ASSEMBLEIA DA REPÚBLICA

EUROPEAN AFFAIRS COMMITTEE

Written Opinion

COM(2018)51 - Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

PART I – INTRODUCTORY NOTE

Pursuant to article 7 of Law 43/2006, of 25 August, which regulates the monitoring, assessment and pronouncement by the Assembleia da República within the scope of the process of constructing the European Union, as amended by Law 21/2012 of 17 May, as well as the methodology for scrutinising European initiatives adopted on 1 March 2016, the European Affairs Committee received the Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU [COM (2018) 51].

Given its purpose, the above-mentioned initiative was addressed to the Health Committee which has examined it and approved the Report attached to this Opinion, which forms an integral part thereof.

PART II - RECITALS

1 - This initiative concerns the Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.[1]

2 - The present initiative begins by stating that health technology assessment (HTA) is a multidisciplinary process which summarises information on medical, social, economic and ethical matters related to the use of such technologies in a systematic, transparent, impartial and rigorous manner. Its purpose is

[1] 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 of 4.4.2011 p. 45).
Directive 2011/24/EU of the European Parliament and of the Council states that the Union shall support and promote cooperation and the exchange of scientific information between Member States within the framework of a voluntary network composed of the national authorities or bodies responsible for the evaluation of health technologies designated by the Member States.

to contribute to the formulation of safe, effective, patient-centred and best-value health policies.

3 - As a result, it is noted that the Committee's *strategic objectives* set out in the present initiative are:
- to ensure a better functioning of the internal market and to contribute to a high level of protection of human health.
Regarding the *specific objectives*, these aim to improve the availability of innovative health technologies for patients in the Union, ensure the efficient use of resources, boost the quality of HTA throughout the Union and improve commercial predictability.

4 - With regard to the benefits to the authorities of the Member States, this initiative states that it includes the following:
- 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.

5 - With regard to patients, it is noted that a European HTA system would provide a framework for their participation in HTA processes. In addition, *the publication of the joint clinical assessment reports will also increase the transparency of decision-making in relation to the availability of health technologies.*
With regard to health professionals and academia, a European HTA system would provide a framework for their participation in the HTA process (in particular, common procedures for the participation of health professionals

and care providers), while the publication of joint evaluation reports would facilitate access to objective, reliable and timely information on health technologies, thereby enabling better informed decisions to be made on the best treatment for their patients.
With regard to industry, this initiative states that there is an obvious potential for improving commercial predictability and savings.
In this regard it is mentioned that, on the whole, a more predictable HTA system has the potential to increase investment in R&D in Europe.

6 - The present initiative also states that a predictable HTA system is expected to redirect the resources of the medical device industry to the development of health technologies and that investment in such technologies will make it possible, for example, to respond to unmet medical needs and lead to improved health outcomes for patients.

7 - The initiative thus addresses the shortcomings of the current EU HTA cooperation model (barriers and distortion of market access for health technologies due to the multiplicity of HTA processes and methodologies across the Union, duplication of the work of national HTA bodies and industry, unsustainability of current cooperation), and provides a long-term sustainable solution that enables HTA authorities and bodies in the Member States to use their HTA resources more efficiently.
Promoting the convergence of HTA instruments, procedures and methodologies reduces the duplication of efforts for HTA bodies and industry and ensures the proper use of joint results in the Member States.

8 - The initiative is therefore an approach that is fully in line with the Union's overall objectives, including the smooth functioning of the internal market, the sustainability of health systems and an ambitious research and innovation agenda.
In addition to being in line with these Union policy objectives, the initiative is compatible and consistent with and complementary to the Union legislation in

force on medicines and medical devices. For example, there are opportunities for mutual information sharing and better alignment of procedural timetables between the joint clinical evaluation and the centralised marketing authorisation procedure for medicinal products.

9 - It is furthermore indicated that *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.*

10 - It should further be mentioned that this initiative can also make a useful contribution to the Digital Single Market agenda and synergies with this agenda, by encouraging innovation and research on advanced health technologies and by developing an European IT infrastructure to support the Union's cooperation in HTA matters.
This initiative is expected to play an important part in supporting innovation for the benefit of patients through its impact on long-term R&D investment decisions by industry.

11 - As a result, it is indicated *that 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.*
The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should also be delegated to the Commission.

12 - Finally, it is stated that in order to ensure that sufficient resources are available for the joint work provided for in this initiative, *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 preparing joint clinical evaluation reports and joint scientific consultation reports. Member States should also be able to delegate national experts to the Committee for the purpose of supporting the secretariat of the Coordination Group.

