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NOTE

From:	Permanent Representatives Committee (Part 1)
To:	Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 - General Approach

INTRODUCTION

1. On 11 March 2025, the Commission submitted to the Council and the European Parliament a proposal for a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest[1]. This proposal, referred to as the Critical Medicines Act (CMA), was adopted alongside a guidance on the application of state aid rules in the context of the CMA.

[1] 6872/25

The proposal was submitted without an Impact Assessment but a Commission staff working document[2] was published on 2 September 2025 summarising the evidence supporting the legislative proposal.

2. The objectives of the proposal, which complements the ongoing revision of the EU pharmaceutical legislation, are to improve the functioning of the internal market by establishing a framework to strengthen the security of supply and the availability of critical medicinal products within the Union. It further aims to improve the availability and accessibility of other medicinal products where the functioning of the market does not otherwise sufficiently ensure this, whilst giving due consideration to the affordability of those medicinal products.

3. The draft Regulation is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).

4. The European Economic and Social Committee delivered its opinion[3] on 18 June 2025. The opinion of the European Committee of the Regions was requested on 11 June 2025 and it is pending.

5. The Senate of the Parliament of the Czech Republic and the Spanish Parliament, each submitted a positive assessment while raising concerns on certain aspects. The Romanian Senate submitted an opinion raising proportionality concerns and making several recommendations. The Italian Senate submitted two resolutions, being one positive and another raising proportionality concerns. The Italian Chamber of Deputies also submitted an opinion raising proportionality concerns. The Swedish Parliament and the French Senate, each submitted a reasoned opinion raising subsidiarity concerns on parts of the proposal.

6. In the European Parliament, the Committee on Public Health (SANT) has the lead responsibility. MEP Tomislav Sokol (EPP, HR) was appointed rapporteur.

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[2] 12444/25
[3] 10782/25

STATE OF PLAY

7. The Polish Presidency organised one meeting of the Working Party on Pharmaceuticals and Medical Devices dedicated to presenting the proposal and held a policy debate at EPSCO (Health) Council on 20 June 2025[4]. The Danish Presidency has devoted 10 Working Party meetings spread over 14 days to the file concluding the first examination and tabling several revised texts. In addition, Coreper at its meeting on 15 October 2025[5] provided further guidance on the demand-side measures (Chapter IV) of the proposal.

8. Based on the examination of the proposal and of the revised texts, on written comments from delegations and building on discussions in the Working Party and on the guidance provided by the Coreper, the Danish Presidency put forward a full revised text which was examined by the Working Party at its meeting on 6 November 2025.

9. Key issues addressed throughout the entire examination were:
   - In Chapters I-II (General provisions): clarifying and adding definitions such as contingency stock requirements or collecting; clarifying what applies to medicines of common interest, and deleting Article 4 on the strategic objectives of the Union to instead refer to this in the recitals;
   - In Chapter III (Enabling conditions for investments): centralising the recognition of a strategic project through the designated authorities and adapting the number of designated authorities to national contexts, clarifying what does administrative and regulatory support entails, specifying that the financial support terms should include what happens if a medicinal product is removed from the Union list and making mandatory that Commission informs the Critical Medicines Coordination Group (CMCG) of possible funding possibilities;

[4] 9066/25
[5] 13579/25

- In Chapter IV (Demand-side measures): enhancing legal clarity and coherence by aligning terminology with the Public Procurement Directive, the introduction of clarifying specifications of resilience requirements for public procurements procedures that goes beyond the price only award criteria and giving further flexibility on the form that those requirements should take, detailing and expanding the exceptions for not applying these requirements, requiring the Commission to issue guidelines to support the use of the resilience procurement requirements and how to determine what manufacturing in the Union entails and a timeline for the Commission to adopt such guidelines, including further information on the scope of international commitments in recitals, simplifying the collaborative procurements' framework, making collaborative procurements on behalf of or in the name of Member States more accessible while ensuring sufficient volumes by adjusting the threshold of participating countries in article 22 from nine to six, further defining safeguards when imposing contingency stock requirements and sharing information when imposing or changing these contingency stock requirements with the CMCG;
- In Chapter V (Critical Medicines Coordination Group): giving a greater role to Member States by including co-chairing the CMCG and further flexibility on the expert attendance by adding an alternate representative and additional experts as necessary, clarifying what happens if consensus is not reached, finetuning the tasks carried out by the CMCG including information exchanges on funded strategic projects and discussions on strategic partnerships;

- In Chapter VIII (final provisions): clarifying the obligations of market actors to provide information including to whom the request is directed, detailing which information is to be provided and how to handle this information, introducing a new article regarding the handling of confidential information, requesting the Commission to pay particular attention to the functioning of Article 18 in their reporting and adding a transition period for the application of the resilience requirement in public procurement procedures giving Member States the opportunity to build upon the guidelines from the Commission.

10. Following the examination by the Working Party on 6 November, the Presidency indicated that it would further adapt the text to address outstanding issues. The following adaptations were made:
    - joint procurements have been deleted from article 22(6a);
    - the explanation of what manufacturing in the Union does not entail in relation to European preference has been deleted from article 18(2);
    - the Commission's responsibilities on collaborative procurements has been clarified in article 24;
    - It has been clarified that healthcare providers are not part of the supply chain in definition 3(18b) and in article 20;
    - the deadline has been extended to 90 days for a reasoned conclusion and to 20 days for exceptions in article 12(2) and 12(3) aligning it to other Regulations;
    - tasking the Commission with only one reporting requirement in article 30 and to pay particular attention to the general developments in the field of public procurement in their overall report.

11. At its meeting on 14 November 2025, the Permanent Representatives Committee (Part I) examined the compromise text and agreed that, subject to some adjustments, to invite the Council to reach a general approach. The compromise text in the Annex to this note includes an additional amendment in recital 26 regarding the vulnerability evaluation.

12. The Presidency considers that the compromise text presented in the Annex effectively responds to concerns expressed by the delegations, is well-balanced and represents the shared position of the Council.

CONCLUSION

13. The Council is invited to reach a general approach on the text as set out in the Annex of this document at its meeting on 2 December 2025. The general approach will constitute the Council's mandate for future negotiations of the European Parliament in the context of the ordinary legislative procedure.

ANNEX

2025/102 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795

(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 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[6],

Acting in accordance with the ordinary legislative procedure,

Whereas:

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[6] OJ C , , p. .

(1) Availability of critical medicinal products is essential for the Union and the functioning of the internal market. Pursuant to Article 9 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in all Union policies and activities. The availability of safe, efficacious and high-quality medicinal products is vital to achieving this objective and to safeguarding public health across the Union. To safeguard the functioning of the internal market it is therefore necessary to create a common Union framework to collectively address the challenges and by strengthening the security of supply and the availability of critical medicinal products.

(2) In recent years, the Union has experienced an increasing number of shortages of medicinal products, including shortages of medicinal products for which insufficient supply results in serious harm or risk of serious harm to patients.

(3) Shortages of medicinal products can have very different and complex root causes, with challenges identified along the entire pharmaceutical value chain. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. These include existing dependencies on a limited number of suppliers globally and lack of Union capacities to produce certain medicinal products, their active substances or key raw pharmaceutical materials. Through diversification of supply sources and investment in local production, the Union can reduce its risk of exposure to shortages of medicinal products.

(4) Industrial challenges and a lack of investments in manufacturing capacities in the Union have contributed to increased dependency on third country suppliers, in particular, for key raw pharmaceutical materials and active substances. Setting up new, or modernising existing manufacturing capacities in the Union for critical medicinal products, their key inputs and active substances, which have often been on the market for a long time and are considered to be relatively inexpensive, is currently not seen as a sufficiently attractive option for private investment, also in view of lower energy costs, lesser environmental and other legal requirements elsewhere in the world. Workforce shortages and the need for specialised skills in pharmaceutical manufacturing further add to the industrial challenges to manufacturing in the Union. Targeted financial incentives, simplified administrative processes, and better Union-level coordination can contribute to supporting efforts to increase manufacturing capacities in the Union and strengthen the supply chains for critical medicines.

