

## CROSS-BORDER HEALTH TECHNOLOGY ASSESSMENT?

### Health Technology Assessment in Europe

Europe, on the whole, has embraced the use of health technology assessment (HTA) as a means of assessing the cost effectiveness of medical treatments within specific healthcare environments. HTA is a process whereby treatments are researched and appraised beyond just their safety, efficacy and therapeutic features, with the results intended to assist national policymakers and third-party payers to make reimbursement decisions relating to such treatments.

Interest in HTA began in Europe in the 1970s, but it was not until the early 1980s that institutions were first created, although these were mainly regional agencies in France and Spain<sup>1</sup>. The first national HTA agency was the Swedish Council on Health Technology Assessment (SBU), which in 1987 was tasked with advising the Swedish Government on how it could use healthcare resources optimally<sup>2</sup>. Since then, nearly all European countries have followed suit and established HTA agencies to advise on the best way to allocate resources within their healthcare systems. This proliferation of HTA institutions in Europe has only ever happened along national lines. This is not surprising considering that healthcare systems themselves only exist on a national basis.

As a result, European HTA has grown in a heterogeneous fashion and each HTA system has reflected the variety of traditions and socioeconomic contexts of their own healthcare system<sup>3</sup>. Some agencies have been created to offer support on the level of investment in equipment for hospitals, for example the Comité d'Evaluation et de Diffusion des Innovations Technologiques (CEDIT) in France, whilst others are used to advise on policies that concern the organisation of the entire healthcare system, for example Gesundheit Österreich GmbH (GÖG) in Austria. Indeed, HTA systems by and large are but one part of the national health system in which they operate. As such, one cannot look at the decisions made within the HTA

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<sup>1</sup> European Observatory on Health Systems and Policies - Policy brief: Health technology assessment - An introduction to objectives, role of evidence, and structure in Europe. See <http://www.euro.who.int/document/e87866.pdf> (Accessed on 21 April 10).

<sup>2</sup> Swedish Council on Health Technology Assessment – About SBU. See <http://www.sbu.se/en/About-SBU/> (Accessed on 12 April 10).

<sup>3</sup> European Observatory on Health Systems and Policies. See <http://www.euro.who.int/document/e87866.pdf> (Accessed on 21 April 10).

system as being isolated from the provision of healthcare in a given country<sup>4</sup>. Despite this, there have been repeated calls from the European Union to bring these national arrangements closer together by encouraging greater collaboration and information sharing on HTA.

### European Union HTA collaboration

The EU has been aiming towards greater HTA collaboration since 1994 when it launched the EUR-ASSESS Program, funded by the European Commission. The programme was established to bring together HTA agencies in Catalonia (Spain), France, The Netherlands, Sweden, Switzerland and the UK. This program paved the way for the HTA Europe Project in 1998, which concluded with a call for a permanent structure of HTA coordination in Europe that was eventually published as a policy document by the European Commission. Further attempts at greater collaboration were made in 2000 with the European Collaboration for Assessment of Health Interventions and Technology (ECHTA) Project. In 2004 the European Commission and the Council of Ministers also announced HTA as “a political priority”, recognising the “urgent need to establish a sustainable European network on HTA”<sup>5</sup>.

In 2006, the European Network for Health Technology Assessment (EUnetHTA) was founded to pilot a framework and to create “practical tools to ensure timely and effective production, dissemination and transfer of HTA results into useful policy advice” to Member States and the EU<sup>6</sup>. This framework is to be developed further by the Commission as part of its Joint Action on Health Technology Assessment, within which the EU's stated aims are: to facilitate efficient use of HTA resources in Europe; to create a sustainable system of HTA knowledge sharing; and to promote good practice in HTA methods and processes. The European Commission is also hoping to achieve progress by incorporating HTA into its “Community framework on the application of patients' rights in cross-border healthcare”<sup>7</sup>.

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<sup>4</sup> Stockholm Network - *Theory versus Practice: Discussing the Governance of Health Technology Assessment Systems*. See [http://www.stockholm-network.org/downloads/publications/Theory\\_versus\\_Practice.pdf](http://www.stockholm-network.org/downloads/publications/Theory_versus_Practice.pdf) (Accessed on 21 April 10)

<sup>5</sup> EUnetHTA - The ECHTA/ECAHI Project. See <http://www.eunetha.net/upload/The%20ECHTA%20Report.pdf> (Accessed on 12 April 10).

<sup>6</sup> European Network for Health Technology Assessment – About. See [http://www.eunetha.net/Public/About\\_EUnetHTA/](http://www.eunetha.net/Public/About_EUnetHTA/) (Accessed on 12 April 10). See also European Commission - High Level Group on Health Care. See [http://ec.europa.eu/health/ph\\_overview/co\\_operation/mobility/high\\_level\\_hsmc\\_en.htm](http://ec.europa.eu/health/ph_overview/co_operation/mobility/high_level_hsmc_en.htm) (Accessed on 12 April 10).

<sup>7</sup> European Commission - A Community framework on the application of patients' rights in cross-border Healthcare. See [http://ec.europa.eu/health/archive/ph\\_overview/co\\_operation/healthcare/docs/com2008415\\_en.pdf](http://ec.europa.eu/health/archive/ph_overview/co_operation/healthcare/docs/com2008415_en.pdf) (Accessed on 15 April 10).

