



EUROPEAN
CANCER
PATIENT
COALITION

Position
on Future Cooperation on
HEALTH TECHNOLOGY ASSESSMENT

JULY 2018

This document represents the updated position of the European Cancer Patient Coalition on the European Commission's proposal for a Regulation on Health Technology Assessment 2018/0018 (COD)ⁱ. Our current position takes into consideration the recent discussions in the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) from 22 June as well as the opinions and amendments tabled by Members of the European Parliament in the responsible Committees.ⁱⁱ

Brussels, Belgium

9 July 2018

European Cancer Patient Coalition contacts:

Kathi Apostolidis, Vice President

kathi.apostolidis@ecpc.org

Lydia Makaroff, Director

lydia.makaroff@ecpc.org

Alex Filicevas, Head of EU Affairs

alex.filicevas@ecpc.org

Executive Summary

While Health Technology Assessments are increasingly being performed by Member States, the wide variety of procedures and methodologies results in significant differences in how data and evidence are assessed. Consequently, cancer patients across Europe are facing disparities and delays in access to innovative treatments, due to the fragmentation of Health Technology Assessment systems.

The proposed cooperation framework would ensure that all the necessary data is generated ahead of the Health Technology Assessment submission. We believe mandatory cooperation and uptake of Joint Clinical Assessment reports is the best option to ensure successful cooperation in this field and provide equal and timely access to health technologies in general and cancer therapies in particular. The European Cancer Patient Coalition therefore welcomes the European Commission's proposalⁱⁱⁱ for future cooperation on Health Technology Assessment in the European Union.

Recent discussions in the Council have, however, shown that although Member States are positive about the possibility of continuing cooperation on Health Technology Assessment, most of them have reported major concerns about the European Commission's proposal and are exploring possible alternatives to the proposed mandatory cooperation framework^{iv}. We are concerned that this may result in an undesired deadlock which would be extremely detrimental to patients as the current inequalities in availability of health technologies would not be tackled. To avoid such a scenario, the European Cancer Patient Coalition calls on Member States to work with the European Parliament to ensure that the current proposal translates into a tangible patient-centred legal framework.

We believe that cancer patients are the most important partners in the fight against cancer and against all the cancer-related issues affecting our society. Considering they are the ultimate beneficiaries of medical technologies, the assessments must capture patients' needs and preferences, when assessing the value of new therapies. More importantly, we believe that patients' involvement must be formalised, the stakeholder network should be a voting member of the Coordination Group, and systematic, to cover all the activities performed under the proposed framework (e.g. Joint Clinical Assessments, Joint Scientific Consultation, Horizon Scanning, definition of the Annual Work Programme of the Coordination Group).

In light of the above, the European Cancer Patient Coalition calls for:

- **Systematic involvement of patient organisations in Health Technology Assessments;**
- **Formalisation of patient organisation involvement in all joint activities completed at EU level, as well as in the assessments of non-clinical domains that are conducted at national level;**
- **Mandatory uptake of Joint Clinical Assessment reports.**

The European Cancer Patient Coalition supports the Commission's objective of reducing existing fragmentation of the internal market for health technologies as provided by article 114^v of the Treaty on the Functioning of the European Union (TFEU). Having regard to the need for high level human health protection which is emphasised in the Charter of Fundamental Rights of the European Union (2000), we welcome the introduction of article 168 TFEU^{vi} as a second legal basis. We agree that a coherent Health Technology Assessment should also aim at setting high standards of quality and safety for medicinal technologies, as per Article 168. We call on the Members of the European Parliament to adopt the corresponding amendments to the Commission's proposal.^{vii}

Patient organisations must be involved in Health Technology Assessment

Patients have unique knowledge, perspectives and experiences, and are the ultimate beneficiaries of medical technologies. The assessments must therefore capture patients' needs and preferences when assessing the value of new therapies. Patient preferences are however seldom considered in Health Technology Assessments while patient organisations are usually not involved in these assessments.

The European Cancer Patient Coalition is of the opinion that national appraisal should be conditional to the establishment of an effective mechanism to guarantee meaningful patient organisation involvement in Health Technology Assessment at European level. It is essential that the co-legislators take into account the vital role that patient organisations play in the decision-making process at National and European level, especially by formalising the participation of patient organisations in joint assessments.

Experience has shown that the involvement of patient organisations in the decision-making process is extremely valuable, as the patient perspective and experience support Health Technology Assessments by drawing on experience in deciding among therapies and therapeutic options. The same applies to horizon scanning where patient organisations can provide critical input on priority setting and the value of emerging therapies. The patient experience could also be of significant added value when communicating on risks and benefits with other patients.