(5) To enhance the security of supply for medicinal products and thereby contribute to a high level of public health protection, the Union has implemented a range of measures that contribute to building a European Health Union. In particular, Regulation (EU) 2022/123 of the European Parliament and of the Council[7] has reinforced the European Medicines Agency's ('the Agency') mandate by enhancing monitoring, coordination, and reporting mechanisms to prevent and mitigate supply disruptions of critical medicinal products across Member States. That Regulation also established the Agency's Executive Steering Group on Shortages and Safety of Medicinal Products ('the MSSG'), which brings together representatives from the Agency and Member States, to coordinate urgent actions within the Union to manage existing shortages and issues related to the quality, safety, and efficacy of medicinal products.

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7 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, 31.2.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj)

(6) In addition, Regulation (EU) …/… of the European Parliament and of the Council[8] No [reference to be added after adoption cf. COM(2023) 193 final] further strengthens the continuity of supply and availability of medicinal products through developing the core tasks already granted to the Agency by Regulation (EU) 2022/123 and setting out a framework for the activities to be deployed by the Member States and the Agency to improve the Union capacity to react efficiently and in coordinated manner to support the shortages management and security of supply of medicinal products, including by strengthening the obligations of marketing authorisation holders as it regards the shortages prevention and reporting.

(7) However, despite regulatory obligations on marketing authorisation holders to ensure the continuous supply of medicinal products to meet patients' demand and the additional regulatory mechanism introduced by Regulation of the European Parliament and of the Council (EU) 2022/123 and Regulation (EU) …/… [reference to be added after adoption cf. COM(2023)193 final] to mitigate and respond to shortages, the functioning of markets alone does not always guarantee the availability of medicinal products. This risk is particularly evident in cases of supply chain disruptions, especially when the supply of a given medicinal product relies on a limited number of global suppliers and production facilities or where there is a high dependency on a single or a limited number of third countries.

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8 Regulation (EU) …/… 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 Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (OJ … [OP: Please complete publication references]).

(8) As the Union market for medicinal products remains fragmented, there is a need for better coordination between Member States to leverage in full the Union's potential to strengthen the security of supply of medicinal products, without calling into question Member States' responsibilities for the organisation and delivery of health services and medical care. Uncoordinated national measures risk disrupting the internal market, fail to address broader supply chain issues, and are insufficient to resolve cross-border issues, including the Union's dependency on third countries. The regulatory framework for medicinal products therefore needs to be complemented by targeted actions providing for further harmonisation.

(9) Some medicinal products of common interest which are key for the provision of adapted care to patients, while not affected by supply security issues, may still not be available and accessible to patients in some Member States. This may be caused by a variety of factors, including product or geographical demand market size, which can impact the timely availability of medicinal products in certain Member States.

(10) The smooth functioning of the internal market and a high level of protection of human health should be ensured as regards medicinal products and it should be aimed to complementing other Union pharmaceutical legislation by providing for a harmonised framework supporting Member States' coordinated efforts to encourage investments in new and existing manufacturing capacities for critical medicinal products, encouraging the strategic use of public procurement instruments by the Member States as well as the coordination of the Member States' approaches, including through leveraging aggregated demand through Commission facilitated collaborative procurement procedures of critical medicinal products and medicinal products of common interest. Due to the international dimension of the security of supply, in particular taking into account that diversification of supply chains and an overall increase of supply are elements of a solution for ensuring the security of supply, international cooperation should be encouraged.

(11) The measures introduced by this Regulation are without prejudice to marketing authorisation holders' obligations, in particular under Directive (EU) …/… of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final], Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) 2022/123, including the obligation to ensure sufficient supplies of medicinal products, within the limits of their responsibility. These measures are aligned with the principles of the internal market. This Regulation is without prejudice to Union competition law, including antitrust merger and state aid rules.

(12) While the primary objective of this Regulation should be to improve the functioning of the internal market by establishing a framework to strengthen the security of supply and ensure the availability of critical medicinal products and the availability and the accessibility of medicinal products of common interest, given a lack of critical medicinal products can affect the functioning of the economy as a whole, this Regulation should also support the Union's competitiveness by fostering a more stable and predictable market environment, encouraging investment and supporting innovation in the pharmaceutical sector. Ensuring the security of supply and availability of critical medicinal products and the availability and accessibility of medicinal products of common interest should moreover contribute to the Union's preparedness, resilience, and economic and overall security, including when cross-border supply chains risk being disrupted.

(13) Taking into account the different root causes of the availability issues affecting critical medicinal products and medicinal products of common interest, some measures should apply to critical medicinal products only.

(14) Ensuring the security of supply and the availability of critical medicinal products for patients in the Union to safeguard public health and the economic and overall security of the Union is a strategic objective of the Union. To achieve this, it is important that the Member States and the Commission work together to strengthen the security of supply and continuous availability of critical medicinal products in the Union through measures that take full advantage of the potential of the internal market. In this effort, the Commission has an important role to support the coordinated efforts of the Members States.

(15) A well-defined list of critical medicinal products is essential to ensure that the measures are targeted, effective, and proportionate. The critical medicinal products covered by this Regulation should be those for which insufficient supply results in serious harm or risk of serious harm to patients. For this reason this Regulation should apply to critical medicinal products on the Union list of critical medicinal products, as established by Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final]. That list builds upon the experiences of the European Medicines Agency and Member States' Agencies that in 2024, in anticipation of the reform of pharmaceutical legislation, identified a list of 276 critical medicinal products.

(16) To ensure that the measures are applied where justified and proportionate, it is necessary to demonstrate that some measures address a vulnerability in the supply chains of a given critical medicinal product. This Regulation should rely on the vulnerability evaluation performed for the purpose of the application of the general pharmaceutical legislation as per Regulation (EU) No …/… [reference to be added after adoption cf. COM(2023) 193 final]. To detect a vulnerability in the supply chains it is necessary to look at aggregated data across all medicinal products authorised in the Union and containing the same active substance, route of administration and formulation. Such an approach allows for the determination whether, for a critical medicinal product with a given active substance, the Union is highly dependent on a single or a limited number of third countries, or a limited number of sites, for active substances, key inputs, or finished dosage forms.

(17) Certain projects can have a positive impact on security of supply as they increase the Union's manufacturing capacity for critical medicinal products and strengthen the resilience of the Union's supply chains. In order to encourage private investments in these projects, the concept of strategic projects should be introduced. Given their role in ensuring the Union's security of supply for critical medicinal products, the relevant permitting authority should consider projects recognised as a strategic project by Member States' designated authority to be in the public interest. To ensure their expedient implementation, national authorities should ensure that the relevant permit granting processes are carried out without undue delay making available, in particular any form of accelerated procedures that exists in applicable Union and national law. National authorities should consider, when possible, their streamlining as well as enable digital submission of required information.

(18) The designated authority should without undue delay assess, whether a given project is a strategic project. In order to accelerate and facilitate their deployment, strategic projects should benefit from streamlined administrative processes, priority status in the context of permit granting procedures and related dispute resolution procedures, where these procedures already exist in national law, as well as, be offered targeted regulatory support. In this context, the Member States should give particular attention to small and medium sized enterprises (SMEs) which should have a fair chance to initiate strategic projects.

(18a) A project promoter is able to request that their application for a permit is granted the status of the highest national significance, if such a status exists in national law, and be treated accordingly. National authorities are to grant the status of the highest national significance to an application for a permit without prejudice to obligations provided for in Union law.

(18b) A project promoter is able to request that any dispute resolution procedure, litigation, appeal and proceedings on judicial remedies related to the permit-granting process and the issuance of permits for a strategic project in the Union before any national courts, tribunals or panels, including with regard to mediation or arbitration, where they exist in national law and can be applied in disputes of this type, is treated as urgent if and to the extent to which national law concerning permit granting processes provides for such an urgency procedure. The applicable rights of defence of individuals or of local communities are to be respected during such urgency procedures.

(19) The production of medicinal products has environmental implications and may negatively impact not only the environment itself but also human health. The environmental assessments and authorisations required under Union law are an integral part of the permit-granting process for strategic projects and an essential safeguard to ensure negative environmental impacts are prevented or minimised. However, to ensure that permit-granting processes for strategic projects are predictable and timely, it should be possible to streamline the required assessments and authorisations by the relevant authority, while not lowering the level of environmental protection.

(20) Land use conflicts can create barriers to the deployment of strategic projects. The relevant national, regional or local authority responsible for preparing zoning, spatial and land use plans should consider whether to introduce in these plans, where appropriate, certain provisions related to strategic projects. Those plans have the potential to help balance the public interest and common good, decreasing the potential for conflict and accelerating the sustainable deployment of strategic projects in the Union.

