Parliament of the Czech Republic

CHAMBER OF DEPUTIES

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61.

RESOLUTION

Committee on European Affairs
of the 9th meeting
of 28 March 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 (document code 5844/18, COM (2018), 51 final, SEC (2018) 82 znění/

The Committee on European Affairs of the Chamber of Deputies of the Parliament of the Czech Republic, after hearing information from the Deputy Minister for Health MrFilip Vrubela posl, after hearing the news reports.Pavel Plzáka, and following a debate,

A p p r o v e s the opinion annexed to this resolution.

Jiří
the verifier

Pavel Plzák Kobza
rapporteur

BENEŠÍK Ondřej
the Chair

Annex to Resolution No61

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, EU Council No 5844/18
Interinstitutional file: 2018/0018/COD (COD)

- **Legal basis:**
  Article 114 of the Treaty on the Functioning of the European Union.
- **Date sent to Chamber of Deputies via the European Affairs Committee:**
  6.2.2018
- **Date of discussion by European Affairs Committee:**
  15.2.2018 (1st round)
- **Procedure:**
  Ordinary legislative procedure.
- **Provisional opinion of the government (pursuant to Paragraph 109a1 of the Rules of Procedure of the Chamber of Deputies):**
  Dated 7 February 2018, delivered to the Committee for European Affairs on 1 March 2018 via the ISAP system.
- Evaluation with regard to the subsidiarity principle:
  See the resolution.
- **Justification and subject:**
  Health technology assessment[1] is a process that is based on scientific evidence and aims to establish the effectiveness of new health technologies compared to existing technologies.Technologies shall be evaluated on the basis of their clinical and non-clinical (e.g. economic) aspects, the clinical aspects of the existing cooperation within the area identified as suitable for EU cooperation.Currently, cooperation between Member States based on a voluntary basis and supported from EU sources.

  Despite the development of this cooperation, the Commission identified several problems.The first problem is the different administrative approaches to HTA bodies, the technology on the market, different markets in individual Member States face different requirements regarding data and evidence.This leads to different time delays, and inequalities in patients' access to technology.The second problem is the duplication of national authorities which evaluates medical technologies.This means that there is a situation where at the same time in different Member States are more clinical trials to one technology, results of clinical trials may be different depending on the requirements in force in the Member State concerned.In the

[1] health technology in the draft Regulation a health technology within the meaning of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare:"a medicinal product or a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.

Commission's view this is inefficient, reduces the predictability and introduces inequality in patients' access to health technologies.Finally, the third problem is the form of past cooperation, based on short-term projects and not on permanent scientific cooperation which can lead to high administrative costs and uncertain conditions for scientific activities.

In particular, on the basis of those reasons the Commission decided to submit a proposal for legislation that would address the problems described above, and thus contribute to the better functioning of the internal market and to ensure a high level of health protection.

- **Content and impact:**
Proposal for a Regulation establishes a coordination group of Member States on health technology assessment.This group (which is managed by the Member States) to ensure cooperation.The sub-group will act within this group composed of experts appointed by the Member States who will perform the tasks provided for in the draft Regulation.

Cooperation under the draft Regulation itself is carried out on the basis of four pillars common clinical trials, scientific consultation, identification of new health technologies and voluntary cooperation.

As regards the **common clinical trials**, the first pillar proposal, those relating to certain medicinal products[2], certain medical devices[3] and in vitro diagnostic medical devices.[4]The purpose of the proposal is relatively broad scope of the evaluation was to be the most innovative technologies and technologies with the greatest impact in terms of public health. Common clinical trials are to be introduced gradually during a transition period.

Common clinical evaluations cover four areas:

- a description of the health problem, which addresses the health technology,
- description of other health technologies currently used to address the same health problem,
- a description of the technical characteristics and technology,
- the relative clinical effectiveness and safety of health technologies

A report on those evaluations.The draft Regulation lays down the procedure for processing such reports and some other procedures (e.g. selection of evaluators or spoluhodnotitelů Member States) will be determined in the tertiary legislation. Health technology complying with all requirements under the proposal for a Regulation, shall be included in a specific list of the technologies for which the clinical evaluation was carried out.The draft Regulation provides that Member States accede to the HTA on the above list, must use the joint reports and not repeat the clinical evaluation in the actual evaluation of health technologies. However, this does not apply to neklinická evaluation of technologies, in particular as regards

[2] in particular medicinal products subject to the centralised marketing authorisation procedure, the new active substances and preparations whose registration is extended to include a new indication.

