European Parliament
2014-2019

TEXTS ADOPTED

P8_TA(2019)0120

Health technology assessment ***I

European Parliament legislative resolution of 14 February 2019 on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU (COM(2018)0051 – C8-0024/2018 – 2018/0018(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2018)0051),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0024/2018),

– having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Czech Chamber of Deputies, the German Bundestag, the French Senate and the Polish Sejm, asserting that the draft legislative act does not comply with the principle of subsidiarity,

– having regard to the opinion of the European Economic and Social Committee of 23 May 2018[1]

– having regard to Rules 59 and 39 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A8-0289/2018),

[1] OJ C 283, 10.8.2018, p. 28.

1. Adopts its position at first reading hereinafter set out[2];

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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2 This position corresponds to the amendments adopted on 3 October 2018 (Texts adopted, P8_TA(2018)0369).

P8_TC1-COD(2018)0018

Position of the European Parliament adopted at first reading on 14 February 2019 with a view to the adoption of Regulation (EU) .../... 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 ~~Article 114~~ ***Articles 114 and 168(4)*** thereof, **[Am. 1]**

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[3],

Having regard to the opinion of the Committee of the Regions[4],

Acting in accordance with the ordinary legislative procedure[5],

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3 OJ C 283, 10.8.2018, p. 28.
4 OJ C ...
5 Position of the European Parliament of 14 February 2019.

Whereas:

(1) The development of health technologies is ~~a key driver of economic growth and innovation in the Union. It forms~~ ***key to achieving the high level of health protection that health policies must ensure, for the benefit of all citizens. Health technologies are an innovative sector of the economy which form*** part of an overall market for healthcare expenditure that accounts for 10 % of EU gross domestic product. Health technologies encompass medicinal products, medical devices and medical procedures, as well as measures for disease prevention, diagnosis or treatment. **[Am. 2]**

(1a) Expenditure on medicines stood at 1,41 % of GDP in 2014 and accounted for 17,1 % of overall health expenditure, of which it is a major component. Health expenditure in the Union amounts to 10 % of GDP, i.e. EUR 1 300 000 million per annum, EUR 220 000 million of which is pharmaceutical expenditure and EUR 110 000 million expenditure on medical devices. **[Am. 3]**

(1b) The Council conclusions of 16 June 2016 and the European Parliament resolution of 2 March 2017 on EU options for improving access to medicines[6] highlighted that there are many barriers to access to medicine and innovative technologies in the Union, with the main barriers being the lack of new treatments for certain diseases and the high price of medicines, which in many cases do not have added therapeutic value. **[Am. 4]**

(1c) Marketing authorisations for medicinal products are granted by the European Medicines Agency on the basis of the principles of safety and efficacy. Normally the national health technology assessment agencies assess comparative effectiveness, because marketing authorisations are not accompanied by a comparative effectiveness study. **[Am. 5]**

6 *OJ C 263, 25.7.2018, p. 4.*

(2) Health Technology Assessment (HTA) is ~~an~~ ***a scientific*** evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on the added ***therapeutic*** value of a health technology in comparison with other new or existing health technologies. **[Am. 6]**

(2a) As the World Health Organization (WHO) stated at the 67th World Health Assembly in May 2014, HTA has to be a tool in support of universal health coverage. **[Am. 7]**

(2b) HTA should be instrumental in promoting innovation which offers the best outcomes for patients and society as a whole and is a necessary tool for ensuring the proper application and use of health technologies. **[Am. 8]**

(3) HTA covers both clinical and non-clinical aspects of a health technology. 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~~,~~ ***(which form the 'HTA Core model')*** 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. The clinical domains are therefore more suited to joint assessment at EU-level on their scientific evidence base, while the assessment of non-clinical domains tends to be more closely related to national and regional contexts and approaches. **[Am. 9]**

(3a) Health professionals, patients and health institutions need to know whether or not a new health technology represents an improvement on existing health technologies, in terms of benefits and risks. Joint clinical assessments therefore aim to identify the added therapeutic value of new or existing health technologies in comparison with other new or existing health technologies, by undertaking a comparative assessment based on comparative trials against the current best proven intervention ('standard treatment') or against the current most common treatment where no such standard treatment exists. **[Am. 10]**

(4) ***HTA is an important tool for promoting high-quality innovation, steering research towards addressing the unmet diagnostic, therapeutic or procedural needs of healthcare systems as well as steering clinical and social priorities. HTA can also improve scientific evidence used to inform clinical decision-making, efficiency in use of resources, the sustainability of health systems, patient access to these health technologies, and the competitiveness of the sector through greater predictability and more efficient research. Member States use*** the outcome of HTA ~~is used~~ ***to augment the scientific evidence that informs decisions to introduce health technologies into their systems, i.e.*** to inform decisions ~~concerning the allocation of budgetary~~ ***on how to allocate*** 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.
[Am. 11]

(4a) Cooperation in the field of HTA can also play a role throughout the health technology cycle: in the early developmental stage through 'horizon scanning' in order to pinpoint technologies that will have a major impact; in the early dialogue and scientific advisory stages; in better study design to ensure greater research efficiency; and in the core stages of the overall assessment, once the technology is already established. Finally, HTA can help in decision-making on divestment in cases where a technology becomes obsolete and unsuitable compared to better alternative options that are available. Greater collaboration between Member States in the field of HTA should also help improve and harmonise standards of care as well as diagnostic and new-born screening practices across the Union. **[Am. 12]**

(4b) Cooperation in the field of HTA can extend beyond pharmaceutical products and medical devices. It can also cover areas such as diagnostics used to supplement treatment, surgical procedures, prevention, screening and health promotion programmes, information and communications technology (ICT) tools, health-care organisation plans and integrated care processes. Different demands are involved in assessing different technologies, depending on their specific features, meaning that a cohesive approach which can cater for these different technologies is needed in the field of HTA. Moreover, in specific areas such as treatments for rare diseases, paediatric medicines, precision medicine and advanced therapies, the added value of cooperation at Union level is likely to be even greater. **[Am. 13]**

(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~~ ***a duplication of*** requests for data~~. It can also lead to both duplications and variations in outcomes~~ that ***could*** increase the financial and administrative burdens that act as a barrier to the free movement of the health technologies concerned and the smooth functioning of the internal market. ***In some justified cases where the specificities of the national and regional healthcare systems and priorities need to be taken into account, a complementary assessment on certain aspects might be necessary. However, assessments that are not relevant for decisions in certain Member States could delay the implementation of innovative technologies and thus access of patients to beneficial innovative treatments.***
[Am. 14]

(6) ~~While~~ Member States have carried out some joint assessments within the framework of the EU co-funded joint actions***.*** ~~the 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~~ ***Those assessments were carried out in three stages, under Article 15 of Directive 2011/24/EU of the European Parliament and of the Council[7], and through three*** joint actions, ~~including their joint clinical assessments, at Member State-level has remained low, meaning that the duplication of~~ ***each with specific objectives and a specific budget: EUnetHTA 1, 2010 to 2012 (EUR 6 million); EUnetHTA 2, 2012 to 2015 (EUR 9,5 million); and EUnetHTA 3, launched in June 2016 with an end date of 2020 (EUR 20 million). Given the timescales for those actions and in the interests of continuity, this Regulation establishes a more sustainable way of ensuring the continuation of the*** joint assessments***. The main outcomes of the cooperation to date include the 'HTA Core Model' assessment model, which provides a framework for HTA reports; a database for sharing projects that are planned, ongoing or recently published by individual agencies (POP database); a data- and knowledge base for the storage of information and the stage reached in the assessment of promising technologies, or*** on the ~~same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed~~ ***request for supplementary studies arising from the HTA; and a set of methodological guides and support tools for HTA agencies, including guidelines for adapting reports from one country to another***. **[Am. 15]**

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

(6a) However, within the joint actions, the production of output has been inefficient and, in the absence of a sustainable model of cooperation, relying on project-based 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. **[Am. 16]**

(7) ~~The Council~~ In its Conclusions of December 2014 ***on innovation for the benefit of patients[8], the Council*** acknowledged the key role of health technology assessment ~~and~~ ***as a health policy tool to support evidence-based, sustainable and equitable choices in health care and health technologies for the benefit of patients. The Council further*** called on the Commission to continue to support cooperation in a sustainable manner***, and asked for joint work between Member States on HTA to be enhanced and for opportunities for cooperation on exchange of information between competent bodies to be explored. In addition, in its Conclusions of December 2015 on personalised medicine for patients, the Council invited Member States and the Commission to strengthen HTA methodologies applicable to personalised medicine, and the Council Conclusions of June 2016 on strengthening the balance in the pharmaceutical systems in the European Union and its Member States provided further evidence that Member States see clear added value in cooperation on HTA. The joint report of October 2016 of the Commission's DG for Economic and Financial Affairs and the Economic Policy Committee further called for enhanced European cooperation on HTA***. **[Am. 17]**

8 ***OJ C 438, 6.12.2014, p. 12.***

(8) The European Parliament, in its resolution of 2 March 2017[9] on EU options for improving access to medicines-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~~ ***and relative effectiveness of health technologies compared with the best available alternative that takes into account the level of innovation and benefit for patients***. **[Am. 18]**

(9) In its 2015 Communication on upgrading the single market,[10] 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.

