EUnetHTA Joint Action 2

2012-2015

FINAL TECHNICAL REPORT

Executive Summary

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The EUnetHTA network collaboration was initiated in 2006 with the EUnetHTA Project that aimed to establish an effective and sustainable European network for Health Technology Assessment (EUnetHTA) that informs policy decisions. An explicit request by EU and Member States (MS) for a sustainable network for Health Technology Assessment (HTA) was formalised at the European level in the **Directive** 2011/24/EU on **patients' rights in cross-border healthcare and Article 15 that** requires the EU to support and facilitate cooperation in HTA through a voluntary network of HTA institutions from the MS. The EUnetHTA Joint Action 2 (JA2), which covered the period from October 1, 2012 to March 31, 2016, was a response to this request.

The general objective of this second Joint Action was to strengthen the practical application of tools and approaches in cross-border HTA collaboration. The JA2 aimed at bringing collaboration to a higher level resulting in better understanding for the Commission and Member States of the ways to establish a sustainable structure for HTA in the EU.

The EUnetHTA JA2 was a complex undertaking that involved multi-disciplinary staffs of 69 organisations in 31 countries across geographical Europe. A total number of 49 government-appointed organisations from 28 EU Member States and Norway and a large number of regional agencies and not-for-profit organisations that produce or contribute to HTA participated in the work in eight Work Packages (WPs). The EUnetHTA JA2 activities were supported by a transparent organisational and governance structure and policy. The Lead and Co-Lead Partners of the WPs, together with the Chair of the Plenary Assembly and three elected member organisations composed the Executive Committee – the main executive body involved in the strategic leadership of the JA. Partner organisations were represented by their heads at the Plenary Assembly, the function of which was to agree policy and discuss vital strategic issues. In order to facilitate information exchange with the stakeholders, a Stakeholder Forum (SF) was a part of the governance structure of EUnetHTA. Nineteen organisations that represented four stakeholder groups (patients/consumers, providers, payers, and industry) joined the JA2 SF.

The main activities of the EUnetHTA JA2 were structured to address the issues of value assessment of health technologies along their Life Cycle. This was achieved through the development of processes for Early Dialogues, early (rapid) HTAs (Rapid Relative Effectiveness Assessments [REAs]), Additional Evidence Collection and Comprehensive (Core) HTAs as well as by developing and applying appropriate tools (the HTA Core Model®, POP Database, EVIDENT), methods (Methodological Guidance), and work process supporting tools. This work resulted in the delivery of a significant number of outputs that included both the initially planned and additional deliverables. An excerpt of the outputs is presented below – a complete list of deliverables and official outputs can be found in the full EUnetHTA JA2 Final Technical Report:

- Twelve REAs (6 on pharmaceutical and 6 on other technologies)
- Three Core HTAs
- Eleven Early Dialogues (9 on pharmaceuticals and 2 on medical technologies)
- Five methodological guidelines
- Evidence submission templates for pharmaceuticals and medical devices
- An updated and upgraded application package of the HTA Core Model®

- More than 40 instances of the national uptake of the results of the joint work performed in EUnetHTA JA2
- A suit of process and procedural guidance to support various types of joint activities within the framework of European cooperation on HTA
- Recommendations on the implementation of a sustainable cooperation on HTA

Throughout the JA2, EUnetHTA initiated collaboration with a number of external parties relevant to HTA and to the European cooperation on HTA. These included collaboration with four EU FP7 funded HTA - projects: AdHopHTA, Advance HTA, Integrate HTA and MedTecHTA; joint actions (PARENT), and information and communication (ICT) projects (MAST). Furthermore, cooperation with EMA matured into a more structured and sustained level of engagement from both parties, based on a three year work plan which included areas and initiatives to improve the efficiency of the processes and conditions for patients' timely access to effective medicines.

