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Committee on Legal Affairs
The Chair

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Ms Adina-Ioana Vălean
Chair
Committee on the Environment, Public Health and Food Safety
STRASBOURG

Subject: Opinion on the legal basis 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)0051 – C8-0024/2018 – 2018/0018(COD))

Dear Chair,

By letter dated 3 July 2018, you asked the Committee on Legal Affairs, pursuant to Rule 39(2) of Parliament's Rules of Procedure, to provide the Committee on the Environment, Public Health and Food Safety with an opinion on the appropriateness of a modification of the legal basis of the proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

More specifically, the Commission proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU) alone. The Rapporteur and another Member tabled similar amendments aiming at changing the legal basis to Articles 114, 168(4) and 168(7) TFEU.[1]

I - Background

"Health technology" is to be understood in a broad sense comprising medicinal products, medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare. Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. That process assesses a new or existing technology and compares it

[1] Considering the amendments in annex to the ENVI letter, the reference to Article 192 TFEU (environment) in the letter itself should be read as a reference to Article 114 TFEU.

with other health technologies and / or the current standard of care. HTA covers different aspects ranging from clinical domains (e.g. safety, clinical effectiveness) to non-clinical domains (e.g. economic, ethical organisational). It is used to inform decision-making in Member States by providing a scientific evidence base for decisions on the pricing and reimbursement of health technologies.

Cooperation between Member States has been ongoing since the 1980s on a voluntary basis. The on-going EU cooperation on HTA mainly consists in EUnetHTA Joint Actions and HTA Network, which was established by the cross-Border Healthcare Directive (Directive 2011/24/EU) in order to provide strategic and political guidance to the scientific and technical cooperation.

The Commission committed in its communication "*Upgrading the Single Market: more opportunities for people and business*" to introduce an initiative on Health technology assessment with a view to improving the functioning of the Single Market of health technologies, in particular in order to avoid duplication of efforts for Member States and industry.

The Commission considers that the on-going EU cooperation on HTA, although having illustrated benefits of EU cooperation, has not contributed to the removal of the fragmentation of the internal market, or the duplication of assessments. It identifies three major problems: 1) impeded and distorted market access due to the fact that technology developers have to deal with diverging national HTA processes and methodologies which can potentially lead to different HTA conclusions; 2) Duplication of work for national HTA bodies means that they carry out in parallel or within a similar time-frame, clinical assessments on the same health technologies. 3) Unsustainability of HTA cooperation, as the current EU cooperation on HTA is project-based with no guarantee for the continuation of activities or their financing in the long-term. By carrying joint clinical assessments, economies of scale, greater business predictability, increased quality and consistency and improved transparency for patients would be achieved in the long run.

II - Relevant Treaty Articles

The following Article of the Treaty on the Functioning of the European Union is presented as the legal basis in the Commission proposal:

Under Chapter 3 on "Approximation of laws":

Article 114
(ex Article 95 TEC)

1. Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.
In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.
When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 258 and 259, the Commission and any Member State may bring the matter directly before the Court of Justice of the European
Union if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic

reasons referred to in Article 36, provisional measures subject to a Union control procedure.

The ENVI request concerns also Article 168 Under Title XIV "Public health" and notably paragraphs 4 and 7:

Article 168
(ex Article 152 TEC)

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.
Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.
The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.
Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation.
The European Parliament shall be kept fully informed.
3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:
(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;
(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and

improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

In addition, given the cross references made, the following Articles should be looked at:

Article 2(5)

5. In certain areas and under the conditions laid down in the Treaties, the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States, without thereby superseding their competence in these areas.

Article 4

1. The Union shall share competence with the Member States where the Treaties confer on it a
competence which does not relate to the areas referred to in Articles 3 and 6.

2. Shared competence between the Union and the Member States applies in the following principal areas:

[...]

(k) common safety concerns in public health matters, for the aspects defined in this Treaty.

[...]

