



eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA Joint Action 2

2012-2015

DELIVERABLE 1

Recommendations on the implementation of a sustainable European cooperation on HTA

Contents

Introduction	3
Factors influencing the scientific and technical cooperation	3
Diverse national and regional HTA production needs	3
Factors influencing the sustainability of the European cooperation on HTA in the long term	4
Recommendations	4
Organisational aspects.....	4
Technical aspects	8
Appendix 1. EU cooperation on HTA – two levels acting in synergy	10
Appendix 2. Levels of engagement in the scientific and technical cooperation on HTA.....	11
Appendix 3. Examples of the added value received through participation in the European cooperation on HTA.....	13
References	14

Introduction

This document forms the Recommendations on the implementation of a sustainable European cooperation on HTA. It is a deliverable from EUnetHTA Joint Action 2 (EUnetHTA JA2) as per the Grant Agreement with the European Commission¹.

EUnetHTA was established in 2005 as a network to facilitate cooperation between HTA bodies focusing on the scientific and technical aspects of cross-border collaboration. Since the EUnetHTA JA2 Grant Agreement was signed with the European Commission in 2011, important developments have taken place. The HTA Network², focusing on strategic aspects of the European cooperation on HTA, has been set up; EUnetHTA JA2 is now mandated to be the scientific and technical level in the European cooperation on HTA working in synergy with the HTA Network according to the implementation of Directive 24/2011/EU on the application of patients' rights in cross-border healthcare³⁴.

The overarching objective of the EUnetHTA JA2 is to strengthen the practical application of tools and approaches to cross-border HTA collaboration and to contribute to the background for a general strategy, the principles and the proposal for actual implementation of a sustainable European cooperation on HTA in the light of the Directive 2011/24/EU.

The focus of the document is on the scientific and technical aspects of cooperation on HTA in Europe. It aims at contributing to the development of content and structure of a possible 3rd Joint Action on HTA and lays out and provides recommendations on

- a) factors influencing the implementation and testing of the scientific and technical cooperation in HTA with regards to both the internal processes of the participating organisations as well as interaction between them within a permanent structure of the European cooperation on HTA, and
- b) organisational, governance and technical aspects (including necessary formal conditions of financing) of the scientific and technical mechanism of the European cooperation on HTA in the period after completion of the current EUnetHTA JA2 (i.e., after 2015).

The recommendations have been developed with the fundamental understanding of and respect for the Member States' responsibility for the definition of their health policy and for the organisation and delivery of health services and medical care, including allocation of resources assigned to them (as per Article 168, paragraph 7 of the Treaty on the Functioning of the European Union).

The document was developed by the EUnetHTA Secretariat and EUnetHTA Executive Committee with comments provided by the EUnetHTA Stakeholder Forum. The document was commented and has been endorsed by the EUnetHTA Plenary Assembly (comprising organisations formally nominated by the Ministries of Health (or equivalent) of the European Union Member States and countries formally participating in the EU Health Programme).

Factors influencing the scientific and technical cooperation

Diverse national and regional HTA production needs

Since its inception in 2005, EUnetHTA has fostered the cooperation between diverse HTA organisations across Europe with the focus on developing tools for HTA and efficient mechanisms for working practically together. After several years of development, a more operational EUnetHTA purpose can now be expressed as *“to facilitate the production of HTA information with a common scientific basis and tailored to the needs of the national/regional HTA organisations. A wide range of tools are offered to facilitate various steps in the HTA production process for various types of health technologies.”*

EUnetHTA has increasingly developed and tested specific tools and approaches to address HTA of various types of technologies at the different stages of their life-cycle⁵. At the same time, more work needs to be done on incorporating the existing EUnetHTA products (tools, methodologies, assessment results) into the

¹ 20112301 EUnetHTA Joint Action 2 Grant Agreement, p. 36

² See Appendix 1

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>

⁴ http://ec.europa.eu/health/technology_assessment/docs/hta_network_rules_procedures_en.pdf

⁵ E.g., starting from early dialogues, to POP Database and collaborations based on it, to producing full/comprehensive HTAs and rapid HTAs (both being results of applying the HTA Core Model®), to facilitating additional evidence generation (EVIDENT Database), to developing methodological guidance, to providing training and facilitating capacity building in HTA

“real life” HTA production processes in European HTA organisations, at the national, regional, institutional, and professional level. The work at all levels of the scientific and technical cooperation (i.e., European, national, regional, institutional and professional) should be guided by an objective of ensuring efficiency, consistency, and quality of HTA.

