EUROPEAN CANCER PATIENT COALITION

HTA & PATIENT INVOLVEMENT

EXAMPLES FROM EU MEMBER STATES

BELGIUM

In Belgium, a semi-governmental institution, Belgian Health Care Knowledge Centre (KCE) is responsible for Health Technology Assessment and provides policy recommendations on healthcare. Established in 2002, it is run by a board of directors with the support of a scientific advisory committee. Although Health Technology Assessment is not directly connected to reimbursement decisions in Belgium, HTA has a clear role in the decision-making process by Belgian decision-making agency National Institute for Sickness and Disability Insurance (INAMI). Currently, Belgium does not have a systematic or structured approach on involving patients in the Health Technology Assessment process yet. However, projects are underway and patient representatives will gradually be incorporated to take part in many kinds of policy research.

ENGLAND

The National Institute for Health and Care Excellence (NICE) is responsible for the Health Technology Assessment in England. NICE assesses the clinical and cost effectiveness of health technologies, such as new pharmaceutical and biopharmaceutical products, but also include procedures, devices and diagnostic agents. This is to ensure that all NHS patients have equitable access to the most clinically-effective and cost-effective treatments that are viable. NICE can be considered as one of the best-practice examples for Health Technology Assessment in Europe, and is set-up in a way to get the best patient engagement as possible. An independent committee, within NICE, considers evidence and makes recommendations on the use of pharmaceutical products in England. NICE also looks at cancer medicines slightly differently, and different set of rules are used, with a higher focus on quality of life aspects. There is realisation that the quality of life between treatments, even if not life extending, can really be crucial. This is why it is extremely important that patient organisations participate and are involved, because clinicians and researchers will not know that. There are two main opportunities for patient organisations to get involved in Health Technology Assessment. It includes the scoping, both the written consultation and a scoping workshop, and the guidance development. There are several ways that patient organisations can get involved in the guidance development as well.

FINLAND

In Finland, a range of public health services are monitored, defined and assessed as a whole by the Council for Choices in Health Care in Finland (COHERE Finland). The Council defines the service choices at a general level and issues recommendations on which examination, treatment and rehabilitation methods should be included in publicly financed healthcare services in Finland.
Decisions on pricing and reimbursement of pharmaceutical treatments are taken by a parallel body which operates under the authority of the Ministry of Social Affairs and Health. It is called the Pharmaceuticals Pricing Board (HILA) and it benefits from opinions provided by an expert group, which includes pharmacologists, medical doctors and health insurers. In this process, patient involvement comes only at an individual level since every kind of treatment has to be mutually agreed with the person.

GERMANY

Germany can arguably be defined as having one of the best-practices in Europe for Health Technology Assessment especially from a patient access perspective.

In principle, all prescription medicines, with an exception of over-the-counter and the so-called lifestyle medicines (weight loss; smoking cessation; etc) are reimbursed in Germany, but at different rates. This leads to one of the fastest, if not the fastest, access to innovative treatment and care for patients in the European Union. Every pharmaceutical product centrally authorised by the European Medicines Agency, is usually immediately available on the German market and then reimbursed – but not necessarily fully – according to a categorisation in Reference Price Groups which have a maximum price set.
In parallel, the Health Technology Assessment process is started at the G-BA, the main decision-making body for healthcare professionals, hospitals and health insurances.
If some treatments show characteristics which are, for example, a greater added value in comparison to the existing gold standard treatment for the disease, or not at all, or for a number of other reasons, negotiations on medicines' price and reimbursement will usually start within three months.
Patients are involved at all levels of the Health Technology Assessment process and patient representatives take part in all the sub-groups (pharmaceuticals; devices; etc) as permanent members or as topic-related members. This, for example, leads to Germany having 93.0% availability of the total number of centrally authorised Orphan Medicinal Products. Also, as of February 2018, out of more than 160 pharmaceutical products that went into price negotiations, only 27 had to be subject to a special arbitration board.