(20a) This Regulation is without prejudice to the obligations under the United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, signed at Aarhus on 25 June 1998, and under the UNECE Convention on environmental impact assessment in a transboundary context, signed at Espoo on 25 February 1991 and its Protocol on Strategic Environmental Assessment, signed in Kyiv on 21 May 2003.

(21) Given the capital-intensive nature of pharmaceutical production, including the establishment, expansion or modernisation of manufacturing sites for critical medicinal products, active substances, and key inputs, targeted financial support can play a crucial role in incentivising production within the Union. To strengthen the security of supply of critical medicinal products, and where private investment alone is not sufficient, financial support of investments in manufacturing capacity within the Union may be justified. Member States should be able to prioritise financial support for strategic projects that address specific vulnerabilities in the supply chains, while ensuring that such support complies with the Union's State aid rules. For this purpose, specific guidance to clarify the application of EU State aid rules to assist the Member States has been provided by the Commission services and will be updated as necessary.

(22) Union-level funding can be leveraged to facilitate investments in strategic projects. Strategic projects can benefit from access to EU funding instruments, including but not limited to the EU4Health Programme[9], Digital Europe Programme[10] and Horizon Europe[11] (relevant, for example, for active substances referred to in Article 5(d) of Regulation (EU)2021/695), as well as the Strategic Technologies for Europe Platform (STEP), when they fulfil the criteria established in these instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 of the European Parliament and of the Council[12] (STEP) should in particular consider supporting strategic projects addressing a vulnerability in the supply chains of critical medicinal products and therefore Regulation (EU) 2024/795 should be amended.

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9 Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of Health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014, (OJ L 107, 26.3.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/522/oj)

10 Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240(OJ L166, 11.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/694/2023-09-21)

11 Regulation (EU) 2021/695 of the European Parliament and of the council of 28 April 2021 establishing Horizon //Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L170, 12.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/695/oj)

12 Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, (OJL 2024/794, 29.2.2024, ELI: http://data.europa.eu/eli/reg/2024/795/oj)

(23) To allow for a more coordinated approach to financial support, it is appropriate that Member States and the Commission exchange the information on financial support to strategic projects. As regards the strategic projects that have received EU funding, the beneficiaries should follow the relevant communication and visibility rules[13].

(24) Given that public authorities or entities are the principal buyers of medicinal products for the inpatient sector and that the public procurement of medicinal products is a powerful tool to improve security of supply, it is necessary to establish rules that promote resilience of supply in public procurement procedures of critical medicinal products falling within the scope of Directive 2014/24/EU.

(24a) Resilience can be promoted through various measures depending on market situations and public health considerations. Active use of award criteria acknowledging quality alongside price are essential levers. Member States and contracting authorities should retain flexibility to decide the most relevant approach, given the market situations and their specific needs. Resilience requirements could inter alia relate to stockholding obligations, the number of diversified suppliers, state of the art monitoring of supply chains, transparency of the supply chain and contract performance clauses on timely delivery and measures in case of non-timely delivery and could be specified further at national level by Member States. These requirements do not preclude contracting authorities from using public procurement procedures resulting in the award of contracts to more than one winner (multi-winner approaches).

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13 Communication and visibility rules - Publications Office of the EU

(25) Across Member States, contracting authorities differ in their introduction and use of resilience requirements in public procurement procedures, which lead to differentiated practices. This could have negative impact on the internal market as it creates obstacles to cross-border participation and a lack of predictability for bidders. In order to avoid such negative outcomes, the use of resilience requirements should be mandatory and a more streamlined practice supported.

(26) To ensure a high level of public health protection and security of supply, it is necessary to procure in a way that promotes diversification of suppliers and favours European manufactured critical medicinal products or their actives substances, where dependency on a single or a limited number of countries outside the Union, threatening the security of supply, has been established through a vulnerability evaluation performed by the Medicines Shortages Steering Group ("MSSG"). This vulnerability evaluation will identify the vulnerabilities with respect to the supply chains of critical medicinal products, including the level of dependency on countries outside the Union, that the Member States can utilise in their efforts to reduce dependencies and promote diversification. Requirements that favour critical medicinal products or their active substances manufactured in the Union should be applied subject to the Union's international commitments including the Government Procurement Agreement in WTO and other relevant international agreements of which the Union is bound and which should be assessed in relation to each of these international agreements.

(27) Member States' responsibilities for the definition of their health policy and for the organisation and delivery of health services and medical care, including the allocation of financial resources, are to be respected, as referred to in Article 168(7) TFEU. The contracting authorities should therefore retain the ability in exceptional cases, where justified by considerations related to market analysis or considerations related to financing of health services, to adopt procurement approaches that differ from those set out in this Regulation as long as they are in line with the Union's international obligations.

(28) The application of requirements in public procurement procedures should take into account the specific market conditions and public health needs of each procurement procedure, whilst bearing in mind the considerations related to affordability of medicinal products. Certain requirements may not be justified if they result in disproportionate cost for procurers, discourage participation, leading to no bids, or in case of no suitable tender or no requests to participate have been submitted in response to a similar public procurement procedure launched by the same contracting authority in the two years prior to the commencement of the planned new procurement procedure. Contracting authorities can presume tenders whose price exceeds the contracting authority's budget as determined and documented prior to the launching of the procurement procedure to be considered as tenders with disproportionate costs. Similarly, contracting authorities should be able not to apply the requirements, where it is strictly necessary due to reasons of extreme urgency brought about by events unforeseeable by the contracting authority and the circumstances invoked to justify extreme urgency are not attributable to the contracting authority.

(29) The Commission should issue guidelines designed to support Member States and contracting authorities in implementing and applying the obligations to use resilience requirements and requirements that favour European manufactured critical medicinal products or their active substances with a view to strengthening the security of supply. The guidelines should include guiding principles on determining whether critical medicinal products or their active substances are manufactured in the Union and address an identified vulnerability in the supply chains and dependency on countries outside the Union. The guidelines should be issued at the latest 6 months after the entry into force of this Regulation.

(30) The procurement of medicinal products is organised differently across Member States, involving various actors. To strengthen the security of supply chains for critical medicinal products, Member States should establish national programmes that promote the consistent use of requirements in public procurement procedures by contracting authorities within their territory. Such programmes could also promote the consistent use multi-winner approaches where beneficial, based on thorough market analysis. To ensure a comprehensive approach, and considering that critical medicinal products are also relevant for outpatient sector where they are often not purchased through public procurement, these programmes may also encompass other measures to strengthen supply chain resilience and sustainability through measures related to pricing and reimbursement, where appropriate. The programmes should be shared with the Commission and the Critical Medicines Coordination Group (CMCG), established by this Regulation, to facilitate the exchange of best practices and coordination between the Member States. This cooperation should enhance the overall effectiveness of the various measures put forward to secure the supply of critical medicinal products, while respecting the principles of subsidiarity and proportionality.

(31) Some Member States impose obligations on marketing authorisation holders and other economic operators in the pharmaceutical supply chain to healthcare providers and patients to hold contingency stocks for the purpose of safeguarding the security of supply of medicinal products within their territory. Contingency stocks are to be distinguished from publicly owned national, regional or local stockpiling in order to anticipate and manage a specific crisis. Contingency stocks can potentially have a negative impact on the internal market including availability of the medicinal products concerned in other Member States. Any such contingency stocks requirements should take into account that any restriction to the free movement of goods are justified by the purpose of safeguarding public health, thus respecting the Treaties and the case law of the Court of Justice of the European Union. To avoid a negative impact on the internal market, Member States should also, when introducing or changing existing contingency stock requirements for any medicinal products, including determining the medicinal products covered, the size of required stocks and timeline for establishment of the stocks, take into consideration the principles of proportionality, transparency and solidarity. Such requirements should not prevent Member States from assisting other Member States requesting support under the voluntary Solidarity Mechanism launched by the Medicines Shortages Steering Group ("MSSG") in 2023. The Member States should give due consideration to forthcoming Commission guidelines designed to facilitate the fulfilment of Member States' obligations as regards compliance with the internal market and the free movement of goods when proposing and defining contingency stock requirements. Member States should comply with existing obligations under Union law for the notification of technical regulations and technical barriers to the internal market, including those set out in Directive (EU) 2015/1535.

(32) Availability and access disparities exist for critical medicinal products and medicinal products of common interest throughout the Union, disproportionately affecting some Member States. The collaborative procurement of critical medicinal products and of medicinal products of common interest can be a powerful tool to improve their security of supply and accessibility.

