Council of the
European Union

Brussels, 24 March 2021
(OR. en)

7310/21

Interinstitutional File:
2018/0018(COD)

PHARM 49
SAN 167
MI 207
COMPET 206
IA 45
CODEC 446

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	5844/18 + COR1 - 5844/18 ADD1 to ADD3 - 5844/18 ADD3 COR1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU *- Partial mandate for negotiations with the European Parliament*

Delegations will find enclosed the mandate for the negotiations with the European Parliament on the above-mentioned subject as agreed by the Committee of Permanent Representatives at its meeting on 24 March 2021.

Draft text for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

(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 Articles 114 and 168 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,
Having regard to the opinion of the Committee of the Regions,
Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The development of health technologies is a key driver of economic growth and innovation in the Union. It forms part of an overall market for healthcare expenditure that accounts for 10% of EU gross domestic product. Health technologies encompass medicinal products, medical devices, *in vitro* diagnostic medical devices and medical procedures, as well as measures for disease prevention, diagnosis or treatment.

(2) Health Technology Assessment (HTA) is an evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on the added value of a health technology in comparison with other new or existing health technologies.

(3) HTA can cover both clinical and non-clinical aspects of a health technology, depending on the healthcare system. The EU co-funded joint actions on HTA (EUnetHTA Joint Actions) have identified nine domains by reference to which health technologies are assessed. Of these nine domains, four are clinical and five are non-clinical. The four clinical domains of assessment concern the identification of a health problem and current technology, the examination of the technical characteristics of the technology under assessment, its relative safety, and its relative clinical effectiveness. The five non-clinical assessment domains concern cost and economic evaluation of a technology, its ethical, organisational, social, and legal aspects.

(4) The outcome of HTA is used to inform decisions concerning the allocation of budgetary resources in the field of health, for example in relation to establishing the pricing or reimbursement levels of health technologies. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients.

(5) The carrying out of parallel assessments by multiple Member States and divergences between national laws, regulations and administrative provisions on the processes and methodologies of assessment can result in health technology developers being confronted with multiple and divergent requests for data. It can also lead to both duplications and variations in outcomes, which is justified by the specific national health care context.

(6) While Member States have carried out some joint assessments within the framework of the EU co-funded joint actions, the voluntary cooperation and production of output has been inefficient, relying on project-based cooperation in the absence of a sustainable model of cooperation. Use of the results of the joint actions, including their joint clinical assessments, at Member State level has remained low, meaning that the duplication of assessments on the same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed.

(7) The Council in its Conclusions of December 2014[1] acknowledged the key role of health technology assessment and called on the Commission to continue to support cooperation in a sustainable manner.

(8) The European Parliament, in its resolution of 2 March 2017[2], called on the Commission to propose legislation on a European system for health technology assessment as soon as possible and to harmonise transparent health technology assessment criteria in order to assess the added therapeutic value of medicines.

(9) In its 2015 Communication on upgrading the single market[3], the Commission declared its intention to introduce an initiative on HTA to increase coordination in order to avoid multiple assessments of a product in different Member States and improve the functioning of the Single Market for health technologies.

(10) This Regulation aims to achieve a high level of protection of health for patients and users while ensuring the smooth functioning of the internal market as regards medicinal products, *in vitro* diagnostic medical devices and medical devices. At the same time, this Regulation establishes a framework to support Member States cooperation and the measures needed for clinical assessment of health technologies. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation sets the procedures and the rules for carrying out joint work and establishing a framework at Union level. As regards Article 168 TFEU, whilst aiming at providing a high level of health protection, this Regulation allows for the cooperation between Member States on certain aspects of HTA.

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1 OJ C 438, 6.12.2014, p. 12

2 European Parliament resolution of 2 March 2017 on EU options for improving access to medicines – 2016/2057(INI)

3 COM(2015) 550 final p. 19

(11) Health technology developers often face the difficulty of submitting the same information, data, analyses and other evidence to different Member States, and also at various points in time. The duplication of submissions and consideration of different timings for submission across Member States may constitute a significant administrative burden for health technology developers, in particular for smaller companies with limited resources, and might contribute to an impeded and distorted market access, leading to a lack of business predictability, higher costs, and, in the long run, to negative effects on innovation. Thus, this Regulation should provide for a mechanism that ensures that any information, data, analyses and other evidence required for the joint clinical assessment should be submitted only once at Union level by the health technology developer.

(12) In accordance with Article 168(7) TFEU, the Member States are responsible for the definition of their health policies and for the organisation and delivery of their health services and medical care. These responsibilities of the Member States include the management of health services and medical care and especially the allocation of the resources assigned to them. Therefore, it is necessary that Union action is limited to those aspects of HTA that relate to the joint clinical assessment of a health technology, and to ensure in particular that there are no value judgements in joint clinical assessments in order to sustain the responsibilities of Member States pursuant to Article 168(7) TFEU. The outcome of joint clinical assessments should therefore neither affect the discretion of Member States to carry out assessments on the added clinical value of the technologies concerned nor predetermine subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement decisions, which may depend on both clinical and non-clinical considerations individually, or together, and which remain solely a matter of national competence.

(13) Member States should be able to perform complementary clinical analyses, which are necessary for their overall national health technology assessment process, on the health technologies for which a joint clinical assessment report is available. In particular, Member States should be able to perform complementary clinical analyses relating, *inter alia*, to patient groups, comparators or outcomes other than those included in the joint clinical assessment report, or using a different methodology if that methodology would be required in the overall national health technology assessment process of the Member State concerned. Should additional information, data, analyses and other evidence be needed for complementary assessment, Member States should be able to ask the health technology developers to submit this necessary information, data, analyses and other evidence. This Regulation should not restrict in any way Member States' rights to perform non-clinical assessments on the same health technology prior to, during the preparation of, or after the publication of a joint clinical assessment report.

(14) In order to guarantee the highest quality of joint clinical assessments, ensure a wide acceptance and enable pooling of expertise and resources across national HTA bodies, it is appropriate to follow a stepwise approach, starting with a small number of jointly assessed medicinal products and only at a later stage and, after careful review, require joint clinical assessments to be carried out for all medicinal products undergoing the centralised marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council[4], which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication.

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4 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1)

(15) Joint clinical assessments should also be carried out on certain medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council[5] which are in the highest risk classes and for which the relevant expert panels have provided their opinions or views, as well as on *in vitro* diagnostic medical devices classified as class D pursuant to Regulation (EU) 2017/746[6].

(16) Taking into consideration the complexity of certain medical devices and *in vitro* diagnostic medical devices, and the expertise required to assess them, Member States should be able, where they see an added-value, to undertake voluntary cooperation on HTA on medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 which are software and do not fall within the scope of joint clinical assessments under this Regulation.

(17) In order to ensure that joint clinical assessments carried out on health technologies remain accurate and relevant, it is appropriate to establish conditions for the updating of assessments, in particular where additional data available subsequent to the initial assessment has the potential to increase the accuracy of the assessment.

(18) A coordination group composed of Member States' representatives, in particular from health technology assessment authorities and bodies, should be established with responsibility for overseeing the carrying out of joint clinical assessments and other joint work.

(19) The Commission should neither take part in votes on joint clinical assessments nor comment on the content of joint clinical assessment reports.

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5 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)

6 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176)

(20) The Coordination Group should ensure that the scientific joint work as well as the procedures and methodology for the preparation of joint clinical assessment reports and joint scientific consultation outcome documents guarantee the highest quality, are prepared in a timely manner and reflect the state of the art of medical science at the time of their preparation.

(21) In order to ensure a Member State-led approach to joint clinical assessments and scientific consultations, Member States should designate the members of the Coordination Group. Those members should be designated with the goal to ensure a high level of competence in the Coordination Group. Members of the Coordination Group should designate health technology authorities and bodies to the subgroups, which provide adequate technical expertise for carrying out joint clinical assessments and joint scientific consultations taking into account the need to provide expertise on the HTA of medicinal products, medical devices and *in vitro* diagnostic medical devices.