[3]Therefore devices classified in class IIb and III in accordance with Article 51 of Regulation (EU) 2017/745, the relevant expert groups to provide a scientific opinion within the clinical evaluation consultation procedure in accordance with Article 54 of that Regulation.

[4]I.e. in vitro diagnostic medical devices classified in class D in accordance with Article 47 of Regulation (EU) 2017/746 17, the relevant expert groups to provide their opinion in the framework of the procedure in accordance with RuleParagraph 486 of the Regulation.E.g. the means selected by the expert groups for unmet medical need, an important cross-border dimension or added value for the EU, etc.

economic, organisational or ethical aspects.In these areas, Member States can carry out the evaluation without restrictions.

The second pillar of the proposed amendments are **common scientific consultation**.These consultations are, in substance, the preliminary or early dialogue between the evolving technology and the coordination group. Such a procedure should serve to entities operating healthcare technologies could adjust their activities to any future clinical evaluation requirements already at the development stage.The result of the joint scientific consultation to be reports on joint scientific consultations which will however be closed and will not be binding either for the body concerned.

The third pillar is **the area of new health technologies**.Under the draft Regulation, the coordination group has prepared an annual study to timely identify new medical technologies, and will focus on those which can have a significant impact on the patients or the healthcare system.

The fourth pillar of the proposed modification is **voluntary cooperation**.The proposal is to allow Member States, on a voluntary basis, cooperate at EU level in areas which do not fall under the common clinical trials. These are areas related to the non-clinical health technology assessments;kolaborativními assessments of medical devices;health technology assessments other than medicinal products or medical devices;by providing additional evidence necessary to support health technology assessment.

The proposal also sets out common rules for clinical trials at national level, to be elaborated in detail through tertiary legislation.These rules should lead to clinical trials will be carried out in an independent, transparent and without conflicts of interest.As regards the enabling framework, financing the activities of the coordination group provides the Union;similarly provides administrative and IT support.

Impact on the state budget and legal order of the Czech Republic:

The **issue of the compliance of the proposal with the principle of subsidiarity.The issue of the legal basis.**

Under the principle of subsidiarity, enshrined in Art.Paragraph 53 of the Treaty on European Union (TEU) and Protocol (No.2 on the application of the principles of subsidiarity and proportionality, that 'the Union shall *act in areas which do not fall within its exclusive competence only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States at central, regional or local level, but rather, by reason of its scale or effects, can be better achieved at Union level 'Very simply this means that a draft legislative act* is assessed according to whether the added value that the issue is transferred from the competence of the Member States at EU level.In the event that the assessment is negative, it can be considered that the proposed adjustment is not in line with this principle.On the contrary, in the event that the proposal is found to be added value, considering that the proposed adjustment is in line with the principle of subsidiarity.

In the context of the parliamentary scrutiny of the subsidiarity principle is the result of a specific proposal for assessment of compliance with the principle of subsidiarity and the differences in political beliefs and value orientation of a member of a national parliament.The starting point for the considerations under the proposed regulation is a crucial question whether the clinical trial (or a significant part of it) be made at EU level, or be left to Member States.

The second aspect of this issue may be linked to an incorrect legal basis of a proposal for a legislative act or even contradiction of the proposal with the provisions of the Treaties.In this case, whilst it is indicated as a legal basis Art.114 of the TFEU, which allows the adoption of provisions with a view to the establishment of the internal market but there are nevertheless views (see opinion of the Czech Government) that the issue can ultimately also relate to Art.Paragraph 1687 TFEU, which stipulates that the organisation of health care and health policy, including the allocation of resources, is the responsibility (and thus within the competence of the Member States and the European Commission in the form of ingerence legislative proposals is excluded.In this context is the question of whether the proposal in its consequences (in particular with regard to the clinical trial) does not affect the power of the Member States to organise health system because, according to these views clinical trials not necessarily separable from the specific national conditions and consequences of the non-clinical evaluation of clinical trial may negatively reflected for example in the balance of the health system.On the other hand, the Commission believes that the proposal by strictly separates neklinická clinical evaluation, and does not interfere with the competence of the Member States and is thus konformní with the requirements of EU law.

