

EUROPEAN CANCER PATIENT COALITION RESPONSE

TO THE PROPOSAL ON FUTURE COOPERATION ON HEALTH TECHNOLOGY ASSESSMENT 2018/0018 (COD)

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

The European Cancer Patient Coalition welcomes the European Commission's proposal for future cooperation on Health Technology Assessment in the European Union. We urge the European Parliament and the Member States to adopt the proposal without unnecessary delay, as well as to continue work to substantiate and harmonise patient organisations' participation in Health Technology Assessment.

Having regard to:

1. The Charter of Fundamental Rights of the European Union (2000/C 364/01), and specifically:

Preamble

The peoples of Europe, in creating an ever-closer union among them, are resolved to share a peaceful future based on common values;

Dignity

Article 1: Human dignity

Human dignity is inviolable. It must be respected and protected;

Article 2: Right to life

1. Everyone has the right to life;
2. No one shall be condemned to the death penalty, or executed;

Article 3: Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity;
2. In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law, the prohibition of eugenic practices, in particular those aiming at the selection of persons, the prohibition on making the human body and its parts as such a source of financial gain, the prohibition of the reproductive cloning of human beings;

Article 35: Health care

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities;

2. And to the Consolidated Version of the Treaty for the Functioning of the European Union (Official Journal of the European Union, C 326/47), and specifically:

Article 9

In defining and implementing its policies and activities, the Union shall take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health;

Article 168

(ex Article 152 TEC) 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;

We put forth the case for actively involving patient organisations in all decision-making processes, pertaining to and including that of HTA, for the protection of individual human health and for the overall public health.

The EU Transparency Directive (Council Directive 89/105/EEC) specifies a limit of 180 days for national implementation, following Marketing Authorisation. Adherence with this deadline varies considerably among the Member States. The European Cancer Patient Coalition is confident that high quality Joint Clinical Assessments have the potential to reduce workload on Member States and create efficiencies, reduce risk, increase safety, and underpin faster access to life-preserving treatments, provided key governance aspects are sufficiently discussed and addressed in a transparent and comprehensive manner with all stakeholders. There is also the potential to increase meaningful patient organisation involvement in Health Technology Assessment by more actively involving the Stakeholder Group.

Patient organisations must be involved in Health Technology Assessment

The European Cancer Patient Coalition calls for:

- **Systematic involvement of patient organisations in Health Technology Assessments.**
- **Formalisation of patient organisation involvement throughout all activities of Health Technology Assessment at the EU level, as well as in the assessments of non-clinical domains that are conducted at the national level.**

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

If we are not able to establish an effective mechanism to guarantee meaningful patient organisation involvement in Health Technology Assessment at the European level, it will be extremely difficult to implement this process at the national level. It is essential that the European Union underlines the vital role that patient organisations play in the decision-making process by formalising the participation of patient organisations.

The involvement of patient organisations in the decision-making process has already been established as extremely valuable. There is a need to understand the experience of living with a disease and the experience in deciding among therapies and therapeutic options, which can be used to select relevant therapies and assess them. It is important to take into account the experience of taking one or more treatments concurrently or consecutively, and use the patient experience to better communicate aspects of risk and benefit to other patients. The patient voice must also be brought into deliberations regarding the value of emerging therapies, as it can critically inform on priority setting, as well as facilitate development of innovation that improves individual and public health.

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 at the Zorginstituut Nederland (ZINL) in the Netherlands, have all had very positive results when incorporating patient organisations as active partners in their decision-making processes. These agencies have already established frameworks that can be utilised as best practice in the generation of EU and national processes for involvement of patient organisations.

Whilst best practices for patient engagement in Health Technology Assessment already exist in some Member States, in others, patient involvement is not only absent, but the methodology and decision-making practices lack transparency. The European Cancer Patient Coalition also questions the role that some national medicines agencies play in the production of Health Technology Assessment reports, such as in Agenzia Italiana del Farmaco (AIFA) in Italy, or as in Greece the recently established "HTA Committee" (L.4512/2018), that has its seat at the National Regulator's Office and reports to the Minister of Health, who has also veto rights.

A body independent from medicine agencies and national ministries must be in charge of producing Health Technology Assessment reports. This will help to avoid any possible conflict of interest or exploitation of Health Technology Assessment for political or economic reasons. It is also critical to ensure transparency across the production of Health Technology Assessments and appraisal procedures.

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 this proposal, this stakeholder network should be more actively involved. The Commission should organise regular meetings between the Stakeholder Network and the Coordination Group, in order to collect contributions of the stakeholders for the work of the Group and provide for a regular exchange of information on the work of the Coordination Group (Article 26 – Point 3).