Article 6

The Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States. The areas of such action shall, at European level, be:

(a) protection and improvement of human health;

[...]

III – CJEU case law on the choice of legal basis

The Court of Justice has traditionally viewed the question of the appropriate legal basis as an issue of constitutional significance, guaranteeing compliance with the principle of conferral of powers (Article 5 TEU) and determining the nature and scope of the Union's competence.[1] The choice of a legal basis is therefore not discretionary. According to settled case law of the Court of Justice, the choice of legal basis for a Union measure must rest on objective factors amenable to judicial review, which include in particular the aim and content of the measure. If examination of a measure reveals that it pursues a twofold purpose or that it has a twofold component one of which is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, that measure must be based on a single legal basis, namely that required by the main or predominant purpose or component.[2]

IV - Aim and content of the proposal

The Explanatory Memorandum enumerates the objectives of the proposal, and distinguishes between the *general objectives*, namely to ensure a better functioning of the internal market and to contribute to a high level of human health protection, the *specific objectives*, namely to improve the availability of innovative health technologies for EU patients, to ensure efficient use of resources and strengthen the quality of HTA across the EU, and to improve business predictability, and the *operational objectives*, namely promote convergence in HTA tools, procedures and methodologies, reduce duplication of efforts for HTA bodies and industry, ensure the use of joint outputs in Member States, ensure the long-term sustainability of EU HTA cooperation.

Recital 5 states that *"the carrying out of parallel assessments by multiple Member States and divergences between national laws, regulations and administrative provisions on the processes and methodologies of assessment can result in health technology developers being confronted with multiple and divergent request for data"* and that *"[i]t can also lead to both duplication and variations in outcomes that increase the financial and administrative burdens that act as a barrier to the free movement of the health technologies concerned and the smooth functioning in the internal market"*.

According to recital 6, *"the duplication of assessments on the same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed."*

Recital 10 provides that *"[I]n order to ensure a better functioning of the internal market and contribute to a high level of human health protection it is appropriate to approximate the rules on carrying out clinical assessments at national level and clinical assessments of certain health technologies at Union level, and which also support the continuation of voluntary cooperation between Member States on certain aspects of HTA."*

Recital 16 states that *"[i]n order that the harmonised procedures fulfil their internal market objective, Member States should be required to take full account of the results of joint clinical assessments and not repeat those assessments."*

[1] *Opinion 2/00* [2001] ECR I-9713, paragraph 5

[2] See judgment of 8 September 2009, Commission v Parliament and Council, C-411/06, EU:C:2009:518, paragraphs 45 to 47

Finally, according to recital 34, the objectives of the proposed regulation is *"to approximate the rules of the Member States on carrying out clinical assessments at national level and establish a framework of mandatory joint clinical assessments of certain health technologies at Union level"*.

Article 1 of the proposal explains that the regulation establishes a support framework and procedures for cooperation on health technology assessment at Union level and common rules for the clinical assessment of health technologies. It should be noted that the scope of the proposed regulation is limited to those aspects of HTA that relate to the clinical assessment of a health technology.

To this end, Chapter II establishes the four pillars of the future cooperation between Member States (namely: joint clinical assessments, joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation) and Chapter III (Articles 20 to 23) sets out harmonised rules - including common procedural rules and methodology - for joint clinical assessments and clinical assessments of medicinal products and medical devices carried out by Member States.

More specifically, the proposal establishes the Member State Coordination Group on Health Technology Assessment (Article 3) that shall carry out joint clinical assessments (Article 5) on certain medicinal products, medical devices and in vitro diagnostic medical devices.
According to Article 8(1), Member States shall not carry out a clinical assessment where such assessment has been done in accordance with the Regulation and shall apply joint clinical assessment reports adopted under the Regulation, in their health technology assessments at Member State level. At the same time, Article 34 contains a "*safeguard clause*" according to which Member States may, subject to the Commission approval, carry out a clinical assessment using means other than the rules provided for in Chapter III of the Regulation, if it is to protect public health in the Member State concerned and provided the measure is justified, necessary and proportionate as regards achieving that aim. The proposal gives the Commission the power to adopt, by means of implementing acts, detailed procedural rules for joint clinical assessment.

