



Council of the
European Union

Brussels, 2 February 2018
(OR. en)

5844/18

Interinstitutional File:
2018/0018 (COD)

PHARM 6
SAN 49
MI 61
COMPET 53
CODEC 133

PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	1 February 2018
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2018) 51 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU

Delegations will find attached document COM(2018) 51 final.

Encl.: COM(2018) 51 final



Brussels, 31.1.2018
COM(2018) 51 final

2018/0018 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

{SWD(2018) 41 final} - {SWD(2018) 42 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner. Its aim is to inform the formulation of safe and effective health policies that are patient focused and seek to achieve best value. The term "health technology" is to be understood in a broad sense comprising medicinal products, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.

HTA is thus an evidence-based process that independently and objectively assesses a new or existing technology and compares it with other health technologies and / or the current standard of care. HTA is primarily used to inform decision-making in Member States by providing a scientific evidence base for decisions on the pricing and reimbursement of health technologies. HTA can cover different aspects (domains) ranging from clinical domains (e.g. safety, clinical effectiveness) to non-clinical domains (e.g. economic, ethical, organisational). This proposal focuses on clinical assessments which are typically based on global evidence (e.g. worldwide clinical trials in the case of medicinal products and multi-national clinical trials for medical devices) compared with non-clinical assessments which include domains that are often more sensitive to national / regional contexts.

At EU level, cooperation on HTA has been ongoing since the 1980s. To support cooperation between HTA bodies, the European Union has made substantial investments. Two Joint Actions (EUnetHTA JA) have been carried out together with a number of projects. A third Joint Action (EUnetHTA Joint Action 3) was launched in June 2016 and runs until 2020 with a total budget of EUR 20 million. Participation in the Joint Actions has been very high, including participation from all EU Member States. The third Joint Action focuses on developing common assessment methodologies, piloting and producing joint clinical assessments and full HTA reports, and on developing and maintaining common ICT tools. In addition, following the adoption of the Cross-Border Healthcare Directive (Directive 2011/24/EU), the HTA Network was established in 2013 to provide strategic and political guidance to the scientific and technical cooperation at Union-level.

- **Reasons for and objectives of the proposal**

Despite the achievements of the current EU cooperation, a number of problems have been identified, which cannot be sufficiently addressed by continued project-based voluntary cooperation on HTA.

Problem 1. Impeded and distorted market access

The different national processes and methodologies of national and regional HTA bodies mean that health technology developers who want to introduce a health technology in multiple Member States are confronted with various data and evidence requests. This in turn contributes to impeded and distorted market access, leading to a lack of business predictability, higher costs, and, in the long run, negative effects on innovation. Differences in national processes and methodologies also lead to differences in how evidence is considered in

assessments, which can contribute to delays and inequalities in availabilities of innovative health technologies for patients.

Problem 2. Duplication of work for national HTA bodies

Clinical assessments of the same technologies are being conducted in parallel or within a similar time-frame by HTA bodies in different Member States, resulting in duplication of work and inefficient use of resources. In addition, the current low levels of use at national level of the joint clinical assessments produced through the Union-level cooperation result in duplication and incur additional work and costs. The duplication may be associated with different outcomes/conclusions, which negatively affect business predictability and contribute to delays and inequalities in availabilities to patients of the most innovative health technologies.

Problem 3. Unsustainability of HTA cooperation

The current Union-level cooperation on HTA is project-based. This means its funding is short-term, needs to be secured and renegotiated in every financial cycle, and there is no guarantee for the continuation of activities in the long-term. During the initiation and closing of each such large-scale project, substantial time and resources are spent on organisational issues leading to disruption in the output of the scientific cooperation.

With regard to the problems identified, the objectives of the current proposal are the following:

General objectives:

- Ensure a better functioning of the internal market;
- Contribute to a high level of human health protection.

Specific objectives:

- Improve the availability of innovative health technologies for EU patients;
- Ensure efficient use of resources and strengthen the quality of HTA across the EU;
- Improve business predictability.

Operational objectives:

- Promote convergence in HTA tools, procedures and methodologies;
- Reduce duplication of efforts for HTA bodies and industry;
- Ensure the use of joint outputs in Member States;
- Ensure the long-term sustainability of EU HTA cooperation.

- **Consistency with existing policy provisions in the policy area**

Currently the Union-level HTA cooperation is facilitated through Article 15 of the Cross-Border Healthcare Directive (Directive 2011/24/EU). This Directive provides for the establishment of a network of Member States' HTA authorities and bodies to facilitate cooperation and the exchange of scientific information among Member States. The objectives of the HTA Network are, *inter alia*, to support cooperation between national HTA bodies, support the provision and

exchange between Member States of information on the relative efficacy of health technologies and to avoid duplication of assessments. The network thus provides a strategic steer to the scientific cooperation carried out under it and through the EU-funded initiatives described above (i.e. the Joint Actions).

This proposal incorporates the provisions of Article 15 of Directive 2011/24/EU and builds upon these through reinforced cooperation at Union-level. The proposal thus deletes Article 15 of that Directive. The definition of 'health technology' used in Directive 2011/24/EU is also used in this proposal, ensuring a consistent approach across the two texts.

- **Consistency with other Union policies**

The proposal is in line with the EU's overarching objectives, including a smooth functioning of the internal market, sustainable health systems, and an ambitious research and innovation agenda. In addition to coherence with these EU policy objectives, the proposal is also consistent with and complementary to existing EU legislation related to medicinal products and medical devices¹. For example, while the regulatory process and the HTA process will remain well separated as they have different purposes, there are opportunities to create synergies, through mutual information-sharing and better alignment of the timing of procedures between the proposed joint clinical assessments and the centralised marketing authorisation for medicinal products². Synergies are also expected between joint clinical assessments of medical devices and some of the provisions in the new EU Regulations for medical devices and *in vitro* diagnostics (e.g. strengthened rules on clinical evaluation and clinical investigation; EU-level expert panels for high-risk medical devices).

Given the recent entry into force of the new Regulations on medical devices, their on-going implementation, and the impact of this on medical device authorities and manufacturers, a coherent approach has been taken to ensure that the implementation of the provisions in this proposal will be phased in, to avoid overlapping timelines and to ensure that the implementation of both sets of legislation meet their respective objectives without creating uncertainty or undue administrative burden in the sector.

Moreover, the joint scientific consultations provided for by this proposal, through which advice can be given to health technology developers in the development phase of a technology, will contribute to the objectives of related EU legislation on clinical trials to ensure that the evidence generated in clinical studies is robust and benefits patients and public health.

In addition, the proposal will provide useful input to and synergies with the EU Digital Single Market agenda by encouraging innovation and research of high-tech health technologies, facilitate information sharing on registries of real world evidence, and by supporting the development of a Union-level IT infrastructure supporting EU cooperation on HTA.

¹ Relevant legislation includes Directive 2001/83/EC, Regulation (EC) No 726/2004, Regulation (EU) 536/2014, Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

² Note that the need for improved synergies has been recognised by Member States in the HTA Network Reflection Paper "Synergies between regulatory and HTA issues on pharmaceuticals" as well as by EUnetHTA and EMA in their joint "Report on the implementation of the EMA-EUnetHTA three-year work plan 2012-2015".