(33) Directive 2014/24/EU of the European Parliament and of the Council[14] provides for the possibility of procurement involving contracting authorities from different Member States. Whereas it has been found helpful to make small markets attractive for suppliers, thereby achieving better availability of medicinal products, its implementation is time- and resource-intensive, especially in the starting phase, and considered a limiting factor. To facilitate the deployment of procurement initiatives involving contracting authorities from different Member States, the Commission, when requested, should provide its assistance during the preliminary phase of setting up such a procurement initiative. The involved Member States are able to agree to continue the procedure without the Commission's facilitation, including by agreement on another facilitator in accordance with Directive 2014/24/EU. Any involved Member State can withdraw from the procedure at any stage before the signature of the procurement contract. Withdrawal by one Member State would not in itself affect the continuation of the procedure by the remaining participating Member States, provided that the minimum requirements under this Regulation are still met.

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[14] 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).

(34) Taking into account experiences resulting from the implementation of joint procurement of medical countermeasures pursuant to Regulation (EU) 2022/2371 of the European Parliament and of the Council[15] and of COVID-19 vaccines, pursuant to Council Regulation (EU) 2016/369[16] in the context of the EU Vaccines Strategy and acknowledging potential benefits that leveraging of several Member States demand in one procurement procedure may have, Member States should be able to consider requesting the Commission to procure on their behalf, or in their name, where such procurement could contribute to the achievement of the objectives of this Regulation.

(35) To ensure that the collaborative procurement initiatives contribute to the achievement of the objectives of this Regulation, while fully respecting the principle of subsidiarity, the Commission's involvement in procurement on behalf, or in the name of the Member States, should be limited to cases where the conditions set out in the relevant Articles are met. For this reason, derogation from Article 168 (3) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[17] should be provided.

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15 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).

16 Council Regulation (EU) 2016/296 of 15 March 2016 on the provision of the emergency support within the Union (OJ L 70, 13.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/369/oj)

17 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).

(36) In accordance with Article 168 of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council, the Commission should act only within the limits of the mandate given by the participating Member States, and any actions outside such mandate remain the sole responsibility of the Commission. To ensure transparency, legal clarity, and effective coordination, a structured agreement between the Member States and the Commission should govern procurement procedures under this Regulation that rely on an active Commission involvement. Such an agreement should set out the division of responsibilities, decision-making processes, the information to be shared as relevant to the procurement procedure, including information on Member States' participation in parallel negotiations through different channels in relation to the same medicinal products or the same active substances as appropriate, and liability provisions, ensuring a fair and efficient framework for participating Member States while preventing market distortions and supply disruptions. This Regulation is without prejudice to and does not prevent the use of joint procurement procedures established under Regulation (EU) 2022/2371 of the European Parliament and of the Council for those critical medicinal products and other medicinal products that also fall within the definition of medical countermeasures as set out in that Regulation. This Regulation is without prejudice to Council Regulation (EU) 2022/2372[18] setting the framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

[18] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, p. 64, ELI: http://data.europa.eu/eli/reg/2022/2372/oj)

(37) In order to ensure a structured and coordinated approach as well as coherent information exchange to strengthen the security of supply of critical medicinal products, collaboration between the Member States and the Commission is required. To facilitate this, the CMCG should be established to facilitate effective coordination across the relevant policy areas. The CMCG should be composed of a permanent representative with strategic expertise in medicinal product procurement policies, industrial policy related to pharmaceuticals and public health. As necessary, Member States may appoint additional expert representatives to accompany the permanent Member State representative in order to support the different tasks of the CMCG. The Commission should be a member of the group. To ensure structured discussions a representative of the Member States and a representative of the Commission should co-chair. The Commission should perform the functions of its secretariat.

(38) To ensure coordinated implementation of this Regulation, the CMCG should enable exchanges of information related to funding of strategic projects and facilitate the strategic orientation of financial support for strategic projects. The CMCG should also facilitate the exchange of information on national programmes to promote best practices, and where appropriate, voluntary cooperation on Member States public procurement policies with regard to critical medicinal products. The CMCG should furthermore facilitate strategic discussions on collaborative procurement initiatives, exchanges on guiding principles on contingency stocks requirements and discussions on the need to prioritise the vulnerability evaluation for specific critical medicinal products. The coordination work of the CMCG should be distinct from the work of the MSSG established under Article 3 of Regulation (EU) 2022/123 and whose tasks are set out in Regulation (EU) 2022/123 and Regulation (EU) No …/… [reference to be added after adoption cf. COM(2023) 193 final]. Whereas, the main tasks of the MSSG are to coordinate Union-level responses to actual or potential shortages of medicinal products during public health emergencies or major events, to monitor the supply and demand of critical medicines and to provide recommendations to prevent or mitigate shortages, the focus of the CMCG is to facilitate coordination of the measures envisaged in this Regulation creating the necessary conditions on investments and public procurement coordination and collaboration to proactively reduce dependencies and strengthen EU production capacity.

(39) The Union could further enhance the availability and security of supply of critical medicinal products by providing access to alternative sources of supply in third countries. The Union could, to that end, rely on its network of existing trade agreements and additionally pursue strategic partnerships with third countries to further deepen bilateral cooperation, especially with candidate countries. In this context, the Commission should assess whether existing partnerships effectively address the intended aims or could be further improved or upgraded, and what types of potential partnerships could be concluded with the most relevant third countries. This should be done without prejudice to the prerogatives of the Council in accordance with the Treaties.

(40) To ensure the application of this Regulation, it is necessary that market actors make available information to the competent authorities. The national competent authorities or the Agency, as relevant, must therefore be able to request, when necessary and avoid duplication of information requests, the information necessary for the application of this Regulation. Information acquired in the course of implementing this Regulation should be used only for the purposes of this Regulation and should be protected by the relevant Union and national law. Any obligations on sharing information pursuant to this Regulation should not apply to data that concerns the essential interests of the Member States' security or defence.

(41) In order to ensure that this Regulation effectively meets its objectives, it is essential to assess its implementation and impact over time. The Commission should carry out an evaluation of this Regulation at the latest five years after its application and every five years thereafter. This evaluation should include an assessment of the extent to which the Regulation's objectives, as set out in Article 1, have been achieved, including its impact on stakeholders, regulatory procedures, and market dynamics. The evaluation should also include an assessment of the scope, functioning and efficiency of Article 18 as well as coherence of the Regulation with developments within the field of public procurement. In particular, the Commission's evaluation should take into account the views of Member States, markets actors, contracting authorities and other relevant stakeholders, ensuring that their feedback contributes to the continuous improvement of the regulatory framework. The results of the evaluation should be presented to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. In order to facilitate this evaluation, national authorities, market actors, contracting authorities and other relevant stakeholders should provide relevant data and information upon request to support the Commission's assessment.

(42) Since the objectives of this Regulation to improve the functioning of the internal market by establishing a framework to strengthen the availability and security of supply of critical medicinal products within the Union and to improve the availability and accessibility of medicinal products of common interest through coordinated and targeted action of Member States cannot be sufficiently achieved by the Member States acting alone, but can rather, by reason of its scale, 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 TFEU. 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 its objectives.

HAVE ADOPTED THIS REGULATION:

Chapter I
General provisions

Article 1

Objectives and subject matter

1. The objective of this Regulation is to improve the functioning of the internal market by establishing a framework to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby ensuring a high level of public health protection and supporting the security of the Union. The objective of this Regulation is also to improve the availability and accessibility of medicinal products of common interest where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the affordability of those medicinal products.

2. To achieve the objectives referred to in paragraph 1, this Regulation sets out a framework to:

   (a) facilitate investments in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union;

   (b) lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification and resilience in the public procurement procedures of critical medicinal products and other medicinal products of common interest;

   (c) leverage the aggregated demand of participating Member States through collaborative procurement procedures, and

   (d) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.

Article 2

Scope

1. This Regulation applies to the critical medicinal products listed in the Union List of Critical Medicinal Products with the exception of Article 21, which only applies to medicinal products of common interest.

