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Proposal for the EUnetHTA Collaboration

June 16, 2008

1. Introduction

The Steering Committee of the Project for the European network on Health Technology Assessment (EUnetHTA) has formally met to discuss the proposal for a sustainable, permanent collaboration for health technology assessment in Europe. Following the discussions and amendments agreed at that meeting on 29 May 2008, the Steering Committee endorsed the proposal for the permanent collaboration. Thus, this document represents the final proposal from the Steering Committee and presents the background, organisational structure and functions of the permanent collaboration, called the '**EUnetHTA Collaboration**'. The EUnetHTA Collaboration will support the development, production and use of timely, relevant and high quality health technology assessments in the countries of Europe. This will cover assessments of all forms of health technologies (including medical and surgical procedures, drugs, devices, and administrative support systems). This will be achieved following the principle of subsidiarity and the basic condition that assessments should be reported in the policy context of the countries and their national priorities and health care systems (Annex 1).

1.1 Background

The EUnetHTA Project was established in 2006 following the request of EU Member States in the High Level Group on Health Services, endorsed by the Council of Ministers of Health and the European Commission to establish a sustainable network for health technology assessment (HTA). The Project was co-funded for three years by the European Commission. The Project has established an effective European network for HTA that aims to inform policy decisions on the use of health technologies at the national or regional level. A total of 63 HTA institutions and organisations have joined the EUnetHTA Project, which is organised as an open network with extensive communications facilities.

HTA is a systematic, broad-ranging evaluation of the implications of using technologies within a particular health care system (Annex 2). The EUnetHTA partners have developed practical tools to share methodological frameworks and scientific evidence for HTA. The tools facilitate sharing of information across national or regional systems when health technologies are assessed for new or continued use in health care systems. This cross border collaboration on HTA can be used to reduce duplication of effort, to save time and resources of individual countries.

The EUnetHTA Project is a network that worked on specific tasks focussed on creating practical tools to produce HTAs, tools for local adaptation of existing HTAs as well as generation of information and models to monitor new technologies and to inform decision-makers on emerging technologies. This practically driven collaborative work has raised interest among HTA institutions, among the professionals and researchers that contribute to the production of HTAs, among stakeholders and at policy level because of its innovative tools, and high level of communication and collaboration.

International HTA organisations have shown interest in EUnetHTA because the Project partners have already developed new methods and produced HTA information that can be shared among producers of HTA information and reports and thus been at the forefront of methodological developments in the sphere of HTA.

Co-funding from the European Commission for the EUnetHTA Project ceases at the end of 2008. The experience of collaboration among partners in EUnetHTA is positive and to ensure that communication, collaboration networks and activities are continued, the partners have decided to create a sustainable, permanent European HTA collaboration. This will involve HTA Agencies and other producers of HTA information, with support from European governments, the European Commission and international health organisations.

1.2 Focus on HTA collaboration in Europe

The EUnetHTA Collaboration aims to support HTA in Europe. At the outset, work will focus on HTA agencies and institutional producers of HTA in the 27 Member States of the European Union (EU) and the countries in the European Economic Area (EEA) and European Free Trade Association (EFTA). The EUnetHTA Collaboration will also continue the collaboration between HTA agencies and producers in other European countries that has been established in the EUnetHTA Project and develop links with new organisations and countries. The fact that EUnetHTA Collaboration will focus its collaboration on institutions in countries in Europe should not be seen as a sign of lack of interest in HTA activities in other parts of the world, or at global level, but is a question of capacity to engage in spheres of interest that can be influenced and that influence the implementation of HTA in health policy, and to provide unique added value compared with other HTA networks.

Different health care systems exist across the countries of Europe as a result of national and regional history and policy developments and priorities. Despite these differences, common interests and policies are being explored and developed at the European Union and wider European level (e.g. the World Health Organisation (WHO)) that impact on national health care practice. Furthermore collaboration about scientific information and development projects which are carried out through support from a range of EU funding mechanisms is expanding in the health field.

Following the principle of subsidiarity, and in order to be most relevant, HTA must be undertaken within the policy context of the country rather than at the European level, taking account of national priorities and systems, including regionalisation. This principle of subsidiarity is paramount and must be observed, but collaboration among European countries can support and improve national HTA processes.

The European Region of WHO consists of 53 member countries that develop their health care systems according to local needs and opportunities, according to policy at national levels and according to inspiration and input from intergovernmental collaboration such as between ministries of health in the context of the WHO Region for Europe. The EUnetHTA Collaboration will explore ways of coordination and collaboration with WHO in Europe.