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU).

Article 114 TFEU allows for the adoption of measures for the approximation of the provisions laid down by law, regulation or administrative action in the Member States, provided they are necessary for the establishment or functioning of the internal market, whilst at the same time ensuring a high level of public health protection. Article 114 TFEU provides an appropriate legal basis given the objectives of the proposal, namely to remove some of the existing divergences in the internal market for health technologies caused by procedural and methodological differences in clinical assessments carried out in Member States along with the considerable duplication of such assessments across the EU.

In line with Article 114(3) (TFEU), a high level of human health protection has been considered in the preparation of the proposal which is expected to improve the availability of innovative health technologies for EU patients.

- **Subsidiarity (for non-exclusive competence)**

The diversity and multitude of approaches to clinical assessments across the Member States means that, due to their scale and effect, only action at Union-level can eliminate the obstacles described. Without action at EU-level it is unlikely that national rules on how HTAs are carried out would be further aligned and thus the current fragmentation of the internal market would persist.

While the on-going cooperation, namely the Joint Actions and the HTA Network, has illustrated benefits of EU cooperation, in terms of establishing the professional network, the tools and methodologies for cooperation and piloting joint assessments, this cooperation model has not contributed to the removal of the fragmentation of national systems and the duplication of efforts.

The impact assessment report accompanying this proposal identified a distinction between clinical assessments where there is considerable scope for alignment in the Member States' procedures for carrying out such assessments, assessment methods and the types of data requested and non-clinical assessments which focus more on domains (e.g. economic, organisational, ethical) which are linked more to national contexts, and which are closer to the final decisions on pricing and reimbursement which remain strictly in the hands of Member States. By thus focusing on clinical assessments, the proposal targets the domains of HTA where EU added value is considered to be strongest.

The aims of this initiative cannot therefore be achieved sufficiently without strengthened HTA cooperation at EU-level.

- **Proportionality**

The proposal constitutes a proportionate and necessary response to addressing the problems described in section 1. In particular, the proposed requirement of not repeating at national level joint clinical assessments performed at Union-level and the nature of the joint clinical assessment, which will be limited to the assessment of the evidence, is necessary to reduce duplication and avoid

discrepancies. At the same time, the proposal will avoid any interference with Member States competences in decisions concerning access to the health technologies assessed at Union-level. By focusing the joint work on clinical aspects of HTA, where EU cooperation can bring both quality and efficiency gains, the proposal does not go beyond what is necessary. The assessment of more context-specific HTA domains (e.g. economic, organisational, ethical) and decision-making on pricing and reimbursement remain at Member State-level.

By reducing the current duplication and fragmentation, the proposal will optimise resources in Member States and also reduce the administrative burden for health technology developers currently undergoing assessments on the same health technology in multiple national systems.

The proposal is proportionate in that it limits the scope of joint work to specific types of medicinal products and medical devices and allows flexibility concerning the timing of joint clinical assessments for medical devices. This takes into account the differences between medicinal product and medical device sectors and their market access pathways. By focusing on the type of health technologies where current duplication of work among HTA bodies is most prominent and the benefit of joint assessment is strongest the proposal brings clear added value.

The proportionality of the proposal is also well reflected in the approach adopted for medical devices. The proposal does not introduce any new requirements on health technology developers when these are not already set out in national legislation. On the other hand, the proposal will ensure that when HTA is performed, the methodologies and procedures applied are more predictable across the EU and when subject to joint clinical assessment such assessments are not repeated, avoiding duplication and discrepancies.

Finally, the proposal respects the principle of proportionality by allowing sufficient time for both Member States and industry to adapt to the new EU system through a phase-in approach for the number of assessments carried out at Union-level and a transitional period for Member State participation.

- **Choice of the instrument**

The proposal takes the form of a new Regulation. This type of instrument is considered to be the most suitable considering that a key element of the proposal is the establishment of procedures and structures for cooperation on joint work at Union-level. While inevitably such a transition to a Union-wide approach will require some adjustments to national rules, for example, as regards allowing for the use of joint clinical assessments at national level as part of the overall HTA, that transition does not result in a need for significant implementing measures establishing those procedures and structures at national level.

In addition, the majority of detailed national rules on how HTA is actually carried out are contained in the administrative provisions of Member States' HTA bodies rather than in national legislation. This suggests that a suitable adaptation period before the date of application of a Regulation would be a more adequate and proportionate approach than the transposition needed for a

Directive, in ensuring use of joint clinical assessments and common rules at national level.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Stakeholder consultations**

Extensive consultation with stakeholders took place in the preparation of this proposal. In order to reach all interested stakeholders and to ensure a high quality and balanced input, a combination of consultation methods was used:

- Besides the feedback received in response to the publication of the Inception Impact Assessment, the Commission held a broad online public consultation between October 2016 and January 2017. In addition, position statements from different interest groups were received by email;
- Bilateral meetings with interested stakeholder representatives were organised throughout the preparation phase to allow in-depth discussion on specific topics and the expression of non-organised interests;³
- Consultation of experts was carried out through the existing cooperation mechanisms, EUnetHTA Joint Action 3 and the HTA Network. Presentations at external events were used to reach out to stakeholders, to explain the main elements of the initiative, to invite them to participate in the public consultation, and listen to their views and opinions.

A large majority of stakeholders emphasised that EU cooperation beyond 2020 is needed to ensure a constant exchange of information and knowledge between HTA institutions in Europe, to increase synergies between Member States, to streamline HTA methodologies, to increase transparency and evidence-based decision-making, as well as to ensure business predictability. The possibility to access a larger number of HTA reports with less duplication of work and better allocation of resources by HTA bodies was highlighted.

While all representatives of public administrations are in favour of continuing EU cooperation on HTA beyond 2020, some indicated a preference for voluntary cooperation while others supported a system with mandatory elements (i.e. a legal framework for EU cooperation on HTA to streamline interoperability of HTA national systems). Most contributors highlighted that in case of a mandatory system, use of joint work should be limited to clinical and technical matters, whereas assessment of non-clinical domains (e.g. economic, legal, ethical) should be carried out individually or jointly by interested Member States/HTA bodies on a voluntary basis. The idea of progressive implementation was also raised.

Citizens, patients and consumers representatives, as well as healthcare providers and academia were extremely positive, with most of them in favour of a collaboration covering both the clinical and economic parts of assessments. They underlined the need for involving patients and healthcare professionals in the HTA process, the need for transparency (e.g. making the summaries of HTA reports publicly available, including criteria and rationale

³ https://ec.europa.eu/health/technology_assessment/events_en#anchor3

for evaluation), and the need to ensure the independence of HTA bodies from industry and other interests.

As regards health technology developers, the pharmaceutical industry and their trade associations supported the harmonisation of clinical assessments at the time of the launch of their health technologies. It was stressed that the economic part of assessments should remain the responsibility of Member States. Medical device manufacturers and their trade associations reiterated the importance of taking into account the particularities of their sector and the need for a Member State-driven approach. It was underlined that HTA should focus on products that are innovative and address high unmet patient needs in disease areas where appropriate clinical and economic evidence has been or can be generated (e.g. transformative *in vitro* diagnostics and medical devices).