ITALY

In Italy, currently there is no proper Health Technology Assessment agency or body in existence. For instance, Health Technology Assessment related activities for medical devices are conducted by the National Agency for Regional Health Services (AGENAS), while pharmaceuticals are assessed by the Italian Medicine Agency (AIFA). In fact, AIFA is the same body responsible for granting the marketing authorisation.
Furthermore, health services are organised and delivered at a regional level, whilst the Ministry of Health outlines the fundamental principles and distributes funds to the regions according to the priorities set at the National level.
Although AIFA conducts a partial assessment of new medicines, it does not produce or publish a final report. Therefore, there is no opportunity for patient organisations to collaborate in the process of Health Technology Assessments at the national level in Italy, and the decisions on pricing and reimbursement in Italy currently lack transparency.

NETHERLANDS

The Zorginstituut Nederland (ZINL) is responsible for the Health Technology Assessment and reimbursement evaluation in the Netherlands. The final decision is taken by the Ministry of Health (VWS) based on the advice provided by ZINL. The system of price and reimbursement is similar to the one in Germany. Treatments distributed out-of-hospital (i.e. purchased in a pharmacy) are automatically approved and clustered with existing products. Every cluster has a maximum amount of reimbursement set and the patient need to pay any additional amount out of pocket (known as out-of-pocket payments). There are also special clusters for treatments that show peculiarities in such instances, the pharmaceutical company is required to provide further documentation and negotiations are started.
All cancer treatments fall into a separate category - the in-hospital distributed products. In principle, all hospital products go into the reimbursement system automatically. Only a small number of treatments are selected for further investigation and their reimbursement stopped before a decision has been made.

If the treatment shows no therapeutic added value, the decision will be made not to reimburse the treatment. If the treatment shows a therapeutic added value, but no cost-effectiveness (based also on patient-centred endpoints) the product will not enter the system unless a better price has been negotiated.
Patients are invited to provide their view on the position and the value of the product, and all stakeholders are required to judge the assessment report in writing when conducting Health Technology Assessment.

ROMANIA

Romania to date has very limited experience in Health Technology Assessment. The first specific Health Technology Assessment unit as part of the Ministry of Health was established only in 2013. It was then integrated into the National Health Technology Assessment agency/body called National Agency of Medicines and Medical Devices (NAMMD) in 2014. At present, its activity is limited to the scoring of Health Technology Assessment submissions from pharmaceutical manufacturers. According to this evaluation, the treatment is then included in the reimbursement formulary, or not reimbursed at all.

However, legal frameworks for the whole process are still incomplete and lacking clarity. No public institution, so far, has had the capacity to undertake rigorous evaluation of new pharmaceutical products or to undertake de novo Health Technology Assessment. As it stands at the moment, patient involvement is lacking completely in this process in Romania.

SWEDEN

The Health Technology Assessment agency/body in Sweden is the Statens Beredning för Medicinsk och Social Utvärdering (SBU). It is a fully operative agency that conducts a full assessment process and provides recommendations to the ultimate decision-maker - the Swedish Dental & Pharmaceutical Benefits Agency (TLV). TLV also receives advice from a board consisting of representatives of the 18 city councils. Since the county councils are responsible for the local healthcare budgets and recommend the medicines on local formularies, eventually Health Technology Assessment is also made at a very local level.

Both TLV and SBU have patient representatives in their board and therefore end-user's perspective on health technologies is highly considered in the process.
Sweden has a higher per capita spending on healthcare than the average of the OECD countries and Health Technology Assessment is seen not as a mere appraisal process for centrally authorised products, but as a tool to set priorities and accordingly, redistribute funding in a more cost-effective way.

This information was collected from various experts and ECPC members experiences, via interviews in 2018.

If you would like to comment or contribute to this list, please visit ecpc.com/edu/HTA to find out more or contact us at info@ecpc.org