By focussing on collaboration on HTA in Europe the EUnetHTA Collaboration will:

- help reduce unnecessary duplication of HTA activities
- develop and promote good practice in HTA methods and processes
- share what can be shared
- facilitate local adaptation of HTA information.

1.3 The added value of HTA collaboration in Europe

During the EUnetHTA Project the added value of HTA collaboration among the European partners has already manifested itself:

- advancing methodological developments in the practical application of HTA
- discussion about the contents of HTA, i.e. which aspects of the application of technologies should be assessed
- providing an arena for increased international collaboration between agencies, institutions, and individuals working with HTA
- improved understanding of usefulness of European collaboration for HTA work at the country level
- access to a bigger pool of knowledge
- increased international visibility and credibility through participation in the EUnetHTA
- challenge current working processes
- improved understanding of the role of HTA in relation to other processes in healthcare policy making
- better connected to HTA colleagues in Europe
- better informed about HTA processes in Europe
- increased attention to stakeholder involvement
- opportunities to learn about management of big international projects.

Furthermore, during the EUnetHTA Project faster information exchange took place between agencies and institutions as shown in the cases of national HTA reports on HPV-vaccination and on antibody based treatment of age-related macular degeneration.

1.4 Phases of development of the EUnetHTA Collaboration

The co-funding from the European Commission for the EUnetHTA Project ends in 2008. In order to safeguard the practical collaborative links established in the EUnetHTA Project, the partners want to continue their collaboration immediately after the official closing of the EUnetHTA Project by establishing the permanent "EUnetHTA Collaboration". The EUnetHTA partners recognize that the full functioning of a permanent collaboration will develop over time. At the end of the EUnetHTA Project the functions of the permanent EUnetHTA Collaboration will be developed and organizational and financial structures will be put in place. This initial phase is called phase 1 of the permanent collaboration.

1.5 EUnetHTA results and products

Work in the EUnetHTA Project is still ongoing. The final results and products will be presented at the concluding conference on 20 November 2008 in the Pasteur Institute in Paris (www.eunethta.net/Home/EUnetHTA_Conference_HTAs_Future_in_Europe/). All work will be reported in full in February 2009 in the final technical and financial reports for the European Commission and papers will be published in peer reviewed journals during 2009.

The main organisational drivers of the Project network are the active partners that participate in developing the work, the Secretariat and the communication facilities such as the EUnetHTA website with its numerous facilities for internal and public information sharing and communication.

The partners in the EUnetHTA Project have already achieved a great deal - they have developed the first suite of tools to facilitate the whole process of HTA. Achievements include publication of a comprehensive common framework for HTA information (HTA Core Model) and the first pilot core model application for a medical device, an Adaptation Toolkit for local health care systems and a process for providing information on emerging technologies and sharing information on monitoring new health technologies.¹

The HTA Core Model is a tool that provides a framework for comprehensive analysis of the elements to be included in a robust health technology assessment. The model embraces nine thematic domains each of which consist of specific building bricks of information (so-called assessment elements, presented as “cards”) in relation to health technology. Each element defines a question that should be answered within an HTA. The strategic power of the element cards lies in the fact that questions and many of the answers can be shared, and therefore HTA producers in the Collaboration have access to information – and need not retrieve the same information. Even sharing the same relevant questions to be addressed at the country level can improve efficiency. The structure and the use of the HTA Core Model will be presented in a handbook that will provide instruction on the practical application and further development of the Model.

Based on the HTA Core Model, work on developing HTA core information has been carried out for one medical device, Drug Eluting Stents and one diagnostic technology, Multislice CT coronary angiography in heart disease. The data, analysis and other information collected and analysed for these two technologies is available for the EUnetHTA partners to use for their national context (regional / institutional / health insurance system) to produce HTA-reports.

The Adaptation Toolkit is a toolkit to help HTA agencies adapt HTA reports from other countries, regions or settings for their own use. The purpose of adaptation is to enable an HTA agency in one setting to make use of an HTA report produced elsewhere, thus saving time and money. The toolkit is composed of a series of checklists, questions and information about additional resources. Its purpose is to enable assessment of a report’s relevance, reliability and transferability. By doing so, the users can determine whether a report, or parts of a report, written for another setting, can be adapted for their own report in the context of their own setting. An instruction manual will present the tools (checklists, questions and resources) and explain how to use them.