(22) The assessment scope for joint clinical assessments should be inclusive and should reflect all Member States' requirements in terms of data and analyses to be submitted by the health technology developer.

(23) When joint clinical assessments are used to prepare subsequent administrative decisions at Member State level, they constitute one of several preparatory steps in a multi-step procedure. Member States remain the sole entity responsible for national HTA processes, for the conclusions on the value of a health technology and for the decisions resulting from the health technology assessments. Member States may determine at which step of their health technology assessment process, and by which authority or body, the joint clinical assessment reports should be considered.

(24) Member States should remain responsible for drawing conclusions at national level on the clinical added value of a health technology, as such conclusions depend on the specific healthcare context in any given Member State, and on the relevance of individual analyses included in the joint clinical assessment report (*e.g.* several comparators could be included in the joint clinical assessment report, of which only a selection is relevant to a given Member State). The joint clinical assessment report should include a description of the relative effects observed for the health outcomes analysed, including numerical results and confidence intervals, and an analysis of scientific uncertainty and strengths and limitations of the evidence (*e.g.* internal and external validity). The joint clinical assessment report should be factual and should not contain any value judgement, or ranking of outcomes, nor conclusions on the overall benefit or added clinical value of the assessed health technology, nor any position on the target population in which the technology should be used, nor any position on the place the technology should have in the therapeutic, diagnostic or preventive strategy.

(25) Where Member States conduct HTA at national or regional level for health technologies that have been assessed at Union level, they should consider the joint clinical assessment reports at that level. In this regard, especially taking into account that different timing can apply for national HTA decisions, Member States should be able to take into account other information, data, analyses and other evidence that were not part of the joint clinical assessment at EU level.

(26) In the context of this Regulation, the term "give due consideration", when applied to a joint clinical assessment report, means that the report should be part of the documentation of bodies or organisations involved in HTA activities at Member State or regional level and should be considered for any health technology assessment at Member State level. If the joint clinical assessment report is available, it should be part of the documentation that supports the national HTA process. However, the content of the report, scientific in nature, should not be binding on those bodies, organisations or on Member States. If a joint clinical assessment report is not available at the time when the national HTA is finalised, this should not delay any subsequent process at Member State level. A joint clinical assessment report should have purely internal administrative effect for any health technology assessment at Member State level and no external impact for applicants and other parties other than the Member States.

(27) The obligation on Member States not to request at national level any information, data, analyses and other evidence which has been submitted by health technology developers at Union level reduces, where health technology developers comply with information submission requirements stipulated pursuant to this Regulation, the administrative and financial burden for them resulting from being confronted with multiple and divergent requests for information, data, analyses and other evidence at Member State level. This obligation should however not exclude the possibility for Member States to ask for clarification to health technology developers about the submitted information, data, analyses and other evidence.

(28) The obligation on Member States not to request at national level the same information, data, analyses and other evidence that has been already submitted by health technology developers at Union level should not encompass requests of information, data, analyses and other evidence within the scope of early access programmes at Member State level. Such early access programmes at Member State level are aimed at providing patient access in situations of high unmet medical needs before a centralised marketing authorisation has been granted.

(29) Health technology developers should not submit any information, data, analyses and other evidence at national level that has been already submitted at Union level. This guarantees that Member States can only request information, data, analyses and other evidence from health technology developers at Member State level that are not already available at Union level.

(30) For medicinal products, randomised blinded controlled directly comparative studies, the methodology of which conforms to international standards of evidence-based medicine, should be preferentially considered when conducting a joint clinical assessment. This should however not *per se* exclude observational studies, including those based on real world data, when such studies are accessible.

(31) The timeframe for joint clinical assessments for medicinal products should be fixed, as far as possible, by reference to the timeframe applicable to the completion of the centralised marketing authorisation procedure provided for under Regulation (EC) No 726/2004. Such coordination should ensure that clinical assessments could effectively facilitate market access and contribute to the timely availability of innovative technologies for patients. Health technology developers should therefore respect the deadlines established pursuant to this Regulation when submitting the requested information, data, analyses and other evidence.

(32) The establishment of a timeframe for the joint clinical assessments for medical devices and *in vitro* diagnostic medical devices should take into account the highly decentralised market access pathway for these products and the availability of appropriate evidence data required to carry out a joint clinical assessment. As the required evidence may only become available after the medical device or the *in vitro* diagnostic medical device has been placed on the market, and in order to allow for the selection of medical devices and *in vitro* diagnostic medical devices for joint clinical assessment at an appropriate time, it should be possible for assessments of such devices to take place following their placing on the market.

(33) In all cases, the joint work carried out under this Regulation, in particular the joint clinical assessments, should aim to produce high-quality and timely results, and not delay or interfere with the CE marking of medical devices and *in vitro* diagnostic medical device or the market access of health technologies. This work should be separate and distinct from the regulatory assessments of the safety, quality, efficacy and performance of health technologies carried out pursuant to other Union legislation and should have no impact on decisions taken in accordance with other Union legislation.

(34) In order to facilitate the process of preparing joint clinical assessments, health technology developers should, in appropriate cases, be afforded the opportunity to engage in joint scientific consultations with the Coordination Group in order to obtain guidance on the information, data, analyses and other evidence that are likely to be required from clinical studies. Clinical studies comprise clinical trials of medicinal products, clinical investigations required for the clinical evaluation of medical devices and performance studies required for performance evaluations of *in vitro* diagnostic medical devices. Given the preliminary nature of the consultation, any guidance offered should not be legally binding either on the health technology developers or on HTA authorities and bodies. Such guidance should, however, reflect the state of the art of medical science at the time of the scientific consultation.

(35) Where joint scientific consultations are carried out in parallel with the preparation of scientific advice on medicinal products provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council or in parallel with the consultation on medical devices provided for in Regulation (EU) 2017/745 of the European Parliament and of the Council, those parallel processes, including information exchange between the subgroup<u>s</u> and the European Medicines Agency or the expert panel on medical devices, should be carried out with a view to ensure that the evidence generation fulfils the needs of the respective frameworks, while the remits should remain separate.

(36) Joint clinical assessments and joint scientific consultations necessitate the sharing of confidential information between health technology developers and HTA authorities and bodies. In order to ensure the protection of such information, information provided to the Coordination Group in the framework of assessments and consultations should only be disclosed to a third party after a confidentiality agreement has been concluded. In addition, it is necessary that any information made public about the results of joint scientific consultations is presented in an anonymised format with the removal of any information of a commercially sensitive nature.

(37) In order to ensure the efficient use of available resources, it is appropriate to provide for a "horizon scanning", to allow the early identification of emerging health technologies that are likely to have a major impact on patients, public health and healthcare systems. Such horizon scanning could be used to support the Coordination Group in planning its work, in particular in relation to joint clinical assessments and joint scientific consultations, and could also provide information for long term planning purposes at both Union and national levels.

(38) The Union should continue to support voluntary cooperation on HTA between Member States in areas such as the development and implementation of vaccination programmes and capacity building of national HTA systems. Such voluntary cooperation should also facilitate synergies with initiatives under the digital single market strategy in relevant digital and data-driven healthcare areas with a view to provide additional real world evidence relevant for HTA.

(39) In order to ensure the inclusiveness and transparency of the joint work, the Coordination Group should engage and consult widely with stakeholders. However, in order to preserve the integrity of the joint work, rules should be developed in this Regulation to ensure the independence and impartiality of patients, clinical and other experts involved.

(40) In order to ensure a uniform and Member State-driven approach to the joint work provided for in this Regulation, the Coordination Group should develop its detailed procedural steps and their timing for joint clinical assessments, updates of joint clinical assessments and joint scientific consultations. Where appropriate, distinct rules should be developed for medicinal products, medical devices and *in vitro* diagnostic medical devices. When developing these rules, the Coordination Group may take into account the results of the work undertaken in the EUnetHTA Joint Actions.

(41) The Coordination Group should develop methodological guidance on the joint work provided for in this Regulation, following international standards of evidence-based medicine, and guidance on the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations, including on the scientific expertise required to implement the joint work stipulated in this Regulation.

