

EUnetHTA Strategy 2012 and beyond

Background of EUnetHTA

Knowledge from research is one of the inputs to healthcare decision-making processes. HTA provides scientifically sound, relevant information on the safety, effectiveness, cost-effectiveness and societal implications of health technologies (more information about HTA can be found in Annex 1). In order to maximise the relevance of HTA for decision making, it needs to be undertaken within the policy context of the country rather than at the European level. Policy context takes into account national priorities and systems, as well as cultural and social differences. Despite the differences in structure and priorities of healthcare systems across Europe, reducing unnecessary duplication of HTA activities, developing and promoting good practices in HTA, and facilitating local adaptation of HTA information have been considered essential for efficient use of HTA resources.

Common interests and policies in relation to HTA have been explored and developed at the strategic level in the European Union for ten years. EUnetHTA (European network for HTA) has been a major platform for supporting this process, since its inception in 2006. Operating currently through Joint Action 1 (2010-12) and entering Joint Action 2 (2012-15), EUnetHTA continues collaborative production of HTA information between partner organisations and developing tools for such.

The added value of EUnetHTA has been manifested by:

- joint HTA topic selection based on common interests
- sharing of work in collaborative HTA projects
- access to a large pool of expertise
- methodological developments in HTA
- scientific, independent arenas for communication between agencies, institutions, and individuals working with HTA
- increased international visibility
- providing an opportunity for capacity building in countries where HTA is new
- increased understanding of national HTA practices and the varied role of HTA in national healthcare decision processes
- increased attention to stakeholder involvement

Vision

EUnetHTA is a preferred facilitator of high-quality HTA collaboration in Europe. HTA agencies consider EUnetHTA an efficient way of collaborating.

Mission

To support collaboration between European HTA organisations that brings added value to healthcare systems at the European, national and regional level.

Through its activities, EUnetHTA

- supports efficient production and use of HTA in countries across Europe
- provides an independent and science-based platform for HTA agencies in countries across Europe to exchange and develop HTA information and methodology

- provides an access point for communication with stakeholders to promote transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations
- develops alliances with contributing fields of research to support a stronger and broader evidence base for HTA while using the best available scientific competence.

Values

- European Union values for health systems (universality, access to good quality care, equity and solidarity)
- Efficiency in HTA production
- Sustainability of the healthcare systems
- The principle of subsidiarity of the European Union
- The use of best evidence, common methodological standards, trust and transparency

EUnetHTA finds it important to recognise and facilitate solutions to overcome barriers caused by language, variations in terminology, and culture.

Objectives of EUnetHTA 2012 and beyond

1. Increase collaborative production of timely and fit for purpose HTA information that is applicable in national or regional HTA production and decision making
2. Increase reliability, quality and relevance of HTA thus expanding its applicability for policy making
3. Build capacities in HTA

Strategies

EUnetHTA allows flexible engagement by HTA organisations, in terms of variation in commitment and responsibility in activities, such as production of information, tools development, coordination, project management, and training. Responsibilities are distributed among partners according to their experience in previous projects, expressed expertise and availability.

For the various activities each partner HTA organisation determines the level of collaboration at which it will contribute to the activity. The level is determined by extent of an organisation's engagement in the activities it takes part in. Depending on the type of activity, an organisation may participate at the following levels: Level 1: sharing and exchange of information and methods (within the agreed EUnetHTA framework), Level 2: development of common generic guidelines for HTA including piloting the standardisation of and use of the guidelines at the national level (within defined time lines, with access to resources supporting such piloting and with a requirement to report on the experience), Level 3: application of common standards and tools in national (regional) HTA production and in collaborative HTA projects with re-use of HTA information at national level. For example, an organisation may participate at level 1 in certain activities and level 3 in other activities.

An example of a collaborative activity at Level 3 could be the building of a joint registry for generation of new evidence. To ensure viability of the structure and activities of EUnetHTA, thorough considerations must be made about the access level to the EUnetHTA tools and services as well as the type and level of financial contribution with regards to the extent of engagement an organisation is willing and able to commit to.

