

Courtesy translation



THE SENATE
OF THE PARLIAMENT OF THE CZECH REPUBLIC
11TH TERM

365th

RESOLUTION OF THE SENATE

Delivered on the 13th session held on 4th April 2018

**on the Proposal for a Regulation of the European Parliament and of the Council
on health technology assessment and amending Directive 2011/24/EU**

(Senate Print no. N 110/11, COM(2018) 51)

The Senate

I.

1. Appreciates and supports

in general the effort of the European Commission to improve the cooperation between the Member States regarding health technology assessment, the purpose of which is the improvement of the availability of innovative health technology for patients in the EU, removal of the duplicate assessment, i.e. on the EU level and on the national level, improvement of the quality of the undertaken health technology assessments and of the predictability for the enterprises;

2. Disagrees

with the position of the Government as it is currently formulated, mainly regarding the preference for the voluntary cooperation at the EU level and promotion of the principle of subsidiarity in the case of the methodology of clinical assessments;

3. Is of the opinion

in this regard that a highly qualified, critical, objective and respected assessment of benefits of the concrete medical innovation cannot be permanently secured only on the national level or only on the voluntary basis and that this activity has to be managed in a standardised, reliable manner and without unnecessary delay; on the contrary, decision-making about the reimbursement, economic and social benefits and consequences of the internationally recommended innovations should remain within the competence of a Member State reflecting its own conditions;

4. Emphasizes

- that the Commission has an obligation to comply with a high level of protection of health when submitting a proposal based on the Article 114 of the Treaty on the Functioning of the EU which primarily seeks to achieve the approximation of the law, regulation and administrative action with the objective of the establishment of a functioning internal market;
- that the aim of the Proposal and all the related measures should be, in the first place, the increase of the quality of the health technology assessment undertaken at the EU level;

5. Demands

clarification of decision-making rules of the Coordination Group because the Senate considers the wording of Article 6(12), according to which the Coordination Group approves the reports "wherever possible by consensus or, where necessary, by simple majority of Member States", to be vague;

6. Disagrees

with the extensive empowerment of the Commission to adopt delegated or implementing acts because it makes an overall assessment of the content of the Proposal considerably more difficult; in this regard, the Senate recalls its resolution No. 26 from 30th November 2016 on 2015 annual reports from the Commission on relations between the Commission and the national parliaments and on subsidiarity and proportionality;

7. Points out

to the fact that the Proposal is empowering the Commission to establish procedural rules for the joint scientific consultations and joint clinical assessments, such as rules for submitting information, data and evidence by the relevant health technology developers or for the appointments of assessors and co-assessors;

8. Requires

the substance of these matters to be regulated in the legislative act itself because the legislative act is adopted in a more transparent procedure in the Council and the European Parliament;

II.

1. Requests

the Government to inform the Senate about the way this resolution was taken into account and about further development of negotiations once the political agreement of the required number of Member States on the main elements of the proposal is reached, or at an earlier time, should the results of negotiations in the Council begin to depart considerably from the position of the Czech Republic expressed in the General Position of the Government;

2. Authorises

the President of the Senate to forward this Resolution to the European Commission.

Milan Štěch
sign manual
President of the Senate

Zdeňka Hamousová
sign manual
Senate Verifier