the members of the coordination group referred to in Article 40 of Directive (EU) 2026/…[+], together with their professional qualifications and with the declarations referred to in Article 154(2) of this Regulation;

   (b) agendas and minutes from each meeting of the committees referred to in Article 148, points (d) and (e), of this Regulation, and of the coordination group referred to in Article 40 of Directive (EU) 2026/…[+] as regards pharmacovigilance activities;

   (c) the risk management plans for medicinal products authorised in accordance with this Regulation;

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(d) information about how to report to competent authorities of the Member States suspected adverse reactions to medicinal products and the standard structured forms referred to in Article 104 for their web-based reporting by patients and healthcare professionals, including links to national websites;

(e) Union reference dates and frequency of submission of periodic safety update reports established in accordance with Article 112 of Directive (EU) 2026/…[+];

(f) protocols and public abstracts of results of the post-authorisation safety studies referred to in Articles 122 and 124 of Directive (EU) 2026/…[+];

(g) the initiation of the procedure laid down in Article 57 of this Regulation, and Articles 98, 118, 119 and 120 of Directive (EU) 2026/…[+], the active substances or medicinal products concerned and the issue being addressed, any public hearings pursuant to that procedure and information on how to submit information and to participate in public hearings;

(h) conclusions of assessments, recommendations, opinions, approvals and decisions taken by the Agency and its scientific committees under this Regulation and Directive (EU) 2026/…[+];

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(i) conclusions of assessments, recommendations, opinions, approvals and decisions taken by the coordination group referred to in Article 40 of Directive (EU) 2026/…[+], the competent authorities of the Member States and the Commission in the framework of the procedures set out in Articles 17, 109, 110 and 111 of this Regulation and of Chapter IX, Sections 3 and 7, of Directive (EU) 2026/…[+].

2. In the development and review of the European medicines web portal, the Agency shall consult relevant stakeholders, including patient and consumer groups, healthcare professionals, not-for-profit entities and industry representatives.

Article 107

European register of studies for environmental risk assessment

The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a register of results of environmental risk assessment studies conducted for the purpose of supporting an environmental risk assessment for medicinal products authorised in the Union, unless relevant data are made public in accordance with Regulation (EU) 2025/2455 of the European Parliament and of the Council[41].

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

[41] Regulation (EU) 2025/2455 of the European Parliament and of the Council of 26 November 2025 establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals (OJ L, 2025/2455, 12.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2455/oj).

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Information in the register referred to in the first paragraph shall be publicly available, unless restrictions are necessary to protect commercially confidential information. For the purpose of setting up that register, the Agency may request marketing authorisation holders and competent authorities to submit results of any such study already completed for products authorised in the Union by … [24 months from the date of application of this Regulation].

Article 108

Literature monitoring

1. The Agency shall monitor selected medical literature for reports of suspected adverse reactions to medicinal products containing certain active substances. It shall publish the list of active substances being monitored and the medical literature subject to this monitoring.

2. The Agency shall enter into the Eudravigilance database relevant information from the selected medical literature.

3. The Agency shall, in consultation with the Commission, Member States and interested parties, draw up a detailed guide regarding the monitoring of medical literature and the entry of relevant information into the Eudravigilance database.

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Article 109

Monitoring of safety of medicinal products

1. The obligations of marketing authorisation holders and of Member States laid down in Articles 108 and 110 of Directive (EU) 2026/…[+] shall apply to the recording and reporting of suspected adverse reactions for medicinal products for human use authorised in accordance with this Regulation.

2. The obligations of marketing authorisation holders laid down in Article 111 of Directive (EU) 2026/…[+] and the procedures under Articles 111 and 112 of that Directive shall apply to the submission of periodic safety update reports, the establishment of Union reference dates and changes to the frequency of submission of periodic safety update reports for medicinal products for human use authorised in accordance with this Regulation.

   The provisions applicable to the submission of periodic safety update reports laid down in Article 112(2), second subparagraph, of that Directive shall apply to marketing authorisation holders of marketing authorisations which were granted before 2 July 2012 and for which the frequency and dates of submission of the periodic safety update reports are not laid down as a condition to the marketing authorisation until such time as another frequency or other dates of submission of the reports are laid down in the marketing authorisation or are determined in accordance with Article 112 of that Directive.

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3. The assessment of the periodic safety update reports shall be carried out by a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee. The rapporteur shall closely collaborate with the rapporteur appointed by the Committee for Medicinal Products for Human Use or the reference Member State for the medicinal products concerned.

Within 60 days of receipt of the periodic safety update report, the rapporteur shall prepare an assessment report and shall send it to the Agency and to the members of the Pharmacovigilance Risk Assessment Committee. The Agency shall send the report to the marketing authorisation holder.

Within 30 days of receipt of the assessment report, the marketing authorisation holder and the members of the Pharmacovigilance Risk Assessment Committee may submit comments to the Agency and to the rapporteur. Where the report includes questions addressed to the marketing authorisation holder, the marketing authorisation holder shall provide answers within those 30 days.

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Within 15 days of receipt of the comments referred to in the third subparagraph of this paragraph, the rapporteur shall update the assessment report taking into account any comments received, and forward it to the Pharmacovigilance Risk Assessment Committee. The Pharmacovigilance Risk Assessment Committee shall adopt the assessment report with or without further changes at its next meeting and shall issue a recommendation. That recommendation shall mention any divergent positions and specify the grounds on which they are based. The Agency shall include the adopted assessment report and the recommendation in the repository set up under Article 105, and forward both to the marketing authorisation holder.

4. In the case of an assessment report that recommends any action concerning the marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the report by the Pharmacovigilance Risk Assessment Committee, consider the report and adopt an opinion on the maintenance, variation, suspension or revocation of the marketing authorisation concerned, including a timetable for the implementation of any necessary regulatory action as stated in that opinion. Where this opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.

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Where the opinion states that regulatory action concerning the marketing authorisation is necessary, the Commission shall adopt a decision, by means of implementing acts, to vary, suspend or revoke the marketing authorisation in accordance with Article 14. Where the Commission adopts such a decision, it may also adopt a decision addressed to the Member States pursuant to Article 59.

5. In the case of a single assessment of periodic safety update reports concerning more than one marketing authorisation in accordance with Article 114(1) of Directive (EU) 2026/…[+] which includes at least one marketing authorisation granted in accordance with this Regulation, the procedure laid down in Articles 114 and 116 of that Directive shall apply.

6. The final recommendations, opinions and decisions referred to in paragraphs 3, 4 and 5 of this Article shall be made public by means of the European medicines web-portal referred to in Article 106.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Article 110

Agency pharmacovigilance related activities

1. The Agency shall, in collaboration with the Member States, take the following measures in relation to medicinal products for human use authorised in accordance with this Regulation:

   (a) monitor the outcome of risk minimisation measures contained in risk management plans and of conditions referred to in Article 13(4), points (d) to (i), or in Article 21(1), first subparagraph, points (a), (b) and (c), and in Article 19(1), in Article 20, and in Article 34(2) and (3);

   (b) assess updates to the risk management system;

   (c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have changed and whether those risks have an impact on the benefit-risk balance.

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2. The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or changes to the benefit-risk balance. Where it considers that follow-up action may be necessary, the assessment of those signals and agreement on any subsequent action concerning the marketing authorisation shall be conducted in a timescale commensurate with the extent and seriousness of the issue. Where appropriate, the assessment of those signals may be included in a pending assessment of a periodic safety update report or a pending procedure in accordance with Article 98 and Articles 118 to 120 of Directive (EU) 2026/…[+] or Articles 49 and 57 of this Regulation.

3. The Agency and competent authorities of the Member States and the marketing authorisation holder shall inform each other in the event of new risks or risks that have changed or changes to the benefit-risk balance being detected.

Article 111

Non-interventional post-authorisation safety studies

1. For non-interventional post-authorisation safety studies concerning medicinal products for human use authorised in accordance with this Regulation which have been imposed in accordance with Articles 14 and 21 of this Regulation, the procedure laid down in Article 121(3) to (7), Articles 122, 123, 124 and Article 125(1) of Directive (EU) 2026/…[+] shall apply.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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2. Where, in accordance with the procedure referred to in paragraph 1 of this Article, the Pharmacovigilance Risk Assessment Committee issues recommendations for the variation, suspension or revocation of the marketing authorisation, the Committee on Medicinal Products for Human Use shall adopt an opinion taking into account the recommendation, and the Commission shall adopt a decision in accordance with Article 14.

Where an opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences, together with the recommendation.

Article 112

Exchange of information with other organisations

1. The Agency shall collaborate with the World Health Organization in matters of pharmacovigilance and shall take the steps necessary to promptly submit to it appropriate and adequate information regarding the measures taken in the Union which could have a bearing on public health protection in third countries.

The Agency shall make promptly available all suspected adverse reaction reports occurring in the Union to the World Health Organization.

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2. The Agency and the European Union Drugs Agency established by Regulation (EU) 2023/1322 of the European Parliament and of the Council[42] shall exchange information that they receive on the abuse of medicinal products including information related to illicit drugs.

Article 113

International collaboration

At the request of the Commission, the Agency shall participate in collaboration with the Member States in international harmonisation and standardisation of technical measures in relation to pharmacovigilance.

Article 114

Cooperation with Member States

The Agency and the Member States shall cooperate to continuously develop pharmacovigilance systems capable of achieving high standards of public health protection for all medicinal products, regardless of the routes of marketing authorisation, including the use of collaborative approaches, to maximise use of resources available within the Union.

[42] Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006 (OJ L 166, 30.6.2023, p. 6, http://data.europa.eu/eli/reg/2023/1322/oj).

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Article 115

Reports on pharmacovigilance tasks

The Agency shall perform regular independent audits of its pharmacovigilance tasks and shall report the results to the Management Board on a two-yearly basis. The results of those audits shall be published by the Agency.

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Chapter IX
Regulatory sandboxes

Article 116

Regulatory sandbox

1. The Commission may establish on a case-by-case basis a regulatory sandbox in accordance with this Chapter, where all of the following conditions are met:

   (a) it is not possible to develop and authorise a medicinal product or a category of medicinal products in full compliance with the requirements applicable to medicinal products laid down in this Regulation and Directive (EU) 2026/…[+] due to methods related to the medicinal product or due to the scientific or technical characteristics inherent to the medicinal product, for which certain targeted and technical adaptations to the requirements laid down in this Regulation and Directive (EU) 2026/…[+] are considered indispensable;

   (b) based on available scientific evidence, the methods or characteristics referred to in point (a) are likely to positively and distinctively contribute to the quality, safety or efficacy of the medicinal product or category of medicinal products as provided for in this Regulation and Directive (EU) 2026/…[+] or provide a major contribution to patient access to prevention, diagnosis or treatment, or to patient care.

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2. A regulatory sandbox sets out a controlled regulatory framework consisting of specific requirements and may allow certain targeted technical adaptations that are necessary during the development, authorisation and placing on the market of a medicinal product or category of medicinal products referred to in paragraph 1 of this Article under the conditions set out in this Chapter. The regulatory sandbox may allow targeted technical adaptations to certain requirements of this Regulation, Directive (EU) 2026/…[+] or Regulation (EC) No 1394/2007 that are necessary for the purpose of assessing whether an authorisation can be granted for a medicinal product referred to in paragraph 1 of this Article, and to the life cycle management of that medicinal product in accordance with Article 117 of this Regulation, and which ensure that the principles of quality, safety and efficacy laid down in this Regulation and Directive (EU) 2026/…[+] are respected.

A regulatory sandbox shall operate under direct supervision of the competent authorities of the Member States concerned with a view to ensuring compliance with the requirements of this Regulation and, where relevant, of other acts of Union and national law concerned by the regulatory sandbox in relation to activities that take place on their territory. Any non-compliance with the detailed conditions laid down in the decision referred to in paragraph 6 or any risks to health and to environment identified shall be notified without delay to the Commission and to the Agency.

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3. The Agency shall monitor the field of emerging medicinal products and may request information and data from the competent authorities of the Member States, marketing authorisation holders, developers, independent experts and researchers, and representatives of healthcare professionals and of patients and may engage with them in preliminary discussions.

4. Where, based on available scientific evidence, the Agency considers it appropriate to establish a regulatory sandbox for medicinal products which are likely to fall within the scope of this Regulation and meet the conditions laid down in paragraph 1, it shall provide a recommendation to the Commission, following appropriate consultations, including consultation with the competent authorities of the Member States or, where appropriate, other competent authorities responsible for the establishment of other relevant regulatory frameworks. The recommendation of the Agency shall list eligible medicinal products or category of medicinal products and include a recommended regulatory sandbox plan referred to in paragraph 5.

The Agency shall not recommend to establish a regulatory sandbox for a medicinal product that is already advanced in its development programme.

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5. The Agency shall develop the regulatory sandbox plan based on data submitted by developers of eligible medicinal products. The regulatory sandbox plan shall provide a clinical, scientific and regulatory justification for the necessity to establish a regulatory sandbox, including the identification of the requirements of this Regulation, Directive (EU) 2026/…[+] and Regulation (EC) No 1394/2007 whose adaptations are considered indispensable from a technical and scientific viewpoint for the development and authorisation of such medicinal products while ensuring that the principles of quality, safety and efficacy laid down in this Regulation and Directive (EU) 2026/…[+] are respected. The regulatory sandbox plan shall include a proposed timeline for the duration of the regulatory sandbox. Where appropriate, the regulatory sandbox plan shall provide recommendations for alternative or mitigation measures. Where appropriate, the Agency shall also recommend measures in order to mitigate any possible distortion of market conditions as a consequence of establishing a regulatory sandbox. The Agency shall levy a fee for activities under this Article.

6. The Commission shall, by means of implementing acts, adopt a decision establishing a regulatory sandbox for the eligible medicinal products or category of medicinal products taking into account the recommendation of the Agency and the regulatory sandbox plan pursuant to paragraph 4 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 179(2).

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7. A decision establishing a regulatory sandbox under paragraph 6 shall be limited in time and shall lay down detailed conditions for its implementation. It shall include:

(a) the final regulatory sandbox plan, taking into account the recommended regulatory sandbox plan of the Agency, specifying the specific requirements and the targeted technical adaptations, in accordance with paragraphs 2 and 5 of this Article, to the requirements of this Regulation and of Directive (EU) 2026/…[+] and Regulation (EC) No 1394/2007;

(b) the duration of the regulatory sandbox and its expiry taking into account the time needed for development, and, if applicable, for obtaining a marketing authorisation and for placing on the market the medicinal products concerned;

(c) the participants of the regulatory sandbox.

8. The Commission may, by means of implementing acts, suspend or revoke a decision establishing a regulatory sandbox at any time in any of the following cases:

(a) the requirements and conditions laid down in paragraphs 6 and 7 are no longer met;

(b) it is appropriate to protect public health, or to avoid serious risks for the environment.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 179(2).

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Where the Agency receives information that one of the cases referred to in the first subparagraph may be fulfilled, it shall inform the Commission accordingly.

9. Where, after the decision to establish the regulatory sandbox in accordance with paragraph 6 of this Article, risks to public health are identified but these risks can be fully mitigated by laying down supplementary conditions, the Commission may, after consultation with the Agency, amend its decision referred to in paragraph 6 of this Article and, where applicable, revoke a suspension decision adopted under paragraph 8 of this Article by means of implementing acts. The Commission may also prolong the duration of a regulatory sandbox by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 179(2).

Article 117

Medicinal products developed under a regulatory sandbox

1. When authorising a clinical trial for a medicinal product covered by a regulatory sandbox, Member States shall take the regulatory sandbox plan referred to in Article 116(5) into consideration.

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2. A medicinal product developed under a regulatory sandbox shall be placed on the market only when authorised in accordance with Article 14, 19 or 20. Such authorisation may be granted only if the benefit-risk balance of the medicinal product is favourable. The initial validity of such authorisation shall not exceed the duration of the regulatory sandbox as specified in the implementing act referred to in Article 116(6) and (7). The authorisation may be renewed at the request of the marketing authorisation holder in accordance with Article 18. The marketing authorisation holder shall submit the renewal application to the Agency at least nine months before the validity of the marketing authorisation expires.

3. Where necessary, the marketing authorisation adopted in accordance with Article 14, 19 or 20 of a medicinal product developed under the regulatory sandbox shall specify in its conditions the adaptations that apply to the specific medicinal product pursuant to the decision referred to in Article 116(7). Each adaptation specified in those conditions shall be limited to what is apt and strictly necessary to attain the objectives pursued and duly justified. It shall not exceed the adaptations specified in the decision referred to in Article 116(6) and (7) establishing the regulatory sandbox concerned.

4. For medicinal products developed under a regulatory sandbox for which a marketing authorisation has been granted in accordance with paragraph 2 and where appropriate paragraph 3, the summary of product characteristics and the package leaflet shall indicate that the medicinal product has been developed under a regulatory sandbox. This requirement shall apply for the duration of the regulatory sandbox.

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5. Without prejudice to Article 198 of Directive (EU) 2026/…[+], the Commission shall suspend or revoke a marketing authorisation granted in accordance with paragraph 2 of this Article, where the regulatory sandbox has been suspended or revoked in accordance with Article 116(8) of this Regulation.

6. The Commission shall vary the marketing authorisation to take account of the temporary measures taken in accordance with Article 118.

7. In addition to the situations referred to in Articles 57 and 58, where the Agency concludes that a holder of a marketing authorisation granted under a regulatory sandbox has failed to comply with the specific conditions laid down in the marketing authorisation in accordance with paragraph 3 of this Article, the Agency shall inform the Commission accordingly. The Commission shall adopt a decision to vary, suspend or revoke that marketing authorisation in accordance with the procedure laid down in Article 14.

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Article 118

General regulatory sandbox provisions

1. The regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities of the Member States and the Agency. In cases where risks to public health or safety concerns associated with the use of medicinal products developed under a regulatory sandbox are identified, competent authorities of the Member States and the Agency shall take immediate and adequate temporary measures in order to suspend or restrict their use and inform the Commission and the Agency in accordance with Article 116(2).

   Where it is not possible to take such measures or where such measures prove to be ineffective, the development and testing process shall be suspended without delay until the risks referred to in the first subparagraph of this paragraph have been effectively mitigated. In the absence of such effective mitigation, the Agency shall recommend to the Commission to suspend or revoke a regulatory sandbox in accordance with Article 116(8). If applicable, the marketing authorisation provided for in accordance with Article 117 shall be suspended or revoked accordingly.

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2. Participants in the regulatory sandbox, including the marketing authorisation holder of the medicinal product concerned, shall remain liable under applicable Union and national law for any harm inflicted on third parties as a result of the development and testing taking place under the regulatory sandbox. They shall inform the Agency without undue delay of any information which might entail the amendment of the regulatory sandbox or of any concerns relating to the quality, safety or efficacy of medicinal products developed under a regulatory sandbox.

3. The detailed arrangements for, and the conditions of, the operation of the regulatory sandboxes, including the eligibility criteria and the procedure for the application for a regulatory sandbox, the selection of eligible medicinal products, the participation in a regulatory sandbox and exiting from it, and the rights and obligations of the participants, shall be provided for by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 179(2).

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4. The Agency shall, on the basis of input from Member States, submit annual reports to the Commission, the European Parliament and the Council on the results of the implementation of regulatory sandboxes, including a breakdown on the number of regulatory sandboxes granted, trends on medicinal products eligible for a regulatory sandbox, good practices, difficulties encountered, lessons learnt, reflections on possible future adaptations to the regulatory framework and recommendations on their establishment and, where relevant, on the application of this Regulation and other Union legal acts applicable within the regulatory sandbox. Those reports as well as lay summaries shall be made publicly available by the Commission.

5. The Commission shall review the annual reports referred to in paragraph 4 of this Article and, where appropriate, submit legislative proposals with a view to amending the legal acts referred to in Article 116(2) of this Regulation or adopt delegated acts in accordance with Article 31 of Directive (EU) 2026/…[+].

