Why health technology assessment is here to stay

Health technology assessment (HTA) is a way of analysing whether new medical technologies meet the needs of patients at a cost that is acceptable to society. Originally introduced as a way for governments to prioritise spending on health, HTA has now become a key factor in drug development. Among other things, HTA bodies in Europe inform reimbursement desisions for new drugs. Companies developing new drugs thus need to take HTA requirements into account, even as they are planning their drug development programmes. And it is on this shaky basis that they must seek investors. This article explains what companies need to know about the changing landscape for HTA in Europe.

European policy on HTA is as diverse as the national healthcare systems it supports. Some European Union member states such as the UK have advanced HTA systems, whereas others are only just beginning to incorporate HTA into their healthcare policies. Some have several HTA bodies that focus on different disciplines or product types, and others have only one. Some HTA bodies are linked to government health ministries, others are independent, and a few can even be found under the same roof as the medicines regulator. Some countries carry out HTA assessments before marketing authorisation from a drug regulator and others do so afterwards. Moreover, some countries use HTA to inform national healthcare policy and others, such as Spain, use HTA to support regional reimbursement decisions.

Despite these differences, a common thread is that the use of HTA is on the rise.

A global issue

Pressure on healthcare budgets has increased so much that harmonising requirements for HTA across Europe has become a political priority at EU level. The European Commission, for example, is contributing millions of euros towards an initiative on HTA collaboration with EU member states called the European Network of Health Technology Assessment (EUnetHTA) Joint Action (JA).[1]

This is in line with the EU Cross-Border Healthcare Directive (2011/24/EU), which member states have to transpose into national law by October 2013.[2] It calls on the Commission to "adopt the necessary measures" for the creation of a voluntary EU-wide HTA network to support co-operation between national authorities and avoid duplication of assessments, among other tasks.

Though EUnetHTA precedes Directive 2011/24/EC, the Commission plans to build on the network's activities to achieve the goals envisioned in the legislation.[3] It is comprised of government-appointed organisations, regional agencies and not-for-profit entities that produce or contribute to HTA in 29 European countries, including 23 member states.[4] Its overarching objective is to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level. The EUnetHTA JA picks up where previous European initiatives left off. By the end of 2012, it intends to provide an online service for retrieving information about HTA and guidance on methodology for making relative effectiveness assessments.

European HTA agencies recognise that there is a need to collaborate at a global level. As such, many of EUnetHTA's members are also part of the International Network of Agencies for HTA (INAHTA).

Furthermore, broader forums play a key role in providing a platform for other stakeholders such as researchers, academia, industry, health service providers and patients/consumers. The two main platforms for wider discussion on HTA are the International Society for Pharmacoeconomics and Outcomes Based Research and Health Technology Assessment International (HTAi), which also work with EUnetHTA and INAHTA.

Of particular interest is HTAi's Green Park Collaborative, an international initiative launched last year with the Center for Medical Technology Policy to explore the scientific feasibility of developing guidance for the life sciences industry on the design of clinical studies to meet the needs of HTA organisations and coverage bodies.[5]

The aim is to produce prototype 'evidence guidance documents' that will provide therapeutic-area specific trial design recommendations, as well as general methodological advice that can be applied across therapeutic areas. It is developing a pilot guidance document for Alzheimer's disease, building on the relevant regulatory guidance.

The pilot is run by a steering group whose members participate as individuals and not as representatives of their organisations. Nonetheless, it boasts some European HTA trailblazers such as Finn Børlum Kristensen of Denmark's National Board of Health, who is also director of the EUnetHTA Secretariat.

Regulators in the group include Hans-Georg Eichler, senior medical officer at the European Medicines Agency (EMA), and Kent Woods, chief executive of the UK Medicines and Healthcare products Regulatory Agency (MHRA).

HTAi managing director Logan Mardhani-Bayne told *MedNous* that the current project timeline extends to mid-2013, but this may be amended as the project proceeds.

He also pointed out that HTAi had recently launched an interest subgroup on HTA-regulatory interactions, which will serve as a repository of the different initiatives that are taking place. Among other aims, the subgroup, which is co-chaired by Franz Pichler, manager of HTA Programmes at the UK-based Centre for Innovation in Regulatory Science (CIRS), and Mel Walker, GlaxoSmithKline's senior director for value expert engagement & collaborations, will seek to avoid unnecessary duplication of efforts.

HTAi's Policy Forum offers another opportunity for senior people from public and private sector organisations with interests in HTA to carry out strategic discussions. The main topic of discussion in this forum over recent months has been disinvestment, said Mr Mardhani-Bayne.