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

10 COM(2015)0550, p. 19.

(10) In order to ensure a better functioning of the internal market and contribute to a high level of human health protection it is appropriate to approximate the rules on carrying out clinical assessments at national level and clinical assessments of certain health technologies at Union level, and which also support the continuation of voluntary cooperation between Member States on certain aspects of HTA. ***That approximation should guarantee the highest quality standards and be aligned to best available practice. It should not stimulate a convergence towards the lowest common denominator nor force HTA bodies with more expertise and higher standards to accept lower requirements. It should rather lead to an improvement of the HTA capacity and quality at the national and regional level.*** **[Am. 19]**

(11) In accordance with Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the Member States remain responsible for the organisation and delivery of their healthcare. As such, it is appropriate to limit the scope of Union rules to those aspects of HTA that relate to the clinical assessment of a health technology.~~,~~ ~~and in particular, to ensure that the~~ ***The joint clinical*** assessment ~~conclusions are confined to findings relating~~ ***provided for by this Regulation constitutes a scientific analysis of the relative effects of health technology on efficacy, safety and effectiveness, commonly referred to as clinical outcomes, that is evaluated in relation*** to the comparative ~~effectiveness of a health technology~~ ***indicators currently deemed appropriate and chosen groups or subgroups of patients, taking into account the HTA Core Model criteria. It will include consideration of the degree of certainty on the relative outcomes, based on the available evidence***. The outcome of such ***joint clinical*** assessments should not therefore affect the discretion of Member States in relation to subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement which may depend on both clinical and non-clinical considerations, and which remain solely a matter of national competence. ***The assessment conducted by each Member State as part of its national appraisal therefore falls outside the scope of this Regulation.*** **[Am. 20]**

(12) In order to ensure a wide application of harmonised rules ***and to foster collaboration among Member States*** on clinical aspects of HTA and enable pooling of expertise and resources across HTA bodies***, thereby reducing waste and ineffectiveness in healthcare***, it is appropriate to require joint clinical assessments to be carried out for all medicinal products undergoing the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council[11], which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication. 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[12] ~~which are in the highest risk classes and for which the relevant expert panels have provided their opinions or views. A selection of medical devices for joint clinical assessment should be made based on specific criteria~~***, given the need for greater*** clinical ***evidence concerning all of those new health technologies***. **[Am. 21]**

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11 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).

12 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).

(13) In order to ensure that joint clinical assessments carried out on health technologies remain accurate, ~~and~~ relevant***, of high quality and based on the best scientific evidence available at any given time***, it is appropriate to establish ~~conditions~~ ***a flexible, regulated procedure*** for the updating of assessments, in particular ~~where~~ ***when new evidence or*** additional data ***becomes*** available subsequent to the initial assessment ~~has the potential to~~ ***and such new evidence or additional data may augment the scientific evidence and thus*** increase the ~~accuracy~~ ***quality*** of the assessment. **[Am. 22]**

(14) A coordination group composed of representatives from Member States' health technology assessment authorities and bodies should be established with responsibility ***and proven expertise*** for overseeing the carrying out of joint clinical assessments and other joint work ***within the scope of this Regulation.*** **[Am. 23]**

(15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should designate national ***or regional*** HTA authorities and bodies which inform decision-making ***to conduct such assessments,*** as members of the Coordination Group. The designated authorities and bodies should ensure an appropriately high level of representation in the Coordination Group and technical expertise in its sub-groups, taking into account the ~~need to provide~~ ***possibility of providing*** expertise on the HTA of medicinal products and medical devices. ***The organisational structure should respect the distinctive mandates of the sub-groups conducting the joint clinical assessments and the joint scientific consultations. Any conflict of interest should be avoided.*** **[Am. 24]**

(15a) Transparency and public awareness of the process is essential. All clinical data being evaluated should have therefore the highest level of transparency and public awareness in order to gain confidence in the system. In case there is confidential data for commercial reasons, the confidentiality needs to be clearly defined and justified and the confidential data well delimitated and protected. **[Am. 25]**

(16) In order that the harmonised procedures fulfil their internal market objective ***and reach their aim of improving innovation and the quality of clinical evidence,*** Member States should ~~be required to~~ take ~~full~~ account of the results of joint clinical assessments and not repeat ~~those assessments~~ ***them***. ***According to national needs, Member States should have the right to complement the joint clinical assessments with additional clinical evidence and analyses to account for differences in comparators or the national specific treatment setting. Such complementary clinical assessments should be duly justified and proportionate and should be notified to the Commission and the Coordination Group. In addition,*** compliance with this obligation does not prevent Member States from carrying out non-clinical assessments on the same health technology, or from drawing conclusions on the ***clinical*** added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as ***the*** non-clinical data and criteria ***specific to the Member State concerned, at national and/or regional level***. It also does not prevent Member States from forming their own recommendations or decisions on pricing or reimbursement. **[Am. 26]**

(16a) In order for the clinical assessment to be used for the purposes of the national reimbursement decision, it should ideally concern the population for which the drug would be reimbursed in a given Member State. **[Am. 27]**

~~(17) The time-frame for joint clinical assessments for medicinal products should, in as far as possible, be fixed by reference to the time-frame applicable to the completion of the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004. Such coordination should ensure clinical assessments can effectively facilitate market access and contribute to the timely availability of innovative technologies for patients. As a rule, the process should be completed by the time of the publication of the Commission decision granting marketing authorisation.~~ **[Am. 28]**

(17a) The joint scientific consultation, when addressing orphan medicinal products, has to ensure that any new approach should not result in unnecessary delays for the orphan medicinal products assessment compared to the current situation and taking into account the pragmatic approach undergone through the EUnetHTA. **[Am. 29]**

(18) The establishment of a time-frame for the joint clinical assessments ~~for medical devices~~ ***health technologies*** should take into account the ~~highly decentralised market access pathway~~ ***time-frames set out in Regulation (EC) No 726/2004 for completing the centralised procedure for authorising medicines and the CE conformity marking*** for medical devices ~~and~~ ***provided for in Regulation (EU) 2017/745 and the CE conformity marking for in vitro diagnostic medical devices provided for in Regulation (EU) 2017/746 of the European Parliament and of the Council[13]. In any event, those assessments must take into account*** the availability of appropriate ***scientific*** evidence ~~data~~ ***and supporting data in the quantity*** required to carry out a joint clinical assessment, ~~As the required evidence may only become available after a medical device has been placed on the market and in order to allow for the selection of medical devices for joint clinical assessment at an appropriate time, it~~ and should ~~be possible for assessments of such devices to~~ take place ~~following market launch of medical devices~~ ***in a time-frame as close as possible to their marketing authorisation, in the case of medicines, and, in any case, without unjustified and unnecessary delay.*** **[Am. 30]**

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13 ***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).***

(19) In ~~all cases~~ ***any event*** the joint work carried out under this Regulation, in particular the joint clinical assessments, should produce high quality and timely results, ~~and not delay or interfere~~ ***without delaying or interfering*** with the CE marking of medical devices ~~or market access of health technologies. This work should be separate and distinct from regulatory assessments of the safety, quality, efficacy or performance of health technologies carried out~~ pursuant ~~to other Union legislation and have no bearing on decisions taken in accordance with other Union legislation~~. **[Am. 31]**

(19a) HTA work covered under this Regulation should be separate and distinct from regulatory assessments of the safety and efficacy of health technologies carried out pursuant to other Union legislative acts and should have no bearing on other aspects falling outside the scope of this Regulation adopted in accordance with other Union legislative acts. **[Am. 32]**

(19b) In the case of orphan medicinal products, the joint report should not re-assess the criteria of the orphan designation. However, assessors and co-assessors should have full access to the data used by the authorities responsible for granting the marketing authorisation of a medicinal product, as well as the possibility of using or generating additional relevant data for the purpose of assessing a medicinal product in the context of a joint clinical assessment. **[Am. 33]**

(19c) Regulation (EU) 2017/745 concerning medical devices and Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices provide for the authorisation of such devices on the basis of the principles of transparency and safety and not on efficacy. However, the gradual increase in the supply of medical devices to address clinical conditions has heralded a paradigm shift towards a new model in which the market is highly fragmented, innovation is chiefly incremental and clinical evidence is lacking, which means that closer cooperation and more frequent exchanges of information between assessment bodies are needed. It is therefore necessary to move towards a centralised authorisation system that assesses devices on the basis of safety, efficacy and quality. It is also one of the areas in which Member States are calling for greater collaboration via a future European HTA. Currently 20 Member States, together with Norway, have HTA systems for medical devices in place and 12 Member States, together with Norway, have established guidelines and are engaging in initial dialogues. EUnetHTA has been conducting high-quality evaluations of the relative efficacy of medical devices based on a methodology that can be taken as a benchmark for this Regulation. **[Am. 34]**

(20) ~~In order to facilitate effective participation by~~ Health technology developers ~~in joint clinical assessments, such developers should, in appropriate cases, be afforded an opportunity to engage in~~ ***can conduct*** joint scientific consultations with the Coordination Group ***or working groups set up for this purpose and composed of professionals from national or regional assessment bodies*** to obtain guidance on the ***clinical needs of research and the optimal design of studies to obtain the best possible*** evidence and ~~data that is likely to be required for the purposes of clinical assessment~~ ***maximise research efficiency***. Given the preliminary nature of the consultation, any guidance offered should not bind either the health technology developers or HTA authorities and bodies. **[Am. 35]**

(20a) Joint scientific consultations should concern the clinical study design, the determination of best comparators based on the best medical practice in the interest of patients. The consultation process should be transparent. **[Am. 36]**

(21) ~~Joint clinical assessments and~~ Joint scientific consultations ***could*** necessitate the sharing of ***commercially*** 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 for any information made public about the results of joint scientific consultations to be presented in an anonymised format with the redaction of any information of a commercially sensitive nature. **[Am. 37]**

(21a) Joint clinical assessments necessitate all available clinical data and publicly available scientific evidence from health technology developers. The clinical data employed, the studies, the methodology and the clinical results used should be made public. The highest possible level of public openness in scientific data and assessments will allow progress to be made in biomedical research and ensure the highest possible level of confidence in the system. Where commercially sensitive data is shared, the confidentiality of such data should be protected by presenting it in an anonymised format with the redaction of reports before publication, preserving the public interest. **[Am. 38]**

(21b) According to the European Ombudsman, where information in a document has implications for the health of individuals (such as information on the efficacy of a medicine), the public interest in disclosure of that information will generally defeat any claim of commercial sensitivity. Public health should always prevail over commercial interests. **[Am. 39]**

(22) In order to ensure the efficient use of available resources, it is appropriate to provide for "horizon scanning", to allow the early identification of emerging health technologies that are likely to have the most impact on patients, public health and healthcare systems***, as well as to steer research strategically***. Such scanning should facilitate the prioritisation of technologies that are to be selected ***by the Coordination Group*** for joint clinical assessment. **[Am. 40]**