This shall be done while

- taking into account the voluntary nature of individual HTA organisations’ engagement in the activities of the European cooperation on HTA
- taking into account, and integrating with, the various professional and health-care systems’ dynamics of managing healthcare technologies (*Member State (MS) level*)
- taking into account various abilities and conditions for engagement in the European cooperation on HTA in different Member States and their specific HTA organisations when developing and testing concrete feasible and sustainable types of engagement at various levels (*MS level*)
- ensuring that developments in the scientific and technical cooperation and related developments in its partner organisations are in synergy with changes in the health policy interaction between MS (*European level*) and with regulatory interactions between MS for various technologies
- ensuring that all types of technologies can be subject to HTA
- exploring, creating and exploiting opportunities for cooperation with leading research and academic institutions in science, research and development, e.g., by way of the Horizon 2020 programme (*European level*)
- continuing to interact with the stakeholders in ways that ensure maximum value and appropriate engagement for the scientific and technical cooperation in HTA across Europe
- taking into account health policy developments at European and global level⁶, as well as progress in science and applied research (*MS, European and global levels*).

Factors influencing the sustainability of the European cooperation on HTA in the long term

- The degree of commitment of all parties (from individual HTA researchers, HTA agencies and national/regional healthcare decision-making bodies to stakeholder groups and their constituencies) to participate in creating, applying, and using the output of the European scientific and technical cooperation.
- Output of the European scientific and technical cooperation offering a common and trustworthy scientific basis for informing national/regional decision processes, fully respecting local (i.e., national/regional) laws, regulations and policies.
- The priority given to activities, including appropriate organisational and financial support for their implementation, to meet the specific objectives for the next phase in the development of the scientific and technical cooperation. Such prioritisation must also respect the need for coherence between the various activities.
- The level and type of financing as well as the management of operations of the scientific and technical cooperation to safeguard continuity and permanency of the European cooperation on HTA.
- The degree of voluntary adjustments in working processes of participating organisations to allow for appropriate integration of the European cooperation activities in routine HTA production processes on the national/regional level. Such adjustments should reflect the level of engagement and participation in the European activities that each organisation decides on its own.
- Developments that support good governance and management in healthcare systems in Europe and globally.

Recommendations

Organisational aspects

- 1. Define and attribute distinct tasks to the strategic level and the scientific/technical level in the European cooperation on HTA while ensuring synergy between the levels with a clear separation of their remits and mandates.**

⁶ http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R23-en.pdf

The remit of the scientific and technical cooperation is *to facilitate the availability of robust, common and sharable scientific knowledge and to support the production of HTA information tailored to the needs of the national/regional HTA organisations participating in the scientific and technical cooperation on HTA in Europe*. The mandate of the scientific and technical collaboration is 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.

The strategic level (the HTA Network) and scientific and technical level shall work in synergy in the development of the strategic priorities as well as in defining specific activities to be undertaken in the next phases of the European cooperation on HTA, specifically in the phase after completion of the current EUnetHTA JA2. The activities of the scientific and technical cooperation should be fit-for-purpose to meet the goals and priorities of the HTA Network.

Intellectual and scientific independence of the scientific and technical cooperation must be respected and safeguarded.