- **Collection and use of expertise**

In addition to the extensive stakeholder consultation described in previous sections, the following three external studies were conducted to support assessing the impacts of this initiative:

- Mapping of HTA National Organisations, Programmes and Processes in EU and Norway. 2017, Contract No. 17010402/2016/734820
- Mapping of HTA Methodologies in EU and Norway. 2017, DG SANTE Contract No. 17010402/2016/736040
- Study on Impact Analysis of Policy Options for Strengthened EU Cooperation on HTA. 2017. Sogeti, Austrian Public Health Institute, London School of Economics. (CHAFEA/2016/Health/16)

The Commission has also used and benefitted from, the vast pool of expertise available in the HTA Network and EUnetHTA Joint Action 3.

- **Impact assessment**

The impact assessment report⁴ provides an in-depth analysis of four policy options: No Joint Actions after 2020 (policy option 1, baseline scenario); Project-based cooperation on HTA activities (policy option 2); Permanent cooperation on common tools, procedures and early dialogues (policy option 3); and Permanent cooperation on common tools, procedures, early dialogues and joint clinical assessments (policy option 4). Based on this analysis, the impact assessment report presents a preferred policy option, which has provided the basis for the contents of this proposal (see section 8 of Impact Assessment). This preferred option builds primarily on policy option 4, but also integrates elements of policy option 2 as well as some adjustments (e.g. transitional arrangements for Member States and progressive implementation of the product scope for joint clinical assessments).

As described in more detail in the impact assessment report, the preferred option is considered to provide for the best combination of effectiveness and efficiency in reaching the policy objectives, while also respecting the principles of subsidiarity and proportionality. It allows for the best possible achievement of the internal market objectives by promoting convergence in procedures and

⁴ http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf

methodologies, reducing duplication (e.g. of clinical assessments) and therefore the risk of divergent outcomes, thus contributing to improving the availability of innovative health technologies for patients. Moreover, it provides Member States with a sustainable framework, allowing them to pool expertise, reinforce evidence-based decision-making, and supporting them in their efforts to ensure the sustainability of national health systems. The preferred option is also cost efficient in the sense that the costs are significantly outweighed by savings for Member States and industry, as a result of pooling of resources, avoiding duplication and improving business predictability.

The Regulatory Scrutiny Board gave its initial opinion on the impact assessment report on 27 October 2017 and asked for resubmission of a revised version. On 4 December 2017, the Regulatory Scrutiny Board delivered its second opinion (positive with reservations), indicating a number of points where further changes to the report were needed. The necessary changes have been made in the final version of the report. In particular, the final version of the report provides further clarifications on the proportionality of the preferred option and describes in more detail the rationale for and implications of mandatory use of the joint work. Further details are also provided on how views expressed by Member States have been taken into account in the preferred option. Finally, the report describes in more detail how possible risks and implementation challenges are addressed by the preferred option.

- **Regulatory fitness and simplification**

The proposal is relevant for small and medium-sized enterprises (SMEs), which are particularly prominent in the medical device sector. However, no specific provisions are foreseen for micro-enterprises, as these are not expected to play a major role in bringing new health technologies to the market. The proposal is expected to benefit SMEs by reducing the current administrative burden and compliance costs linked to submissions of multiple dossiers to meet different national HTA requirements. In particular, joint clinical assessments and joint scientific consultations foreseen by the proposal would increase business predictability for industry. This is particularly relevant for SMEs, as they tend to have a smaller product portfolios and more limited dedicated resources and capacities for HTA. Of note, the proposal does not provide for fees for joint clinical assessments or joint scientific consultations. Improved business predictability due to joint work on HTA across the EU is expected to positively impact on the competitiveness of the EU health technology sector.

The IT infrastructure foreseen by the proposal relies on standard IT tools (e.g. for databases, document exchange, internet-based publication), building on tools that have already been developed by the EUnetHTA Joint Actions.

- **Fundamental rights**

The proposal has limited consequences for the protection of fundamental rights. Where personal data is processed to fulfil the provisions of the proposal this will be done in line with the relevant Union legislation on personal data protection. The proposal contributes to achieving a high level of human health protection and is thus consistent with the Charter of Fundamental Rights in this regard.

4. BUDGETARY IMPLICATIONS

The implementation of this proposal has no impact on the current Multiannual Financial Framework 2014-2020 as the current cooperation on HTA is financed by the Public Health Programme. The financial impact on the EU budget post-2020 will be part of the Commission's proposals for the next Multiannual Financial Framework.

The budgetary implications are mainly related to the support framework provided for in this proposal, namely a central secretariat hosted by the European Commission, which will provide:

- administrative support (e.g. organisation of meetings, travel arrangements etc.) to the Coordination Group and its sub-groups including HTA experts nominated by the Member States' authorities who will carry out the joint work (e.g. joint clinical assessments, joint scientific consultations, studies on emerging health technologies, and provide expertise for the development and update of common rules and methodologies);
- scientific support (e.g. advice for the meetings of the coordination group and sub-groups, preparation of the documentation, manage procedures for involving stakeholders, ensure quality management including scientific scrutiny of reports and support the implementation of the joint work etc.);
- IT support (e.g. establish, host, and maintain an IT platform, including databases/repositories of joint and national HTA reports, secure communication etc.).

The proposal foresees remuneration in the form of special allowance to Member States' HTA bodies carrying out the joint work as assessors and co-assessors and travel expenses for Member State experts contributing to the activities of the coordination group and its sub-groups.

In-kind contribution from the Member States is foreseen in the form of seconded national experts⁵ to the central secretariat and by national experts who will participate in the meetings and contribute to the activities of the Coordination Group and relevant sub-groups (e.g. on joint clinical assessments and joint scientific consultations).

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The proposal provides for regular Commission monitoring and reporting on the implementation of the proposed Regulation starting, at the latest, one year after its date of application. To facilitate monitoring and reporting, Member States would be required to provide the Commission with the information necessary for the monitoring programme which will also benefit from the annual reports of the Coordination Group which will summarise the outputs of the joint work.

⁵ Seconded national experts are national civil servants or persons employed in the public sector who are working temporarily for an EU Institution. They remain in the service of that employer throughout the period of secondment and receive a daily allowance from the European Commission in line with the provisions in the Staff Regulation.

The Commission will also carry out a formal evaluation of the Regulation and report on the conclusions of this evaluation.

An obligation is also placed on the Commission to report specifically on the implementation of the scope of the joint clinical assessments and support framework no later than five years after the date of application. This will allow the Commission to consider whether the proposed Regulation ensures that the most innovative health technologies are being assessed, taking into account technological developments in the sector. The report will also allow for an assessment of whether the support framework provided by the Commission continues to provide the most efficient and cost-effective governance mechanism for the joint work.

The proposal would place on the Commission an obligation to verify the joint clinical assessment reports prior to their publication. This will allow the Commission to ensure that the reports have been prepared in accordance with the requirements proposed and help to build trust in the system. The Commission will also monitor both the implementation of the common rules and the use of the joint work at Member State-level. In order to facilitate this task and also allow for the exchange of information between Member States, the proposal provides for specific reporting obligations on the Member States where they use joint clinical assessment reports at Member State-level and where they carry out clinical assessments based on the common rules.