(23) The Union should continue to support voluntary cooperation on HTA between Member States in ***other*** areas such as in 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 areas of health and care with a view to the provision of additional real world evidence relevant for HTA~~. **[Am. 41]**

(24) ~~In order to ensure the inclusiveness and transparency of the joint work, the Coordination Group should engage and consult widely with interested parties and stakeholders. However,~~ In order to preserve the ~~integrity~~ ***objectivity, transparency and quality*** of the joint work, rules should be developed to ensure the independence, ***public openness*** and impartiality of the joint work and ensure that such consultation does not give rise to any conflicts of interest. **[Am. 42]**

(24a) Dialogue between the Coordination Group and patient organisations, consumer organisations, health non-governmental organisations, health experts and professionals should be ensured, especially through a stakeholder network, with a guarantee of the independence, transparency and impartiality of the decisions taken. **[Am. 43]**

(24b) In order to ensure efficient decision-making and facilitate access to medicines, an appropriated cooperation between decision-makers at key stages of the medicines' life-cycle is important. **[Am. 44]**

(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, ~~implementing powers~~ ***the Coordination Group, composed of national and/or regional authorities and bodies responsible for health technology assessment, with proven capacity, independence and impartiality,*** should ~~be conferred on~~ ***draw up the methodology for ensuring high quality of work as a whole.*** The Commission ~~to~~ ~~establish~~ ***should endorse, by means of implementing acts, that methodology and*** a common procedural ~~and methodological~~ framework ~~for clinical assessments,~~ ~~procedures~~ for joint clinical assessments and ~~procedures for~~ joint scientific consultations. Where appropriate***, and in justified cases***, distinct rules should be developed for medicinal products and medical devices. In the development of such rules, the ~~Commission should take into account the~~ results of the work already undertaken in the EUnetHTA Joint Actions***,*** ~~It should also take into account~~ ***and in particular the methodological guidelines and evidence submission templates,*** initiatives on HTA funded through the Horizon 2020 research programme, as well as regional initiatives on HTA such as the Beneluxa and Valletta Declaration initiatives ***should be taken into account***. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[14].
[Am. 45]

[14] 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).

(25a) The methodological framework, in accordance with the Declaration of Helsinki, should guarantee high quality and high clinical evidence by choosing the most appropriate benchmarks. It should be based on high standards of quality, the best available scientific evidence, stemming primarily from double-blind randomised clinical trials, meta-analysis and systematic reviews; and should take into account clinical criteria that are useful, relevant, tangible, concrete and tailored to suit the given clinical situation, with preference given to end points. The documentation to be provided by the applicant should relate to the most up-to-date and public data. **[Am. 46]**

(25b) Any specificities in the methodology, such as for vaccines, should be justified and adapted to very specific circumstances, should have the same scientific rigour and the same scientific standards, and should never be to the detriment of the quality of health technologies or clinical evidence. **[Am. 47]**

(25c) The Commission should provide administrative support for the joint work of the Coordination Group, which, after consultation with the stakeholders, should submit the final report on this work. **[Am. 48]**

(26) ~~In order to ensure that this Regulation is fully operational and to adapt it to technical and scientific development, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to~~ The Commission ~~in respect of the contents of documents to be submitted, reports, and summary reports of~~ ***should adopt implementing acts on procedural rules for the joint*** clinical assessments, ~~the contents of documents for requests, and reports~~ of joint scientific consultations, and ~~the rules~~ for selecting stakeholders. ~~It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.[15] In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council should receive all documents at the same time as Member States' experts, and their experts systematically should be granted access to meetings of Commission expert groups dealing with the preparation of delegated acts.~~ **[Am. 49]**

~~[15] 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).~~

(27) In order to ensure that sufficient resources are available for the joint work ***and stable administrative support*** provided for under this Regulation, the Union should ~~provide~~ ***ensure stable and permanent public*** funding ***under the Multiannual Financial Framework*** for the joint work and voluntary cooperation, ~~and~~ ***as well as*** for the support 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. ***The Commission should establish a system of charges for health technology developers requesting both joint scientific consultations and joint clinical assessments for research on unmet medical needs. Under no event can those fees be used to fund the joint work provided for in this Regulation.*** **[Am. 50]**

(28) 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***, as well as all information on the procedure, methodology, training and interests of assessors of and participants in the stakeholder network, and the reports and results of the joint work, which should be made public***. The Commission should also ensure a link between the IT platform and other data infrastructures relevant for the purposes of HTA such as registries of real world data. **[Am. 51]**

(28a) Cooperation should be based on the principle of good governance, which encompasses transparency, objectivity, independent experience and fair procedures. Trust is a precondition for successful cooperation and can only be achieved if all stakeholders make genuine commitments and if there is access to high-quality experience, capacity-building and the highest quality of execution. **[Am. 52]**

(28b) Since there is currently no commonly agreed definition of what constitutes high-quality innovation or added therapeutic value, the Union should adopt definitions of these terms with the agreement or consensus of all parties. **[Am. 53]**

(29) 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 provide for a transitional period allowing a progressive expansion of the number of joint assessments carried out annually. The number of assessments to be carried out should be determined with due regard for the resources available and the number of Member States participating with a view to reaching full capacity by the end of the transitional period. The establishment of such a transitional period should also afford Member States an opportunity to fully align their national systems with the framework for joint work in terms of resource allocation, timing, and prioritisation of assessments.

(30) During the transitional period, participation in joint clinical assessments and joint scientific consultations should not be mandatory for Member States. ~~This should not affect the obligation of Member States to apply harmonised rules to clinical assessments carried out at a national level.~~ ***Moreover,*** during the transitional period, Member States not participating in the joint work may at any time decide to participate. In order to ensure a stable and smooth organisation of the joint work and the functioning of the internal market, Members States which are already participating should not be allowed to withdraw from the framework for joint work. ***Clinical assessments which have started in Member States before the application of this Regulation should be continued, unless Member States decide to stop them.***
[Am. 54]

(31) ~~In order to ensure that the support framework continues to be as efficient and cost-effective as possible~~***After the transitional period and before the harmonised system for HTA established under this Regulation becomes mandatory***, the Commission should ***submit an impact assessment*** report on the ~~implementation~~ ***whole*** of the ~~provisions on~~ ***procedure that has been introduced. That impact assessment report should evaluate, among other criteria, the progress made in relation to patients access to new health technologies and the functioning of the internal market, the impact on the quality of innovation and on the sustainability of health systems, as well as the appropriateness of*** the scope of the joint clinical assessments and on the functioning of the support framework. ~~no later than two years after the end of the transitional period. The report may in particular consider whether there is a need to move this support framework to a Union agency and introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint work~~. **[Am. 55]**

(32) The Commission should carry out an evaluation of this Regulation. Pursuant to paragraph 22 of the Interinstitutional Agreement on Better Law-Making of 13 April 2016, that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU added value and should be supported by a monitoring programme. ***The results of that evaluation should also be communicated to the European Parliament and Council.*** **[Am. 56]**

(33) Directive 2011/24/EU provides that the Union is to support and facilitate 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.

(34) Since the objectives of this Regulation, namely to approximate the rules of the Member States on carrying out clinical assessments ~~at national level and establish a framework of mandatory joint clinical assessments of certain~~ ***of the*** health technologies ~~at Union level~~ ***falling under the scope of this Regulation***, cannot be sufficiently achieved by the Member States ***alone*** but can rather, by reason of their scale and effects, be better achieved at Union-level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective, **[Am. 57]**

HAVE ADOPTED THIS REGULATION:

Chapter I

General Provisions

Article 1

Subject Matter

1. ***Taking into account the results of the work already undertaken in the EUnetHTA Joint Actions,*** this Regulation establishes: **[Am. 58]**

   (a) a support framework and procedures for cooperation on ***the clinical assessment of*** health technology ~~assessment~~ at Union level; **[Am. 59]**

   (b) common ~~rules~~ ***methodologies*** for the clinical assessment of health technologies. **[Am. 60]**

2. This Regulation shall not affect the rights and obligations of Member States with regard to the organisation and delivery of health services and medical care and the allocation of resources assigned to them. ***Furthermore, this Regulation shall not interfere with the exclusive national competence of Member States for national pricing or reimbursement decisions.*** **[Am. 61]**

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 of the European Parliament and of the Council[16];

(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; **[Am. 62]**

(bb) 'assessment of a medical device' means the assessment of a method composed of more than one medical device or a method composed of a medical device and a defined care chain of other treatments; **[Am. 63]**

16 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).

