EUROPEAN COMMISSION

Brussels, 24.7.2018
C(2018) 4743 final

Dear Presidents,

The Commission would like to thank the Houses of the Oireachtas for their Opinion on the proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU {COM(2018) 51 final}.

The Commission would like to recall that the proposal is based on 20 years of voluntary cooperation in the area of Health Technology Assessment. Despite this long-standing cooperation, the Commission notes that the uptake of joint work continues to be low. It therefore believes that it is time to increase Member States' commitment, further pooling resources and exchanging expertise, which would in particular be beneficial to smaller Member States with less capacity to carry out Health Technology Assessments.

The Commission is pleased that the Houses of the Oireachtas support the objectives and potential benefits of the proposal. Moreover, the Commission welcomes the opportunity to provide a number of clarifications regarding its proposal and trusts that these will allay the Houses of the Oireachtas' concerns.

The Commission notes the Houses of the Oireachtas' suggestion that health technology developers should be required to submit evidence for the assessment process.

In that regard, the Commission would like to clarify that the proposal provides for a system of mandatory submissions of information, data and evidence by health technology developers necessary for the joint clinical assessments. This requirement is provided for in Article 6(1) of the proposal in conjunction with its Article 11(1)(a). Health technology developers who do not submit the necessary evidence would be unable to submit such evidence at national level as the joint clinical assessments would not be repeated at Member State level.

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The Houses of the Oireachtas also consider that the publication of joint clinical assessment reports should not delay the launch of medicinal products.

The Commission would like to emphasise that the proposal would provide for an alignment with the timing of the marketing authorisation procedure and the joint clinical assessments. As stated in recital 17 of the proposal, the intention is to complete the joint clinical assessment by the time of the marketing authorisation decision. As members of the Coordination Group and the sub-group for joint clinical assessments, Member States' health technology assessment bodies will also have access to draft reports before publication of the final joint clinical assessment report.

As regards the Houses of the Oireachtas' suggestion to include class C in vitro diagnostic devices as part of the scope of joint clinical assessments, the Commission would like to recall that the scope of joint clinical assessments for medical devices takes into account the need to provide legal certainty on the types of products to be assessed, a choice to allow for the assessment of the most innovative devices, and the likely (limited) volume of assessments. In this sense, the Commission assessed that it would not be appropriate to also include class C in vitro diagnostic devices within the scope of the joint clinical assessments. However, provision is made for the possibility of collaborative assessments of such devices as part of the voluntary cooperation provided for in the proposal. In addition, the Commission will report two years after the end of the transitional period referred to in Article 33(1) of the proposal, on the implementation of the provisions, notably on the scope of the joint clinical assessment.

The Commission also notes the Houses of the Oireachtas' suggestion that the Commission should not play a role in verifying the substantive nature of joint clinical assessment reports. The Commission would like to clarify that its role in verifying these reports would be limited to ensuring that the requirements laid down in the proposal have been met. The Commission would not seek to assess the quality of the report produced or question the findings of the report.

The Commission takes note of the Houses of the Oireachtas' view that assessment reports should be translated into all official languages and will seek to establish an appropriate regime for the notifications under Article 8(2) of the proposal and the reports to be provided to the Commission, taking into account the need for translation. The Commission would like to stress that it does not intend to carry out a quality assessment of national assessment reports.

Finally, the Commission notes the Houses of the Oireachtas' concern that the response time by the Commission once the safeguard clause has been invoked would be unnecessarily long. In that regard, the Commission would like to point out that the time period provided for in Article 34 of the proposal is a maximum time period and that the Commission would endeavour to approve or reject the requests before the end of this period. The Commission would not seek to unduly delay national assessments under this clause. However, it considers a maximum period of three months necessary in order to allow for a thorough assessment of the request, taking into account the need to ask for additional information or clarifications on the information provided.

The points made in this reply are based on the initial proposal presented by the Commission which is currently in the legislative process involving both the European Parliament and the Council.

The Commission hopes that the clarifications provided in this reply address the issues raised by the Houses of the Oireachtas and looks forward to continuing the political dialogue in the future.

Yours faithfully,

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First Vice-President

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Member of the Commission