## The European Union argument

The argument for cooperation made by the EU is that HTA is international in scope and that there is little difference between the medical treatments used by most health systems. Furthermore, in making their appraisals, HTA agencies will use essentially the same sources and, as a result, there can be a large degree of duplication in the research conducted. By reducing this duplication, it is believed that the EU can maximise and utilise resources, whilst strengthening HTA decisions themselves and helping to spread best practices. Certainly, in the pharmaceutical industry there is a keenness to simplify regulations around drug reimbursement, while many patients also do not understand why countries have different HTA systems. The EU has been keen to stress that it advocates **co-ordinating** HTA information and that joint action by the Union is not aimed at providing policy solutions or recommendations to Ministries of Health<sup>8</sup>.

## Reservations

There are nevertheless real reservations about the EU proposals and concerns about the potential for a more EU-driven HTA system. These concerns maintain that HTA should remain solely focused at the national level because the outcomes of HTA should only ever reflect local circumstances, medical practices and healthcare priorities. Coordinated EU institutions could complicate matters if healthcare decisions continue to be made by payers, which will be influenced by national pricing and reimbursement arrangements, as well as available state resources<sup>9</sup>. As a result, by adding another layer to the HTA process, it is feared that patients would be left with no more clarity as to what is funded by national healthcare systems.

Furthermore, some argue that the EU is overstepping its authority by becoming involved in healthcare planning, undermining the responsibility of Member States for the organisation and delivery of health services, as enshrined in Article 152 of the Treaty on European Union<sup>10</sup>. Article Five of the same treaty also ensures that Community action is taken in accordance with the principle of subsidiarity, which means that decisions are supposed to be taken as closely as possible to the citizen. This broader point is fundamental to

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<sup>8</sup> European Commission – 2<sup>nd</sup> Meeting of the National HTA Appointed Bodies for the Setting up of a Joint Action Between the Commission and the Member States. See [http://ec.europa.eu/health/ph\\_systems/docs/ev20090415\\_mi\\_en.pdf](http://ec.europa.eu/health/ph_systems/docs/ev20090415_mi_en.pdf) (Accessed on 21 April 10).

<sup>9</sup> The European Federation of Pharmaceutical Industries and Associations (EFPIA) - *The Use of Health Technology Assessments (HTA) to Evaluate Medicines*. See <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=1350> (Accessed on 15 April 10).

<sup>10</sup> European Public Health Alliance - Health Technology Assessments - understanding the political challenges. See <http://www.epha.org/a/3398> (Accessed on 15 April 10). See also European Union – Treaty on European Union. See <http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/ce321/ce32120061229en00010331.pdf> (Accessed on 16 April 10).

the current obstacles blocking the passage of the cross-border healthcare directive and to the argument that healthcare decisions should be made as closely to patients as possible.

### Conclusion

Fundamentally, it makes sense that HTA, a method of identifying cost-effectiveness, should be as efficient as possible. If in researching medical treatments, HTA agencies are unnecessarily duplicating their workloads then it is certainly in their interests to work together with other agencies to save valuable time and money. In this respect, there is nothing new. For example the International Network of Agencies for Health Technology Assessment (INAHTA) was established in 1993 to achieve such aims. In Europe too, the International Information Network on New and Emerging Health Technologies (EuroScan) was created as a "horizon scanner", or "early warning system", to make it easier for HTA agencies to share information about new and emerging health technologies<sup>11</sup>.

However, at the heart of this debate is whether there is a justification for cooperation to be developed at a specifically-EU level. Why is it relevant for the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom to collaborate with the State Health Care Accreditation Agency (VASPVT) in Lithuania and not the Medical Services Advisory Committee (MSAC) or Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, when actually the UK has a healthcare system more similar to Australia? Italian HTA and healthcare is more regionalised, therefore wouldn't it be more appropriate for them to work more closely with the Canadian agencies that exist within similar environments? The fear, of course, is that moves towards more harmonised HTA along EU boundaries will be used in the future as a platform for setting a "regional" health policy at the expense of the national ability to do so.

There is a valid argument that an EU network could offer a greater emphasis on transparency and, undoubtedly, HTA decisions should be as open as possible to the patients that they affect. However, it would be unfair to hold HTA decisions accountable outside of the arrangements and environment within which they were taken. Scientific evidence is indeed universal but the implementation of this evidence, taken in context, will be subjective and narrow. In addition, any creation of additional layers of HTA governance should not make it easier for reimbursement decision to be hidden behind a European "scientific veil" that would result in less transparency for citizens.

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<sup>11</sup> EuroScan International Network - About EuroScan. See <http://www.euroscan.org.uk/about/> (Accessed on 16 April 10).

In an even more general sense, this debate also questions attitudes towards HTA within Europe. A competitive market is the preferred way of allocating resources and rewarding innovation, however healthcare does not exist under genuine market conditions. As a result, many states have decided that they need a mechanism that uses evidence-based appraisals to allocate resources within tight healthcare budgets. These arrangements were created to suit their needs and to fit their specific healthcare system and priorities. By establishing a Community framework, there is cause for concern that the EU would treat HTA as an objective rather than a tool and that it might encourage HTA systems to be artificially created in order to fit into EU networks. This would be a mistake and could threaten to undermine the independence of healthcare policymakers to make decisions for their citizens and encourage HTA systems to be created where there is no enthusiasm for them.

Overall, the EU needs to be more realistic about what it wants to achieve and how far it can realistically go with these ambitions. HTA certainly needs cooperation that shares expert knowledge and reduces the duplication of information needed to make an assessment, but many of these networks can be formed voluntarily. Furthermore, individual appraisals should remain an activity at the national level and ultimately the impetus and scope of those assessments should remain with the national authority.