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Chapter X

Availability and security of supply of medicinal products

SECTION 1

MONITORING AND MANAGEMENT OF SHORTAGES AND CRITICAL SHORTAGES

Article 119

Exemptions from the application of provisions of this Chapter

1. Insofar as obligations applicable to marketing authorisation holders and other relevant actors under Articles 120(4), 121(3), 124(3), 125(7), 133(5), 135, Article 136(2), first subparagraph, point (c), and Article 136(4), point (c), imply a risk to national security and defence, Member States may exempt those marketing authorisation holders and other actors from those obligations where:

   (a) the medicinal products concerned are manufactured for military and defence use only; or

   (b) the specific batches of medicinal products concerned are supplied for military and defence purposes.

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2. Member States may exempt competent authorities within their territory from the obligations under Articles 125 and 133 to communicate information related to the medicinal products referred to in paragraph 1 of this Article insofar as such obligations imply a risk to national security and defence.

3. A Member State may exempt a marketing authorisation holder in possession of a marketing authorisation for a medicinal product authorised in that Member State in accordance with Article 208 of Directive (EU) 2026/…[+] from complying with the obligations laid down in Articles 120, 121, 123, 130, 134 and 139 of this Regulation.

4. Member States shall notify the Commission of the use of the exemptions referred to in this Article without undue delay.

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Article 120

Marketing authorisation holder notifications

1. Without prejudice to the provisions on notification referred to in Article 25 of this Regulation and Article 206 of Directive (EU) 2026/…[+], the holder of a national marketing authorisation for a medicinal product and the holder of a centralised marketing authorisation for a medicinal product (both referred to in this Chapter as 'the marketing authorisation holder') shall notify the competent authority of the Member State on whose market that medicinal product has been placed and, in addition, for a centrally authorised medicinal product, the Agency (both referred to in this Chapter as 'the competent authority concerned') of the following, and explain the reasons therefor:

   (a) any decision to permanently cease the marketing of a medicinal product in that Member State no less than 12 months before the last supply of that medicinal product into the market of that Member State by the marketing authorisation holder;

   (b) any request to withdraw the marketing authorisation for that medicinal product authorised in that Member State no less than 12 months before the last supply of that medicinal product into the market of that Member State by the marketing authorisation holder;

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(c) any decision to temporarily suspend the marketing of a medicinal product in that Member State as soon as possible and no less than six months before the start of the temporary suspension of supply of that medicinal product into the market of that Member State by the marketing authorisation holder;

(d) any temporary disruption in supply of a medicinal product in that Member State of an expected duration of more than two weeks based on the demand forecast of the marketing authorisation holder, as soon as possible and in any event no less than six months before the start of such temporary disruption of supply.

By way of derogation from point (d) of the first subparagraph, marketing authorisation holders shall notify the temporary disruption in supply of a medicinal product in that Member State as soon as they become aware of such temporary disruption where exceptional circumstances directly related to the supply disruption, which shall be duly identified and substantiated to the competent authority concerned, prevented the marketing authorisation holders from complying with the deadline specified therein.

The marketing authorisation holder shall make the notification electronically and in the formats made available by the Agency. The Agency shall consult the Member States when drawing up the formats.

2. For the purposes of the notifications made in accordance with paragraph 1, first subparagraph, points (a), (b) and (c), the marketing authorisation holder shall provide the information set out in Part I of Annex IV.

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For the purposes of the notifications made in accordance with paragraph 1, first subparagraph, point (d), the marketing authorisation holder shall provide the information set out in Part III of Annex IV.

The marketing authorisation holder shall immediately notify the competent authority concerned, as appropriate, of any relevant changes to the information provided in accordance with this paragraph.

3. The Commission is empowered to adopt delegated acts in accordance with Article 181 in order to amend Annex IV as regards the information to be provided in the event of a temporary disruption of supply, in the event of a temporary suspension or of a permanent cessation of the marketing of a medicinal product, or of a withdrawal of the centralised or national marketing authorisation of a medicinal product, or the information to be provided on the content of the shortage prevention plan referred to in Article 121.

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4. Where the marketing authorisation holder intends to withdraw the marketing authorisation for, or permanently cease to market in one or more Member States where the marketing authorisation is valid, a critical medicinal product identified by the competent authority of a Member State pursuant to Article 133(1) and included on the Union long list adopted by the Commission pursuant to paragraph 2 of that Article, an additional medicinal product identified in accordance with Article 132(4) or a priority antimicrobial pursuant to Article 41(3), the marketing authorisation holder shall, prior to the notification referred to in paragraph 1, first subparagraph, point (a) or (b) of this Article, as applicable:

(a) publish a declaration of its intention to offer to transfer the marketing authorisation or its intention to issue a letter of access as referred to in Article 15 of Directive (EU) 2026/…[+] via a dedicated webpage on its website and communicate the electronic link to such webpage to the competent authority of the Member State and the Agency; the Agency shall compile and publish a list of such electronic links;

(b) offer, on reasonable terms, to transfer the marketing authorisation or issue a letter of access to a third party that has declared its intention to place on the market that medicinal product or to allow the use of the pharmaceutical non-clinical and clinical documents contained in the file of that medicinal product for the purpose of submitting an application in accordance with Article 15 of Directive (EU) 2026/…[+];

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(c) inform the competent authority concerned on the outcome of the negotiations with the third party or parties.

For the purposes of this paragraph, the marketing authorisation holder shall provide as part of the notification referred to in paragraph 1, first subparagraph, points (a) and (b), information proving that they have taken steps to offer to transfer the marketing authorisation or to issue a letter of access to third parties on reasonable terms.

Article 121

The shortage prevention plan

1. The marketing authorisation holder shall establish and maintain an up-to-date shortage prevention plan for medicinal products subject to medical prescription and for medicinal products identified in accordance with Article 132(4). That plan shall include the information specified in Part V of Annex IV and shall be established in accordance with the guidance drawn up by the Agency pursuant to paragraph 2 of this Article.

2. The Agency, in collaboration with the working party referred to in Article 125(1), point (d), shall draw up guidance for marketing authorisation holders for the shortage prevention plan. That guidance shall, in particular, indicate the relevant type and detail of information for the shortage prevention plan according to the different level of risk, including descriptions of the relevant shortage management measures.

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3. Whenever a medicinal product is subject to a shortage prevention plan in accordance with this Article, the competent authority of the Member State and the Agency at any time, or the Commission in accordance with Article 132(3), may request the marketing authorisation holder to submit that plan to it at any time. The marketing authorisation holder shall submit that plan within two days of receipt of such request.

4. Where relevant, the marketing authorisation holder shall update the shortage prevention plan to include additional information, taking into account recommendations of the – MSSG, established by Article 3(1) of Regulation (EU) 2022/123, in accordance with Articles 128(3) and 138(1) of this Regulation.

Article 122

Shortage monitoring by the competent authority of the Member State or the Agency

1. Based on the reports referred to in Article 124(1) and Article 125(1), point (d), information referred to in Article 123, Article 124(3) and Article 125 and the notification made pursuant to Article 120(1), first subparagraph, points (a) to (d), and Article 124(2), the competent authority concerned shall continuously monitor any expected or actual shortage of the medicinal products which are the subject of those reports. In addition, the competent authority concerned may use information contained in the repositories referred to in Article 70(2), second subparagraph, point (e), of Directive (EU) 2026/…[+] or in a national repository.

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The Agency shall carry out that monitoring in collaboration with the competent authority of the Member State where those medicinal products are authorised under this Regulation or when coordinated Union action is required.

2. For the purposes of paragraph 1 of this Article, the competent authority concerned may request any information from the marketing authorisation holder. In particular, it may request the marketing authorisation holder to submit a shortage mitigation plan in accordance with Article 123(2), a risk assessment of impact of suspension, cessation or withdrawal in accordance with Article 123(3), or the shortage prevention plan referred to in Article 121. The competent authority concerned shall set a deadline for the submission of the information requested.

3. For the purposes of paragraph 1 of this Article, the Agency may request additional information from the competent authority of a Member State, through the working party referred to in Article 125(1), point (d). The Agency may set a deadline for the submission of the information requested.

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Article 123

Obligations on the marketing authorisation holder

1. The marketing authorisation holder shall:

(a) submit the information requested in accordance with Article 122(2), Article 129(2), first subparagraph, point (b), or Article 121(3) to the competent authority concerned, without undue delay, using the tools, methods of and criteria for the monitoring and reporting established pursuant to Article 127(4), point (a), by the deadline set by that competent authority;

(b) provide updates to the information provided in accordance with point (a), where necessary;

(c) justify any failure to provide any of the requested information;

(d) where necessary, submit a request to the competent authority concerned for an extension of the deadline set by that competent authority in accordance with point (a); and

(e) indicate whether the information provided in accordance with point (a) contains any commercially confidential information, identify the relevant parts of that information having a commercially confidential nature and explain why that information is of such nature.

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2. To prepare the shortage mitigation plan referred to in Article 122(2), the marketing authorisation holder shall include the information specified in Part IV of Annex IV and take into account the guidance drawn up by the Agency in accordance with Article 127(4), point (b).

3. To prepare a risk assessment of the impact of suspension, cessation or withdrawal referred to in Article 122(2), the marketing authorisation holder shall include information set out in Part II of Annex IV and take into account the guidance drawn up by the Agency in accordance with Article 127(4), point (b).

4. In the case of medicinal products that are not subject to the obligation of preparing a shortage prevention plan, the marketing authorisation holder shall carry out a regular documented risk assessment of potential supply chain risks and, where necessary, take mitigating measures.

   The competent authority of the Member State or the Agency may request the marketing authorisation holder to submit that documented risk assessment at any time. The marketing authorisation holder shall submit that documented risk assessment within two days of receipt of such request.

5. The marketing authorisation holder shall be responsible for providing correct, not misleading, and complete information as requested by the competent authority concerned.

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6. The marketing authorisation holder shall cooperate with the competent authority of the Member State or the Agency and disclose, on its own motion, any relevant information to that authority and update the information as soon as new information becomes available.

Article 124

Obligations on other actors

1. Wholesale distributors, and natural or legal persons that are authorised or entitled to supply to the public medicinal products authorised to be placed on the market of a Member State pursuant to Article 6 of Directive (EU) 2026/…[+], may report a shortage of a given medicinal product to the competent authority of the Member State concerned.

2. For centrally or nationally authorised medicinal products, Member States may require that a wholesale distributor who is not the marketing authorisation holder and who intends to distribute a medicinal product in another Member State provide the competent authority of the source Member State with information about that intention. That information shall include:

(a) the name of the medicinal product and authorisation number;

(b) active substances;

(c) pharmaceutical form;

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(d) strength;

(e) pack size;

(f) the quantity of the medicinal product which will be obtained from the source Member State.

Based on the information provided by the wholesale distributor and on the information available pursuant to this Chapter, the source Member State may take measures to prevent or to mitigate shortages in the source Member State. The source Member State shall notify the Agency of any measures taken pursuant to in this subparagraph.

The information requirement referred to in the first subparagraph and measures referred to in the third subparagraph shall, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaties.

3. For the purposes of Article 122(1), where relevant, upon request from the competent authority concerned, entities including other relevant marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers or wholesale distributors, as well as stakeholder representative associations, or natural or legal persons that are authorised or entitled to supply medicinal products to the public shall provide any information requested within the time limit specified by the competent authority concerned.

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Article 125

Role of the competent authority of the Member State

1. The competent authority of the Member State shall:

(a) collect and assess information received in accordance with Article 120(1), points (a) to (d), and Articles 123 and 124 in order to continuously monitor any expected or actual shortages pursuant to Article 122(1);

(b) assess the merits of each confidentiality claim made by the marketing authorisation holder in accordance with Article 123(1), point (e), and protect information which that competent authority considers to be commercially confidential from unjustified disclosure;

(c) publish information on actual shortages that has been assessed by that competent authority, and provide regular updates of that information, on a publicly available and user-friendly website and ensure that such information, including regarding available alternatives, has been actively communicated to representatives of healthcare professionals and patients;

(d) report to the Agency, through the single points of contact of the working party referred to in Article 3(6) of Regulation (EU) 2022/123, any shortage that it identifies as a critical shortage in that Member State without undue delay;

(e) consider the use of appropriate regulatory measures to mitigate the shortage.

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2. Following the reporting referred to in paragraph 1, point (d), of this Article, and to facilitate the monitoring referred to in Article 122(1), the competent authority of the Member State shall, through the working party referred to in paragraph 1, point (d), of this Article:

(a) submit to the Agency the information referred to in Article 122(3) or Article 129(2), first subparagraph, point (a), using the tools, methods of and criteria for the monitoring and reporting established pursuant to Article 127(4), point (a), by the deadline set by the Agency;

(b) where necessary, provide updates to the information provided in accordance with point (a) to the Agency;

(c) justify any failure to provide any of the information referred to in point (a) to the Agency;

(d) where necessary, submit a request to the Agency to extend the deadline set by the Agency referred to in point (a);

(e) indicate whether the marketing authorisation holder has indicated the existence of any commercially confidential information and provide the marketing authorisation holder's explanation of why that information is of a commercially confidential nature, in accordance with Article 123(1), point (e);

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(f) inform the Agency of any actions planned or taken by that Member State to mitigate the shortage at national level without undue delay.

3. After the expansion of the scope referred to in Article 127(6) of the European Shortages Monitoring Platform (ESMP) established by Regulation (EU) 2022/123, and for the purposes of Article 122(1) and Article 125(2), point (a), competent authorities of the Member States shall make reasonable efforts that their national IT systems are gradually made interoperable with the ESMP and allow for the automated exchange of information with the ESMP while avoiding duplication of reporting.

4. Where the competent authority of the Member State has any relevant information in addition to the information to be provided pursuant to this Article, it shall immediately provide such information to the Agency through the working party referred to in paragraph 1, point (d).

5. Following the addition of a medicinal product on the list of critical shortages of Union concern referred to in Article 127(1), the competent authority of the Member State shall, through the working party referred to in paragraph 1, point (d), of this Article, provide any information requested pursuant to Article 129(2), first subparagraph, point (a), to the Agency.

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6. Following any MSSG recommendations provided in accordance with Article 128(3), the competent authority of the Member State shall, through the working party referred to in paragraph 1, point (d), of this Article:

(a) report to the Agency any information received from the marketing authorisation holder of the medicinal product concerned or from other actors pursuant to Article 124(2) and (3);

(b) coordinate the actions that it has taken or that it plans to take with any relevant measures taken by the Commission;

(c) take into account any MSSG recommendations referred to in Article 128(3);

(d) inform the Agency of any actions planned or taken by that Member State in accordance with points (b) and (c) and report on any other actions taken to mitigate or resolve the critical shortage in the Member State, as well as the results of these actions, without undue delay.

Where Member States take an alternative course of action at national level which is not in line with the recommendations of the MSSG, they shall communicate the reasons for doing so to the MSSG in a timely manner.

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7. The competent authority of the Member State may require wholesale distributors, and natural or legal persons that are authorised or entitled to supply to the public medicinal products authorised to be placed on the market of a Member State pursuant to Article 6 of Directive (EU) 2026/…[+], to report a shortage of a medicinal product marketed in the Member State concerned.

8. The Member States may request that the MSSG provide further recommendations pursuant to Article 128(3).

Article 126

National websites on medicinal product shortages

The website referred to in Article 125(1), point (c), shall include the following information:

(a) the trade name of the medicinal product and International Non-proprietary Name, for interoperability purposes;

(b) the therapeutic indication for the medicinal product of which there is a shortage;

(c) reasons for the shortages and mitigation measures taken to address the shortages, after the deletion of any commercially confidential information;

(d) the start and expected end dates of the shortage;

(e) where relevant, other information for healthcare professionals and patients, including information about available alternative medicinal products.

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Article 127

Role of the Agency concerning shortages

1. On the basis of Article 122(1), the Agency, in collaboration with the working party referred to in Article 125(1), point (d), shall establish and update a list of critical shortages of Union concern whenever a Member State requests to do so for the medicinal products for which a critical shortage in the Member State cannot be resolved without Union coordination.

2. The Agency shall inform the MSSG of the critical shortages in the Member States that have been listed as critical shortages of Union concern pursuant to paragraph 1.

3. The Agency shall establish in its web-portal referred to in Article 106 a publicly available and user-friendly webpage that provides information on actual critical shortages of Union concern. This webpage shall also provide references to the lists of actual shortages published by the competent authorities of the Member States pursuant to Article 125(1), point (c).

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4. For the purpose of fulfilling the tasks referred to in Article 122(1) and Articles 128 and 129, the Agency shall, in consultation with the working party referred to in Article 125(1), point (d):

(a) specify the tools, including the ESMP once its scope is expanded pursuant to paragraph 6 of this Article, the methods of and criteria for the monitoring and reporting provided for in Articles 123(1), point (a), and 125(2), point (a);

(b) draw up guidance to allow marketing authorisation holders to put in place the risk assessment of the impact of suspension, cessation or withdrawal and the shortage mitigation plan as referred to in Article 122(2);

(c) specify the methods for the provision of recommendations referred to in Article 128(3);

(d) publish information covered by points (a), (b) and (c) of this paragraph on a dedicated webpage on its web-portal referred to in Article 106.

5. For the duration of the critical shortage of Union concern, the Agency shall regularly report to the Commission the results of the monitoring referred to in Article 129 of this Regulation, and in particular, it shall report any event that is likely to lead to a major event, as defined in Article 2 of Regulation (EU) 2022/123. Where a public health emergency is recognised in accordance with Regulation (EU) 2022/2371 or where an event is recognised as a major event in accordance with Regulation (EU) 2022/123, Regulation (EU) 2022/123 prevails.

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6. By … [one year after the entry into force of this Regulation], the Agency shall expand the scope of the ESMP for the purposes of implementing this Chapter, including to support the exchange of information for the purposes of the vulnerability evaluation. The Agency shall ensure that, where relevant, data are interoperable between the ESMP, Member States' IT systems and other relevant IT systems and databases, while avoiding duplication of reporting.

Article 128

Role of the MSSG

1. The MSSG, following consultation of the working party referred to in Article 125(1), point (d), shall review the status of the critical shortage of Union concern whenever necessary and shall recommend the Agency to update the list in accordance with Article 127(1).

2. The MSSG shall amend its rules of procedure, and the rules of procedure of the working party referred to in Article 125(1), point (d), in accordance with the provisions laid down in this Regulation.

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3. The MSSG may provide recommendations on measures to resolve or to mitigate the critical shortage of Union concern, in accordance with the methods referred to in Article 127(4), point (c), to relevant marketing authorisation holders, the Member States, the Commission, the Agency, the representatives of healthcare professionals or other entities. The MSSG may recommend Member States to forecast and monitor demand for medicinal products on the list of critical shortages of Union concern, taking into account the demand forecast from the marketing authorisation holder.

4. The MSSG shall provide recommendations to the Commission regarding the possibility, pursuant to Article 121(1), to require a shortage prevention plan for a medicinal product that is not subject to medical prescription. In doing so, the MSSG shall take into account the criteria set out in Article 132(4).

Article 129

Management of the critical shortage of Union concern

1. Following the addition of a medicinal product to the list of critical shortages of Union concern pursuant to Article 127(1) and based on the continuous monitoring carried out in accordance with Article 122(1), the Agency, in coordination with the competent authority of the Member State concerned, shall continuously monitor the critical shortage of Union concern of that medicinal product.

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2. For the purposes of paragraph 1, the Agency may, if that information is not already available to the Agency, request relevant information on that critical shortage of Union concern from:

(a) the competent authority of the Member State concerned through the working party referred to in Article 125(1), point (d);

(b) the marketing authorisation holder;

(c) the other actors listed in Article 124(3).

For the purposes of this paragraph, the Agency shall set a deadline for the submission of the information requested.

