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NOTE

From:	Presidency
To:	Council
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Subject:	**Employment, Social Policy, Health and Consumer Affairs Council session on 22 June 2018** Proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU *- Policy debate*

1. On 31 January 2018 the Commission presented the proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU.

2. The Working Party on Pharmaceuticals and Medical Devices examined the proposal in three meetings (14 February, 17 April, 7 May) under the Bulgarian Presidency.

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3. On 6 June 2018, the Permanent Representatives Committee was informed by the Presidency about the preparations for the policy debate on the proposal for a Regulation on Health Technology Assessment scheduled to take place at the Council (EPSCO) session on 22 June 2018[1].

4. The Council is therefore invited to hold a public exchange of views on the basis of the Presidency note set out in the Annex to this document.

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[1] See document 9503/18.

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ANNEX

Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

POLICY DEBATE

BACKGROUND

1. On 31 January 2018 the Commission adopted its proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU, and submitted it to the Council and to the European Parliament.

2. The legal basis proposed by the Commission is Article 114 TFEU. The ordinary legislative procedure applies. The proposed legal instrument is a regulation.

3. The proposal is stated to be aimed at improving the functioning of the internal market by harmonising the Member States' rules on carrying out clinical assessments for health technologies at national level, and at establishing a framework for mandatory joint clinical assessment at Union level.

4. Health Technology Assessment is a process whose aim is to inform the formulation of safe and effective health policies that are patient-focused and seek to achieve best value. It compares a new or existing health technology[2] with other existing health technologies and/or the current standard of care.

[2] Medicinal product, medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.

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5. Health Technology Assessment is primarily used by Member States, in the context of organising the delivery of health services and medical care, to provide a scientific evidence base for decisions on pricing and reimbursement of medicinal products and medical devices[3].

6. Currently the legal basis for cooperation on health technology assessment is Directive 2011/24/EU (the 'Directive'). Article 15 of the Directive contains an obligation for the Union to support a voluntary network of national authorities or bodies responsible for health technology assessment (the 'HTA Network')[4]. The proposal envisages the deletion of that legal basis.

CONSULTATIONS

7. In accordance with Protocol No 2 to the Treaties, the Member States' national parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity. The German Bundestag[5], the French Senate[6] and the Czech Chamber of Deputies[7] provided reasoned opinions on subsidiarity and proportionality grounds, and the Polish Senate[8] and the Polish Sejm[9] provided a contribution in the same direction.

8. The Irish House of the Oireachtas[10] and the Portuguese Parliament[11] provided political contributions, too, broadly welcoming the proposal.

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3 See Explanatory memorandum to the proposal, p. 1.
4 See in particular recital 58 and Article 15. The Union has also provided funding on a project basis, within three joint actions on HTA, in the framework of the Multiannual Programme for Health.
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6 7840/18+COR1
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9. The European Economic and Social Committee delivered a positive opinion on the proposal. The European Committee of the Regions did not deliver an opinion.

STATE OF PLAY IN THE EUROPEAN PARLIAMENT

10. On 8 February 2018, the Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament appointed as rapporteur Ms Soledad Cabezon Ruiz (S&D, Spain).

11. The draft report was published on 4 May 2018[12] and is currently awaiting Committee decision in the light of the amendments tabled.

STATE OF PLAY IN THE COUNCIL

12. Taking into account the date of publication of the legislative proposal and the time needed for Member States and national parliaments to adopt positions, the Presidency organised three rounds of discussions at preparatory level in the Council.

13. The Commission presented its proposal to the Working Party on Pharmaceuticals and Medical Devices (hereinafter the 'Working Party') at the meeting on 14 February 2018. While all delegations maintained a scrutiny reservation, that first initial exchange already indicated significant concerns regarding key aspects of the proposal.

[12] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-622.011+01+DOC+PDF+V0//EN&language=EN

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14. The Regulatory Scrutiny Board of the Commission had flagged possible issues in its opinion[13]. It listed reservations over: the unclear support for key aspects by Member States; the mandatory uptake of joint HTA as a necessary solution to the identified issues; 'uncertainties, risks, trade-offs and implementation challenges associated with the preferred option'.

15. The positions expressed by many delegations confirmed that those concerns were still not resolved by the final proposal. The Presidency therefore focused on identifying the extent of actual support for cooperation on HTA as proposed by the Commission, as an important first step on the way to exploring possibilities for establishing it on a solid basis in the future.

16. The Impact Assessment accompanying the proposal, in line with the Interinstitutional Agreement on Better Law-Making, was discussed in-depth at the following meeting of the Working Party on 17 April 2018. At that meeting Member States were also given the opportunity to present their views on the proposal itself.

17. With regard to the public consultation, the Impact Assessment states that '*industry was the major contributor with 52 % of all replies, followed by public administration (14 %), patients and consumer associations (13 %) healthcare providers' organisations and scientific societies (13 %) and payers (3 %)*'[14]. According to it, representatives of different authorities from 15 Member States participated in the consultation.

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[13] First opinion 'Negative', Second opinion 'Positive with reservations': https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_ia_rsbopinion_en.pdf

[14] See p. 114 of the Impact Assessment.

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18. Although the Impact Assessment noted that '*some Member States have indicated a preference for voluntary cooperation, while others support a system with mandatory elements*'[15], the predominant preference expressed during all meetings of the Working Party was for voluntary cooperation.

19. While the Commission has justified the choice of policy option (mandatory cooperation on HTA) as being the most efficient option for harmonising clinical assessments and hence streamlining the functioning of the internal market, Member States have not identified mandatory uptake of joint HTA as a necessary solution.

20. Key aspects have been questioned, including the problem identified (fragmentation of the internal market), the adequacy of the solution proposed (harmonisation of HTA assessments), scope, mechanism and other aspects.