(42) In order to ensure a uniform approach to the joint work provided for in this Regulation, implementing powers should be conferred on the Commission to establish general procedural rules for ensuring that health technology assessment authorities and bodies carry out joint clinical assessments in an independent and transparent manner, free from conflicts of interest, for the mechanisms concerning the interaction between health technology bodies and health technology developers during joint clinical assessments, to establish the format and the templates of submission and report documents and for the consultation of stakeholders. Where appropriate, distinct rules should be developed for medicinal products, medical devices and *in vitro* diagnostic medical devices. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[7], as referred to in Article 30.

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

(43) When preparing the implementing acts foreseen in this Regulation, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including with the Coordination Group and at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[8].

(44) In order to ensure that sufficient resources are available for the joint work provided for under this Regulation, the Union should provide funding for the joint work and voluntary cooperation, and for the framework to support these activities. The funding should cover the costs of producing joint clinical assessment and joint scientific consultation reports. Member States should also have the possibility to second national experts to the Commission in order to support the secretariat of the Coordination Group.

(45) In order to facilitate the joint work and the exchange of information between Member States on HTA, provision should be made for the establishment of an IT platform that contains appropriate databases and secure channels for communication. The Commission should ensure a link between the IT platform and other data infrastructures relevant for the purposes of HTA such as registries of real world data.

(46) In order to ensure the smooth establishment and operation of Union-level joint assessments, as well as to safeguard their quality, it is appropriate to start with a small number of joint assessments. After three years of the date of application of this Regulation, the Commission should be empowered to adopt implementing acts stipulating a progressive expansion of the number of joint clinical assessments carried out annually. The number of assessments to be carried out should be determined with due consideration of the resources of Member States participating and thus, prior to the adoption of such implementing acts, the Commission should gather all necessary expertise and in particular consult the Coordination Group in order to ensure a manageable workload.

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8 Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission of 13 April 2016 on Better Law-Making (OJ L 123, 12.5.2016, p. 1)

(47) In order to ensure that the support framework continues to be as efficient and cost-effective as possible, the Commission should report to the European Parliament and to the Council on the implementation of this Regulation no later than three years after its application. The report should focus on reviewing the added value of the joint work for Member States. The report may in particular consider whether there is a need to introduce a fee-paying mechanism, which would ensure the independence of the Coordination Group, through which health technology developers would also contribute to the financing of joint scientific consultations. In addition, the report should review the effect of the non-duplication of the request of information, data, analyses and other evidence for joint clinical assessment in terms of reducing administrative burden for Member States and health technology developers, facilitating market access for new and innovative products and reducing costs.

(48) Member States should no later than two years after the beginning of assessing medicinal products that fall under the scope of this Regulation report to the Commission on the application of this Regulation and, in particular, on their assessment of the added value of the joint clinical assessment reports in their national health technology assessment processes and the workload of the Coordination Group.

(49) In order to adjust the list of information to be submitted by health technology developers, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in view of amending Annex I and Annex II. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(50) Directive 2011/24/EU of the European Parliament and of the Council[9] provides that the Union is to support and facilitate the cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. As those matters are governed by this Regulation, Directive 2011/24/EU should be amended accordingly.

(51) The objectives of this Regulation, namely to establish a framework of joint clinical assessments of certain health technologies at Union level, can only be sufficiently achieved by cooperation of the Member States at Union-level. The Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 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 that objective.

HAVE ADOPTED THIS REGULATION:

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9 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45)

Chapter I
General Provisions

Article 1

Subject Matter

1. This Regulation establishes:
   (a) a support framework and procedures for cooperation of Member States on health technologies at Union level;
   (b) a mechanism stipulating that any information, data, analyses and other evidence required for the joint clinical assessment is submitted by the health technology developer only once at Union level;
   (c) common rules and methodologies for the joint clinical assessment of health technologies at Union level.

2. This Regulation shall not affect Member States' competence to draw conclusions on the relative effectiveness of health technologies and to take decisions on the use of a health technology in their specific national health context. It shall not interfere with the exclusive national competence of Member States, including those for national pricing and reimbursement decisions, nor does it affect any other competences which concern Member States' management and delivery of health services and medical care and the allocation of resources assigned to them.

Article 2

Definitions

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

(a) 'medicinal product' means a medicinal product for human use as defined in Directive 2001/83/EC[10];

(b) 'medical device' means a medical device as defined in Regulation (EU) 2017/745;

(ba) '*in vitro* diagnostic medical device' means an *in vitro* diagnostic medical device as defined in Regulation (EU) 2017/746;

(c) 'health technology' means a health technology as defined in Directive 2011/24/EU;

(d) 'health technology assessment' means a multidisciplinary process, that summarises information about the medical, patient and social aspects, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner;

(e) 'joint clinical assessment' of a health technology means the scientific compilation and the description of a comparative analysis of the available clinical evidence on a health technology in comparison with one or more other health technologies or existing procedures, in accordance with an agreed assessment scope performed under this Regulation and based on the scientific aspects of the following clinical domains of health technology assessment: the description of the health problem addressed by the health technology and the current use of other health technologies addressing that health problem, the description and technical characterisation of the health technology, the relative clinical effectiveness, and the relative safety of the health technology;

(f) 'non-clinical assessment' means the part of a health technology assessment based on the following non-clinical domains of health technology assessment: the cost and economic evaluation of a health technology, and the ethical, organisational, social and legal aspects related to its use;

(g) 'collaborative assessment' means a clinical assessment of a medical device or an *in vitro* diagnostic medical device carried out at Union level by a number of interested health technology assessment authorities and bodies participating on a voluntary basis;

(h) 'assessment scope' means the set of the parameters for joint clinical assessment in terms of population, intervention, comparators and outcomes requested by Member States.

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10 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)

Article 3

The Member State Coordination Group on Health Technology Assessment

1. The Member State Coordination Group on Health Technology Assessment (the 'Coordination Group') is hereby established.

2. Member States shall designate their members of the Coordination Group and inform the Commission thereof and of any subsequent changes. The Members of the Coordination group shall appoint their representatives in the Coordination Group on an *ad-hoc* or permanent basis, and inform the Commission of their appointment and any subsequent changes.

3. The members of the Coordination Group shall designate their national or regional authorities and bodies as members of the subgroups. The members of the sub-group shall appoint their representatives, who should have the appropriate HTA expertise, in the sub-groups on an *ad-hoc* or permanent basis, and inform the Commission of their appointment and any subsequent changes.

4. The Coordination Group shall, in principle, act by consensus. Where consensus cannot be reached, the adoption of a decision shall require support by members representing [majority][11] of the Member States. Each Member State shall have one vote. The results of the votes shall be recorded in the minutes of the Coordination Group's meetings. Where a vote takes place, members may ask for divergent opinions to be recorded in the minutes of the meeting in which the vote took place.

5. Meetings of the Coordination Group shall be chaired and co-chaired by two elected members from the group, representing different Member States, for a set term to be determined in its rules of procedure. The Commission shall act as the Secretariat of the Coordination Group and support its work in accordance with Article 25.

11 To be discussed later

6. The Coordination Group shall:

(a) adopt its rules of procedure for the conduct of its meetings and update them where necessary;

(b) adopt its annual work programme and annual report pursuant to Article 4;

(c) provide strategic direction for the work of its sub-groups;

(d) adopt methodological guidance on joint work following international standards of evidence-based medicine;

(e) adopt its detailed procedural steps and their timing for joint clinical assessments and for updates of joint clinical assessments;

(f) adopt detailed procedural steps and their timing for joint scientific consultations, including submissions of request from health technology developers;

(g) adopt guidance on the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations, including on the scientific expertise required;

(h) coordinate and approve the work of its sub-groups;

(i) ensure cooperation with relevant Union level bodies established pursuant to Regulation (EC) No 726/2004, Regulation (EU) 2017/745 and Regulation (EU) 2017/746 to facilitate additional evidence generation necessary for its work;

(j) ensure appropriate involvement of stakeholders in its work;

(k) establish sub-groups, in particular for the following:

(i) joint clinical assessments;

(ii) joint scientific consultations;

(iii) identification of emerging health technologies;

(iv) development of methodological and procedural guidance.