There is an increasing need for reliable, timely information on emerging/new technologies and monitoring of their introduction into health care systems when information is not sufficient to decide on appropriate implementation in healthcare practice. The EUnetHTA Project has prepared tools to assist in the prioritisation and selection of topics to undergo HTA and provided a pilot information service (newsletter) on emerging technologies. In addition, tools to support monitoring activities have been developed. These tools consist of structured and standardized questionnaires and a dedicated database for storing and obtaining information to facilitate exchange and sharing of data and results of this monitoring among countries. The purpose is to provide easy and quick access to information about evaluations/decisions related to early and conditional introduction of emerging/new technologies into the health care system and about additional data being or planned to be collected in different countries. The results will be presented in an overview document on the

¹http://www.eunethta.net/Communication/Press_Releases/First_results_delivered_by_EUnetHTA__report_from_the_EUnetHTA_workshop_June_17_Barcelona_Spain/

monitoring systems that have been set up in different countries. A prototype of the interactive tools, i.e. the standardised questionnaires and information on the first technologies entered into the database, will be presented. It will be accompanied by an instruction manual.

A need for systems to support development of HTA agencies was realised and addressed. The mandate and terms of reference of HTA agencies varies across Europe according to history, needs and policy. Likewise the avenues for achieving competence in producing HTAs vary considerably. EUnetHTA has identified various types of HTA agencies, including definition of the recommended minimum components related to the scope, structure, the work process and visibility of a unit, agency, or program of HTA. In parallel, an up-to-date overview of educational programmes relevant to HTA training around the world has been created. The results will be presented in a handbook that can be used for capacity development of new and existing HTA institutions and a curriculum development proposal for HTA training.

Illustrations of the relations between HTA and health care policy making were analysed with the aim of contributing more clarity on roles in the “policy-HTA-policy interface” (see Appendix 2). The book on the HTA – health policy interface being prepared in the EUnetHTA Project describes the policy structures and processes related to the production and use of HTAs in policy making in selected Member States. The examples and considerations presented in the book help identify the demands on HTA from health care and clinical policy makers in Member States and the EU and thus is of value for engagement with stakeholders in the EUnetHTA Collaboration.

The EUnetHTA Project has been supported by a range of transparent governance mechanisms. An important element of this is the internal evaluation workstream that has been responsible for internal audit (using surveys and interviews) throughout the lifetime of the Project. The final results of internal evaluation will be published in October 2008. The knowledge gained from this work will be used to inform the development of the future sustainable network.

2. Strategic plan for the EUnetHTA Collaboration

The active and enthusiastic participation of EUnetHTA partners and calls for practical support for continuous collaboration that appeared as responses to the consultation process in the EU regarding “Community Action on health services” in 2006 have been an encouragement for the EUnetHTA partners when they considered the development of a sustainable collaboration at the end of the EUnetHTA Project in 2008. This includes recognition from Ministries of Health and regional governments that there is emerging added value from European collaboration on HTA and there is support to provide a gateway to European HTA agencies and institutions on matters concerning the production and use of HTA in health policy in Europe.

2.1 Strategic framework for the EUnetHTA Collaboration

All activities of the EUnetHTA Collaboration arise from the premise that its outputs will be used to inform but not mandate the content of national / regional / institutional HTA and appraisal reports.

2.1.1 Values

The partners in the EUnetHTA Collaboration share the overarching values of the European Union for health systems: universality, access to good quality care, equity and solidarity².

² Official Journal of the European Union, C 146, Volume 49, June 22 2006

The partners see HTA reports as contributions to improve the health of European citizens by providing input to decision making at an appropriate level that promotes good quality care, equity in access to health care and best value for money, and is implemented according to the principle of subsidiarity.

The following values for quality processes are fundamental to the work of the EUnetHTA Collaboration: use of best available evidence, common methodological and process standards and common review processes.

2.1.2 Vision

The EUnetHTA Collaboration will contribute to the generation of HTAs to inform policy and health care decision making in European countries so that new health technologies can be adopted and obsolete technologies abandoned in a well-informed and robust manner, hence bringing about high quality, safe, accessible, sustainable, ethical and efficient health care for citizens across Europe.

2.1.3 Mission

The mission of the EUnetHTA Collaboration is to support effective HTA collaboration in Europe that brings added value at the European, national and regional level by:

- facilitating the efficient use of HTA in countries across Europe
- supporting long-term strategic planning for the development of HTA taking account of emerging policy challenges and needs expressed by stakeholders providing an access point for expert advice on HTA across Europe, thus providing a gateway to European HTA agencies and producers
- creating sustainable systems for knowledge sharing and provision of tools to assist the production of HTA in European countries by allowing HTA information to be shared and adapted, thus supporting processes and enhancing efficiency in HTA at the country level
- providing an access point for communication with European umbrella stakeholder organisations to encourage HTAs to systematically cover a wide range of perspectives in their scoping, development and dissemination, and with sufficient transparency to indicate how stakeholder perspectives are incorporated
- developing alliances with contributing fields of research to support a stronger and broader evidence base for HTA.

