## Basic information

| | |
|---|---|
| **2018/0018(COD)**<br>COD - Ordinary legislative procedure (ex-codecision procedure)<br>Regulation | Procedure completed |
| Health technology assessment<br>Amending Directive 2011/24/EU 2008/0142(COD)<br>**Subject**<br>4.20.05 Health legislation and policy | |

## Key players

European Parliament

| Committee responsible | Rapporteur | Appointed |
|---|---|---|
| ENVI Environment, Public Health and Food Safety | WÖLKEN Tiemo (S&D) | 26/02/2018 |
| | Shadow rapporteur<br>COLIN-OESTERLÉ Nathalie (PPE)<br>KOPCIŃSKA Joanna (ECR)<br>RIVASI Michèle (Verts/ALE) | |

| Former committee responsible | Former rapporteur | Appointed |
|---|---|---|
| ENVI Environment, Public Health and Food Safety | CABEZÓN RUIZ Soledad (S&D) | 26/02/2018 |

| Former committee for opinion | Former rapporteur for opinion | Appointed |
|---|---|---|
| ECON Economic and Monetary Affairs | The committee decided not to give an opinion. | |
| EMPL Employment and Social Affairs | The committee decided not to give an opinion. | |
| ITRE Industry, Research and Energy | WIERINCK Lieve (ALDE) | 15/03/2018 |
| IMCO Internal Market and Consumer Protection | BUŞOI Cristian-Silviu (PPE) | 21/03/2018 |
| JURI Legal Affairs | The committee decided not to give an opinion. | |

| | | |
|---|---|---|
| FEMM Women's Rights and Gender Equality | The committee decided not to give an opinion. | |

| Former committee for opinion on the legal basis | Former rapporteur for opinion | Appointed |
|---|---|---|
| JURI Legal Affairs | VOSS Axel (PPE) | 26/07/2018 |

| | |
|---|---|
| Council of the European Union | |
| European Commission | |

| Commission DG | Commissioner |
|---|---|
| Health and Food Safety | ANDRIUKAITIS Vytenis Povilas |

| |
|---|
| European Economic and Social Committee |
| European Committee of the Regions |

**Key events**

| Date | Event | Reference | Summary |
|---|---|---|---|
| 31/01/2018 | Legislative proposal published | COM(2018)0051 | Summary |
| 08/02/2018 | Committee referral announced in Parliament, 1st reading | | |
| 13/09/2018 | Vote in committee, 1st reading | | |
| 24/09/2018 | Committee report tabled for plenary, 1st reading | A8-0289/2018 | Summary |
| 01/10/2018 | Debate in Parliament | | |
| 03/10/2018 | Decision by Parliament, 1st reading | T8-0369/2018 | Summary |
| 03/10/2018 | Results of vote in Parliament | | |
| 03/10/2018 | Matter referred back to the committee responsible for interinstitutional negotiations | | |
| 13/02/2019 | Debate in Parliament | | |
| 14/02/2019 | Decision by Parliament, 1st reading | T8-0120/2019 | Summary |
| 14/02/2019 | Results of vote in Parliament | | |
| 16/04/2021 | Committee decision to open interinstitutional negotiations after 1st reading in Parliament | | |
| 26/04/2021 | Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 73) | | |
| 13/07/2021 | Approval in committee of the text agreed at early 2nd reading interinstitutional negotiations | PE696.384 | |

| | | | |
|---|---|---|---|
| 18/11/2021 | Council position published | 10531/3/2021 | |
| 25/11/2021 | Committee referral announced in Parliament, 2nd reading | | |
| 30/11/2021 | Vote in committee, 2nd reading | | |
| 01/12/2021 | Committee recommendation tabled for plenary, 2nd reading | A9-0334/2021 | Summary |
| 13/12/2021 | Decision by Parliament, 2nd reading | T9-0484/2021 | Summary |
| 13/12/2021 | Debate in Parliament |  | |
| 15/12/2021 | Final act signed | | |
| 22/12/2021 | Final act published in Official Journal | | |

