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Subject:	**Employment, Social Policy, Health and Consumer Affairs Council session on 7 December 2018** Proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU - *Information from the Presidency*

Delegations will find in the Annex a note from the Presidency on the above-mentioned subject to be raised under "Any Other Business" at the session of the Council (EPSCO) on 7 December 2018.

ANNEX

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/EU to the European Parliament and to the Council. The legal basis for the proposal is Article 114 (Internal Market) of the Treaty on the Functioning of the European Union.

2. The proposal creates a framework for joint assessment at EU level by Member States' bodies of the relative clinical effectiveness of certain medicines and medical devices, hereinafter called "Joint Clinical Assessment" or simply "JCA". Such JCA would need to be considered when a health technology assessment ("HTA") is performed at national level.

3. On 23 May 2018 the European Economic and Social Committee delivered a positive opinion 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 organised three Working Party meetings. The first one was dedicated to the presentation of the proposal, the second to discussing the impact assessment and the third to discuss the key provisions as identified by the Bulgarian Presidency from previous Working Party meetings.

6. On 22 June 2018, the Council (EPSCO) held a policy debate providing guidance for the continued examination of the proposal by its preparatory bodies.

7. On 3 October 2018 the European Parliament plenary voted 199 amendments, but not its legislative resolution, thereby keeping open the possibility to reach an agreement at first reading.

Progress during the Austrian Presidency

8. During the Austrian Presidency, the Working Party on Pharmaceuticals and Medical Devices met in all during seven days to examine in detail the Commission proposal in its entirety.

9. The examination at the first three meetings showed that the main concern of delegations vis-à-vis the proposal is to clarify how the proposal, once adopted, will influence national decisions on the reimbursement of medicines or medical devices by national health insurance schemes. In this regard, a large majority of delegations considered that Member States should have the possibility to carry out national clinical assessments when necessary. Other important issues identified are linked to the quality and timely delivery of JCA and to the structures, procedures and methodologies for achieving those. All delegations agree that JCA must be at least as good as national clinical assessments and must be available sufficiently early to be used in national decision-making. Furthermore, there was overall consensus on the importance of transparency regarding the overall assessment process as well as on the process for including reports on JCA in the List of Assessed Health Technologies and the need for strict provisions on conflicts of interest to guarantee an independent assessment process. In order to ensure transparency throughout all procedures in the Regulation, it was suggested to develop a separate Article on this issue. One delegation provided a first draft for such an Article, which was briefly examined and gained broad support. The discussions on this topic and on the specificities of that Article as such should continue.

10. In October, the Presidency tabled a revised text, based on written and oral contributions by delegations, covering Articles 1 to 8 and 34 and seeking to address, in particular, the concerns and issues referred to above. The Presidency revised text was examined by the Working Party during four further meeting days. As regards the concerns related to how JCA influence national decisions, the Presidency proposed to provide for complementary national clinical assessments and the possibility to adapt the JCA to the needs of the national decision making process (Article 8). With regard to the quality and timely delivery of JCA, the Presidency text included changes to the structures for deciding upon JCA and to the procedures for carrying out JCA. It also limited the number of health technologies which undergo JCA. The proposed governance structure should allow for a Member State driven process. As explained in more detail in Sections A and B below, both how JCA influence national decisions and the quality and timely delivery of JCA require further consideration at technical level, as do other issues raised by delegations.

11. An important addition to the text was suggested by some delegations, namely to define an assessment's scope. In response, the Presidency has introduced provisions that require that the content of the JCA be defined, in respect of interventions, comparators, patient population and patient-relevant health outcomes.

12. Many delegations have raised the issue of what the consequences would be if a health technology developer were not to deliver the data required for performing the JCA. There is a need for further clarification on consequences of noncompliance with the obligations set out in the Regulation.

13. To further help advance the discussions, the Working Party has invited the Council Legal Service to issue an opinion on the legal implications of the proposed procedure for the approval of JCA.

A. The quality and timely delivery of Joint Clinical Assessments (JCA)

14. The Presidency has further clarified the selection of experts to carry out JCA, transparency and confidentiality rules for participating in the joint EU work, the information to be submitted by the industry as well as the procedural steps and timelines. The main difficulties encountered in this context arise from the difference in timing for performing HTA in different Member States (due sometimes to delayed market entry) as well as from procedural and methodological differences.

15. A majority of delegations agree that further technical elaboration on how to ensure both quality and a timely delivery is necessary, and discussions are on-going on this issue. Many delegations consider that limiting the number of JCA contributes to a higher quality. The future discussion should also include the role and competences of the Coordination Group in the timely preparation of high quality JCA as well as the level of detail to be included in the Regulation itself and the aspects that could be laid down in tertiary legislation.

B. Member States' use of Joint Clinical Assessments in their national, overall HTA process

16. By further strengthening the requirements on quality and timely delivery of JCA the Presidency intended to meet concerns of delegations regarding their use in national decision-making. The Presidency also considers that there may be special circumstances where JCA will not cover all necessary aspects, and therefore, it amended the text to provide Member States with the possibility to carry out their own clinical assessments when needed. The discussion on this topic was inconclusive and would need to be continued.

17. Several delegations cannot agree to any degree of mandatory use of JCA in their national procedures and consider that JCA cannot bind Member States, since HTA is used for pricing and reimbursement decisions and those are of national competence. Those delegations hold that, as the JCA is a purely scientific process, it could only be a tool for decision-making and not in itself be legally binding.

18. Several other delegations consider that the Presidency text needs to be further developed with regard to possibilities for Member States to carry out national clinical assessments.

19. On the contrary, other delegations consider that the revised text, as suggested by the Presidency, allows for enough flexibility for Member States when using the JCA for carrying out national HTA assessments. In this context, the argument was also raised that if it were not to contain any obligation for Member States, this Regulation, would impose an undue burden on the pharmaceuticals and medical devices industry.

Future Work

20. All delegations hold that the discussions should continue at technical level.