1. Strategies to increase collaborative production of HTA core information and to facilitate its use in national reporting

EUnetHTA will continue to develop tools and practices which make collaborative HTA projects both efficient and attractive. Many tools have already been launched by EUnetHTA. The Planned and Ongoing Projects (POP) database enables identification of HTA topics of common interest. The HTA Core Model is the tool for joint production of HTA information; it provides structure and methodological guidance within a common electronic project platform. An adaptation toolkit was developed in the EUnetHTA Project and its further utilisation will be considered in Joint Action 1. The EVIDENT database will serve collaborative additional evidence generation for new technologies. Communication tools, such as an e-meeting facility, contact database, project calendars and folders for storing documents, are also in place. EUnetHTA will facilitate efforts to disseminate and implement its tools in the work of HTA organisations. Efforts will be made to facilitate exchange of expertise and project management skills.

2. Strategies to increase the reliability and relevance of HTA

EUnetHTA develops tools and practices to support the production of high quality, robust and relevant information for decision making. Common methodologies for identifying reliable information sources, appraising the scientific quality of the information, synthesising and interpreting information have been provided in the HTA Core Model and separate methodological guidelines were developed during the EUnetHTA Project and Joint Action 1. EUnetHTA will further develop tools and methodological guidance to enable their use and will make efforts to enable dissemination and implementation of tools and guidelines in the work of HTA organisations. EUnetHTA seeks ways to collaborate with the international HTA community, relevant organisations and regulatory bodies which are essential in developing valid and reliable methodologies for producing and sharing of information. Efforts will be made to further refine the roles and tasks of the Stakeholder Forum and its Stakeholder Advisory Groups in order to increase the relevance of HTA.

Functions of the permanent EUnetHTA

The main functions of EUnetHTA are to:

1. be a contact point for the HTA community in Europe
2. maintain a shared HTA Information and Communication system
3. develop common processes for performing and reporting HTA
4. pilot processes for the collaborative production of HTA information taking into account also European priorities in the healthcare field
5. facilitate adequate evidence generation
6. facilitate the establishment and continuous development of HTA institutions

Organisation

The EUnetHTA Joint Action 2 to start October 2012 will have the same organisational and governance structure as the Joint Action 1. The structure of the permanent network to be established according to Article 15 of Directive 2011/24 EU on the application of patients' rights in cross-border healthcare will be determined by the results of *comitology* and a Commission decision

during 2012-13.¹ The experience gathered by EUnetHTA since its foundation on how to manage and govern a cross-border network for HTA will be shared with the Committee.

Funding

The main financing will come from the Commission with some co-financing by partner organisations. Other currently approved, but yet not implemented financing opportunities are grants and fees. In all cases, grants should be unrestricted and conflicts of interests should be disclosed.

¹ **The Cross border Directive (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>)**

- Article 15 of the Directive 2011/24 EU states the following objectives:
- (a) support cooperation between national authorities or bodies;
- (b) support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies;
- (c) support the analysis of the nature and type of information that can be exchanged;
- (d) avoid duplication of assessments.
- In order to fulfil the objectives set out in paragraph 2, the network on health technology assessment may receive Union aid. Aid may be granted in order to:
 - (a) contribute to the financing of administrative and technical support;
 - (b) support between Member States in developing and sharing methodologies for health technology assessment including relative effectiveness assessment;
 - (c) contribute to the financing of the provision of transferable scientific information for use in national reporting and case studies commissioned by the network;
 - (d) facilitate cooperation between the network and other relevant institutions and bodies of the Union;
 - (e) facilitate the consultation of stakeholders on the work of the network.

Annex 1.

