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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2021) 696 final
Subject:	COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT pursuant to Article 294(6) of the Treaty on the Functioning of the European Union concerning the position of the Council on the adoption of a Regulation of the European Parliament and of the Council on Health Technology Assessment and amending Directive 2011/24/EU

Delegations will find attached document COM(2021) 696 final.

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pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

concerning the

position of the Council on the adoption of a Regulation of the European Parliament and of the Council on Health Technology Assessment and amending Directive 2011/24/EU

(Text with EEA relevance)

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1. BACKGROUND

Date of transmission of the proposal to the European Parliament and to the Council (document COM (2018) 51 final, 2018/0018 (COD)):	31 January 2018.
Date of the opinion of the European Economic and Social Committee on the proposal:	23 May 2018.
Date of the position of the European Parliament, first reading:	14 February 2019.
Date of the opinion the European Economic and Social Committee on the amended proposal:	27 April 2021.
Date of transmission of the amended proposal:	N/A.
Date of adoption of the position of the Council:	9 November 2021.

2. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The proposal aims to replace the current system of EU-funded project-based cooperation between Member States on health technology assessment with a permanent framework for joint work at EU-level. This framework would cover work on joint clinical assessments, joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation. The proposal seeks to address a number of identified weaknesses in the current system through the following objectives:

Specific objectives:

– Improve the availability of innovative health technologies for EU patients;

– Ensure efficient use of resources and strengthen the quality of HTA across the EU;

– Improve business predictability.

Operational objectives:

– Promote convergence in HTA tools, procedures and methodologies;

– Reduce duplication of efforts for HTA bodies and industry;

– Ensure the use of joint outputs in Member States;

– Ensure the long-term sustainability of EU HTA cooperation.

3. COMMENTS ON THE POSITION OF THE COUNCIL

The position of the Council as adopted at first reading fully reflects the political agreement reached between the European Parliament and the Council on 21 June 2021. The Commission can accept this agreement. The main points of this agreement are the following:

- Progressive implementation: A phase-in period of five years has been introduced, during which the volume of joint clinical assessments for medicinal products is increased in a step-wise manner, based on particular product categories. As of the date of application, in a first step, joint clinical assessments will be carried out on medicinal products containing new active substances for which the therapeutic indication is the treatment of cancer and on medicinal products which are regulated as advanced therapy medicinal products. This approach fully supports Europe's Beating Cancer Plan. Interim dates for each step are set out in the agreed text. This is acceptable considering that the Commission proposal also included the concept of a gradual phase-in (via a transitional period envisaged in the Commission proposal) and the definition of clear product categories and their interim steps provide predictability for health technology developers.
- Obligations on Member States: Member States will be required to "give due consideration" to the joint clinical assessment reports. This wording is less stringent than that of the original Commission proposal. However, this approach can be accepted taking into account that a number of safeguards were introduced to strengthen obligations on Member States, namely the requirement to annex the joint clinical assessment report to the national health technology assessment and to report on how each joint clinical assessment report was given due consideration in the health technology assessment at national level. Further additions include the strengthened level of obligations on health technology developers to provide all data and evidence necessary for the assessment, and the requirement for Member States to not duplicate requests for data and evidence to be used for the joint clinical assessments.
- Quality, transparency, timeliness and enhanced level of involvement of external experts and stakeholder organisations: A number of changes were introduced in the agreed text to further detail the provisions in the Commission's proposal on quality and transparency. These include the addition of specific provisions on quality assurance, transparency and conflicts of interest. More details were also added to the text on the level of involvement of external experts and stakeholder organisations, on the procedures for joint clinical assessments, including the timing of the submissions of data and the end of the assessment, and on submission dossier requirements that are set out in the agreed text. While in the Commission proposal, most of these aspects were to be further developed in tertiary legislation, specifying some important elements already in the main text is acceptable.
- Voting regime of the Coordination Group and finalisation of joint clinical assessments: The Coordination Group of Member States authorities and bodies responsible for HTA shall take its decisions by simple majority based on a principle of one vote per Member State, as foreseen by the Commission proposal. An exception was introduced in the agreed text for the adoption by the Coordination

Group of its annual work programme and its annual report, which will be adopted by a qualified majority of Member States. By way of derogation from the simple majority voting system, the joint clinical assessment report shall, where consensus cannot be reached, include the diverging scientific opinions and the scientific grounds on which these are based. In addition, according to the agreed text the Commission shall conduct procedural reviews and publish joint clinical assessment reports considered to be compliant with the procedural rules. The agreed text is acceptable as it preserves the approach that scientific reports (such as the joint clinical assessments) are agreed by consensus. The role of the Commission in the procedural review as well as the publication and finalisation of the reports ensures legal certainty in the process and is acceptable.

4. CONCLUSION

The Commission supports the results of the inter-institutional negotiations and can therefore accept the Council's position at first reading.