- **Opinion of the Czech Government:**
  The Government of the Czech Republic generally welcomes the Commission initiative in the field of clinical health technology assessment, however, the content of the proposal has major reservations.Rejects the proposal in principle laid down the obligation to adopt common clinical trial of pharmaceuticals in HTA at national level within the meaning of the sole possible, final and selection of comparators limited conclusion.Considers that such a practice is at odds with the principle of subsidiarity and with ArticleParagraph 1687 TFEU.The Czech Republic also calls into question the purpose of the proposal, which is to improve and accelerate patients' access to new technologies, while considering that hamper access prices and costs of new technologies rather than differences in the clinical trial.In the framework of health technology assessment for medical devices also believes that decision-making at EU level should not be binding on Member States.

- **Senate discussion in the Czech Republic**
  The draft Regulation was discussed in Committee on Health and Social Policy and the Committee on EU Affairs.Committee on Health and Social Policy (hereinafter "the VZSP") in its opinion welcomed the[5] Commission initiative."VZSP *disagrees with the opinion of the Government, as currently formulated, in particular regarding the preference for voluntary cooperation at EU level and promoting the principle of subsidiarity in clinical trials methodology." In its opinion further* takes the view that 'highly qualified, critical, objective *evaluation of the benefits of specific medicínských respektované innovation cannot be permanently ensure only at national level or on the basis of voluntary cooperation, and that this activity should be to manage standardizovaně, reliably and without undue delay;On the contrary, remain within the competence of the States to decide how payments, economic and social benefits and consequences of the internationally recommended innovation in that country according to their own circumstances.*In its opinion, also requested to clarify the *rules, particularly for decisions of the coordination group when the group shall act by consensus and moves to a vote by simple majority, as it considers that the Coordination Group approves the wording 'if possible by consensus, or by simple majority of the Member States, where necessary, referred to in Article 612 vague."*

[5]See Annex resolution VZSP No94/2018

The Committee on EU Affairs adopted a similar opinion[6] in which it expressed support for EU efforts in the area of health technology assessment.However, compared to the opinion *"VZSP disagreed with extensive mandate for the Commission to issue delegated acts or implementing acts, since this greatly hinders a comprehensive assessment of the content of the proposal;recalls, in this context, the Senate resolution No26 of 30 November 2016 of the Commission's annual report for 2015 on relations between the Commission and national Parliaments and on subsidiarity and proportionality.' It pointed out that "the proposal confers on the Commission the power to lay down the procedural rules for joint scientific consultation and common clinical trials, such as rules on the submission of information, data and evidence of health technology development bodies or for the appointment of evaluators and spoluhodnotitelů" Committee on EU Affairs "demands, in this context, that* these questions substantivně covered directly in the legislative act, which is adopted in a more transparent way based on the discussion at the Council and the European Parliament."

- **Envisaged timetable in the EU institutions:**
  As the committee responsible for the discussion of this document at the European Parliament designated the Committee on the Environment, Public Health and Food Safety.Yet not discussed in this document.

- **Conclusion:**

  European Affairs Committee

  1. **He is aware** of 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. **Is of the opinion 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, is in breach of the subsidiarity principle referred to in ArticleParagraph 53 of the Treaty on European Union, since the clinical aspects of health technology assessment cannot simply be separated from economic aspects in particular health technology assessment and thus interferes with the proposed adjustment of the responsibility of Member States for health systems and health care (including allocation of resources) as defined in ArticleParagraph 1687 TFEU;

  3. **Adopt** a reasoned opinion within the meaning of ArticleProtocol (No 6)2) on the application of the principles of subsidiarity and proportionality;

  4. **Supports the** framework position of the government;

  5. **Instructs** the President of the European Affairs Committee, in accordance with the Rules of Procedure of the Chamber of Deputies forward this resolution via government of President of the Chamber of Deputies, the President of the Senate, the President of the European Parliament, the President of the Council and the President of the European Commission;

[6]See Annex to Resolution No21th meeting of the VEU 188 from 21.3.2018.

6. **T h e** proposal for a Regulation and the framework position of the Government Committee for Health for information.

Jiří
the verifier

Pavel Plzák Kobza
rapporteur

BENEŠÍK Ondřej
the Chair