Health Technology Assessment

Definition

Health technology assessment (HTA) is defined as a multidisciplinary field of policy analysis. It studies the medical, social, ethical and economic implications of the development, diffusion and use of health technology. The term 'health technology' covers a wide range of interventions used in health care and health promotion including methods for prevention, diagnosis, treatment and rehabilitation (such as vaccines, pharmaceuticals, medical devices, medical and surgical procedures), and the systems within which health is protected and maintained.

The overall aim of HTA is to systematically and objectively assess evidence to inform decision makers in their formulation of national/regional/local health policies to provide patients with equitable and timely access to safe, effective, high quality health technologies that achieve best value.

HTA informs policy /decision making but does not define policies or make decisions.

Annex 2.

Functions of a permanent EUnetHTA

1. Contact point for the HTA community in Europe

Aims

Developments in both HTA and in European health policy - particularly the development of the new European Union Health Strategy 2014-2020, Health for Growth, and Directive 2011/24 EU – promote closer collaboration in Europe to address common challenges. While the responsibility for the organisation and management of healthcare lies with the individual Member States, policy development in the EU may have implications for all Member States. Therefore it is useful to facilitate involvement of the partners as well as the wider HTA Community in discussions about European issues. National policy can be informed by the activities and results of EUnetHTA but EUnetHTA has no direct role to play in decision making at the national level.

Short description of the function

This function will be to: facilitate communication among those in Europe involved in the production and use of HTA, provide a discussion platform on HTA, and facilitate establishment of links with fields of research that contribute a stronger and broader evidence base and methodology for HTA. The function will serve to:

- promote HTA as an input to decision-making processes in healthcare systems across Europe
- lead European cross-border collaboration on aspects related to HTA
- serve as a gateway for giving expert advice on matters concerning the use of HTA in health policy in European countries and in the European Union

Proposed priorities:

- develop good channels of communication with the HTA community and establish and sustain different forms of communication with the European Commission and relevant institutions and bodies of the Union
- facilitate the consultation of stakeholders on the work of the network and further develop procedures for appropriate stakeholder consultation with the Stakeholder Forum
- respond to European policy documents related to HTA issues in order to present shared positions of those in EUnetHTA
- contact HTA agencies and supporting institutions in Europe that are not yet involved in EUnetHTA to encourage participation in the collaboration
- produce and disseminate information about EUnetHTA and the partners to increase awareness of EUnetHTA activities among users of HTA

2. European HTA Information Management Infrastructure and Services (IMIS)

IT development was characterised by individual tool development by single institutions during the early phases of EUnetHTA. The greatly varying policies and regulations on access to the information resulted in an additional challenge to the creation of a shared IMIS. At present, effort is put into creating a basic layer of interoperability between tools such as a centralised authentication system, common vocabulary and guidelines for layout.

Aims

- To develop and maintain an efficient Information Management System taking into account the requirements of end users
- To ensure interoperability of the developed tools by hosting a meeting place for all EUnetHTA tools developers, the IMIS working group.

Short description of IMIS

Tools

- Public Website
- Single authentication system for all EUnetHTA tools
- Intranet with Contact database
- Work rooms, Web conferencing tool, mailing lists server
- e-learning platform
- Planned and Ongoing Projects database
- HTA Core Model online
- Document repository (temporary name)
- EVIDENT database

Services

- Monitor content of, communicate about, and offer support and technical training for the tools maintained / developed by the IMIS team.
- Facilitate active brokering for collaboration on identical topics identified through the POP database.
- Maintain interoperability standards between EUnetHTA tools; and promote interoperability with HTA tools outside EUnetHTA where possible
- Provide a helpdesk for users of the Intranet and of other team work supporting tools.

Surveys

Partners will be surveyed on a regular basis in order to assess and improve the IMIS.

