IPPOSI

WELCOMES THE ADOPTION BY THE EUROPEAN PARLIAMENT OF A NEW REGULATION ON HEALTH TECHNOLOGY ASSESSMENT (HTA)

The assessment of innovative medicines, as well as of certain medical devices, medical equipment, and prevention and treatment methods, is changing in Europe with the recent adoption by the European Parliament of a new regulation on health technology assessment (HTA).

The regulation, entered into effect on January 12, 2022, represents an important commitment between Member States to increase cooperation around the review of clinical evidence during the health technology assessment (HTA) process, as well as around horizon scanning and scientific advice. Currently, national HTA bodies complete much of this lengthy and onerous work on an individual basis, resulting in significant duplication of effort and resources by governments, industry, and patients alike. The regulation offers a new, centralised approach and the potential to build greater collaboration between Member States within the HTA space in the future.

Our patient members hope that the regulation will address some of the many existing concerns around access, transparency, and involvement within the assessment process. From our interactions with our members, we understand that patients have repeatedly highlighted major challenges, such as differences in the treatment of evidence by national HTA bodies, the unpredictable timeframes for decision-making, and the poor consideration of patient evidence.

We call on all Member States, in implementing the regulation, to learn from best practices among national HTA bodies and to work to establish procedures and methods at the European level which adhere to the highest standards of assessment. It is important that governments and citizens have confidence in the new system and that quality, timely, person-centred outputs emerge from this joint endeavour.

Transparency around what recommendations are made and what evidence is used to inform these recommendations is essential, and this detail must be clearly and publicly communicated. To this end, joint clinical assessments and subsequent national assessment reports should be accessible, with minimum levels of redaction for commercial confidentiality, and complemented by shorter, explanatory lay summaries.

We urge Member States to view the regulation as an opportunity to innovate by increasing the involvement of patients both in the general governance of the new regulation, as well as across specific elements of the joint clinical assessment, horizon scanning, and scientific advice processes. We invite the Coordination Group to think carefully about how they can meaningfully include patients, especially as their work involves the critical elements of planning the programme of work and evaluating the work completed. Across the HTA process, both at the national and European levels, it is essential that Member States co-create with patients a framework or guidelines for their early, equal, and sustained involvement.

AS THE CONSENSUS VOICE OF IRISH PATIENTS IN THIS AREA, WE ARE FOCUSED ON OUR OWN PREPAREDNESS HERE IN IRELAND, AND WE ENCOURAGE THE DEPARTMENT OF HEALTH TO:

- Review national HTA policies and processes for their compatibility with the letter and the spirit of the new regulation, in particular, the provisions for a single pan-European clinical assessment model
- Engage the Irish patient community in a dialogue around the procedures and methods proposed for the joint clinical assessment, horizon scanning, and scientific advice; and feed this perspective back to EUnetHTA and those tasked with finalising the governance and process arrangements
- Establish a national, multi-stakeholder advisory committee to inform national HTA reform in advance of January 2025, comprising of patient, science and industry representatives with an interest in horizon scanning, scientific advice, clinical assessment, non-clinical assessment, real-world evidence, and patient experience
- Ensure current national timelines are aligned with the EU process to minimise delays and commit sufficient resources and expertise to national HTA to allow Ireland to review joint clinical assessment reports, consider non-clinical factors, and make timely recommendations about new technologies apace with other Member States
- Consider the impact of greater cooperation in the area of assessment on existing joint cooperation in the area of pricing and reimbursement (such as Ireland's participation in BENELUXA), and share findings with other Member States

A more efficient, predictable, administratively lean, and evidence-based HTA process is a worthy goal that many stakeholders can collectively get behind. As patients, we stand ready to support our national HTA bodies when and where we can. We ask that you engage with us in preparing for the implementation of this regulation in Ireland, and we ask that we use this opportunity to address shortcomings in our existing process so that Irish patients can be guaranteed equitable and timely access to the life-changing or life-saving technologies that they need to achieve the best possible health outcomes.

FREQUENTLY ASKED QUESTIONS

What is health technology assessment (HTA)?

HTA is defined in the Regulation as “a multidisciplinary process that summarises information about the medical, patient and social aspects and the economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner."

In short, HTA supports decision-making in healthcare. It helps national governments, with limited resources, decide what should be funded and what should not. It can be carried out to assess a new medicine, device, equipment, programme, or procedure. It is most commonly used to assess new medicines. A full HTA assessment includes a review of the evidence relating to clinical and non-clinical (social, economic, ethical) factors.

What does the new HTA regulation aim to do?

The regulation identifies four main areas where cooperation could be improved:

1. Joint clinical assessments
2. Joint scientific consultations (early dialogue with health technology providers)
3. Joint horizon scanning (the identification of emerging health technologies)
4. Joint voluntary cooperation

The joint clinical assessment procedure will allow an EU competent authority to make a determination on the clinical evidence relating to a health technology.

What does the new HTA regulation not do?

The regulation does not provide for the joint assessment of non-clinical factors (social, economic, ethical) – these will continue to be reviewed at the national level. The regulation does not also tackle issues related to the pricing or reimbursement of new technologies. These issues are left to national governments to decide, or where appropriate, to multi-Member State initiatives like BENELUXA.

What happens next?

The regulation entered into effect in January 2022 and will apply from January 2025. Preparations around the necessary governance structures are underway, including the establishment of the Coordination Group and the Stakeholders Network. Work will also start around the development of the necessary implementing and delegated acts, which will define the procedures & methodology to be followed when completing joint assessments.

Coordination Group: this group comprises of representatives from national HTA authorities and agencies who will carry out the joint clinical assessments. The Coordination Group shall meet with the stakeholder network at least once each year.

Stakeholders Network: this network comprises eligible stakeholder organisations, in particular patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals, selected following a call for expressions of interest. A list of members will be made publicly available.

How does this affect you as a patient or a member of the public?

As HTA ultimately helps national governments decide what should be funded and what should not, it is a very important process – especially for patients who are waiting on new innovative technologies to cure or reduce the burden of one or more health conditions.

When HTA is carried out at the national level, different Member States arrive at different conclusions and within different timeframes. It is therefore possible that health technologies may end up being available in one Member State and not in another. This perpetrates health inequalities between European citizens.

It is hoped that the regulation will help standardise how Member States assess new technologies, as well as work towards a timely and person-centred approach to assessment. Information about the latest HTA currently taking place in Ireland can be found on the website of the National Centre for Pharmacoeconomics (NCPE), together with the details of how to make a patient submission in relation to a new technology under assessment.

How can you get involved?

IPPOSI believes that patients and the health-interested public should be supported to know more about the various aspects of the medicines research and development process, including HTA assessment. Working with the National Centre for Pharmacoeconomics (NCPE), we have developed a six-week module around HTA which provides an introduction to the process and to the methodologies used to assess the clinical and non-clinical factors of a new health technology.

We also believe that the person or the patient should be at the heart of the HTA process, and in 2019, we published a Charter for Patient Involvement in Medicines Assessment and Reimbursement in Ireland. The Charter was signed by 35 Irish patient organisations and endorsed by the European Patients' Forum, EURORDIS, and Health Technology Assessment International (HTAi). The Charter was preceded by two reports (2017, 2018) on the access to medicines situation in Ireland.

IPPOSI also currently chairs the European Patient Round Table of ISPOR - the International Society For Pharmacoeconomics and Outcomes Research. ISPOR is a non-profit, international, educational and scientific organization that fosters excellence in health economics and outcomes research and the use of outcomes research information in health care decisions. For more information on the Society, go to www.ispor.org.

Where do I find more information?

https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_6773