The recommended tasks for the scientific and technical level should aim at

- identification and prioritisation of the scientific and technical means (i.e., tools/methods/ways of organising the work) to perform the tasks of the scientific and technical level
- standardisation and harmonisation of scientific methods and tools for producing HTA information while taking into account and appropriately integrating relevant results of other recognised international scientific collaborations
- consolidation of collaborative production (more efficient, less duplication of effort among participating organisations)
- regular sharing of information on activity programmes and projects (ongoing and planned) in the participating HTA organisations
- capacity-building activities allowing for efficient uptake of the results of the joint work and effective participation in the activities of the scientific and technical cooperation
- facilitation, as appropriate, of use of HTA information developed at European level in local assessments
- efforts to improve transparency of the joint work and national HTAs

2. Continue to provide flexibility of participation in the scientific and technical cooperation in line with the decided degree of commitment and responsibility in activities – levels of engagement

Three incremental levels of engagement in specific commonly defined activities (e.g., relative effectiveness assessment (REA), full/comprehensive HTA, common methodological work) in the post-2015 phase shall be explicitly introduced.⁷

Level 1: sharing and exchange of information produced and methods applied individually by participating organisations;

Level 2: contributing to the development, support and application of common tools (e.g., databases, models for structuring and reporting of HTA information, capacity-building activities) and scientific methods (e.g., methodological guidelines and templates) to support HTA production processes;

Level 3: contributing to production of joint assessment reports and application of the results of joint assessment reports in the national/regional HTA production processes.

Differences between the levels shall be expressed in

- a) the extent and type of input an organisation provides to the defined activity and
- b) degree of rights and responsibilities associated with each level.

The agreed specific engagement level for each organisation and the availability of competence/ expertise would need to be considered to determine an organisation's participation in specific activities.

To ensure viability of the structure and activities of the scientific and technical level, the level of engagement in the activities of the cooperation that a participating organisation chooses to engage at shall correspond to a defined level of access to the output, services and/or financial resources of the cooperation.

⁷ See Appendix 2 on the proposed Levels of engagement (developed by EUnetHTA JA1)

3. **Focus on a transition from piloting of cooperation activities to routine implementation and uptake of the joint output in national/regional HTA production processes**

The objectives of cooperation activities in EUnetHTA JA1 and JA2 were focused on creating the conditions and supporting methodology guidance, tools, etc., for piloting joint production processes. With the experience gained and lessons learned, all future activities in the cooperation need to clearly show utility of the joint work⁸ outputs for the national/regional/institutional HTA production processes.

Measuring the national uptake of the results of the scientific and technical cooperation activities should focus on the **scientific output** produced by European cooperation and its use in the national/regional/local HTA production processes (e.g., **in the form of adaptation of methodologies and results of the scientific work**).

The recommended specific approaches to support the desired changes:

- Build on the achievements and results of the EUnetHTA JA1 and JA2 to inform and facilitate continuous commitment and delivery as per mutually agreed conditions, requirements and shared - as well as individual - responsibilities of the network members
- Limit the number of activities while prioritising those areas of cooperation that demonstrate return on investment in the cooperation to both the participating Member States and the European Union
- Accelerate/improve efforts in the partner organisations to facilitate “readiness to change” in their routine working processes – by informing and working with the executive management as well as by expanding the “exposure” of as many staff members as possible to the results and tools produced by EUnetHTA
 - Systematic searches in the POP Database should be introduced into the working processes at the start of each new project (doing so will offer a concrete approach to finding an opportunity to capitalise on the work done by others, to engage in joint work and to share own work and results)
 - Regularly informing the national/regional decision makers who commission topics to HTA agencies (where a commissioning mechanism is used to fund HTAs) of the available results of the EUnetHTA joint work (e.g., REAs, full/comprehensive HTAs). Such a routine could facilitate an increase in the number of topics for joint work that will be relevant/common to a larger number of countries
- Determine which criteria are used to make national decisions on identifying opportunities for collaboration (to allow extrapolation and understanding of specific differences between countries and HTA organisations in their decisions to engage in the joint work)
- Collect and disseminate the information on the added value of participation in the European cooperation on HTA⁹ to the decision-/policy makers both at the European and national/regional levels. Organisations participating in the production of joint work need to demonstrate the use of the specific joint work in their national decision making.

Value added by the European cooperation on HTA should be determined by putting together benefits offered and experienced through participating in various activities. Benefits include the realisation of positive effects of economy of scale, coherent and fit-for-purpose capacity building, standardisation of scientific methods, and improvement of the quality and appropriateness of the data produced at various stages of the lifecycle of health technologies. However, benefits will not only be possible (and should not only be assessed) via single, stand-alone activities, e.g. REA and implementation of their results nationally. The cumulative effect of all activities performed by the voluntary cooperation that are found to bring value to different HTA agencies in various EU countries should also be counted as benefit.