Proposed priorities:

- Promote interoperability standards between tools
- Promote common standards for tools developers
- Provide tools that support and facilitate collaborative work
- Maintain and further develop tools (e.g. POP database)
- Provide services, including active brokering of collaboration on similar topics

3. Developing and improving common processes for performing and reporting HTA

Aim

The aim is to

- maintain and update the HTA Core Model infrastructure developed within EUnetHTA since 2006
- support training and implementation of the Core Model

Short description of the function

This function will support new developmental work and maintain ongoing work on the HTA Core Model and the Adaptation Toolkit, including sharing of information, attendance at conferences,

shared training programmes, staff exchange schemes (linking with function 6) etc. Major developmental work will be focused around particular projects, funded externally (e.g. EU's Research Framework Programme 7, and its successor, the Horizon 2020 Programme) wherever possible.

This function will also work with HTA organisations and academic units to encourage methodological development and to improve standards, both in constituent disciplines of HTA (effectiveness research, economic evaluation, organisational analysis, etc.), and within international HTA activities (through e.g. INAHTA, HTAi, and ISPOR).

Proposed priorities:

- promote further methodological development of the HTA Core model, methodological guidelines, and Adaptation Toolkit.
- to establish a continuous process of development and review of sound methodological standards for HTA in close collaboration with academic units
- maintain a tool and database to host and make available the HTA Core model and information produced by way of using the Model
- revise the HTA Core Model taking account of experiences gained in piloting processes
- support activities that aim at increased awareness and utilisation of common processes for performing and reporting HTA
- update of existing HTA Core Model applications for the nine domains to ensure that they are consistent with current methodological developments
- promote use of the Adaptation Toolkit and gather experience to develop it further
- establish database(s) to describe use and case studies of these tools.

4. Piloting processes for production of HTA core information taking into account also European priorities in the field of healthcare²

Aims

This function will pilot use of the HTA Core Model to produce shared, structured HTA information that can be used by national and regional HTA agencies in their local reports. The experience of the HTA Core Model working groups will be used to further improve the usability of the Model and to ensure that it is fit for purpose.

Short description of the function

The HTA Core Model will be used by clusters of volunteering partners to share the workload of producing HTA information. This can take various forms, building on the experience of Joint Actions and produce different kinds of HTA products using EUnetHTA tools. Such products may take the form of extensive collections of HTA information, or more limited sets resembling rapid HTAs, or even more limited information packages focused e.g. merely on the effectiveness or ethics of a given technology.

The working groups will be managed by partner organisations according to project management guidelines to be developed during EUnetHTA Joint Action 2 and will be facilitated by the

² Besides priorities for HTA identified by the partners at the national level EUnetHTA should also take into consideration priorities that have been identified at a European level. As an example, COUNCIL RECOMMENDATION of 8 June 2009 on an action in the field of rare diseases recommends "the sharing Member States' assessment reports on the therapeutic or clinical added value of orphan drugs at Community level where the relevant knowledge and expertise is gathered, in order to minimise delays in access to orphan drugs for rare disease patients". In line with this recommendation, it is necessary to ensure that the network incorporates orphan drugs in the scope of its actions, notably the production of core HTA information to facilitate the production of HTA reports in each concerned member state. Actions to improve the quality of initial as well as additional evidence generation are also of importance for orphan drugs as well as for other technologies for the diagnosis, prevention or treatment of rare diseases.

EUnetHTA Secretariat in terms of general project management. Funding of these piloting activities is likely to come from several sources including general funding from the Commission, specific project type funding from EUnetHTA (based on a project description and budget), and in-kind contribution of expertise and manpower from participating organisations.

Proposed priorities:

- Identify topics to be assessed by the network from the POP-database and from EU Commission requests
- Run a Delphi exercise to prioritise technology(ies) to be assessed
- Establish clusters of partners who would like to form working groups to pilot production and use of the HTA core information using the HTA Core Model
- The Secretariat and each working group agree a process for the pilot
- Create a process for production of the HTA core information outlining stakeholder involvement
- Produce HTA core information
- Partners produce the local HTAs based on the HTA core information
- Evaluate experiences

5. Facilitating adequate evidence generation

Aim

The aim of this function is to promote coordinated actions to facilitate adequate evidence generation, both at the stage of the initial development of the technology and after an early assessment has been done at time of the introduction of the technology to healthcare...

