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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	**Employment, Social Policy, Health and Consumer Affairs Council session on 9 December 2019** Regulation on health technology assessment and amending Directive 2011/24/EU *- Information from the Presidency on the state of play*

Delegations will find in the Annex a note from the Presidency on the state of play regarding the examination of the proposal for a Regulation on health technology assessment. This note has been prepared to provide information under "Any Other Business" at the session of the Council (EPSCO) on 9 December 2019

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ANNEX

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/EU[1] 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 opinion[2] on the proposal.

4. National Parliaments in three Member States (the Czech Republic, Germany, 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.

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1 5844/18

2 OJ C 283, 10.8.2018, p. 28–34

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5. The Bulgarian Presidency, the Austrian Presidency and the Romanian Presidency organised several meetings of the Working Party on Pharmaceuticals and Medical Devices to examine the proposal at technical level. The Bulgarian Presidency concentrated on presentations of the proposal and the impact assessment and on a discussion on key provisions. 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. 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 conflict of interests and quality assurance.

6. On 22 June 2018, the Council (EPSCO) held a policy debate[3] providing guidance for the continued examination of the proposal by its preparatory bodies. On 7 December 2018[4] and on 14 June 2019[5] the Council (EPSCO) was informed on the state of play of the file.

7. On 14 February 2019, the European Parliament adopted its legislative resolution[6] at first reading. In September 2019, the EP decided not to change the legislative resolution adopted under the previous legislature and appointed Tiemo Wölken (S&D, DE) as Rapporteur[7].

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3 9805/18
4 14694/18
5 9770/19
6 6462/19
7 He replaced Soledad Cabezón Ruiz (S&D, ES).

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Progress during the Finnish Presidency

8. During the Finnish Presidency term, the Working Party on Pharmaceuticals and Medical Devices held six meetings and a seventh meeting is scheduled for 3 December 2019. The Presidency decided to focus on joint clinical assessments, more specifically on Articles 5 to 9 of the proposal. In the view of the Presidency this part of the proposal is essential to achieve the goals of the Regulation, as it regulates which health technologies are subject to the obligation to carry out JCAs, the procedures for carrying out a JCA and approving a JCA report, the obligations for health technology developers and Member States in relation to JCAs and the updating of JCA reports.

9. The Presidency organised many in-depth discussions on technical issues within those Articles. In order to set the basis for these discussions, the Presidency's team prepared several papers with detailed explanations on various steps and elements of clinical assessments, health technologies to undergo such assessments as well as the role of health technology developers and HTA bodies. These papers aimed to achieve a better understanding of the requirements of the future joint clinical assessment process and were used when re-drafting the legal text.

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Health technologies subject to JCA

10. Most delegations agree that there is a need for a stepwise approach, successively increasing the number of health technologies that are subject to JCA, with each step lasting 2 to 3 years. In this way, the number of JCA to be carried out by the Coordination Group will be relatively small in the beginning, about 10 health technologies per year, and grow at a steady pace until the full capacity is reached. The aim of this stepwise approach is to gather experience and develop working methods and thus to allow for successively building a robust system.

11. For medicines, several delegations agree that JCA shall be compulsory for a large number of centrally authorised medicines. In accordance with the stepwise approach, the Presidency has proposed which of the categories of medicines that are already defined in Annex I of Regulation (EC) No 726/2004[8] shall be included in each step, which will allow for predictability also in terms of numbers of medicines to undergo JCA. Some delegations prefer to group categories differently than the Presidency has proposed and some other delegations prefer selection of medicines, *e.g.* via a Work Programme, for each step. Many delegations would like to have the possibility to cover a few additional health technologies should the need arise, provided a legally sound and predictable solution can be found.

12. For medical devices, the Presidency has presented a document intended to initiate a more detailed discussion in the Working Party. Most delegations continue to support that medical devices should be included among health technologies undergoing JCA. However, there are some concerns among delegations on how the requirements for JCA will link to the implementation of the new Regulations on medical devices and *in vitro* diagnostic medical devices. Discussions on medical devices will have to continue during the next Presidencies.

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[8] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

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Procedure for JCA

13. Throughout the negotiations, delegations have asked for a more prominent role for the Coordination Group in carrying out and approving JCA and a less prominent role for the Commission. Bearing in mind that the Coordination Group has no legal personality and cannot impose obligations on third parties, the Presidency has clarified the role of the Coordination Group by laying down its task explicitly in the Regulation. Along the same line, the Presidency has removed some of the tasks of the Commission. As regards approval and contents of JCA reports, the Presidency has proposed that reasoned divergent scientific views shall be annexed to the reports and that the reports shall be approved by consensus.

14. Many delegations support the Presidency approach. However, there are also many delegations that request a stronger role for the Commission in verifying that the procedure has been respected for each JCA and that the result of that verification is considered in the approval of the JCA report. Further clarification and discussion is required as concerns the role of the Commission.

15. For medicines, the procedure to carry out JCA has been clarified further to take into account concerns of delegations regarding the quality of JCA and its timing.

16. As much of the discussions have focused on medicines, the examination of the provisions regarding medical devices are not yet as advanced, and more detailed discussions are needed during forthcoming Presidencies.

Obligations for health technology developers and Member States

17. The Presidency proposed changes to the text to clarify that the obligations for health technology developers to provide information for JCA stem directly from the text of the Regulation and are not imposed via a request by the Coordination Group. A majority of delegations agree to the proposed changes.

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18. The Presidency has furthermore clarified the obligations for Member States in order to ensure that there is no duplication of information to be provided by a developer of a health technology subject to JCA in the framework of the JCA and the HTA processes at national level. The obligations on Member States as regards uptake of JCA have been softened, but maintain an obligation on Member States to consider the JCA in HTA processes at national level. While many delegations agree with these principles, further fine-tuning of the text is necessary.

Updates of JCA reports

19. The Presidency has proposed a discussion on updates of JCA reports. However, many issues need further clarification, such as: should updates be carried out for all or only for some of the initial JCA, when should updates be carried out and what kind of information would be necessary for an update.

Conclusions

20. The Presidency considers that the revised text for Articles 5 to 8 has been sufficiently well-received by delegations to constitute a basis for continued discussion on how to establish a legally sound system for cooperation on HTA to the benefit of Member States.

21. The Presidency has scheduled a meeting of the Working Party for 3 December in order to continue the discussion of open issues in the provisions on joint clinical assessments.

22. The Council is invited to take note of the information set out in this document from the Presidency.

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