WECAN

Workgroup of European
Cancer Patient Advocacy Networks

21 June 2018

Introduction

This is a position statement from the Workgroup of European Cancer Patient Advocacy Networks (WECAN) on further EU integration of HTA. The signatories of this document support the European Commission plans for joint HTA clinical assessment and the proposal for a regulation of the European Parliament and of the Council on health technology assessment (HTA) and amending Directive 2011/24/EU (COM(2018)0051 – C8-0024/2018 – 2018/0018(COD)). We strongly believe that the proposal should be adopted given the extensive benefits it offers to patients and healthcare systems across Europe.

About WECAN

WECAN is an informal network of leaders of 21 cancer patient umbrella organisations active in Europe. Collectively, WECAN represents the voice of millions of European cancer patients (see below for membership list). The objective of WECAN is to strengthen European patient advocacy to improve outcomes for all cancer patients, see: http://www.wecanadvocate.eu

Position statement

WECAN recognises that Health Technology Assessment, HTA, plays a key role in providing equitable and sustainable universal healthcare. We support a joint HTA clinical assessment as an important step towards improving evidence-based and equitable decision making across Europe.

Individual national clinical assessments in HTA currently lead to duplication across Europe and often result in unnecessary costs and delays in accessing new medicines and technologies, having an impact on patient outcomes. Implementing joint HTA clinical assessments at a European level, if designed and implemented in the right way, has the potential to streamline the HTA process.

At the same time this would allow national healthcare systems to retain their autonomy on decisions about the value and affordability of new medicines.

The European Commission proposal on HTA will build on the excellent work that has already been done at the European level through EUnetHTA. WECAN acknowledges that EUnetHTA has enabled a platform for exchange and alignment between European HTA agencies and has delivered tangible outcomes, most notably the EUnetHTA core model. We also note and appreciate the important role that EUnetHTA plays in supporting the establishment of effective HTA processes in newer EU Member States. The momentum gained through EUnetHTA should be built upon to ensure that European health economies continue to collaborate to develop a stable systems for European HTA and to ensure that the work/investment to date is not lost.

We recognise that health systems and the HTA process are rooted in national traditions and cultures. But as European citizens, we strongly believe that we will only master future health challenges as well as benefit from future opportunities in healthcare through effective collaboration at European level.

EUnetHTA has demonstrated that such collaboration and alignment is not straight forward but it is possible. It does not need to encompass whole-system change "overnight", but rather provide a commitment to collaborate on an incremental and evidence-based transition towards increasingly harmonised joint clinical assessments. The proposal also protects national autonomy to conduct the full HTA of medicines, including considerations around cost-effectiveness and what constitutes societal value of new medicines.

WECAN comments on the European Commission proposal are outlined below. We consider that joint scientific assessments within HTA, have the potential to:

1. **Ensure consistent, high-quality and efficient HTAs**. One of the most important considerations of the Commission proposal is the aim to produce high-quality HTA scientific assessments for all European countries and to speed up the assessment process for new medicines. Particularly if the joint clinical assessment is done in parallel with a European Medicines Agency (EMA) approval. This can be done through pooling HTA scientific expertise at the EU level to ensure that all new medicines are assessed systematically and within a reasonable timeline. It can also be supported through an

effective system of horizon-scanning for new medicines, so European health economies anticipate upcoming medicines.

For oncology patients, time is a key consideration and unnecessary delays in access to new medicines are not acceptable. For many patients this is a matter of life and death.

2. **Avoidance of waste and duplication.** The proposal suggests areas where combined evaluation avoids duplication and waste. WECAN fully supports this concept. Countries currently without an effective HTA system could benefit from the resulting clinical assessments; this would promote good practice in HTA processes. We fully support the possibility of additional voluntary HTA collaboration that could lead to even further harmonisation and standardisation in the future.