⁸ “Joint work” is described in the glossary of the current (as of August 18, 2014) draft of the HTA Network strategy paper (reference to be included when available). In addition and to specify further, “joint work” includes both work on a) joint development and then application of the tools and methods in the production of HTA information both at the European and national/regional/institutional levels, and b) joint production of joint assessments and then uptake.

⁹ See Appendix 3 for a list of concrete examples of the value-added experienced by the organisations that participated in EUnetHTA project, Joint Action 1 and Joint Action 2.

4. Adjust stakeholder involvement to match the remits and mandates of the two levels of activities¹⁰ in the European cooperation on HTA.

Based on the experience gained in EUnetHTA JA1 and JA2, the kind of stakeholder interactions that bring highest value to the scientific and technical cooperation are derived from public consultations, expert meetings and direct interaction with relevant stakeholder groups where there is a focus on specific scientific and technical topics in relation to concrete production of HTA information. It is recognised that modalities of stakeholder interaction seeking input from the four identified stakeholder groups (patient and healthcare consumers, healthcare providers (professionals and hospitals), industry, and payers) need to account for a) variations in access to structural and financial resources supporting provision of input, and b) differing positions of each stakeholder group in the healthcare systems.

At the scientific and technical level the focus of offering specific stakeholder involvement shall be on
1) attaining the scientific and technical subject matter knowledge, scientific and technical competence, and other special knowledge of relevance to the subject matter, and
b) regularly providing information about the progress of the work.

A review of the currently identified stakeholder groups should be performed to ensure their relevance to the future needs of the scientific and technical cooperation.

Stakeholder organisations participating and benefiting from the activities of the European cooperation on HTA should also be charged with the responsibility to disseminate information on the value they receive from the cooperation and to align their working processes and competencies with the outputs and requirements of the cooperation.

5. Develop approaches to overcome organisational barriers in the HTA organisations participating in the European cooperation on HTA

- Review formal conditions in commissioning of assessments to find opportunities to allow appropriate engagement in the joint work or utilisation of the results of the joint work
- Review and make explicit legal requirements or other formal arrangements that either facilitate or hinder implementation of the results of joint work in national/local activities
- Explore opportunities to use English language to share output of the national/regional HTA production processes
- Develop an insight into the timing, process and needs in the national/regional HTA production to allow proactive management of the common usage of the joint work output
 - Different local characteristics, needs and state of development of HTA within healthcare systems must be taken into account when considering readiness to use specific outputs of the scientific and technical cooperation - not all output would be interesting/useful to the same degree/in equal measure to all participating organisations.

6. Aim at the European Commission's and Member States' financial support to facilitate sustainability of the operations of the European cooperation on HTA

Financial support from the European Union and participating Member States has a decisive impact on the continuing success of the European cooperation on HTA. Therefore, the possibility of accessing EU funds to finance various activities in European cooperation on HTA via the EU budget, e.g. various EU programmes such as the Health Programme and Horizon 2020 - including access to EU structural funds (especially for capacity-building), is key to secure sustainability of the cooperation.

While respecting the provisions set by the EU Financial Regulations, any financial aid which may be granted to support the activities of the scientific and technical cooperation should

- enable budget flexibility which facilitates access to funds by eligible participating organisations based on their competence and expertise relevant to the specific activities at different points in time during the total financial period of a future collaboration phase.

¹⁰ Scientific- technical level and strategic level

- allow allocation of resources which depends on the level of involvement and specific requirements to carry out the tasks.
- consider contribution of the staff of public bodies as an expense that should not also be an income to the budget of the scientific and technical cooperation.
- allow allocation of sufficient resources to a) collaborative project management, b) maintenance and further improvement of EUnetHTA tools (e.g., HTA Core Model, databases, etc) and c) individual participating HTA agencies' voluntary efforts to 1) transform their routine work practices to apply the tools and results of joint work and the HTA production results of other participants and/or 2) to make their scientific and technical outputs more usable by others in the cooperation.
- enable formation of clusters of HTA organisations to work on common topics of interest. This will allow testing of new models of working together. Flexibility in doing the work in terms of time of their formation, composition, and duration of their work should be allowed. The choice of topics and decision to form such clusters need to be in synergy with the priorities and goals set by the strategic level of the European cooperation on HTA (the HTA Network).

