EUROPEAN COMMISSION

Brussels, 28.6.2018
C(2018) 4106 final

Dear President,

The Commission would like to thank the Poslanecká sněmovna 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 seriously the concerns expressed by the Poslanecká sněmovna as regards the proposal's compliance with the principle of subsidiarity, in particular in relation to the choice of legal basis and the rights and obligations of Member States under Article 168(7) of the Treaty on the Functioning of the European Union. The Commission is pleased to have this opportunity to provide a number of clarifications regarding the proposal and trusts that these will allay the Poslanecká sněmovna's concerns.

The Poslanecká sněmovna questions whether Article 114 of the Treaty on the Functioning of the European Union is an appropriate choice of legal basis for the proposal. In that regard, 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 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. The Commission therefore finds that Article 114 of the Treaty on the Functioning of the European Union is the proper legal basis for the proposal.

The Poslanecká sněmovna recalls 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 Poslanecká sněmovna questions whether the proposal respects this provision.

Mr Radek VONDRÁČEK
President of the Poslanecká sněmovna
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The Commission does not share the Poslanecká sněmovna's view that the proposed Regulation would impinge upon the 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 not, however, 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 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 Poslanecká sněmovna and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Frans Timmermans
First Vice-President

Vytenis Andriukaitis
Member of the Commission