2.1.4 Aims

Work emerging from the EUnetHTA Collaboration aims to:

- assure quality through use of the best available evidence, common methodological and process standards and good review processes
- promote methodological and scientific independence thus contributing to high integrity of HTA products
- make analyses transparent and facilitate sharing of information
- be responsive to the needs of decision makers for timely, high quality HTAs on important health technologies
- maintain the independent role of each HTA Agency and institution in the production and use of assessments of evidence and conclusions
- promote information about frameworks for national stakeholder engagement in HTA, including with consumers
- be inclusive and share information to ensure that all relevant information is included in HTA
- support advancements both in research and in medical care.

The EUnetHTA Collaboration will recognise and facilitate solutions to overcome barriers caused by language, variations in perceptions of terminology and will facilitate national solutions to deliver context specific reporting in the most appropriate manner.

2.1.5 Added value of the EUnetHTA Collaboration

By making the collaboration in EUnetHTA permanent the added value is expected to increase by:

- creating a direct system for collaboration with European colleagues leading to increased efficiency
- responding to developments in the EU and elsewhere that are relevant to HTA collaboration in Europe
- increased use of the products of EUnetHTA such as the HTA Core Model and Adaptation Toolkit to produce HTA core information
- providing easy access to databases with a variety of information about ongoing and completed HTAs, HTA organisations, experts and training
- sharing a variety of information on health technologies (from emerging to established and disinvested technologies)
- enabling production of national / regional / institutional HTA reports that incorporate information generated in collaboration.

2.2 Participants in the EUnetHTA Collaboration

The EUnetHTA Collaboration will facilitate the use of HTA in policy and decision making in European countries. European Union Member State representatives and the Commission have indicated the desire to create a sustainable network for HTA collaboration in Europe (see Annex 1). HTA institutions in EU Member States and countries in the EEA (Norway, Iceland) and EFTA (Switzerland) have taken an active role in the EUnetHTA Project. Hence it is logical that HTA organisations in the EU, EEA and EFTA take the lead in establishing the Collaboration with the support of governments at country / regional level and the European Commission.

2.2.1 Partners in EUnetHTA Collaboration

All ‘publicly funded’³ organisations that produce or contribute to HTA can become partners in the EUnetHTA Collaboration. For clarity and transparency, the mandate of each partner and the partner’s link to health policy in its country setting will have to be described in detail.

Furthermore, partners should commit to active engagement in collaborative work within the functions, services and activities that are described in Section 2.3. At an Executive Committee meeting in April 2008, seven EUnetHTA Project Lead and Associate Partners expressed interest in collaborating in general methods development and information sharing or specific tasks such as establishing a Secretariat, new and emerging technologies work and development of the HTA Core Model and Adaptation Toolkit.

To show that the EUnetHTA Collaboration is a substantive response to the need expressed for a sustainable network for HTA in Europe there needs to be a “significant mass” of partners from a majority of EU Member States.

³ Details of the extent of public funding need to be determined – some organisations have concerns if organisations with a large proportion of private funding will be permitted, whereas other organisations (particularly those in academia and in smaller countries) argue that HTA research could not be funded without substantial grant-aided income.

Countries that do not have any organisations working in HTA could appoint a relevant ministry division or a governmental unit to function as a national contact point for HTA if they have the intention to develop an HTA unit that will take on partner status in the future. Such representation would have the status of “observer”.

This proposal suggests that a minimum of 15 EU/EFTA/EEA Member States should be represented by one or more HTA agencies / institutions contributing to HTA/ observer institutions by the end of 2009.

2.2.2 Governments

Governments (at national and/or regional level) should be invited to support the EUnetHTA Collaboration.

The High Level Group on Health Services has been a channel for the EUnetHTA Project to update and consult with EU Member State governments. This proposal will be sent to the High Level Group for consultation through the European Commission in June 2008.

Information about the EUnetHTA Collaboration will be presented to a wider group of European countries at the WHO European Ministerial Conference on Health Systems on 25 June 2008.

In addition, it is essential that every EUnetHTA Project partner makes direct contact with the government/administration in their own country/health care system, using a variety of approaches to inform about the EUnetHTA Collaboration and explain its value to their specific country.

2.2.3 Stakeholders

The EUnetHTA Collaboration acknowledges the interests of stakeholders in general issues related to HTA processes, in specific HTAs at the national level and in the general work of the EUnetHTA Collaboration. The bye-laws/statutes of the EUnetHTA Collaboration will ensure that its obligations relate to its partners, funders and the work they undertake, and are independent of stakeholder interest. However, the views of stakeholders will be sought in a systematic way to inform EUnetHTA's work and its development.