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

(d) 'health technology assessment' means a multidisciplinary comparative assessment process, based on clinical and non-clinical assessment domains, which compiles and evaluates the available evidence about the clinical and non-clinical issues related to the use of a health technology;

(e) '***joint*** clinical assessment' means ~~a compilation and evaluation of the available~~ ***the systematic collection of*** scientific ~~evidence on a~~ ***information and its comparative evaluation and a synthesis of these procedures, the comparison of the*** health technology in ~~comparison~~ ***question*** with one or more other health technologies ***or existing procedures, constituting a benchmark for a particular clinical indication and,*** based on ***the best available clinical scientific evidence and on patient relevant clinical criteria, taking into account*** 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 ***or procedures*** 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; **[Am. 64]**

(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 ethical, organisational, social, and legal aspects related to its use;

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

(ga) 'appraisal' means drawing conclusions on the added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as non-clinical data and criteria in the national care context; **[Am. 65]**

(gb) 'patient-relevant health outcomes' means data that captures or predicts mortality, morbidity, health-related quality of life and adverse events. **[Am. 202]**

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 national ***or regional*** authorities and bodies responsible for health technology assessment ~~as members~~ ***at national level as members*** of the Coordination Group and its sub-groups ~~and inform the Commission thereof and of any subsequent changes. Member States may designate more than one authority or body responsible for health technology assessment as members of the Coordination Group and one or more of its sub-groups~~. **[Am. 66]**

3. The Coordination Group shall act by consensus, or, where necessary, vote by ~~simple~~ ***qualified*** majority. ~~There shall be one vote per Member State.~~

Procedures undertaken by the Coordination Group shall be transparent with meeting minutes and votes documented and made publicly available, including any dissensions. **[Am. 203]**

4. Meetings of the Coordination Group shall be co-chaired by the Commission***, without the right to vote,*** and a co-chair elected ~~from~~ ***annually from among*** the members of the group ~~for a set term to be determined in its rules of procedure~~ ***on a rotating basis. Co-chairs shall perform purely administrative functions***. **[Am. 68]**

5. Members of the Coordination Group***, being national or regional assessment authorities or bodies,*** shall appoint their representatives in the Coordination Group and the sub-groups in which they are members, on an ad-hoc or permanent basis***.*** ~~and inform~~***. Member States may terminate such appointments where it is warranted by the requirements of the appointment. However, in view of the workload, the composition of sub-groups, or the specific knowledge required, there may be more than one expert assessor for each Member State, without prejudice to the principle that, for the purposes of decision-taking, each Member State shall have one vote only. The appointments shall take into account the expertise necessary in order to achieve the objectives of the sub-group. The European Parliament, the Council and*** the Commission ~~of their~~***, shall be informed of all appointments and possible terminations of*** appointment. ~~and any subsequent changes~~. **[Am. 69]**

6. ***In order to ensure high quality of work,*** members of the Coordination Group~~, and their appointed representatives~~ shall ***be drawn from national or regional health technology assessment agencies or bodies responsible for that field.*** ~~respect the principles of independence,~~

Members serving in the Coordination Group, and experts and assessors in general, shall not have financial interests in any type of health technology developer industry or insurance company that may affect their impartiality.~~, and~~ ***They shall undertake to act independently and in the public interest and shall make an annual declaration of interests. Those declarations of interests shall be recorded on the IT platform referred to in Article 27 and shall made accessible to the public.***

At every meeting, members of the Coordination Group shall declare any specific interest that may be considered to adversely affect their independence in relation to agenda items. When a conflict of interest arises, the member of the Coordination Group concerned shall withdraw from the meeting whilst the relevant items of the agenda are being dealt with. The procedural rules for conflicts of interest shall be laid down in accordance with point (a)(iiia) of Article 22(1).

In order to ensure transparency and public awareness of the process and to promote confidence in the system, all clinical data being evaluated shall have the highest level of transparency and public communication. Where data is confidential for commercial reasons, its confidentiality ***shall be clearly defined and justified and the confidential data shall be well delimitated and protected***. **[Am. 70]**

7. The Commission shall publish ~~a~~ ***an up-to-date*** list of the designated members of the Coordination Group and its sub-groups ***and other experts, together with their qualifications and areas of expertise and their annual declaration of interest,*** on the IT platform referred to in Article 27.

The information referred to in the first subparagraph shall be updated by the Commission annually and whenever considered necessary in the light of possible new circumstances. Those updates shall be publicly accessible. **[Am. 71]**

8. The Coordination Group shall:

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

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

(c) ~~ensure cooperation~~ ***cooperate*** with relevant ~~Union level~~ ***Union-level*** bodies to facilitate additional evidence generation necessary for its work; **[Am. 72]**

(d) ensure appropriate ~~involvement of~~ ***consultation of relevant*** stakeholders ~~in~~ ***and experts when pursuing*** its work***. Such consultations shall be documented, including publicly available declarations of interest from the stakeholders consulted and shall be incorporated in the final joint assessment report***; **[Am. 73]**

(e) establish sub-groups for the following:

(i) joint clinical assessments;

(ii) joint scientific consultations;

(iii) identification of emerging health technologies;

(iv) voluntary cooperation;

(v) preparation of the annual work programmes and annual reports, and updates of the common rules and working documents.

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

10. The Coordination Group may establish separate sub-groups for the following categories of health technology: medicinal products, medical devices, and other health technologies.

10a. The rules of procedure of the Coordination Group and its sub-groups, the agendas for their meetings, the decisions adopted, and the details of votes and explanations of votes, including minority opinions, shall, in any event, be accessible to the public. **[Am. 74]**

Article 4

Annual Work Programme and Annual Report

1. The sub-group designated in accordance with Article 3(8)(e) shall prepare an annual work programme for approval by the Coordination Group by 31 December of each year.

2. The annual work programme shall set out the joint work to be carried out in the calendar year following its approval, covering:

   (a) the planned number of joint clinical assessments and the types of health technologies to be assessed;

   (b) the planned number of joint scientific consultations;

   (c) voluntary cooperation.

   Points (a), (b) and (c) of the first subparagraph shall be determined according to the extent of their impact on patients, public health or health care systems.
   [Am. 75]

3. In the preparation of the annual work programme, the designated sub-group shall:

(a) have regard to the annual study on emerging health technologies referred to in Article 18;

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

(c) consult the Commission ***and the stakeholder network, at annual meetings under Article 26,*** on the draft annual work programme and take into account ~~its opinion~~ ***their comments***. **[Am. 76]**

4. The designated sub-group shall prepare an annual report for approval by the Coordination Group by 28 February of each year.

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

5a. Both the annual report and the annual work programme shall be published on the IT platform referred to in Article 27. **[Am. 77]**

Chapter II

Joint Work on Health Technology Assessment at Union Level

SECTION 1

JOINT CLINICAL ASSESSMENTS

Article 5

Scope of Joint Clinical Assessments

1. The Coordination Group shall carry out joint clinical assessments on:

   (a) medicinal products subject to the authorisation procedure provided for in Regulation (EC) No 726/2004, including where an amendment has been made to the Commission Decision to grant a marketing authorisation based on a change in the therapeutic indication or indications for which the original authorisation was granted, with the exception of medicinal products authorised under Articles 10 and 10a of Directive 2001/83/EC;

(aa) other medicinal products not subject to the authorisation procedure provided for in Regulation (EC) No 726/2004 where the health technology developer has opted for the centralised authorisation procedure, provided that the medicinal products in question constitute a major technical, scientific or therapeutic innovation, or their authorisation is in the interest of public health; **[Am. 78]**

(b) 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 considered to be a significant innovation and with potential significant impact on public health or health care systems;*** **[Am. 79]**

(c) *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 considered to be a significant innovation and with potential significant impact on public health or health care systems.*** **[Am. 80]**

2. The Coordination Group shall select the medical devices referred to in paragraph 1 points (b) and (c) for joint clinical assessment based on the following criteria:

(a) unmet medical needs;

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

(c) significant cross-border dimension;

(d) major Union-wide added value;

(e) the available resources;

(ea) the need for greater clinical evidence; **[Am. 81]**

(eb) at the request of the health technology developer. **[Am. 82]**

Article 6

Preparation of Joint Clinical Assessment Reports

1. The Coordination Group shall initiate joint clinical assessments of health technologies on the basis of its annual work programme by designating a sub-group to oversee the preparation of the joint clinical assessment report on behalf of the Coordination Group.

The joint clinical assessment report shall be accompanied by a summary report***,*** ~~and~~ ***which shall contain at least the clinical data compared, the end-points, the comparators, the methodology, the clinical evidence used, and conclusions as regards efficacy, safety, and relative efficacy, the limits of the assessment, diverging views, a summary of the consultations carried out, and the observations made.*** They shall be prepared in accordance with the requirements ~~in this~~ ***laid down by the Coordination Group and shall be made public, regardless of the report´s conclusions.***

For medicinal products referred to in ***point (a) of*** Article ~~and the requirements established pursuant to Articles 11, 22, and 23~~ ***5(1), the joint clinical assessment report shall be adopted by the Coordination Group within 80-100 days in order to ensure compliance with timelines for pricing and reimbursement set out in Council Directive 89/105/EEC[17].*** **[Am. 83]**

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17 ***Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8)***.

2. The designated sub-group shall request ~~relevant~~ ***the*** health technology ~~developers~~ ***developer*** to submit ***all available up-to-date*** documentation containing the information, data and ~~evidence~~ ***studies, including both negative and positive results, that is*** necessary for the joint clinical assessment. ***That documentation shall include the available data from all tests performed and from all the studies in which the technology was used, both of which are of paramount importance to ensure that assessments are of high quality.***

For medicinal products referred to in point (a) of Article 5(1), the documentation shall at least include:

(a) the submission file;

(b) an indication of the marketing authorisation status;

(c) if available, the European public assessment report (EPAR), including the Summary of Product Characteristics (SPC); the European Medicines Agency shall provide the relevant adopted scientific assessment reports to the Coordination Group;

(d) where applicable, the results of additional studies requested by the Coordination Group and available to the health technology developer;

(e) where applicable and if available to the health technology developer, already available HTA reports on the health technology concerned;

(f) information on studies and study registries available to the health technology developer.

Health technology developers shall be obliged to submit all of the requested data.

Assessors may also access public databases and sources of clinical information, such as patient registries, databases or European Reference Networks, where such access is deemed necessary to complement the information provided by the developer and to perform a more accurate clinical assessment of the health technology. The reproducibility of the assessment implies that such information shall be made public.

The relationship between evaluators and health technology developers shall be independent and impartial. Developers of health technologies may be consulted but shall not actively participate in the evaluation process. **[Am. 84]**

2a. ***The Coordination Group may justifiably consider, in the case of orphan medicines, that there is no substantive reason or additional evidence to support further clinical analysis beyond the significant benefit assessment already carried by the European Medicines Agency.*** **[Am. 85]**

3. The designated sub-group shall appoint, from among its members, an assessor and a co-assessor to conduct the joint clinical assessment. ***The assessor and a co-assessor shall be different from those previously appointed under Article 13(3) except in exceptional and justified situations where the necessary specific expertise is not available, and subject to approval of the Coordination Group.*** The appointments shall take into account the scientific expertise necessary for the assessment. **[Am. 86]**

4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint clinical assessment report and the summary report.