2. Articles 1, 22, 24, 26(2) points (c) and (db) and 26(3) also apply to medicinal products of common interest.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(1) ‘medicinal product’ means a medicinal product as defined in Article 4 point (1) of Directive (EU) …/… of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];

(2) ‘key input’ means input material, other than an active substance, required in the manufacturing process of a given medicinal product, including starting materials and raw materials for production of active substances or excipients, primary packaging materials, excipients, solvents and reagents;

(3) ‘active substance’ means an active substance as defined in Article 4 point (3) of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];

(3a) ‘starting material’ means material as defined in Article 4 point (4) of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];

(3b) ‘excipient’ means an excipient as defined in Article 4 point (5) of Directive (EU) …/… [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];

(3c) ‘collecting’ means collection of substances of human or animal origin for the purpose of being processed into active substances of critical medicinal products;

(4) ‘critical medicinal product’ means a medicinal product listed in the Union List of Critical Medicinal Products referred to in Article 131 of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final].

(5) ‘medicinal product of common interest’ means a medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States;

(6) ‘vulnerability in the supply chains’ means risks and weaknesses within the supply chains of critical medicinal products, identified at the aggregated level taking into account all authorised medicinal products in the Union and grouped under a common name with the same route of administration and formulation, that compromise the continuous supply of such medicinal products to patients in the Union;

(7) ‘vulnerability evaluation’ means the evaluation of the supply chains of critical medicinal products in order to identify their vulnerabilities performed by the Medicines Shortages Steering Group (“MSSG”) in accordance with Regulation (EU) …/… of the European Parliament and of the Council[19] [reference to be added after adoption cf. COM(2023) 193 final];

(8) ‘common name’ means a common name as defined in Article 4 (1), point (48) of Directive (EU) …/… of the European Parliament and of the Council [reference to be added to corresponding Article after adoption of cf. COM(2023)192 final];

(9) ‘contracting authorities’ means contracting authorities as defined in Article 2(1) point (1) of Directive 2014/24/EU;

(10) ‘strategic project’ means an industrial project recognised as a strategic project by a designated authority as referred to in Article 6 pursuant to the criteria set out in Article 5;

(11) ‘project promoter’ means any undertaking or consortium of undertakings developing a strategic project;

(12) ‘permit granting process’ means a process covering all relevant permits to build and operate a strategic project, including building, chemical and grid connection permits and environmental assessments and authorisations where those are required and encompassing all applications and procedures;

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[19] Regulation (EU) …. 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 Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (OJ …) [D.G.: Title according to COM(2023) 193 final. Please check against latest version of this draft Regulation].

(13) ‘innovative manufacturing process’ means a novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, Artificial Intelligence, platform techniques, 3D manufacturing;

(15) ‘Member States’ cross-border procurement’ means a procurement procedure initiated at the request of Member States and involving contracting authorities from different Member States pursuant to Article 39 of Directive 2014/24/EU;

(16) ‘procurement on behalf of or in the name of the Member States’ means a procurement procedure initiated at the request of Member States and mandating the Commission to act as a central purchasing body on behalf of, or in the name of, the requesting Member States, as provided for in Article 168(3) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council;

(18b) ‘contingency stocks requirement‘ means an obligation imposed by a Member State on marketing authorisation holders and other economic operators in the supply chain of medicinal products to healthcare providers and patients to hold stocks of certain medicinal products to safeguard the security of supply and which obligation is imposed by law, regulations or administrative provisions, including stockholding obligations in public procurement procedures.

(19) ‘strategic partnership’ means a commitment between the Union and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products that is established through a non-binding instrument and which facilitates beneficial outcomes for both the Union and the relevant third country, group of third countries or international organisation.

Chapter III

Enabling conditions for investment

SECTION I

CRITERIA AND PROCEDURE FOR THE RECOGNITION OF STRATEGIC PROJECTS

Article 5

Strategic Projects

A project located in the Union and related to creating, modernising or increasing manufacturing capacity of critical medicinal products shall be recognised as a strategic project if meets at least one of the following criteria:

(a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances;

(b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency;

(c) it creates or increases manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances where it is demonstrated that there are supply constraints or limited manufacturing capacity in the Union;

(d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs.

Article 6

Recognition of Strategic Projects

1. Each Member State shall designate an authority (‘the designated authority’) that shall assess whether an industrial project meets at least one of the criteria set out in Article 5 and therefore shall be recognised as a strategic project.
   A Member State may designate more than one designated authority.

2. In order for a project to be recognised as a strategic project a promoter of an industrial project shall request the designated authority to assess whether the project is a strategic project. The request shall contain justification and relevant evidence related to the fulfilment of at least one of the criteria set out in Article 5. The designated authority shall provide its assessment to the promoter without undue delay.

2a. The submission of a request for a project to be recognised as a strategic project as provided for in paragraph 2 does not preclude the promoter of the project from simultaneously initiating application procedures with other authorities for the permits needed for the project.

3. Member States shall communicate to the Commission the designated authorities for the purposes of paragraph 1 of this article and Article 16(2).

4. The Commission shall provide a simple, accessible webpage on which the contact details and other relevant information on the tasks of Member States’ designated authorities shall be clearly listed.

5. Any other authority in the Member State that receives a request from a promoter concerning Articles 7, 8, 11, 12, 13 and 15 shall rely on the decision of the designated authority pursuant to paragraph 1 as to whether that given project is recognised as a strategic project .

SECTION II

FACILITATING ADMINISTRATIVE AND PERMIT-GRANTING PROCESSES FOR STRATEGIC PROJECTS

Article 7

Priority status of strategic projects

1. Strategic projects shall be considered as contributing to the security of supply of critical medicinal products in the Union and, therefore, to be in the public interest.

2. The Member States' authorities shall ensure that the relevant permit granting processes related to strategic projects are carried out without undue delay , making available, in particular, any form of accelerated procedures that exists in applicable Union and national law.

Article 8

Administrative support

1. Upon request of a project promoter, a Member State's authorities shall with regard to the relevant permit-granting processes related to strategic projects provide to a strategic project located on its territory the administrative support to facilitate its implementation, including assistance in accordance with national law:

   (a) with regard to the project promoter's compliance with applicable administrative and reporting obligations;

   (b) to the project promoter along the permit-granting process.

2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium size enterprises (SMEs) and, where necessary , may establish a dedicated channel for communication with SMEs to provide guidance and respond to queries related to the implementation of this Regulation.

Article 11

Regulatory support from competent authorities for medicinal products

1. Upon request of a project promoter, a Member State's competent authority for medicinal products shall provide regulatory support to a strategic project located on its territory, where relevant. Such support shall include administrative support for obtaining the necessary authorisations from the competent authority.
   A Member State's competent authority shall, when feasible, prioritise Good Manufacturing Practices inspections for approval of new and extended manufacturing sites and for the manufacturing sites modernised in the context of the concerned strategic project.

2. Upon request of a project promoter, the European Medicines Agency ('the Agency') shall provide dedicated regulatory advice to assist project promoters developing projects relying on innovative manufacturing processes. Where this advice includes aspects related to Good Manufacturing Practices, which would be subject to review during inspections for manufacturing sites in a Member State, the Agency shall involve the relevant national competent authority for medicinal products in the provision of this advice.

2a. For the purposes of paragraphs 1 and 2, the competent authorities and the Agency shall act within the limits of the competences conferred upon them.

Article 12

Environmental assessments and authorisation

1. A project promoter may request, where the obligation to assess the effects on the environment arises simultaneously from two or more of Council Directive 92/43/EEC[20], Directive 2000/60/EC of the European Parliament and of the Council[21], Directive 2001/42/EC of the European Parliament and of the Council[22], Directive 2008/98/EC of the European Parliament and of the Council[23], Directive 2009/147/EC of the European Parliament and of the Council[24], Directive 2010/75/EU of the European Parliament and of the Council[25], Directive 2011/92/EU of the European Parliament and of the Council[26] or Directive 2012/18/EU of the European Parliament and of the Council[27], that a coordinated or joint procedure fulfilling the requirements of those Union legislative acts are applied.

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20 Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7, ELI: http://data.europa.eu/eli/dir/1992/43/oj).

21 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

22 Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7.2001, p. 30, ELI: http://data.europa.eu/eli/dir/2001/42/oj).

23 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: http://data.europa.eu/eli/dir/2008/98/oj).

24 Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7, ELI: http://data.europa.eu/eli/dir/2009/147/oj).

25 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

26 Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2011/92/oj).

27 Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1, ELI: http://data.europa.eu/eli/dir/2012/18/oj).

Under the coordinated procedure referred to in the first subparagraph, a competent authority shall coordinate the various individual assessments of the environmental impact of a particular project required by the relevant Directive.