In addition, monitoring and evaluation of the specific objectives will use several means of data collection, including a number of quantitative indicators to assess effectiveness, as outlined in section 9 of the Impact Assessment Report, evaluation of the wider impacts will also require a number of qualitative tools such as desk research, surveys, focus groups and Delphi surveys.

- **Detailed explanation of the specific provisions of the proposal**

The proposal consists of five chapters comprising a total of 36 articles.

Chapter I – General provisions

This chapter outlines the subject matter of the proposal and defines the key terms used in the proposed Regulation. To ensure consistency with other Union legislation, the definitions of 'medicinal product', 'medical device', and 'health technology' in the proposal are aligned with those applied in Directive 2001/83/EC, Regulation (EU) No 2017/745, and Directive 2011/24/EU respectively. The Member State Coordination Group on Health Technology Assessment (the Coordination Group) is formally established in Article 3 along with its composition, roles and responsibilities to oversee the joint work referred to in Chapter II.

The Coordination Group will be Member State-led and manage the overall governance of the joint work. The Group will meet regularly to provide guidance and steer the cooperation. Under the authority of the Coordination Group, a number of sub-groups consisting of experts nominated by Member States will carry out the joint work foreseen in this proposal. For example, for the joint clinical assessments, Member States' HTA bodies acting as assessor and co-assessor will carry out the clinical assessment, prepare a draft report and consult relevant stakeholders. The Coordination Group will thereafter

approve the joint reports which will then be published by the Commission and included in a list of health technologies having undergone joint clinical assessments.

This joint work is based on the annual work programme of the Coordination Group which is outlined in Article 4 of the proposal. The annual work programme provides clarity on the planned work of the Group and allows health technology developers to foresee any expected involvement they may have in the joint work for the year ahead.

Chapter II - Joint work on health technology assessment at Union-level

This chapter establishes the four pillars of the future cooperation between Member States at Union-level (the joint work) namely, joint clinical assessments, joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation. The work will be Member State-led through the Coordination Group.

Section 1 - Joint clinical assessments

The joint clinical assessments will be one of the main proponents of the future joint work and, following the end of the transitional period, participation in the assessments and use of the joint clinical assessment reports at Member State-level will be mandatory. As described below, there will be a progressive phase-in approach to the annual number of joint clinical assessments carried out during the transitional period.

Scope

Joint clinical assessments are limited to:

- medicinal products undergoing the central marketing authorisation procedure, new active substances and existing products for which the marketing authorisation is extended to a new therapeutic indication; and
- certain classes of medical devices and *in vitro* diagnostic medical devices for which the relevant expert panels established in accordance with Regulations (EU) 2017/745 and 2017/746 have given their opinions or views and which have been selected by the Coordination Group set up under this Regulation based on the following criteria:
 - unmet medical need;
 - potential impact on patients, public health, or healthcare systems (e.g. burden of disease, budget impact, transformative technology);
 - significant cross-border dimension;
 - Union-wide added value (e.g. relevance to a large number of Member States);
 - the resources available to it.

This relatively limited scope and the selection criteria reflect the need to take a proportionate approach concerning the type and amount of health technologies assessed at Union level. By focusing on the most innovative technologies and selecting those with the most Union-wide and public health impact, the EU added value of the assessments will be maximised.

The timing of the procedure for joint clinical assessments for medicinal products will be coordinated with that of the central marketing authorisation procedure (i.e. the joint clinical assessment report will be available at the time of or shortly after the final Commission Decision granting marketing authorisation), ensuring its timeliness for supporting Member States decision-making at the time of market launch.

Taking into account the more decentralised market access pathway for medical devices, the timing of the joint clinical assessment will not necessarily be aligned with the timing of the conformity assessment i.e. it will not always be at the time of market launch. Instead, the Coordination Group will consider the most appropriate time point for a joint clinical assessment in line with the abovementioned selection criteria.

The identified scope and phase-in approach take into account the current level of duplication among Member States' HTA bodies, the EU added value of a joint approach, and stakeholder views and concerns.

Progressive implementation

The proposal provides for progressive implementation of the amount of joint clinical assessments during the transitional period. This means that the number of joint clinical assessments will increase gradually during the first three years after the date of application, taking into account specific selection criteria (same as those used permanently for medical devices, described above). The Coordination Group will select the health technologies based on these criteria and include them in the annual work programme. Following the end of the transitional period, all medicinal products falling within the scope and granted marketing authorisation in a given year will be assessed, while a selection of medical devices falling within the scope will undergo assessment.

Preparation of joint clinical assessment reports

The joint clinical assessments will cover the four assessment domains described in the definition of 'clinical assessment' in Chapter I. A step-by-step procedure on how the joint clinical assessment reports will be prepared is outlined in this section. Member States, through their HTA authorities and bodies, will be in the lead, selecting the assessor authority or body which will draft the report providing support and comments throughout the drafting process, and approving the final reports. The selection of the assessors and co-assessors will be a particularly important step in ensuring the quality of the report and the independence of the drafting process and this selection will thus be made based on specific procedural rules to be developed in tertiary legislation. The health technology developer whose health technology is the subject of the report, as well as patients, clinical experts and other stakeholders will also be given opportunities to provide input in order to ensure a thorough, independent and transparent assessment process. Once verified by the Commission, the final reports will be published and then used by the Member States.

The detailed procedural rules for each step in the process will be further developed in tertiary legislation while the common rules and documentation developed in tertiary legislation for clinical assessments at Member State-level will also be used for joint clinical assessments, ensuring a consistent approach

across national and Union-level clinical assessments. The development of the tertiary legislation will take as a basis the work on common procedures, methodologies and documents already being developed in the EUnetHTA Joint Action 3.

Use of joint clinical assessment reports by Member States

The proposal does not oblige Member States to carry out a HTA on health technologies which are the subject of joint clinical assessments. However, where Member States do carry out HTAs on such health technologies, there is a requirement for mandatory use of the joint clinical assessment report and no repetition of the clinical assessment in Member States' overall HTA processes. This means that Member States will continue to carry out non-clinical assessments i.e. on the non-clinical HTA domains (e.g. economic, organisational, ethical) and will draw conclusions on the overall added value of the assessed health technology based on the joint clinical assessment report and their own non-clinical assessment.

Section 2 - Joint scientific consultations

The proposal provides for the possibility for health technology developers to make a request to the Coordination Group for a joint scientific consultation. The joint scientific consultations, commonly referred to as 'early dialogues', allow a developer in the development phase of a health technology to seek the advice of HTA authorities and bodies on the data and evidence likely to be required as part of a potential future joint clinical assessment. The Coordination Group will carry out an annual number of joint scientific consultations based on its annual work programme, taking into account the resources available to it.

The preparation of joint scientific consultation reports will mirror the approach taken for joint clinical assessments as described above. The main difference will be that the joint scientific consultation reports approved by the Coordination Group will be addressed to the health technology developer, will not be published, nor will they bind the developer or the Member States at the time of (joint) clinical assessment. To ensure transparency, information on the consultations will be included in the Coordination Group's annual reports.

Section 3 - Emerging health technologies

The joint work would also encompass an annual study to be carried out under the responsibility of the Coordination Group on the identification of emerging health technologies. This exercise, commonly referred to as 'horizon scanning', will act as a key input for the annual work programmes, helping to ensure that the health technologies expected to have a major impact on patients, public health or healthcare systems are identified at an early stage in their development and are included in the joint work of the Coordination Group. The proposal requires the Coordination Group to fully consult with all relevant interest groups during this exercise.

