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European collaboration on health technology assessment: looking backward and forward

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Abstract

The establishment of health technology assessment (HTA) has been an important topic in Europe for many years. There have been a series of activities starting with first projects in 1994 leading to joint actions from the European Network of HTA (EUnetHTA) ending in 2021. This long interval of engagement with HTA structures, methodology, and processes by all member states led to a reliable basis for European collaboration in HTA. This article shows milestones and developments from EUR-ASSESS in 1994 through the progress of EUnetHTA and the accompanying EU-HTA-Network up to the recent elaboration of the EU-HTA-Regulation. With the EU-HTA-Regulation HTA collaboration is taken out of the trial phase of more than 15 years. Through the previous EU HTA collaboration, the appreciation and understanding of the differences and complexities behind the HTA processes in the EU healthcare systems have improved. It is now necessary to make the final steps toward a sustainable European Network for HTA.

Looking backward

The introduction of a European health technology assessment (HTA) has been a high priority for the EU Commission for many years. Some of the reasons frequently mentioned have been the need of a smart management of scarce healthcare resources, the minimization of HTA duplication among the Member States, and the need of facilitating patient access to the best healthcare technologies (1). The first activities started as early as 1994 with the EUR-ASSESS project (2), continuing in 1997 with the "HTA-Europe" project, and led to the "ECHTA/ECAHI" project 2000–2 (European Collaboration in HTA/European Collaboration in Assessment of Health Interventions). ECHTA/ECAHI, composed of the fifteen then members states of the EU, delivered, based on the findings of the former projects, recommendations for "HTA in Policy and Practice," "Best (methodological) Practice in HTA," "Joint Assessments," "Exchange of Information," and "Education and Training:" in fact comprehensive foundations for Europe-wide HTA cooperation (3). Already in 2002, one of the main conclusions of the ECHTA/ECAHI project was the need to create a permanent and sustainable European network of HTA Agencies (3). However, the EU was ahead of its time with this. The integration of HTA into the health policy decision-making process of the member states was low. Just some countries had their own HTA organizations, like Sweden (SBU, founded 1987), France (Agence du Médicament, 1993 then HAS), and the United Kingdom (NICE, founded 1999). Some other EU countries went through similar developments (4). Whereas other countries had more difficulties in introducing structured and formalized evidence-based decision-making processes. Against this background, a new EU project, EUnetHTA, was launched in 2006 (5).

The overall strategic goal of the EUnetHTA project (2006–8) was to link EU public national HTA agencies, research institutions, and ministries of health to enable effective information exchange and support for policy decisions by the Member States. The aim was to produce reliable, transparent, and transferable information on the short- and long-term effectiveness of health technologies as input for decision-making within the EU. The result was several tools, such as for adapting HTA reports from other countries to one's own needs, the design of a "clearinghouse" as an interactive platform for communication and joint production of reports, and proposals for integrating HTA into decision-making processes. An important outcome of the project was the development of the philosophy of a "Common Core" of pieces of HTA information in reports and the first version of the EUnetHTA HTA Core Model based on it (6). This idea of identifying core elements that are common between HTA and that can serve as components of individual national

HTA became the heart of further EUnetHTA development. All participating HTA organizations shared the understanding that a shareable core of HTA elements can reduce the burden of reporting, reduce duplication of work and increase the recognition of HTA. However, this was not enough to establish a European-wide HTA network as early as 2008. Nevertheless, many HTA organizations were so convinced of the need for a network that they financed the continuation of the work around EUnetHTA on their own for over a year. These organizations are referred to as the "founding members" of EUnetHTA.

Based on the cooperation of the founding members, a new EU-funded project could be set up with Joint Action (JA) 1 (7).

In addition to establishing network structures, JA1 aimed to develop HTA in the sense of a "relative effectiveness assessment" (REA) accompanied by a corresponding methodology and web-based tools. Focus was also on the further development of the EUnetHTA Core Model as a methodological framework (7). The representatives of JA1 succeeded in integrating the principle for an EUnetHTA network into a legal form. In 2011, the so-called "Patient Mobility Directive" (Directive on the Exercise of Patients' Rights in Cross-Border Healthcare 2011/24/EU) stipulated that the EU establish a "health technology assessment network (HTAN)" (8).

This directive created the legal basis for a voluntary European "HTAN" which was established in 2013 (9). The HTAN was seen as the political and strategic body of HTA in Europe.

EUnetHTA, on the other hand, was an independent scientific and technical part of the European HTA collaboration. As a result, the funding of EUnetHTA was not secured through legal requirements. The members of HTAN were representatives of the health ministries of the Member States, as well as national HTA experts and observers from industry, advocacy groups, and patient associations. In contrast, EUnetHTA included representatives from organizations who are either producers or users of HTA nominated by their national authorities (9).

