Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Opening statement to the Joint Committee on Health

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Chairperson, members, I wish to thank you for the invitation to address the Joint Committee on Health this afternoon. I am accompanied by HIQA's Chief Scientist, Dr. Conor Teljeur.

HIQA and Health Technology Assessment (HTA)

We were invited to the committee to discuss the proposed regulation on Health Technology Assessment, published by the European Commission in January of this year.

I will begin by defining Health Technology Assessment (HTA), outlining HIQA's role in HTA, describing HTA activity undertaken to date and detailing how efficiency is achieved through international collaboration. I will then describe the anticipated impact on HIQA of the proposed regulation on HTA.

What is HTA?

HTA is a multidisciplinary, scientific, research-based activity that collates all of the information that decision-makers need to support evidence-based decisions. HIQA's HTA process is independent, transparent, impartial and robust, and aims to ensure maximum public confidence.

Health technology assessment is a tool used to comprehensively assess new and existing technologies and ensure that relevant reimbursement, investment or disinvestment decisions are informed by the best available evidence. For the purposes of HTA, technologies include drugs, devices, procedures, diagnostics and public health interventions.

What is HIQA's role in HTA?

HIQA holds the statutory function for Health Technology Assessment (HTA) in accordance with the Health Act 2007. The purpose of HIQA's HTAs is to develop independent, scientific advice in line with international best practice. The advice is then provided to the Minister for Health or the HSE to inform a decision on reimbursement or investment.

HTA activity in HIQA

Currently, HIQA conducts comprehensive HTAs to inform national health policy and health service decisions. HTAs typically address clinical aspects of the technology, cost-effectiveness, and budget and resource impacts, as well as domains covering organisational, ethical, social or medico-legal issues. Demand for HTA advice from HIQA greatly exceeds capacity to deliver, thus a formal prioritisation process was implemented in 2014.

How does HIQA undertake HTAs?

All HTAs are undertaken by HIQA staff, with occasional input from external experts as necessary. All HTAs are undertaken in compliance with a comprehensive quality assurance framework aligned to international best practice. An expert advisory group comprising representation from all relevant stakeholders, including, for example, clinicians, patients, decision-makers, and international experts, is convened for each HTA to inform the assessment. Oversight is provided by the Board of HIQA.

For HTAs on topics of public interest, a targeted and public consultation is undertaken prior to completion of the assessment. Technology providers are also invited to make submissions in relation to their product, which may be used to inform the HTA.

What is the output of the HTA?

The final draft report is approved by the Board of HIQA and published on HIQA's website within one week of approval.

What HTAs has HIQA conducted to date?

Examples of HTAs conducted to date at the request of the Minister for Health include:

- BCG vaccination (2015)
- smoking cessation interventions (2017)
- HPV vaccine for boys (ongoing).

Examples of HTAs conducted to date at the request of the HSE include:

- HPV DNA as the primary screening test for cervical screening (2017)
- mechanical thrombectomy for large vessel occlusive stroke (European HTA December 2015, Irish HTA February 2017).

International collaboration

New health technologies are frequently considered for investment in many countries concurrently or within a similar timeframe. This offers the opportunity for joint production of HTA information, while economic models developed for one jurisdiction may be adapted to reflect healthcare delivery models in another.

The conduct of HTA requires substantial staff resources, but equally many of the elements of a HTA are ideal for sharing across national borders. To minimise duplication of effort and to maximise our efficiency, almost all HTAs carried out by HIQA to date have leveraged off work conducted elsewhere by updating evidence reviews or adapting economic models. Equally, evidence reviews and models developed by HIQA have been used by other European agencies. Strong positive

relationships with other HTA agencies enable this collaboration.

How does HIQA collaborate with international HTA agencies?

Since 2007, HIQA has represented Ireland on the EU-funded Joint Action projects on HTA (EUnetHTA). The objective of EUnetHTA is to facilitate effective and sustainable HTA collaboration that brings added value at both the European and national levels.