7. The Coordination Group may meet in different configurations, notably for the following categories of health technology: medicinal products, medical devices, *in vitro* diagnostic medical devices and other health technologies.

Article 3a

Quality Assurance

1. The Coordination Group shall ensure that the joint work carried out pursuant to Chapter II is of the highest quality, follows international standards of evidence-based medicine, and is delivered in a timely manner. To this aim, the Coordination Group shall establish procedures that are systematically reviewed.

2. In particular, the Coordination Group shall establish and regularly review standard operating procedures describing:
   (a) transparent criteria and procedures for the selection of assessors and external experts;
   (b) the necessary skills, expertise and the required resources of the assessors;
   (c) its procedure for determining methodologies and the procedure for Joint Clinical Assessments and Joint Scientific Consultations.

3. The Coordination Group shall regularly review, and where necessary update guidance prepared in accordance with paragraph 6 of Article 3, including:
   (a) methodological guidance, that reflects the state of the art, on joint clinical assessments and joint scientific consultations;
   (b) guidance on the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations, including on the scientific expertise required;
   (c) guidance on the review of the procedures and methods used and the work of assessors performing joint clinical assessments and joint scientific consultations;
   (d) the detailed procedural steps of joint clinical assessments and their timing.

4. Where appropriate, specific rules shall be developed for medicinal products, medical devices and *in vitro* diagnostic medical devices.

Article 3b

Transparency and conflict of interest

1. The Coordination Group shall carry out its activities in an independent, impartial and transparent manner.

2. Representatives appointed to the Coordination Group, its sub-groups, patients, clinical and other experts participating in any joint work shall not have any financial nor other interests in the health technology developers' industry which could affect their independence or impartiality.

3. The representatives shall make a declaration of their financial and other interests and update them annually and whenever necessary. They shall disclose any other facts of which they become aware that might in good faith judgment reasonably be expected to involve or give rise to a conflict of interest.

4. Representatives who participate in meetings of the Coordination Group and its sub-groups shall declare, before each meeting, any interests which could be considered to be prejudicial to their independence or impartiality with respect to the items on the agenda. Where the Commission decides that a declared interest constitutes a conflict of interest, that representative shall not take part in any discussions and decision, nor obtain any information concerning that item of the agenda. Such declarations of representatives and the decision of the Commission shall be recorded in the summary minutes of the meeting.

5. Patients, clinical experts and other experts shall declare any financial and other interests relevant to the joint work in which they are due to participate. Such declarations and any actions taken as a result shall be recorded in the summary minutes of the meeting and in the outcome documents of the joint work in question.

6. Representatives appointed to the Coordination Group and its sub-groups as well as patients, clinical experts and other experts involved in the work of any sub-group shall, even after their duties have ceased, be subject to a requirement of professional secrecy.

7. The Commission shall lay down rules for the implementation of this Article in accordance with Article 22(1)(i) and in particular rules for the assessment of conflict of interest referred to in paragraphs 3, 4 and 5 and the action to be taken where a conflict or potential conflict of interest arises.

Article 4

Annual Work Programme and Annual report

1. The Coordination Group shall each year, at the latest by 30 November, adopt an annual work programme and subsequently amend it if necessary.

2. The annual work programme shall set out the joint work to be carried out in the calendar year following its adoption, covering:
   (a) the planned number and type of joint clinical assessments, and the planned number of updates of joint clinical assessments according to Article 9;
   (b) the planned number of joint scientific consultations;
   (c) the planned number of assessments in the area of voluntary cooperation.

3. In the preparation or amendment of the annual work programme, the Coordination Group shall:
   (a) take into account the reports on emerging health technologies referred to in Article 18;
   (b) take into account the information from the European Medicines Agency, provided by the Commission pursuant to Article 25 on the status of submitted and upcoming marketing authorisation applications for medicinal products referred to in Article 5. As ongoing new regulatory data becomes available, the Commission shall share such information with the Coordination Group so that the annual work programme can be amended;

(c) take into account information provided by the Medical Devices Coordination Group established in Article 103 of Regulation (EU) 2017/745 or other sources, and provided by the Commission pursuant to Article 25 on the work of the relevant expert panels;

(d) consult the stakeholder network referred to in Article 26;

(e) take into account the resources available to the Coordination Group for the joint work;

(f) consult the Commission on the draft annual work programme and take its opinion into account.

4. The Coordination Group may amend the annual work programme, if required, in accordance with this Article.

5. The Coordination Group shall each year, at the latest by 28 February, adopt its annual report.

6. The annual report shall provide information on the joint work carried out in the calendar year preceding its adoption.

Chapter II

Joint Work on Health Technology Assessment at Union Level

SECTION 1

JOINT CLINICAL ASSESSMENTS

Article 5

Health technologies subject to Joint Clinical Assessments

1. The following health technologies shall be subject to joint clinical assessments:

   (a) medicinal products for human use that are provided for in Regulation (EC) No 726/2004, pursuant to Article 3(1) and (2)(a) thereof and for which the application for a marketing authorisation in accordance with Regulation (EC) No 726/2004 is submitted after the relevant dates set pursuant to paragraph 2 and that application is based on Article 8(3) of Directive 2001/83/EC;

   (b) medicinal products for which a joint clinical assessment report has been published, in cases where an authorisation is granted pursuant to the second subparagraph of Article 6(1) of Directive 2001/83/EC for a variation to an existing marketing authorisation in order to include a new therapeutic indication;

   (c) medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation, and subject to selection pursuant to paragraph 2a;

   (d) *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation, and subject to selection pursuant to paragraph 2a.

2. The dates to be set in accordance with paragraph 1 point (a) shall be as follows:

(a) [*the date of application of this Regulation*], for medicinal products with new active substances for which the therapeutic indication is the treatment of cancer.

(b) Three years after the date of application of this Regulation, the Commission is empowered to adopt an implementing act that sets out the date as from which the obligation to prepare joint clinical assessments shall apply for medicinal products which are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000 and medicinal products which are regulated as advanced therapy medicinal products pursuant to Regulation (EC) No 1394/2007;

(c) Five years after the date of application of this Regulation, the Commission is empowered to adopt an implementing act that sets out the date as from which the obligation to prepare joint clinical assessments shall apply for medicinal products for which the therapeutic indication is the treatment of any of the diseases referred to in point 3 of Annex I to Regulation (EC) No 726/2004 other than cancer;

(d) Eight years after the date of application of this Regulation, for all medicinal products referred to in paragraph 1.

2a. After the date of application of this Regulation, the Commission, upon a recommendation of the Coordination Group, shall select, by way of implementing act and at least every two years, the medical devices and in-vitro diagnostic medical devices referred to in paragraph 1 points (c) and (d) for joint clinical assessment based on one or more of the following criteria:

(a) unmet medical needs;

(b) first in class;

(c) potential impact on patients, public health or healthcare systems;

(d) incorporating software using artificial intelligence, machine learning technologies or algorithms.

3. By way of derogation from paragraph 2, the Commission, upon a recommendation of the Coordination Group and by way of implementing act, shall decide that medicinal products referred to in paragraph 2 shall be subject to joint clinical assessment at an earlier date than the dates set out in paragraph 2 points (a) to (d), provided that the medicinal product, in particular according to Article 18, has the potential to address an unmet medical need or public health emergencies or has a significant impact on health care systems.

4. The implementing acts referred to in paragraphs 2, 2a and 3 shall be adopted in accordance with the examination procedure referred to in Article 30(2).

Article 6

Scoping Process for Joint Clinical Assessments

1. The Coordination Group shall carry out joint clinical assessments on health technologies on the basis of its annual work programme.

2. The Coordination Group shall initiate joint clinical assessments of health technologies by designating the sub-group on joint clinical assessments to oversee the conduct of the joint clinical assessment on behalf of the Coordination Group.

3. The joint clinical assessment shall be conducted in accordance with the procedure established by the Coordination Group according to the requirements set out in this Article, in point (e) of paragraph 6 of Article 3 and in Articles 3a, 6a, 6b, 6c, 6d, as well as the requirements to be established pursuant to Articles 11, 22 and 23.