The HTAN produced a series of reports including the "Strategy of EU Cooperation on HTA" (10) and reflection papers such as on "Synergies between Marketing Authorization and HTA of Medicines" (11). In addition, HTAN adopted work programs (Multiannual Work Program 2016–20) (12) that supported the activities in EUnetHTA.

The strategic outcomes from HTAN supported the further development of EUnetHTA. A JA2 was established (2012–6) followed by the JA3 (2016–21). JA3 was the largest JA to date with a volume of over €20 million and over eighty participating HTA organizations from almost all EU Member States and beyond. The JA2 was intended to enable the application of the tools and approaches developed in JA1 to cross-border HTA collaboration, to improve the understanding and trust of decision-makers in HTA (13). The JA3 went a step further and aimed to define and validate the model of joint work as well as increase the use, quality, and efficiency of the joint HTA work, ensuring reuse in regional and national HTA reports and activities (14). Results of JA3 are of major importance for a sustainable EU HTA system. Together with the implementation of common tools, processes, and methods, JA3 has reinforced joint assessments of health technologies and set up a strong organization of joint HTA early dialogues for scientific consultations (15), with the option of a parallel consultation together with EMA and on Post-Launch-Evidence-Generation (15).

The work of HTAN and EUnetHTA has shown that the text about an HTA network in the Patient Mobility Directive cannot be used as a reliable basis for such a complex structure. This can only be ensured by a separate EU HTA legislation. In its 2017 Work Programme, the Commission's Directorate-General for Health and Food Safety announced that it would launch this new initiative to strengthen EU cooperation on HTA. This stems from the Commission's overall objective to improve the functioning of the internal market for medicines and medical devices. Thus, in parallel to the scientific and technical work of EUnetHTA, a proposal for a Regulation of the European Parliament and of the Council on HTA and amending Directive 2011/24/EU (Patient Mobility Directive) was prepared by the Commission and presented in 2018.

From old to new: transition period for HTA in the EU

The new beginning for EU HTA collaboration is marked by the formal end of EUnetHTA JA3 and the adoption of the new EU HTA Regulation setting the scene for what is to come. A significant amount of work and decisions lie ahead to which the HTA community and their system partners will be challenged to respond. At the same time this change has been expected, and more so, has been actively worked toward by many HTA bodies across Europe.

The EUnetHTA JA1–JA3 were cofinanced by the participating EU/EEA member states and the European Commission providing the financial and legal framework for the collaborative activities of HTA in Europe under the EUnetHTA umbrella. The EUnetHTA JAs have shown that a common European assessment is feasible and is used by the Member States in their national processes. The implementation analysis made in the JA3 found 298 examples of national use of the twenty-seven EUnetHTA assessments. The analysis also showed that partners of the project began to adapt national processes for implementation of joint products(16). However, it was a rocky road until then. Different requirements of the MS, often based on legal specifications, were one main obstacle; the other a different understanding of HTA methodology and processes. These differences in requirements and understanding led to the need to establish a quality management system to support best possible quality and standardization of processes and continuous improvement of processes. The implementation of the quality management system revealed shortcomings of a project-based voluntary approach. For example, some prioritized JAs could not be undertaken because technology developers were unwilling to submit and submissions received were accompanied by discussions about data completeness. These findings allowed further investigation on whether such collaboration should be supported at a union level via a new legislation, resulting in the 2018 EC proposal for an HTA Regulation.

This legislative initiative, the EU-HTA regulation, was adopted in December 2021 (17). It foresees the establishment of a Coordination Group, composed of representatives of the Member States and the creation of subgroups to perform technical HTA work. Four areas of joint work are planned, (i) Joint Clinical Assessments (JCA) for medicines and high-risk medical devices and in vitro medical devices; (ii) Joint Scientific Consultations (JSC), whereby health technology developers (i.e., pharmaceutical industry and device manufacturers) can seek advice from HTA agencies; (iii) identification of emerging health technologies, with a view to identifying promising technologies at an early stage, and (iv) continuing voluntary cooperation in other aspects of HTA. Methods, processes, and tools shall base on the developments and results of EUnetHTA including general rules on independence, transparency, and stakeholder involvement.