In relation to the HTA-process, the EUnetHTA Collaboration focuses on methodological development, information collection and analysis of specific health technologies with the aim of presenting information that may be used at national or regional level for context specific HTA. The EUnetHTA Collaboration has an interest in communicating with stakeholders about general HTA processes and issues and will as such engage with stakeholders that are partnership or interest based umbrella organisations working at the European level. The EUnetHTA Collaboration will not play a role in stakeholder involvement at national or regional level.

The points of contact for engagement with stakeholders are European umbrella stakeholder groups with interests in the HTA-processes, for example including:

- national/regional policymakers
- policymakers at hospital level or in statutory health insurance or health maintenance organisations
- patient organisations
- health care professionals and their organisations
- industry
- health related media.

Clear, transparent stakeholder involvement processes will be developed (including issues such as rules of engagement, disclosure of competing interests, etc) to ensure that balanced stakeholder views are obtained to advise on the work of EUnetHTA Collaboration. (See Advisory Council in section 4.)

2.3 Functions, services and activities of the permanent EUnetHTA Collaboration

The main functions, services and activities of the permanent EUnetHTA Collaboration are a number of distinct undertakings and facilitation services. The functions, services and activities in the EUnetHTA Collaboration are proposed because they:

- are of practical value to EUnetHTA Collaboration partners
- are of practical value to HTA producers in general and the HTA community
- contribute structured information across the wide ranging domains of HTA to national HTA production and thus are of value for national and regional governments and statutory health insurance organisations in Europe
- facilitate communication and information sharing among partners
- facilitate communication and information about HTA to policy stakeholders
- do not replicate already existing HTA collaborative efforts but add unique value to collaboration in Europe.

A driving force when determining the functions for the EUnetHTA Collaboration is to reduce duplication of effort and ensure that the EUnetHTA Collaboration adds value. To achieve this, the range of services provided by existing HTA collaborative organisations have been considered. The EUnetHTA Collaboration will only provide functions comparable to existing ones where *unique value* is provided.

The main functions of the EUnetHTA Collaboration are:

- contact point to provide a gateway to the HTA community in Europe
- European HTA Information and Communication system
- developing and improving common processes for performing and reporting HTA
- providing information on emerging/new technologies and facilitating new evidence generation
- facilitating the establishment and continuous development of HTA institutions
- piloting processes for production of HTA core information.

In addition to these main 'service functions' there are important underlying administrative and organisational functions that will be required to enable the collaboration to be efficient and effective. It is paramount that an adequately resourced secretariat is in place to coordinate and manage the basic communication and tools of the EUnetHTA Project that can be utilized in the EUnetHTA Collaboration. The Secretariat will:

- support the establishment of the Collaboration
- support the daily operation of the Collaboration
- coordinate the work plan implementation
- be responsible for delivering the permanent functions (including by sub-contracting).

The six functions will be serviced and facilitated by the EUnetHTA Collaboration Secretariat. The functions are described in more detail in the following sub-sections and the actions to initiate the functions in the first phase of the EUnetHTA Collaboration are proposed.

2.3.1 Contact point to provide a gateway to the HTA community in Europe

Aims

Developments in both HTA and in European health policy - particularly the development of the new European Union Health Strategy⁴ – promote closer collaboration in Europe to address common challenges. The competence for organizing and managing of health care lies with the national competence but policy development in the European Union may affect all Member States. Therefore it is useful to establish and promote a gateway that can access partners of the EUnetHTA Collaboration to facilitate timely and appropriate involvement of the partners as well as the wider HTA Community in discussions about European issues.

The principle of subsidiarity is the premise on which the EUnetHTA Collaboration aims to support the basic methods and processes that are used within the context of each European country. Issues relating to national policy can be informed by EUnetHTA Collaboration activities and results but the EUnetHTA Collaboration has no direct role to play in decision making at the national level.

Short description of the function

This function of the EUnetHTA Collaboration will facilitate communication among those in Europe involved in producing HTA and using HTA, provide a discussion platform on the position of HTA in healthcare systems in Europe, and facilitate establishment of links with fields of research that contribute to HTA.

The function is structured around information facilities, the web-site and secretarial support. The function will serve to:

- support and improve communication about HTA activities in Europe
- promote HTA as an input to decision-making processes in health care 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
- develop alliances with contributing fields of research to support a stronger and broader evidence base and methodology for HTA.

Proposed priorities for phase 1:

- develop good channels of communication with partners (the HTA community) to share information from Europe on health initiatives and feed information back, thus creating a clear gateway
- establish and sustain different forms of communication with European Commission, WHO Europe and other European groups
- respond to European policy documents related to HTA issues in order to present the positions of those in the EUnetHTA Collaboration
- contact HTA agencies and supporting institutions in Europe that are not yet involved in EUnetHTA to encourage participation in the Collaboration
- produce information about the EUnetHTA Collaboration and the partners
- promotion of information about the EUnetHTA Collaboration across Europe.

