Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation 2018/0018(COD)	Awaiting Council's 1st reading position
Health technology assessment Amending Directive 2011/24/EU 2008/0142(COD) Subject 4.20.05 Health legislation and policy	

Key players

European Parliament			
	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		26/02/2018
		S&D CABEZÓN RUIZ Soledad	
		Shadow rapporteur	
		epp GROSSETÊTE Françoise	
		ECR PIECHA Bolesław G.	
		MEISSNER Gesine	
		RIVASI Michèle	
		EFD PEDICINI Piernicola	
		ENF MÉLIN Joëlle	
	Committee for opinion	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		15/03/2018
		WIERINCK Lieve	
	IMCO Internal Market and Consumer Protection		21/03/2018
		epp BUŞOI Cristian-Silviu	
	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.	
	Committee for opinion on the legal basis	Rapporteur for opinion	Appointed

	JURI Legal Affairs	26/07/2018
	epp VOSS Axel	
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

31/01/2018	Legislative proposal published	COM(2018)0051	Summary
08/02/2018	Committee referral announced in Parliament, 1st reading/single reading		
13/09/2018	Vote in committee, 1st reading/single reading		
24/09/2018	Committee report tabled for plenary, 1st reading/single reading	A8-0289/2018	Summary
01/10/2018	Debate in Parliament		
03/10/2018	Results of vote in Parliament		
03/10/2018	Decision by Parliament, 1st reading/single reading	T8-0369/2018	Summary
03/10/2018	Matter referred back to the committee responsible		
13/02/2019	Debate in Parliament		
14/02/2019	Decision by Parliament, 1st reading/single reading	T8-0120/2019	Summary

Technical information

Procedure reference	2018/0018(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Directive 2011/24/EU 2008/0142(COD)
Legal basis	Rules of Procedure EP 59-p4; Treaty on the Functioning of the EU TFEU 114
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	ENVI/8/12220

Documentation gateway

Legislative proposal		COM(2018)0051	31/01/2018	EC	Summary

Document attached to the procedure		SWD(2018)0041	01/02/2018	EC	
Document attached to the procedure		SWD(2018)0042	01/02/2018	EC	
Committee draft report		PE622.011	04/05/2018	EP	
Reasoned opinion	DE_BUNDESTAG	PE620.932	04/05/2018	NP	
Reasoned opinion	CZ_CHAMBER	PE620.962	30/05/2018	NP	
Reasoned opinion	FR_SENATE	PE620.963	30/05/2018	NP	
Amendments tabled in committee		PE623.757	18/06/2018	EP	
Amendments tabled in committee		PE623.758	18/06/2018	EP	
Committee opinion	IMCO	PE622.139	20/07/2018	EP	
Specific opinion	JURI	PE627.727	11/09/2018	EP	
Amendments tabled in committee		PE627.728	11/09/2018	EP	
Committee opinion	ITRE	PE620.890	12/09/2018	EP	
Reasoned opinion	PL_SEJM	PE626.700	13/09/2018	NP	
Committee report tabled for plenary, 1st reading/single reading		A8-0289/2018	24/09/2018	EP	Summary
Text adopted by Parliament, partial vote at 1st reading/single reading		T8-0369/2018	03/10/2018	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T8-0120/2019	14/02/2019	EP	Summary
Commission response to text adopted in plenary		SP(2019)354	16/04/2019	EC	

Additional information

Research document	Briefing

Health technology assessment

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

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

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.

Health technology assessment

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.

Parliaments 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.