

Opinion No. 30
of the European Union Affairs Committee of the Sejm of the Republic of Poland
on
“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)”
adopted at the 191st meeting on 22 March 2018

The European Union Affairs Committee of the Sejm of the Republic of Poland:

1. 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 final)”;
2. welcomes the position of the government of the Republic of Poland on the above-mentioned matter;
3. notes that pursuant to Article 6 of the TFEU the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States in the area of the protection and improvement of human health;
4. also stresses that the competence of the Union shall not supersede the competence of the Member States related to that area, whereas acts of the Union shall not entail harmonisation of Member States' laws or regulations (Article 2(5) of the TFEU);
5. considers that 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)” does not comply with the principle of subsidiarity;
6. notices the risk of partial loss of the basic competence of the Member States to manage health services and medical care and to allocate the resources assigned to them, which could make it impossible to develop a state health policy, including a drug policy, and make rational plans and predictably use public resources on the drug reimbursement system, taking into account Polish conditions and national interests;
7. notices that pursuant to Article 168(7) of the TFEU Member States shall be responsible for the protection of citizens against any health risks;
8. considers that the adoption of the form of the Proposal for a Regulation by the European Commission does not comply with the principle of proportionality and believes that the implementation of the objectives set and the achievement of greater coherence by individual states does not require adoption of a regulation;

9. calls the European Commission to propose soft non-legislative tools, such as recommendations, development of cooperation under the European network for Health Technology Assessment (EUnetHTA) or joint activities;
10. assesses that the excessive application of delegated and implementing acts to make the Proposal more specific violates the principles of sound legislation and hinders proper evaluation of the Proposal, especially as it does not specify such acts;
11. notices that such an approach may restrict the influence of individual Member States on the final provisions of delegated acts, whereas such acts are not adopted under a regulation;
12. states that it will submit the adopted opinion, as part of the political dialogue, to the President of the European Commission, the President of the European Parliament and to the Bulgarian Presidency.

Chair of the European Union Affairs Committee

/-/ Izabela Kloc