5. The conclusions of the joint clinical assessment report shall ~~be limited to the following~~ ***include***: **[Am. 87]**

   (a) an analysis of the relative ~~effects~~ ***effectiveness and safety*** of the health technology being assessed ~~on the patient-relevant health outcomes~~ ***in terms of the clinical end-points relevant to the clinical entity and patient group*** chosen for the assessment***, including mortality, morbidity and quality of life, and compared to one or more comparator treatments to be determined by the Coordination Group***; **[Am. 88]**

(b) the degree of certainty on the relative effects based on the ***best*** available ***clinical*** evidence ***and compared to the best standard therapies***. ***The assessment shall be based on the clinical end-points established in accordance with international standards of evidence-based medicine, in particular with regard to improving the state of health, shortening the duration of the disease, prolonging survival, reducing side effects or improving the quality of life. Reference shall also be made to subgroup-specific differences.*** **[Am. 89]**

The conclusions shall not include an appraisal.

The assessor and the co-assessor shall make sure that the choice of relevant patient groups is representative of the participating Member States in order to enable them to take appropriate decisions on funding these technologies from national health budgets. **[Am. 90]**

6. Where, at any stage in the preparation of the draft joint clinical assessment report, the assessor considers that additional evidence from the submitting health technology developer is necessary in order to complete the report, it may request the designated sub-group to suspend the time period set for the preparation of the report and to request additional evidence from the health technology developer. Having consulted the health technology developer on the time needed to prepare the necessary additional evidence, the request from the assessor shall specify the number of working days for which the preparation shall be suspended. ***Where new clinical data become available during the process, the health technology developer concerned shall also proactively communicate this new information to the assessor.*** **[Am. 205]**

7. The members of the designated sub-group ***or the Coordination Group, in a minimum period of 30 working days,*** shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report. ~~The Commission may also provide comments.~~ **[Am. 92]**

8. The assessor shall provide the draft joint clinical assessment report and the summary report to the ~~submitting~~ health technology developer ~~and set a time-frame in which the developer may submit~~ ***for*** comments. **[Am. 93]**

9. ~~The designated sub-group shall ensure that stakeholders, including~~ Patients***, consumer organisations, health professionals, NGOs, other health technology developer associations*** and clinical experts~~, are given an opportunity to provide~~ ***may submit*** comments during the ~~preparation of the draft~~ joint clinical assessment ~~report and the summary report and set~~ ***within*** a time-frame ~~in which they may submit comments~~ ***set by the designated sub-group.***

The Commission shall make public the declarations of interest of all consulted stakeholders in the IT platform referred to in Article 27. **[Am. 94]**

10. Following receipt and consideration of any comments provided in accordance with paragraphs 7, 8, and 9, the assessor, with the assistance of the co-assessor, shall finalise the draft joint clinical assessment report and summary report, and submit those reports to the ~~designated sub-group and to the Commission~~ ***Coordination Group*** for comments. ***The Commission shall publish all comments, which shall be duly answered, on the IT platform referred to in Article 27.*** **[Am. 95]**

11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the ~~designated sub-group and the Commission~~ ***Coordination Group*** and submit a final draft joint clinical assessment report and the summary report to the Coordination Group for ***a final*** approval. **[Am. 96]**

12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by ~~a simple~~ ***qualified*** majority of Member States.

Diverging positions and the grounds on which those positions are based shall be recorded in the final report.

The final report shall include a sensitivity analysis if there is one or more of the following elements:

(a) different opinions on the studies to be excluded on the grounds of severe bias;

(b) diverging positions if studies shall be excluded as they do not reflect the up-to-date technological development; or

(c) controversies as to the definition of irrelevance thresholds regarding patient-relevant endpoints.

The choice of the one or more comparators and patient-relevant endpoints shall be medically justified and documented in the final report.

The final report shall also include the results of the joint scientific consultation carried out in accordance with Article 13. The scientific consultation reports shall be made public upon completion of the joint clinical assessments. **[Am. 206]**

13. The assessor shall ensure ~~the removal of any information of a commercially sensitive nature from~~ ***that*** the approved joint clinical assessment report and the summary report ***contain the clinical information which is the subject of the assessment and set out the methodology and studies used. The assessor shall consult the developer on the report before its publication. The developer shall have 10 working days to notify the assessor about any information it considers to be confidential and to justify its commercially sensitive nature. As a last resort, the assessor and the co-assessor shall decide as to whether the developer's claim of confidentiality is justified.*** **[Am. 98]**

14. The Coordination Group shall provide the approved joint clinical assessment report and the summary report to the submitting health technology developer and the Commission***, which shall include both reports on the IT platform***. **[Am. 99]**

14a. Upon receipt of the approved joint clinical assessment report and summary report, the submitting health technology developer may notify its objections in writing to the Coordination Group and the Commission within seven working days. In such a case, the developer shall provide detailed grounds for its objections. The Coordination Group shall evaluate the objections within seven working days and shall revise the report, as necessary.

The Coordination Group shall approve and submit the final joint clinical assessment report, the summary report and an explanatory document setting out how the objections of the submitting health technology developer and the Commission were addressed. **[Am. 100]**

14b. ***The joint clinical assessment report and the summary report shall be ready in not less than 80 days and not more than 100 days, except in justified cases where, owing to clinical necessity, the process needs to be accelerated or delayed respectively.*** **[Am. 101]**

14c. ***Where the submitting health technology developer withdraws the application for a marketing authorisation, giving reasons, or where the European Medicines Agency terminates an assessment, the Coordination Group shall be informed so that it terminates the joint clinical assessment procedure. The Commission shall publish the reasons for withdrawal of the application or termination of the assessment on the IT platform referred to in Article 27.*** **[Am. 102]**

Article 7

The List of Assessed Health Technologies

1. ~~Where~~ The Commission ~~considers that the approved joint clinical assessment report and summary report comply with the substantive and procedural requirements laid down in this Regulation, it~~ shall include the name of the health technology which has been the subject of the ~~approved~~ report and ***the approved*** summary report***, regardless of whether or not it has been adopted***, in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health Technologies" or the "List") at the latest 30 days after receipt of the approved report and summary report from the Coordination Group. **[Am. 103]**

2. Where, within 30 days of receipt of the approved joint clinical assessment report and the summary report, the Commission concludes that the approved joint clinical assessment report and summary report do not comply with the ~~substantive and procedural~~ ***procedural legal*** requirements laid down in this Regulation, it shall inform the Coordination Group of the reasons for its conclusions and request ~~it to~~ review ~~the report and summary report~~ ***of the assessment, giving reasons***. **[Am. 104]**

3. ~~The designated sub-group shall consider the conclusions referred to in paragraph 2 and invite the health technology developer to submit comments by a specified deadline.~~ The designated sub-group shall review the joint clinical assessment report and summary report taking into account the comments provided by the ~~health technology developer. The assessor, with the assistance of the co-assessor, shall modify the joint clinical assessment report and summary report accordingly and submit them to the Coordination Group. Article 6, paragraphs 12 to 14 shall apply~~ ***Commission, from a procedural point of view, prior to a final opinion.*** **[Am. 105]**

4. ~~Following the submission of the modified approved joint clinical assessment report and summary report, and where the Commission considers that the modified approved joint clinical assessment report and summary report comply with the substantive and procedural requirements laid down in this Regulation, it shall include the name of the health technology which has been the subject of the report and summary report, in the List of Assessed Health Technologies.~~ **[Am. 106]**

5. If the Commission concludes that the modified approved joint ~~clinical~~ assessment report and summary report do not comply with the ~~substantive and~~ procedural requirements laid down in this Regulation, ~~it shall decline to include the name of~~ the health technology ***which is the subject of the assessment shall be included*** in the List***, together with the summary report of the assessment and the Commission's comments, and all of which shall be published on the IT platform referred to in Article 27***. The Commission shall inform the Coordination Group thereof, setting out the reasons for the ~~non-inclusion~~ ***negative report***. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report. **[Am. 107]**

6. For those health technologies included on the List of Assessed Health Technologies, the Commission shall publish***, on the IT platform referred to in Article 27,*** the approved joint clinical assessment report and summary report ~~on the IT platform referred to in Article 27~~ ***as well as all the comments by stakeholders and interim reports,*** and make them available to the submitting health technology developer at the latest 10 working days following their inclusion in the List. **[Am. 108]**

Article 8

Use of Joint Clinical Assessment Reports at Member State Level

1. ***For the health technologies included on the List of Assessed Health Technologies or in respect of which a joint clinical assessment has been initiated,*** Member States shall: **[Am. 109]**

(a) ~~not carry out a clinical assessment or an equivalent assessment process on a health technology included in the List of Assessed Health Technologies or for which a~~ ***use the*** joint clinical assessment ~~has been initiated~~ ***reports in their health technology assessments at Member State level***; **[Am. 110]**

(b) ~~apply~~ ***not duplicate the*** joint clinical assessment ~~reports, in their health technology assessments~~ at Member State level. **[Am. 111]**

1a. The requirement set out in point (b) of paragraph 1 shall not prevent Member States or regions from carrying out assessments on the added clinical value of the technologies concerned as part of national or regional appraisal processes which may consider clinical as well as non-clinical data and evidence specific to the Member State concerned which were not included in the joint clinical assessment and which are necessary to complete the health technology assessment or the overall pricing and reimbursement process.

Such complementary assessments may compare the technology concerned against a comparator which represents the best available and evidence-based standard of care in the Member State concerned and which, despite that Member State´s request during the scoping phase, was not included in the joint clinical assessment. They may also assess the technology in a care context specific to the Member State concerned, based on its clinical practice, or the setting chosen for reimbursement.

Any such measure shall be justified, necessary and proportionate to achieving this aim, shall not duplicate work done at Union level and shall not unduly delay patient access to those technologies.