## Technical information

| | |
|---|---|
| **Procedure reference** | 2018/0018(COD) |
| **Procedure type** | COD - Ordinary legislative procedure (ex-codecision procedure) |
| **Procedure subtype** | Legislation |
| **Legislative instrument** | Regulation |
| **Amendments and repeals** | Amending Directive 2011/24/EU 2008/0142(COD) |
| **Legal basis** | Rules of Procedure EP 61<br>Treaty on the Functioning of the European Union TFEU 114 |
| **Other legal basis** | Rules of Procedure EP 165 |
| **Mandatory consultation of other institutions** | European Economic and Social Committee<br>European Committee of the Regions |
| **Stage reached in procedure** | Procedure completed |
| **Committee dossier** | ENVI/9/05741 |

## Documentation gateway

**European Parliament**

| Document type | Committee | Reference | Date | Summary |
|---|---|---|---|---|
| Committee draft report | | PE622.011 | 04/05/2018 | |
| Amendments tabled in committee | | PE623.757 | 18/06/2018 | |
| Amendments tabled in committee | | PE623.758 | 18/06/2018 | |
| Committee opinion | IMCO | PE622.139 | 20/07/2018 | |
| Specific opinion | JURI | PE627.727 | 11/09/2018 | |
| Committee opinion | ITRE | PE620.890 | 12/09/2018 | |
| Committee report tabled for plenary, 1st reading/single reading | | A8-0289/2018 | 24/09/2018 | Summary |
| Text adopted by Parliament, partial vote at 1st reading /single reading | | T8-0369/2018 | 03/10/2018 | Summary |
| Text adopted by Parliament, 1st reading/single reading | | T8-0120/2019 | 14/02/2019 | Summary |
| Committee letter confirming interinstitutional agreement | | PE696.384 | 16/07/2021 | |

| | | | | |
|---|---|---|---|---|
| Committee draft report | | PE699.301 | 10/11/2021 | |
| Committee recommendation tabled for plenary, 2nd reading | | A9-0334/2021 | 01/12/2021 | Summary |
| Text adopted by Parliament, 2nd reading | | T9-0484/2021 | 13/12/2021 | Summary |

**Council of the EU**

| Document type | Reference | Date | Summary |
|---|---|---|---|
| Council position | 10531/3/2021 | 18/11/2021 | |
| Draft final act | 00080/2021/LEX | 15/12/2021 | |

**European Commission**

| Document type | Reference | Date | Summary |
|---|---|---|---|
| Legislative proposal | COM(2018)0051 | 31/01/2018 | Summary |
| Document attached to the procedure | SWD(2018)0041 | 01/02/2018 | |
| Document attached to the procedure | SWD(2018)0042 | 01/02/2018 | |
| Commission response to text adopted in plenary | SP(2019)354 | 16/04/2019 | |
| Commission communication on Council's position | COM(2021)0696 | 17/11/2021 | |

**National parliaments**

| Document type | Parliament/Chamber | Reference | Date | Summary |
|---|---|---|---|---|
| Contribution | PT_PARLIAMENT | COM(2018)0051 | 04/04/2018 | |
| Contribution | PL_SENATE | COM(2018)0051 | 11/04/2018 | |
| Contribution | IE_HOUSES-OF-OIREACHTAS | COM(2018)0051 | 27/04/2018 | |
| Contribution | DE_BUNDESRAT | COM(2018)0051 | 02/05/2018 | |
| Reasoned opinion | DE_BUNDESTAG | PE620.932 | 04/05/2018 | |
| Reasoned opinion | CZ_CHAMBER | PE620.962 | 30/05/2018 | |
| Reasoned opinion | FR_SENATE | PE620.963 | 30/05/2018 | |
| Reasoned opinion | PL_SEJM | PE626.700 | 13/09/2018 | |
| Contribution | FR_SENATE | COM(2018)0051 | 02/07/2020 | |

