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OPINION OF THE LEGAL SERVICE[1]

From:	Legal Service
To:	Working Party on Pharmaceuticals and Medical Devices
Subject:	Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU - Legal effects of Article 7

I. INTRODUCTION

1. On 31 January 2018, the Commission submitted a proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU[2] ('the Proposal'). The legal basis for the Proposal is Article 114 TFEU (internal market).

[1] This document contains legal advice protected under Article 4(2) of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, and not released by the Council of the European Union to the public. The Council reserves all its rights in law as regards any unauthorised publication.

[2] Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU from 31 January 2018 (COM/2018/051 final - 2018/0018 (COD)) or Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45–65).

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3. This opinion responds to the request of the Working Party.

4. **DELETED**

II. THE LEGAL CONTEXT

i) Union measures on HTA

5. Health technology assessment ('HTA') has been described as '*the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision-making regarding health technologies*'[3].

6. HTA cooperation at EU level began in the 1980s and a large number of projects and joint actions have been carried out at Union level from that time up until today[4]. EU cooperation on HTA also takes place within the HTA Network. The HTA Network was established in 2013 pursuant to Article 15 of the Cross-Border Patients' Rights Directive 2011/24/EU[5], as implemented by the Commission[6].

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[3] See Wikipedia, where some alternative definitions are also provided. In Article 2(d) of the Proposal the following definition is provided: 'a *multidisciplinary comparative assessment process, based on clinical and non-clinical assessment domains, which compiles and evaluates the available evidence about the clinical and non-clinical issues related to the use of a health technology*.'

[4] For more information, see Commission Staff Working Document Impact Assessment – Strengthening of the EU Cooperation on Health Technology Assessment (HTA) – Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU, 31.1.2018, (SWD/2018/41) final – point 1.4.2. and Annex IV.

[5] Article 15(1) of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45–65) reads as follows: '*The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The Member States shall communicate their names and contact details to the Commission. The members of such a health technology assessment network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established. That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.*'

[6] Commission Implementing Decision of 26 June 2013 providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment, 2013/329/EU (OJ L 175, 27.6.2013, p. 71–72); the Decision was adopted according to Article 15(4) of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45–65), that reads as follows: *'The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.'*

7. In addition to these measures on cooperation at Union level on HTA, Union legislation also affects HTAs carried out at national level. The Transparency Directive 89/105/EEC[7] sets a procedural framework for decisions regarding the pricing and reimbursement levels for medicinal products. This Directive improves the functioning of the internal market of medicinal products by increasing transparency. It enables developers to verify that national pricing and reimbursement decisions comply with free movement rules. The Transparency Directive does not substantially regulate HTA processes. Instead, it sets specific time-limits for pricing and reimbursement decisions. Since HTA constitutes a step in the pricing and reimbursement decision-making process, the assessments are covered by these time-limits.

8. In 2012, the Commission proposed replacing the Transparency Directive with a new Directive[8] in order to address some perceived deficiencies in the former[9]. However, due to a lack of political support in the Council, the Commission withdrew its proposal in 2015[10].

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7 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8–11).

8 Proposal for a Directive relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems (COM(2012) 84 final 2012/0035/COD).

9 The Commission later amended its proposal through Amended proposal for a Directive of the European Parliament and of the Council on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems, COM/2013/0168 final - 2012/0035 (COD).

10 OJ C 80, 7.3.2015, p. 17.

ii) The Commission Proposal

9. In its Explanatory Memorandum to the Proposal, the Commission has identified three main problems with the current framework for Union cooperation on HTA that the Proposal is intended to address. Firstly, the existing differences in national HTA processes and methodologies impede health technology developers' access to the internal market for health technologies. Secondly, assessments of the same technology being conducted in parallel or within a similar time frame by HTA bodies in different Member States lead to duplication of work and inefficient use of resources. In the same vein, the low national uptake of Union-level HTAs also leads to inefficient use of resources. Thirdly, the current project-financed HTA cooperation through Joint Actions cannot guarantee continuity in the long-term.

10. The Proposal would repeal Article 15 of the Cross-Border Patients' Rights Directive, but would not modify the Transparency Directive, which will therefore continue to apply.

11. The subject matter set out in the Proposal (Article 1) consists of establishing a support framework and procedures for Union-level cooperation on HTAs, as well as common rules for the clinical assessment[11] of health technologies.

12. According to the Proposal, the work of assessing health technologies is to be carried out by a Member State-driven 'Coordination Group' established by the Regulation (see in particular Articles 3 to 6). According to Article 6(12) and (14): '*(12) The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by a simple majority of Member States. […] (14) The Coordination Group shall provide the approved joint clinical assessment report and the summary report to the submitting health technology developer and the Commission*'.

[11] The concepts of 'clinical assessment' and 'non-clinical assessment', which are both part of the HTA process, are defined in Article 2(e) and (f) of the Proposal. The definitions clearly exclude issues of pricing and reimbursement from the concept of 'clinical assessment'.

13. Article 7 lays down provisions on the inclusion by the Commission of health technologies in the List. The basis for the Commission's considerations are the JCA reports and summary reports approved by the Coordination Group in accordance with Article 6(14).

14. Article 7(1) provides that '[*w*]*here the Commission considers that the approved joint clinical assessment report and summary report comply with the substantive and procedural requirements laid down in this Regulation, it shall include the name of the health technology which has been the subject of the approved report and summary report, in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health Technologies" or the "List") at the latest 30 days after receipt of the approved report and summary report from the Coordination Group.*'

15. As regards the health technologies not to be included in the List, Article 7(5) provides the following: '*If the Commission concludes that the modified approved joint clinical assessment report and summary report do not comply with the substantive and procedural requirements laid down in this Regulation, it shall decline to include the name of the health technology in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the non-inclusion. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report.*'

16. Article 8 contains the following provisions on the obligations of Member States: '*Member States shall: (a) not carry out a clinical assessment or an equivalent assessment process on a health technology included in the List of Assessed Health Technologies or for which a joint clinical assessment has been initiated; (b) apply joint clinical assessment reports, in their health technology assessments at Member State level.*'

17. Other relevant provisions in the Proposal set out transitional arrangements for the introduction of the JCAs (Article 10) and the Commission's empowerment to adopt detailed procedural rules for the JCAs (Article 11).

III. LEGAL ANALYSIS

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