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STATEMENT OF THE COUNCIL'S REASONS

Subject:	Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU - Statement of the Council's reasons

I. INTRODUCTION

1. On 31 January 2018, the Commission adopted a 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. The proposal for a Regulation was based on Article 114 of the Treaty on the Functioning of the European Union.

2. 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.

3. The Working Party on pharmaceuticals and medical devices examined the proposal on 39 occasions under the Bulgarian, Austrian, Romanian, Finnish, Croatian, German and Portuguese Presidencies.

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

5. The European Parliament adopted its position at first reading on 14 February 2019[3]. In September 2019, the European Parliament decided not to change the legislative resolution adopted under the previous legislature.

1 5844/18
2 OJ C 283, 10.8.2018, p. 28
3 6462/19

6. On 24 March 2021, the Permanent Representatives Committee agreed on a partial mandate[4] for the Presidency to enter into negotiations with the European Parliament with a view to reaching an early second reading agreement on the proposal, postponing the discussion on the voting mechanism in the Coordination Group in Article 3(4) to a later stage. In the light of the changes introduced in the Council partial mandate as compared to the original proposal, the Permanent Representative Committee agreed also to re-consult the European Economic and Social Committee and to consult the Committee of the regions.

7. On 16 April 2021, the European Parliament Committee on the Environment, Public Health and Food Safety decided to open inter-institutional negotiations, which started on 26 April 2021.

8. On 28 April 2021, the European Economic and Social Committee provided its second opinion[5] and, by letter received on 11 June 2021, the Committee of the regions indicated that it would not issue an opinion.

9. On 16 June 2021, further to the second trilogue that took place on 31 May 2021, the Permanent Representatives Committee complemented the partial mandate by agreeing on a way forward on the voting mechanism in the Coordination Group in Article 3(4) and granted some flexibilities to the Presidency on Article 5[6], Article 6d[7] and Article 8[8] of the Council's mandate.

10. On 21 June 2021, the third and last trilogue took place, whereby the Council and the European Parliament agreed *ad referendum* on an overall compromise package.

11. The Presidency presented the outcome of the last trilogue to the Permanent Representatives Committee on 23 June 2021. Two technical meetings between the Council and the European Parliament were subsequently held to clean up the text in conformity with the overall compromise package.

12. On 30 June 2021, the Permanent Representatives Committee examined the final compromise text[9] and confirmed its agreement on it.

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4 7310/21
5 8330/21
6 Article 5 of Council's mandate corresponds to Article 7 of the consolidated text
7 Article 6d of Council's mandate corresponds to Article 12 of the consolidated text
8 Article 8 of Council's mandate corresponds to Article 13 of the consolidated text
9 10094/21

13. On 16 July 2021, the Chair of the European Parliament Committee on the Environment, Public Health and Food Safety addressed a letter to the Chair of the Permanent Representatives Committee stating that, should the Council transmit formally to the European Parliament its position as agreed *ad referendum*, subject to legal-linguistic verification, he would recommend to the Plenary that the Council's position be accepted without amendment at Parliament's second reading.

II. OBJECTIVES

The proposal includes provisions for the use of common health technology assessment 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.

III. ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING

1. General

The compromise text as consolidated in the Council's position at first reading fully reflects the agreement reached between the co-legislators. It maintains the overall objectives of the Commission proposal and, at the same time, takes on board the most important amendments adopted by the European Parliament in its first reading.

2. Main issues

a) Scope and timeframe

In Article 7 on health technologies subject to joint clinical assessment, both the principle of a stepwise approach and the timeframes for medicinal products for the treatment of cancer and for orphan medicinal products, were agreed among co-legislators.

In order to address European Parliament's concerns on the timeframe, the stepwise approach as initially proposed by the Council was slightly amended so that advanced therapy medicinal products would be subject to joint clinical assessment at the date of application of the Regulation, as medicinal products containing new active substances for the treatment of cancer. Furthermore, it was agreed that orphan medicinal products and all remaining medicinal products under the scope of the Regulation would be added respectively three and five years after the date of application of the Regulation.

b) Finalisation of the joint clinical assessment

In Article 12 paragraph 2 concerning the endorsement of joint clinical assessment reports by the Coordination Group, the Council text was adapted to make clear that the scientific grounds, on which the diverging opinions would be based, would have to be provided. A new Recital was added to emphasise that the normal rule for the endorsement of joint clinical assessment reports should be consensus.

c) Vote by the Coordination Group

In Article 3 paragraphs (4) and (5) on the voting mechanism in the Coordination Group, the use of different types of majorities, depending on the type of decisions adopted, was agreed. The default rule would be that, when consensus cannot be reached, decisions in the Coordination Group would be adopted by simple majority. By way of derogation, qualified majority would be required for the adoption of the annual work programme and the annual report as well as for the provision of strategic direction to the work of the sub-groups (respectively points (b) and (c) of paragraph 7 of Article 3).

d) Member States' rights and obligations

In Article 13 , the following changes were introduced:

– in Article 13 paragraph 1, the text remains as in the Council's mandate, with the addition of a new point that specifies that Member States shall annex the published joint clinical assessment reports to the health technology assessment report produced at national level and a clarification under point (a) that the published reports are the published joint clinical assessment reports;

– in Article 13 paragraph 2, compared to the Council's mandate, a reference was added to specify that Member States shall provide also information on how joint clinical assessment reports have been considered when carrying out national health technology assessment.

In addition, further adjustments to the Council's mandate were agreed:

- in Article 31 paragraph (2) and in Article 30 paragraph (3) point (j), to make clearer in both cases that the information to be provided by the Member States includes information on how joint clinical assessment reports have been considered when carrying out national health technology assessments;
- in the last sentence of Recital 31, to delete therein the part of the text reading "have purely internal administrative effect for any health technology assessment at Member State level".

e) Stakeholders' involvement

In Article 11 paragraph 4, an agreement was found to make clear that the sub-groups shall ensure that patients, clinical and other relevant experts are involved in the assessment by being given the opportunity to provide input on the draft reports, while provisions were also agreed in Article 5 to ensure transparency and absence of conflict of interest during joint work.

IV. CONCLUSION

The Council's position at first reading fully reflects the agreement reached between the co-legislators, as confirmed by the above-mentioned letter from the Chair of the European Parliament's Committee on the Environment, Public Health and Food Safety to the President of the Permanent Representatives Committee, dated 16 July 2021.