Under the joint procedure referred to in the first subparagraph, a competent authority shall provide for a single assessment of the environmental impact of a particular project required by the relevant Directive.

2. Member States shall ensure that the competent authorities issue the reasoned conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 90 days of receiving all necessary information.

3. In exceptional cases, where the nature, complexity, location or size of the proposed project so requires, Member States may extend the time limit referred to in paragraph 2 once by a maximum of 20 days, before its expiry and on a case-by-case basis. In that event, the competent authority shall inform the project promoter in writing of the reasons justifying the extension and of the deadline for its reasoned conclusion.

4. The deadlines for consulting the public concerned as referred to in Article 1(2), point (e), of Directive 2011/92/EU and the authorities referred to in Article 6(1) of that Directive on the environmental impact assessment report referred to in Article 5(1) of that Directive shall not be longer than 85 days and not shorter than the 30 day period referred to in Article 6(7) of that Directive.

5. With regard to the environmental impacts or obligations referred to in Article 4(7) of Directive 2000/60/EC, Article 9(1), point (a), of Directive 2009/147/EC, Articles 6(4) and 16(1) of Directive 92/43/EEC and for the purposes of Article 4(14) and (15) and Article 5(11) and (12) of Regulation (EU) 2024/1991 strategic projects in the Union may be considered to have an overriding public interest and to serve the interests of public health and safety provided that all the conditions set out in those acts are fulfilled.

Article 13

Planning

1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all relevant spatial planning data is available.

2. Where plans including provisions for the development of strategic projects are subject to an assessment pursuant to Directive 2001/42/EC of the European Parliament and of the Council and pursuant to Article 6(3) of Directive 92/43/EEC, those assessments shall be combined. Where applicable, the combined assessment shall also address the impact on potentially affected water bodies referred to in Directive 2000/60/EC. Where Member States are required to assess the impacts of existing and future activities on the marine environment, including land-sea interactions, in accordance with Article 4 of Directive 2014/89/EU of the European Parliament and of the Council28, the combined assessment shall also cover those impacts.

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28 Directive 2014/89/EU of the European Parliament and of the Council of 23 ELI: http://data.europa.eu/eli/dir/2014/89/oj July 2014 establishing a framework for maritime spatial planning (OJ L 257, 28.8.2014, p. 135, ELI: http://data.europa.eu/eli/dir/2014/89/oj).

SECTION III

FINANCIAL INCENTIVES

Article 15

Financial support by Member States

1. Without prejudice to Union state aid rules as set out in Articles 107 and 108 Treaty of the Functioning of the European Union (TFEU), Member States may prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products identified following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines Coordination Group ('CMCG') referred to in Article 26(2) point (a).

2. For as long as the critical medicinal product is on the Union List of Critical Medicinal Products, an undertaking that has benefitted from financial support for a strategic project shall prioritise supply to the Union market and use its very best efforts to ensure that the critical medicinal product remains available in all the Member States where it is being marketed. Where appropriate, the terms of the financial support shall stipulate for how long the obligation shall continue to apply in case the critical medicinal product is removed from the Union List of Critical Medicinal Products.

3. The Member State that provided financial support to a strategic project may require such undertaking to prioritise supply and provide the necessary supplies of a critical medicinal product, active substance or key inputs, as applicable, to the Union market to avoid shortages in one or more Member States.

   Any Member State that encounters a threat of shortages of the critical medicinal product in question may request the Member State that provided financial support to submit a request on its behalf.

Article 16

Financial support from the Union

1. Financial support for strategic projects under the Multiannual Financial Framework 2021-2027[29] may be provided by the Union from Union programmes including but not limited to, the EU4Health Programme established by Regulation (EU) 2021/522, Horizon Europe established by Regulation (EU) 2021/695, and the Digital Europe Programme established by Regulation (EU) 2021/694, provided that such support is in line with the objectives set out in the respective regulations establishing those programmes.
   The amount of Union financial contribution provided under this Article shall be established in accordance with the rules of the respective Union programmes as part of the annual budgetary procedure, subject to the availability of funding.

2. At the request of a project promoter, justified by the necessity to provide results of vulnerability evaluation for the purpose of an application for Union funding, the designated authority shall verify whether a strategic project addresses a vulnerability in the supply chains identified following the vulnerability evaluation. The designated authority shall provide the verification to the project promoter within 15 working days of receiving the request. The designated authority shall inform the Commission about the strategic projects identified as addressing an existing vulnerability in the supply chains without delay.
   Where the designated authority considers that the submitted particulars accompanying the request referred to in the first subparagraph is incomplete, it shall inform the project promoter accordingly and shall set a time line for submitting the missing information and documentation. In case the designated authority sets such a timeline, the timeline referred to in the first subparagraph shall be suspended until such time as the supplementary information and documentation required has been provided for.

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29 Council Regulation (EU, Euratom) 2020/2093 laying down the multiannual financial framework for years 2021 to 2027, as amended (OJ LI 433, 22.12.2020, p.11, ELI: http://data.europa.eu/eli/reg/2020/2093/oj).

Article 17

Exchange of information on financial support

1. Member States shall, without prejudice to their right to decide whether to provide financial support to strategic projects, inform the CMCG, referred to in Article 25, of the intention to provide such financial support sufficiently in advance to enable the CMCG to carry out its coordination task as set out in Article 26.

2. The Commission and Member States shall regularly inform the CMCG of the strategic projects receiving financial support from the Union and Member States respectively to enable the CMCG to carry out its coordination task.

3. The Commission shall inform the CMCG of planned proposals for the establishment of funding possibilities specifically designed to address vulnerabilities in the supply chains as well as inform of any other programmes that may benefit the availability of critical medicinal products, under specific rules and conditions of these Union funding programmes.

Chapter IV

Demand side measures

SECTION I

REQUIREMENTS FOR PUBLIC PROCUREMENT PROCEDURES AND RELATED MEASURES

Article 18

Incentivising resilience in public procurement procedures

1. For public procurement procedures of critical medicinal products falling within the scope of Directive 2014/24/EU, contracting authorities shall apply requirements that promote the resilience of supply in the Union for these critical medicinal products.
These resilience requirements shall take the form of at least one of the following:

   (a) selection criteria within the meaning of Article 58 of Directive 2014/24/EU; or

   (b) technical specifications within the meaning of Article 42 of Directive 2014/24/EU; or

   (ba) best price-quality ratio as contract award criteria within the meaning of Article 67 of Directive 2014/24/EU; or

   (c) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU.

   The resilience requirements may, inter alia, relate to stockholding obligations, the number of diversified suppliers, monitoring of supply chains, transparency of the supply chains and contract performance clauses on timely delivery.

2. For public procurement procedures of critical medicinal products for which a vulnerability in the supply chains has been identified through a vulnerability evaluation pointing to the high level of dependency on a single or a limited number of countries outside the Union, the contracting authorities shall favour critical medicinal products or their active substances manufactured in the Union that address the vulnerability and dependency identified.

Contracting authorities shall favour the critical medicinal products or their active substances referred to in the first subparagraph by applying requirements that take the form of at least one of the following:

(-a) technical specifications or requirements within the meaning of Article 42 of Directive 2014/24/EU; or

(a) best price-quality ratio as contract award criteria within the meaning of Article 67 of Directive 2014/24/EU which may be assessed on the basis of criteria also relating to delivery condition for the critical medicinal products or their active substances; or

(b) contract performance clauses within the meaning of Article 70 of Directive 2014/24/EU.

These requirements shall be applied subject to the Union’s international commitments.

3. The requirements set out in paragraphs 1 and 2 shall apply irrespective of whether products are supplied or provided by the successful tenderer or by a subcontractor. These requirements do not preclude contracting authorities from using multi-winner approaches.

3b. This Article shall not preclude Member States from specifying the requirements set out in paragraphs 1 and 2 and laying down additional requirements in accordance with Directive 2014/24/EU in national laws, regulations, administrative provisions or in their national programmes referred to in Article 19 of this Regulation.

4. This Article shall not preclude contracting authorities from using additional qualitative requirements, including in relation to environmental sustainability and social considerations.