⁴ http://ec.europa.eu/health/ph_overview/Documents/strategy_discussion_en.pdf

2.3.2 European HTA Information and Communication system

The Information and Communication system is a system and service function that integrates the functions provided in the EUnetHTA Collaboration.

Aims

The web-based HTA Information System of the EUnetHTA Collaboration will support knowledge management in Europe with a focus on the needs and requirements of partners. It will contain a public area and a 'partners only' area to allow facilitation of ongoing work not ready for wider distribution.

It will provide the basic functions to respond to information requests and support the processes leading to HTA products. Compared with existing databases such as the INAHTA HTA database, the basic functionalities are focussed on production of HTA information and sharing information about HTA reports from partners. The IT functions will add value by providing efficient, secure information sources, databases that support the other functions of the EUnetHTA Collaboration and a user-friendly website.

Short description of the function

The functions included within the information system will facilitate information and communication requests both among partners of the Collaboration and stakeholders. The starting point is the information platform already in place in the EUnetHTA Project (www.eunethta.net). This facility contains a large number of information tools that can continue and their functionality can be enhanced.

In addition to the already functioning information platform, a prototype of a clearing house system is being developed in the EUnetHTA Project to take account of the feedback from all Work Package Lead Partners in the current EUnetHTA Project.

The following items have been identified and prioritised.

Priorities for phase 1:

Supportive systems:

- create a database of contact information for partner institutions and individual experts in those organisations
- develop the information platform of the EUnetHTA Project to reflect the new structure, working practices and functions of the EUnetHTA Collaboration using:
 - web-based communication tools allowing virtual collaboration (eg, web-based/e-meeting facilities)
 - web-site, including members-only function, information exchange area, etc (based on www.eunethta.net)
- support the other EUnetHTA Collaboration functions to develop their databases and other tools to ensure interoperability among tools and provision of an interactive interface for users

Additional functions:

- create an instant 'messenger system'
- access to information resources, literature databases, search strategies, appraisal tools, reference handling tools etc.

- connections to other HTA-databases
- database of suggested and selected topics for HTA
- information on publications and ongoing and planned HTAs with protocols,
- additional metadata and extensions to the INAHTA HTA database
- information about final HTA reports published by Partners with additional information not included in the printed report (such as search strategies, data extractions, etc)
- preprints of HTA reports prior to publication
- database of clinical policy decisions in different settings that were based on HTA.

2.3.3 Developing and improving common processes for performing and reporting HTA

Aim

The aim is to utilize and further develop the EUnetHTA Project work that has devised methods for performing and reporting HTA (e.g. HTA Core Model and Adaptation Toolkit) and to encourage methodological developments across all research disciplines that contribute to HTA.

The EUnetHTA Collaboration will aim to support the methodological development of HTA in Europe:

- promoting continuing methodological development to support all aspects of HTA
- encouraging the use of common methods between partners
- developing methodological tools to support all forms of HTA
- disseminating and implementing robust, up-to-date methods for producing HTA among partner agencies
- facilitating peer review of the methodological quality of HTA reports.

The EUnetHTA Collaboration will provide a library of tools to help partners enhance quality of assessments, to share resources and to set up effective collaboration. Tools will:

- help produce robust information for national HTAs
- facilitate adaptation of HTA reports from other countries.

In the longer term, use of the EUnetHTA tools should assure HTA agencies, their funders and their users that HTA reports are timely, created according to high and internationally accepted methodological standards, using efficient, state-of-art processes.

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. Ongoing work will include sharing of information, attendance at conferences, shared training programmes, staff exchange schemes (linking with function 5) etc. Developmental work will be focused around particular projects, funded externally (e.g. EU's Research Framework Programme 7)⁵ wherever possible.

This function will also work with other HTA organisations and academic units to encourage methodological development and improve standards, both in constituent disciplines of HTA (effectiveness research, economic evaluation, organisational analysis, qualitative research to capture patient and citizen views, etc), and within international HTA activities (through INAHTA, HTAi, and other organisations). It will seek to add value by speeding up the processes for agreeing on and disseminating methodological standards.

⁵ http://ec.europa.eu/research/fp7/understanding/fp7inbrief/home_en.html

Proposed priorities for phase 1:

- promote further methodological development of the HTA Core model and Adaptation Toolkit.
- work with academic units to develop a framework to promote methodological developments in HTA that fit with the work of the EUnetHTA Collaboration
- establish a database to host the HTA Core model with the 9 domains and EUnetHTA card system
- revise the HTA core model taking account of experiences gained in the piloting of processes for production of HTA core information (see section 2.3.6)
- create an electronic tool to facilitate adaptation of existing HTA reports to different national/regional settings
- promote use of the Adaptation Toolkit and document experience to develop refinements
- establish database(s) to describe use and case studies of these tools.