Member States shall notify the Commission and the Coordination Group of their intention to complement the joint clinical assessment together with a justification for doing so. **[Am. 112]**

2. Member States shall ~~notify the Commission of the outcome of a health technology assessment on a health technology which has been subject to a joint clinical assessment within 30 days from its completion. That notification shall be accompanied by~~ ***submit*** information ~~on how the conclusions of the joint clinical assessment report have been applied in the overall health technology assessment. The Commission shall facilitate the exchange of this information between Member States~~ through the IT platform referred to in Article 27***, on how account has been taken of the joint clinical assessment report in the health technology assessment at Member State level as well as other clinical data and additional evidence taken into account so that the Commission may facilitate the exchange of this information among Member States***. **[Am. 113]**

Article 9

Updates of Joint Clinical Assessments

1. The Coordination Group shall carry out updates of joint clinical assessments where:

(a) the Commission Decision to grant the marketing authorisation of a medicinal product referred to in Article 5(1)(a) was conditional on the fulfilment of additional post-authorisation requirements;

(b) the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment is available ***within the deadline set in that report;*** **[Am. 114]**

(ba) at the request of a Member State or a health technology developer that considers that there is new clinical evidence; **[Am. 115]**

(bb) five years after the assessment, significant new clinical evidence exist, or earlier when new evidence or clinical data emerges. **[Am. 116]**

1a. ***In the cases referred to under points (a), (b), (ba) and (bb) of the first subparagraph, the technology developer shall submit the additional information. In the event of a failure to do so, the earlier joint assessment would no longer fall within the scope of Article 8.***

The 'EVIDENT' database shall be maintained to gather clinical evidence as it arises from the real-life use of health technology and to monitor the results in terms of health. **[Am. 117]**

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

Updates of joint clinical assessments are requested when new information has been published or made available which was not available at the time of the initial joint report. When an update of the joint clinical assessment report is requested, the member who proposed it can update the joint clinical assessment report and propose it for adoption by other Member States by mutual recognition. When updating the joint clinical assessment report, the Member State shall apply the methods and standards as laid down by the Coordination Group.

Where Member States cannot agree on an update, the case is referred to the Coordination Group. The Coordination Group shall decide whether to carry out an update based on the new information.

When an update is approved by mutual recognition or after the Coordination Group's decision, the joint clinical assessment report is considered updated.
[Am. 118]

3. Updates shall be carried out in accordance with the procedural rules established pursuant to Article 11(1)(d).

Article 10

Transitional Arrangements for Joint Clinical Assessments

During the transitional period referred to in Article 33(1):

(a) the Coordination Group shall:

(i) base the annual number of planned joint clinical assessments on the number of Member States participating and the resources available to it;

(ii) select medicinal products referred to in Article 5(1)(a) for joint clinical assessment based on the selection criteria referred to in Article 5(2).

(b) members of the Coordination Group from Member States not participating in joint clinical assessments shall not:

(i) be appointed as assessors or co-assessors;

(ii) comment on the draft joint clinical assessment reports and summary reports;

(iii) take part in the approval process of the final joint clinical assessment reports and summary reports;

(iv) take part in the preparation and approval process on the parts of the annual work programmes on joint clinical assessments;

(v) be subject to the obligations set out in Article 8 as regards the health technologies which have undergone joint clinical assessment.

Article 11

Adoption of Detailed Procedural Rules for Joint Clinical Assessments

1. The Commission shall ***in accordance with this Regulation,*** develop, by means of implementing acts, procedural rules for: **[Am. 119]**

   ~~(a) submissions of information, data and evidence by health technology developers;~~ **[Am. 120]**

   (b) the appointment of assessors and co-assessors;

   (c) determining the detailed procedural steps and their timing~~, and the overall duration of joint clinical assessments~~; **[Am. 121]**

   (d) updates of joint clinical assessments;

   (e) cooperation with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products;

   (f) cooperation with the ~~notified~~ bodies and expert panels ~~on the preparation and update of joint clinical assessments of medical devices~~. **[Am. 122]**

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 12

Requests for Joint Scientific Consultations

1. Health technology developers may request a joint scientific consultation with the Coordination Group for the purposes of obtaining scientific advice concerning ~~data and evidence likely to be required as part of a joint~~ ***the*** clinical ~~assessment~~ ***aspects for the optimal design of scientific studies and research to obtain the best scientific evidence, improve predictability, align research priorities and enhance the quality and efficiency of said research, in order to obtain the best evidence***. **[Am. 123]**

   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 pursuant to Article 57(1)(n) of Regulation (EC) No 726/2004. In such a case, it shall make that request at the time of submitting an application for scientific advice to the European Medicines Agency.

2. In considering the request for joint scientific consultation, the Coordination Group shall take into account the following criteria:

(a) the likelihood that the health technology under development will be the subject of a joint clinical assessment in accordance with Article 5(1);

(b) unmet medical needs;

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

(d) significant cross-border dimension;

(e) major Union-wide added value;

(f) the available resources;

(fa) Union clinical research priorities. **[Am. 124]**

3. Within 15 working days after receipt of the request, the Coordination Group shall inform the requesting health technology developer whether or not it will engage in the joint scientific consultation. Where the Coordination Group refuses the request, it shall inform the health technology developer thereof and explain the reasons having regard to the criteria laid down in paragraph 2.

Joint scientific consultations shall not prejudice the objectivity and independence of joint technological assessments nor its results or conclusions. The assessor and co-assessor appointed to carry them out pursuant to Article 13(3) shall not be the same as the assessor and co-assessor appointed pursuant to Article 6(3) for the joint technological assessment.

The subject and the summarised substance of the consultations shall be published on the IT platform referred to in Article 27. **[Am. 125]**

Article 13

~~Preparation of~~ Joint Scientific Consultation ~~Reports~~ ***procedure*** **[Am. 126]**

1. Following the acceptance of a request for a joint scientific consultation in accordance with Article 12 and on the basis of its annual work programme, the Coordination Group shall designate a sub-group to oversee the preparation of the joint scientific consultation report on behalf of the Coordination Group.

   The joint scientific consultation report shall be prepared in accordance with the requirements in this Article and in accordance with the ~~procedural rules~~ ***procedure*** and documentation established pursuant to Articles 16 and 17. **[Am. 127]**

2. The designated sub-group shall request the health technology developer to submit the ***available and up-to-date*** documentation containing ~~the~~ ***all stages of*** information ***processing***, data and ~~evidence~~ ***studies*** necessary for the joint scientific consultation***, such as available data from all tests performed and from all the studies in which the technology was used***. ***A tailored clinical assessment pathway may be developed for orphan medicinal products due to the limited number of patients enrolled in clinical trials and/or the lack of a comparator. All that information shall be made publicly available, upon completion of the joint clinical assessments.***

   The designated sub-group and the health technology developer concerned shall hold a joint meeting based on the documentation described in first subparagraph. **[Am. 128]**

3. The designated sub-group shall appoint from among its members, an assessor and a co-assessor, with responsibility for conducting the joint scientific consultation***, who shall not be the same as the assessor and a co-assessor to be appointed pursuant to Article 6(3)***. The appointments shall take into account the scientific expertise ~~necessary for the assessment~~. **[Am. 129]**

4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint scientific consultation report.

5. Where, at any stage in the preparation of the draft joint scientific consultation report, the assessor considers that additional evidence from a health technology developer is necessary in order to complete the report, it may request the designated sub-group to suspend the time period set for the preparation of the report and to request the additional evidence from the health technology developer. Having consulted the health technology developer on the time needed to prepare the necessary additional evidence, the request from the assessor shall specify the number of working days for which the preparation shall be suspended.

6. The members of the designated sub-group shall provide their comments during the preparation of the draft joint scientific consultation report.

7. The assessor shall provide the draft joint scientific consultation report***, and provide it*** to the ~~submitting~~ health technology developer ~~and set~~ ***for comments, setting*** a time-frame ~~in which the developer may submit comments~~ ***for those comments***. **[Am. 130]**

8. The ~~designated sub-group shall ensure that stakeholders, including~~ ***health technology developer,*** patients***, health professionals*** and clinical experts ~~are given an opportunity to provide~~ ***may submit*** comments during the ~~preparation of the draft~~ joint scientific consultation. ~~report and set a time-frame in which they may submit comments.~~ **[Am. 131]**

9. Following receipt and consideration of any ***information and*** comments provided in accordance with paragraphs ***2,*** 6, 7 and 8, the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation report and submit the draft report to the designated sub-group for comments. ***All comments, which shall be public and answered when required, shall be published on the IT platform referred to in Article 27, following finalisation of the joint clinical assessment. The published comments shall include stakeholders comments and any differences of opinion expressed by members of the sub-group in the course of the procedure.*** **[Am. 132]**

10. Where the joint scientific consultation is carried out in parallel with scientific advice given by the European Medicines Agency, the assessor shall seek to coordinate ~~with the Agency as regards the consistency of the conclusions of the joint scientific consultation report with those of the scientific advice~~ ***the time-frame***. **[Am. 133]**

11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the members of the designated sub-group and submit the final draft joint scientific consultation report to the Coordination Group.

12. The Coordination Group shall approve the final joint scientific consultation report, wherever possible by consensus or, where necessary, by a ~~simple~~ ***qualified*** majority of Member States, at the latest 100 days following the start of the preparation of the report referred to in paragraph 4. **[Am. 207]**

Article 14

Joint Scientific Consultation Reports

1. The Coordination Group shall communicate the approved joint scientific consultation report to the requesting health technology developer at the latest 10 working days following its approval.

2. The Coordination Group shall include ~~anonymised~~ summary information on the joint scientific consultations in its annual reports and the IT platform referred to in Article 27. ***That information shall include the subject of the consultations and the comments.***

   The scientific consultation reports shall be made public upon completion of the joint clinical assessments. **[Am. 135]**

3. Member States shall not carry out a scientific consultation or an equivalent consultation on a health technology ***referred to in Article 5*** for which a joint scientific consultation has been initiated***, unless additional clinical data and evidence were not taken into account and such data and evidence are considered necessary. Such national*** ~~and where the contents of the request are the same as those covered by the joint~~ scientific ~~consultation~~ ***consultations shall be submitted to the Commission for publication on the IT platform referred to in Article 27***. **[Am. 136]**

Article 15

Transitional Arrangements for Joint Scientific Consultations

During the transitional period referred to in Article 33(1):

(a) the Coordination Group shall base the annual number of planned joint scientific consultations on the number of Member States participating and the resources available to it;

(b) members of the Coordination Group from Member States not participating in joint scientific consultations shall not:

  (i) be appointed as assessors or co-assessors;

  (ii) comment on the draft joint scientific consultation reports;

  (iii) take part in the approval process of the final joint scientific consultation reports;

  (iv) take part in the preparation and approval process on the parts of the annual work programmes on joint scientific consultations.