Article 130

Obligations on the marketing authorisation holder in the case of a critical shortage of Union concern

Following the addition of a medicinal product to the list of critical shortages of Union concern in accordance with Article 127(1), or having regard to recommendations provided in accordance with Article 128(3), the marketing authorisation holder shall:

(a) provide any additional information that the Agency may request, including regular information on the available stocks of the concerned medicinal product;

(b) provide additional relevant information to the Agency;

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(c) take into account the recommendations referred to in Article 128(3);

(d) take into account the actions taken by the Commission pursuant to Article 132(1);

(e) inform the Agency of any measures taken pursuant to points (c) and (d) and the report on results of such measures;

(f) inform the Agency and the competent authority of the Member State of the end date of the critical shortage of Union concern without undue delay.

Article 131

Voluntary solidarity mechanism for medicinal products

1. In order to mitigate critical shortages in the Member States, Member States may, on a voluntary basis and as a last resort, request to the MSSG the activation of the voluntary solidarity mechanism for medicinal products. The voluntary solidarity mechanism for medicinal products shall be coordinated by the MSSG and supported by the Agency.

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2. The voluntary solidarity mechanism for medicinal products referred to in paragraph 1 may be activated by the MSSG on behalf of a requesting Member State where the following conditions are met:

(a) the Agency has been notified of the critical shortage in the Member State in accordance with Article 125(1), point (d), and the shortage has been brought to the attention of the single points of contact of the working party referred to in Article 3(6) of Regulation (EU) 2022/123;

(b) there are no therapeutic alternatives, or there are insufficient therapeutic alternatives, available in the Member State concerned;

(c) there are insufficient quantities of the medicinal product available in the Member State concerned to treat critical indications;

(d) import of stocks from other Member States or third countries or other short-term measures do not provide a solution in a timely manner or in sufficient quantities;

(e) there is a risk of stockout in the Member State concerned within one month.

3. The MSSG shall establish rules of procedure to facilitate the use of the voluntary solidarity mechanism in accordance with this Article.

4. Where any Member State is ready to provide assistance, the Agency shall put the requesting Member State in contact with the volunteering Member States.

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5. The Agency shall facilitate the exchange of information between Member States, coordinate requests for support, and, where necessary, liaise with marketing authorisation holders.

Article 132

Role of the Commission

1. The Commission shall, where it considers it appropriate and necessary:

   (a) take into account the MSSG recommendations;

   (b) take any actions, within the limits of the powers conferred on the Commission;

   (c) inform the MSSG of the actions taken pursuant to point (b).

2. The Commission may request the MSSG to provide recommendations referred to in Article 128(3).

3. The Commission may request the information gathered by the Agency in accordance with Section 2 of Chapter X. Where relevant, in the context of crisis preparedness, the Commission may request the marketing authorisation holder to submit relevant information, including the shortage prevention plan referred to in Article 121. The Commission shall protect any information that is commercially confidential from unjustified disclosure.

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4. The Commission is empowered to adopt delegated acts supplementing this Regulation to identify additional medicinal products that require a shortage prevention plan, in accordance with the requirements set out in Article 121.

Those delegated acts shall be adopted taking due account of the likelihood of shortages, relevance for public health and patient needs relating to such medicinal products. To that end, the following criteria shall guide the identification of those medicinal products:

(a) the number and frequency of past critical shortages in the Member States reported to the MSSG;

(b) the specific characteristics of the medicinal products concerned and the existence of available alternative authorised medicinal products;

(c) the therapeutic relevance of the medicinal products concerned and the conditions intended to be treated;

(d) potential risks to public health, including crisis preparedness.

When the Commission adopts a delegated act pursuant to this paragraph, it shall take into account MSSG recommendations adopted in accordance with Article 128(4).

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SECTION 2

SECURITY OF SUPPLY

Article 133

Identification and management of critical medicinal products by the competent authority of a Member State

1. The competent authority of a Member State shall consult, where relevant, with healthcare professionals and patient organisations, and shall identify critical medicinal products in that Member State, using the methodology set out in Article 136(1), first subparagraph, point (a).

2. The Commission shall adopt and update, on the basis of the information received from the Agency pursuant to paragraph 3 of this Article, a list of all critical medicinal products identified by the competent authorities of the Member States in accordance with paragraph 1 of this Article (Union long list) by means of implementing acts and communicate the adoption of the list and any updates to the Agency and the MSSG. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 179(2).

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3. The competent authority of a Member State, acting through the working party referred to in Article 125(1), point (d), shall report to the Agency the critical medicinal products in that Member State identified pursuant to paragraph 1 of this Article, and all available data relevant for the vulnerability evaluation referred to in Article 138(2), using the methodology pursuant to Article 136(1), first subparagraph, point (b), as well as the information received from the marketing authorisation holder. The Agency shall inform the Commission on the critical medicinal products identified as critical by Member States pursuant to paragraph 1 of this Article.

4. For the purposes of the identification of critical medicinal products referred to in paragraph 1 of this Article, using the methodology pursuant to Article 136(1), first subparagraph, point (a), and for the purposes of the vulnerability evaluation referred to in Article 138(2), using the methodology pursuant to Article 136(1), first subparagraph, point (b), the competent authority of the Member State concerned may request relevant information from the relevant marketing authorisation holder.

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5. For the purposes of the identification of critical medicinal products referred to in paragraph 1 of this Article using the methodology pursuant to Article 136(1), first subparagraph, point (a), and for the purposes of the vulnerability evaluation referred to in Article 138(2) using the methodology pursuant to Article 136(1), first subparagraph, point (b), the competent authority of the Member State concerned may request relevant information from other entities, including other relevant marketing authorisation holders, importers and manufacturers of medicinal products or active substances, relevant suppliers and wholesale distributors, stakeholder representative associations, or other entities, including natural or legal persons, that are authorised or entitled to supply medicinal products to the public.

6. The competent authority of the Member State concerned shall assess the merits of each confidentiality claim made by the marketing authorisation holder pursuant to Article 134(1), point (e), and shall protect any information that is commercially confidential from unjustified disclosure.

7. For the purposes of the adoption of the Union list of critical medicinal products pursuant to Article 137, each Member State shall, through the competent authority of the Member State concerned:

(a) submit to the Agency the information referred to in Article 136(2), first subparagraph, point (a), using the tools, methods of and criteria for the monitoring and reporting established pursuant to Article 136(1), first subparagraph, point (d), by the deadline set by the Agency;

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(b) provide any relevant information to the Agency, including information on measures that have been taken by the Member State to strengthen the supply of that medicinal product;

(c) provide updates to the information provided in accordance with points (a) and (b) to the Agency, where necessary;

(d) justify any failure to provide any of the requested information;

(e) indicate the existence of any commercially confidential information reported as such by the marketing authorisation holder pursuant to Article 134(1), point (e), and provide the marketing authorisation holder's explanation of why that information is of a commercially confidential nature.

Where necessary, the competent authority of the Member State may request an extension to the deadline set by the Agency to comply with the request for information in accordance with point (a) of the first subparagraph.

8. Following the addition of a medicinal product to the Union list of critical medicinal products in accordance with Article 137 or any recommendations provided in accordance with Article 138(1), Member States shall:

(a) provide any additional information requested by the Agency;

(b) provide additional relevant information to the Agency;

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(c) coordinate their actions with any actions taken by the Commission pursuant to Article 140(1), point (b);

(d) take into account any MSSG recommendations referred to in Article 138(1);

(e) inform the Agency of any actions taken or planned in accordance with points (c) and (d) by that Member State, as well as the results of those actions.

9. Member States that do not coordinate their actions as referred to in paragraph 8, point (c) of this Article, or do not follow any MSSG recommendations referred to in Article 138(1), shall share the reasons therefor with the Agency in a timely manner.

Article 134

Obligations of the marketing authorisation holder with regard to critical medicinal products

1. For the purposes of Article 133(1) and (4), and Article 137(1), the marketing authorisation holder shall:

(a) submit the information requested in accordance with Article 133(4) and Article 136(2), first subparagraph, point (b), and 136(4), point (b), to the competent authority concerned, without undue delay, using the tools, methods and criteria for monitoring and reporting established pursuant to Article 136(1), point (d), by the deadline set by that competent authority concerned;

(b) provide updates to the information provided in accordance with point (a) where necessary;

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(c) justify any failure to provide any of the requested information;

(d) where necessary, submit a request to the competent authority concerned for an extension of the deadline set by that competent authority in accordance with point (a); and

(e) indicate whether the information provided in accordance with point (a) contains any commercially confidential information, identify the relevant parts of that information having a commercially confidential nature and explain why that information is of such nature.

2. The marketing authorisation holder shall be responsible for providing correct, not misleading, and complete information as requested by the competent authority concerned and shall have the duty to cooperate and to disclose on its own motion any relevant information without undue delay to that competent authority and to update the information as soon as that information becomes available.

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Article 135

Obligations on other actors

For the purposes of Article 133(5) and Article 136(2), first subparagraph, point (c), and 136(4), point (c), where relevant, upon request from the competent authority concerned, entities including other relevant marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers and wholesale distributors, as well as stakeholder representative associations or other natural or legal persons that are authorised or entitled to supply medicinal products to the public, shall provide, within the time limit specified by the competent authority concerned, any information and provide updates thereon whenever necessary.

Article 136

Role of the Agency

1. The Agency shall, in collaboration with the MSSG and the working party referred to in Article 125(1), point (d):

   (a) develop a common methodology to identify critical medicinal products on the basis of their therapeutic relevance, and availability of appropriate alternatives to those medicinal products, in consultation, where appropriate, with relevant stakeholders;

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(b) develop a common methodology to evaluate the vulnerabilities with respect to the supply chains of critical medicinal products listed on the Union list of critical medicinal products as referred to in Article 137, including the lack of supply chain diversification and the level of dependency on third countries with respect to those critical medicinal products or their active substances, in consultation, where appropriate, with relevant stakeholders;

(c) specify the procedures and criteria for establishing and reviewing the Union list of critical medicinal products referred to in Article 137, and the procedures and criteria for prioritising the vulnerability evaluation of such medicinal products;

(d) specify the tools, including ESMP, once its scope is expanded pursuant to Article 127(6), methods and criteria for the monitoring and reporting provided for in Articles 133(7), first subparagraph, point (a), and 134(1), point (a);

(e) specify the methods for the provision and review of MSSG recommendations referred to in Article 138(1) and (4).

The Agency shall publish the information referred to in points (a) to (e) on a dedicated webpage on its web-portal.

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2. Following the reports and information provided by the Member States and marketing authorisation holders in accordance with Article 133(3) and (7), and Article 134(1), the Agency, may request any relevant information from:

(a) the competent authority of the Member State concerned;

(b) the marketing authorisation holder of the medicinal product, including the shortage prevention and the shortage mitigation plan, respectively referred to in Article 121 and Article 122(2);

(c) other entities including other relevant marketing authorisation holders, importers and manufacturers of medicinal products or active substances, relevant suppliers and wholesale distributors, stakeholder representative associations, or other entities, including natural or legal persons, that are authorised or entitled to supply medicinal products to the public.

The Agency, in consultation with the working party referred to in Article 125(1), point (d), shall report the information referred to in Article 133(3) and (7), and Article 134(1) to the MSSG.

3. For the purposes of Articles 133(7), point (e), and 134(1), point (e), the Agency shall assess the merits of each confidentiality claim and protect commercially confidential information against unjustified disclosure.

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4. Following the adoption of the Union list of critical medicinal products the Agency may request additional information from:

(a) the competent authority of the Member State concerned;

(b) the marketing authorisation holder;

(c) other entities including other relevant marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers or wholesale distributors, as well as stakeholder representative associations or other entities, including natural or legal persons, that are authorised or entitled to supply medicinal products to the public.

5. Following the adoption of the Union list of critical medicinal products in accordance with Article 137, the Agency shall assess any relevant information received from the marketing authorisation holder pursuant to Article 139 and the competent authority of the Member State in accordance with Article 133(8) and (9) and report on that information to the MSSG.

6. The Agency shall make publicly available via the web-portal referred to in Article 106 the MSSG recommendations referred to in Article 138(1).

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Article 137

The Union list of critical medicinal products

1. Following the reporting referred to in Article 136(2), second subparagraph, and Article 136(5) of this Regulation, the MSSG shall consult the working party referred to in Article 125(1), point (d) of this Regulation. Based on that consultation, the MSSG shall propose a Union list of critical medicinal products authorised to be placed on the market of a Member State pursuant to Article 6 of Directive (EU) 2026/…[+] and for which the coordinated Union level action provided for in this Chapter is necessary.

2. The MSSG shall propose updates to the Union list of critical medicinal products to the Commission, where necessary, in particular taking into account the outcome of vulnerability evaluations referred to in Article 138(2).

   The first revision of the Union list of critical medicinal products shall take place no later than one year after the date of entry into force of this Regulation. Where the results of the vulnerability evaluation are available in accordance with the prioritisation criteria referred to in Article 136(1), first subparagraph, point (c), the revision shall include an update of the list taking into account the results of that evaluation.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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3. The Commission, taking into account the proposal of the MSSG, shall adopt and update the Union list of critical medicinal products by means of implementing acts and communicate the adoption of the list and any updates to the Agency and the MSSG. On the Union list of critical medicinal products, to the extent possible, the Commission shall specify the critical medicinal products for which a vulnerability in the supply chains is established, taking into account the vulnerability evaluation referred to in Article 138(2) and prioritisation criteria referred to in Article 136(1), first subparagraph, point (c). Among those medicinal products the Commission shall also specify those critical medicinal products, including their active substances, which are vulnerable due to a high level of dependency on a single or limited number of third countries. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 179(2).

4. Following the adoption of the Union list of critical medicinal products and of any updates of that list in accordance with paragraph 3 of this Article, the Agency shall without delay publish that list and those updates on the web-portal referred to in Article 106.

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Article 138

Role of the MSSG

1. On the basis of the Union list of critical medicinal products referred to in Article 137(3), in consultation with the Agency and the working party referred to in Article 125(1), point (d), the MSSG may provide recommendations, in accordance with the methods referred to in Article 136(1), first subparagraph, point (e), on appropriate security of supply measures to marketing authorisation holders, the Member States, the Commission, the Agency or other entities, including natural or legal persons. Such measures may include, inter alia, recommendations on diversification of suppliers, inventory management and regulatory flexibilities.

2. The MSSG, relying on the information referred to in Article 136(2) and on the basis of the methodology set out in Article 136(1), first subparagraph, point (b), shall evaluate the vulnerability with respect to the supply chains of the medicinal products listed on the Union list of critical medicinal products and in accordance with the prioritisation criteria referred to in Article 136(1), first subparagraph, point (c).

3. The MSSG shall amend its rules of procedure, and the rules of procedure of the working party referred to in Article 125(1), point (d), in accordance with the tasks set out in this section.

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4. Following the report pursuant to Article 136(5), the MSSG shall review its recommendations in accordance with the methods referred to in Article 136(1), first subparagraph, point (e).

5. The MSSG may request the Agency to request further information from the Member States or marketing authorisation holder of the medicinal product included on the Union list of critical medicinal products or from other relevant actors referred to in Article 135.

Article 139

Obligations on the marketing authorisation holder after the MSSG recommendations

Following the addition of a medicinal product to the Union list of critical medicinal products in accordance with Article 137(3) or having regard to any recommendations provided in accordance with Article 138(1), the marketing authorisation holder for a medicinal product on that list shall:

(a) provide any additional information that the Agency requests;

(b) provide any additional relevant information to the Agency;

(c) take into account the recommendations referred to in Article 138(1);

(d) take into account the actions taken by the Commission in accordance with Article 140(1);

(e) inform the Agency of any measures taken to improve the security of supply and the results of such measures.

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Article 140

Role of the Commission

1. The Commission:

   (a) shall take into account the MSSG recommendations;

   (b) shall take, if appropriate, any necessary actions within the limits of the powers conferred on the Commission, including the development of guidelines to improve the security of supply;

   (c) may foster coordination of Member State measures aimed to ensure security of supply within their territories;

   (d) shall inform the MSSG of actions taken by the Commission;

   (e) may request the MSSG to provide information or an opinion or further recommendations referred to in Article 138(1).

2. If necessary to ensure the smooth functioning of the internal market, the Commission may, taking into consideration the recommendations referred to in paragraph 1, draw up recommendations for national measures to improve security of supply of medicinal products included in the Union list of critical medicinal products.

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3. The adoption of those recommendations shall be limited to cases where the Commission identifies a disruption, or a highly likely disruption, of the internal market which strongly and negatively affects, or which would strongly and negatively affect, the security of supply of critical medicinal products. They shall take into account:

(a) the severity of the disruption of the internal market, or the risk thereof;

(b) the causes of the disruption to security of supply;

(c) the existence of other available measures under this Regulation to mitigate or resolve the disruption, or the risk thereof;

(d) the gravity and scope of risks to public health.

The recommendations shall be based on objective, factual, measurable and substantiated data, including from the Agency and its preparatory bodies, competent authorities of the Member States and relevant economic operators.

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Chapter XI
European Medicines Agency

SECTION 1
TASKS OF THE AGENCY

Article 141
Establishment

This Regulation establishes the European Medicines Agency.

The Agency, previously established under Regulation (EC) No 726/2004, shall continue to function under this Regulation.

The Agency shall be responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human use and of veterinary medicinal products.

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Article 142

Legal status

1. The Agency shall have legal personality.

2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under their laws. It may, in particular, acquire or dispose of movable and immovable property, and be party to legal proceedings.

3. The Agency shall be represented by an Executive Director.

Article 143

Seat

The seat of the Agency shall be established in Amsterdam, the Netherlands.

Article 144

Objectives and tasks of the Agency

1. The Agency shall provide Member States and Union institutions with the best possible scientific opinion on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human use, or veterinary medicinal products, which is referred to it in accordance with the Union legal acts relating to medicinal products for human use or veterinary medicinal products.