Identifying, evaluating and monitoring the diffusion of emerging/new technologies are activities of growing importance in most countries. Monitoring systems have been progressively set up to help manage the introduction in the healthcare systems of high impact new technologies as early as possible, whilst gathering new/additional evidence on their value. In general, this is achieved through conditional coverage mechanisms associating early introduction/coverage in a pre-defined frame of use and collection of additional evidence with the aim of reducing uncertainty.

Tools to share available information about planned or ongoing prospective data collection (including pragmatic trials and registries) have been developed during the EUnetHTA joint actions. This first step allows envisaging further cooperation, notably coordinating the definition of the research question, the most appropriate methodology to get the relevant information, allowing the writing of a common core protocol that could be used in all countries where data collection will be carried out.

This clearly opens the possibility of increasing the adequacy and usefulness of such data collection, as compared to the current uncoordinated process. Such cooperation would be particularly useful for innovative technologies that have a small target population such as orphan drugs as well as many medical devices and procedures for which the number of patients per country is too low to permit the collection of a sufficient quantity of information.

- Initial Evidence Generation

At the time of a first assessment of a technology, data gathered during its development are carefully assessed by way of HTA procedures and are rather often considered not to be fully adequate with regard to the choice of endpoints or other aspects of trial methodology.

As opposed to the activities developed by regulators for pharmaceuticals, early dialogue between assessment bodies and sponsors of the technologies is not yet well developed within the HTA community. However, some HTA bodies have found it useful to be active in this field and have either set up an organised early dialogue activity (early scientific advice) or participated in multi-

stakeholder early dialogue meetings with EMA, other HTA bodies and some stakeholder representatives.

In addition to early dialogue activities, it may be useful to produce condition-specific guidelines that would indicate to technology developers what type of studies would be appropriate for a given disease/condition.

The aim of early dialogue is that technology developers could integrate HTA recommendations (e.g. on adequate endpoints, comparators, patient population or subpopulation) when designing the development plan of the technology in order to generate the best quality data for assessment and decision-making purposes.

Short description of the function

This function will gather information on assessment results, coverage decisions, additional data collection requirements linked to conditional decisions, conditions of use, study protocols and ongoing monitoring studies, by way of standardised questionnaires, and share them through a user-friendly website. This function enables calls for protocol agreements and joint actions. Attempts to liaise with EuroScan International Network will be revisited.

Proposed priorities:

IT development of an interactive website based tools to request and provide information about monitoring activities for new/emerging health technologies, and promotion of the use of the tools

- establish a database of successful case studies of monitored technologies and encourage its use
- establish a system in co-operation with existing activities to collect and share information on planned and ongoing pragmatic trials that could provide important information for HTA
- define a process to reach different levels of collaboration (sharing information, coordinating actions based on a common core study protocol, establishing joint multicentre studies or registries)
- promote further methodological developments on the selection criteria for technologies to be monitored

6. Facilitating the establishment and continuous development of HTA institutions

EUnetHTA promotes awareness and understanding of the usefulness of the EUnetHTA tools, methods and results, good practices and methodologies to support Member States in developing their own capacity in HTA activities and collaborating in the production of HTA information. This will be supported by exchange of information and expertise and by training

Proposed priorities:

- Coordinate production of training material for the EUnetHTA tools and methods (handouts, webcasts, e-learning material, manuals).
- Organise training courses (face-to-face, webinars, e-learning) for EUnetHTA partners on the proper use and implementation of EUnetHTA tools and methods.

Developing and piloting HTA capacity building and education activity for specific stakeholder groups (in cooperation with the Stakeholder Forum) will be explored to enhance stakeholder understanding of EUnetHTA and HTA, its implications, and how HTA can contribute to decisions on e.g. resource allocation processes. The intent of this is to facilitate overall capacity to participate in national HTAs.