European agencies such as the European Medicines Agency, as well as national agencies such as the National Institute for Health and Care Excellence (NICE) in the United Kingdom and the Zorginstituut Nederland (ZINL) in the Netherlands, have benefited from very positive results by incorporating patient organisations as active partners in their decision-making processes. In this regard, it should be considered that best practices for patient engagement in Health Technology Assessment already exist in some Member States and could serve as a model for other Member States to replicate.

A coherent Health Technology Assessment framework should also be based on the principles of transparency and independence while conflicts of interests must be avoided to preserve the credibility and legitimacy of European collaboration. It would therefore be of significant benefit to create a framework governed by an independent body whose assessments could not be influenced by national medicines agency nor Health Ministries as it is the case in some Member States. This will help avoid any possible conflict of interest or exploitation of Health Technology Assessment for political or economic reasons.

We are confident that the European Parliament will keep putting a high premium on ethics and transparency in light of the number of amendments focusing on these critical aspects that have been tabled since the launch of the legislative work.^{viii}

Suggestions for improving EU cooperation on Health Technology Assessment

Stakeholder Network

While the European Cancer Patient Coalition welcomes the incorporation of a Stakeholder Network in the Commission's proposal, the said Network should be more actively involved in the Health Technology Assessment related activities. The European Cancer Patient Coalition urges the co-legislators to provide for the organisation of regular meetings between the Stakeholder Network and the Coordination Group so as to gather feedback from stakeholders and ensure regular exchange of information on the activities of the Coordination Group (Article 26 – Point 3).

The role of the Stakeholder Network should be strengthened and formalised to ensure that the stakeholders' views are represented and incorporated into all the reports issued by the Coordination Group (Article 3 – Point 8). Representatives of the Stakeholder Network should play an active role in the activities of the Coordination Group and be granted the right to vote like other members of the Coordination Group (Article 26 – Point 4). The nomination process could be similar to the one in place at the European Medicines Agency.

There is also a need to define the members of the Stakeholder Network and the eligibility criteria (Article 26 – Point 1). In order to ensure stakeholder dialogue and appropriate representation, there should be a single pool of stakeholders in the Stakeholder Network, with no need to separate the groups representing patients, consumers, health providers, payers, and industry. Including the members of the current European Commission Health Technology Assessment Network Stakeholder Pool in the new Stakeholder Network would ensure continuity, transparency, and expertise. We believe it would be extremely beneficial to foresee training for members of the Stakeholder Network to ensure their knowledge and expertise in Health Technology Assessment related matters is up-to-date and directly feed into the work of the Coordination Group.

The final Regulation establishing the framework for European cooperation on Health Technology Assessment should include specific provisions formalising meaningful involvement of patient organisations in all joint activities – including Joint Clinical Assessments (Article 6 – Points 9 & 11), Joint Scientific Consultations (Article 13 – Point 8), identification of emerging health technologies (Article 18 – point 2), voluntary cooperation (Article 19), preparation of the Annual Work Programme (Article 4), and preparation of the Annual Reports (Article 4) – as patients are the ultimate beneficiaries of medical technologies.

We note with satisfaction that the European Parliament's Committees involved in the HTA discussions have placed emphasis on the need for further stakeholder involvement in the proposed cooperation model.^{ix} In particular, we welcome the amendments which strengthen the role of stakeholders, including patients, by providing them with the possibility to have a say in the Joint Clinical Assessments, Joint Scientific Consultations and horizon scanning processes, and the inclusion of a definition of 'patient-relevant outcomes' in these. The European Cancer Patient Coalition calls on the Members of the European Parliament to ensure that these amendments feature in the final report setting the European Parliament's position on the file.

Implementing acts

The concrete implementation of the proposed framework will be defined in the procedural and legal rules for Joint Clinical Assessments that will be developed by means of implementing acts (Article 11 – point 1). As a result, some of the provisions included in the proposal (e.g. methodologies) remain vague.

The European Cancer Patient Coalition calls on the Commission to take the opportunity of the foreseen implementing and delegated acts to institutionalise stakeholder involvement, by outlining their responsibilities in the production of Joint Clinical Assessment reports, Joint Scientific Consultation reports, the Annual Study on Emerging Health Technologies, and the Annual Work Programme.

We are also concerned that the requirement to act by consensus, or, where necessary, vote by simple majority, may stall proceedings (Article 3 – Point 3; Article 6 – Point 12) if safeguards are not put in place and thus, create a risk of delaying patient access to new treatment options.

Within the implementing acts, there is a need to define how, and by whom, the members of the Coordination Group Sub-groups will be appointed. The required expertise and the objective of each Coordination Group Sub-group must be taken into account when appointing members (Article 3 – Point 5). The Coordination Group should be allowed to establish additional Sub-groups if deemed necessary (Article 3 – Point 10).