4. The designated sub-group shall appoint, from among its members, an assessor and a co-assessor from different Member States to conduct the joint clinical assessment. The appointments shall take into account the scientific expertise necessary for the assessment. If the health technology has been the subject of a joint scientific consultation in accordance with section II of this Chapter, the assessor and the co-assessor shall be different from those appointed pursuant to Article 13 for the preparation of the joint scientific consultation outcome document.

5. Notwithstanding paragraph 4, where the necessary specific expertise is otherwise not available, the same assessor and/or co-assessor involved in the joint scientific consultation may be appointed to conduct the joint clinical assessment. Such appointment shall be justified and subject to approval of the Coordination Group and shall be documented in the joint clinical assessment report.

6. The designated sub-group shall initiate a scoping process in which it identifies the relevant parameters for the assessment scope. The assessment scope shall be inclusive and reflect Member States' needs in terms of parameters and of the information, data, analysis and other evidence to be submitted by the health technology developer. It shall identify in particular all the relevant parameters for the assessment in terms of:
   (a) the patient population;
   (b) the intervention or interventions;
   (c) the comparator or comparators;
   (d) the health outcomes.

   The scoping process shall also take into account input received from patients, clinical and other relevant experts.

7. The Coordination Group shall inform the Commission of the assessment scope of the joint clinical assessment.

Article 6a

The Joint Clinical Assessment Reports and the dossier of the health technology developer

1. A joint clinical assessment shall result in a joint clinical assessment report that shall be accompanied by a summary report (hereinafter "the reports"). The reports shall not contain any value judgement or conclusions on the overall clinical added value of the assessed health technology and shall be limited to a description of the scientific analysis:
   (a) of the relative effects of the health technology as assessed on the health outcomes against the chosen parameters based on the assessment scope as set out pursuant to Article 6;
   (b) of the degree of certainty of the relative effects taking into account the strengths and limitations of the available evidence.

2. The reports shall be based on a dossier of complete and up-to-date information, data, analyses and other evidence submitted by the health technology developer to assess the parameters identified in the scoping process.

2a. The dossier shall meet the following requirements:

(a) the submitted evidence shall be complete with regard to the available studies and data that could inform the assessment;

(b) the data shall be analysed using appropriate methods to answer all research questions of the assessment;

(c) the data presentation shall be well-structured and transparent to allow for an appropriate assessment within the limited timeframes available and to support the understanding of the submission and the assessment by third parties;

(d) it shall include underlying documentation of the information presented to allow the assessors to verify the accuracy of the submitted information.

2b. The dossier for medicinal products shall in particular include the information set out in Annex I, and the dossier for medical devices and *in vitro* diagnostic medical devices shall at least include the information stipulated in Annex II.

3. The Commission is empowered to adopt delegated acts, in accordance with Article 29, to amend the information required in the dossier for medicinal products as set out in Annex I, and in the dossier for medical devices and *in vitro* diagnostic medical devices as set out in Annex II.

Article 6b

Obligations of health technology developers and consequences of non-compliance

1. The Commission shall inform the health technology developer of the assessment scope and request the submission of the dossier (first request). The submission request shall include the deadline for submission as well as the dossier template pursuant to Article 23(1)(i). For medicinal products, the deadline for submission shall be at the latest 45 days prior to the envisaged date of the opinion of the Committee for Medicinal Products for Human Use adopted in accordance with Articles 6(3) and 14(9) of Regulation (EC) No 726/2004.

2. The health technology developer shall submit the dossier to the Commission in accordance with the submission request pursuant to paragraph 1.

3. The health technology developer shall not submit any information, data, analyses or other evidence at the national level that has been already submitted at Union level. This requirement shall not affect requests for additional information on products that fall within the scope of early access programmes at Member State level that aim to provide patient access in situations of high unmet medical needs before a centralised marketing authorisation has been granted.

4. Where the Commission confirms the timely submission of the dossier pursuant to paragraph 1 and that the dossier meets the formal requirements laid out in paragraphs 2 and 2a of Article 6a and Annex I or Annex II, the Commission shall make the dossier immediately available to the members of the Coordination Group via the IT platform referred to in Article 27 and inform the health technology developer thereof.

5. Where the Commission finds that the dossier fails to meet the formal requirements laid out in paragraphs 2 and 2a of Article 6a and Annex I or Annex II, it shall request the missing information, data, analyses and other evidence from the health technology developer (second request), who shall submit the requested information, data, analyses and other evidence within five working days from the receipt of the request.

6. Where the Commission deems that a dossier was not submitted in a timely manner by the health technology developer, or attests that it fails to meet the formal requirements set out in paragraphs 2 and 2a of Article 6a and Annex I or Annex II (after the second request), the Coordination Group shall discontinue the joint clinical assessment. If the assessment is discontinued, the Commission shall make a statement on the IT platform referred to in Article 27 justifying the reasons of the discontinuation and shall inform the health technology developer accordingly. In case of discontinuation of the joint clinical assessment point (c) of paragraph 1 of Article 8 shall not apply.

7. Where the joint clinical assessment has been discontinued and the Coordination Group, pursuant to point (d) of Article 8(1), subsequently receives information, data, analyses and other evidence that formed part of the original submission request in accordance with Article 6b(1) submitted by the health technology developer at Member State level, the Coordination Group may re-initiate a joint clinical assessment in accordance with the procedure pursuant to Article 6a at the latest six months after the submission deadline set in accordance with paragraph 1, once the Commission has confirmed that formal requirements set out in paragraphs 2 and 2a of Article 6a and Annex I or Annex II have been fulfilled.

7a. Without prejudice to paragraph 7, where a joint clinical assessment has been re-initiated, the Coordination Group may request the developer to submit updates of previously provided information, data, analyses and other evidence.

Article 6c

Assessment Process for Joint Clinical assessments

1. On the basis of the dossier submitted by the health technology developer and the assessment scope as set pursuant to Article 6(6), the assessor, with the assistance of the co-assessor, shall prepare the draft reports. The reports shall be endorsed by the Coordination Group according to the timeline set pursuant to point (e) of paragraph 6 of Article 3. The end of that timeline shall be:
   (a) for medicinal products, no later than 30 days following the marketing authorisation granted by the Commission;
   (b) for medical devices and *in vitro* diagnostic medical devices, within a reasonable time after the notified body has provided the health technology developer with a certificate, in accordance with the procedures for joint clinical assessments developed pursuant to point (e) of paragraph 6 of Article 3.

2. Where the assessor, with the assistance of the co-assessor, at any time during the preparation of the reports, considers that further specifications or clarifications or additional information, data, analyses and other evidence are necessary in order to carry out the assessment, the health technology developer shall be requested by the Commission to provide such information. The assessors may also have recourse to databases and other sources of clinical information where deemed necessary.

3. The members of the designated sub-group shall provide their comments on the draft reports.

4. The sub-group shall ensure that specified experts on the assessment topic, including patients, clinical and other relevant experts, are given an opportunity to provide comments on the draft reports. Such comments shall be provided within a defined framework and in a timeframe set pursuant to the procedure devised by the Coordination Group. Comments on the draft reports shall immediately be made available to the Coordination Group *via* the IT platform referred to in Article 27.

5. The draft reports shall also be provided to the health technology developer. The health technology developer shall signal any purely technical or factual inaccuracies within 5 working days after having received the draft reports. The health technology developer shall not provide any comments on the results of the draft assessment.

6. Following receipt and consideration of comments provided in accordance with this Article, the assessor, with the assistance of the co-assessor, shall prepare revised draft reports, and submit those revised draft reports to the Coordination Group *via* the IT platform referred to in Article 27.

Article 6d

Finalisation of the Joint Clinical assessment

1. Upon receipt of the revised draft reports, the Coordination Group shall review the reports.

2. The Coordination Group shall, within the timeline set out in point (e) of paragraph 6 of Article 3 and pursuant to point (c) of paragraph 1 of Article 11, endeavour to endorse the reports by consensus. By way of derogation from paragraph 4 of Article 3, where consensus cannot be reached, all divergent scientific opinions shall be incorporated in the reports and the reports shall be deemed endorsed.

