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OPINION

of the Foreign and European Union Affairs Committee of the Senate of the Republic of Poland

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

adopted at the sitting on 5 April 2018.

- 1. The Foreign and European Union Affairs Committee of the Senate of the Republic of Poland (FEUAC) does not support 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).**
- 2. The FEUAC believes that the proposed Regulation is not compatible with the principle of legality in view of the fact that the European Commission has founded it on an inappropriate legal basis.** Article 114 TFEU allows harmonizing the laws of Member States when it is necessary to ensure functioning of the internal market. The proposal of the Regulation introduces an obligation for Member States to cooperate in health technologies assessment (HTA), to unify the HTA tools, procedures and methodology. Moreover, in some cases, this process is to be supervised by the Commission. In the opinion of the FEUAC, only Article 168 of TFEU is the right one for undertaking actions aimed at improving the quality and safety standards of medical products and medical devices. Particularly, the Commission has not indicated that the purpose of the proposed act is to improve functioning of the internal market. Especially, the Commission has not indicated the impact of the proposed harmonization and unification of the procedures on internal market freedoms (movement of goods and services).
- 3. In relation to the above, the FEUAC's opinion is that the proposed Regulation is inconsistent with the principle of conferral, as defined in Article 5(1) and (2) of TEU.** Taking Article 168 of TFEU for the legal basis makes it impossible to adopt harmonizing measures in the field of public health. According to Article 6 of TFEU, the EU only has the power to support, coordinate or supplement the Member States' actions, but not to replace them.
- 4. In the opinion of the FEUAC, the proposed Regulation is not compatible with the principle of proportionality.** The European Commission has not indicated what forms of coordination and cooperation in health technologies assessment are currently

inadequate or can be improved by harmonizing the procedures in this field and replacing the voluntary principle with obligatory cooperation of entities from different countries. Nor has it indicated how the replacement of national authorities by the Commission would contribute to a better functioning of health technology assessment. Moreover, in the FEUAC's opinion, to achieve the objectives of the proposed regulation it would be sufficient to impose the obligation of taking joint clinical evaluation into account, without simultaneously prohibiting the conduct of own clinical assessment. Such prohibition does not comply with the principle of proportionality.

- 5. In the FEUAC's opinion, the proposed regulation violates Article 290 and 291 TFEU and, consequently, Article 12 TEU.** The proposed regulation assigns many key issues to delegated and implementing acts. These include, among others, all regulations regarding administrative procedures both in the joint clinical evaluation and in the evaluation carried out by Member States. At the same time, the proposal lacks even general information about delegated and implementing acts. In the FEUAC's opinion, these acts will regulate essential elements, which is inconsistent with Article 290 and 291 TFEU. In addition, the consequence of regulating essential elements by means of delegated and implementing acts is to prevent national parliaments from controlling the compliance of adopted acts with the principle of subsidiarity. Thus, the proposed regulation infringes Article 12 TEU in this respect.