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From: General Secretariat of the Council
To: Permanent Representatives Committee

Subject: Proposal for a Regulation of the European Parliament and of the Council
on health technology assessment and amending Directive 2011/24/EU
- Presidency Progress report

Delegations will find in the Annex a report from the Presidency on the progress in the examination of the proposal for a Regulation on health technology assessment during the Croatian Presidency. This Progress report has been prepared to provide information to the Permanent Representatives Committee at its meeting on 17 June 2020.

Information from the Presidency on the progress achieved in the examination of the Proposal for a Regulation on Health Technology Assessment

Background

1. On 31 January 2018 the Commission submitted the proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU¹ to the European Parliament and to the Council. The proposal is subject to the ordinary legislative procedure; qualified majority required.
2. The proposal comprises four main areas of work at EU level: joint clinical assessments (JCAs); joint scientific consultations; identification of emerging health technologies; and voluntary cooperation on health technology assessment. It also intends to set common rules for national clinical assessments.
3. On 23 May 2018, the European Economic and Social Committee delivered its opinion² on the proposal.
4. National Parliaments in three Member States (the Czech Republic, Germany and France) submitted a reasoned opinion, raising subsidiarity concerns and the Polish Parliament also raised subsidiarity concerns, but without submitting a reasoned opinion. The Irish and Portuguese Parliaments submitted positive assessments of the proposal.
5. The Bulgarian Presidency, the Austrian Presidency, the Romanian Presidency and the Finnish Presidency organised several meetings of the Working Party on Pharmaceuticals and Medical Devices to examine the proposal at technical level.
6. The Bulgarian Presidency concentrated on presentations of the proposal and the impact assessment and on a discussion on key provisions.

¹ 5844/18

² OJ C 283, 10.8.2018, p. 28–34

7. The Austrian Presidency tabled revised texts for Articles 1 to 8 and 34, covering the scope of the proposal, definitions, the Coordination Group and the annual work programme, joint clinical assessments and the safeguard clause, which were discussed and developed at technical level.
8. The Romanian Presidency tabled revised texts for Articles 12 to 18 on joint scientific consultations, Articles 24 to 28 on the support framework for the joint work and also proposed to introduce additional provisions on Conflicts of Interest and Quality Assurance.
9. The Finnish Presidency focused on Articles 5 to 9 on joint clinical assessments and tabled several proposals for changes to those Articles.
10. On 22 June 2018, the Council (EPSCO) held a policy debate³ providing guidance for the continued examination of the proposal by its preparatory bodies. On 7 December 2018⁴, 14 June 2019⁵ and on 9 December 2019⁶, the Council (EPSCO) was informed on the state of play of the file.
11. On 14 February 2019, the European Parliament adopted its legislative resolution⁷ at first reading. In September 2019, the European Parliament decided not to change the legislative resolution adopted under the previous legislature and appointed Tiemo Wölken (S&D, DE) as Rapporteur⁸.

³ 9805/18

⁴ 14694/18

⁵ 9770/19

⁶ 14619/19

⁷ 6462/19

⁸ He replaced Soledad Cabezón Ruiz (S&D, ES).

Progress during the Croatian Presidency

12. The Croatian Presidency decided to continue the work on the proposal where the Finnish Presidency left off and set itself the goal to find compromises on the text. To this aim it scheduled six meetings of the Working Party on Pharmaceuticals and Medical devices and divided the text into six parts to be discussed in those meetings.
13. In all, the Presidency team prepared three sets of documents in order to provide the basis for the discussion at the Working Party.
14. The first set was discussed at the Working Party meeting in January and comprised Articles 3-5, 18 and 28, containing provisions on the Member State Coordination Group on Health Technology Assessment, the Annual Work Programme and the Annual Report, the Scope of Health technologies subject to Joint Clinical Assessments, Identification of Emerging Health Technologies and Review, as well as Conflicts of Interest and Quality Assurance. 22 Member States intervened in the discussion.
15. Based on the second set of documents, prepared for the meeting of the Working Party in February, an in-depth discussion on technical aspects of the Joint Clinical Assessment process, from scoping to approval, was held. This discussion included an exchange of views on obligations on Health Technology Developers and consequences of non-compliance, Member State obligations and penalties. This meeting covered Articles from 6 to 8 and Article 34a. 21 Member States participated in the discussion.
16. Due to the outbreak of the COVID-19 pandemic, only two meetings of the Working Party could be held; in January and in February 2020. Documents for the third meeting scheduled to take place in March were prepared and circulated to delegations, but due to the introduction of confinement measures, that meeting could not take place. Those documents covered Joint Scientific Consultations (Articles 9, 10, 11a - 16).

17. During the spread of COVID-19 in the EU Member States, experts dealing with HTA in the Member States were actively involved in emergency tasks related to the fight against COVID-19. As a result, a large number of delegations expressed concerns regarding the possibility to engage in further work on this file during the term of the Croatian Presidency. Therefore, the Presidency decided not to proceed with organising video-meetings or exploring the possibility to hold regular meetings of the Working Party. Instead it decided to give the possibility to delegations to submit comments on the three sets of documents that were distributed until mid-March. Altogether nine Member States submitted written comments.
18. The Presidency decided not to table any new proposals for changes to the text of the HTA Regulation considering that, following a potential partial resumption of meetings in the Council framework, there would not be sufficient time for discussion, and furthermore, due to the ongoing pandemic, delegations would not have equal opportunities to engage in discussions on this important file.

Conclusion

19. The Presidency considers that the text it proposed for Articles 3-8, 18, 28 and 34a, including the Articles on Conflicts of Interest and Quality Assurance and the corresponding recitals, and that was discussed during the two meetings of the Working Party, was well-received by a substantive number of delegations.
20. Based on its bilateral and multilateral discussions with delegations, the Presidency concludes that the outbreak of the COVID-19 pandemic emphasizes the importance of having a legally sound and functioning HTA system in place.
21. The Presidency believes that the texts it proposed together with the comments received from delegations constitute a solid basis for continuing the work on reaching a compromise on the parts of the proposal discussed during its term, thereby contributing to establishing a legally sound system for cooperation on HTA to the benefit of all Member States.

22. Due to the cancellation of the EPSCO (Health) Council scheduled for 12 June as a result of the COVID-19 pandemic, the present progress report will be presented by the Presidency to the Permanent Representatives Committee on 17 June 2020 with the invitation to take note of it.
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