3. The Coordination Group shall submit the endorsed reports to the Commission for procedural review pursuant to Article 25(d). Where the Commission, within 10 working days of receipt of the endorsed reports, concludes that they do not comply with the procedural rules laid down pursuant to this Regulation or depart from the requirements adopted by the Coordination Group pursuant to this Regulation, it shall inform the Coordination Group of the reasons for its conclusion and request a review of the reports. The Coordination Group shall review the reports from a procedural point of view, take any necessary corrective actions, and re-endorse the reports in accordance with the procedure laid down in paragraph 2.

4. The Commission shall publish the procedurally compliant reports endorsed or re-endorsed by the Coordination Group on the publicly accessible section of the IT platform referred to in point (a) of paragraph 1 of Article 27 and shall inform the health technology developer of the publication.

5. If the Commission concludes that the re-endorsed reports still do not comply with the procedural rules referred to in paragraph 3, it shall make available the report and its procedural review on the IT platform referred to point (b) of paragraph 1 of Article 27 for the consideration of Member States and inform the health technology developer.

Article 8

Member States' Rights and Obligations

1. When carrying out a national health technology assessment on a health technology for which reports have been published or in respect of which a joint clinical assessment has been initiated, Member States shall:
   (a) give due consideration to the published reports and all other information available on the IT platform referred to in Article 27, including the statement of discontinuation pursuant to Article 6b(6), concerning that joint clinical assessment in their health technology assessments at Member State level. This shall not affect Member States' competence to draw their conclusions on the overall clinical added value of a health technology in the context of their specific healthcare system and to consider the parts of the reports relevant in this context.
   (b) annex the dossier submitted by the health technology developer in accordance with Article 6b(2) to the documentation of the health technology assessment at Member State level;
   (c) not request at the national level information, data, analyses and other evidence that has been submitted by the health technology developer at EU level according to paragraphs 1 or 5 of Article 6b;
   (d) immediately share through the IT platform referred to in Article 27 any information, data, analyses and other evidence with the Coordination Group that they receive from the health technology developer at Member State level and which forms parts of the submission request made pursuant to Article 6b(1);

2. Member States shall provide the Coordination Group through the IT platform referred to in Article 27 with information on the national health technology assessment on a health technology which has been subject to a joint clinical assessment within 30 days from its completion. The Commission shall, based on information from Member States, summarise the uptake of the reports in health technology assessments at Member State level and publish a report on that overview on the IT platform referred to in Article 27 at the end of each year to facilitate the exchange of information between Member States.

Article 9

Updates of Joint Clinical Assessments

1. The Coordination Group shall carry out updates of joint clinical assessments where the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment becomes available.

2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members.

3. Without prejudice to paragraph 1 and 2, Member States may carry out national updates of assessments on health technologies that have been subject to a joint clinical assessment. Such updates shall be shared with the members of the Coordination Group via the IT platform referred to in Article 27.

Article 11

Adoption of Detailed Procedural Rules for Joint Clinical Assessments

1. The Commission shall develop, by means of implementing acts, procedural rules for:
   (a) exchange of information with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products;
   (b) exchange of information with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices and *in vitro* diagnostic medical devices;
   (c) the procedures for the interaction between the Coordination Group, its sub-groups and the health technology developers during joint clinical assessments.

2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).

SECTION 2

JOINT SCIENTIFIC CONSULTATIONS

Article 11a

Principles for Joint Scientific Consultations

1. The Coordination Group shall carry out joint scientific consultations. Joint scientific consultations have the aim to exchange with health technology developers on their development plans, so evidence can be generated that meets the evidence needs likely to be required as part of a joint clinical assessment. The joint scientific consultation shall encompass a face-to-face or virtual meeting with the health technology developer and result in an outcome document that outlines the scientific recommendation. Joint scientific consultations shall in particular concern all relevant clinical study, or clinical investigation design aspects, including but not be limited to, comparators, interventions, health outcomes, and patient populations. When providing joint scientific consultations on health technologies other than medicinal products, the specificities of those health technologies shall be taken into account.

2. Joint scientific consultations shall be carried out for health technologies likely to be the subject of joint clinical assessments in accordance with Article 5 and, for medicinal products, for which clinical studies are still in the planning stage.

3. The joint scientific consultation outcome document shall not be legally binding on Member States, on the Coordination Group or on health technology developers.

4. Where a Member State carries out a national scientific consultation on a health technology that has been the subject of a joint scientific consultation, it shall inform the Coordination Group thereof *via* the IT platform referred to in Article 27. Joint scientific consultations can take place in parallel with the scientific advice from the European Medicines Agency pursuant to Article 57(1)(n) of Regulation (EC) No 726/2004. Such parallel consultations imply the exchange of information and synchronised timing, while the respective remits remain separate. Joint scientific consultations on medical devices can take place in parallel with the consultation of the expert panels pursuant to Article 61(2) of Regulation (EU) 2017/745.

Article 12

Requests for Joint Scientific Consultations

1. For health technologies referred to in Article 11a(2), health technology developers may request a joint scientific consultation.

2. Health technology developers of medicinal products may request that the joint scientific consultation takes place in parallel with the process of receiving scientific advice from the European Medicines Agency. In such a case, the health technology developer shall make the request for scientific advice to the European Medicines Agency at the time of submitting the request for the joint scientific consultation. Health technology developers of medical devices may request that the joint scientific consultation takes place in parallel with the consultation of an expert panel. In such a case, it shall make the request for a consultation with the expert panel at the time of submitting the request for the joint scientific consultation

3. The Coordination Group shall publish the dates of request periods and state the planned number of joint scientific consultations for each of those request periods on the IT platform referred to in Article 27. At the end of each request period, where the number of eligible requests exceeds the number of planned joint scientific consultations, the Coordination Group shall select the health technologies that shall be subject to joint scientific consultations ensuring the equal treatment of requests concerning health technologies with similar intended indications. The criteria for selecting from eligible requests for medicinal products and medical devices shall be:
   (a) unmet medical needs;
   (b) first in class; or
   (c) potential impact on patients, public health, or healthcare systems.

4. Within 15 working days after the end of each request period, the Coordination Group shall inform the requesting health technology developer whether or not it will engage in the joint scientific consultation and shall explain the reasons.

Article 13

Preparation of the Joint Scientific Consultations Outcome Document

1. Following the acceptance of a request for a joint scientific consultation in accordance with Article 12, the Coordination Group shall initiate the joint scientific consultation by designating a sub-group for the joint scientific consultation.

2. The health technology developer shall submit the documentation containing the information necessary for the joint scientific consultation in the timeframe set pursuant to point (f) of paragraph 6 of Article 3.

3. The designated sub-group shall appoint from among its members an assessor and a co-assessor from different Member States to conduct the joint scientific consultation. The appointments shall take into account the scientific expertise necessary for the consultation.

4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint scientific consultation outcome document in accordance with the requirements set out in this Article and in accordance with the guidance documents and procedural rules established pursuant to point (f) of paragraph 6 of Article 3 and Article 16.

5. The members of the designated sub-group shall have the opportunity to provide their comments during the preparation of the draft joint scientific consultation outcome document. Members of the designated sub-group may, as appropriate, provide additional recommendations specific to their individual Member State.

6. The designated sub-group shall ensure that patients, clinical experts and other experts are given an opportunity to provide input during the preparation of the draft joint scientific consultation outcome document.

7. The designated subgroup shall organise a face-to-face or virtual meeting for an exchange of views with the health technology developer and relevant experts.

8. Where the joint scientific consultation is carried out in parallel with the preparation of a scientific advice given by the European Medicines Agency or the consultation of an expert panel, representatives of the European Medicines Agency or of this panel shall also participate in the face-to-face or virtual meeting.

9. Following receipt and consideration of any comments and input provided in accordance with this Article, the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation outcome document.

10. The assessor, with the assistance of the co-assessor, shall submit the final draft joint scientific consultation outcome document, including any recommendations specific to individual Member States, to the Coordination Group.