Clarification on division of tasks and responsibilities between the policy arm (the HTA Network) and the scientific and technical arm (EUnetHTA) of the European cooperation on HTA was initiated with the establishment of the HTA Network in 2013. The two main strategic documents (HTA Strategy for the European cooperation on HTA and the Recommendations on the implementation of a sustainable European cooperation on HTA) were developed in consultation between the two levels of the European cooperation. Further strengthening of synergies between the levels is expected in the coming years.

A primary target group for EUnetHTA was the producers of HTA. Whereas, the feasibility of the cross-border collaboration in the projects of common interest was proven by production of three full core HTAs and 12 rapid REAs, the usefulness of the joint assessments was indicated by the EUnetHTA partners by adaptation of the produced information to the national or regional level. The growing potential of this joint production to deliver value to the healthcare systems was also gradually acknowledged by the industry (especially pharmaceutical companies). This acknowledgement was manifested in the increasingly more visible and active participation of pharmaceutical and medical technology companies in the process (i.e. expression of interest and scoping meetings) in the second half of JA2. Positive feedback and constructive suggestions to the EUnetHTA overall activities was provided by all stakeholder groups, however, it must be noted that specific processes still remain to be designed to ensure effective involvement of patients and providers.

Focusing on the main JA2 objectives, EUnetHTA provided a structured opportunity to test the capacity of national HTA institutions to cooperate in specific assessments (including rapid REAs) within a network structure and address the issues of utilisation of common structured HTA information in the production of local reports. A direct application of joint assessment reports in local decision making, e.g., on reimbursement of health technologies, should be done with caution and after a thorough check of transferability of the joint work results in relation to the local context and needs. Nonetheless, it is worth noting that already in JA2 there were a limited number of cases of direct use of the joint assessments into making local decisions on reimbursement.

The mandate of EUnetHTA lies within the scientific and technical collaboration with an aim to develop and maintain methodologies, tools/instruments and operational processes that support production of HTA –

and to apply them in joint and local assessment on a voluntary basis. During the most recent three years the collaboration was further strengthened, standards and transparency issues clarified, and quality managed through newly designed processes. The pace and direction shown, if kept in the future, will lead to further building of trust and increase the sense of individual ownership of the joint work outcomes and accountability for the national implementation of the joint work results among the partners.

Whereas mechanisms to improve and ensure the relevance of the results of the joint European assessments at the local (national and regional) levels and a continuous development of the EUnetHTA tools for joint assessments (e.g., the HTA Core Model®) should be further explored, the development of new methodological guidelines needs to be strategically re-organised with a focus on implementing partnerships with recognised scientific societies and scientific projects relevant to HTA. This approach would allow avoiding unnecessary duplications and freeing resources for activities related to effective and high quality production of more joint assessments.

By 2019 a standard process should be implementable for European HTAs, that would cover appropriate generation and assessment of evidence throughout the entire life cycle of health technologies (from early dialogues, through early assessments, additional evidence generation and assessment of technologies already established in the market to technologies which may be already outdated and could be replaced by newer, safer and more effective ones). Such a system should focus on HTA production that will be fit-for-purpose, efficient and of high quality in order to facilitate patients' timely access to safe and effective health technologies across Europe. An appropriate, feasible mechanism of financing permanent operations of such a system needs to be identified. Together with the strategic HTA Network and the European Commission the scientific and technical HTA cooperation needs to clarify and lay out specific organisational and governance criteria and conditions for permanent European scientific and technical cooperation. Assessment of potential options for hosting permanent coordination functions should be based on these criteria and conditions - which must also include definitions of the role, function and specific tasks of the coordinator/coordinating facility to support permanent cooperation. Such clarification must take place early at the start of the next development phase. Based on conclusions of a thorough assessment of the capacity and capability to implement a long-term coordinating function the hosting and viability of such a function must be ensured with an appropriate business model and sustainable funding.

The formal processes, including legislative, need to be initiated in a timely manner to put in place the necessary changes in any formal legislative acts to support the implementation of a specific hosting solution and organisational structures of the permanent European cooperation on HTA.