**Other institutions and bodies**

| Institution/body | Document type | Reference | Date | Summary |
|---|---|---|---|---|
| | Economic and Social Committee: | | | |

| | | | | |
|---|---|---|---|---|
| EESC | opinion, report | CES1784/2021 | 27/04/2021 | |

| Additional information | | |
|---|---|---|
| **Source** | **Document** | **Date** |
| European Parliament | Briefing | |
| European Commission | EUR-Lex | |

| Final act |
|---|
| Regulation 2021/2282<br>OJ L 458 22.12.2021, p. 0001 |

# Health technology assessment

2018/0018(COD) - 13/12/2021 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution **approving**, without amendment, the Council's position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

The proposed regulation includes provisions on the use of common methods, procedures and tools for health technology assessment throughout the EU. Health technology assessment (HTA) is an evidence-based scientific process that enables competent authorities to assess the relative effectiveness of new or existing health technologies. HTA focuses in particular on the added value of a health technology compared to other new or existing technologies.

***Purpose of the Regulation***

The new rules provide for **Member States to cooperate in conducting joint clinical assessments and joint scientific consultations**. They will also join forces to identify emerging health technologies.

The regulation establishes:

- a support framework and procedures for cooperation between Member States on health technologies at EU level;

- a mechanism whereby all information, analysis and evidence required for the common clinical assessment of health technologies is **submitted by the health technology developer only once at EU level**;

- common rules and methods for the common clinical evaluation of health technologies.

***Scope and timeframe***

Advanced **therapy medicinal products** would be subject to a joint clinical assessment at the date of application of the regulation, as would medicinal products containing new active substances for the treatment of **cancer**. In addition, **orphan medicinal products** and all remaining medicinal products within the scope of the Regulation would be added three and five years respectively after the date of application of the Regulation.

***Coordination group***

The Member States Coordination Group on Health Technology Assessment will be established.

The Council's position provides for the use of different types of majorities, depending on the type of decisions adopted. The default rule would be that, where consensus cannot be reached, decisions of the Coordination Group would be adopted by **simple majority**. By way of derogation, a qualified majority would be required for the adoption of the annual work programme and the annual report, as well as for the definition of the strategic direction to be given to the work of the sub-groups.

The Coordination Group will ensure that the joint work carried out is of the highest quality, meets international standards of evidence-based medicine and is timely. It will operate in an independent, impartial and transparent manner.

***Completion of the joint clinical evaluation***

Upon receipt of the draft common clinical assessment reports and revised summary reports, the coordination group should review them. The coordination group should seek to approve the revised draft reports by consensus. Diverging scientific opinions, including the scientific basis for these opinions, should be included in the reports.

*Obligations on Member States*

Member States should '**give due consideration**' to the joint clinical assessment reports. A certain number of safeguards were introduced to strengthen obligations on Member States, namely the requirement to annex the joint clinical assessment report to the national health technology assessment and to report on how each joint clinical assessment report was given due consideration in the health technology assessment at national level.

*Stakeholder involvement*

The Council position states that the subgroups should ensure that patients, clinical experts and other relevant experts participate in the assessment by having the opportunity to provide input on the draft reports. Provisions were also agreed to ensure transparency and absence of conflict of interest during the joint work.

# Health technology assessment

2018/0018(COD) - 01/12/2021 - Committee recommendation tabled for plenary, 2nd reading

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading contained in the report by Tiemo WÖLKEN (S&D, DE), on the Council's position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

The Council's position at first reading reflects the agreement reached between Parliament and the Council in the interinstitutional negotiations at early second reading stage.

As the committee responsible has already confirmed the outcome of these interinstitutional negotiations, it recommends that the plenary confirm the Council's position at first reading, without amendment.