Section 4 - Voluntary cooperation

Under this section, the proposal provides for the possibility for Member States to continue to cooperate on a voluntary basis at Union-level. This voluntary cooperation would allow for HTA on health technologies other than medicinal products or medical devices, non-clinical assessments, collaborative

assessments on medical devices i.e. on medical devices not selected for joint clinical assessment, and cooperation on the provision of additional evidence which can facilitate HTA.

Voluntary cooperation should take advantage of the outputs from research on HTA, such as methods for the use of real world evidence to reduce the uncertainty on effectiveness, the evaluation of innovative technologies (e.g. 'eHealth', personalised medicine) and the assessment of non-clinical domains (e.g. the impact of medical devices on the organisation of care).

This cooperation will benefit from the support framework set up under this proposal while participation in it and use of the results would be fully voluntary.

Chapter III - Rules for clinical assessments

This Chapter lays down common rules for carrying out clinical assessments at Member State-level which will then be developed in detail in tertiary legislation. These rules will ensure a harmonised approach to clinical assessment across EU Member States. In the development of the rules, use will be made of the tools already developed under the EUnetHTA Joint Actions as a base and the common rules will also be used for the joint clinical assessments at EU-level. An important part of these rules will be to ensure that clinical assessments, whether carried out at EU or Member State level, are done in an independent and transparent manner, free from conflicts of interest.

Chapter IV - Support framework

This chapter sets out the support framework which will support the joint work at EU-level. It provides for its funding and support from the Commission acting as its secretariat and providing its IT infrastructure. A stakeholder network is also established under this chapter along with reporting and monitoring obligations placed on the Commission.

The Commission will support the work of the Coordination Group and the sub-groups, in particular by providing scientific, administrative and IT support (as described in detail in the section on budgetary implications).

Chapter V - Final provisions

This chapter outlines the timeline for the implementation of the Regulation. Following the entry into force, a three-year period before the date of application is proposed which will allow for the development and adoption of all tertiary legislation (the implementing and delegated acts) provided for in the proposal as well as the preparatory steps necessary for the joint work. Following the date of application, a further three-year transitional period is envisaged to allow for a phase-in approach in terms of the work undertaken and to allow Member States to fully adapt to the new system. During this transitional period, Member States would have the option to delay their participation in the joint work on joint clinical assessments and joint scientific consultations. Under such circumstances they would not be obliged to use the output of this joint work at Member State-level but would be obliged to use the common rules for their own clinical assessments. Member States will not be able to delay their participation partially i.e. for only one category of health technology or for only one part of the joint work.

The proposal also includes a safeguard clause allowing clinical assessments to be carried out at national level using means other than the common rules, on grounds related to the need to protect public health specific to the Member State wishing to invoke the clause. Such measures would need to be justified and notified to the Commission for an assessment of the justifications presented.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee⁶,

Having regard to the opinion of the Committee of the Regions⁷,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) The development of health technologies is a key driver of economic growth and innovation in the Union. It forms part of an overall market for healthcare expenditure that accounts for 10% of EU gross domestic product. Health technologies encompass medicinal products, medical devices and medical procedures, as well as measures for disease prevention, diagnosis or treatment.
- (2) Health Technology Assessment (HTA) is an evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on the added value of a health technology in comparison with other new or existing health technologies.
- (3) HTA 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, 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.
- (4) The outcome of HTA is used to inform decisions concerning the allocation of budgetary resources in the field of health, for example, in relation to establishing the

⁶ OJ C , , p. .

⁷ OJ C , , p. .

pricing or reimbursement levels of health technologies. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients.

- (5) The carrying out of parallel assessments by multiple Member States and divergences between national laws, regulations and administrative provisions on the processes and methodologies of assessment can result in health technology developers being confronted with multiple and divergent requests for data. It can also lead to both duplications and variations in outcomes that 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.
- (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 joint actions, including their joint clinical assessments, at Member State-level has remained low, meaning that the duplication of assessments on the same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed.
- (7) The Council in its Conclusions of December 2014⁸ acknowledged the key role of health technology assessment and called on the Commission to continue to support cooperation in a sustainable manner.
- (8) The European Parliament, in its resolution of 2 March 2017 on EU options for improving access to medicines,⁹ called on the Commission to propose legislation on a European system for health technology assessment as soon as possible and to harmonise transparent health technology assessment criteria in order to assess the added therapeutic value of medicines.
- (9) In its 2015 Communication on upgrading the single market,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.
- (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.
- (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 assessment conclusions are confined to findings relating to the comparative effectiveness of a health technology. The outcome of such assessments should not therefore affect the discretion of Member States in relation to subsequent decisions on pricing and reimbursement of health technologies, including

⁸ OJ C 438, 6.12.2014, p. 12.

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

¹⁰ COM(2015) 550 final p. 19.

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.

- (12) In order to ensure a wide application of harmonised rules on clinical aspects of HTA and enable pooling of expertise and resources across HTA bodies, 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 Council¹² 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.
- (13) In order to ensure that joint clinical assessments carried out on health technologies remain accurate and relevant, it is appropriate to establish conditions for the updating of assessments, in particular where additional data available subsequent to the initial assessment has the potential to increase the accuracy of the assessment.
- (14) A coordination group composed of representatives from Member States' health technology assessment authorities and bodies should be established with responsibility for overseeing the carrying out of joint clinical assessments and other joint work.
- (15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should designate national HTA authorities and bodies which inform decision-making 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 expertise on the HTA of medicinal products and medical devices.
- (16) In order that the harmonised procedures fulfil their internal market objective, Member States should be required to take full account of the results of joint clinical assessments and not repeat those assessments. 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 added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as non-clinical data and criteria. It also does not prevent Member States from forming their own recommendations or decisions on pricing or reimbursement.
- (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

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).

technologies for patients. As a rule, the process should be completed by the time of the publication of the Commission decision granting marketing authorisation.

- (18) The establishment of a time-frame for the joint clinical assessments for medical devices should take into account the highly decentralised market access pathway for medical devices and the availability of appropriate evidence data 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 should be possible for assessments of such devices to take place following market launch of medical devices.
- (19) In all cases 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 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.
- (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 joint scientific consultations with the Coordination Group to obtain guidance on the evidence and data that is likely to be required for the purposes of clinical assessment. Given the preliminary nature of the consultation, any guidance offered should not bind either the health technology developers or HTA authorities and bodies.
- (21) Joint clinical assessments and joint scientific consultations necessitate the sharing of confidential information between health technology developers and HTA authorities and bodies. In order to ensure the protection of such information, information provided to the Coordination Group in the framework of assessments and consultations should only be disclosed to a third party after a confidentiality agreement has been concluded. In addition, it is necessary 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.
- (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. Such scanning should facilitate the prioritisation of technologies that are to be selected for joint clinical assessment.
- (23) The Union should continue to support voluntary cooperation on HTA between Member States in 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.
- (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 of the joint work, rules

should be developed to ensure the independence and impartiality of the joint work and ensure that such consultation does not give rise to any conflicts of interest.