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The Agency, acting particularly through its scientific committees, shall carry out the following tasks:

(a) coordinate the scientific evaluation of the quality, safety and efficacy of medicinal products for human use, which are subject to the centralised procedure;

(b) coordinate the scientific evaluation of the quality, safety and efficacy of veterinary medicinal products, which are subject to the centralised procedure, in accordance with Regulation (EU) 2019/6 and the performance of other tasks set out in that Regulation and Regulation (EC) No 470/2009;

(c) transmit upon request and make publicly available assessment reports, summaries of product characteristics, labels, package leaflets and antimicrobial resistance (AMR) awareness cards, where applicable, for the medicinal products for human use;

(d) coordinate the environmental risk assessment and, where relevant, provide scientific opinions related to medicinal products for human use which are subject to the centralised procedure in accordance with this Regulation or related to investigational medicinal products for human use consisting of, or containing, GMOs;

(e) coordinate the monitoring of medicinal products for human use which have been authorised in the Union and provide advice on the measures necessary to ensure the safe and effective use of those products, in particular by coordinating the evaluation and implementation of pharmacovigilance obligations and systems and the monitoring of such implementation;

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(f) ensure the collation and dissemination of information on suspected adverse reactions to medicinal products for human use authorised in the Union by means of databases that are permanently accessible to all Member States;

(g) assist Member States with the rapid communication of information on pharmacovigilance concerns relating to medicinal products for human use to healthcare professionals and coordinate the safety announcements of the competent authorities of the Member States;

(h) distribute appropriate information on pharmacovigilance concerns relating to medicinal products for human use to the general public, in particular by setting up and maintaining a European medicines web-portal;

(i) coordinate, as regards medicinal products for human use and veterinary medicinal products, the verification of compliance with the principles of good manufacturing practice, good laboratory practice, good clinical practice, good pharmacovigilance practice and, as regards medicinal products for human use, the verification of compliance with pharmacovigilance obligations;

(j) provide the secretariat of the joint audit programme referred to in Article 56;

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(k) upon request, provide technical and scientific support in order to improve cooperation between the Union, its Member States, international organisations and third countries on scientific and technical issues relating to the evaluation and monitoring of medicinal products for human use and of veterinary medicinal products, in particular in the framework of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and the Veterinary International Conference on Harmonization;

(l) coordinate as referred to in Article 55 a structured cooperation on inspections in third countries between Member States, the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe, the World Health Organization or trusted international authorities, by means of international inspection programmes;

(m) conduct or participate in inspections with Member States in accordance with Article 54;

(n) record the status of marketing authorisations for medicinal products for human use granted in accordance with the centralised procedure;

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(o) create and maintain a user-friendly database on medicinal products for human use, to be accessible to the general public, and ensure that it is updated, and managed independently of pharmaceutical companies; the database is to facilitate the search for product information, including the electronic version of the package leaflet; it is to include a section on medicinal products for human use authorised for the treatment of children; the information provided to the general public is to be worded in an appropriate and comprehensible manner;

(p) assist the Union and its Member States in the provision of information to health-care professionals and the general public about medicinal products for human use and about veterinary medicinal products evaluated by the Agency;

(q) coordinate the provision of scientific advice to undertakings or, as relevant, not-for-profit entities on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products for human use;

(r) support, through enhanced scientific and regulatory advice, the development of priority medicinal products as defined in Article 62;

(s) check that the conditions laid down in Union legal acts on medicinal products for human use and on veterinary medicinal products and in the marketing authorisations are met in the case of parallel distribution of medicinal products for human use and on veterinary medicinal products authorised in accordance with this Regulation or, as applicable, Regulation (EU) 2019/6;

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(t) draw up, at the Commission's request, any other scientific opinion concerning the evaluation of medicinal products for human use and of veterinary medicinal products or the starting materials used in the manufacture of medicinal products for human use;

(u) with a view to the protection of public health, compile scientific information concerning pathogenic agents which might be used in biological warfare, including the existence of vaccines and other medicinal products for human use and other veterinary medicinal products available to prevent or treat the effects of such agents;

(v) coordinate the supervision of the quality of medicinal products for human use and of veterinary medicinal products placed on the market by requesting testing of compliance with their authorised specifications to the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe that coordinates with the relevant Official Medicines Control Laboratory or with a laboratory that a Member State has designated for that purpose; the Agency and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe shall enter into a written contract for the provision of services to the Agency under this point;

(w) forward annually to the budgetary authority aggregated information on procedures related to medicinal products for human use and veterinary medicinal products;

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(x) take decisions as referred to in Article 7(5) of Directive (EU) 2026/…[+];

(y) contribute to the joint reporting with the European Food Safety Authority and European Centre for Disease Prevention and Control on the sales and use of antimicrobials in human and veterinary medicinal products as well as on the situation as regards antimicrobial resistance in the Union based on contributions received by Member States, taking into account the reporting requirements and periodicity in Article 57 of Regulation (EU) 2019/6. Such joint reporting shall be carried out at least every three years;

(z) adopt a decision granting, refusing, transferring or extending the validity of an orphan designation;

(za) adopt decisions on paediatric investigation plans, their modifications, waivers and deferrals in relation to medicinal products;

(zb) provide regulatory support and coordinate the provision of scientific advice for the development of orphan and paediatric medicinal products;

(zc) coordinate assessment of and certify quality master files for medicinal products for human use as well as, where necessary, coordinate inspections of manufacturers applying for or holding a certificate for a quality master file;

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(zd) establish a mechanism for consultation of authorities or bodies active along the life cycle of medicinal products for human use, in particular the SoHO Coordination Board, the Medical Devices Coordination Group, the Member State Coordination Group on Health Technology Assessment and national pricing and reimbursement authorities, as appropriate, in order to exchange of information and pool knowledge on general issues of scientific or technical nature related to the tasks of the Agency;

(ze) develop coherent scientific assessment methodologies in the fields falling within its mission;

(zf) cooperate with Union decentralised agencies and other scientific authorities and bodies established under Union law, in particular the European Chemicals Agency, the European Food Safety Authority, the European Centre for Disease Prevention and Control and the European Environment Agency as regards the scientific assessment of relevant substances, exchange of data including submission of data to the Common Data Platform on Chemicals pursuant to Regulation (EU) 2025/2455 and information and development of coherent scientific methodologies, including replacing, reducing or refining animal testing, and, where possible, prioritising replacement strategies such as non-animal *in vitro* and *in silico* approaches, taking into account the specificities of the assessment of medicinal products;

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(zg) coordinate the monitoring and management of critical shortages of medicinal products included in the list referred to in Article 128(1);

(zh) coordinate the identification and management of the Union list of critical medicinal products referred to in Article 137;

(zi) support the Commission and Member States in relation to critical shortages and critical medicinal products through the working party referred to in Article 125(1), point (d), and the MSSG;

(zj) provide regulatory support and scientific advice for, and facilitate the development, validation and regulatory uptake of, new-approach methodologies that replace the use of animals in testing and report regularly on best practices and key observations on the replacement, reduction and refinement of animal testing submitted by applicants;

(zk) facilitate joint non-clinical studies between applicants and marketing authorisation holders to avoid unnecessary duplication of tests using live animals;

(zl) facilitate data sharing of results from non-clinical studies on live animals;

(zm) draw up scientific guidelines to facilitate the implementation of the definitions established in this Regulation and in Directive (EU) 2026/…[+], and for the environmental risk assessment of medicinal products for human use, in consultation with the Commission and the Member States;

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(zn) support regulatory decision making on the development, authorisation and supervision of medicinal products by accessing and analysing health data, including real-world data, where appropriate;

(zo) where scientific guidelines are provided, ensure that such guidelines are kept up to date and based on the latest scientific developments.

2. The database provided for in paragraph 1, point (o), of this Article, shall include all medicinal products for human use authorised in the Union together with the summaries of product characteristics, the package leaflet and the information shown on the labelling. Where relevant, it shall include the electronic links to the dedicated webpages where the marketing authorisation holders have reported the information pursuant to Article 60 of Directive (EU) 2026/…[+] and to Article 41(4), point (b), of this Regulation.

For the purposes of the database, the Agency shall set up and maintain a list of all medicinal products for human use authorised in the Union. To this effect:

(a) the Agency shall make public a format for the electronic submission of information on medicinal products for human use;

(b) marketing authorisation holders shall electronically submit to the Agency information on all medicinal products for human use authorised in the Union and shall inform the Agency of any new or varied marketing authorisations granted in the Union, using the format referred to in point (a);

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(c) marketing authorisation holders of centrally authorised medicinal products shall electronically submit to the Agency information concerning the Member States in which the medicinal products have been placed on the market.

If a competent authority of a Member State identifies incorrect data in the database against the data they keep regarding medicinal products authorised in accordance with Directive (EU) 2026/…[+], it shall inform the Agency.

Where available, the database shall also include references to clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 81 of Regulation (EU) No 536/2014.

The Commission is empowered to adopt delegated acts in accordance with Article 181, to supplement this Regulation, by adding further information contained in the database, as well as by specifying the rules of updating and maintaining the data in the database. When adopting the delegated acts, the Commission shall take into account internationally recognised standards.

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Article 145

Coherence between scientific opinions of the Agency and of other Union bodies

1. The Agency shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other Union bodies, agencies or independent scientific committees carrying out similar tasks in relation to issues of common concern.

2. Where the Agency identifies a potential source of divergence, it shall contact the Union body, agency or independent scientific committee in question to ensure that all relevant scientific or technical information is shared and in order to identify potentially contentious scientific or technical issues.

3. Where a substantive divergence over scientific or technical issues is identified and the body concerned is a Union body or agency or an independent scientific committee, the Agency and the body or independent scientific committee concerned shall cooperate to resolve the divergence, and inform the Commission without undue delay. The Commission shall facilitate the resolution of the divergence.

4. The Commission may ask the Agency to conduct an assessment concerning the specific use of the substance concerned in medicinal products for human use and veterinary medicinal products. The Agency shall make public its assessment stating clearly the reasons for its specific scientific conclusions.

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5. To enable coherence between scientific opinions and to avoid duplication of tests, the Agency shall make arrangements with other bodies or agencies established or designated under Union law for cooperation on scientific assessments and methodologies. The Agency shall also make arrangements for the exchange of data and information on relevant substances with the Commission, Member States' authorities and other Union agencies, in particular for environmental risk assessments, non-clinical studies and, where applicable, maximum residue limits.

Those arrangements shall seek to ensure that exchanges of data and information are made available in electronic formats and shall protect the commercially confidential nature of the information exchanged and be without prejudice to the provisions on regulatory protection.

Article 146

Scientific opinions in the context of international collaboration

1. The Agency may issue a scientific opinion, in particular in the context of cooperation with the World Health Organization, for the evaluation of certain medicinal products for human use intended for markets outside the Union. For this purpose, an application shall be submitted to the Agency in accordance with Article 7. Such application may be submitted and assessed together with a marketing authorisation application or any subsequent variation for the Union. The Agency may, after consulting the World Health Organization, and as appropriate other relevant organisations, draw up a scientific opinion in accordance with Articles 7, 11 and 13. Article 14 shall not apply.

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2. The Agency shall establish specific procedural rules for the implementation of paragraph 1, as well as for the provision of scientific advice.

Article 147

International regulatory cooperation

1. Insofar as is necessary to achieve the objectives of this Regulation, and without prejudice to the respective competences of Member States and Union institutions, the Agency may cooperate with the competent authorities of third countries and with international organisations.

To that end, the Agency may, subject to prior approval by the Commission, establish working arrangements with the competent authorities of third countries and international organisations, with regard to:

(a) the exchange of information, including non-public information, where relevant jointly with the Commission;

(b) the sharing of scientific resources and expertise, with a view to facilitating collaboration, while maintaining independent assessment in full compliance with the provisions of this Regulation and Directive (EU) 2026/…[+] and under conditions determined beforehand by the Management Board, in agreement with the Commission;

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(c) the participation in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.

Those arrangements shall not create legal obligations incumbent on the Union and its Member States.

2. The working arrangements and cooperation referred to in paragraph 1 shall not amount to the Agency representing a Union position or committing the Union to international cooperation.

3. The Commission may, in agreement with the Management Board and the relevant committee, invite representatives of international organisations with an interest in the harmonisation of technical requirements applicable to medicinal products for human use and to veterinary medicinal products to participate as observers in the work of the Agency. The conditions for participation shall be determined in advance by the Commission.

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SECTION 2

STRUCTURE AND FUNCTIONING

Article 148

Administrative and management structure

The Agency shall comprise:

(a) a Management Board, which shall exercise the functions set out in Articles 149, 150 and 161;

(b) an Executive Director, who shall exercise the responsibilities set out in Article 151;

(c) a Deputy Executive Director who shall exercise the responsibilities set out in Article 151(7);

(d) the Committee for Medicinal Products for Human Use;

(e) the Pharmacovigilance Risk Assessment Committee;

(f) the Committee for Veterinary Medicinal Products set up pursuant to Article 139(1) of Regulation (EU) 2019/6;

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(g) the Herbal Medicinal Products working group established pursuant to Article 145 of Directive (EU) 2026/…[+];

(h) the Emergency task force established pursuant to Article 15 of Regulation (EU) 2022/123;

(i) the MSSG established pursuant to Article 3 of Regulation (EU) 2022/123;

(j) the Medical Device Shortages Steering Group, established pursuant to Article 21 of Regulation (EU) 2022/123;

(k) the inspection working group;

(l) a Secretariat, which shall provide technical, scientific and administrative support to all bodies of the Agency and ensure appropriate coordination between them; which shall provide technical and administrative support for the coordination group referred to in Article 40 of Directive (EU) 2026/…[+] and for the coordination group referred to in Article 142 of Regulation (EU) 2019/6 and ensure appropriate coordination between them and the scientific committees referred to in points (d), (e) and (f) of this Article ('scientific committees'); and which shall undertake the work required of the Agency under the procedures for the assessment and preparation of decisions for paediatric investigation plans, waivers, deferrals or orphan designations.

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Article 149

Management Board

1. The Management Board shall be composed of one representative from each Member State, two representatives of the Commission and two representatives of the European Parliament, all with voting rights.

   In addition, the Council, in consultation with the European Parliament, shall appoint two representatives of patients' organisations, one representative of healthcare professionals' organisations and one representative of veterinarians' organisations, all with voting rights, to the Management Board. Those representatives shall be chosen from a list drawn up by the Commission which includes appreciably more names than there are posts to be filled. That list, together with the relevant background documents, shall be forwarded to the European Parliament. As quickly as possible, and in any case within three months of receipt of the list, the European Parliament may submit its views for consideration to the Council, which shall then appoint the representatives to the Management Board.

   The members of the Management Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the Union.

2. Members of the Management Board and their alternates shall be appointed on the basis of their knowledge, recognised experience and commitment in the field of medicinal products for human or veterinary use, taking into account relevant managerial, administrative and budgetary expertise which are to be used to further the objectives of this Regulation.

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All parties represented in the Management Board shall make efforts to limit turnover of their representatives, in order to ensure continuity of the work of the Management Board. All parties shall aim to achieve a gender balanced representation on the Management Board.

3. Each Member State and the Commission shall appoint their members of the Management Board as well as an alternate who will replace the member in their absence and vote on their behalf.

4. The term of office for members and their alternates shall be four years. That term shall be extendable.

5. The Management Board shall elect a chairperson and a deputy chairperson from among its members.

The chairperson and the deputy chairperson shall be elected by a majority of two-thirds of the members of the Management Board with voting rights.

The deputy chairperson shall automatically replace the chairperson if they are prevented from attending to their duties.

The term of office of the chairperson and the deputy chairperson shall be four years. The term of office may be renewed once. If however, their membership of the Management Board ends at any time during their term of office, their term of office shall automatically expire on that date.

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6. Without prejudice to paragraph 5 of this Article and Article 150, points (e) and (g), the Management Board shall take decisions by absolute majority of its members with voting rights.

7. The Management Board shall adopt its rules of procedure.

8. The Management Board may invite the chairpersons of the scientific committees to attend its meetings, but they shall not have the right to vote.

9. The Management Board may invite any person whose opinion may be of interest to attend its meetings as an observer.

10. The Management Board shall approve the annual work programme of the Agency and forward it to the European Parliament, the Council, the Commission and the Member States.

11. The Management Board shall adopt the annual report on the Agency's activities and send it by 15 June of each year to the European Parliament, the Council, the Commission, the European Economic and Social Committee, the Court of Auditors and the Member States.

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Article 150

Tasks of the Management Board

1. The Management Board shall:

(a) give the general orientations for the Agency's activities;

(b) adopt an opinion on the rules of procedure of the Committee for Medicinal Products for Human Use, the Committee for Veterinary Medicinal Products and the Pharmacovigilance Risk Assessment Committee;

(c) adopt procedures for the performance of scientific services regarding medicinal products for human use in accordance with Article 159;

(d) appoint the Executive Director and the Deputy Executive Director, and where relevant extend their term of office or remove them from office, in accordance with Article 151;

(e) adopt yearly the Agency's draft single programming document before its submission to the Commission for its opinion, and the Agency's single programming document by a majority of two-thirds of members entitled to vote and in accordance with Article 161;

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(f) assess and adopt a consolidated annual activity report on the Agency's activities and send it by 1 July of each year to the European Parliament, the Council, the Commission and the Court of Auditors; the consolidated annual activity report shall be made public;

(g) adopt the annual budget of the Agency by a majority of two-thirds of the members entitled to vote and in accordance with Article 161;

(h) adopt the financial rules applicable to the Agency in accordance with Article 162;

(i) adopt procedures for the reimbursement by the Agency of expenses of members of bodies of the Agency, including civil society representatives;

(j) exercise, with respect to the staff of the Agency, the powers conferred by the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the Union, laid down in Regulation (EEC, Euratom, ECSC) No 259/68 ('Staff Regulations' and 'Conditions of Employment of Other Servants'), on the Appointing Authority and on the Authority Empowered to Conclude a Contract of Employment (the 'appointing authority powers');

(k) adopt implementing rules for giving effect to the Staff Regulations and the Conditions of Employment of Other Servants in accordance with Article 110 of the Staff Regulations;

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(l) develop contacts with stakeholders and stipulate the conditions applicable as mentioned in Article 170;

(m) adopt an anti-fraud strategy, proportionate to risks of fraud taking into account the costs and benefits of the measures to be implemented;

(n) ensure adequate follow-up to findings and recommendations stemming from the internal or external audit reports and evaluations, as well as from investigations of the European Anti-fraud Office (OLAF) and the European Public Prosecutor's Office (EPPO);

(o) adopt rules to ensure the availability to the public of information concerning the authorisation or supervision of medicinal products for human use;

(p) adopt an efficiency gains and synergies strategy;

(q) adopt a strategy for cooperation with third countries or international organisations within the limits of the Agency's mandate;

(r) adopt and implement a strategy for the organisational management and internal control systems including on the operation of the scientific committees, scientific working parties and scientific advisory groups in relation to efficiency as well as scientific expertise and geographic representation of experts;

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(s) assess and adopt a report regarding the performance of the strategy referred to in point (r) of this paragraph by … [four years from the date of application of this Regulation] and by … [ten years from the date of application of this Regulation] and send it to the European Parliament, the Council and the Commission. The report shall, amongst others, contain quantitative data on the involvement of scientific expertise related to the marketing authorisation application assessment and the provision of regulatory and scientific advice for paediatric, orphan and advanced therapy medicinal products and to the evaluation of the environmental risk assessment as well as on the work-share and task distribution between experts nominated by the competent authorities of the Member States and external experts. Subsequent reports shall be prepared to support the evaluation referred to in Article 176(1).

2. In accordance with Article 110 of the Staff Regulations, the Management Board shall adopt a decision based on Article 2(1) of the Staff Regulations and on Article 6 of the Conditions of Employment of Other Servants delegating relevant appointing authority powers to the Executive Director and Deputy Executive Director and defining the conditions under which that delegation of powers may be suspended. The Executive Director shall be authorised to sub-delegate those powers.

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Where exceptional circumstances so require, the Management Board may, by way of a decision, temporarily suspend the delegation of appointing authority powers to the Executive Director and the sub-delegation of those powers by the Executive Director and exercise them itself or delegate them to one of its members or to a staff member other than the Executive Director.

Article 151

Executive Director

1. The Executive Director shall be engaged as a temporary agent of the Agency under Article 2, point (a), of the Conditions of Employment of Other Servants.

2. The Executive Director shall be appointed by the Management Board from a list of candidates proposed by the Commission following an open and transparent selection procedure.

   For the purpose of concluding the contract with the Executive Director referred to in paragraph 1, the Agency shall be represented by the Chairperson of the Management Board.

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Before appointment, the candidate nominated by the Management Board shall be immediately invited to make a statement to the European Parliament and to answer any questions put by its Members.

3. The term of office of the Executive Director shall be five years. By the end of that period, the Commission shall undertake an assessment that takes into account an evaluation of the Executive Director's performance and the Agency's future tasks and challenges.

4. The Management Board, acting on a proposal from the Commission that takes into account the assessment referred to in paragraph 3, may extend the term of office of the Executive Director once, for no more than five years.

An Executive Director whose term of office has been extended may not participate in another selection procedure for the same post at the end of the overall period.

5. The Executive Director may be removed from office only upon a decision of the Management Board acting on a proposal from the Commission.

6. The Management Board shall adopt decisions on appointment, extension of the term of office or removal from office of the Executive Director on the basis of a two-thirds majority of its members with voting rights.

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7. The Executive Director shall be assisted by a Deputy Executive Director. If the Executive Director is absent or indisposed, the Deputy Executive Director shall assume the duties of the Executive Director.

8. The Executive Director shall manage the Agency. The Executive Director shall be accountable to the Management Board. Without prejudice to the powers of the Commission and of the Management Board, the Executive Director shall be independent in the performance of his or her duties and shall neither seek nor take instructions from any government or from any other body.

9. The Executive Director shall report to the European Parliament on the performance of his or her tasks when invited to do so. The Council may invite the Executive Director to report on the performance of those tasks.