The proposed regulation includes provisions on the **use of common methods, procedures and tools for health technology assessment** across the EU. It sets out four pillars around which Member States will work together at EU level, namely (1) joint clinical assessments, (2) joint scientific consultations, (3) identification of emerging health technologies, and (4) voluntary cooperation in areas outside the scope of mandatory cooperation.

The main points of the Council's position are as follows:

*Scope and timeframe*

Advanced therapy medicinal products would be subject to a joint clinical assessment at the date of application of the regulation, as would medicinal products containing new active substances for the treatment of cancer. In addition, orphan medicinal products and all remaining medicinal products within the scope of the Regulation would be added three and five years respectively after the date of application of the Regulation.

*Completion of the joint clinical assessment*

With regard to the approval of the joint clinical assessment reports by the Coordination Group, the Council's position states that where consensus cannot be reached, the joint assessment should include the diverging scientific opinions and the scientific grounds on which these are based.

*Voting regime of the Coordination Group*

The Council position provides for the use of different types of majorities, depending on the type of decisions adopted. The default rule would be that, where consensus cannot be reached, decisions of the Coordination Group will be adopted by a simple majority. By way of derogation, a qualified majority would be required for the adoption of the annual work programme and the annual report, as well as for the definition of the strategic direction to be given to the work of the sub-groups.

*Obligations on Member States*

Member States will be required to “give due consideration” to the joint clinical assessment reports. A certain number of safeguards were introduced to strengthen obligations on Member States, namely the requirement to annex the joint clinical assessment report to the national health technology assessment and to report on how each joint clinical assessment report was given due consideration in the health technology assessment at national level.

*Stakeholder involvement*

The Council position states that the subgroups should ensure that patients, clinical experts and other relevant experts participate in the assessment by having the opportunity to provide input on the draft reports. Provisions were also agreed to ensure transparency and absence of conflict of interest during the joint work.

# Health technology assessment

2018/0018(COD) - 31/01/2018 - Legislative proposal

PURPOSE: foster cooperation between EU Member States in health technology assessment.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: Parliament decides in accordance with the ordinary legislative procedure on an equal footing with Council.

BACKGROUND: health technology assessment (HTA) is a multidisciplinary process (covering medical, social, economic and ethical issues) and 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.

Following the adoption of the Cross-Border Healthcare Directive (Directive 2011/24/EU), a **voluntary European network** of HTAs composed of national HTA agencies or bodies was set up (in 2013) to provide strategic and political guidance to the scientific and technical cooperation at Union-level.

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**. Use of the results of the joint actions, including their joint clinical assessments, at Member State-level has remained low. 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.

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

IMPACT ASSESSMENT: four policy options were analysed. The preferred option is based on Option 4 (**permanent cooperation on common tools, procedures, early dialogues and joint clinical assessments**), integrating certain elements of Option 2 (project-based cooperation on HTA activities) as well as some adjustments (e.g. transitional arrangements for Member States and progressive implementation of the product scope for joint clinical assessments).

CONTENT: the proposed regulation aims to **provide the basis for permanent and sustainable cooperation** at the EU level for joint clinical assessments of new medicines and certain new medical devices. Its general objectives are to ensure a better functioning of the internal market and to contribute to a high level of protection of human health. The specific objectives are to improve the availability of innovative health technologies for EU patients, to ensure an efficient use of resources and to improve the quality of HTA across th EU, and to improve business predictability.

Member States will be able to use common HTA tools, methodologies and procedures across the EU, working together in four main areas:

1) **Joint clinical assessments:** these focus on the **most innovative health technologies** with the most Union-wide and public health impact. These 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 which have been selected by the Coordination Group set up under the Regulation.

Following the end of a **transitional period**, participation in the assessments and use of the joint clinical assessment reports at Member State level will be mandatory. Member States will continue to carry out **non-clinical assessments** (e.g. economic, organisational, ethical) of health technologies and make decisions on pricing and reimbursement.