Article 13b

Approval of Joint Scientific Consultation Outcome Documents

1. The finalised draft joint scientific consultation outcome document shall be subject to the approval of the Coordination Group within the timeline set pursuant to point (f) of paragraph 6 of Article 3.

2. The Coordination Group shall send the joint scientific consultation outcome document to the requesting health technology developer at the latest 10 working days after it has been finalised.

3. The Coordination Group shall include anonymised, aggregated, non-confidential summary information on the joint scientific consultations in its annual reports and on the IT platform referred to in Article 27.

Article 16

Adoption of Detailed Procedural Rules for Joint Scientific Consultations

1. After consulting the Coordination Group, the Commission shall develop, by means of implementing acts, procedural rules for:
   (a) the consultation of patients, clinical experts and other relevant experts;
   (b) exchange of information with the European Medicines Agency on joint scientific consultations on medicinal products where a health technology developer requests the consultation to be carried out in parallel with a process for scientific advice from the European Medicines Agency;
   (c) exchange of information with the expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 on the joint scientific consultations on medical devices where a health technology developer requests the consultation to be carried out in parallel with the consultation of those expert panels.

2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).

Article 17

Contents of Submission and Report Documents and

Rules for Selecting Stakeholders for Joint Scientific Consultations

The Coordination Group shall establish:

(a) the format and templates of:
   (i) requests from health technology developers for joint scientific consultations;
   (ii) dossiers of information, data, analyses and other evidence to be submitted by health technology developers for joint scientific consultations;
   (iii) joint scientific consultation outcome documents.
(b) the rules for determining the stakeholders to be consulted for the purpose of this Section.

SECTION 3
EMERGING HEALTH TECHNOLOGIES

Article 18

Identification of Emerging Health Technologies

1. The Coordination Group shall ensure the preparation of reports on emerging health technologies expected to have a major impact on patients, public health or healthcare systems. The reports shall in particular address the estimated clinical impact and the potential organisational and financial consequences of the emerging health technology for national healthcare systems.

2. The preparation of the reports referred to in paragraph 1 shall be based on existing scientific reports or initiatives on emerging health technologies and information from relevant sources including, but not limited to:
   (a) clinical study registers and scientific reports;
   (b) the European Medicines Agency in relation to upcoming submissions of applications for marketing authorisation for medicinal products referred to in Article 5(1);
   (c) the Medical Device Coordination Group established in Article 103 of Regulation (EU) 2017/745;
   (d) health technology developers on the health technologies they are developing;
   (e) the stakeholder network referred to in Article 26.

SECTION 4
VOLUNTARY COOPERATION ON HEALTH TECHNOLOGY ASSESSMENT

Article 19

Voluntary Cooperation

1. The Commission shall support the cooperation and the exchange of scientific information among Member States on:
   (a) non-clinical assessments on health technologies;
   (b) collaborative assessments on medical devices and *in vitro* diagnostic medical devices;
   (c) health technology assessments on health technologies other than medicinal products, medical devices or *in vitro* diagnostic medical devices;
   (d) the provision of additional evidence necessary to support health technology assessments;
   (e) clinical assessments of health technologies referred to in Article 5 for which a joint clinical assessment is not yet initiated and of health technologies not referred to in Article 5, in particular health technologies for which the study on emerging health technologies referred to in Article 18 has concluded that they are expected to have a major impact on patients, public health or healthcare systems.

2. The Coordination Group shall be used to facilitate the cooperation referred to in paragraph 1.

3. The cooperation referred to in paragraph 1 points (b) and (c) may be carried out using the procedural rules established in accordance with Article 3(6), Article 11 and the general rules established in accordance with Articles 22 and 23.

4. The cooperation referred to in paragraph 1 shall be included in the annual work programmes of the Coordination Group and the results of the cooperation shall be included in its annual reports and on the IT platform referred to in Article 27.

Chapter III
General Rules for Joint Clinical Assessments

Article 20

Rules for Joint Clinical Assessments

The common procedural rules established in accordance with Article 11 and Article 22 and the requirements established in accordance with Article 23 shall apply to joint clinical assessments carried out in accordance with Chapter II.

Article 21

Clinical Assessment Reports

1. Where a clinical assessment on a health technology subject to joint clinical assessment at Union level is carried out by a Member State, that Member State shall provide the national clinical assessment report on that health technology to the Coordination Group through the IT Platform referred to in Article 27 within 30 days from its completion.

2. The Commission shall make the clinical assessment report available to other Member States through that IT platform referred to in Article 27 to facilitate the exchange of information between Member States.

Article 22

General Procedural Rules

1. The Commission shall adopt implementing acts concerning procedural rules for:
   (i) ensuring that the members of the Coordination Group, its sub-groups, as well as patients, clinical experts and other participating experts take part in joint clinical assessments in an independent and transparent manner, free from conflicts of interest;
   (ii) the consultation of stakeholders in joint clinical assessments at Union level.

2. Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).

Article 23

Contents of Submission and Report Documents

1. The Commission shall adopt implementing acts establishing the format and templates of:
   (i) dossiers for information, data, analyses and other evidence to be provided by health technology developers for joint clinical assessments;
   (ii) joint clinical assessment reports;
   (iii) summary joint clinical assessment reports.

2. Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).

Chapter IV

Support Framework

Article 24

Union Funding

1. The financing of the work of the Coordination Group and its sub-groups and activities in support of that work involving its cooperation with the Commission, with the European Medicines Agency, with the Medical Device Coordination Group, with expert panels and with the stakeholder network referred to in Article 26 shall be ensured by the Union. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[12].

2. The funding referred to in paragraph 1 shall include funding for the participation of Member States' designated members of the Coordination Group and of its subgroups in support of the work on joint clinical assessments, joint scientific consultations, including the development of methodological guidance, guidelines and the identification of emerging health technologies. Assessors and co-assessors shall be entitled to a special allowance compensating them for their work on joint clinical assessments and joint scientific consultations in accordance with internal Commission rules.

Article 25

Commission Support for the Coordination Group

The Commission shall support the work of the Coordination Group and act as its secretariat. In particular the Commission shall:

(a) host in its premises the meetings of the Coordination Group and of its subgroups;

(b) decide on conflict of interest in accordance with the requirements set out in this Regulation;

(c) request the dossier from the health technology developer according to Article 6b;

(d) supervise the procedures for joint clinical assessments and inform the Coordination Group about possible breaches;

(e) provide administrative, technical and IT support;

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12 Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1)

(f) set up and maintain the IT platform established pursuant to Article 27;

(g) publish the information and documents on the IT platform according to Article 27;

(h) facilitate the exchange of information with the European Medicines Agency on the joint work referred to in this Regulation related to medicinal products including the sharing of confidential information;

(i) facilitate the exchange of information with expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 and the Medical Devices Coordination Group established pursuant to Article 103 of Regulation (EU) 2017/745 on the joint work referred to in this Regulation related to medical devices and *in vitro* diagnostic medical devices including the sharing of confidential information.

Article 26

Stakeholder Network

1. The Commission shall establish a stakeholder network. The stakeholder network shall support the work of the Coordination Group and its subgroups upon request.

2. The stakeholder network shall be established through an open call for applications and consist of all eligible stakeholder organisations based on eligibility criteria established by the Coordination Group. The criteria shall be included in the open call for applications.

3. Organisations applying to become part of the stakeholder network shall declare their membership and sources of funding.

4. The list of stakeholder organisations included in the stakeholder network and the declarations of those organisations on sources of funding shall be made publicly available.

5. The Coordination Group shall meet with the stakeholder network at least once per year in order to:

   (a) update stakeholders on the work of the Group;

   (b) provide for an exchange of information.

6. The Coordination Group may invite members of the stakeholder network to attend its meetings as observers.

Article 27

IT Platform

1. The Commission shall set up and maintain an IT platform consisting of:
   (a) a publicly accessible webpage;
   (b) a secure intranet for the exchange of information between members of the Coordination Group and its sub-groups;
   (c) a secure system for the exchange of information between the Coordination Group and its sub-groups with health technology developers and experts participating in the joint work referred to in this Regulation, as well as with the European Medicines Agency and the Medical Devices Coordination Group.