3. **Improve equitable access to new therapies**. WECAN supports the importance of a singular approach to elements of HTA which will support the delivery of more equitable assessments across Europe. Diverging assessments of identical datasets effectively undermine the principles of the Cross-Border Healthcare Directive which we as European citizens consider unacceptable.

4. **Promoting accessible sustainable innovation in healthcare.** Non-harmonised data requirements for HTA between countries mean that at present, only large pharmaceutical companies have the financial resources to generate the necessary data packages in every country. Harmonisation and standardisation would allow European small and medium sized enterprises (SMEs) to compete and provide European patients with additional healthcare innovation. Potentially at a fraction of the current cost and thereby help Europe to set an example for healthcare that is innovative, universal and sustainable.

WECAN would also like to add some additional comments:

1. WECAN believes that patient-centricity is the only way to ensure that healthcare is adequate and relevant. For this reason, WECAN would like to see the role of patients, caregivers and patient advocates clarified in the proposed stakeholder network, the coordination Group and in any clinical assessments. We support the European Patient Forum's (EPF) call for mandatory and meaningful involvement of

the patient community in order to ensure HTAs are conducted in the interest of patients.

We believe the work by the EMA could be seen as the starting point for a constructive model for future HTA collaboration. Here roles of patients, caregivers and patient advocates have been clarified and institutionalised.

There are good examples of patient engagement in HTA in other countries, such as Canada, which can be used to form the basis of how patient representatives and caregivers are involved in the process of joint clinical assessments. This will signal to national HTA bodies how best-practice patient/caregiver involvement looks at the national level.

2. Harmonisation and standardisation of elements of HTA have the potential to create a single "port-of-call" for industry to engage with on scientific advice (as early on as possible) and provides the opportunity of collective guidance from EU HTA on the types of national data/engagement requirements, trial design and submissions that are fit-for-purpose.

3. Disease specific patient relevant/reported health outcomes' (PROs), quality of life and patient preference data, as an active component of the clinical assessment, are fully endorsed by WECAN. These measures will help determine the true value of any medicine or technology; provide clarity on benefits and risks to the patient and help clarify the overall benefit to society. WECAN would like to point out the essential distinction between outcomes 'reported by patients' and outcomes 'relevant to patients'.

4. The Commission proposal suggests cost savings might be achieved through a centralised approach. It is important to acknowledge that these longer term savings might demand up-front resource and expert resource allocation that could pose particular challenges in countries new to HTA procedures.

5. It is important that any new system developed is transparent and accountable. We believe that citizens have the right to understand how decisions affecting patients' survival have been reached.

WECAN considers the Commission's proposals offer a vital opportunity to accelerate access to innovative healthcare. European healthcare systems are set to gain from this proposal assisting them to improve the sustainability of the system and enhance transparency. Furthermore, it will save on the increasing costs and burden of conducting individual HTA assessments for every medicine and technology in each country.

In conclusion, WECAN strongly encourages the creation of a practical and robust framework for all HTAs to follow in European countries which guarantees meaningful involvement of patients, caregivers and patient advocates along the entire HTA pathway.

Signatories to this document:

Acute Leukemia Advocates Network (ALAN);
ARCrare - Romanian Association for Rare Cancers;
Childhood Cancer International (CCI);
CML Advocates Network;
EuropaColon;
European Men's Health Forum (EMHF);
European Organisation for Rare Diseases (EURORDIS);
European Waldenström's Macroglobulinemia Network;
International Brain Tumour Alliance (IBTA);
International Kidney Cancer Coalition (IKCC);
International Neuroendocrine Cancer Alliance;
Lymphoma Coalition Europe;
Melanoma Patients Network Europe (MPNE);
Myeloma Patients Europe (MPE);
Thyroid Cancer Alliance (TCA);
Youth Cancer Europe.

Additional members of WECAN:
EuropaDonna; EuropaUomo; European Network of Gynaecological Cancer Advocacy Groups; Lung Cancer Europe (LUCE); Pancreatic Cancer Europe (PCE); International MDS Alliance; Sarcoma Patients Euronet Association (SPAEN)