**2) Joint scientific consultations**: these 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.

**3) Identification of emerging health technologies**: This exercise will act as a key input for the annual work programmes, helping to identify at an early stage of their development, the health technologies expected to have a major impact on patients. The Coordination Group will fully consult with all relevant interest groups during this exercise.

**4) Voluntary cooperation in other areas**: this cooperation could include the assessment of health technologies other than medicinal products or medical devices, non-clinical assessments or collaborative assessments of medical devices not subject to common clinical assessments.

Lastly, the proposal lays down **common implementing rules** in order to ensure harmonisation of the way in which Member States carry out clinical assessments. A key objective of these rules will be to ensure that clinical assessments, whether at EU or at Member State level, are carried out in an independent and transparent manner, free from conflicts of interests.

BUDGETARY IMPLICATIONS: the implementation of the 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.

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.

# Health technology assessment

2018/0018(COD) - 14/02/2019 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution on the proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

Parliament's position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

The proposed Regulation shall define a support framework and procedures for cooperation on clinical assessment of health technologies at Union level and common methodologies for the clinical assessment of health technologies. Pricing and reimbursement of medicines shall fall within the exclusive national competence of the Member States.

The amended text stipulated that HTA shall be used to promote innovations that produce the best results for patients and society in general. It should enable health professionals, patients and health institutions to know whether or not a new health technology represents an improvement on existing health technologies, in terms of benefits and risks

*Independence and transparency*

Cooperation should be based on the principle of good governance, which encompasses transparency, objectivity, independent experience and fair procedures. Members insisted that trust is a precondition for successful cooperation.

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

In order to ensure high quality of work, members of the Coordination Group shall be drawn from national or regional health technology assessment agencies or bodies responsible for that field. Members serving in the Coordination Group, and experts and assessors in general, shall not have financial interests in any type of health technology developer industry or insurance company that may affect their impartiality. They shall undertake to act independently and in the public interest and shall make an annual declaration of interests. In the event of a conflict of interest, they shall withdraw from the meeting whilst the relevant agenda items are being discussed.

The coordination group shall ensure that relevant stakeholders and experts are consulted in its work.

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

Parliament stressed the need to ensure a dialogue between the coordination group and patient organisations, consumer organisations, non-governmental health organisations, experts and health professionals, in particular through a stakeholder network, whose independence, transparency and impartiality of decisions would be guaranteed.

*Joint clinical assessment report*

The report shall be accompanied by a summary report, which shall contain at least the clinical data compared, the end-points, the comparators, the methodology, the clinical evidence used, and conclusions as regards efficacy, safety, and relative efficacy, the limits of the assessment, diverging views, a summary of the consultations carried out, and the observations made.

The report should be accompanied by a summary report including at least the following elements: (i) comparative clinical data, (ii) efficacy criteria, (iii) efficacy criteria, (iii) comparators, (iv) method, (iii) clinical data used, (iv) conclusions on effectiveness and safety, relative efficacy and evaluation limitations, (v) divergent positions, (vi) summary of consultations carried out and comments received.

The conclusions of the joint clinical assessment report shall include:

- an analysis of the relative effectiveness and safety of the health technology being assessed in terms of the clinical end-points relevant to the clinical entity and patient group chosen for the assessment, including mortality, morbidity and quality of life;

- the degree of certainty of relative effects based on the best available clinical data and compared to the best standard therapies.

*Avoid duplication*

In order for harmonised procedures to achieve their objective of the internal market and improving innovation and the quality of clinical evidence, Member States shall take account of the results of joint clinical assessments and not repeat them.

However, the amended text stated that according to national needs, Member States shall have the right to complement the joint clinical assessments with additional clinical evidence and analyses to account for differences in comparators or the national specific treatment setting. Such complementary clinical assessments shall be duly justified and proportionate and shall be notified to the Commission and the Coordination Group.