5. Contracting authorities may exceptionally decide not to apply paragraphs 1 and 2 where:

(a) the required critical medicinal product can only be supplied by a specific economic operator as defined in Article 2(1) point (10) of Directive 2014/24/EU and no reasonable alternative or substitute exists and the absence of competition is not the result of an artificial narrowing down of the parameters of the public procurement procedure; or

(b) no suitable tenders or no suitable requests to participate have been submitted in response to a similar public procurement procedure launched by the same contracting authority in the two years prior to the commencement of the planned new procurement procedure; or

(c) their application would oblige that contracting authority to acquire critical medicinal products having disproportionate costs; or

(d) it is strictly necessary due to reasons of extreme urgency brought about by events unforeseeable by the contracting authority and the circumstances invoked to justify extreme urgency are not attributable to the contracting authority.

6. By [6 months after the date of entry into force of this Regulation], the Commission shall issue guidelines designed to support Member States in implementing the obligations of this Article and to facilitate the application of these obligations by contracting authorities. The guidelines shall inter alia include guidance on determining whether critical medicinal products or their active substances are manufactured in the Union and address an identified vulnerability and dependency for the purposes of the requirements set out in paragraph 2.
The guidelines shall respect the responsibilities of the Member States for the management of health services and medical care and the allocation of the resources assigned to them.

Article 19

National programmes supporting resilience in public procurement procedures

1. By 12 months after entry into force of this Regulation each Member State shall, with due respect to the organisation of the procurement of medicinal products within the Member State, establish a national programme supporting security of supply of critical medicinal products, including in public procurement procedures. Such programmes shall promote the consistent use of requirements in public procurement procedures by contracting authorities within a given Member State. Such programmes may also promote the consistent use of multi-winner approaches, where beneficial in light of the market analysis, and may include measures supporting security of supply of critical medicinal products that are not purchased through public procurement procedures.

2. Member States shall inform the Commission in its role of the secretariat of the CMCG about their programmes. The Commission shall ensure the distribution to all members of the CMCG forthwith. The CMCG shall facilitate a discussion as referred to in Article 26(2), point (b) on the national programmes aiming to ensure coordination of national programmes including as regards the application of the requirements set out in Article 18(2).

Article 20

Safeguards related to Member States' contingency stocks requirements

1. When imposing requirements on marketing authorisation holders and other economic operators in the supply chain to healthcare providers and patients to hold contingency stocks for the purpose of safeguarding the security of supply of critical medicinal products within their territory, or making changes to existing requirements, Member States shall aim at avoiding that any form of such requirements negatively impacts the security of supply in other Member States in compliance with the internal market provisions of the TFEU.

2. Member States shall ensure that any contingency stock requirements referred to in paragraph 1 , including the extent and implementation timeline, are proportionate and respect the principles of transparency and solidarity.

3a. Member States shall, without prejudice to their right to decide to impose contingency stocks requirements, inform the CMCG of their intention to impose such requirements or make significant changes to existing requirements, for the purpose of transparency and to enable exchanges on the guiding principles of proportionality and solidarity referred to in paragraph 2. The Commission shall, based on data available to the Commission, regularly inform the CMCG of contingency stocks requirements imposed by Member States, for the purpose of transparency.

4. This Article is without prejudice to obligations under Union law for the notification of technical regulations and technical barriers to the internal market, including those set out in Directive (EU) 2015/1535.

SECTION II

VOLUNTARY COLLABORATIVE PROCUREMENTS

Article 21

Commission facilitated Member States' cross-border procurement

1. Upon a reasoned request from three or more Member States ('the request'), the Commission may act as facilitator for the requesting Member States' cross-border procurement as laid down in Article 39 of Directive 2014/24/EU30 where the procurement concerns medicinal products of common interest.

2. Having received the request, the Commission shall inform all other Member States of the request and set a deadline of 20 working days for Member States to declare their interest in participating in the procedure. Participation in the procedure shall be voluntary for Member States.

3. The Commission shall assess the request in light of the objectives of this Regulation. The Commission shall inform the interested Member States of its decision on whether it agrees to facilitate the proposed request within 15 working days of receiving the request.

4. If the Commission declines the request, it shall state its reasons for the refusal.

5. If the Commission accepts the request, the Commission shall provide secretarial and logistical support to the participating Member States. The Commission shall facilitate communication and cooperation between the involved Member States and provide advice on applicable Union public procurement rules and on regulatory matters related to medicinal products.

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30 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/2014/24/2024-01-01).

6. The facilitation offered by the Commission shall be limited in time and shall end at the latest upon signature of the procurement contract by the participating contracting authorities. Member states participating in the cross-border procurement shall procure at their cost only.

7. The Commission can be held liable in accordance with Article 340 TFEU.
The Commission shall not be responsible, nor held liable, for any breaches of Union or national procurement laws by the participating contracting authorities. The Commission shall bear no liability associated with the conduct of the procurement procedure by participating Member States or for the implementation of the contract resulting from the procedure.

Article 22

Commission procurement on behalf of or in the name of Member States

1. By way of derogation from Article 168(3) of Regulation (EU, Euratom) 2024/2509 where six or more Member States jointly request the Commission to procure on their behalf, or in their name and at their costs (`the joint request`), the Commission may initiate a procurement procedure under the conditions laid down in this Article when the procurement concerns medicinal products belonging to one of the following categories below;

   (a) critical medicinal products for which a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative;

   (b) medicinal products of common interest, for which a joint clinical assessment report has been published pursuant to Article 12(4) Regulation 2021/2282/EU [18], or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States pursuant to Article 23(1) point (e) of that Regulation.

2. The joint request referred to in paragraph 1 shall only be submitted where the medicinal product concerned fulfils one of the criteria laid down in that paragraph and where the requested procurement procedure is expected to improve the security of supply and availability of critical medicinal products in the Union or to ensure the availability and accessibility of medicinal products of common interest, as applicable.

3. The participation in the procurement procedure shall be open to all Member States. Having received the joint request, the Commission shall inform all other Member States of the joint request, through the CMCG, and set a deadline of 20 working days for Member States to declare their interest in participating in the procedure. Participation in the procurement procedure shall be voluntary for Member States.

4. The Commission shall assess whether the joint request is justified in light of the objectives of this Regulation. The Commission shall in particular verify whether the procurement could result in discrimination or restriction on trade or a distortion of competition taking into account the utility, necessity and proportionality of the joint request.

5. Within 20 working days of receiving the joint request, the Commission shall inform the interested Member States of its decision and state its reasons in case of a refusal.

6. Where based on its assessment, the Commission may, if necessary to achieve the objectives of this Regulation, make the initiation of the procurement procedure conditional upon the interested Member States accepting binding minimum quantities, in accordance with their national need, or refraining from participating in competing subsequent procurement processes. Such a procurement procedure may only be initiated once these conditions have been accepted by the interested Member States.

7. Except for the derogations provided for in this Regulation, the procurement referred to in this Article shall be carried out in accordance with Article 168 (3) of Regulation (EU, Euratom) 2024/2509[31].

Article 24

Agreement concerning procedures under Article 22

1. Member States participating in the procurement procedures covered by Article 22, shall share with the Commission any information relevant for the procurement procedure. The participating Member States shall provide the resources necessary for the successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge.

2. An agreement between the Member States and the Commission shall determine the practical arrangements governing the procurement procedure, liabilities to be assumed and the decision-making process. The procedure shall be carried out in accordance with the mandate given to the Commission by the Member States.

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31 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 (recast) (OJ L, 26.9.2024, p. 1, ELI: http://data.europa.eu/eli/reg/2024/2509/oj).

Chapter V

Critical Medicines Coordination Group

Article 25

Establishment of Critical Medicines Coordination Group

1. A Critical Medicines Coordination Group (‘CMCG’) is hereby established.

2. The Member States and the Commission are Members of the CMCG . Each Member State shall appoint one permanent representative, with strategic expertise relevant for implementing the different measures set out in this Regulation. As necessary , Member States may appoint an alternate permanent representative and additional expert representatives to accompany the permanent Member State representative in order to support the different tasks of the CMCG. The Agency shall have an observer status.

3. The CMCG shall work closely with the MSSG, the Agency, and national competent authorities for medicinal products. For discussions where input from the medicines regulatory authorities’ perspective is necessary, the CMCG may organise joint meetings with the MSSG.

4. The Commission shall organise and coordinate the work of the CMCG by means of the Secretariat. The CMCG shall establish its rules of procedure, including procedures relating to the working group referred to in paragraph 6.

5. The CMCG shall be co-chaired by a representative of the Commission and by a representative of the Member States, who shall be elected by and from among the representatives of the Member States.