2. The Commission shall ensure appropriate levels of access to the information contained in the IT platform for Member State, members of the stakeholder network, and the general public.

3. The publicly accessible webpage shall contain, in particular:
   (a) a list of the members of the Coordination Group and their appointed representatives, together with their declarations of conflict of interest after the finalisation of the joint work;
   (b) a list of the members of the sub-groups and their appointed representatives together with their declarations of conflict of interest after the finalisation of the joint work;
   (c) the rules of procedure of the Coordination Group;
   (d) all documentation according to Articles 6a(1), 6.b(2) and (5) and 6c(1) at the time the report is published, according to Article 6b (7) in case the joint clinical assessment was discontinued, and according to Articles 11, 22 and 23;
   (e) agendas and summary minutes of the Coordination Group's meetings;
   (f) eligibility criteria for stakeholders;
   (g) the annual work programmes and annual reports;

(h) information on planned, on-going, and completed joint clinical assessments, including updates according to Article 9;

(i) the joint clinical assessment reports considered procedurally compliant according to Article 6d together with all comments received during their preparation;

(j) information on Member States' national clinical assessment reports referred to in Article 8(2) and Article 21;

(k) anonymised, aggregated, non-confidential summary information on joint scientific consultations;

(l) studies on the identification of emerging health technologies;

(m) anonymised, aggregated, non-confidential information from the emerging health technology reports referred to in Article 18;

(n) results of the voluntary cooperation between Member States undertaken pursuant to Article 19;

(o) where a joint clinical assessment is discontinued, the statement pursuant to Article 6b(6) including the list of information, data, analyses and other evidence that were not submitted by the health technology developer;

(p) the procedural review of the Commission according to Article 6d(3);

(q) standard operating procedures and guidance regarding quality assurance pursuant to Article 3a.

Article 28

Evaluation and Reporting

1. No later than three years after the date of application, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation. The report shall focus on reviewing:
   (a) the added value for Member States of the joint work carried out pursuant to Chapter II and, in particular, whether the health technologies subject to joint clinical assessments in accordance with Article 5 and the quality of those joint clinical assessments correspond to the needs of Member States;
   (b) the non-duplication of the request of information, data, analyses and other evidence for joint clinical assessment in terms of reducing administrative burden for Member States and health technology developers;
   (c) the functioning of the support framework referred to in this Chapter and, in particular, whether there is a need to introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint scientific consultations.

2. No later than two years after the date of application, Member States shall report to the Commission on the implementation of this Regulation and, in particular, on the consideration of joint work pursuant to Chapter II in their national health technology assessment processes and the workload of the Coordination Group.

3. In the preparation of that report, the Commission shall consult the Coordination Group and use:
   (a) the information provided by Member States in accordance with paragraph 2;
   (b) the reports on emerging health technologies prepared in accordance with Article 18;
   (c) the information provided by Member States in accordance with Article 8(2) and Article 9(3).

4. The Commission shall, if appropriate, present a legislative proposal based on that report in order to update the provisions set out in this Regulation.

Chapter V
Final Provisions

Article 29

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 6(a)(3) shall be conferred on the Commission for an indeterminate period of time from [date of entry into force of the basic legislative act or any other date set by the co-legislators].

3. The delegation of power referred to in Article 6(a)(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 6(a)(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of [two months] of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by [two months] at the initiative of the European Parliament or of the Council.

Article 30

Committee Procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 32

Preparation of Implementing Acts

1. The Commission shall adopt the implementing acts referred to in Articles 11, 16 and 22 at the latest by the date of application of this Regulation.

2. When preparing an implementing act pursuant to Article 5(2) the Commission shall gather all necessary expertise, including through consultation of the Coordination Group. Implementing acts adopted pursuant to Article 5(2) shall in particular seek to achieve a manageable workload for the Coordination Group.

3. When preparing those implementing acts, the Commission shall take into account the distinctive characteristics of the medicinal product, medical device and *in vitro* diagnostic medical devices sectors.

Article 35

Amendment of Directive 2011/24/EU

1. Article 15 of Directive 2011/24/EU is deleted.

2. References to the deleted Article shall be construed as references to this Regulation.

Article 36

Entry into Force and Date of 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 [insert date 3 years after date of entry into force].

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

Done at Brussels,

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

Annex I

DOSSIER SPECIFICATIONS FOR MEDICINAL PRODUCTS

The dossier referred to in Article 6a (2) and (2a) of this Regulation shall for medicinal products include the following information:

1. The dossier for medicinal products shall generally include:
   (a) the clinical safety and efficacy data included in the submission file to the European Medicines Agency;
   (b) all up-to-date published and unpublished information, data, analyses and other evidence as well as study reports and study protocols and analysis plans from studies with the medicinal product for which the health technology developer was a sponsor and all available information on ongoing or discontinued studies with the medicinal product for which the health technology developer is a sponsor or otherwise financially involved, and corresponding information about studies by third parties if available, relevant to the assessment scope set in accordance with paragraph 6 of Article 6, including the clinical study reports and clinical study protocols if available to the health technology developer;
   (c) HTA reports on the health technology subject to the joint clinical assessment;
   (d) information on study registries;
   (e) if a health technology has been subject to a Joint Scientific Consultation, the developer shall explain any deviation from the recommended evidence.

2. More specifically the dossier for medicinal products shall include:

(a) the characterisation of the medical condition to be treated including the target patient population;

(b) the characterisation of the medicinal product under assessment;

(c) the research question of the dossier, pursuant to Article 6(6) elaborated in the submission dossier; reflecting the assessment scope;

(d) the description of methods used by the health technology developer in the development of the content of the dossier;

(e) the results of information retrieval;

(f) the characteristics of included studies;

(g) the results on effectiveness and safety of the intervention under assessment and the comparator;

(h) the relevant underlying documentation related to point (a) until (g) of this paragraph.

Annex II

DOSSIER SPECIFICATIONS FOR MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES

1. The dossier referred to in Article 6a (2) and (2a) of this Regulation shall for medical devices at least include:
   (a) the clinical evaluation assessment report;
   (b) the manufacturer's clinical evaluation documentation submitted to the notified body pursuant to Annex II Section 6.1(c) and (d) of Regulation (EU) 2017/745;
   (c) the scientific opinion provided by the relevant expert panels in the framework of the clinical evaluation consultation procedure;
   (d) all up-to-date published and unpublished information, data, analyses and other evidence as well as study reports and clinical study protocols and analysis plans from clinical studies with the medical device for which the health technology developer was a sponsor and all available information on ongoing or discontinued clinical studies with the medical device for which the health technology developer is a sponsor or otherwise financially involved, and corresponding information about clinical studies by third parties if available, relevant to the assessment scope set in accordance with of Article 6(6), including the clinical study reports and clinical study protocols if available to the health technology developer;
   (e) HTA reports on the health technology subject to a joint clinical assessment, where appropriate;
   (f) data from registries concerning the medical device and information on study registries;
   (g) if a health technology has been subject to a joint scientific consultation, the developer shall explain any deviation from the recommended evidence.

More specifically the dossier for medical device shall include:

(a) the characterisation of the medical condition to be treated including the target patient population;
(b) the characterisation of the medical device under assessment, including its instructions for use;
(c) the research question of the dossier, pursuant to Article 6(6) elaborated in the submission dossier; reflecting the assessment scope;
(d) the description of methods used by the health technology developer in the development of the content of the dossier;
(e) the results of information retrieval;
(f) the characteristics of included studies.

2. The dossier referred to in Article 6a (2) and (2a) of this Regulation shall for *in vitro* diagnostic medical devices at least include:
(a) the performance evaluation report of the manufacturer;
(b) the manufacturer´s performance evaluation documentation, referred to in Annex II Section 6.2 of Regulation (EU) 2017/746;
(c) the scientific opinion provided by the relevant expert panels in the framework of the performance evaluation consultation procedure;
(d) the report of the EU reference laboratory.