EUROPEAN COMMISSION

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Dear Chair,

The Commission would like to thank the Sejm 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 Sejm and is pleased to have this opportunity to provide a number of clarifications regarding its proposal and hopes that these will allay the Sejm's concerns.

The Commission notes the Sejm's remark that the Union's competence in the field of human health is limited to actions to support, coordinate or supplement the actions of Member States. Moreover, the Sejm 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.

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. 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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Moreover, the Commission does not share the Sejm's view that the proposed Regulation would impinge 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 the health technology assessment, in cases covered by the proposal, is to 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. 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 also notes the Sejm's view that the legal instrument proposed is not appropriate and that soft law tools could be used to meet the stated 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 under the European Network for Health Technology Assessment. As outlined in the impact assessment report accompanying the proposal, this cooperation has shown the potential of Member States working together on health technology assessment at Union level, but it has not substantially dealt with the impeded and distorted market access or the duplication of health technology assessment across Member States. 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 a Regulation is the most appropriate tool for dealing with the problems identified and for achieving the objectives of the initiative.

Finally, the Commission notes the Sejm's objection to the proposed delegation of powers to the Commission. The Commission's approach to the delegation of power is based on the principle that acts adopted through a legislative procedure best ensure the democratic legitimacy envisaged by the Treaty. However, properly used, delegated powers are an integral tool of better law-making, contributing to simple and up-to-date legislation and its efficient and swift implementation. On that basis the Commission is convinced that all essential elements of the initiative have been included in the proposal and that the balance between the contents 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 case-law of the European Court of Justice.

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 is confident that these discussions will allow taking the Sejm's concerns into account and will conclude with a text presenting an ambitious approach that paves the way for further cooperation between the Union and its Member States.

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

Yours faithfully,

Frans Timmermans
First Vice-President

Vytenis Andriukaitis
Member of the Commission