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session on 14 June 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 14 June 2019.

**Presidency Progress Report on 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 for adoption by Council.
2. The proposal comprises four main areas of work at EU level: joint clinical assessments; 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 a positive opinion² on the proposal.
4. National Parliaments in three Member States (Czechia, 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.
5. The Bulgarian Presidency and the Austrian Presidency organised three and seven meetings of the Working Party on Pharmaceuticals and Medical Devices respectively to examine the proposal at technical level. 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.

¹ 5844/18

² OJ C 283, 10.8.2018, p. 28–34

6. 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 2018 the Council (EPSCO) was informed on the state of play of the file⁴.
7. On 14 February 2019, the European Parliament adopted its legislative resolution⁵ at first reading.

Progress during the Romanian Presidency

8. During the Romanian Presidency, the Working Party on Pharmaceuticals and Medical Devices held eight meetings. The Presidency decided to focus on two of the main areas of joint work at EU level, as referred to in point 2, namely joint scientific consultations and the identification of emerging health technologies (Articles 12 to 18) as well as on the Support Framework (Articles 24 to 28). Based on the discussions, the Presidency extensively redrafted the text of the articles corresponding to these provisions. In addition, the Presidency proposed to introduce provisions on conflict of interests and quality assurance.
9. As regards joint scientific consultations, their aim and nature were clarified. The text was modified to reflect experiences gained from similar consultation processes in which some Member States currently participate. The procedure for carrying out joint scientific consultations was simplified. Furthermore, the interaction with the European Medicines Agency was better described and the process for interaction with bodies involved in the assessment of medical devices was made explicit. For the identification of emerging health technologies, the Presidency revised the text with the aim to stress non-duplication with other initiatives for identifying such technologies and extending its time horizon. One of the points of intensive discussion concerned the introduction of fees for joint scientific consultations. After profound reflection, the Presidency proposed that the system should initially be financed from the EU budget and the possibility to introduce fees should be reassessed after a certain time, based on experience gained from the use of the system.

³ 9805/18

⁴ 14694/18

⁵ 6462/19

10. The Support Framework part of the proposal was significantly modified in order to clarify the provisions on the stakeholder network and the IT platform. The scope of the implementation report in Article 28 was widened.
11. Most Delegations welcomed the Presidency revised texts referred to in points 9 and 10, while noting that further changes might prove necessary after discussions on other parts of the proposal. Some delegations stressed that at this stage, mainly due to the links with other parts of the proposal, they could not give a definite opinion.
12. On request by some delegations, the Presidency proposed provisions on conflicts of interest and quality assurance, which after intensive debates are now in an advanced stage of discussion. Most delegations are generally positive towards these new provisions, while requesting further fine-tuning. A few delegations, however, consider that those provisions require further strengthening.
13. Recently, the Working Party re-started discussions on the structure and tasks of the Coordination Group.

Conclusions

14. The Presidency considers that the revised texts it has presented at Working Party level on joint scientific consultations, identifying emerging health technologies and the support framework are robust and accurately reflect the discussion and comments made by delegations. This does not preclude that changes to other parts of the proposal might make it necessary to adapt these revised texts.
15. The Presidency recommends that discussion on the structure and tasks of the Coordination Group as well as on the newly introduced provisions on conflicts of interest and quality assurance should continue at technical level.
16. The Council is invited to take note of this report from the Presidency.