10. The Executive Director shall be the legal representative of the Agency. The Executive Director shall be responsible for:

(a) the day-to-day administration of the Agency;

(b) implementing decisions adopted by the Management Board;

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(c) managing all the Agency resources necessary for conducting the activities of the scientific committees, including making available appropriate scientific and technical support to those committees, and for making available appropriate technical support to the coordination group referred to in Article 40 of Directive (EU) 2026/…[+] and to the coordination group referred to in Article 142 of Regulation (EU) 2019/6;

(d) ensuring that the time limits specified in Union legal acts for the adoption of opinions by the Agency are complied with;

(e) ensuring appropriate coordination between the scientific committees and, where necessary, between those committees, the coordination group referred to in Article 40 of Directive (EU) 2026/…[+] and the coordination group referred to in Article 142 of Regulation (EU) 2019/6, or other working groups of the Agency;

(f) the preparation of the draft statement of estimates of the Agency's revenue and expenditure, and execution of its budget;

(g) the preparation of the draft single programming document and the submission it to the Management Board after consulting the Commission;

(h) implementing the single programming document and report to the Management Board on its implementation;

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(i) preparing the Agency's consolidated annual activity report on the Agency's activities and presenting it to the Management Board for assessment and adoption;

(j) all staff matters;

(k) providing the secretariat for the Management Board;

(l) without prejudice to the competences of OLAF and EPPO, protecting the financial interests of the Union by applying preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by recovering amounts wrongly paid and, where appropriate, by imposing effective, proportionate and dissuasive administrative and financial penalties;

(m) reporting, on the basis of key performance indicators agreed by the Management Board, on the IT infrastructure developed by the Agency by means of implementation of legislation, in terms of timing, budgetary compliance and quality.

11. Each year the Executive Director shall submit a draft report covering the activities of the Agency in the previous year and a draft work programme for the coming year to the Management Board for approval, making a distinction between the Agency's activities concerning medicinal products for human use, those concerning herbal medicinal products and those concerning veterinary medicinal products.

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The draft report referred to in the first subparagraph shall include information about the number of applications evaluated by the Agency, the time taken for completion of the evaluation, and the medicinal products for human use and veterinary medicinal products authorised, rejected or withdrawn.

Article 152

Deputy Executive Director

The Executive Director shall, following consultation with the Commission, propose two candidates for the post of Deputy Executive Director. The Management Board shall adopt its decision by a two-thirds majority of its members with a right to vote. The Deputy Executive Director shall be appointed on the grounds of merit and appropriate administrative and management skills, including relevant professional experience. The Management Board shall have the power to dismiss the Deputy Executive Director by means of a decision adopted by a two-thirds majority of its members with a right to vote.

The term of office of the Deputy Executive Director shall be five years. The Management Board may extend that term once, for a period of no more than five years. The Management Board shall adopt such a decision by a two-thirds majority of its members with the right to vote.

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Article 153

Scientific committees – general provisions

1. The scientific committees shall be responsible for providing the scientific opinions or recommendations to the Agency, each within their own spheres of competence, and shall have the possibility, where necessary, of organising public hearings.

2. The membership of the scientific committees shall be made public. When an appointment is published, the professional qualifications of the member shall be specified.

3. The Executive Director of the Agency or their representative and representatives of the Commission shall be entitled to attend all meetings of the scientific committees, working parties and scientific advisory groups and all other meetings convened by the Agency or its scientific committees.

4. Members of the scientific committees referred to in Article 148, points (d) and (e), appointed by Member States and experts responsible for evaluating medicinal products nominated by Member States shall rely on the scientific evaluation and resources available to competent authorities of the Member States responsible for marketing authorisation, and on external experts proposed by Member States or selected by the Agency. Each competent authority of the Member States shall monitor the scientific level and independence of the evaluation carried out and facilitate the activities of those members and experts.
Member States shall refrain from giving those members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.

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5. The members of the scientific committees referred to in Article 148, points (d) and (e), may be accompanied by experts in specific scientific or technical fields.

6. When preparing any opinion or recommendation, the scientific committees referred to in Article 148, points (d) and (e), shall use their best endeavours to reach a scientific consensus. If such a consensus cannot be reached, the opinion shall consist of the position of the majority of members and divergent positions, with the grounds on which they are based.

7. The scientific committees referred to in Article 148, points (d) and (e), may, if they consider it appropriate, seek guidance on important questions of a general scientific or ethical nature.

8. The scientific committees referred to in Article 148, points (d) and (e), and any scientific working parties and scientific advisory groups established in accordance with Article 157 shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products for human use, in particular patient and consumer organisations and healthcare professionals' associations. For that purpose, working groups of patient and consumer organisations and healthcare professionals' associations shall be established by the Agency. They shall ensure a fair representation of healthcare professionals, patients and consumers covering a wide range of experience and disease areas, including orphan, paediatric and geriatric diseases and advanced therapy medicinal products, and a broad geographical range.

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Rapporteurs appointed by those scientific committees may, on an advisory basis, establish contacts with representatives of patient organisations and healthcare professionals' associations relevant to the therapeutic indication of the medicinal product for human use.

9. The Committee for Veterinary Medicinal Products shall operate in accordance with Regulation (EU) 2019/6 and paragraphs 1, 2 and 3 of this Article.

Article 154

Impartiality and conflict of interest

1. Members of the Management Board, members of the scientific committees, rapporteurs, experts and inspectors of the Agency shall not have financial or other interests in the pharmaceutical and medical devices industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial and other interests including indirect interests which could relate to this industry. The Agency shall make those declarations public.

The Agency's code of conduct shall provide for the implementation of this Article with particular reference to the acceptance of gifts.

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2. Members of the Management Board, members of the scientific committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence or impartiality with respect to the items on the agenda. These declarations shall be made available to the public.

3. Where a declared interest is considered by the Agency to be prejudicial to the independence or impartiality of a member or expert with respect to an item on the agenda, the member of the Management Board, member of the scientific committee or expert concerned shall not have any involvement and not take part in the discussions or decision-making with respect to that item.

4. By way of derogation from paragraphs 1 and 3, experts who declare an interest that would prevent them from participating in the work of the scientific committees and other bodies may in exceptional and duly justified cases be called upon, in the interest of public health, to provide written or oral observations. Those observations shall be provided separately from the discussion or decision-making with respect to the concerned item.

5. The Agency shall establish procedures with regard to the application of the provisions on conflict of interest and impartiality, to be adopted by the Management Board.

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6. The Executive Director shall, after leaving the service, continue to be bound by the rules of the Staff Regulations as regards the acceptance of certain appointments or benefits and engaging in an occupational activity for the period referred to in Article 16 of the Staff Regulations. Prior to engaging in any such activity, the former Executive Director shall inform the Agency and the Management Board which shall verify whether that activity is in line with the Staff Regulations and its implementing rules adopted in accordance with Article 150.

Article 155

Committee for Medicinal Products for Human Use activities

1. The Committee for Medicinal Products for Human Use shall be responsible for drawing up the opinion of the Agency on any matter concerning:

(a) the admissibility of the files submitted in accordance with the centralised procedure;

(b) the granting, variation, suspension or revocation of an authorisation for a medicinal product for human use;

(c) pharmacovigilance; and

(d) scientific advice.

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For the fulfilment of its pharmacovigilance tasks, including the approval of risk management systems and monitoring their effectiveness provided for under this Regulation, the Committee for Medicinal Products for Human Use shall rely on the scientific assessment and recommendations of the Pharmacovigilance Risk Assessment Committee referred to in Article 148, point (e).

2. In addition to their task of providing scientific opinions to the Union and Member States on the questions which are referred to them, the members of the Committee for Medicinal Products for Human Use shall ensure that there is appropriate coordination between the tasks of the Agency and the work of the competent authorities of the Member States, including the consultative bodies concerned with the marketing authorisation.

3. The Committee for Medicinal Products for Human Use shall be composed of the following:

(a) one member and one alternate member appointed by each Member State, in accordance with paragraph 7;

(b) two members and two alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent healthcare professionals' organisations;

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(c) two members and two alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations.

4. The Committee for Medicinal Products for Human Use may co-opt a maximum of seven additional members chosen on the basis of their specific scientific competence. Those members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.

With a view to the co-opting of such members, the Committee for Medicinal Products for Human Use shall identify the specific complementary scientific competence of the additional member or members. Co-opted members shall be chosen among experts nominated by Member States or the Agency.

5. Members appointed under paragraph 3, point (b), shall jointly be entitled to one vote, and members appointed under paragraph 3, point (c), shall jointly be entitled to one vote.

6. The alternate members shall represent and vote for the members in their absence and may also be appointed to act as rapporteurs in accordance with Article 159.

Members and alternate members shall be chosen for their role and experience in the evaluation of medicinal products for human use as appropriate and shall represent the competent authorities of the Member States.

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7. The members and alternate members of the Committee for Medicinal Products for Human Use shall be appointed on the basis of their relevant expertise in the assessment of medicinal products covered by Directive (EU) 2026/…[+] and by this Regulation, including medicinal products for rare and paediatric diseases, advanced therapy medicinal products, biological medicinal products and biotechnological medicinal products, in order to guarantee the highest level of specialist qualifications and a broad spectrum of relevant expertise. That relevant expertise shall also include the environmental risk assessment. The Member States shall cooperate in order to ensure that the final composition of the Committee for Medicinal Products for Human Use provides appropriate and balanced coverage of all scientific areas relevant to its tasks taking into account scientific developments and new types of medicinal products. For this purpose, Member States shall liaise with the Management Board.

8. The members and alternate members of the Committee for Medicinal Products for Human Use shall be appointed for a term of three years, which may be renewed following the procedures referred to in paragraph 7. That Committee shall elect its chairperson and vice-chairperson from among its members for a term of three years, which may be extended once for a further period of three years.

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9. The Committee for Medicinal Products for Human Use shall establish its own rules of procedure.

Those rules shall, in particular, lay down:

(a) the procedures for appointing and replacing the chairperson;

(b) the procedures relating to working parties and scientific advisory groups; and

(c) a procedure for the urgent adoption of opinions, particularly in relation to the provisions of this Regulation on market surveillance and pharmacovigilance.

The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board.

Article 156

Pharmacovigilance Risk Assessment Committee activities

1. The mandate of the Pharmacovigilance Risk Assessment Committee shall cover all aspects of the risk management of the use of medicinal products for human use including the detection, assessment, minimisation and communication relating to the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product for human use, the design and evaluation of post-authorisation safety studies and pharmacovigilance audit.

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2. The Pharmacovigilance Risk Assessment Committee shall be composed of the following:

(a) one member and one alternate member appointed by each Member State, in accordance with paragraph 3;

(b) six members appointed by the Commission, with a view to ensuring that the relevant expertise is available within the Pharmacovigilance Risk Assessment Committee, including clinical pharmacology and pharmacoepidemiology, on the basis of a public call for expressions of interest;

(c) two members and two alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent healthcare professionals;

(d) two members and two alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations.

Members appointed under point (c) of the first subparagraph shall jointly be entitled to one vote and members appointed under point (d) of the first subparagraph shall jointly be entitled to one vote.

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The alternate members shall represent and vote for the members in their absence. The alternate members referred to in point (a) of the first subparagraph may be appointed to act as rapporteurs in accordance with Article 159.

3. A Member State may delegate its tasks in the Pharmacovigilance Risk Assessment Committee to another Member State. Each Member State may represent no more than one other Member State.

4. The members and alternate members of the Pharmacovigilance Risk Assessment Committee shall be appointed on the basis of their relevant expertise in pharmacovigilance matters and risk assessment of medicinal products for human use, in order to guarantee the highest level of specialist qualifications and a broad spectrum of relevant expertise. For this purpose, Member States shall liaise with the Management Board in order to ensure that the final composition of that Committee covers the scientific areas relevant to its tasks.

5. The members and alternate members of the Pharmacovigilance Risk Assessment Committee shall be appointed for a term of three years, which may be renewed. That Committee shall elect its chairperson and vice-chairperson from among its members for a term of three years, which may be extended once for a further period of three years.

6. The Pharmacovigilance Risk Assessment Committee shall establish its own rules of procedure, laying down in particular:

(a) procedures for appointing and replacing the chairperson;

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(b) procedures relating to working parties and scientific advisory groups;

(c) a procedure for the urgent adoption of recommendations.

The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board.

Article 157

Scientific working parties and scientific advisory groups

1. The scientific committees may establish scientific working parties and scientific advisory groups in connection with the performance of their tasks.

The scientific committees may rely on scientific working parties for the performance of certain tasks. The scientific committees shall retain final responsibility for the scientific assessments and opinions related to those tasks.

Working parties established by the Committee for Veterinary Medicinal Products are governed by Regulation (EU) 2019/6.

2. The Committee for Medicinal Products for Human Use shall establish, for the evaluation of specific types of medicinal products or treatments, working parties with scientific expertise in the fields of pharmaceutical quality, methodologies, non-clinical and clinical evaluations.

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For the provision of scientific advice, the Committee for Medicinal Products for Human Use shall establish a scientific advice working party.

The Committee for Medicinal Products for Human Use shall, where necessary, establish an Environmental Risk Assessment working party, working parties with scientific expertise on paediatric medicinal products and orphan medicinal products and other scientific working parties.

3. The composition of the working party and the selection of members shall be based on the following criteria:

(a) a high level of scientific expertise;

(b) meeting the needs for the specific multi-disciplinary expertise of the working party to which they will be appointed.

The majority of the members of the working parties shall consist of experts from the competent authorities of the Member States by ensuring the broadest possible geographical distribution. Where appropriate, the Committee for Medicinal Products for Human Use may, following consultation with the Management Board, set a minimum number of experts from the competent authorities in a working party. Where a specific area of expertise can be fulfilled by an expert nominated by a competent authority of a Member State, that expert shall have priority over external experts.

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4. Representatives of patients, healthcare professionals and academia may, as appropriate and based on their expertise, be included as members of the working parties.

5. Competent authorities of the Member States that are not represented in a working party may attend meetings of working parties as an observer.

6. The Agency shall make documents discussed in working parties accessible to all competent authorities of the Member States.

7. The scientific committees may seek advice from scientific advisory groups in connection with the evaluation of specific medicinal products or treatments.

8. When establishing working parties and scientific advisory groups, the scientific committees shall in their rules of procedure provide for:

(a) the appointment of members of those working parties and scientific advisory groups on the basis of the lists of experts referred to in Article 158(2); and

(b) the consultation of those working parties and scientific advisory groups.

Article 158

Scientific experts

1. The Agency or any of the scientific committees may use the services of experts and service providers for the discharge of specific tasks for which they are responsible.

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2. Member States shall transmit to the Agency the names of national experts with proven experience in the evaluation of medicinal products for human use and veterinary medicinal products who, taking into account conflicts of interest pursuant to Article 154, would be available to serve on working parties or scientific advisory groups of any of the scientific committees, together with an indication of their qualifications and specific areas of expertise.

3. Where appropriate, for the nomination of other experts, the Agency shall publish a call for expressions of interest after endorsement by the Management Board of the necessary criteria and fields of expertise, in particular to ensure a high level of public health and animal protection.

   The Management Board shall adopt the appropriate selection procedures on a proposal from the Executive Director.

4. The Agency shall establish and maintain a pool of experts. That expert pool shall include the national experts referred to in paragraph 2 and any other experts appointed by the Agency or the Commission, and shall be updated.

5. Experts shall have access to training provided by the Agency, as appropriate.

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6. Rapporteurs for any of the scientific committees may use the services of experts for the fulfilment of their tasks in accordance with Article 159. Any remuneration of such experts shall be deducted from the remuneration due to the rapporteurs. The use of the services of national experts referred to in paragraph 2 by rapporteurs shall be subject to the agreement of the relevant competent authorities. The Agency may facilitate those agreements in accordance with Article 159(2).

7. The remuneration of experts and service providers for services used by the Agency under paragraph 1 shall be financed through the Agency's budget, in accordance with the financial rules applicable to the Agency.

Article 159

Rapporteurship

1. Where, in accordance with this Regulation, any of the scientific committees is required to evaluate a medicinal product for human use, it shall appoint, with the exception of members representing healthcare professionals' organisations and patients organisations, one of its members to act as rapporteur, taking into account existing expertise in the Member State. The scientific committee concerned may appoint a second member to act as co-rapporteur.

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A member of a scientific committee shall not be appointed rapporteur for a particular case if they declare, in accordance with Article 154, any interest that might be, or might be perceived as, prejudicial to the impartial assessment of that case. The scientific committee concerned may replace the rapporteur or co-rapporteur by another member at any time, if they are unable to fulfil their duties within the prescribed time limits, or if an actual or potential prejudicial interest is detected.

A rapporteur appointed for that purpose by the Pharmacovigilance Risk Assessment Committee shall closely collaborate with the rapporteur appointed by the Committee for Medicinal Products for Human Use or the Reference Member State for the medicinal product for human use concerned.

When consulting the scientific advisory groups referred to in Article 157, the relevant scientific committee shall forward to them the draft assessment report or reports drawn up by the rapporteur or the co-rapporteur. The opinion issued by the scientific advisory group shall be forwarded to the chairperson of the relevant scientific committee in such a way as to ensure that the deadlines laid down in Article 7 are met.

The substance of the opinion shall be included in the assessment report published pursuant to Article 17(3).

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2. Without prejudice to Article 158(7), the provision of services by rapporteurs or experts shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and the person's employer.

The person concerned, or the person's employer, shall be remunerated pursuant to the financial arrangements established by the Management Board in accordance with Regulation (EU) 2024/568.

The first and second subparagraphs shall also apply:

(a) to the services provided by the chairpersons of the scientific committees; and

(b) to the work of rapporteurs in the coordination group referred to in Article 40 of Directive (EU) 2026/…[+] as regards the fulfilment of the tasks of that group in accordance with Articles 112, 114, 116, 120 and 125 of Directive (EU) 2026/…[+].

Article 160

Methods to determine added therapeutic value

At the request of the Commission, the Agency shall, in respect of authorised medicinal products for human use, collect any available information on methods that competent authorities of the Member States use to determine the added therapeutic value that any new medicinal product for human use provides.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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SECTION 3

FINANCIAL PROVISIONS

Article 161

Adoption of the budget of the Agency

1. Estimates of all the revenue and expenditure of the Agency shall be prepared for each financial year, corresponding to the calendar year, and shall be shown in the budget of the Agency.

2. The revenue and expenditure shown in the budget shall be in balance.

3. The Agency's revenue shall consist of:

   (a) a contribution from the Union;

   (b) a contribution from third countries participating in the work of the Agency with which the Union has concluded international agreements for that purpose;

   (c) fees paid by undertakings and not-for-profit entities:

      (i) for obtaining and maintaining centralised marketing authorisations for medicinal products for human use and for veterinary medicinal products and for other services provided by the Agency, as provided for in this Regulation and in Regulation (EU) 2019/6; and

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(ii) for services provided by the coordination group referred to in Article 40 of Directive (EU) 2026/…[+] as regards the fulfilment of its tasks in accordance with Articles 112, 114, 116, 120 and 125 of Directive (EU) 2026/…[+];

(d) charges for other services provided by the Agency;

(e) Union funding in the form of contribution agreements or grants for participation in research and assistance projects, in accordance with the Agency's financial rules referred to in Article 162(11) and with the provisions of the relevant instruments supporting the policies of the Union.

The European Parliament and the Council ('the budgetary authority') shall re-examine, when necessary, the level of the Union contribution, referred to in the first subparagraph, point (a), on the basis of an evaluation of needs and by taking account of the level of revenue provided by the sources referred to in the first subparagraph, points (c), (d) and (e).

4. Activities relating to the assessment of marketing authorisation applications, subsequent variations, pharmacovigilance, the operation of communications networks and market surveillance shall be performed by the Agency under the permanent budgetary control of the Management Board in order to guarantee the independence of the Agency. This shall not preclude the Agency from charging fees to marketing authorisation holders for performing those activities on the condition that its independence is strictly guaranteed.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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5. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure costs, and operational expenditure. In respect of operational expenditure, budgetary commitments for actions which extend over more than one financial year may be broken down over several years into annual instalments, as necessary.