Article 16

Adoption of Detailed Procedural Rules for Joint Scientific Consultations

1. The Commission shall develop, by means of implementing acts, procedural rules for:

(a) submissions of requests from health technology developers; ~~and their involvement in the preparation of joint scientific consultation reports;~~ **[Am. 137]**;

(b) the appointment of assessors and co-assessors;

(c) determining the detailed procedural steps and their timing;

(d) the ~~consultation of~~ ***submission of comments by*** patients, ***health professionals, patient associations, social partners, non-governmental organisations,*** clinical experts and other relevant stakeholders; **[Am. 138]**

(e) cooperation 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 Agency;

(f) cooperation with the expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 on the joint scientific consultations on medical devices.

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

Article 17

Documentation and Rules for Selecting Stakeholders for Joint Scientific Consultations

The Commission shall be empowered to adopt ~~delegated~~ ***implementing*** acts in accordance with ~~Article 31~~ ***Articles 30 and 32*** concerning: **[Am. 139]**

(a) the ~~contents of~~ ***procedure for***: **[Am. 140]**

(i) requests from health technology developers for joint scientific consultations;

(ii) dossiers of information, data and evidence to be submitted by health technology developers for joint scientific consultations;

(iii) joint scientific consultation reports;

(iiia) stakeholder involvement for the purpose of this section, including rules on conflict of interest. Declarations of interest shall be made publicly available for all stakeholders and experts consulted. Stakeholders and experts with a conflict of interest shall not participate in the process. **[Am. 141]**

~~(b) the rules for determining the stakeholders to be consulted for the purpose of this Section.~~ **[Am. 142]**

SECTION 3

EMERGING HEALTH TECHNOLOGIES

Article 18

Identification of Emerging Health Technologies

1. The Coordination Group shall annually prepare a study on emerging health technologies expected to have a major impact on patients, public health or healthcare systems.

2. In the preparation of the study, the Coordination Group shall consult:

   (a) health technology developers;

   (b) patient ***and consumer*** organisations ***and health professionals at its annual meeting***; **[Am. 143]**

   (c) clinical experts;

   (d) the European Medicines Agency including on the pre-notification of medicinal products prior to marketing authorisation applications;

   (e) the Medical Devices Coordination Group established in Article 103 of Regulation (EU) 2017/745.

2a. ***When preparing the study, the Coordination Group shall ensure that commercially confidential information provided by the health technology developer is adequately protected. To that end, the Coordination Group shall give the health technology developer an opportunity to submit comments with respect to the contents of the study and shall take due account of those comments.*** **[Am. 144]**

3. The conclusions of the study shall be summarised in the Coordination Group's annual report and shall be taken into account in the preparation of its annual work programmes.

SECTION 4

VOLUNTARY COOPERATION ON HEALTH TECHNOLOGY ASSESSMENT

Article 19

Voluntary Cooperation

1. The Commission shall support ***any further*** cooperation and the exchange of scientific information among Member States on ***the following issues***: **[Am. 145]**

(a) non-clinical assessments on health technologies;

(b) collaborative assessments on medical devices;

(c) health technology assessments on health technologies other than medicinal products or medical devices;

(d) the provision of additional evidence necessary to support health technology assessments;

(da) clinical assessments of medicinal products and medical devices carried out by Member States; **[Am. 146]**

(db) measures relating to compassionate use in clinical practice in order to improve the evidence basis and to create a register for this purpose; **[Am. 147]**

(dc) the development of best medical practice guides based on scientific evidence; **[Am. 148]**

(dd) disinvestment in obsolete technologies; **[Am. 149]**

(de) the tightening of the rules on clinical evidence generation and its monitoring. **[Am. 150]**

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)~~ ***(c), (db) and (de)*** may be carried out using the procedural rules established in accordance with Article 11 and the common rules established in accordance with Articles 22 and 23. **[Am. 151]**

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 the IT platform referred to in Article 27.

Chapter III

Rules for Clinical Assessments

Article 20

Harmonised Rules for Clinical Assessments

1. The common procedural rules and methodology established in accordance with Article 22 and the requirements established in accordance with Article 23 shall apply to:

(a) joint clinical assessments carried out in accordance with Chapter II.

~~(b) clinical assessments of medicinal products and medical devices carried out by Member States.~~ **[Am. 152]**

1a. ***Where relevant and appropriate, Member States shall be encouraged to apply the common procedural rules and methodology referred to in this Regulation for the clinical assessment of medicinal products and medical devices not falling within the scope of this Regulation and carried out by Member States at national level.*** **[Am. 153]**

Article 21

Clinical Assessment Reports

1. Where a clinical assessment is carried out by a Member State, that Member State shall provide the Commission with the clinical assessment report and summary report at the latest 30 working days after the completion of the health technology assessment.

2. The Commission shall publish the summary reports referred to in paragraph 1 in the IT platform referred to in Article 27 and make the clinical assessment reports available to other Member States through that IT platform.

Article 22

Common Procedural Rules and Methodology

1. ***Taking into account the results of the work already undertaken in the EUnetHTA Joint Actions, and after consulting all relevant stakeholders,*** the Commission shall adopt implementing acts concerning: **[Am. 154]**

(a) procedural rules for:

(i) ensuring that ~~health technology authorities and bodies~~ ***the members of the Coordination Group*** carry out clinical assessments in an independent and transparent manner, free from conflicts of interest***, in accordance with Article 3(6) and (7)***; **[Am. 155]**

(ii) the mechanisms for the interaction between health technology bodies and health technology developers during clinical assessments***, subject to the provisions of the previous articles***; **[Am. 156]**

(iii) ~~the consultation~~ ***comments*** of patients***, health professionals, consumer organisations***, clinical experts, and other stakeholders in clinical assessments ***and the duly justified replies, subject to the provisions of the previous articles***; **[Am. 157]**

(iiia) addressing potential conflicts of interest; **[Am. 158]**

(iiib) ensuring that the assessment of medical devices is able to take place at the appropriate point in time after market launch, allowing for the use of clinical effectiveness data, including real world data. The appropriate time point shall be identified in cooperation with relevant stakeholders. **[Am. 159]**

(b) ~~methodologies used to formulate the contents and design of clinical assessments~~ ***in order to guarantee the quality of the process, a penalty mechanism in the event of non-compliance by the technology developer with the requirements concerning the available information to be provided***.
[Am. 160]

1a. Within [6 months] from the date of entry into force of this Regulation, the Coordination Group shall draw up a draft implementing regulation concerning the methodologies to be consistently used to carry out joint clinical assessments and consultations and shall define the content of those assessments and consultations. The methodologies shall be developed on the basis of the existing EUnetHTA methodological guidelines and evidence submission templates. In any case, the methodologies shall comply with the following criteria:

(a) the methodologies are based on high standards of quality, the best available scientific evidence, stemming, where practically feasible and ethically justifiable, primarily from double-blind randomised clinical trials, meta-analysis and systematic reviews;

(b) the assessments of relative effectiveness are based on end-points which are relevant to the patient with useful, relevant, tangible and specific criteria suited to the clinical situation concerned;

(c) the methodologies take into account the specificities of new procedures and certain types of medicinal products with less clinical evidence available at the time of the marketing authorisation (such as orphan medicinal products or conditional marketing authorisations). However, any such lack of evidence does not prevent the generation of additional evidence required to be post monitored and which may require post-assessment and shall not affect patients' security or scientific quality;

(d) the comparators are the reference comparators for the clinical entity concerned and the best and/or most commonly used technological or process based comparator;

(e) for medicinal products, the technology developers, for the purpose of clinical assessment, provide the coordination group with the dossier in eCTD format submitted to the European Medicines Agency for centralised authorisation. That dossier shall include the clinical study report;

(f) the information to be provided by the health technology developer relates to the most up-to-date and public data. Failure to comply with that requirement may trigger a penalty mechanism;

(g) clinical trials are the studies par excellence in the biomedical field, so the use of another type of study, for example, epidemiological studies, may be carried out in exceptional cases and shall be fully justified;

(h) common methods as well as data requirements and outcome measures take into account the specificities of medical devices and in vitro diagnostic medical devices;

(i) regarding vaccines, the methodology takes into account the lifelong effect of a vaccine through an appropriate time horizon of the analyses; indirect effects such as herd immunity; and elements independent from the vaccine as such, for example coverage rates linked to programmes;

(j) where practically feasible and ethically justifiable, the health technology developer conducts at least one randomised controlled clinical trial, comparing its health technology in terms of clinically relevant outcomes with an active comparator considered among the best current proven intervention at the time the trial was designed (standard treatment), or the most common intervention when no standard treatment exists. The technology developer shall provide the data and results of conducted comparative trials in the documentation dossier submitted for the joint clinical assessment.

In the case of a medical device, the methodology shall be adapted to its characteristics and specificities, taking as a basis the methodology already developed by EUnetHTA.

The Coordination Group shall submit the draft implementing regulation to the Commission for endorsement.

Within [3 months] of receipt of the draft measure, the Commission shall decide whether to endorse it by means of an implementing act adopted in accordance with the examination procedure referred to in Article 30(2).

Where the Commission intends not to endorse a draft measure or to endorse it in part or where it proposes amendments, it shall send the draft back to the Coordination Group, setting out the reasons. Within a period of [6 weeks], the Coordination Group may amend the draft measure on the basis of the Commission's indications and proposed amendments, and resubmit it to the Commission.