7. *Hosting of the overall coordination function*

The scientific and technical cooperation for HTA needs to clarify and layout specific organisational and governance criteria and conditions for a permanent European scientific and technical cooperation on HTA. Assessment of potential options for hosting permanent coordination functions should be based on these criteria and conditions (this will also include definition of the role, function and specific tasks of the coordinator/coordinating facility to support the permanent cooperation). Such clarification must take place early at the start of the next development phase (no later than 2016). 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.

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

Technical aspects

1. **Test and deliver a final workable business model for the permanent European cooperation on HTA.** The business model that was previously proposed by EUnetHTA should be part of the basis for such testing¹¹. Consolidation of collaborative production as the corner-stone to build such a model on should include
 - a. Improvement of the topic selection and prioritisation processes to better align with the HTA production needs at the national and regional level
 - b. Field-testing the concept of “activity centres” specialising in certain key modes of technical and scientific cooperation to provide focused coordination and facilitation in a defined area of activity¹² together with a facility for the overall coordination of the scientific and technical cooperation i.e., meta coordination between the activity centres.
 - c. Field-testing the concept of “clusters of organisations” utilising the results of joint work within the real world production routines in the participating countries. “Clusters of organisations” can be formed on a time-limited basis to deliver a specific defined output, eg, rapid HTA on a specific topic.
 - d. Implementation and field-testing of active brokering of joint work on shared topics for HTA including early appropriate engagement with users of HTA information - specifically providers, patients and payers on prioritisation of joint HTA production
2. **Engage in a continuous dialogue with the executive management of partner organisations** to facilitate “readiness to change” in their organisation’s routine working processes.
3. **Develop a robust evaluation of the use of joint assessments** for national utility and impact of joint assessments

¹¹

<http://www.eunethta.eu/sites/5026.fedimbo.belgium.be/files/EUnetHTA%20Business%20Model%20report%20as%20of%20May%202012.pdf>

¹² P. 10 of EUnetHTA JA2 Plenary Assembly 2014 Meeting Report

4. **Continue advancing collaboration with regulators through cooperation with the European Medicines Agency (EMA)**, specifically in the area of early dialogue and post-authorisation studies
5. **Continue advancing engagement with industry**, specifically through the activities of early dialogue, submission requirements and application of the HTA Core Model¹³
6. **Explore concrete ways of multi-technology assessment** (i.e., HTA on complex interventions, companion diagnostics and ICT (information and communication technology) applications) **and of contributing HTA information to the development of the clinical practice guidelines**
7. **Focus on capacity-building activities** that allow for exchange of experts and training-on-the-job/internships between the HTA organisations participating in the European cooperation on HTA
8. **Continue updating and adapting as well as developing (if necessary) a formally agreed common** methodological guidance in HTA while avoiding duplication of efforts with other international collaborative initiatives developing methodological guidance
9. **Develop more effective and strategic communication approaches** and practices to support and promote the activities of the scientific and technical cooperation

¹³ <http://www.eunetha.eu/hta-core-model>

Appendix 1. EU cooperation on HTA – two levels acting in synergy

The HTA Network has been set up by Article 15 of Directive 2001/24/EU on the application of patients' rights in cross-border healthcare. The HTA Network started its activities in 2013 following the adoption of the Commission Implementing Decision of 26 June 2013 providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment¹⁴.

The HTA Network defines long-term-strategies, discusses general policies of cooperation and gives guidance and priorities on the work programme of the scientific and technical level. Members of the HTA Network are the national authorities or bodies responsible for HTA nominated by the Member States, in most cases Ministries of Health¹⁵.

