



EUROPEAN COMMISSION

*Brussels, 24.7.2018  
C(2018) 4109 final*

*Dear President,*

*The Commission would like to thank the Senát 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 main objectives of the proposal is 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. The Commission appreciates the Senát's support to the approach taken on joint clinical assessments and the important aim of improving the quality of health technology assessments undertaken at European Union level. Moreover, the Commission welcomes the opportunity to provide a number of clarifications regarding its proposal and trusts that these will allay the Senát's concerns.*

*The Senát considers that the requirement in Article 6(12) of the proposal concerning the approval by the Coordination Group of the joint clinical assessment reports is not clear.*

*The Commission would like to stress that the proposal intends to create a system whereby Member States' health technology assessment authorities and bodies would work together to produce joint clinical assessment reports which they themselves will use in their national health technology assessments. The assessor and co-assessor for each joint clinical assessment would lead this work and the other members would have an opportunity to comment on the draft reports at sub-group level. These health technology assessment bodies will thus take turns as assessors and peer review each other's work, building trust amongst them. Once agreement is reached on the draft reports at sub-group level, the Commission expects that an approval of the reports at Coordination Group level will be possible by consensus in the vast majority of cases. Where a vote is necessary, the proposal provides for a system of one vote per Member State, and a simple majority of members would be needed to approve the reports.*

*Mr Milan ŠTĚCH  
President of the Senát  
Valdštejnské náměstí 17/4  
CZ – 118 01 PRAGUE 1*

*The Commission notes the Senát's objection to the proposed delegation of powers to the Commission and its view that more detail should be included in the basic act concerning the substance of the joint clinical assessments and joint scientific consultations.*

*In that regard, the proposal sets out four pillars of joint work at Union level, of which cooperation on clinical assessments and joint scientific consultations are two. With respect to 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 a similar level of detail on joint scientific consultations.*

*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 European Court of Justice.*

*The Commission trusts that the 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.*

*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 Senát and looks forward to continuing the political dialogue in the future.*

*Yours faithfully,*

*Frans Timmermans  
First Vice-President*

*Vytenis Andriukaitis  
Member of the Commission*