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**NOTE**

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| From: | General Secretariat of the Council |
| To: | Permanent Representatives Committee |
| No. Cion doc.: | 5844/18 + COR1 - 5844/18 ADD1 to ADD3 - 5844/18 ADD3 COR1 |
| Subject: | Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU<br>*- Mandate for negotiation with the European Parliament*<br>*- Decision to consult an institution or body* |

## I. BACKGROUND

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

2. The legal basis of the proposal is Article 114 of the Treaty on the Functioning of the European Union (TFEU). The ordinary legislative procedure is applicable.

3. The proposal includes provisions for the use of common health technology assessment (HTA) tools, methodologies and procedures across the EU. It sets out four pillars for joint work of Member States at EU-level *i.e.* (i) joint clinical assessments, (ii) joint scientific consultations, (iii) identification of emerging health technologies, and (iv) voluntary cooperation in areas outside the scope of mandatory cooperation.

[1] 5844/18

4. Member States' National Parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity and proportionality. National Parliaments in the Czech Republic, Germany, France and Poland submitted opinions raising subsidiarity and/or proportionality concerns. The Irish and Portuguese Parliaments submitted positive assessments of the proposal.

5. The European Economic and Social Committee was consulted and issued its opinion[2] on the proposal on 23 May 2018.

6. The European Parliament has appointed MEP Tiemo Wölken (S&D, DE) as Rapporteur. In September 2019, the European Parliament decided not to change the legislative resolution[3] adopted under the previous legislature.

## II. STATE OF PLAY

7. Extensive work has been carried out under the Bulgarian, Austrian, Romanian, Finnish, Croatian, German and Portuguese Presidencies. 39 meetings of the Working Party on Pharmaceuticals and Medical Devices were organised to examine the proposal at technical level. The impact assessment accompanying the proposal was discussed during the Working Party meeting held on 17 April 2018 under the Bulgarian Presidency.

8. On 22 June 2018, the Council (EPSCO) held a policy debate[4] providing guidance for the continued examination of the proposal by its preparatory bodies. On 7 December 2018[5], 14 June 2019[6], on 9 December 2019[7], on 2 December 2020 and on 16 March 2021, the Council (EPSCO) was informed on the state of play of the file. On 17 June 2020[8], the Permanent Representatives Committee was informed of the progress achieved in the examination of the proposal.

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2 OJ C 283, 10.8.2018, p. 28–34
3 6462/19
4 9805/18
5 14694/18
6 9770/19
7 14619/19
8 8737/20

9. Building on the compromise texts prepared on various parts of the proposal by the Austrian, Romanian, Finnish and Croatian Presidencies, the German Presidency presented a draft compromise text on the entire proposal. This draft compromise text aimed at addressing the main issues highlighted by the delegations on the original proposal *e.g.* the legal basis, the scope of the Regulation, the respective roles of the Coordination Group and of the Commission, the assessment process for joint clinical assessments and the obligations on Member States.

10. Under the Portuguese Presidency, the Working Party has pursued the work. It has thoroughly examined the draft compromise text, focusing on the main remaining outstanding issues, in particular on the scope and the finalisation of the joint clinical assessment.

11. The latest Presidency compromise text[9] was examined by the Working Party at its meeting of 19 February 2021. Although the text received a broad support from delegations[10], it was not possible to find an agreement among delegations on two issues:
    a) The voting modalities to adopt decisions, in case consensus cannot be reached within the Coordination Group, as set out in Article 3(4), were left open until an agreement on the required majority is reached at Coreper level;
    b) The modalities for the endorsement of the joint clinical assessment reports by the Coordination Group, as set out in Article 6d(2) and (3). A first group of delegations considered that the endorsement should take place by consensus, as this is a scientific report and all divergent scientific views would be attached to it. A second group of delegations, supported by the Commission, was of the opinion that a voting mechanism should be introduced to address situations where consensus would not be reached in order to avoid the blockage of the process, arguing that this could jeopardize the functioning of the system.

