EUROPEAN COMMISSION

Brussels, 24.7.2018
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Dear President,

The Commission would like to thank the Senat for its 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 takes seriously the concerns expressed by the Senat as regards the choice of the legal basis, the principle of proportionality and the proposed empowerments to adopt implementing and delegated acts. The Commission is pleased to have this opportunity to provide a number of clarifications regarding the proposal and trusts that these will allay the Senat's concerns.

The Senat points out that pursuant to Article 6 of the Treaty on the Functioning of the European Union, the Union competence in the field of human health is limited to actions to support, coordinate or supplement the actions of Member States. Moreover, the Senat considers that Article 168 of that Treaty would be a more appropriate legal basis than Article 114.

The Commission would like to stress that the choice of legal basis has been made taking into account the content and objectives of the proposal, in view of the problems identified in the impact assessment. While medicines and medical devices are products which benefit from the principle of free movement of goods within the internal market, the currently existing diversity of national rules contributes to distorted market access for health technologies. The main objectives of the proposal are to ensure a better functioning of the internal market, while contributing to a high level of human health protection. This is to be achieved by improving patients' access to the most innovative health technologies in a more timely and equitable manner across the Union. Therefore, the Commission considers that the proposal must be based on Article 114 of the Treaty on the Functioning of the European Union.

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As regards the Senat's concerns on proportionality, the Commission would like to stress that the proposal provides for the clinical assessment part of health technology assessment to be carried out, in cases covered by the proposal, at Union level, not by the Commission but by Member States' health technology assessment bodies working together within the Coordination Group. Member States would continue to carry out the non-clinical assessment part. The proposal does not oblige Member States to carry out an assessment on health technologies which are the subject of joint clinical assessments. Member States would also remain free to decide on (i) what the national health technology assessment process is i.e. whether to carry out a non-clinical assessment and/or an appraisal process to supplement the joint clinical assessment, (ii) the conclusions on the overall added value of the assessed health technology based on the joint clinical assessment report and (iii) how the results of the overall assessment process, if there is one, should be used as part of pricing and reimbursement decisions.

The Commission would also like to recall that considerable cooperation on health technology assessment at Union level has already taken place in the form of a voluntary network of Member States' health technology assessment authorities and bodies, and through European Union-funded initiatives such as the three Joint Actions under the European Network for Health Technology Assessment. As outlined in the impact assessment report accompanying the proposal, while this cooperation has shown the potential of Member States working together on health technology assessment at Union level, it has not substantially dealt with the impeded and distorted market access or the duplication of health technology assessment across the Union. In particular, the limitations of a model of voluntary cooperation have been shown through the low levels of use at Member State level of the outputs of the joint work.

The Commission therefore considers that the proposal constitutes a necessary and proportionate approach to dealing with the problems identified and to achieving the objectives of the initiative. The Commission is confident that the current discussions with the European Parliament and the Council will allow for these elements to be reflected in a clear and jointly agreed way so as to ensure an efficient and inclusive system.

Finally, the Senat considers that essential elements of the proposed Regulation are conferred to the Commission to be adopted via implementing and delegated acts, including the detailed procedures for carrying out clinical assessments.

The Commission would like to recall that the proposal sets out four pillars of joint work at Union level, of which cooperation on clinical assessments is one. With respect to the clinical assessments, the proposal includes a definition of this term, which sets boundaries on what is included in these assessments, clear limitations on the conclusions of joint clinical assessment reports, detailed procedures for carrying out joint clinical assessments and a support framework for joint work at Union level. The proposal also sets out three additional pillars of joint work on joint scientific consultations, the identification of emerging health technologies and voluntary cooperation.

The Commission is convinced that all essential elements of the initiative have been included in the proposal and that the balance between the content of the basic act and the use of tertiary legislation is appropriate, as is the choice made between the use of implementing and delegated powers. In making these choices, the Commission acted in full respect of Articles 290 and 291 of the Treaty on the Functioning of the European Union and the relevant jurisprudence of the Court of Justice of the European Union. Consequently, the Commission believes that the proposal does not prevent the Senat from carrying out an assessment of its compliance with the principle of subsidiarity.

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 Senat and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Frans Timmermans
First Vice-President

Vytenis Andriukaitis
Member of the Commission