6. The CMCG , at the proposal of the co-chair or any of its members, may decide to establish a working group.

7. The CMCG shall use its best endeavours to reach consensus, where possible, when providing advice as referred to in Article 26(2) points (d) and (db) and providing an opinion as referred to in Article 26 (2) point (a) and (3). If such consensus cannot be reached, the CMCG shall issue its position by a majority of two-thirds of its members. Each Member State shall have one vote. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the CMCG's position.

Article 26

Tasks of the Critical Medicines Coordination Group

1. The CMCG shall facilitate coordination in the implementation of this Regulation, including, where appropriate advise to the Commission or Member States at their request, so as to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market or on national healthcare systems.

2. In order to attain the objectives referred to in paragraph 1, the CMCG shall perform the following tasks:

   (a) facilitate coordination and, on its own initiative or upon a request from the Commission, provide an opinion on strategic orientation of the financial support for strategic projects, including by exchanging information, where available, on the manufacturing capacity for a given critical medicinal product, existing or planned, in the Member States and facilitate discussion on the capacity needed in the Union to strengthen its supply security and availability of critical medicinal products, their active substances and key inputs within the Union;

(-a) engage in dialogue with the industry and other relevant stakeholders in order to promote synergies towards strategic projects.

(aa) enable the exchanges of information between the Member States and the Commission as referred to in Article 17 and, where necessary, facilitate coordination of respective actions aiming to attain the objectives of this Regulation.

(b) facilitate exchanges on the national programmes referred to in Article 19 and promote best practice and, where appropriate, voluntary cooperation on Member States public procurement policies with regard to critical medicinal products;

(ba) facilitate exchanges of information and guiding principles on contingency stocks requirements as referred to in Article 20(3a).

(c) facilitate strategic discussion on collaborative procurement initiatives ;

(d) advise the MSSG to provide the order of priority of critical medicinal products for vulnerability evaluation as set out in Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final], and propose a review or an update of existing evaluations where necessary.

(da) regularly discuss the potential contribution of strategic partnerships to the objectives of this Regulation and the consistency and potential synergies between Member States' cooperation with relevant third countries and the actions carried out by the Union.

(db) where appropriate, advise the Commission or Member States, at their request, on matters relating to the implementation of this Regulation.

3. The CMCG , at the Commission's or Member States` request, may provide an opinion where providing advice as referred to in paragraph 2, points (d) and (db) and may, on its own initiative or at the Commission's request, provide an opinion as referred to in point (a).

Chapter VI

International cooperation

Article 27

Strategic partnerships

Without prejudice to the prerogatives of the Council, the Commission, shall explore possibilities of concluding strategic partnerships aiming to diversify sourcing of critical medicinal products, their active substances and key inputs to increase the security of supply of critical medicinal products in the Union. The Commission shall also explore the possibility of building on existing forms of cooperation, where appropriate , to support security of supply and reinforce efforts to strengthen the production of critical medicinal products in the Union. The Commission shall regularly inform the CMCG about their ongoing considerations and assessments.

Chapter VII

Amendments to Regulation (EU) 2024/795

Article 28

Regulation (EU) 2024/795 is amended as follows:

(a) in Article 2, (1) point (a), subparagraph (iii) is replaced by the following:

‘(iii) biotechnologies, and any other technologies relevant for manufacturing of critical medicinal products as defined in Critical Medicines Act *;

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* Regulation (EU) … of the European Parliament and of the Council laying down a framework for strengthening the availability and security of supply of critical medicinal products as well as for improving the availability of, and access to, medicinal products of common interest, and amending Regulation (EU) 2024/795.' [D.G.: reference to be completed with the definitive title of the 'Critical Medicines Act' and with its publications references once they are available];'

(b) in Article 2, the following subparagraph is added in paragraph 3:

'By way of derogation from the first subparagraph of this paragraph, the value chain for the development or manufacturing of medicinal products that fall within the scope of the [Critical Medicines Act] and that are referred to in paragraph 1, point (a)(iii) of this Article, relates to finished dosage forms, as well as to active pharmaceutical ingredients and other key inputs necessary for the production of the finished dosage forms of critical medicinal products as defined in the Regulation.;'

(c) in article 2, paragraph 8 is added:

'8. Strategic projects designated in accordance with the [Critical Medicines Act] that address a vulnerability in the supply chains of critical medicinal products shall be deemed to contribute to the STEP objective referred to in paragraph 1, point (a)(iii).;'

(d) in Article 4, paragraph 7 is replaced by the following:

‘7. Strategic projects recognised in accordance with the relevant provisions of the Net-Zero Industry Act, the Critical Raw Materials Act [and the Critical Medicines Act] that fall within the scope of Article 2 of this Regulation and that receive a contribution under the programmes referred to in Article 3 of this Regulation may also receive a contribution from any other Union programme, including funds under shared management, provided that those contributions do not cover the same costs. The rules of the relevant Union programme shall apply to the corresponding contribution to the strategic project. The cumulative funding shall not exceed the total eligible costs of the strategic project. The support from the different Union programmes may be calculated on a pro rata basis in accordance with the documents setting out the conditions for support.;’

(e) in Article 6, paragraph 1, point c is replaced by the following:

‘(c) details of projects that have been recognized as strategic projects under the Net-Zero Industry Act, the Critical Raw Materials Act and the [Critical Medicines Act], to the extent that they fall within the scope of Article 2 of this Regulation. ’

Chapter VIII
Final provisions

Article 29

Obligation of the market actors to provide information

1. For the purposes of Articles 6, 8, 11(1), 12, 15, 16(2) and 26(2) point (a) the national competent authorities concerned may request information from promoters of industrial projects, project promoters, marketing authorisation holders and other actors in the supply and distribution chains of critical medicinal products, their active substances or key inputs, including from importers and manufacturers of medicinal products, active substances or key inputs and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public.

   For the purposes of Article 30 the national competent authorities may request information from the market actors referred to in paragraph 1, contracting authorities and other stakeholders.

   For the purposes of Article 11(2) the Agency may request information from project promoters, marketing authorisation holders, manufacturers of medicinal products and manufacturers or suppliers of active substances or key inputs.

2. Where information is requested by national competent authorities or the Agency, as relevant, pursuant to paragraph 1, an actor may indicate that the information requested has already been provided to the national competent authority concerned or the Agency pursuant to other relevant Union legal acts. In such cases the national competent authority concerned or the Agency shall take due account of the information already provided in so far as this information has been provided and may be used also for the purposes of this Regulation.

3. Where a market actor submits information pursuant to paragraph 1, the actor shall indicate whether the information provided 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. The national competent authority or the Agency, as relevant, shall assess the merits of each confidentiality claim made by the actors and shall protect any information that is commercially confidential against unjustified disclosure in accordance with Article 29a.

Article 29a

Handling of confidential information

1. Information acquired in the course of implementing this Regulation shall be used only for the purposes of this Regulation and shall be protected by the relevant Union and national law.

2. Member States, the Commission and the Agency shall ensure the protection of trade and business secrets and other commercially confidential information obtained and processed in application of this Regulation, in accordance with Union and relevant national law.

3. The Commission, the Agency and the national competent authorities, their officials, employees and other persons working under the supervision of those authorities shall ensure the confidentiality of information obtained in carrying out their tasks and activities in accordance with relevant Union or national law. This obligation also applies to all representatives of Member States, observers, experts and other participants attending meetings of the CMCG pursuant to Article 25.

4. Any obligations on sharing information pursuant to this Regulation shall not apply to data that concerns the essential interests of the Member States' security or defence.

Article 30

Evaluation

1. By [OP please insert the date of:] at the latest five years after the date of application of this Regulation and every five years thereafter, the Commission shall evaluate this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.

2. The Commission shall in its evaluation assess the impact of this Regulation and to what extent its objectives as established in Article 1 have been achieved. The evaluation shall include an assessment of the scope, functioning and efficiency of Article 18 as well as coherence of this Regulation with developments within the field of public procurement.

3. The national authorities shall, upon request, provide the Commission with any relevant information they have and that is necessary for the Commission for its assessment and review pursuant to paragraphs 1 and 2.

Article 31

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

2. It shall apply from [….].

3. Article 18 (1) and (2) shall apply from [12 months after the date of application in paragraph 2]. The requirements in Article 18 (1) and (2) shall apply to public procurement procedures launched after this date.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg,

For the European Parliament	*For the Council*
The President	*The President*