12. In light of the above, the Presidency concluded by noting that there was a broad support for the latest Presidency compromise text with the exception of Articles3(4) and Article 6d(2) and (3) and indicated that the Permanent Representatives Committee would be invited to agree on a way forward for these two issues. In addition, the Presidency indicated that it would further

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**9** 6057/21

**10** Three delegations indicated that they had still some problems with several parts of the text

adapt the compromise text to take on board the suggestions from delegations which had received a broad support and ensure the consistency and clarity of the text.

13. Regarding Article 3(4) and the voting modalities therein, in case consensus cannot be reached within the Coordination Group, the Presidency has developed two options, as set out in the Annex to this Note. The option 1 foresees a vote requiring the two-thirds majority of the Member States The option 2 foresees a vote requiring the qualified majority, as laid down in Article 16(4) of the Treaty on the European Union.

14. Regarding Article 6d(2) and (3), the Presidency has developed a text for a possible compromise which emphasises that the Coordination Group should aim at endorsing the joint clinical assessment reports by consensus, but makes clear that, where consensus cannot be reached and all divergent scientific opinions have been incorporated in the report, the report shall be deemed endorsed. The corresponding text is laid down in the redrafted Article 6d(2) of the Presidency compromise text set out in document 6590/21.

15. Lastly, the Presidency has further adapted the latest Presidency compromise text, in line with its conclusions at the last Working Party meeting (see point 12). Most of the adaptations aim to improve the clarity and the consistency of the text, including a better alignment of the Recitals with the corresponding Articles. In addition, a change in the order of the legal basis (*i.e.* Article 114 TFEU mentioned before Article 168 TFEU) in the citation and a rewording of Article 6d(4), (5) and (5a) were necessary to ensure the coherence and the legal certainty of the text. The resulting Presidency compromise text[11] is set out in document 6590/21.

16. As the present mandate extends the legal basis of the original proposal to Article 168 TFEU, the Committee of the Regions shall be consulted on the overall compromise text. Due to the substantial changes made to the original proposal, the Presidency also proposes to re-consult the European Economic and Social Committee.

[11] See redrafted Article 6d (3), (4) and (5)

## III. CONCLUSION

17. In the light of the above, the Permanent Representatives Committee is invited to:

a) examine the two proposed options developed by the Presidency regarding Article 3(4), as set out in the Annex to this Note, and decide on the preferred option;

b) confirm the agreement on the overall compromise text, as set out in document 6590/21 and as amended in accordance with point a) above;

c) mandate[12] the Presidency to enter into negotiations with the European Parliament in view to reach an agreement at early second reading on the proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU;

d) take note of the consultation of the Committee of the Regions pursuant to Article 168 TFEU and agree on the re-consultation of the European Economic and Social Committee;

e) instruct the Working Party on Pharmaceuticals and Medical Devices to assist the Presidency as necessary during the negotiations with the European Parliament.

[12] In accordance with the approach on legislative transparency endorsed by the Permanent Representatives Committee on 14 July 2020 (doc. 9493/20), and in full consistency with Regulation (EC) No 1049/2001 and the Council's Rules of Procedure, the agreed mandate will be made public.

# Article 3(4)

**Option 1 - two-thirds majority**

*Article 3(4) would read as follows:*

4. The Coordination Group shall, in principle, act by consensus. Where consensus cannot be reached, the adoption of a decision shall require support by members representing the two-thirds majority of the Member States. Each Member State shall have one vote. The results of the votes shall be recorded in the minutes of the Coordination Group's meetings. Where a vote takes place, members may ask for divergent opinions to be recorded in the minutes of the meeting in which the vote took place.

**Option 2 - qualified majority, as laid down in Article 16(4) of the Treaty on the European Union**

*Article 3(4) would read as follows:*

4. The Coordination Group shall, in principle, act by consensus. Where consensus cannot be reached, the adoption of a decision shall require the qualified majority laid down in Article 16(4) of the Treaty on European Union. Each Member State shall have one vote. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in this Article. The results of the votes shall be recorded in the minutes of the Coordination Group's meetings. Where a vote takes place, members may ask for divergent opinions to be recorded in the minutes of the meeting in which the vote took place.