The proposal also provides for the possibility for health technology developers to request the Coordination Group a joint scientific consultation in order to obtain scientific advice concerning data and evidence likely to be required as part of a joint clinical assessment (Article 12). When a joint consultation has been initiated on a health technology, Member States shall not carry out a scientific consultation or an equivalent consultation when the content of the requests are the same (Article 14(3)).

The Coordination Group shall annually prepare a study on emerging health technologies expected to have a major impact on patients, public health or healthcare systems (Article 18). The Commission shall support cooperation and the exchange of scientific information among Member States on a range of topics (Article 19).

Finally, the proposal provides for a support framework and in particular rules on Union funding, and deletes Article 15 of Directive 2011/24/EU, which deals with cooperation on health technology assessment.

V- Analysis of the legal basis

It has to be noted from the outset that this analysis is based on the Commission's proposal. Further analysis of the legal basis could be necessary if amendments adopted in the vote in committee substantially altered the aim and content of the proposal.

Article 114(1) TFEU establishes that the Parliament and the Council are to adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. According to case-law, while a mere finding of disparities between national rules is not sufficient to justify having recourse to Article 114 TFEU, it is otherwise where there are differences between the laws, regulations or administrative provisions of the Member States which are such as to obstruct the fundamental freedoms and thus have a direct effect on the functioning of the internal market. It is also settled case-law that although recourse to Article 114 TFEU as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade as a result of divergences in national laws, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them. [1]

The Court has also held that, provided that the conditions for recourse to Article 114 TFEU as a legal basis are fulfilled, the EU legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made.[2]
The first subparagraph of Article 168(1) TFEU provides that a high level of human health protection is to be ensured in the definition and implementation of all EU policies and activities, and that Article 114(3) TFEU explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed."[3]

Art. 168(4) TFEU sets out that, by way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) that provides that the Union shares competence with the Member States regarding "*common safety concerns in public health matters, for the aspects defined in [the] Treaty*", the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in Article 168 through adopting, in order to meet common safety concerns, certain measures relating to public health. Those measures shall contribute to the achievement of the objective of ensuring a high level of human health protection set out in Art. 168(1) TFEU, "*in order to meet common safety concerns*".
Among those measures, Article 168(4)(c), which provides for *"measures setting high standards of quality and safety for medicinal products and devices for medical use",* is a priori the only one relevant for the legislative proposal at issue.
It should be added that, contrary to the measures adopted under Article 168(5), Article 168(4) does not exclude any harmonisation of the laws and regulations of the Member States.

[1] See e.g. judgement of 4 May 2016, *Philip Morris*, C-547/14, EU:C:2016:325, para. 57-64.
[2] See in *British American Tobacco (Investments) and Imperial Tobacco*, C- 491/01, EU:C:2002:741, paragraph 62; *Arnold André*, C- 434/02, EU:C:2004:800, paragraph 32; *Swedish Match*, C- 210/03, EU:C:2004:802, paragraph 31; and *Germany v Parliament and Council*, C- 380/03, EU:C:2006:772, paragraph 39.
[3] See e.g. judgement of 4 May 2016, *Philip Morris*, C-547/14, EU:C:2016:325, para. 57-64.

Article 168(7) TFEU does not provide for the adoption of any legal act by the Union and consequently is not a legal basis. It will therefore not be assessed further.

According to the Court, the legal basis of an act must be determined having regards to its aim and content.