*Financing*

In order to ensure the availability of sufficient resources for joint work and stable administrative support provided for in the Regulation, the Union shall ensure stable and permanent public funding, as provided for in the multiannual financial framework, for joint work and voluntary cooperation, as well as for the support framework for these activities. Member States shall also have the possibility to second national experts to the Commission in order to support the secretariat of the coordination group.

# Health technology assessment

2018/0018(COD) - 24/09/2018 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Soledad CABEZÓN RUIZ (S&D, ES) on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

The committee recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the Commission's proposal as follows.

**Purpose**: the proposed Regulation shall define a support framework and procedures for cooperation on clinical assessment of health technologies at Union level and common methodologies for the clinical assessment of health technologies. It shall not interfere with the exclusive national competence of Member States for national pricing or reimbursement decisions.

**Cooperation in the field of health technology assessment (HTA)**: Members considered that the cooperation between HTA authorities shall be based on the principle of **good governance**, objectivity, independence and transparency. They stressed that **trust** is a precondition for successful cooperation.

HTA shall be used to **promote innovations that produce the best results for patients and society in general**. Health professionals, patients and health institutions need to know whether or not a new health technology represents an improvement on existing health technologies, in terms of benefits and risks. Members therefore considered that joint clinical assessments should therefore aim to identify the **added therapeutic value** of new or existing health technologies in comparison with other new or existing health technologies, by undertaking a comparative assessment based on comparative trials.

Cooperation shall, *inter alia*:

- promote **high-quality innovation**, steering research towards addressing the unmet diagnostic, therapeutic or procedural needs of healthcare systems as well as steering clinical and social priorities;
- **improve scientific evidence** used to inform clinical decision-making, efficiency in use of resources, the sustainability of health systems, patient access to these health technologies, and the competitiveness of the sector through greater predictability and more efficient research;
- ensure that Member States **use the outcome of HTA** to augment the scientific evidence that informs decisions to introduce health technologies into their systems;
- play a role **throughout the health technology cycle**;
- help in decision-making on **divestment** in cases where a technology becomes obsolete;
- contribute to improving and harmonising **standards** of care as well as diagnostic and new-born screening practices across the Union;
- cover areas such as diagnostics used to supplement treatment, surgical procedures, prevention, screening and health promotion programmes, information and communications technology (ICT) tools.

**Avoid duplication**: in order for harmonised procedures to achieve their objective of the internal market and improving innovation and the quality of clinical evidence, Member States shall take account of the results of joint clinical assessments and not repeat them.

However, according to national needs, Member States shall have the right to **complement the joint clinical assessments** with additional clinical evidence and analyses to account for differences in comparators or the national specific treatment setting. Such complementary clinical assessments shall be duly justified and proportionate and shall be notified to the Commission and the Coordination Group.

**Transparency**: in order to ensure high quality of work, members of the Coordination Group shall be drawn from **national or regional** health technology assessment agencies or bodies responsible for that field. Members serving in the Coordination Group, and experts and assessors in general, shall not have financial interests in any type of health technology developer industry or insurance company that may affect their impartiality. They shall undertake to act independently and in the public interest and shall make an annual declaration of interests. In the event of a **conflict of interest**, they shall withdraw from the meeting whilst the relevant agenda items are being discussed.

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

**Financing**: in order to ensure the availability of sufficient resources for joint work and stable administrative support provided for in the Regulation, the Union shall ensure **stable and permanent public funding**, as provided for in the multiannual financial framework, for joint work and voluntary cooperation, as well as for the support framework for these activities. Member States shall also have the possibility to second national experts to the Commission in order to support the secretariat of the coordination group.

# Health technology assessment

2018/0018(COD) - 03/10/2018 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted, by 576 votes to 56 with 41 abstentions, **amendments** to the proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

The matter was referred to the committee for interinstitutional negotiations.

