Health Technology Assessment

Moving towards HTA cooperation in Europe

The pharmaceutical industry and other stakeholders such as regulators and payers widely support the European Union's (EU's) ongoing efforts to share across its 28 member states scientific information and methodologies for assessing the value of new medical technologies to society. However, until late October 2014, there was no formal strategy on how this could be achieved.

The aim, as set out in the *Cross-Border Healthcare Directive (Directive 2011/24/EU)*, is to facilitate cooperation between member states on health technology assessment (HTA), for example, by reusing jointly produced HTA information such as relative effectiveness assessments (REAs), at national, regional and local levels. The manifold benefits include avoiding duplication, promoting consistent approaches to HTA, optimising efficiency in health systems and getting new health technologies such as drugs and medical devices to patients faster.

This is good news in theory, but making it work in practice is a major challenge when each member state is bound by its own legislative framework and definition of 'value'. It is thus the job of the HTA Network, established just over a year ago under *Directive 2011/24/EU*, to iron out the scientific, technical and strategic details necessary to implement a sustainable HTA collaboration across the EU. The goal is to create a 'global evidence, local decision' system, which reflects the fact that the HTA bodies have access to the same data but make recommendations that lead to decisions, in line with local law and practice.

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> *Alric Rüther, IQWiG*

The scientific and technical arm of this task is being carried out by the European Network for HTA (EUnetHTA), an EU-funded initiative set up several years ago to facilitate cooperation among HTA bodies across Europe. EUnetHTA's current work, the so-called 'Joint Action 2' (JA2), covers the period 2012-2015. Under JA2, EUnetHTA has stepped up its efforts to develop a core set of HTA methodologies that can be used uniformly across the EU. These methodologies are the tools that will generate the global evidence that governments and payers will eventually use to make informed reimbursement and other healthcare policy-related decisions. EUnetHTA has also been running pilots for companies on rapid REAs and early dialogues (essentially scientific advice) with multiple HTA bodies from different member states, among other activities.

New Strategy for EU cooperation on HTA

The HTA Network, a more political body whose ministerial-level representatives are appointed by member states, is responsible for the strategic part. To this end, it introduced a Strategy for EU Cooperation on Health Technology Assessment at EUnetHTA's conference in Rome, Italy, on 30-31 October 2014.[1] The document provides much-needed guidance for paving the way to the next phase of activity aimed at joining up the 'global evidence' with the 'local decision'.

Among other things, the strategy calls for increased use of common methodologies and cooperation over the full life cycle of health technologies, including the early stages of development. In the document, the HTA Network also commits itself to exploring models for the long-term sustainability of European HTA collaboration, as the activities to date have been piloted (and funded under Joint Actions by the EU) but have not been made permanent.

The HTA Network's document sets out a broad strategy, but how HTA bodies can increase the uptake of joint HTA work at the national/regional/local level will depend on each member state. In this context, the HTA Network has recently set up a new working group to provide scientific, technical and strategic recommendations in the form of a reflection paper, which is expected to be adopted at the HTA Network's next meeting in spring 2015.

Later in 2015, the HTA Network will address the topic of improving interactions between regulators and HTA bodies. The network is also expected to produce a reflection paper with recommendations, to be adopted in the second half of next year.

This ties in with work being done by the European Medicines Agency (EMA), which is now reviewing comments received on its draft best practice guidance for pilot parallel scientific advice procedures with HTA bodies published in May 2014.[2] When finalising the guidance, the EMA told *MedNous* it will also take into consideration the results of EUnetHTA's JA2 and the outcome of the EMA-HTA parallel scientific advice pilot. The pilot, launched in 2010, seeks to help pharmaceutical companies form a development plan that generates data that both the EMA and HTA bodies can use to determine a medicine's benefit-risk balance and value, respectively.

In addition, the EMA is associated with the Shaping European Early Dialogues for health technologies (SEED) consortium, which is financed by the Commission to explore a number of scenarios for conducting early dialogues. The results of these dialogues will also feed into the agency's final guidance.

Another overlapping regulatory consideration is the EMA's ongoing pilots to look at 'adaptive pathways' for the licensing of certain medicines, especially those treating an unmet need. The approach starts with the early authorisation of a medicine in a restricted patient population, followed by iterative phases of evidence gathering and the adaptation

of the marketing authorisation to allow broader patient populations to access the medicine.

HTA will also be considered in this context, and the Commission, in the setting of the Pharmaceutical Committee, has set up a working group with member states to examine the concept and its relevance to the existing legal framework. The working group is expected to start activities before the end of 2014 and it will make links with the HTA Network's activities to ensure there is coordination.