As mentioned above, the proposal aims at approximating the rules of the Member States on carrying out clinical assessments at national level and establish a framework of mandatory joint clinical assessments of certain health technologies at Union level. It will remove some of the divergences in the internal market arising from procedural and methodological differences in clinical assessments carried out in Member States and the duplication of those across the EU. By fully harmonising certain procedures on HTA, it is to remove certain existing obstacles and will genuinely enhance the functioning of the internal market. The regulation has a clear internal market objective and as stated above, the fact that public health protection is a component of the proposal does not prevent the regulation from being based on Article 114 TFEU. According to Article 168(1) TFEU, a high level of human health protection must be ensured in the definition and implementation of all Union policies and activities. This implies that high level of human health protection has to be ensured also when the Union acts under other provisions of the Treaty. Given that the conditions for recourse to Article 114 TFEU as a legal basis are fulfilled, the regulation shall rely on this legal basis even when public health protection is a decisive factor in the choices made; in this respect Article 114 TFEU explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed taking account in particular of any new development based on scientific facts.

When it comes to Article 168(4), in order to be a valid second legal basis, the public health component should not be secondary in respect to the internal market component. It does not clearly appear from the aim and content of the proposal that the proposed instrument has two equal-ranking objectives. In addition, the proposed regulation should contribute to the achievement of the public health objectives set for in Article 168 TFEU and shall set "*measures setting high standards of quality and safety for medicinal products and devices for medical use*" (Article 168(4)(c)) in order to meet common safety concerns. Although the proposal addresses the relative quality and safety of products, it is not obvious whether there is any genuine "*common safety concern*" to which it would respond, or whether it really sets health standards in a way that would justify recourse to the specific legal basis in Article 168(4)(c) (either in combination with Art. 114 TFEU or alone).

Finally, according to case-law, a general Treaty article constitutes a sufficient legal basis even though the measure in question also seeks, in a subordinate manner, to attain an aim sought by a specific Treaty article[1]. The choice of Article 114 TFEU appears therefore to be correct and sufficient.

Having said that, a possible recourse to the twofold legal basis of Articles 114 and 168(4)(c) TFEU would not put at risk the validity of the act. In fact, according to the case-law, a possible error in the citations of an act is no more than a purely formal defect, unless it gave

[1] See judgement of 9 October 2001, *Netherlands v. European Parliament and Council*, C-377/98, EU:C:2001:523, paras 27-28; judgement of 10 December 2002, *British American Tobacco (Investments) and Imperial Tobacco*, C491/01, EU:C:2002:741, paras 93-94

rise to irregularity in the procedure applicable to the adoption of that act. If recourse to a twofold legal basis does not give rise to irregularity in the procedure for adopting the legislative act, such act would in principle not be annulled by the Court on that account.[1]

VI - Conclusion and recommendation

Based on the Commission proposal and in light of the above, it should be concluded that the Commission proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU has been rightly based on Article 114 TFEU. Further analysis of the legal basis could be necessary if amendments adopted in the vote in committee substantially altered the aim and content of the proposal.

The addition of Article 168 paragraph 4 (c) TFEU would not give rise to irregularity in the procedure that renders the regulation invalid.

Article 168 paragraph 7 TFEU is not a legal basis and therefore cannot be added as such in the citations.

At its meeting of 10 September 2018 the Committee on Legal Affairs accordingly decided unanimously[2] to recommend to the Committee on the Environment, Public health and Food safety to retain Article 114 TFEU as the appropriate legal basis of the proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. Addition of Article 168(4)(c) would not seem to result in invalidity of the measure.

Yours sincerely,

Pavel Svoboda

[1] See judgment of 14 December 2004, *Swedish Match*, C-210/03, EU:C:2004:802, p. 43-44.

[2] The following were present for the final vote: Pavel Svoboda (Chair), Mady Delvaux, Laura Ferrara (Vice-Chair), Axel Voss (rapporteur for opinion), Alex Mayer (for Mary Honeyball pursuant to Rule 200(2)), Joëlle Bergeron, Geoffroy Didier, Pascal Durand, Sylvia-Yvonne Kaufmann, Julia Reda, Evelyn Regner, Virginie Rozière, Francis Zammit Dimech, Tadeusz Zwiefka.