EUROPEAN COMMISSION

Brussels, 5.6.2018
C(2018) 3682 final

Dear President,

The Commission would like to thank the Bundestag for its Reasoned 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 very seriously the concerns expressed by the Bundestag as regards the principles of subsidiarity and proportionality and the rights and obligations of Member States under Article 168(7) of the Treaty on the Functioning of the European Union. The Commission believes that the proposal complies with these principles and is pleased to have this opportunity to provide a number of clarifications regarding the proposal, trusting that these will allay the Bundestag's concerns.

The Bundestag notes that under Article 168(7) of the Treaty on the Functioning of the European Union, Member States retain the responsibility for the definition of their health policy and for the organisation and delivery of health services and medical care. On that basis, the Bundestag questions whether the proposal complies with this provision.

The Commission would like to stress that medicines and medical devices are products which benefit from the principle of free movement of goods within the internal market, while the currently existing diversity of national rules contributes to distorted market access for health technologies. Against that background, the proposal aims 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 European Union. The Commission therefore considers that Article 114 of the Treaty on the Functioning of the European Union constitutes the proper legal basis for the proposal.

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The Commission does not share the view that the proposed Regulation would encroach upon Member States' rights and obligations under Article 168(7) of the Treaty on the Functioning of the European Union. The proposal provides that the clinical assessment part of health technology assessment in cases covered by the proposal, would be carried out at Union level, while Member States would continue to carry out the non-clinical assessment part. The proposal does however not oblige Member States to carry out an assessment on health technologies which are the subject of joint clinical assessments. The 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 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.

The Bundestag also questions whether the mandatory nature of the joint clinical assessments is a necessary and proportionate response to the stated objectives of the proposal and whether continued voluntary cooperation could not equally achieve these objectives.

The Commission would 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 EU-funded initiatives such as the three Joint Actions (EUnetHTA). As outlined in the impact assessment 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 output of the joint work. The Commission therefore considers that the mandatory use of joint clinical assessment reports is a necessary and proportionate approach to dealing with the problems identified and for achieving the objectives of the proposal.

The Bundestag also considers that the output of the joint work at Union level may be of a lower quality than the assessments currently produced by the German health technology assessment bodies.

The Commission would like to stress that, as outlined in recital 19 of the proposal, high quality and timely assessment reports are a key proponent of the joint work. For this reason, the Commission would expect Member States to nominate health technology assessment bodies with a high level of expertise as members of the coordination group and its sub-groups. Assessors and co-assessors bodies for each assessment would be selected based on their expertise and suitability to lead each assessment and all member

bodies of the relevant sub-group would have an opportunity to review the draft reports and provide their inputs.

Moreover, there is an important link between the quality of the assessments and the mandatory nature of both submissions from health technology developers and the use of the assessment report at Member State level. By ensuring that the reports will be used by Member States in their national health technology assessment processes, incentives would be created for both health technology developers to provide quality and complete submissions of data and evidence and for Member States' bodies to work together to produce high quality reports to be used in their national systems.

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 above clarifications address the issues raised by the Bundestag and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Frans Timmermans
First Vice-President

Vytenis Andriukaitis
Member of the Commission