Plans for the future take shape

In terms of long-term sustainability, the HTA Network's strategy addresses post-JA2 funding. With JA2 finishing in October 2015, the network plans to be actively involved in preparing proposals for a new Joint Action on HTA (JA3). The Commission will propose January 2016 as the start date for JA3, although the funding has not been approved yet. It would likely run until 2020 and would provide the project money needed for further pilots, while stakeholders can look into long-term plans for funding a permanent system of EU HTA cooperation.

A new set of recommendations released by EUnetHTA in Rome will also feed into the development of JA3, according to EUnetHTA Executive Committee chairman Finn Børlum Kristensen, who spoke to *MedNous* shortly after the conference in Rome.[3] "The recommendations from EUnetHTA will be relevant to those developing the content of a Joint Action," he commented. A number of the recommendations focus on the transition from piloting cooperation activities to routine implementation and uptake of the joint HTA output in national/regional/local HTA processes. In addition, the recommendations introduce a tiered system for member states to participate in HTA activities (e.g. REA, full/comprehensive HTA, common methodological work) after 2015. This offers greater flexibility to countries that may choose not to participate in certain aspects of the cooperation because of their legal framework or for other reasons.

Dr Kristensen said, for example, that Germany's Institute for Quality and Efficiency in Health Care (IQWiG) and the UK's National Institute for Health and Care Excellence (NICE) had chosen not to participate in joint REAs, but that they are very active in other areas of EUnetHTA's work.

National HTA perspective

Alric Rüther, who heads the Department of Health Care Quality and is responsible for International Affairs at IQWiG, provided the perspective of a well-established national HTA body. He stressed that although IQWiG is a founding member of EUnetHTA and it is very interested in the organisation's efforts, national HTA reports are still necessary due to the substantial differences between the national health systems. "We already have a very high standard so we wouldn't encourage HTA reports that would lower the standard, even at international level," he told *MedNous*.

Moreover, he pointed out that "we have to stick to our legal framework, which is very strict for HTA. This to some extent makes it difficult for us to reuse international HTA reports. Other agencies have this problem, too. It doesn't mean that we wouldn't like to share our reports and work, which we're already doing. We support the just-adopted strategy of the EU HTA Network which among other things aims to improve the exchange and joint production of HTA information."

IQWiG is actively participating in EUnetHTA's early dialogues work, as well as co-leading its Work Package 7 (WP7). Under the latter, EUnetHTA participants are developing guidelines and pilots to improve the quality and adequacy of initial and additional evidence generation. Another WP7 deliverable is to create methodological guidelines and templates to support the production of core HTA information, which could be used for rapid assessments, for example.

In explaining just how different each member state's HTA system is, Dr Rüther noted that under the German system, if a medicine has a proven benefit, then it is regarded as necessary regardless of cost. He gave the example of price negotiations for drugs, which are conducted based on the amount of 'added benefit'. Moreover, IQWiG is purely about the science; it is Germany's Joint Federal Committee (G-BA) that makes decisions about reimbursement. In the UK, on the other hand, costs play a more dominant role and thus NICE looks at cost effectiveness in terms of quality-adjusted life years (QALYs), among other factors, when it makes recommendations on which medicines should be available on the National Health Service.

When *MedNous* asked Richard Bergström, director of the European Federation of Pharmaceutical Industries and Associations (Efpia), about the industry's views on recent HTA developments, he also pointed to the challenge of integrating EU-level assessment reports on relative effectiveness, focussing on the clinical part of HTA, into national/regional appraisals. Mr Bergström said that another major issue was ensuring that national health services are involved, as "there is an element of post-approval data capture that must be considered". To this end, he said that the activities of the HTA Network and EUnetHTA need to be looked at in conjunction with other EU initiatives established under *Directive 2011/24/EU* such as the eHealth Network and European Reference Networks of highly specialised healthcare providers, as well as the EU-funded cross-border patient registries initiative (PARENT) and of course the EMA's activities involving HTA. All of these, he said, need to be made permanent, as the current focus is on piloting and standard setting.

References:

1. EU HTA Network, Strategy for EU Cooperation on HTA, 29 October 2014, http://ec.europa.eu.
2. EMA, Draft best practice guidance for pilot European Medicines Agency health technology assessment parallel scientific advice procedures, 8 May 2014, www.ema.europa.eu.
3. EUnetHTA, Recommendations on the Implementation of a sustainable European cooperation on HTA, October 2014, www.eunethta.eu.

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