Because of financial restraints, disinvestment in low value technology uses may be necessary and "those pressures aren't going away", but he prefers to approach it from a more positive perspective, calling it "optimisation of technology use". Regardless of the terminology, HTAi hopes to work out how and where HTA can be relevant to informing those decisions.

Regulator involvement

The regulators are also doing their part, both at EU and national level. The EMA continues to increase its engagement with HTA bodies as part of the objectives set out in its Road Map to 2015.[6] The agency and EUnetHTA began collaborating two years ago on a project that resulted in a new European Public Assessment Report (EPAR) template, which has been in use since late 2010. It is now working with EUnetHTA to see where EPAR requirements can be further refined to make a better contribution to REAs, according to an agency spokesperson.

The EMA is also engaging with HTA bodies through its provision of scientific advice early in medicine development and throughout the medicinal product's lifecycle, the spokesperson added. The aim is to harmonise advice given to companies on the development of a medicine from regulators and HTA bodies wherever possible.

Interest in joint scientific advice is picking up. "We have seen an increased number of joint scientific advice requests: nine completed, one ongoing, four pre-announced", the spokesperson told *MedNous*.

As part of its efforts to increase transparency with HTA bodies, the EMA also says it will place more emphasis on the quantitative aspects of benefit:risk assessment. "EMA has made real headway with [the] project on benefit:risk methodologies", she said. The project, which began in 2009, is intended to move regulators from implicit decision-making to explicit decision-making through gradual adoption of benefit:risk methodologies and tools, she explained.

Now that the conceptual phase is completed – it has already published three work packages and the fourth is imminent – the agency will initiate a number of pilot projects over the next year or so.

To ensure the product-lifecycle concept is better integrated into the EPAR, the EMA is also exploring the concept of "staggered" approvals (or progressive authorisation) for situations not covered by conditional marketing authorisations under exceptional circumstances. The agency plans to start piloting this concept by year-end.

The EMA has also been involved in a series of pilots launched in 2010 to test multi-country, multi-stakeholder consultations in early-stage drug development. The purpose of the consultations is to improve clarity and alignment among the stakeholders (ie regulators, pharmaceutical companies, HTA bodies, clinicians, patient representatives and payers) regarding what constitutes a medicine's value and the evidence required to demonstrate that value most effectively.

The pilots, run by Tapestry Networks via its European Healthcare Innovation Leadership Network, are ongoing. The network hopes to develop a pragmatic model for establishing and maintaining a more permanent platform for multi-stakeholder consultations.[7]

National regulators, such as the MHRA, are also working more closely with HTA bodies. Ian Hudson, director of the MHRA's Licensing Division, says that the agency's joint scientific advice pilot with the National Institute for Health and Clinical Excellence (NICE) is ongoing, "however interest has been surprisingly limited".[8]

Dr Hudson said the plan had been to trial a number of procedures and then decide whether it was a service worth pursuing. However, there has only been one meeting to date. Despite the slow uptake, he said the meeting was "very useful and showed that we had very common views on the programme".

In future, Dr Hudson foresees closer collaboration between HTA bodies and regulators across a range of issues, such as design of clinical programmes, choice of endpoints, etc.

Industry weighs in

Industry is seeking to ramp up its involvement in HTA, particularly via EUnetHTA. In December 2011, the European Federation of Pharmaceutical Industries and Associations (Efpia), along with the other major organisations representing the European life sciences industry, released a paper entitled 'The value of industry involvement in HTA'.[9]

They believe their substantial in-house HTA capacity can be valuable in the development of policies and methodologies, acknowledging at the same time that HTA bodies must retain their independence in providing advice to payers and governments.

As far as current involvement with EUnetHTA, Efpia participates in its stakeholder forum, but it plays "a more reactive role at this stage", director of the federation's HTA Task Force Edith Frénoy explained to *MedNous*. It plans to get more involved when the EUnetHTA JA rolls out pilots on scientific advice and collaborative REA between 2013 and 2015.

Mrs Frénoy also pointed out that the new EU pharmacovigilance legislation coming into effect this year has more scope for post-market surveillance. It authorises the EMA to require post-approval efficacy studies in certain circumstances, which "goes in the direction of relative effectiveness", she said.

Much progress has been made but there are still many hurdles to overcome before some kind of alignment can be achieved. With the advent of personalised medicine and the increasing use of biomarkers, these obstacles may grow in number before they diminish.

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This article was written by Karen Finn, contributing editor to *MedNous*.