- (25) In order to ensure a uniform approach to the joint work provided for in this Regulation, implementing powers should be conferred on the Commission to establish a common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint scientific consultations. Where appropriate, 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 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. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.¹³
- (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 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 2016.¹⁴ 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.
- (27) In order to ensure that sufficient resources are available for the joint work provided for under this Regulation, the Union should provide funding for the joint work and voluntary cooperation, and for the 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.
- (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. 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.
- (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

¹³ 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).

¹⁴ 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).

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. 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, Member States which are already participating should not be allowed to withdraw from the framework for joint work.
- (31) In order to ensure that the support framework continues to be as efficient and cost-effective as possible, the Commission should report on the implementation of the provisions on 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.
- (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.
- (33) Directive 2011/24/EU of the European Parliament and of the Council¹⁵ 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 health technologies at Union level, cannot be sufficiently achieved by the Member States 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,

¹⁵ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

HAVE ADOPTED THIS REGULATION:

Chapter I

General Provisions

Article 1

Subject Matter

1. This Regulation establishes:
 - (a) a support framework and procedures for cooperation on health technology assessment at Union level;
 - (b) common rules for the clinical assessment of health technologies.
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.

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/EC¹⁶;
- (b) 'medical device' means a medical device as defined in Regulation (EU) 2017/745;
- (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) 'clinical assessment' means a compilation and evaluation of the available scientific evidence on a health technology in comparison with one or more other health technologies based on the following clinical domains of health technology assessment: the description of the health problem addressed by the health technology and the current use of other health technologies addressing that health problem, the description and technical characterisation of the health technology, the relative clinical effectiveness, and the relative safety of the health technology;
- (f) 'non-clinical assessment' means the part of a health technology assessment based on the following non-clinical domains of health technology assessment: the cost and economic evaluation of a health technology, and 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.

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).

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 authorities and bodies responsible for health technology assessment 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.
3. The Coordination Group shall act by consensus, or, where necessary, vote by simple majority. There shall be one vote per Member State.
4. Meetings of the Coordination Group shall be co-chaired by the Commission and a co-chair elected from the members of the group for a set term to be determined in its rules of procedure.
5. Members of the Coordination Group 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 the Commission of their appointment and any subsequent changes.
6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality.
7. The Commission shall publish a list of the designated members of the Coordination Group and its sub-groups on the IT platform referred to in Article 27.
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 with relevant Union level bodies to facilitate additional evidence generation necessary for its work;
 - (d) ensure appropriate involvement of stakeholders in its work;
 - (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.

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 December 31st 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.
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 on the draft annual work programme and take into account its opinion.
4. The designated sub-group shall prepare an annual report for approval by the Coordination Group by February 28th of each year.
5. The annual report shall provide information on the joint work carried out in the calendar year preceding its approval.

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;

- (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;
 - (c) *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746¹⁷ for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation.
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.

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 they shall be prepared in accordance with the requirements in this Article and the requirements established pursuant to Articles 11, 22, and 23.

2. The designated sub-group shall request relevant health technology developers to submit documentation containing the information, data and evidence necessary for the joint clinical assessment.
3. The designated sub-group shall appoint, from among its members, an assessor and a co-assessor to conduct the joint clinical assessment. The appointments shall take into account the scientific expertise necessary for the assessment.
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:
- (a) an analysis of the relative effects of the health technology being assessed on the patient-relevant health outcomes chosen for the assessment;
 - (b) the degree of certainty on the relative effects based on the available evidence.

¹⁷ 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).

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.
7. The members of the designated sub-group shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report. The Commission may also provide comments.
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 comments.
9. The designated sub-group shall ensure that stakeholders, including patients and clinical experts, are given an opportunity to provide comments during the preparation of the draft joint clinical assessment report and the summary report and set a time-frame in which they may submit comments.
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 for comments.
11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the designated sub-group and the Commission and submit a final draft joint clinical assessment report and the summary report to the Coordination Group for approval.
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 majority of Member States.
13. The assessor shall ensure the removal of any information of a commercially sensitive nature from the approved joint clinical assessment report and the summary report.
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.

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 summary report, 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.
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 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.

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.
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.
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 in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the non-inclusion. 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.
6. For those health technologies included on the List of Assessed Health Technologies, the Commission shall publish the approved joint clinical assessment report and summary report on the IT platform referred to in Article 27 and make them available to the submitting health technology developer at the latest 10 working days following their inclusion in the List.

Article 8

Use of Joint Clinical Assessment Reports at Member State Level

1. Member States shall:
 - (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 joint clinical assessment has been initiated;
 - (b) apply joint clinical assessment reports, in their health technology assessments at Member State level.
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 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.

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.
2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members.
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 develop, by means of implementing acts, procedural rules for:
 - (a) submissions of information, data and evidence by health technology developers;
 - (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;
 - (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.
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 clinical assessment.
- 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.
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.

Article 13

Preparation of Joint Scientific Consultation Reports

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 and documentation established pursuant to Articles 16 and 17.

2. The designated sub-group shall request the health technology developer to submit the documentation containing the information, data and evidence necessary for the joint scientific consultation.
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. The appointments shall take into account the scientific expertise necessary for the assessment.
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 to the submitting health technology developer and set a time-frame in which the developer may submit comments.
8. The designated sub-group shall ensure that stakeholders, including patients and clinical experts are given an opportunity to provide comments during the preparation of the draft joint scientific consultation report and set a time-frame in which they may submit comments.
9. Following receipt and consideration of any comments provided in accordance with paragraphs 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.
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.
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 majority of Member States, at the latest 100 days following the start of the preparation of the report referred to in paragraph 4.

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.
3. Member States shall not carry out a scientific consultation or an equivalent consultation on a health technology for which a joint scientific consultation has been initiated and where the contents of the request are the same as those covered by the joint scientific consultation.

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;
 - (b) the appointment of assessors and co-assessors;
 - (c) determining the detailed procedural steps and their timing;
 - (d) the consultation of patients, clinical experts and other relevant stakeholders;
 - (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 acts in accordance with Article 31 concerning:

- (a) the contents of:
 - (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.
- (b) the rules for determining the stakeholders to be consulted for the purpose of this Section.

SECTION 3

EMERGING HEALTH TECHNOLOGIES

Article 18

Identification of Emerging Health Technologies

1. The Coordination Group shall 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 organisations;
 - (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.
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 cooperation and the exchange of scientific information among Member States on:
 - (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.
2. The Coordination Group shall be used to facilitate the cooperation referred to in paragraph 1.
3. The cooperation referred to in paragraph 1 points (b) and (c) may be carried out using the procedural rules established in accordance with Article 11 and the common rules established in accordance with Articles 22 and 23.
4. The cooperation referred to in paragraph 1 shall be included in the annual work programmes of the Coordination Group and the results of the cooperation shall be included in its annual reports and the IT platform referred to in Article 27.

Chapter III

Rules for Clinical Assessments

Article 20

Harmonised Rules for Clinical Assessments

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.