The Agency may award grants related to the fulfilment of the tasks incumbent upon it under this Regulation or other relevant Union legal acts or related to the fulfilment of other tasks entrusted to it.

6. Each year the Management Board, on the basis of a draft drawn up by the Executive Director, shall produce an estimate of revenue and expenditure for the Agency for the following financial year. That estimate, which shall include a draft establishment plan, shall be sent by the Management Board to the Commission by 31 March.

7. The estimate shall be forwarded by the Commission to the budgetary authority together with the preliminary draft general budget of the European Union.

8. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Articles 213 and 314 TFEU.

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9. The budgetary authority shall authorise the appropriations for the subsidy to the Agency.

The budgetary authority shall adopt the establishment plan for the Agency.

10. The budget of the Agency shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.

11. Any modification of the establishment plan and of the budget of the Agency shall be the subject of an amending budget, which is forwarded for the purposes of information to the budgetary authority.

12. The Management Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of the Agency's budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of six weeks from the date of notification of the project.

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Article 162

Implementation of the Agency's budget

1. The Executive Director shall implement the budget of the Agency in accordance with Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[43].

2. By 1 March of financial year n+1, the Agency's accounting officer shall send the provisional accounts for year n to the Commission's accounting officer and to the Court of Auditors.

3. By 31 March of financial year n+1, the Executive Director shall send the report on the budgetary and financial management for year n to the European Parliament, to the Council, to the Commission and to the Court of Auditors.

4. By 31 March of financial year n+1, the Commission's accounting officer shall send the Agency's provisional accounts for year n, consolidated with the Commission's provisional accounts, to the Court of Auditors.

   On receipt of the Court of Auditors' observations on the Agency's provisional accounts pursuant to Article 252 of Regulation (EU, Euratom) 2024/2509, the Agency's accounting officer shall draw up the Agency's final accounts and the Executive Director shall submit them to the Management Board for an opinion.

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43 Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (OJ L, 2024/2509, 26.9.2024, ELI: http://data.europa.eu/eli/reg/2024/2509/oj).

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5. The Management Board shall deliver an opinion on the Agency's final accounts for year n.

6. The Agency's accounting officer shall, by 1 July of financial year n+1, send the final accounts, together with the Management Board's opinion, to the European Parliament, to the Council, to the Court of Auditors and to the Commission's accounting officer.

7. The final accounts for year n shall be published in the *Official Journal of the European Union* by 15 November of financial year n+1.

8. The Executive Director shall send to the Court of Auditors a reply to its observations by 30 September of financial year n+1. The Executive Director shall also send that reply to the Management Board.

9. Upon request, the Executive Director shall submit to the European Parliament any information required for the smooth application of the discharge procedure for the financial year concerned, as laid down in Article 267(3) of Regulation (EU, Euratom) 2024/2509.

10. The European Parliament, upon a recommendation from the Council, shall, before 15 May of financial year n+2, give a discharge to the Executive Director in respect of the implementation of the budget for year n.

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11. The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They shall not depart from Commission Delegated Regulation (EU) 2019/715[44] unless specifically required for the Agency's operation and with the Commission's prior consent.

Article 163

Fraud prevention

1. In order to combat fraud, corruption and other illegal activities, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[45] shall apply without restriction.

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[44] Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (OJ L 122, 10.5.2019, p. 1, ELI: http://data.europa.eu/eli/reg_del/2019/715/oj).

[45] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1, ELI: http://data.europa.eu/eli/reg/2013/883/oj).

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2. The Agency shall accede to the Interinstitutional Agreement of 25 May 1999[46] concerning internal investigations by OLAF and shall adopt, without delay, the appropriate provisions applicable to all the employees of the Agency using the template set out in the Annex to that Agreement.

3. The Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot checks, over all grant beneficiaries, contractors and subcontractors who have received Union funds from the Agency.

4. OLAF may carry out investigations, including on-the-spot checks and inspections with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant or a contract funded by the Agency, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 and Council Regulation (Euratom, EC) No 2185/96[47].

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[46] Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-fraud Office (OLAF) (OJ L 136, 31.5.1999, p. 15, ELI: http://data.europa.eu/eli/agree_interinstit/1999/531/oj).

[47] Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2, ELI: http://data.europa.eu/eli/reg/1996/2185/oj).

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5. Working agreements with third countries and international organisations, contracts, grant agreements and grant decisions of the Agency shall contain provisions expressly empowering the Court of Auditors and OLAF to conduct such audits and investigations, according to their respective competences.

6. In accordance with Council Regulation (EU) 2017/1939[48], the EPPO may investigate and prosecute fraud and other illegal activities affecting the financial interests of the Union as provided for in Directive (EU) 2017/1371 of the European Parliament and of the Council[49].

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48 Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') (OJ L 283, 31.10.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/1939/oj).

49 Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29, ELI: http://data.europa.eu/eli/dir/2017/1371/oj).

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SECTION 4

GENERAL PROVISIONS GOVERNING THE AGENCY

Article 164

Liability

1. The contractual liability of the Agency shall be governed by the law applicable to the contract in question. The Court of Justice of the European Union ('the Court') shall have jurisdiction pursuant to any arbitration clause contained in a contract concluded by the Agency.

2. In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or by its staff in the performance of their duties.

   The Court shall have jurisdiction in any dispute relating to compensation for any such damage.

3. The personal liability of its staff towards the Agency shall be governed by the provisions laid down in the Staff Regulations or Conditions of Employment of Other Servants applicable to them.

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Article 165

Access to documents

Regulation (EC) No 1049/2001 shall apply to documents held by the Agency.

The Agency shall set up a register pursuant to Article 2(4) of Regulation (EC) No 1049/2001 to make available all documents that are publicly available pursuant to this Regulation.

The Management Board shall adopt the arrangements for implementing Regulation (EC) No 1049/2001.

Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may give rise to the lodging of a complaint with the Ombudsman or form the subject of an action before the Court, under the conditions laid down in Articles 228 and 263 TFEU respectively.

Article 166

Privileges

Protocol No 7 on the Privileges and Immunities of the European Union annexed to the TFEU shall apply to the Agency and its staff.

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Article 167

Staff

The Staff Regulations and Conditions of Employment of Other Servants and the rules adopted by agreement between the institutions of the Union for giving effect to those Staff Regulations and Conditions of Employment of Other Servants shall apply to the staff of the Agency.

The Agency may make use of seconded national experts or other staff not employed by the Agency.

The Management Board, in agreement with the Commission, shall adopt the necessary implementing provisions.

Article 168

Security rules on the protection of classified and sensitive non-classified information

The Agency shall adopt security rules equivalent to the Commission's security rules for protecting European Union Classified Information (EUCI) and sensitive non-classified information, as set out in Commission Decisions (EU, Euratom) 2015/443[50] and 2015/444[51]. The security rules of the Agency shall cover, inter alia, provisions for the exchange, processing and storage of such information.

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[50] Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41, ELI: http://data.europa.eu/eli/dec/2015/443/oj).

[51] Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53, ELI: http://data.europa.eu/eli/dec/2015/444/oj).

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Members of the Management Board, the Executive Director, members of the scientific committees, external experts participating in ad hoc working groups, and members of the staff of the Agency shall comply with the confidentiality requirements under Article 339 TFEU, even after their duties have ceased.

The Agency may take the measures necessary to facilitate the exchange of information relevant to its tasks with the Commission and the Member States and, where appropriate, the relevant Union institutions, bodies, offices and agencies. Any administrative arrangements concluded to that end with regard to the sharing of EUCI or, in the absence of such arrangements, any exceptional ad hoc release of EUCI, shall have received the Commission's prior approval.

Article 169

Consultation process

1. The Agency shall establish a consultation process with relevant authorities or bodies of the Member States for the exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency, in particular guidelines on unmet medical needs and the design of clinical trials, other studies and the generation of evidence along the life cycle of medicinal products.

   The consultation process shall include bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 and national bodies responsible for pricing and reimbursement.

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The conditions of participation shall be set by the Management Board in agreement with the Commission.

2. The Agency shall, where appropriate, extend the consultation process to patients, medicinal products developers, healthcare professionals, the industry or other stakeholders as relevant.

Article 170

Contacts with civil society representatives

The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the healthcare professionals. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.

Article 171

Support to SMEs and to not-for profit entities

1. The Agency shall ensure that SMEs and not-for-profit entities are offered a support scheme.

2. The support scheme shall be comprised of regulatory, procedural and administrative support and reduction, deferral or waivers of fees.

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3. The scheme shall cover the various steps involved in pre-authorisation procedures, and in particular scientific advice, the submission of the marketing authorisation application, and the post-authorisation procedures.

4. The SMEs shall benefit from the incentives laid down in Commission Regulation (EC) No 2049/2005 and Regulation (EU) 2024/568.

5. For not-for-profit entities the Commission shall adopt specific provisions clarifying the definitions, establishing waivers, reductions or deferrals of fees, as appropriate, in accordance with the procedure referred to in Article 11 and Article 13 and Annex V to Regulation (EU) 2024/568.

Article 172

Transparency

To ensure an appropriate level of transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products for human use which is not of a confidential nature.

The internal rules and procedures of the Agency, its scientific committees and its working groups shall be made available to the public at the Agency and on the Internet.

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The Agency may engage in communication activities on its own initiative within its field of competence. The allocation of resources to communication activities shall not be detrimental to the effective exercise of the tasks of the Agency. Communication activities shall be carried out in accordance with relevant communication and dissemination plans adopted by the Management Board.

Article 173

Protection against cyber attacks

The Agency shall equip itself with a high level of security controls and processes against cyber attacks, cyber espionage and other data breaches to ensure the protection of health data and the normal functioning of the Agency at all times, especially during public health emergencies or major events at Union level.

For the purposes of the first subparagraph, the Agency shall actively take measures to ensure its compliance with a high common level of cybersecurity adopted within Union institutions, bodies, offices and agencies, and identify and implement up-to-date cybersecurity best practices for preventing, detecting, mitigating, and responding to cyber attacks.

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Article 174

Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and Directive (EU) 2019/1937 of the European Parliament and of the Council[52] and existing national law and legal practices in Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the commercially confidential information and trade secrets of natural or legal persons in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council[53], including intellectual property rights.

2. Without prejudice to paragraph 1, all parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition within the meaning of Article 101 TFEU.

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52 Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17, ELI: http://data.europa.eu/eli/dir/2019/1937/oj).

53 Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1, ELI: http://data.europa.eu/eli/dir/2016/943/oj).

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3. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities of the Member States, and between competent authorities of the Member States and the Commission and the Agency, shall not be disclosed without the prior agreement of the authority from which that information originates.

4. Paragraphs 1, 2 and 3 do not affect the rights and obligations of the Commission, the Agency, Member States or other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor do they affect the obligations of the persons concerned to provide information under criminal law.

5. The Commission, the Agency, and Member States may exchange commercially confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 175

Processing of personal data

1. To support its public health tasks and in particular the evaluation and monitoring of medicinal products or the preparation of regulatory decisions and scientific opinions, the Agency may process personal health data, from clinical trials and other sources including real world data for the purpose of improving the robustness of its scientific assessment or verifying claims of the applicant or marketing authorisation holder in the context of the evaluation or supervision of medicinal products.

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Additionally, the Agency may process such data for the performance of regulatory science activities, as defined in paragraph 2, provided that the processing of those personal data:

(a) is strictly required and duly justified to achieve the objectives of the project or of the horizon scanning activities concerned;

(b) as regards special categories of personal data, is strictly necessary and subject to appropriate safeguards, and protects the rights of data subjects in accordance with Union law, including technical and organisational measures such as pseudonymisation.

2. For the purposes of this Article, ‘regulatory science activities’ means scientific projects to complement available scientific evidence with regard to diseases or horizontal questions related to medicinal products, to fill evidence gaps that cannot be fully addressed through data in the possession of the Agency, or to support horizon scanning activities.

3. The processing of personal data by the Agency in the context of this Article shall be guided by the principles of transparency, explainability, fairness, and accountability.

4. The Management Board shall establish the general scope for the regulatory science activities in consultation with the Commission and the European Data Protection Supervisor.

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5. The Agency shall keep documentation containing a detailed description of the process and of the rationale behind the training, testing and validation of algorithms to ensure transparency of the process and the algorithms, including their compliance with the safeguards provided for in this Article, and to allow for verification of the accuracy of the results based on the use of such algorithms. Upon request, the Agency shall make relevant documentation available to interested parties, including Member States.

6. If the personal data to be processed for the regulatory science activities have been directly provided by a Member State, a Union body, a third country or an international organisation, the Agency shall request authorisation from that provider of data, unless the provider of data has granted its prior authorisation to such processing for the purposes of regulatory science activities, either in general terms or subject to specific conditions.

7. Processing of personal data under this Regulation shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable. The Agency shall adopt adequate data governance practices and the required standards to ensure the appropriate use and protection of personal health data in accordance with Union law.

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Article 176

Evaluation

1. By … [five years from the date of application of this Regulation], and every 10 years thereafter, the Commission shall commission an evaluation of the Agency's performance in relation to its objectives, mandate, tasks, governance and location(s) in accordance with Commission's guidelines. The evaluation shall include, amongst others, based on the reports referred to in Article 150, points (r) and (s), a quantitative assessment of the efficiency gain, the appropriate involvement of scientific expertise in particular regarding orphan medicinal products, paediatric medicinal products and advanced therapy medicinal products as well as the broad geographical representation of national experts in the work of the scientific committees referred to in Article 148, points (d) and (e), advisory groups and working parties.

2. The evaluation shall, in particular, address the possible need to modify the mandate of the Agency, and the financial implications of any such modification.

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3. On the occasion of every second evaluation, there shall be an assessment of the results achieved by the Agency having regard to its objectives, mandate, governance and tasks, including an assessment of whether the continuation of the Agency is still justified with regard to these objectives, mandate, governance and tasks. This assessment shall also include the experience acquired as a result of the operation of the procedures laid down in this Regulation and in Chapter III, Sections 4 and 5, of Directive (EU) 2026/…[+] on the basis of input from Member States and the Coordination group referred to in Article 40 of Directive (EU) 2026/…[+].

4. The Commission shall report to the European Parliament, the Council and the Management Board on the evaluation findings. The findings of the evaluation shall be made public.

5. By … [10 years from the date of application of this Regulation], the Commission shall assess the application of this Regulation and present an evaluation report to the European Parliament and the Council on the progress towards achievement of its t objectives, including an assessment of the resources required to implement this Regulation.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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6. The Commission shall, following the use of the first two data exclusivity vouchers pursuant to Article 42(3), or by … [five years from the date of application of this Regulation], whichever is the earliest, and every five years thereafter, carry out an evaluation of Articles 41 to 44 and present a report on the main findings of that evaluation to the European Parliament and the Council. The evaluation shall include an assessment of the effectiveness of the data exclusivity voucher in addressing the market failure as an incentive for the development of priority antimicrobials tackling antimicrobial resistance, taking also into account other existing Union level market incentives for authorised priority antimicrobials, an assessment of the actual and expected costs, as well as an assessment of whether it is appropriate to adjust the value of the annual gross sales referred to in Article 42(1) to inflation and of whether it is appropriate to increase the number of data exclusivity vouchers granted referred to in Article 44. On the basis of the evaluation, the Commission shall, where appropriate, submit a legislative proposal to the European Parliament and to the Council in order to amend this Regulation.

7. By … [five years from the date of application of this Regulation], the Commission shall carry out an evaluation of the voluntary subscription model referred to in Article 45 and present a report on the main findings of that evaluation to the European Parliament and the Council. That evaluation shall cover at least the following:

(a) the implementation and uptake of the voluntary subscription model by Member States;

(b) the impact of the voluntary subscription model on the development and supply of antimicrobials;

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(c) the effectiveness and appropriateness of the voluntary subscription model, including an assessment of whether that model could be improved by introducing a voluntary Union level subscription model for the purchase of antimicrobials.

The evaluation shall be based on information provided by Member States related to the practical application of Article 45. The Commission shall, where appropriate, submit a legislative proposal to the European Parliament and to the Council, based on the evaluation, in order to amend this Regulation.

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Chapter XII
General provisions

Article 177

Penalties at national level

1. By …. [six months before the date of application of this Regulation], Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

2. Member States shall inform the Commission immediately of any litigation instituted for infringement of this Regulation regarding centrally authorised medicinal products.

Article 178

Union penalties

1. The Commission may impose financial penalties in the form of fines or periodic penalty payments on the marketing authorisations holders granted under this Regulation if they fail to comply with any of the obligations laid down in Annex II in connection with the marketing authorisations.

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2. The Commission may, insofar as specifically provided for in the delegated acts referred to in paragraph 10, point (b), impose the financial penalties referred to in paragraph 1 on a legal entity or legal entities other than the marketing authorisation holder provided that such entities form part of the same economic entity as the marketing authorisation holder and that such other legal entities:

(a) exerted a decisive influence over the marketing authorisation holder; or

(b) were involved in, or could have addressed, such failure to comply with the obligation by the marketing authorisation holder.

3. Where the Agency or a competent authority of a Member State is of the opinion that a marketing authorisation holder has failed to comply with any of the obligations referred to in paragraph 1, it may request the Commission to investigate whether to impose financial penalties pursuant to that paragraph.

4. In determining whether to impose a financial penalty and in determining its appropriate amount, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness and take into consideration, where relevant, the seriousness and the effects of the failure to comply with the obligations.

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5. For the purposes of paragraph 1, the Commission shall take into account:

(a) any infringement procedure initiated by a Member State against the same marketing authorisation holder on the basis of the same legal grounds and the same facts;

(b) any sanctions, including penalties, already imposed on the same marketing authorisation holder on the basis of the same legal grounds and the same facts;

(c) the nature, gravity and duration of the infringement and its consequences;

(d) the intentional or negligent character of the infringement;

(e) any action taken by the infringing party to mitigate the damage caused by the infringement;

(f) the risk to public health.

6. Where the Commission finds that the marketing authorisation holder has failed, intentionally or negligently, to comply with its obligations, as referred to in paragraph 1, it may adopt a decision imposing a fine not exceeding 5 % of the marketing authorisation holder's Union turnover in the business year preceding the date of that decision.

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Where the marketing authorisation holder continues to fail to comply with its obligations referred to in paragraph 1, the Commission may adopt a decision imposing periodic penalty payments per day not exceeding 2,5 % of the marketing authorisation holder's average daily Union turnover in the business year preceding the date of that decision.

Periodic penalty payments may be imposed for a period running from the date of notification of the relevant Commission's decision until the failure to comply with the obligation by the marketing authorisation holder, as referred to in paragraph 1, has been brought to an end.

7. When conducting the investigation on a failure to comply with any of the obligations referred to in paragraph 1, the Commission may cooperate with competent authorities of the Member States and rely on resources provided by the Agency.

8. Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders for the protection of their business secrets.

9. The Court shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. The Court may cancel, reduce or increase the fine or periodic penalty payment imposed by the Commission.

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10. The Commission is empowered to adopt delegated acts in accordance with Article 181 in order to supplement this Regulation by laying down:

(a) procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of the defence, access to file, legal representation and confidentiality;

(b) further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;

(c) rules on duration of procedure and limitation periods;

(d) elements to be taken into account by the Commission when setting the level of and imposing fines and periodic penalty payments, as well as the conditions and methods for their collection.

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Chapter XIII
Delegated and implementing acts

Article 179

Standing Committee on Medicinal Products for Human Use and examination procedure

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use established by Article 217 of Directive (EU) 2026/…[+]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where the opinion of the Standing Committee is to be obtained by written procedure and reference is made to this paragraph, that procedure shall be terminated without result only when, within the time limit for delivery of the opinion, the chair of the Standing Committee so decides.