I am currently the Chairperson of the Assembly of EUnetHTA members and participate in the executive board. HIQA actively contributes to EUnetHTA's work, for example, HIQA was the lead author of a European rapid assessment of endovascular therapy using mechanical thrombectomy devices for acute ischaemic stroke.

I also represent Ireland on the Health Technology Assessment Network. This is a permanent network of HTA agencies established by the European Commission with the objective of fostering permanent strategic and scientific collaboration on HTA across the EU from 2020 onwards.

European collaboration on HTA across Europe has culminated in the development of the proposal for a HTA regulation, which I will now discuss.

Implications for HIQA of the proposal for a regulation on health technology assessment

The proposed HTA regulation outlines four key outputs:

- joint assessments comprising the clinical HTA domains
- joint scientific consultations for technology developers
- horizon scanning to identify new and emerging technologies
- a framework to support collaborative working, e.g. HTAs of other technologies such as public health programmes, and non-clinical joint assessments such as economic assessment.

The standardisation of methods and processes, and the use of common tools required by the proposed regulation, will build heavily on development work already conducted by EUnetHTA. Methods for systematic review of the clinical evidence base are already standardised internationally. The Irish national HTA Guidelines developed by HIQA align with international best practice and EUnetHTA standard approaches. Work is already well underway in HIQA to standardise our methods and processes to the EUnetHTA framework, which will be a requirement of the regulation if implemented.

Article 22 of the regulation requires the standardisation of national HTA procedures to guarantee that the scientific evidence is produced in a manner that espouses independence, transparency and stakeholder engagement. All of these principles are already embedded in conduct of HTA by HIQA.

Joint production of assessments of medicines and high-risk medical devices will increase the availability of systematically-produced reviews of the international evidence on clinical effectiveness and safety of relevant technologies. The availability of joint clinical assessments will add to the efficiency of HIQA's processes by obviating the need for one of the key steps in the production of HTAs.

Issues of concern

Scrutiny of the proposal for the regulation on HTA by HIQA has raised a number of issues, which will ideally be addressed or clarified before it enters into force:

- Article 3(1)(d): the potential that in vitro diagnostic devices classified as class C can be added to the scope for joint clinical assessments should be considered as these technologies which include self-testing diagnostics are becoming increasingly important.
- Article 4(3): the course of action should a health technology developer refuse to comply with a request to submit information and documentation relating to a health technology that is to undergo joint clinical assessment should be clarified.
- Article 5(1): the Commission shall publish joint clinical assessment reports where it considers that the report complies with the substantive and procedural requirements of the regulation. Any assessment of the substantive nature of a HTA report should be conducted by HTA agency experts.
- Article 6(2): what outcome must be notified to the Commission within 30 days of the completion of a HTA on a health technology that has been subject to a joint clinical assessment? It should be clarified whether this means notification that the national HTA has been published, the recommendations of the national HTA or what investment decision has been taken informed by the HTA.
- Article 21(1): the Commission will publish the summary reports of all clinical assessments carried out as part of national HTAs outside the scope of the regulation, thereby facilitating access to work undertaken in other Member States. It is not clear if these summary reports will be subject to a quality assessment prior to publication, or indeed if they will be published in a common language. Meeting both these criteria would enhance the usefulness to HIQA of work carried out in other Member States.

- Article 37: Member States may carry out a clinical assessment using means other than those set out in the regulation on grounds of public health protection following approval by the Commission within three months of notification of intent by the Member State. This seems an unnecessarily long response time by the Commission in the context of the rare circumstance of a potential public health emergency.

Conclusion

Today I have provided an overview of how international collaboration is leveraged by HIQA to enhance the quality and efficiency of HTA. I have also outlined the implications for HIQA of the proposed regulation on HTA.

I would like to thank the committee for inviting us here this afternoon. We are happy to take any questions you may have.

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