If, on the expiry of the [6-week period], the Coordination Group has not submitted an amended draft measure, or has submitted a draft measure that is not amended in a way consistent with the Commission's proposed amendments, the Commission may adopt the implementing regulation with the amendments it considers relevant or reject it.

In the event that the Coordination Group does not submit a draft measure to the Commission within the time limit in accordance with [paragraph 1], the Commission may adopt the implementing regulation without a draft having been submitted from the Coordination Group. **[Am. 208/rev]**

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 and Rules for Selecting Stakeholders

The ~~Commission shall be empowered to adopt delegated acts in accordance with~~ ***Coordination Group, following the same procedure set up in point (a) of*** Article ~~31~~ ~~concerning~~ ***2(1) shall establish***: **[Am. 162]**

(a) the ~~contents~~ ***format and templates*** of: **[Am. 163]**

(i) dossiers of information, data and evidence to be provided by health technology developers for clinical assessments;

(ii) clinical assessment reports;

(iii) summary clinical assessment reports.

(b) the rules for determining the stakeholders to be consulted for the purposes of Section 1 of Chapter II and of this Chapter***, notwithstanding Article 26***. **[Am. 164]**

Chapter IV

Support Framework

Article 24

~~Union~~ Funding **[Am. 165]**

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, 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) No 966/2012 of the European Parliament and of the Council[18].

2. The funding referred to in paragraph 1 shall include funding for the participation of Member States' designated health technology authorities and bodies in support of the work on joint clinical assessments and joint scientific consultations. Assessor 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 provisions.

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18 Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

2a. ***The Union shall ensure stable and permanent public funding for the joint work on HTA that shall be conducted without the direct or indirect funding by developers of health technologies.*** **[Am. 166]**

2b. ***The Commission may establish a system of charges for health technology developers requesting both joint scientific consultations and joint clinical assessments which it shall use to finance research regarding unmet medical needs or clinical priorities. Such a system of charges shall under no circumstances used to finance activities under this Regulation.*** **[Am. 167]**

Article 25

Commission Support for the Coordination Group

The Commission shall support the work of the Coordination Group. In particular the Commission shall:

(a) host on its premises and co-chair ***– with the right to speak, but not to vote –*** the meetings of the Coordination Group; **[Am. 168]**

(b) provide the secretariat for the Coordination Group and provide administrative, ~~scientific~~ and IT support; **[Am. 169]**

(c) publish on the IT platform referred to in Article 27 the Coordination Group's annual work programmes, annual reports, summary minutes of its meetings, and reports and summary reports of joint clinical assessments;

(d) verify that the work of the Coordination Group is carried out in an independent and transparent manner***, in accordance with the established rules of procedure***; **[Am. 170]**

(e) facilitate cooperation with the European Medicines Agency on the joint work on medicinal products including the sharing of confidential information;

(f) facilitate cooperation with the relevant Union level bodies on the joint work on medical devices including the sharing of ~~confidential~~ information. **[Am. 171]**

Article 26

Stakeholder Network

1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications***, such as legitimacy, representation, transparency and accountability***.

The organisations to be addressed by the open call for applications shall be patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals.

Best practices in preventing conflict of interest shall apply to the selection of members of the stakeholder network.

The European Parliament shall have two representatives in the stakeholder network. **[Am. 172]**

2. The Commission shall publish the list of stakeholder organisations included in the stakeholder network. ***Stakeholders shall not have conflict of interest and their declarations of interests shall be published in the IT platform.*** **[Am. 173]**

3. The Commission shall organise ~~ad-hoc meetings~~ ***a meeting*** between the stakeholder network and the Coordination Group ***at least once a year*** in order to ***promote a constructive dialogue. The roles of the stakeholder network shall include***: **[Am. 174]**

(a) ~~update stakeholders~~ ***exchange of information*** on the work of the ***Coordination*** group ***and the assessment process***; **[Am. 175]**

(b) ~~provide for an exchange of information on the work of the Coordination Group~~ ***participation in seminars or workshops or specific actions on particular aspects***; **[Am. 176]**

(ba) supporting access to real-life experiences on diseases and their management and on the actual use of health technologies, in the interests of a better understanding of the value which stakeholders attach to the scientific evidence provided during the assessment process; **[Am. 177]**

(bb) contributing to more focused and efficient communication with and between stakeholders in order to support their role in the safe and rational use of health technologies; **[Am. 178]**

(bc) drawing up a list of priorities for medical research; **[Am. 179]**

(bd) seeking input into the annual work programme and the annual study prepared by the Coordination Group. **[Am. 180]**

The interests and the founding documents of the stakeholders, as well as a summary of annual meetings and possible activities, shall be published on the IT platform referred to in Article 27. **[Am. 181]**

4. On the request of the Coordination Group, the Commission shall invite patients***, health professionals*** and clinical experts nominated by the stakeholder network to attend meetings of the Coordination Group as observers. **[Am. 182]**

5. On the request of the Coordination Group, the stakeholder network shall support the Coordination Group in the identification of patient and clinical expertise for the work of its sub-groups.

Article 27

IT Platform

1. ***Building on the work already undertaken by the EUnetHTA Joint Actions,*** the Commission shall develop and maintain an IT platform containing information on: **[Am. 183]**

(a) planned, on-going, and completed joint clinical assessments and Member State health technology assessments;

(b) joint scientific consultations;

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

(d) results of the voluntary cooperation between Member States;

(da) a list of members of the Coordination Group, its sub-groups and other experts, together with their declaration of financial interests; **[Am. 184]**

(db) all information whose publication is required under this Regulation; **[Am. 185]**

(dc) final joint clinical assessment reports and summary reports in a lay-friendly format in all official languages of the European Union; **[Am. 186]**

(dd) a list of organisations included in the stakeholder network. **[Am. 187]**

2. The Commission shall ensure ~~appropriate levels of~~ ***public*** access to the information contained in the IT platform. ~~for Member State bodies, members of the stakeholder network, and the general public.~~ **[Am. 188]**

Article 28

~~Implementation Report~~ ***Evaluation report on the transitional period*** **[Am. 189]**

~~No later than two years after~~ ***At*** the end of the transitional period referred to in Article ~~33(1)~~ ***33 and before the harmonised system for health technology assessment established under this Regulation becomes mandatory***, the Commission shall ***submit an impact assessment*** report on the ~~implementation~~ ***whole*** of the ~~provisions on~~ ***procedure that has been introduced, which shall evaluate, among other criteria, the progress made in relation to patient access to new health technologies and the functioning of the internal market, the impact on the quality of innovation, such as the development of innovative medicinal products in areas of unmet need, on the sustainability of health systems, the HTA quality and the capacity at the national and regional level, as well as the appropriateness of*** the scope of the joint clinical assessments and ~~on~~ the functioning of the support framework ~~referred to in this Chapter~~. **[Am. 190]**

Chapter V

Final Provisions

Article 29

Evaluation and Monitoring

1. No later than five years after the publication of the report referred to in Article 28, the Commission shall carry out an evaluation of this Regulation, and report on its conclusions.

2. By … [*one year after the date of application*] at the latest, the Commission shall establish a programme for monitoring the implementation of this Regulation. The monitoring programme shall set out the means by which and the intervals at which the data and other necessary evidence will be collected. The monitoring programme shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.

3. The annual reports of the Coordination Group shall be used as part of the monitoring programme.

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.

~~Article 31~~

~~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 Articles 17 and 23 shall be conferred on the Commission for an indeterminate period of time from … *[insert date of entry into force of this Regulation*].~~

~~3. The delegation of power referred to in Articles 17 and 23 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 on Better Law-Making of 13 April 2016.~~

~~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 Articles 17 and 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and 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.~~ **[Am. 191]**

Article 32

Preparation of Implementing ~~and Delegated~~ Acts **[Am. 192]**

1. The Commission shall adopt the implementing ~~and delegated~~ acts referred to in Articles 11, 16, 17 ***and*** 22, ~~and 23,~~ at the latest by the date of application of this Regulation. **[Am. 193]**

2. When preparing those implementing ~~and delegated~~ acts, the Commission shall take into account the distinctive characteristics of the medicinal product and medical device sectors***, and shall consider the work already undertaken in the EUnetHTA Joint Actions***. **[Am. 194]**

Article 33

Transitional Provisions

1. Member States may delay their participation in the system of joint clinical assessments and joint scientific consultations referred to in sections 1 and 2 of Chapter II until ... [~~3~~ ***4*** years after the date of application] ***for medicinal products referred to in points (a) and (aa) of Article 5(1), and until ... [7 years after the date of application] for medical devices referred in Article point (b) of Article 5(1) and for in vitro diagnostic medical devices referred in point (c) of Article 5(1).***
[Am. 195]

2. Member States shall notify the Commission where they intend to make use of the transitional period set out in paragraph 1 at the latest one year before the date of application of this Regulation.

3. Member States which have delayed their participation in accordance with paragraph 1 may begin participating with effect from the next financial year after having notified the Commission at least three months before the beginning of that financial year.

Article 34

Safeguard Clause

1. Member States may carry out a clinical assessment using means other than the rules provided for in Chapter III of this Regulation, ***on the grounds set out in Article 8(1a), and*** on grounds related to the need to protect public health in the Member State concerned and provided the measure is justified, necessary and proportionate as regards achieving that aim. **[Am. 196]**

2. Member States shall notify the Commission ***and the Coordination Group*** of their intention to carry out a clinical assessment using other means together with the justifications for doing so. **[Am. 197]**

2a. The Coordination Group may assess whether the request fulfils the grounds referred to in paragraph 1, and may submit its conclusions to the Commission. **[Am. 198]**

3. The Commission shall, within three months of the date of receiving the notification provided for in paragraph 2, approve or reject the planned assessment after having verified whether or not it complies with the requirements referred to in paragraph 1 and whether or not it is a means of arbitrary discrimination or a disguised restriction on trade between Member States. In the absence of a decision by the Commission by the end of the three month period, the planned clinical assessment shall be deemed to be approved. ***The Commission's decision shall be published on the IT platform referred to in Article 27.*** **[Am. 199]**

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 … [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 ...,

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