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. The Commission shall adopt implementing acts concerning:
 - (a) procedural rules for:
 - (i) ensuring that health technology authorities and bodies carry out clinical assessments in an independent and transparent manner, free from conflicts of interest;
 - (ii) the mechanisms for the interaction between health technology bodies and health technology developers during clinical assessments;
 - (iii) the consultation of patients, clinical experts, and other stakeholders in clinical assessments.
 - (b) methodologies used to formulate the contents and design of clinical assessments.
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 Article 31 concerning:

- (a) the contents of:
 - (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.

Chapter IV

Support Framework

Article 24

Union Funding

1. The financing of the work of the Coordination Group and its sub-groups and activities in support of that work involving its cooperation with the Commission, with the European Medicines Agency, 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.

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 the meetings of the Coordination Group;
- (b) provide the secretariat for the Coordination Group and provide administrative, scientific and IT support;
- (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;
- (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.

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.
2. The Commission shall publish the list of stakeholder organisations included in the stakeholder network.
3. The Commission shall organise ad-hoc meetings between the stakeholder network and the Coordination Group in order to:
 - (a) update stakeholders on the work of the group;
 - (b) provide for an exchange of information on the work of the Coordination Group.

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).

4. On the request of the Coordination Group, the Commission shall invite patients and clinical experts nominated by the stakeholder network to attend meetings of the Coordination Group as observers.
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. The Commission shall develop and maintain an IT platform containing information on:
 - (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.
2. The Commission shall ensure appropriate levels of access to the information contained in the IT platform for Member State bodies, members of the stakeholder network, and the general public.

Article 28
Implementation Report

No later than two years after the end of the transitional period referred to in Article 33(1), the Commission shall report on the implementation of the provisions on the scope of the joint clinical assessments and on the functioning of the support framework referred to in this Chapter.

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 ... [*insert date 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.

Article 32
Preparation of Implementing and Delegated Acts

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

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 ... *[insert date 3 years after the date of application]*.
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 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.
2. Member States shall notify the Commission of their intention to carry out a clinical assessment using other means together with the justifications for doing so.
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.

Article 35
Amendment of Directive 2011/24/EU

1. Article 15 of Directive 2011/24/EU is deleted.
2. References to the deleted Article shall be construed as references to this Regulation.

Article 36
Entry into Force and Date of Application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. It shall apply from *[insert date 3 years after date of entry into force]*.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

- 1.1. Title of the proposal/initiative
- 1.2. Policy area(s) concerned in the ABM/ABB structure
- 1.3. Nature of the proposal/initiative
- 1.4. Objective(s)
- 1.5. Grounds for the proposal/initiative
- 1.6. Duration and financial impact
- 1.7. Management mode(s) planned

2. MANAGEMENT MEASURES

- 2.1. Monitoring and reporting rules
- 2.2. Management and control system
- 2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected
- 3.2. Estimated impact on expenditure
 - 3.2.1. *Summary of estimated impact on expenditure*
 - 3.2.2. *Estimated impact on operational appropriations*
 - 3.2.3. *Estimated impact on appropriations of an administrative nature*
 - 3.2.4. *Compatibility with the current multiannual financial framework*
 - 3.2.5. *Third-party contributions*
- 3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council on Health Technology Assessment, and amending Directive 2011/24/EU

1.2. Policy area(s) concerned in the ABM/ABB structure

Public Health (Possibly to be amended depending on MFF negotiations)

1.3. Nature of the proposal/initiative

- The proposal/initiative relates to **a new action**
- The proposal/initiative relates to **a new action following a pilot project/preparatory action**¹⁹
- The proposal/initiative relates to **the extension of an existing action**
- The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objective(s)

1.4.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

The Commission's strategic objectives targeted by this proposal are:

- To ensure a better functioning of the internal market;
- To contribute to a high level of human health protection.

1.4.2. *Specific objective(s) and ABM/ABB activity(ies) concerned*

The specific objectives of the proposal are:

- Improve the availability of innovative health technologies for EU patients;
- Ensure efficient use of resources and strengthen the quality of HTA across the EU;
- Improve business predictability.

ABM/ABB activity(ies) concerned

Health

¹⁹ As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

1.4.3. *Expected result(s) and impact*

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

Member States authorities will benefit from:

- Better evidence for national decision-makers (i.e. due to high quality and timely joint clinical assessment reports). Furthermore, focusing joint assessments on clinical data makes them relevant to all decision-makers, without affecting national competences on pricing and reimbursement decisions.
- Cost savings and optimisation of resources.
- Pooling expertise and enhanced capacity to address more health technologies. HTA bodies in the EU will be able to specialise in different topics (e.g. orphan medicines, medical devices), rather than to keep a general profile of both their tasks and staff.

As regards patients, an EU HTA system would provide for a framework for the involvement of patients in the HTA processes. Additionally, the publication of the joint clinical assessment reports will also increase the transparency of decision-making in relation to the availability of health technologies.

For healthcare professionals and academia, an EU HTA system would provide for a framework for their involvement in the HTA process (i.e. common procedures for involving healthcare professionals and providers), while the publication of the joint assessment reports would facilitate access to reliable, timely and objective information on health technologies allowing for better informed decisions on the best treatment for their patients.

For industry the proposal has a clear potential to improve business predictability and provide for savings.

It may also have a potential positive impact on time to market and it will reduce duplication of work through harmonisation of tools and methodologies. Overall, a more predictable HTA system has the potential to increase investments in R&D activities in Europe.

The proposal takes into account the more decentralised market access pathway for medical devices and does not link the timing of the joint clinical assessments to the timing of the conformity assessment, thus avoiding putting an additional burden on the manufacturers at market launch. In addition the selection/priority mechanism foreseen in the proposal to decide which medical devices will be subject to joint clinical assessments aims at focusing on devices where cooperation brings the most added value to Member States and the sector as a whole. Overall, a predictable HTA system is expected to re-direct medical device industry resources towards the development of and investment in health technologies which would for instance address unmet medical needs and lead to the improvement of health outcomes for patients.

1.4.4. *Indicators of results and impact*

Specify the indicators for monitoring implementation of the proposal/initiative.

- Number of Member States joining the Coordination Group in the transitional period;
- Number of HTA authorities and bodies and their areas of expertise;
- Number of national assessments carried out using the joint clinical assessment reports;
- Number of assessments carried out at national level using the common clinical assessment rules and methodologies;
- Number of national HTA reports (carried out at national level using the common clinical assessment rules and methodologies) reused by HTA bodies in other Member States;
- Number of joint clinical assessments on medicinal products;
- Number of joint clinical assessments on medical devices;
- Number of joint scientific consultations on medicinal products;
- Number of joint scientific consultations on medical devices;
- Number of days to carry out a joint clinical assessment by the assessor and co-assessor;
- Number of days to carry out a joint scientific consultation by the assessor and co-assessor;
- Number of emerging health technologies identified as candidate health technologies for joint clinical assessments.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The proposal addresses the shortcomings of the current model of EU cooperation on HTA (impeded and distorted market access for health technologies due to various HTA processes and methodologies across the EU, duplication of work for national HTA bodies and industry, unsustainability of the current cooperation) by providing a long-term sustainable solution which enables Member States' HTA authorities and bodies to use their HTA resources more efficiently. It promotes convergence of HTA tools, procedures and methodologies, reduces duplication of efforts for HTA bodies and industry, and ensures the adequate uptake of joint outputs in Member States.