EUnetHTA was established in 2005 to contribute to the development of a sustainable network for HTA in Europe focusing on the scientific and technical aspects of cross-border collaboration. After the initial EUnetHTA Project co-funded in 2006-08 by the Health Programme of the European Commission EUnetHTA is working by way of a Joint Action co-funded by the Health Programme in two different phases (JA1 2010-2012 and JA 2 2012-2015)¹⁶. EUnetHTA JA 2 is acting as the scientific and technical level of the European cooperation on HTA, in line with article 1.1. of the rules of procedure of the HTA Network¹⁷. The scientific-technical cooperation coordinates the exchange and the production of HTA information, including work on methodologies; it defines procedures and addresses scientific and technical aspects of HTA.

Members of the scientific-technical cooperation are the organisations or bodies performing HTA or using HTA to inform decision making with an explicit mandate at national or regional level. Members of the scientific-technical cooperation are also nominated by the EU Member States.

Stakeholders are associated with both the strategic and the scientific-technical level, with the appropriate modalities for involvement at each level.

¹⁴ http://ec.europa.eu/health/technology_assessment/docs/impl_dec_hta_network_en.pdf

¹⁵ http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm

¹⁶ <http://www.eunetha.eu/outputs/technical-annex-eunetha-ja2-grant-agreement>

¹⁷ http://ec.europa.eu/health/technology_assessment/docs/hta_network_rules_procedures_en.pdf

Appendix 2. Levels of engagement in the scientific and technical cooperation on HTA

The following incremental levels of engagement were developed based on the EUnetHTA Strategy 2012 (Deliverable of EUnetHTA Joint Action 1), further discussions in the EUnetHTA Plenary Assembly and experiences gained in the EUnetHTA Joint Action 2¹⁸. Each organisation can choose to participate at different levels for specific, commonly defined activities, e.g., REA, full/comprehensive HTA, methodology development. The indicative levels of financing will allow for incremental financial support depending on the degree of overall participation by the organisation. .

Level 1: sharing and exchange of information produced and methods applied individually by participating organisations.

Responsibilities: free provision of information about the organisation's scientific output and methods to the participants of the cooperation (details on the specific conditions of such provision of information to be described, e.g., provision of the above mentioned information free-of-charge, upon request from individual organisations participating in the cooperation and from the coordinating facilities of the cooperation; within a specified agreed-upon time frame, etc) (*obligatory*). No requirement to get engaged in joint work performed by the participants in the European cooperation on HTA. Dissemination of general information about EUnetHTA, its activities and outputs (focus on dissemination efforts at national/regional level of the participating organisation's country).

Rights: access to the basic support functions of the scientific and technical mechanism (to be described further); access to information resources of the scientific and technical mechanism (extent to be defined further to reflect and correspond to Level 1 of engagement); access to funding (if available) at minimum level (to be defined, e.g., covering 30% of the eligible expenses associated with participation in the activities at Level 1).

Level 2: contributing to the development, support and application of common tools (e.g., databases, models for structuring and reporting of HTA information, capacity-building activities) and scientific methods (e.g., methodological guidelines and templates) to support HTA production processes.

Responsibilities: active participation in the joint work on development of the common tools and/or methods within the agreed time-frames and according to the specific tasks assigned to individual organisations (*voluntary to join; obligatory to deliver as per the tasks assigned after joining*); explicit application and appropriate adaptation and introduction of the developed tools and methods in the internal HTA production processes of individual participating organisations (*obligatory*). No requirement to get engaged in producing joint assessments or applying results of joint assessments in producing national/regional HTA reports. Dissemination of general information about EUnetHTA, its activities and outputs (focus on dissemination efforts at national/regional level of the participating organisation's country).

Rights: access to support functions of the scientific and technical mechanism (including capacity-building activities) – to be described in detail further; access to funding (if available) at higher level (to be defined, e.g., covering 50% of the eligible expenses associated with participation in the activities at Level 2).

Level 3: contributing to production of joint assessment reports and application of the results of joint assessment reports in the national/regional HTA production processes.

Responsibilities: active participation in the production of joint assessments within the agreed time-frames and according to the specific tasks assigned to individual organisations (*voluntary to join; obligatory to deliver as per the tasks assigned after joining*); appropriate adaptation and uptake of the joint assessment results in the internal HTA production processes of individual participating organisations (*obligatory*). Dissemination of general information about EUnetHTA, its activities and outputs (focus on dissemination efforts at national/regional level of the participating organisation's country).