21. While consultation with some stakeholders provided the basis for the proposal, the lack of Member States' perspective in it confirmed the need for a profound reflection on the content of the proposed cooperation on HTA. This is particularly important given that expertise on HTA is concentrated in national authorities and bodies.

22. During the subsequent Working Party meeting on 7 May, delegations discussed key articles, clustered in accordance with the issues identified at the previous meetings. Among the most problematic provisions were those envisaging assessments with a binding impact on Member States and a prohibition of national assessments (Article 8), harmonised rules for clinical assessments (Articles 20-22) and notification of national measures (Article 34).

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15 See p. 26, paragraph 1, of the Impact Assessment.

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23. There has been intense debate on the mandatory nature of Joint Scientific Assessments as proposed in Article 8. While a significant number of delegations favoured deleting or significantly redrafting the provision, the Presidency has also noted voices (albeit a minority) supporting that article, based on concerns that a recommendation-based system might lead to a lack of implementation of joint EU work on HTA.

24. The following issues were repeatedly and consistently raised by the majority of delegations during all of the meetings:

- The positioning of HTA as an instrument enabling market access, instead of as a basis for decisions related to health and patient access:

  The proposal has a strong focus on overcoming impeded and distorted market access in the context of a better functioning of the internal market. Health is included only in so far as ensuring a high level of protection is a general requirement for all legislative proposals concerning health, based on Article 114 of the Treaty on the Functioning of the European Union (TFEU).
  Member States pointed out that this is a change in the perception of health technology assessment, which currently forms part of health policy at national level. In view of the fact that HTA is, in reality, essentially concerned with human health, there was a reminder from Member States that Article 168 TFEU would be a more appropriate legal basis than Article 114 TFEU. HTA is aimed at ensuring patient access to necessary, effective and timely treatment, not at addressing issues caused by (duplication of) requests for data from national authorities[16].

[16] Compare Article 34 in relation with Article 8 of the proposal.

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- Identified problem, proposed framework and proportionality:

  Member States pointed out that the problems identified (impeded market access, duplication of work and unsustainable cooperation at Union level) are just some among many problems associated with ensuring access to treatment. Some noted that the Impact Assessment does not demonstrate in a convincing manner that the adequate and proportionate solution to those problems is a harmonisation of HTA assessments.

  The low uptake of the current joint work and the existing significant diversity between national HTA systems were considered to argue against, rather than in favour of scaling-up and harmonisation. It was noted that the benefits of cooperation in the HTA Network are not limited to avoiding duplication of assessments. Rather, it also allows for cooperation between national authorities and exchange and analysis of information related to assessments and methodologies. Some Member States explicitly questioned whether "duplication" itself was a problem.

- A mismatch between the option preferred by the Commission and the preference expressed by the Member States:

  It has been noted by several delegations that the preferred option was not chosen on the basis of either the public consultation, which resulted in a different outcome, or the consultations with Member States.

  Support has been expressed repeatedly for continuing the existing cooperation on a voluntary basis, rather than introducing cooperation based on mandatory assessments. Some Member States argue that a better structuring of the EU-HTA cooperation through EU legislation could improve the uptake without needing it to be mandatory.

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- Clinical assessments as an intrinsic part of the full assessment of health technologies

  A number of delegations have repeatedly noted that it is practically impossible to separate the clinical part of the assessment from the economic part, which in turn is an essential instrument for steering national pharmaceutical public policies and is the basis for pricing and reimbursement decisions at national level.

  This is also reflected in the reasoned opinions on subsidiarity and proportionality of the German, French and Czech national parliaments, as well as in the position of the Polish parliament. Concerns with regard to subsidiarity and/or proportionality were repeatedly expressed by a number of other Member States.

  Reference was also made to the requirement to notify and justify national measures before they are adopted, which is intrinsic to the proposed legal basis.

- Doubts regarding the expected quality and timeliness of the assessments were among the main concerns raised, with references to national procedures currently ensuring timely access to treatment for patients.

- In addition to the above-mentioned issues concerning the core of the proposal, criticisms were expressed with regard to the proposed scope, mechanism, structure, decision-making, voting rules, and obligations of the industry.

25. Throughout the discussions, the Presidency has noted the constructive spirit of all parties. Despite fundamental concerns raised with regard to legal basis and national competencies, there has been a genuine attempt from all delegations to focus on identifying content for future HTA cooperation that could be acceptable to Member States, which ultimately are responsible for implementing and enforcing a system to the benefit of patients.

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26. Therefore, based on the outcome of discussions in the Working Party, the Presidency notes that in general, delegations are positive about the possibility of continuing cooperation on health technology assessment, which is currently established on a voluntary basis under the existing legislation, and is also supported in Council conclusions[17].

27. However, the Presidency also notes that there is a need to explore and exhaust possibilities other than the proposed mandatory system of HTA, which has not been confirmed by delegations as the appropriate policy option for sustainable cooperation. Continuing to explore only this option could minimise the chances of reaching an agreement among Member States.

28. In light of the above, political guidance from the Health Ministers on the desirable direction for the upcoming negotiations in the Council's preparatory bodies is essential. A public deliberation in the Council will also ensure transparency for the public regarding this important file.

QUESTIONS FOR DISCUSSION:

As a precondition for more detailed discussions, the Council is invited to provide direction and guidance to its preparatory bodies by responding to the following question:

- **Bearing in mind that the current voluntary cooperation has been perceived positively by Member States, could you support discussion on alternative ways of ensuring its long-term sustainability, other than the proposed mandatory participation and/or uptake (Article 8)?**

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[17] Council conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical system in the EU and its Member States, OJ C 269, 23.7.2016, p. 31.

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