1.5.2. Added value of EU involvement

The diversity and multitude of approaches to HTA across the Member States means that, due to their scale and effect, only action at Union level can eliminate the obstacles described. Without action at EU level it is unlikely that national rules on how HTAs are carried out would be harmonised and thus the current fragmentation of the internal market would persist.

1.5.3. *Lessons learned from similar experiences in the past*

As proven by the public consultation, the existing EU cooperation on HTA including the HTA Network (the strategic arm) and the EUnetHTA Joint Action (as the scientific and technical arm) has been useful for building trust between HTA bodies and stakeholders, for increasing knowledge of working procedures and methodologies in Member States, and for the sharing of best practices and capacity building. The public consultations also confirmed the existence of important shortcomings which cannot be addressed by the current cooperation model (e.g. changes in human resources with important consequences on the progress of the activities, delayed recruitment of staff and implementation of an efficient and reliable IT infrastructure, inconsistency of quality and timely delivery of joint outputs, low uptake at national level).

While this proposal builds on the tools, methodologies and experience from the EUnetHTA Joint Actions, it addresses the abovementioned shortcomings, taking into account not only the needs of the Member States authorities but also those of industry, healthcare professionals and patients (See section 1.4.3. Expected result(s) and impact).

1.5.4. *Compatibility and possible synergy with other appropriate instruments*

The proposal constitutes a coherent approach, well in line with the EU's overarching objectives, including a smooth functioning of the internal market, sustainable health systems and an ambitious research and innovation agenda. In addition to coherence with these EU policy objectives, the proposal is compatible, coherent and complementary to existing EU legislation related to medicinal products and medical devices.

For example, there are opportunities for mutual information-sharing and better alignment of the timing of procedures between the joint clinical assessment and the centralised marketing authorisation for medicinal products. Synergies are also expected between joint clinical assessments for medical devices and some of the provisions foreseen by the new EU Regulations for medical devices and *in vitro* diagnostics (e.g. strengthened rules on clinical evaluation and clinical investigation; EU-level expert panels for high-risk medical devices). Moreover, the joint scientific consultations foreseen in this proposal will contribute to the objectives of related EU legislation on clinical trials to ensure that the evidence generated in clinical studies is robust and benefits patients and public health. The proposal could also provide useful input to and synergies with the Digital Single Market agenda by encouraging innovation and research of high-tech health technologies and by supporting the development of a European IT infrastructure supporting EU cooperation on HTA. The proposal is expected to play an important role in supporting innovation for the benefit of patients by influencing longer-term R&D investment decisions by industry.

1.6. Duration and financial impact

- Proposal/initiative of **limited duration**
 - Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY
 - Financial impact from YYYY to YYYY
- Proposal/initiative of **unlimited duration**
 - Implementation with a start-up period from 2023 to 2026,
 - followed by full-scale operation.

1.7. Management mode(s) planned

- Direct management** by the Commission
 - by its departments, including by its staff in the Union delegations;
 - by the executive agencies
- Shared management** with the Member States
- Indirect management** by entrusting budget implementation tasks to:
 - third countries or the bodies they have designated;
 - international organisations and their agencies (to be specified);
 - the EIB and the European Investment Fund;
 - bodies referred to in Articles 208 and 209 of the Financial Regulation;
 - public law bodies;
 - bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;
 - bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;
 - persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.
 - *If more than one management mode is indicated, please provide details in the 'Comments' section.*

Comments

The Commission intends to ensure the provision of the services concerned via centralised direct management through its own services, including technical, scientific and logistic support.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

The Coordination Group and sub-groups will provide a regular platform to discuss issues related to the implementation of the new regulatory framework. Monitoring of the implementation will also be facilitated by the IT Platform to be set up.

No later than two years after the end of the transitional period foreseen by this proposal, the Commission will report on the implementation of the scope and support framework. The proposal also lays down a requirement for regular monitoring and reporting by the Commission on the implementation of the Regulation.

2.2. Management and control system

2.2.1. Risk(s) identified

Risks related to the number of joint outputs:

- The number of health technologies receiving central marketing authorisation (for medicinal products)/CE marking (for medical devices) may vary from one year to another;
- Challenges to achieve scientific consensus on the joint clinical assessments.

Risks related to the IT platform supporting the strengthened EU cooperation on HTA:

- Besides an interface open to the general public, the IT infrastructure will have an intranet, which will contain confidential information (i.e. commercially sensitive data, personal information) which could be disclosed due to hacking or software failure.

2.2.2. Information concerning the internal control system set up

Control methods regarding the risks related to the number of joint outputs:

- As regards the risk of variable output, this risk can be mitigated by a methodical study to identify emerging health technologies before the adoption of the annual work programme by the Coordination Group;
- Cooperation with the European Medicines Agency will help to ensure the identification of emerging medicinal products to be assessed, especially in the transitional phase;
- Cooperation with the Medical Devices Coordination Group will help to ensure the identification of emerging medical devices;
- The strong involvement of Member States in selection, preparation and approval of clinical assessments and the expected format of the clinical assessment report will facilitate consensus building.

Control methods related to the risks related to the IT platform supporting the strengthened EU cooperation on HTA:

- The Commission has experience with IT tools requiring a high level of sensitivity regards its functioning. Control methods and audits regarding IT procedures and handling of confidential information will be implemented.

2.2.3. *Estimate of the costs and benefits of the controls and assessment of the expected level of risk of error*

Control methods regarding the risks related to the number of joint outputs:

- The costs of the controls are included in the costs allocated to the exercise on the identification of emerging new technologies to be assessed at EU-level and the joint clinical assessments. Cooperation with the relevant bodies for medicinal products and medical devices will minimise the risks of errors when drawing up the work programme of the Coordination Group.

Control methods related to the risks related to the IT platform supporting the strengthened EU cooperation on HTA:

- The costs of the controls are included in the IT costs. The risk of error is similar to the risk for other IT platforms hosted by the Commission.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

In addition to the application of all regulatory control mechanisms, the Commission's responsible service(s) will devise an anti-fraud strategy in line with the Commission's anti-fraud strategy (CAFS) adopted on 24 June 2011, in order to ensure, *inter alia*, that its internal anti-fraud related controls are fully aligned with the CAFS and that its fraud risk management approach is geared to identify fraud risk areas and adequate responses. Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases related to the financing of implementing activities under this proposal will be set up. In particular a series of measures will be put in place such as:

- decisions, agreements and contracts resulting from the financing of implementing activities under this proposal will expressly entitle the Commission, including the Anti-Fraud Office (OLAF), and the Court of Auditors, to conduct audits, on-the-spot checks and inspections;
- during the evaluation phase of a call for proposals/tender, the proposers and tenderers are checked against the published exclusion criteria based on declarations and the Early Detection and Exclusion System (EDES);
- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;
- regular training on issues related to fraud and irregularities for all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

Moreover, the Commission will oversee a strict application of the rules on conflicts of interests provided for in the proposal.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL

As the budgetary consequences of the proposal are expected to take effect from 2023 onwards, the contribution from the EU budget post-2020 will be discussed within the framework of the preparation of the Commission's proposals for the next Multiannual Financial Framework (MFF) and will reflect the outcome of the negotiations on the MFF post-2020.

The proposal is compatible with the current MFF.