¹⁸ As an overarching principle and in line with the Directive 2011/24/EU, Art.15, paragraph 1, the responsibilities listed under the levels of engagement are to take place in accordance with the legislation of the Member State where the respective Network Members are established

Rights: full access to the full range of support functions of the scientific and technical mechanism (including capacity-building activities, project management support to engage in production of joint assessments, etc.) – to be further described in detail; access to funding (if available) will depend on the number of levels of activities an organisation is involved in (e.g., covering 70% of the eligible expenses associated with participation in the activities at all three levels, i.e. including active participation in the production of joint assessments and adaptation and uptake of the joint assessment results).

Appendix 3. Examples of the added value received through participation in the European cooperation on HTA

The following **examples** were provided by representatives of organisations that participated in the joint work at the European level supported via EUnetHTA JA1 and JA2 activities¹⁹:

- Accelerated and real-time information exchange between HTA agencies in Europe on relevant topics in areas of common interest such as reimbursement status updates in different countries, regulatory activities, stakeholder involvement practices “know-how”
- Particularly for new/“young” HTA agencies participation in and contribution to joint work in a EU-wide cooperation brings benefits of improving
 - a) local competence and capacity in HTA
 - b) national awareness and political recognition of concrete benefits of HTA for the national/regional healthcare systems
 - c) methodologies and professionalism in local HTA processes
 - d) effective communication and cooperation with relevant national/regional policy- and decision-makers (e.g., higher standing of HTA with the national policy makers through e.g., recognition of improved efficiency via national leveraging of the HTA work done somewhere else, contribution to the quality improvement of the national work, etc).
- Development and strengthening of the EU cooperation on HTA has brought about an actual change in
 - a) using English as the publication language for the HTA reports (while local languages are used to publish the summaries of the reports), e.g., in Norway, Austria, Finland, Italy
 - b) the local HTA production processes, i.e., a new project is not started without checking the POP database and identifying work already done by others or identifying potential partners for a joint work or at least information exchange on the topic, e.g., Finland (THL, FIMEA), Belgium (KCE), Austria (LBI), Croatia (AZZ), Ireland (HIQA) already widely practiced this approach.
- Being engaged in the joint work at an EU-level directly contributes to standardisation of the HTA methodologies and indirectly influences the HTA production routines in various HTA agencies towards more consistent/coherent approaches across borders due to the staff being constantly “exposed” to different working methods and solutions in the partner HTA organisations.
- Development of consistent and coherent stakeholder involvement practice in EUnetHTA increases attention to stakeholder involvement issues at the national and regional level and assists the development of national stakeholder involvement processes and communication with stakeholders

Principles of transparency employed in EUnetHTA JA1 and JA2 practices have a strong potential to contribute positively to developing similar national practices, however, it is a process that requires time, initiative and consistent effort at the national level

- Increased international visibility of the participating organisations

¹⁹ http://www.eunetha.eu/sites/5026.fedimbo.belgium.be/files/EUnetHTA%20JA2_PlenaryAssembly%202014_SummaryReport_FINAL.pdf

References

1. EUnetHTA Strategy 2012 and beyond,
<http://www.eunetha.eu/sites/5026.fedimbo.belgium.be/files/EUnetHTA%20Strate.g.y%202012%20and%20beyond.pdf>
2. HTA Network Work Programme,
http://ec.europa.eu/health/technology_assessment/docs/hta_network_wp2014_15_en.pdf
3. Minutes of the HTA Network meetings and WG on long-term strategic provisions,
http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm
4. EUnetHTA Joint Action 1 (2010-2012) Final Technical Report,
<http://www.eunetha.eu/outputs/eunetha-ja1-final-technical-report>
5. EUnetHTA JA2 Plenary Assembly 2014 Meeting Report, <http://www.eunetha.eu/outputs/eunetha-plenary-assembly-meeting-april-10-11-2014-madrid-spain-report>
6. World Health Assembly May 2014, Health intervention and technology assessment in support of universal health coverage, http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R23-en.pdf