2.3.4. Providing information on emerging/new technologies and facilitating new evidence generation

Aim

Monitoring the diffusion of emerging/new technologies is a new and growing activity being developed in different countries. Monitoring systems have been progressively set up to manage the introduction of high impact new technologies as early as possible, whilst gathering new/additional evidence on their value. In general, this is achieved through conditional mechanisms associating early introduction/coverage in a pre-defined frame of use and collection of additional information in order to reduce uncertainty. All levels of collaboration are possible and very useful in this function.

Information related to monitoring activities is generally scarce and not easily accessible. By sharing available information, it should be possible to obtain timely and useful information about planned or ongoing prospective systematic data collection including pragmatic trials. The EUnetHTA Collaboration could also encourage the establishment, funding and recruitment of pragmatic trials and promote coordinated actions to generate such new evidence. This could include coming to an agreement on a common set of criteria for data collection, e.g. common core study protocols that could be conducted simultaneously or collaboratively in a number of countries. Moreover, in this field, collaboration at the highest level (level 3), using 'joint actions', will undoubtedly add value for all involved.

The ultimate objective is to gather a critical mass of data quickly to e.g. enable countries that apply conditional coverage to reach a robust final decision after a provisional period of coverage. This should contribute to achieving the goal of timely adoption of high-value technologies.

Short description of the function

This function will provide structured information about emerging technologies in the form of a newsletter and a structured way of requesting and providing information on monitoring activities, i.e. standardized questionnaires. In relation to existing structured information on emerging technologies, work is under way with EuroScan in which several EUnetHTA project partners are already members. Information among countries will be exchanged and shared through a user-friendly website. The interface will automatically feed a database containing the following information on the technology of interest: assessment results, coverage decisions, additional data collection requirements linked to conditional decisions, conditions of use, study protocols, ongoing

monitoring studies, trials or registries, as well as the results of monitoring (access to results of studies or registries). This function will also enable calls for protocol agreements and joint actions.

Proposed priorities for phase 1:

- IT development of interactive website based tools to request and provide information about monitoring activities for new/emerging health technologies, and promotion of use of the tools
- establish a database of successful case studies of monitored technologies and encourage its use
- establish a system to collect and share information on planned and ongoing pragmatic trials that could provide important information to an 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 selection criteria of technologies to monitor
- publish a biannual newsletter on emerging technologies.

2.3.5 Facilitating the establishment and continuous development of HTA institutions

Aims

The main aim of this function is to support the continuous development of HTA institutions across Europe in countries with limited experience in HTA, without institutionalised HTA, and also those with established HTA units. This support system will be sensitive to the special needs in different health care systems (tax based, health insurance financed etc.) and will propose criteria for minimum competencies, functions of an HTA agency and a generic curriculum for HTA training.

Short description of the function

The general activities coordinated by the EUnetHTA Collaboration will provide models of good practice for the methodology and processes supporting HTA. Training courses could be built around these methods, which could be useful, not only for new and existing HTA organisations, but also for continuous professional development of those in existing HTA organisations. Specific activities will be developed for those with little or no HTA capacity such as a support system, facilitation of access to experts in different HTA topic areas throughout Europe and help in dissemination of products. The focus would be on practical functions of building capacity and knowledge. The training activities could also be used to educate those working on the periphery of HTA, e.g. public health administrators, or health policy makers and their advisors.

Proposed priorities for phase 1:

- establishing a database of experts that will take on consulting for HTA agencies that ask for guidance in developing a new or existing HTA agency based on criteria and advice in the EUnetHTA handbook on capacity development in HTA agencies
- establishing a work group of experts in training about HTA in order to collect, analyse and prepare a generic structure of the content for an HTA curriculum:
 - basic HTA training to public health administrators and newly appointed HTA-professionals (HTA -schools)
 - systematic training in the use of the HTA Core Model and element cards
 - systematic training in the use of Adaptation Toolkit
 - Training on methods to develop evidence on emerging technologies (registries etc).

2.3.6 Piloting processes for production of HTA core information

Aims

This function will pilot the processes for producing HTA core information (based on the HTA Core Model) to understand how the Core Model works in practice when generation of HTA core information is shared among HTA organisations and how they can use that information to inform national/regional HTA reports.

Short description of the function

The HTA Core model will be used by subsets of volunteering partners to share the workload of producing HTA information. This collaboration can take various forms.