The main amendments to the Commission proposal adopted in plenary session concern the following points:

**Purpose**: the proposed Regulation shall define a support framework and procedures for cooperation on clinical assessment of health technologies at Union level and common methodologies for the clinical assessment of health technologies. Pricing and reimbursement of medicines shall fall within the exclusive national competence of the Member States.

**Cooperation in the field of health technology assessment (HTA)**: Members considered that the cooperation between HTA authorities shall be based on the principle of **good governance**, objectivity, independence and transparency. They stressed that **trust** is a precondition for successful cooperation.

The amended text stipulated that HTA shall be used to **promote innovations that produce the best results for patients and society in general**. It should enable health professionals, patients and health institutions to know whether or not a new health technology represents an improvement on existing health technologies, in terms of benefits and risks.

Members therefore considered that joint clinical assessments should therefore aim to identify the **added therapeutic value** of new or existing health technologies in comparison with other new or existing health technologies, by undertaking a comparative assessment based on comparative trials.

Cooperation shall, *inter alia*:

- promote **high-quality innovation**, steering research towards addressing the unmet diagnostic, therapeutic or procedural needs of healthcare systems as well as steering clinical and social priorities;
- **improve scientific evidence** used to inform clinical decision-making, efficiency in use of resources, the sustainability of health systems, patient access to these health technologies, and the competitiveness of the sector through greater predictability and more efficient research;
- ensure that Member States **use the outcome** of HTA to augment the scientific evidence that informs decisions to introduce health technologies into their systems;
- play a role **throughout the health technology cycle**;
- help in decision-making on **divestment** in cases where a technology becomes obsolete;
- contribute to improving and harmonising **standards** of care as well as diagnostic and new-born screening practices across the Union;
- cover areas such as **diagnostics** used to supplement treatment, surgical procedures, prevention, screening and health promotion programmes, information and communications technology (ICT) tools.

In the absence of a **commonly agreed definition** of what constitutes a high-quality innovation or therapeutic added value, Members called for such definitions to be adopted at EU level.

**Avoid duplication**: in order for harmonised procedures to achieve their objective of the internal market and improving innovation and the quality of clinical evidence, Member States shall take account of the results of joint clinical assessments and not repeat them.

However, the amended text stated that according to national needs, Member States shall have the right to **complement the joint clinical assessments** with additional clinical evidence and analyses to account for differences in comparators or the national specific treatment setting. Such complementary clinical assessments shall be duly justified and proportionate and shall be notified to the Commission and the Coordination Group.

**Independence and transparency**: a **coordination group** composed of representatives from Member States' health technology assessment authorities and bodies should be established with responsibility and proven expertise for overseeing the carrying out of joint clinical assessments and other joint work within the scope of this Regulation.

In order to ensure high quality of work, members of the Coordination Group shall be drawn from **national or regional** health technology assessment agencies or bodies responsible for that field. Members serving in the Coordination Group, and experts and assessors in general, shall not have financial interests in any type of health technology developer industry or insurance company that may affect their impartiality. They shall undertake to act independently and in the **public interest** and shall make an annual declaration of interests. In the event of a conflict of interest, they shall withdraw from the meeting whilst the relevant agenda items are being discussed.

The coordination group shall ensure that **relevant stakeholders and experts** are consulted in its work.

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

Membersstressed the need to ensure a **dialogue** between the coordination group and patient organisations, consumer organisations, non-governmental health organisations, experts and health professionals, in particular through a **stakeholder network**, whose independence, transparency and impartiality of decisions would be guaranteed.

**Financing**: in order to ensure the availability of sufficient resources for joint work and stable administrative support provided for in the Regulation, the Union shall ensure **stable and permanent public funding**, as provided for in the multiannual financial framework, for joint work and voluntary cooperation, as well as for the support framework for these activities. Member States shall also have the possibility to second national experts to the Commission in order to support the secretariat of the coordination group.