4. The Standing Committee on Medicinal Products for Human Use shall ensure that its rules of procedure are adapted to the need to make medicinal products swiftly available to patients.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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Article 180

Implementing measures related to authorisation and pharmacovigilance activities

1. In order to harmonise electronic transmissions provided for in this Regulation, the Commission may adopt implementing measures covering the format and content of electronic transmissions by marketing authorisation holders.

   Those measures shall take account of the work on international harmonisation carried out in the area and shall, where necessary, be revised to take account of technical and scientific progress. Those measures shall be adopted in accordance with the examination procedure referred to in Article 179(2).

2. In order to harmonise the performance of the pharmacovigilance activities provided for in this Regulation, the Commission shall adopt implementing measures as provided for in Article 126 of Directive (EU) 2026/…[+] covering the following areas:

   (a) the content and maintenance of the pharmacovigilance system master file kept by the marketing authorisation holder;

   (b) the minimum requirements for the quality system for the performance of pharmacovigilance activities by the Agency;

   (c) the use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(d) the minimum requirements for the monitoring of data included in the Eudravigilance database to determine whether there are new risks or whether risks have changed;

(e) the format and content of electronic transmission of suspected adverse reactions by Member States and marketing authorisation holders;

(f) the format and content of electronic periodic safety update reports and risk management plans;

(g) the format of protocols, abstracts and final study reports of the post-authorisation safety studies.

Those measures shall take account of the work on international harmonisation carried out in the area of pharmacovigilance and shall, where necessary, be revised to take account of technical and scientific progress. Those measures shall be adopted in accordance with the examination procedure referred to in Article 179(2).

Article 181

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

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2. The power to adopt delegated acts referred to in Articles 3(5), 20(8), 22, 49(5), 51(2), 65(2), 69(2), 76(4), 77(3), 83(4), 120(3), 132(4), 144(2) and 178(10) shall be conferred on the Commission for a period of five years from … [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 3(5), 20(8), 22, 49(5), 51(2), 65(2), 69(2), 76(4), 77(3), 83(4), 120(3), 132(4), 144(2) and 178(10) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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6. A delegated act adopted pursuant to Articles 3(5), 20(8), 22, 49(5), 51(2), 65(2), 69(2), 76(4), 77(3), 83(4), 120(3), 132(4), 144(2) and 178(10) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

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Chapter XIV

Amendments to other legal acts

Article 182

Amendments to Regulation (EC) No 1394/2007

Regulation (EC) No 1394/2007 is amended as follows:

(1) Articles 5, 8 and 17 and Articles 20 to 23 are deleted;

(2) in Article 9(3), the fourth subparagraph is replaced by the following:

‘If the application does not include the results of the assessment, the Agency shall seek an opinion on the conformity of the device part with Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council* from a notified body identified in conjunction with the applicant, unless the Committee for Medicinal Products for Human Use advised by its experts for medical devices decides that involvement of a notified body is not required.

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* Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj).’;

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(3) the following article is inserted:

‘*Article 7a*

Adapted frameworks for advanced therapy medicinal products

The adapted frameworks established in accordance with Article 31 of Directive (EU) 2026/…[*+] of the European Parliament and of the Council may also apply for the purpose of obtaining a centralised marketing authorisation in accordance with Regulation (EU) 2026/…of the European Parliament and of the Council[**++].

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[*] Directive (EU) 2026/… of the European Parliament and of the Council of … on the Union code relating to medicinal products for human use, and repealing Directives 2001/83/EC and 2009/35/EC (OJ L, …, ELI: …).

[**] Regulation (EU) 2026/… of the European Parliament and of the Council of … laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006 (OJ L, …, ELI: …).’.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Directive, including its ELI number.

[++] OJ: Please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Regulation, including its ELI number.

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Article 183

Amendments to Regulation (EU) No 536/2014

Regulation (EU) No 536/2014 is amended as follows:

(1) the following article is inserted:

‘*Article 5a*

Environmental risk assessment for investigational medicinal products consisting of, or containing, genetically modified organisms (“GMOs”)

1. Where the application in accordance to Article 5 of this Regulation concerns clinical trials with investigational medicinal products for human use consisting of, or containing, genetically modified organisms as defined in Article 2, point (2), of Directive 2001/18/EC of the European Parliament and of the Council*, the sponsor shall submit an environmental risk assessment (ERA) in the EU portal.

2. The ERA referred to in paragraph 1 shall be conducted in accordance with the principles set out in Annex II to Directive 2001/18/EC and the scientific guidelines developed by the Agency in coordination with the competent authorities of the Member States, established in accordance with Directive 2001/18/EC for this purpose and the delegated act referred to in paragraph 8.

3. Articles 6 to 11 of Directive 2001/18/EC shall not apply to investigational medicinal products for human use consisting of, or containing, genetically modified organisms.

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4. The Committee for Medicinal Products for Human Use referred to in Article 155 of Regulation (EU) 2026/… of the European Parliament and of the Council[**+] shall assess the ERA referred to in paragraph 1 of this Article in the form of a scientific opinion. The Committee for Medicinal Products for Human Use shall submit its opinion to the competent authority of the reporting Member State within 45 days of the validation date referred to in Article 5(3) of this Regulation. Where appropriate, the opinion shall include risk mitigation measures. The sponsor shall provide evidence to the reporting Member State and the Member States concerned that these measures will be implemented.

5. The Committee for Medicinal Products for Human Use may request, with justified reasons, via the EU portal, additional information from the sponsor regarding the assessment referred to in paragraph 1 of this Article, which shall be provided only within the period referred to in Article 6(5), points (a) and (b).

[+] OJ: Please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Regulation, including its ELI number.

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6. To obtain and review the additional information referred to in paragraph 5, the Agency may extend the period referred to in that paragraph by a maximum of 31 days. The sponsor shall submit the requested additional information within the period set by the Agency. Where the sponsor does not provide that information within the period set by the Agency, the application referred to in paragraph 1 shall be deemed to have expired in all Member States concerned. The Agency shall inform the reporting Member State via the EU portal and the Member States concerned about the extension of the period referred to in paragraph 5 in accordance with this paragraph as well as the period set for the sponsor to submit the requested information.

7. In the case of first-in-class products or when a novel question arises during the assessment of the submitted ERA as referred to in paragraph 1, the Agency shall, if necessary, consult with bodies that Member States have set up in accordance with Directive 2001/18/EC or Directive 2009/41/EC of the European Parliament and of the Council***. If a consultation is necessary, a technical dossier addressing in sufficient detail the information specified in Annex III to Directive 2001/18/EC shall be included to support the ERA, where appropriate.

8. The Commission shall be empowered to adopt a delegated act in accordance with Article 89 to supplement this Regulation in order to specify the procedure for the submission and the harmonised assessment of the ERA for investigational medicinal products consisting of, or containing, genetically modified organisms as set out in paragraphs 1 to 8 of this Article.

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The delegated act referred to in the first subparagraph shall establish that the ERA constitutes an independent part of the application referred to in paragraph 1.

The delegated act referred to in the first subparagraph shall specify the content of the ERA taking into account the common application forms and Good Practice Documents for genetically modified human cells and for adeno-associated viral vectors that were published by the Agency.

The delegated act referred to in the first subparagraph shall contain a provision to update the ERA requirements for investigational medicinal products consisting of, or containing, genetically modified organisms following scientific developments and changes of Directive 2001/18/EC.

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* Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC(OJ L 106, 17.4.2001, p. 1, http://data.europa.eu/eli/dir/2001/18/oj).

** Regulation (EU) 2026/… of the European Parliament and of the Council of … laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006 (OJ L, …, ELI: …).

*** Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75, ELI: http://data.europa.eu/eli/dir/2009/41/oj).’;

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(2) in Article 6(1), the following point is inserted:

‘(ca) If requested by an applicant, whether the investigational medicinal product can be manufactured through decentralised manufacturing;’;

(3) in Article 6(1), the following subparagraph is added:

‘When assessing a request pursuant to the first subparagraph, point (ca), of this paragraph to use decentralised manufacturing, Article 29(1) of Directive (EU) 2026/…[*+] of the European Parliament and of the Council shall apply *mutatis mutandis*. The Commission may specify by means of an implementing act the detailed arrangements for the application of that Article. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 88(2) of this Regulation.

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[*] Directive (EU) 2026/… of the European Parliament and of the Council of … on the Union code relating to medicinal products for human use, and repealing Directives 2001/83/EC and 2009/35/EC (OJ L, …, ELI: …).’;

(4) in Article 25(1), point (d) is replaced by the following:

‘(d) measures to protect subjects, third persons and the environment;’;

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Directive, including its ELI number.

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(5) Article 26 is replaced by the following:

‘*Article 26*

Language requirements

The language of the application dossier, or parts thereof, shall be determined by the Member State concerned.

The language for the environmental risk assessment (ERA) shall preferably be English.

Member States, in applying the first subparagraph, shall consider accepting, for the documentation not addressed to the subject, a commonly understood language in the medical field.’;

(6) in Article 37(4), the following subparagraph is inserted after the first subparagraph:

‘In the case of a clinical trial which involves the use of a medicinal product in the paediatric population, the time limit referred to in the first subparagraph to submit to the EU database a summary of the results of the clinical trial shall be six months.’;

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(7) Article 61 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The manufacturing and import of investigational medicinal products in the Union shall be subject to the holding of an authorisation.

In the case of decentralised manufacturing as referred to in Article 6(1), point (ca), the manufacturing authorisation shall not be required for decentralised sites carrying out manufacturing steps, including testing under the responsibility of a qualified person of a central site as referred to in paragraph 2, point (b), of this Article.

The holder of the manufacturing authorisation for a central site responsible for decentralised manufacturing of the investigational medicinal products shall ensure that the activities of the central site and decentralised sites are compliant with the good manufacturing practice for investigational medicinal products referred to in Article 63(1).

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However, the import of investigational medicinal products from other parts of the United Kingdom into Northern Ireland and, until 31 December 2024, into Cyprus, Ireland and Malta shall not be subject to the holding of such an authorisation provided that all of the following conditions are fulfilled:

(a) the investigational medicinal products have undergone certification of batch release either in the Union or in parts of the United Kingdom other than Northern Ireland to verify compliance with the requirements set out in Article 63(1);

(b) the investigational medicinal products are only made available to subjects in the Member State into which those investigational medicinal products are imported or, if imported into Northern Ireland, are only made available to subjects in Northern Ireland.';

(b) in paragraph 2, point (a) is replaced by the following:

'(a) it shall have at its disposal, for manufacture or import, suitable and sufficient premises, technical equipment and control facilities complying with the requirements set out in this Regulation and, where appropriate, in the case of investigational medicinal products consisting of, or containing, genetically modified organisms, in Directive 2009/41/EC;';

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(c) the following paragraph is added:

‘3a. The Commission shall adopt delegated acts supplementing this Regulation by specifying the particulars required in an application for a manufacturing authorisation for a central site responsible for decentralised manufacturing of investigational medicinal products, pursuant to this Article and Article 6(1), point (ca), as well as the arrangements of the registration process for the decentralised sites and clarifying the arrangements of the manufacturing authorisation holder for a central site as well as sponsors as regards the registration and supervision of those decentralised sites.’;

(d) paragraph 4 is replaced by the following:

‘4. Article 146(1), (2), (4) and (5), Articles 148, 149 and 150, Article 151(1), points (a), (b), (d), (e) and (f), and Article 152(9) to (13) of Directive (EU) 2026/…[+] shall apply *mutatis mutandis* to the authorisation referred to in paragraph 1.’;

(8) in Article 66(1), point (c) is replaced by the following:

‘(c) information to identify the medicinal product, including, where appropriate, the text “This IMP contains genetically modified organisms.”;’;

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(9) Article 89 is amended as follows:

(a) paragraphs 2 and 3 are replaced by the following:

‘2. The power to adopt delegated acts referred to in Articles 6, 28, 40, 47, 65(1) and 72 shall be conferred on the Commission for a period of five years from the date referred to in the second subparagraph of Article 101(2). The Commission shall draw up a report in respect of the delegated powers not later than nine months before the end of the five-year period. The delegation of powers shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 6, 28, 40, 47, 65(1), and 72 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.’;

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(b) the following paragraph is inserted:

‘3a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission of 13 April 2016 on Better Law-Making*.

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* OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.’;

(c) paragraph 5 is replaced by the following:

‘5. A delegated act adopted pursuant to Articles 6, 28, 40, 47, 65(1), and 72 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.’;

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(10) Article 91 is replaced by the following:

'*Article 91*

Relation with other Union legal acts

This Regulation shall be without prejudice to Council Directive 97/43/Euratom[*], Council Directive 96/29/Euratom[**], Directive 2004/23/EC of the European Parliament and of the Council[***], Directive 2002/98/EC of the European Parliament and of the Council[****] and Directive 2010/53/EU of the European Parliament and of the Council[*****].

In the context of inspections referred to in Article 54(3) of Regulation (EU) 2026/…[+] the criteria set out in Annex III to that Regulation shall apply *mutatis mutandis*.

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[*] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22, ELI: http://data.europa.eu/eli/dir/1997/43/oj).

[**] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (OJ L 159, 29.6.1996, p. 1, ELI: http://data.europa.eu/eli/dir/1996/29/oj).

[+] OJ: Please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)).

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*** Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48, ELI: http://data.europa.eu/eli/dir/2004/23/oj).

**** Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 033, 8.2.2003, p. 30, ELI: http://data.europa.eu/eli/dir/2002/98/oj).

***** Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14, ELI: http://data.europa.eu/eli/dir/2010/53/oj).';

(11) in Annex I, section B, the following paragraph is inserted:

'8a. The cover letter shall indicate whether – and, if yes, why – the decentralised manufacturing of investigational medicinal products has been proposed by the sponsor.'.

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Article 184

Amendments to Regulation (EU) 2022/123

Regulation (EU) 2022/123 is amended as follows:

(1) in Article 18, the following paragraph is added:

‘7. Where a request has been made in accordance with Article 18(3) of this Regulation and there is an application for a temporary emergency marketing authorisation for the medicinal product concerned in accordance with Article 31 of Regulation (EU) 2026/… of the European Parliament and of the Council[*+], the procedure initiated under that Regulation shall prevail.

[*] Regulation (EU) 2026/… of the European Parliament and of the Council of … laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006 (OJ L, …, ELI: …).’;

(2) Articles 33 and 34 are deleted.

[+] OJ: Please insert in the text the number of the Regulation in document ST 7105/26 (2023/0131(COD)) and in the corresponding footnote the number, date of adoption and publication reference of that Regulation, including its ELI number.

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Chapter XV
Final provisions

Article 185

Repeals

1. Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006 are repealed.

   References to the repealed Regulations shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex V.

2. Commission Implementing Regulation (EU) No 198/2013[54] is repealed.

Article 186

Transitional provisions

1. The provisions of Article 121 of this Regulation shall also apply to marketing authorisations for medicinal products for human use granted in accordance with Regulation (EC) No 726/2004 and in accordance with Directive 2001/83/EC of the European Parliament and of the Council[55] before … [the date of application of this Regulation].

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[54] Commission Implementing Regulation (EU) No 198/2013 of 7 March 2013 on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring (OJ L 65, 8.3.2013, p. 17, ELI: http://data.europa.eu/eli/reg_impl/2013/198/oj).

[55] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

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2. The procedures concerning the applications for marketing authorisations for medicinal products for human use that have been submitted, before … [date of application of this Regulation] and that were pending on … [the day before the date of application of this Regulation] shall be completed in accordance with Article 10 of Regulation (EC) No 726/2004.

3. Procedures concerning imposed post-authorisation studies that were initiated in accordance with Article 10a of Regulation (EC) No 726/2004, before … [date of application of this Regulation] and that were pending on … [the day before the date of application of this Regulation] shall be completed in accordance with Article 21 of this Regulation.

4. For medicinal products authorised before … [the day before the date of application of this Regulation] and for which the validity expires after that date, the renewal of the marketing authorisation shall follow the procedures referred to in Article 18.

5. By way of derogation from Article 187, second paragraph, of this Regulation the periods of regulatory protection referred to in Article 30 of this Regulation shall not apply to reference medicinal products for which an application for marketing authorisation has been submitted before … [the date of application of this Regulation]. Article 14(11) of Regulation (EC) No 726/2004 shall continue to apply to them.

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6. By way of derogation from Article 187, second paragraph, of this Regulation, the reporting obligations as referred to in Article 60 of Directive (EU) 2026/…[+], shall not apply with regard to medicinal products authorised in accordance with this Regulation before … [36 months from the date of entry into force of this Regulation].

7. Orphan designations granted before … [the date of application of this Regulation], entered into and not removed from the Community Register of Orphan Medicinal Products in accordance with Article 5, paragraphs 8 and 12, respectively, of Regulation (EC) No 141/2000 and not granted a marketing authorisation in accordance with Article 7(3) of Regulation (EC) No 141/2000 corresponding to the orphan designation shall be considered to comply with this Regulation and shall be entered into the Register of Designated Orphan Medicinal Products.

8. Orphan designations granted before … [the date of application of this Regulation] which are either removed from the Community Register of Orphan Medicinal Products in accordance with Article 5(12) of Regulation (EC) No 141/2000 or granted a marketing authorisation in accordance with Article 7(3) of Regulation (EC) No 141/2000 shall not be considered to be orphan designations and shall not be entered into the register of designated orphan medicinal products.

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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9. The seven-year validity of an orphan designation referred to in Article 68 of this Regulation for orphan medicinal products granted before … [the date of application of this Regulation], entered into and not removed from the Community Register of Orphan Medicinal Products in accordance with Article 5(8) and (12), respectively, of Regulation (EC) No 141/2000 and not granted a marketing authorisation in accordance with Article 7(3) of Regulation (EC) No 141/2000 corresponding to the orphan designation shall begin to run from … [the date of application of this Regulation].

10. By way of derogation from Article 187, second paragraph, of this Regulation, the periods of market exclusivity referred to in Article 73(2) of this Regulation shall not apply for orphan medicinal products for which an application for marketing authorisation has been submitted before … [the date of application of this Regulation]. Those orphan medicinal products shall benefit from the period referred to in Article 8(1) of Regulation (EC) No 141/2000. This derogation shall only apply to the initial marketing authorisation.

However, any other application for an orphan medicinal product containing the same active substance submitted before … [the date of application of this Regulation], shall be subject to the provisions of this Regulation with regard to the market exclusivity periods, in particular Article 73(3) and Article 74.

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11. When a paediatric investigation plan, a waiver or a deferral has been granted in accordance with Regulation (EC) No 1901/2006 before … [the date of application of this Regulation], it shall be considered to comply with this Regulation.

The procedures concerning the application for a paediatric investigation plan, a waiver or a deferral submitted before … [the date of application of this Regulation], shall be completed in accordance with Regulation (EC) No 1901/2006.

12. Regulations (EC) No 2141/96, (EC) No 2049/2005, (EC) No 507/2006 and (EC) No 658/2007 shall remain in force and continue to apply unless and until repealed.

13. Regulation (EC) No 1234/2008 shall continue to apply unless and until repealed as regards medicinal products for human use that are covered by Regulation (EC) No 726/2004 and Directive 2001/83/EC and that are not excluded from the scope of Regulation (EC) No 1234/2008 pursuant to Article 23b(4) and (5), of Directive 2001/83/EC.

14. Commission Regulation (EC) No 847/2000[56] shall continue to apply unless and until repealed as regards orphan medicinal products that are covered by this Regulation.

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[56] Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts ‘similar medicinal product’ and ‘clinical superiority’ (OJ L 103, 28.4.2000, p. 5, ELI: http://data.europa.eu/eli/reg/2000/847/oj).

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15. By way of derogation from Article 44, data exclusivity vouchers granted before … [15 years from the date of entry into force of this Regulation] or before the date when the Commission has granted a total of five data exclusivity vouchers in accordance with Chapter III, whichever date is the earliest, shall continue to be valid according to the conditions set out in Chapter III.