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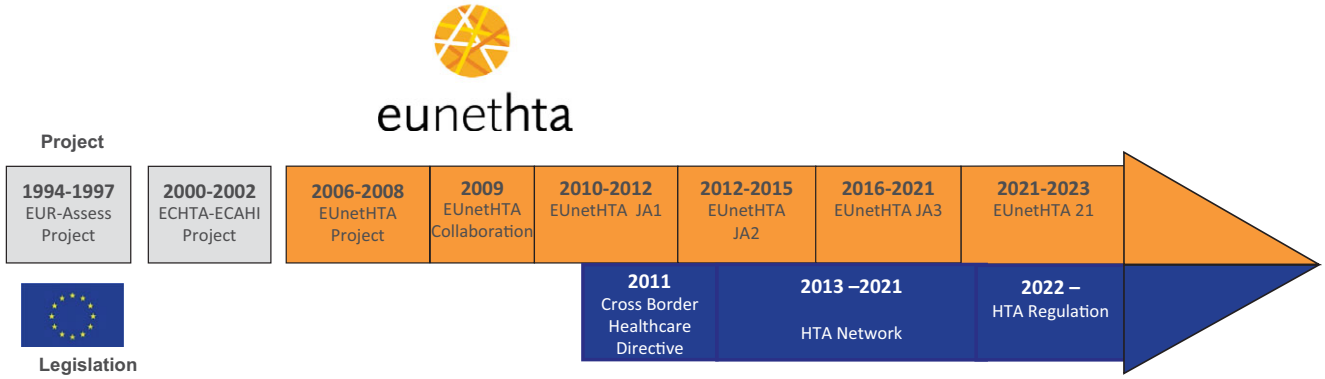

Figure 1. Timeline of establishment of an health technology assessment network in Europe.

After it is coming into force, the legislation allows a 3-year interval for implementation in order to provide the necessary time for the new EU HTA system and its governing bodies to constitute themselves and create the relevant infrastructure, rules, guidelines, processes, and procedures necessary for the future system.

The workload, to provide all necessary details for the functioning of the envisioned EU HTA system, is considerable. At the same time, this work is based upon the vast experience and results of the EUnetHTA JAs. The last JA alone has produced documents totaling more than 50,000 pages of text. Therefore, it was the aim of EUnetHTA JA3 to support the transition toward a sustainable collaborative system with a comprehensive piece of work—the "White Paper" describing the learnings and recommendations from the JA3 (15).

To provide further support for system set-up, the European Commission has tendered a service contract, which specifically focuses on the further development of methodology for HTA collaboration for potential application in the future EU HTA system. Together with the outcomes and developments of JA3 the results shall provide a high-quality methodological and procedural backbone for the future EU HTA system. This service contract, scheduled between 2021 and 2023, was awarded to a consortium representing HTA agencies of twelve EU member states, who have been amongst the leading partners of EUnetHTA JA3. This consortium, called EUnetHTA 21 (18), is seeking to provide a body of work to fill the legal framework provided by the EU HTA Regulation.

The transition period between the voluntary collaboration under the EUnetHTA JAs to an EU HTA system will be supported by a concerted effort from all parties involved. The main tasks of the EC will include setting up the infrastructure and secretariat to facilitate the future system. EU HTA agencies have committed to support this process via their own means with one mechanism being the Heads of Agencies Group (HAG) (19).

The HAG group was created during JA3 in response to a need to provide greater direction to the EUnetHTA Executive Board. The HAG group brought together the relevant Heads of HTA Agencies represented in the EUnetHTA JA3 Executive Board. This group took the role of a strategic advisory body for the work of the EUnetHTA JA3 Executive Board. The HAG decided to carry on its work beyond the framework of EUnetHTA JA3 and has constituted itself now as a separate body consisting of the Heads of the public national HTA organizations whose work is within the remit of the EU HTA-regulation. The HAG will support the development of the new EU-HTA system and provide a platform for process, methodology, and quality of HTA (https://htahag.eu) (19).

Conclusion

The trial phase of more than 15 years allowed a stepwise development of awareness of HTA collaboration on European level, providing participants—industry, patients, HTA agencies, and all other stakeholders—the necessary time to learn, to deal with cultural differences and to prepare and adapt resource management. The changes will allow the creation of a single EU HTA system ensuring predictability of processes. It will create a system in which member states HTA agencies will produce and use joint assessments for their own reimbursement and pricing decisions and their own appraisal processes. The European Council fought hard to ensure that each member state remains in full control of the application, interpretation, and adaptation of these joint assessments. This subsidiarity, rightfully so, is imperative. Some might have wished that the EU HTA legislation had gone further. But the outcome of the legislative process should not be seen as a limitation but as an opportunity, as it allows an outstanding chance to learn and develop from joint work. Through EU HTA collaboration we have started to appreciate and understand the differences and complexities behind the HTA processes in our healthcare systems. The more these complexities are appreciated, the better HTA agencies will be able to work efficiently together (Figure 1).

Conflicts of Interest. The authors declare that they have no conflict of interest.

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