The role of the Stakeholder Network should be strengthened to ensure that stakeholder views are represented and incorporated into all the reports produced by the Coordination Group (Article 3 – Point 8). Representatives of the Stakeholder Network should have an active participatory role equivalent to that of the other members of the Coordination Group Sub-groups members (Article 26 – Point 4) and their 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 HTA Network Stakeholder Pool in the new Stakeholder Network would ensure continuity, transparency, and expertise. The Commission should foresee training for members of the Stakeholder Network, so that they can update their knowledge and expertise in HTA related matters.

The Regulation should make specific provisions for ensuring the meaningful involvement of patient organisations in all of its activities, since patient organisations are the most important stakeholder group in the Health Technology Assessment process. **Patients are the people directly and immediately affected by the results of Health Technology Assessments.** The European Commission's proposal would be strengthened by involving patient organisations in all activities of the HTA process, 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).

Patient Reported Outcomes in Joint Scientific Consultations

The proposal provides for Joint Scientific Consultations, commonly referred to as 'early dialogues', through which advice can be given to health technology developers in the development phase of a technology (Article 12). The European Cancer Patient Coalition acknowledges that the Joint Clinical Assessments in this legislative proposal are limited to the clinical aspects of HTA, leaving the socio-economic aspects linked more closely to the national context. However, it is important that socio-economic, and ethical aspects are taken into account during the Joint Scientific Consultations, and patient-reported outcomes, such as quality of life, should be recommended as a secondary endpoint in all relevant Phase II, Phase III, and Phase IV clinical trials.

Implementing acts

Most of the details will need to be defined in the procedural and legal rules (Article 11 – point 1). The methodologies within this legislative proposal are not clearly defined and should be further developed in the future. Currently, substantial parts of the proposal are vague, and are set to be determined in more detail as implementing and delegated acts are defined, and also through tertiary legislation. They are likely to be based on the procedures, documents and methodologies developed in the EUnetHTA Joint Action 3. The implementing acts must institutionalize the involvement of the stakeholder network, establishing their work in the Coordination Group, and in the production of the Joint Clinical Assessment reports, Joint Scientific Consultation reports, Annual Study on Emerging Health Technologies, and the Annual Work Programme.

It is also essential that the issue of consensus is addressed. The requirement to act by consensus can give the European Commission the right to cancel decisions on important topics if consensus is not reached. Failure to reach unanimous consensus may stall proceedings, if safeguards are not put in place to address this possible barrier (Article 3 – Point 3; Article 6 – Point 12).

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 of its members and the objective of each Coordination Group Sub-group must be taken into account when appointing members (Article 3 – Point 5). Furthermore, the Coordination Group should be given an authority to establish one or more additional Sub-groups if it is deemed necessary for the conduct of their mandate (Article 3 – Point 10).

Medical Devices

Additional limitations on medical devices could result in delays in access to beneficial innovations for patients due to extra layers of unnecessary regulation. Medical devices are already addressed under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices. Furthermore, Member States have other means to ensure the most cost-efficient use for medical devices. Thus, medical devices should be excluded from this proposal, to reduce administrative work, ensure that there is not an unreasonable burden on access to medical devices, and to reduce the duplication of assessments on medical devices (Article 5 – Points 1 & 2).

Member State decision-makers in HTA

In mandatory cooperation, there is a missing link between the authorities who will use the Joint Clinical Assessment report to make decisions about HTA, and the members of the Member State Coordination Group who produce the Joint Clinical Assessment report, especially in establishing the methodologies to be used. Member State decision-makers in HTA should be consulted by or directly involved in the Coordination Group (Article 4 – Point 3). Member State HTA decision-makers should also be independent from national health and medicine authorities.

High quality timely delivery

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 and endpoints used in

the Joint Clinical Assessments are the most relevant, the requirements for evidence are clear, and production is of the highest possible quality. There is also a need for timely delivery before the Member States' regulatory approval processes begin, to ensure reports are used.

Appeal mechanisms

There is currently no mechanism within the proposal to establish appeal mechanisms for Joint Clinical Assessments or an adequate description of how objections will be handled, and how this may affect the Joint Clinical assessments 'regulatory' clock and, ultimately, timely access. This mechanism should be established.

Conclusion

We hope that the European Commission 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 work with the European Commission to inform Members of the European Parliament and with our member national patient organisations to inform at the national level about this important proposal. We have already begun initial conversations with Members of the European Parliament and national patient organisations, and we will continue to engage in fruitful dialogue in the coming months.

The European Cancer Patient Coalition hopes to see continued synergy in the efforts of the European Parliament and the European Commission to work towards better health of European citizens. Article 8 A of the Treaty of Lisbon states that every citizen shall have the right to participate in the democratic life of the Union, and decisions shall be taken as openly and as closely as possible to the citizen. Closer cooperation on Health Technology Assessment will contribute to ensuring the protection of this right.