16. Marketing authorisations for medicinal products authorised in accordance with Article 6(1) of Directive 2001/83/EC shall be deemed to have been issued in accordance with Article 6(1) of Directive (EU) 2026/…[+], irrespective of whether those medicinal products are covered by Annex I to this Regulation.

Article 187

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from … [24 months from the date of entry into force of this Regulation. OJ: please make sure that the date is identical to the date of application of the Directive contained in document ST 7106/26 (2023/0132(COD))].

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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However:

(a) Article 69 shall apply from … [six months from the date of application of this Regulation];

(b) Articles 41 to 45, Articles 116 to 119, Articles 133 to 140, Article 147 and Article 161(5) shall apply from the date of entry into force of this Regulation;

(c) Articles 120 to 132 shall apply from … [six months from the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at …,

For the European Parliament	*For the Council*
The President	*The President*

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ANNEX I

Medicinal products to be authorised by the Union

1. Medicinal products developed by means of one of the following biotechnological processes:

   – recombinant nucleic acid technology,

   – controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells.

2. Advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007.

3. Medicinal products for human use containing a new active substance which on … [date of application of this Regulation] was not authorised in the Union, excluding allergen medicinal products or herbal medicinal products.

4. Medicinal products for human use containing a new active substance, which on 20 May 2004 was not authorised in the Union and which is not covered by point 3, for which the therapeutic indication is the treatment of any of the following diseases:

   – acquired immune deficiency syndrome,

   – cancer,

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– neurodegenerative disorder,

– diabetes,

– auto-immune diseases and other immune dysfunctions,

– viral diseases.

5. Designated orphan medicinal products.

6. Medicinal products authorised in accordance with a paediatric use marketing authorisation.

7. Priority antimicrobials as referred to in Article 41.

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ANNEX II

List of the obligations referred to in Article 178

(1) the obligation to submit complete and accurate particulars and documents in an application for marketing authorisation submitted to the Agency or in response to obligations laid down in this Regulation to the extent that the failure to comply with the obligation concerns a material particular;

(2) the obligation to comply with conditions or restrictions included in the marketing authorisation and concerning the supply or use of the medicinal product for human use, as referred to in Article 13(4), point (c), and in Article 14(1), fourth subparagraph;

(3) the obligation to comply with conditions or restrictions included in the marketing authorisation with regard to the safe and effective use of the medicinal product for human use as referred to in Article 13(4), points (b), (d), (e), (f) and (g), and in Article 14(1);

(4) the obligation to introduce any necessary variation to the terms of the marketing authorisation to take account of technical and scientific progress and enable the medicinal products for human use to be manufactured and checked by means of generally accepted scientific methods, as provided for in Article 47(1);

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(5) the obligation to supply any new information which can entail a variation to the terms of the marketing authorisation, to notify any prohibition or restriction imposed by the competent authorities of any Member State or third country in which the medicinal product for human use is made available on the market, or to supply any information that can influence the evaluation of the risks and benefits of the medicinal product, as provided for in Article 47(2);

(6) the obligation to keep product information up to date with current scientific knowledge, including the conclusions of the assessment and recommendations made public on the European medicines web-portal, as provided for in Article 47(3);

(7) the obligation to provide, at the request of the Agency, any data demonstrating that the benefit-risk balance remains favourable, as provided for in Article 47(5);

(8) the obligation to place the medicinal product for human use on the market in accordance with the content of the summary of product characteristics and the labelling and package leaflet as contained in the marketing authorisation;

(9) the obligation to comply with the conditions referred to in Article 19(1) and Article 20;

(10) the obligation to notify the Agency of the dates of placing on the market and to provide to the Agency data relating to the volume of sales and the volume of medical prescriptions of the medicinal product for human use, as provided in Article 17(4);

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(11) the obligation to operate a comprehensive pharmacovigilance system for the fulfilment of pharmacovigilance tasks, including the operation of a quality system, maintenance of a pharmacovigilance system master file and performance of regular audits, in accordance with Article 101 of this Regulation in conjunction with Article 102 of Directive (EU) 2026/…[+];

(12) the obligation to submit, at the request of the Agency, a copy of the pharmacovigilance system master file, as provided for in Article 47(5);

(13) the obligation to operate a risk management system as provided for in Article 23 and Article 101(2) of this Regulation in conjunction with Article 102(4) of Directive (EU) 2026/…[+];

(14) the obligation to record and report suspected adverse reactions for medicinal products for human use, in accordance with Article 109(1) of this Regulation in conjunction with Article 108 of Directive (EU) 2026/…[+];

(15) the obligation to submit periodic safety update reports, in accordance with Article 109(2) of this Regulation in conjunction with Article 111 of Directive (EU) 2026/…[+];

(16) the obligation to conduct post-authorisation studies, including post-authorisation safety studies, post-authorisation efficacy studies and post-authorisation environmental risk assessment studies, and to submit them for review, as provided for in Article 21;

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(17) the obligation to ensure that public announcements relating to information on pharmacovigilance concerns are presented objectively and are not misleading and to notify them to the Agency, as provided for in Article 107 of Directive (EU) 2026/…[+];

(18) the obligation to comply with the time limits for initiating or completing measures specified in the Agency's decision on deferral following the initial marketing authorisation of the medicinal product for human use concerned and in accordance with the definitive opinion referred to in Article 83(2);

(19) the obligation to submit to the Agency an updated version of the paediatric investigation plan in accordance with the agreed timing as provided for in Article 76(2) and Article 76(3);

(20) the obligation to place the medicinal product for human use on the market within two years of the date on which the paediatric indication is authorised, as provided for in Article 62 of Directive (EU) 2026/…[+];

(21) the obligation to notify the Agency the intention to discontinue the placing on the market of the product no less than 12 months before the discontinuation as provided for in Article 63 of Directive (EU) 2026/…[+];

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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(22) the obligation to transfer the marketing authorisation or to allow a third party to use documentation contained in the file of the medicinal product, as provided for in Article 63 of Directive (EU) 2026/…[+];

(23) the obligation to notify the Agency of the intention to discontinue the conduct of an agreed paediatric investigation plan and provide the reasons for such discontinuation no less than six months before the discontinuation as provided in Article 90;

(24) the obligation to submit paediatric studies to the Agency or to the Member States, including the obligation to enter information on third country clinical trials into the EU database, as provided for in Article 96;

(25) the obligation to submit to the Agency a paediatric investigation plan with a request for agreement or an application for a waiver from it, before the initiation of safety and efficacy clinical studies, except in duly justified cases, as provided for in Article 78(1);

(26) the obligations in accordance with Article 120(1), first subparagraph, points (a), (b), (c) and (d), Article 121, Article 123, Article 130, Article 134 and Article 139;

(27) the obligations to report on financial support and research and development costs as laid down in Article 60 of Directive (EU) 2026/…[+].

[+] OJ: Please insert in the text the number of the Directive in document ST 7106/26 (2023/0132(COD)).

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ANNEX III

Inspections in the interest of the Union

An inspection is in the interest of the Union when there is a need to ensure faster or continuous access to medicinal products for patients and when the inspection is justified based on at least one of the following grounds:

(a) to prevent, mitigate or address shortages of medicinal products, or their active substances or other supply issues;

(b) to prevent, mitigate or address a possible threat to public health, a public health emergency or a major event which requires immediate action;

(c) to address a suspicion of non-compliance of the manufacturing site; or

(d) to enable the process of granting the marketing authorisation for centrally authorised products/emergency use authorisation and for their active substance master files.

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ANNEX IV

Definitions

For the purposes of Part II and Part IV of this Annex, the following definitions apply:

(1) ‘supply’ means ‘supply’ as defined in Article 2, point (f), of Regulation (EU) 2022/123;

(2) ‘demand’ means, in relation to medicinal products, ‘demand’ as defined in Article 2, point (g), of Regulation (EU) 2022/123.

AVAILABILITY

Part I

Information to be provided in the case of a suspension
or cessation of marketing of a medicinal product
or withdrawal of the marketing authorisation of a medicinal product

For the purposes of the notification in accordance with Article 120(1), first subparagraph, points (a), (b) and (c), the marketing authorisation holder shall notify at least the following information:

(1) Medicinal product details:

(a) Product name;

(b) Active substances and active substance suppliers;

(c) Finished product manufacturer;

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(d) Anatomical Therapeutic Chemical (ATC) code;

(e) Therapeutic indications;

(f) Pharmaceutical form;

(g) Strengths;

(h) Route(s) of administration;

(i) Affected pack sizes;

(j) Alternative, pharmaceutical form, strength, route of administration or pack size, not affected by the suspension, cessation or withdrawal;

(k) Details of authorisation: procedure type (national (including Member States involved) / centralised marketing authorisation) and marketing authorisation number;

(l) Member States in which the product is placed on the market.

(2) Details of action (suspension, cessation or withdrawal):

(a) Category of action (suspension, cessation or withdrawal);

(b) Available stock up to start date of action;

(c) Start date of action, per Member State;

(d) Reason for action and information on alternative medicinal products, where relevant;

(e) Impacted EU/ EEA countries;

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(f) Reference to pending regulatory action, Rapid Alert (quality/ safety) or Quality Defect Report related to the action, if relevant;

(g) Other competent authorities of the Member States and the Agency notified;

(h) Any actions completed or planned based on a request of the competent authorities of the Member State concerned.

(3) Contact details

(a) Marketing authorisation holder name and address;

(b) Name and contact details of person notifying.

Part II

Risk assessment of impact of suspension, cessation or withdrawal

For the purposes of the request made by the competent authority concerned in accordance with Article 122(2), the marketing authorisation holder shall notify at least the following information:

(1) Risk assessment of impact of suspension, cessation or withdrawal, including:

(a) Potential alternative medicinal products;

(b) Estimated market share per Member State in previous 12 months;

(c) Quantities delivered per month per Member State in previous 12 months;

(d) Manufacturing capacity globally per manufacturing site;

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(e) Forecast of supply per month and per Member State until suspension, cessation or withdrawal occurs;

(f) Forecast of demand per month and per Member State in the next six months;

(g) Impact on the supply of other medicinal products from the same marketing authorisation holder;

(h) Potential impact on the consumption of or demand for other medicinal products.

(2) Any risk-mitigating measures taken by the marketing authorisation holder to address the shortage.

Part III

Information to be provided in the case of a temporary disruption of supply

For the purposes of the notification in accordance with Article 120(1), first subparagraph, point (d), the marketing authorisation holder shall notify at least the following information:

(1) Product details

(a) Product name;

(b) Active substances and active substance manufacturers;

(c) Finished product manufacturer;

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(d) Therapeutic indications;

(e) ATC code;

(f) Pharmaceutical form;

(g) Strengths;

(h) Routes of administration;

(i) Affected pack size;

(j) Alternative, pharmaceutical form, strength, route of administration or pack size, not affected by the supply disruption;

(k) Details of authorisation: procedure type (national (including Member States involved) / centralised marketing authorisation) and marketing authorisation number;

(l) Member States in which the product is placed on the market.

(2) Details of supply disruption

(a) Shortage status (actual, expected or potential);

(b) Available stock per month;

(c) Expected start date of shortage by Member State;

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(d) Expected end date of shortage by Member State;

(e) Reason for shortage providing information on:

(i) Manufacturing issues including, but not limited to:

– Unavailability of active pharmaceutical ingredient

– Unavailability of excipients

– Unavailability of other materials, including raw materials

– Issues with the equipment

– Delay in the release of the finished product

– GMP non-compliance

– Manufacturing site transfer

– Capacities issues

– Other manufacturing issues

(ii) Quality issues;

(iii) Distribution issues, including but not limited to:

– Export restrictions/bans

– Import/export delays

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– Transport issues

– GDP non-compliance

– Other distribution issues

(iv) Unexpected increase in demand, including but not limited to:

– Changes in prescribing behaviour

– Unavailability from other MAHs

– Other issues related to increased demand

(v) Commercial reasons; including but not limited to:

– Change of the MAH Business strategy

– Insolvency proceedings of the manufacturer or MAH

– Other commercial reasons

(vi) Regulatory issues, such as:

– Pending variation to the terms of the marketing authorisation

– Other regulatory issues

(vii) any other reasons.

(f) Impacted EU/ EEA countries and, where available, other impacted third countries;

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(g) Reference to pending regulatory action, Rapid Alert (quality/ safety) or Quality Defect Report related to the action, if relevant;

(h) Other competent authorities of the Member States or the Agency notified;

(i) Any actions completed or planned based on a request by the competent authorities of the Member State concerned.

(3) Contact details

(a) Marketing authorisation holder name and address;

(b) Name and contact details of person notifying.

Part IV

The Shortage Mitigation Plan

For the purposes of the request made by the competent authority concerned in accordance with Article 122(2), the marketing authorisation holder shall notify at least the following information:

Shortage mitigation plan, detailing the risk assessment of impact of shortage, including, where available:

(a) Potential alternative medicinal products;

(b) Estimated market share by Member State in the previous 12 months;

(c) Quantities delivered per month per Member State, in the previous 12 months;

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(d) Manufacturing capacity globally per manufacturing site;

(e) Forecast of supply per month and per Member State for the duration of the shortage,

(f) Forecast of demand per month and per Member State for the duration of the shortage;

(g) Impact on the supply of other medicinal products from the same marketing authorisation holder;

(h) Potential impact on the consumption of or demand for other medicinal products;

(i) Any risk-mitigating measures taken or planned by the marketing authorisation holder to address the shortage.

Part V

The shortage prevention plan

The Shortage Prevention Plan referred to in Article 121 shall include at least the following information:

(1) Product details:

(a) Product name;

(b) Active substances and active substance manufacturers;

(c) Finished product manufacturer;

(d) ATC code;

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(e) Therapeutic indications;

(f) Pharmaceutical form;

(g) Strengths;

(h) Routes of administration;

(i) Pack sizes;

(j) Details of authorisation: procedure type (national (including Member States involved) / centralised marketing authorisation) and marketing authorisation number;

(k) Member States in which the product is placed on the market.

(2) Shortage prevention measures and supply chain risk assessment:

(a) Patient impact of potential supply disruptions, considering therapeutic indication and alternative marketed medicinal products and estimated market share by Member States in the previous 12 months;

(b) Supply chain risk assessment, including:

(i) Supply chain map, including the list of manufacturing sites, their location and share of production volumes per manufacturing site at the different steps of manufacturing process with particular attention to supply chain vulnerabilities and dependencies;

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(ii) A record of root causes of resolved shortages and mitigation measures taken for those shortages;

(c) Final risk classification (low, medium, high) covering both supply chain vulnerability and public health impact, with separate risk classification if necessary.

(3) Shortage management measures, including:

(a) a risk control strategy in place, to include information on strategies to minimise risks of shortages and how these are implemented;

(b) a process for the detection and notification of supply disruptions.

(4) Process for check of effectiveness, review and update of the shortage prevention plan.

(5) Methodology for establishing the demand forecast.

(6) Contact details

(a) Name and address of marketing authorisation holder;

(b) Name and contact details of contact person.

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ANNEX V

Correlation table

Regulation (EC) No 726/2004	Directive 2001/83/EC	Regulation (EC) No 141/2000	Regulation (EC) No 1901/2006	This Regulation
Article 1				Article 1
	Article 1, point (2)			Article 2, point (1)
				Article 2, point (2)
				Article 2, point (3)
	Article 1, point (3)			Article 2, point (4)
	Article 1, point (3a)			Article 2, point (5)
				Article 2, point (6)
	Article 1, point (6)			Article 2, point (7)
	Article 10(2), point (a)			Article 2, point (8)
	Article 1, point (5)			Article 2, point (9)
	Article 1, point (26)			Article 2, point (10)
	Article 1, point (25)			Article 2, point (11)
				Article 2, point (12)

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Regulation (EC) No 726/2004	Directive 2001/83/EC	Regulation (EC) No 141/2000	Regulation (EC) No 1901/2006	This Regulation
				Article 2, point (13)
				Article 2, point (14)
				Article 2, point (15)
	Article 1, point (15)			Article 2, point (16)
	Article 1, point (11)			Article 2, point (17)
				Article 2, point (18)
	Article 1, point (28a)			Article 2, point (19)
	Article 1, point (28c)			Article 2, point (20)
	Article 1, point (28b)			Article 2, point (21)
	Article 1, point (28d)			Article 2, point (22)
	Article 1, point (28e)			Article 2, point (23)
				Article 2, point (24)
	Article 1, point (26a)			Article 2, point (25)
				Article 2, point (26)
				Article 2, point (27)
				Article 2, point (28)

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Regulation (EC) No 726/2004	Directive 2001/83/EC	Regulation (EC) No 141/2000	Regulation (EC) No 1901/2006	This Regulation
				Article 2, point (29)
				Article 2, point (30)
				Article 2, point (31)
	Article 1, point (4)(b)			Article 2, point (32)
				Article 2, point (33)
				Article 2, point (34)
				Article 2, point (35)
		Article 2, point (b)		Article 2, point (36)
		Article 2, point (c)		Article 2, point (37)
				Article 2, point (38)
				Article 2, point (39)
				Article 2, point (40)
				Article 2, point (41)
	Article 10(2), point (b)			Article 2, point (42)
				Article 2, point (43)
			Article 2, point (2)	Article 2, point (44)

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Regulation (EC) No 726/2004	Directive 2001/83/EC	Regulation (EC) No 141/2000	Regulation (EC) No 1901/2006	This Regulation
			Article 2, point (1)	Article 2, point (45)
	Article 1, point (22)			Article 2, point (46)
			Article 2, point (4)	Article 2, point (47)
Article 3(1)				Article 3(1)
Article 3(2), point (b)				Article 3(2), introductory sentence and point (a)
				Article 3(2), points (b), (c) and (d)
Article 4(2)				Article 3(4)
				Article 3(5)
Article 3(3), introductory sentence, points (a) and (b)				Article 4, introductory sentence and first paragraph, points (a) and (b)
				Article 4, second paragraph, point (c)
Article 2, second subparagraph				Article 5(1)

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Regulation (EC) No 726/2004	Directive 2001/83/EC	Regulation (EC) No 141/2000	Regulation (EC) No 1901/2006	This Regulation
				Article 5(2) to(7)
				Article 6
Article 6(1)				Article 7(1)
				Article 7(2)
Article 6(1), second subparagraph				Article 7(3)
				Article 7(4) and (5)
Article 6(3)				Article 7(6)
Article 14(9), first subparagraph, second sentence				Article 7(7), first subparagraph
Article 14(9), second subparagraph				Article 7(7), second subparagraph
				Article 7(8)
				Article 8
				Article 9
				Article 10

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Regulation (EC) No 726/2004	Directive 2001/83/EC	Regulation (EC) No 141/2000	Regulation (EC) No 1901/2006	This Regulation
Article 7				Article 11(1), points (a) and (b)
				Article 11(2)
				Article 11(3)
Article 8(1)				Article 12(1)
Article 8(2), first and second subparagraph				Article 12(2), first and second subparagraph
				Article 12(2), third subparagraph
Article 9(1)				Article 13(1)
Article 9(2), first subparagraph				Article 13(2), first subparagraph
Article 62(1), fifth subparagraph, second sentence				Article 13(2), second subparagraph
Article 9(2), second subparagraph				Article 13(2), third subparagraph
Article 9(3)				Article 13(3)

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Regulation (EC) No 726/2004	Directive 2001/83/EC	Regulation (EC) No 141/2000	Regulation (EC) No 1901/2006	This Regulation
Article 9(4)				Article 13(4), points (a) to (m)
				Article 13(4), point (n)
Article 14(10)				Article 13(5)
Article 10(1)				Article 14(1)
Article 10				Article 14(2) to (4)
Article 11				Article 15
Article 12				Article 16
Article 13				Article 17(1), (2) and Article 17 (3) point (a) and (c), and Article 17(4)
				Article 17(3), point (c)
Article 14(1)				Article 18(1)
Article 14(2)				Article 18(2)
Article 14(8)				Article 19
Article 14-a(1)				Article 20(1)

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