In view of the provisions of this proposal, the following questions should be raised:

a) On the Legal Basis

The legal basis for this proposed initiative is Article 114 of the Treaty on the Functioning of the European Union.
Article 114 of the TFEU allows the adoption of measures to approximate the legislative, regulatory and administrative provisions of the Member States, provided that they are necessary for the establishment or functioning of the internal market, while at the same time ensuring a high level of protection of public health.
Article 114 of the TFEU provides an appropriate legal basis, considering the objectives of the initiative, in particular, to eliminate some of the divergences in the internal market in health technologies caused by procedural and methodological differences in the clinical evaluations carried out in the Member States, as well as the considerable duplication of such evaluations across the Union.
In accordance with Article 114(3) of the TFEU, a high level of human health protection was kept in mind when drawing up this initiative, which should improve the availability of innovative health technologies for patients in the EU.

b) On the Principle of Subsidiarity and Proportionality

The diversity and multiplicity of approaches in the field of HTA in Member States means that, given their scale and effects, only action at Union level can remove the obstacles described. Without action at EU level, national standards on the implementation of HTAs are unlikely to be harmonised and the current fragmentation of the internal market would continue.

In view of the fact that the objectives of this initiative, namely the convergence of Member States' standards for national clinical evaluations and the establishment of a framework for the joint clinical evaluation of certain health technologies, cannot be fully achieved by the Member States but can, 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 European Union. In accordance with the principle of proportionality, as set out in that Article, this initiative does not go beyond what is necessary in order to achieve that objective

PART III - OPINION

In light of the above recitals and considering the Report of the competent committee, the European Affairs Committee is of the opinion that:

1 - This initiative is not in breach with the principles of subsidiarity and proportionality insofar as the objective to be achieved will be more effectively achieved through Union action and the proposal does not go beyond what is necessary.

2 - In relation to the initiative in question, the scrutiny process is concluded.

S. Bento Palace, 3 April 2018

Rapporteur **Committee Chair**

(Ana Oliveira) **(Regina Bastos)**

PART IV - APPENDIX

Report of the Health Committee.

ASSEMBLEIA DA REPÚBLICA

HEALTH COMMITTEE

Report

COM(2018)51, on health technology assessment and amending Directive 2011/24/EU

Rapporteur:

MP Isaura Pedro (PSD)

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PARTE I – RECITALS

As part of its task of monitoring, assessment and pronouncement on EU legislative initiatives, the Health Committee was called upon to give its opinion on the proposal for a Regulation, COM(2018)51 on health technology assessment and amending Directive 2011/24/EU.

The general objective of the proposed Regulation, according to its own formulation, is to ensure a better functioning of the internal market and to contribute to a high level of protection of human health.

The specific objectives of the proposed Regulation under consideration are to improve the availability of innovative health technologies for patients in the Union, to ensure the efficient use of resources and boost the quality of HTA throughout the Union, and to improve commercial predictability.

Finally, the operational objectives of the initiative are to promote the convergence of HTA instruments, procedures and methodologies, to reduce the duplication of efforts by HTA bodies and industry, to ensure the use of joint results in the Member States and to secure the long-term sustainability of EU cooperation with respect to HTA.

The legal basis for the proposed initiative is Article 114 of the Treaty on the Functioning of the European Union. This allows the adoption of measures to approximate the legislative, regulatory and administrative provisions of the Member States, provided that they are necessary for the establishment or functioning of the internal market, while at the same time ensuring a high level of protection of public health.

The proposal takes the form of a new regulation as this type of instrument is considered to be the most appropriate, bearing in mind that one of the essential elements of the proposal is the establishment of procedures and structures for cooperation in the matter of working together at EU level.

According to Article 5(3) of the Treaty on European Union, "*Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.*"

Article 168(7) of the Treaty on the Functioning of the European Union, meanwhile, establishes that Member States are responsible for drawing up their own health policies and for organising their health systems, as well as for sharing out the resources allocated to health services and medical care.

Article 2(2) of the initiative provides that "*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.*"

However, the explanation of the reasons underlying this initiative states that "*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.*"

The proposal further warns that, "*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.*"

Considering the general meaning and content of the initiative in question, it has not been established that it opposes the legislative solutions currently found in national law, although the meeting of the requirements of Article 114 of the Treaty on the Functioning of the European Union should be duly considered.

PART II - PERSONAL VIEW OF THE RAPPORTEUR

The Rapporteur refrains from expressing her political opinion on the Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

PART III - CONCLUSIONS

In view of the foregoing, the Health Committee is of the opinion that the Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU should accordingly be referred to the European Affairs Committee.

S. Bento Palace, 27 March 2018

Rapporteur	**Committee Vice-Chair**
(Isaura Pedro)	***(Maria Antónia Almeida Santos)***