National uptake of Joint Clinical Assessment Reports

We see the benefits of Joint Health Technology Assessments as long as the authorities who will use the Joint Clinical Assessment reports to make decisions on the national level are involved in the activities of the Coordination Group (Article 4 – Point 3).

The European Cancer Patient Coalition also sees positively the developments in the European Parliament's Committees in relation to the national uptake of Joint Clinical Assessment reports. We agree with the suggestion to allow Member States to complement the clinical evidence used in Joint Clinical Assessments as part of national appraisal processes.^x

The standardisation of methodologies in Joint Clinical Assessments should safeguard the quality and reliability of Health Technology Assessments throughout the European Union, ensuring public health interests are adequately protected. It is essential that the scientific evidence used in the Joint Clinical Assessments be relevant and that the requirements for evidence be clear, to ensure that the assessed technology is of the highest possible quality while ensuring timely delivery.

Conclusion

Although the recent discussions in the Council have sparked uncertainty about the potential future mandatory cooperation framework, we see positively the latest developments in the European Parliament's Committees.

We hope that the co-legislators will support our position on the importance of actively involving patient organisations in Health Technology Assessments. The European Cancer Patient Coalition is ready and willing to collaborate with the European institutions as well as with their member national patient organisations to inform national policy-makers, including Members of National Parliaments, about this crucial proposal. We are looking forward to continuing our conversations with Members of the European Parliament and national patient organisations, and to engaging in fruitful dialogue.

The European Cancer Patient Coalition hopes to see continued synergy in the efforts of the European Parliament, the European Commission and the Member States to work towards better health of European citizens. Article 10(3) of the Treaty on the European Union states that every citizen shall have the right to participate in the democratic life of the Union, and that decisions shall be taken as openly and as closely as possible to the citizen. We are convinced that closer cooperation on Health Technology Assessment will contribute to guaranteeing this right.

Endnotes

ⁱ Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51_en.pdf

ⁱⁱ European Parliament: Committee on Industry, Research and Energy; Committee on Internal Market and Consumer Protection; and Committee on Environment, Public Health and Food Safety

ⁱⁱⁱ European Commission, Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. Available at:

[http://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2018/0051/COM_COM\(2018\)0051_EN.pdf](http://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2018/0051/COM_COM(2018)0051_EN.pdf)

^{iv} Council of the European Union, Employment, Social Policy, Health and Consumer Affairs Council (Social policy and health), 21-22/06/2018. Available at: <http://www.consilium.europa.eu/en/meetings/epsco/2018/06/21-22/>

^v Lisbon Treaty, Treaty on the Functioning of the European Union, Article 114 (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.”

^{vi} Lisbon Treaty, Treaty on the Functioning of the European Union, Article 168(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.”

^{vii} European Parliament, Committee on the Environment, Public Health and Food Safety, Draft report on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. Available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-622.011+01+DOC+PDF+V0//EN&language=EN> / European Parliament, Committee on Industry, Research and Energy, Amendments 24-149. Available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-622.255%2b01%2bDOC%2bPDF%2bV0%2f%2fEN>

^{viii} European Parliament, Committee on the Environment, Public Health and Food Safety, Draft report on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. Available at:

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-622.011+01+DOC+PDF+V0//EN&language=EN> / European Parliament, Committee on Industry, Research and Energy, Draft report on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. Available at:

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-620.890%2b01%2bDOC%2bPDF%2bV0%2f%2fEN> / European Parliament, Committee on the Internal Market and Consumer Protection, Draft report on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. Available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-622.139%2b01%2bDOC%2bPDF%2bV0%2f%2fEN>

^{ix} European Parliament, Committee on the Environment, Public Health and Food Safety, Draft report on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. Available at:

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-622.011+01+DOC+PDF+V0//EN&language=EN> / European Parliament, Committee on Industry, Research and Energy, Draft report on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. Available at:

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-620.890%2b01%2bDOC%2bPDF%2bV0%2f%2fEN> / European Parliament, Committee on the Internal Market and Consumer Protection, Draft report on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. Available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-622.139%2b01%2bDOC%2bPDF%2bV0%2f%2fEN>

^x European Parliament, Committee on the Internal Market and Consumer Protection, Amendments 38-181. Available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-623.737%2b01%2bDOC%2bPDF%2bV0%2f%2fEN> / European Parliament, Committee on Industry, Research and Energy, Amendments 24-149.

Available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bCOMPARL%2bPE-622.255%2b01%2bDOC%2bPDF%2bV0%2f%2fEN> / European Parliament, Committee on the Environment, Public Health and Food Safety, Amendments 407-598. Available at:

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-623.758+01+DOC+PDF+V0//EN&language=EN> / European Parliament, Committee on the Environment, Public Health and Food Safety, Amendments 172-406. Available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-623.757+01+DOC+PDF+V0//EN&language=EN>