For example, one option is for a subset of volunteering partners to identify, prioritise, and select a number of technologies for assessment, assign one technology to each partner to undertake the HTA and then share the HTA information among all volunteers. Another option is for a subset of volunteering partners to prioritise and select, and work on one technology, each taking one or two domains and then bring together the entire information to be used by all volunteering partner-agencies. A subset of volunteering partners could also pilot the feasibility of gathering primary research evidence to feed into national/regional HTA reports.

Current collaborative projects in the Nordic region involve two to four HTA Agencies in the production of HTA reports, so to show added value the EUnetHTA Collaboration should ensure that one of these pilot processes for production of HTA core information uses a subset of at least five active, committed partners. The partners should ideally be representative of the partners in the EUnetHTA Collaboration. An example of how this might work is that a 'working group' of partners willing to produce the HTA core information is established. The technology(ies) to be assessed are selected in a process involving a Delphi exercise by the partners who decide to take part. The working group distribute work amongst themselves. They also need to consider how stakeholders will be involved in the work and collect structured feedback on their processes.

The working groups will be serviced and facilitated by the EUnetHTA Collaboration Secretariat. Funding of these piloting activities is likely to come from a variety of sources including general funding from the EUnetHTA Collaboration, or specific project type funding from the EUnetHTA Collaboration (based on a project description and budget), and in-kind by delivery of expertise and manpower from participating organisations.

Proposed priorities for phase 1:

- Establish subsets of partners who would like to form working groups to pilot production and use of the HTA core information using HTA Core Model
- Secretariat and each working group agree process for the pilot, e.g.
 - Run a Delphi exercise to select technology(ies) to be assessed
 - Create a process for production of the HTA core information outlining stakeholder involvement
 - Produce HTA core information
 - Evaluate experiences and inform the Collaboration

3. Levels of collaboration

Collaboration will take place on a general level involving all partners and at specific levels related to functions and products involving groups of partners according to topic and interest. Some partners will choose to focus on using the information services of the EUnetHTA Collaboration and others will engage in collaboration on products that are defined in specific collaborative efforts.

The frameworks for collaboration should be flexible and transparent and allow for this variation in commitment and responsibility and should facilitate the development and changes in collaboration that will occur over time.

The key mechanisms by which the EUnetHTA Collaboration will work can be classified according to a spectrum of collaboration expressed as levels of collaboration (Figure 1).

Level 0:

- Basic level; sharing and exchange of information (on a voluntary basis). Currently existing HTA network organisations work on this level (e.g. sharing of completed HTA reports).

Level 1:

- Sharing and exchange of essential information among partners of the Collaboration on a more committed basis. An example of this would be that (subsets of) partners decide to share literature search strategies, health economic models and other relevant information and methodology for their own specific country level purposes under a common framework.

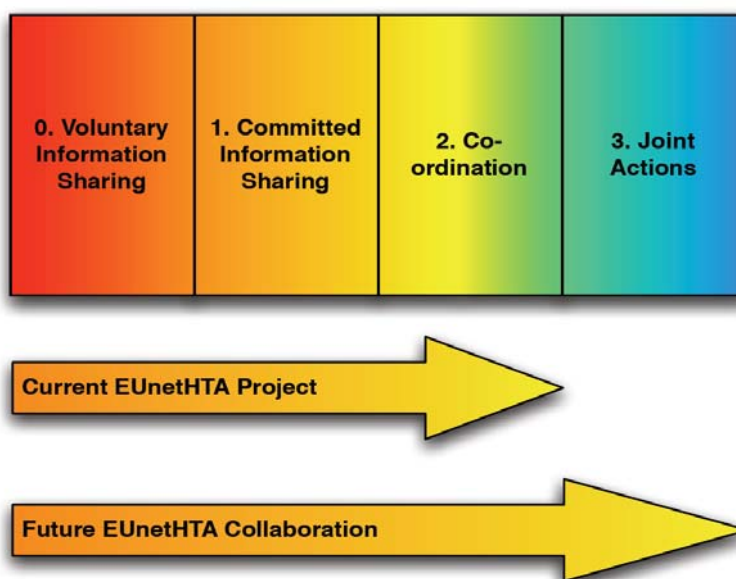
Level 2:

- More advanced and committed to collaboration in a harmonised manner; coordination of common activities where the EUnetHTA Collaboration partners decide and implement HTA activities individually while applying common standards/tools at their own discretion (e.g. creation of HTA core information).

Level 3:

- Higher level of collaboration; partners who wish to engage in joint/common work: sharing workload in a harmonised manner whilst using common standards and tools within the framework of the EUnetHTA Collaboration (e.g. joint multicentre studies or registries for generation of new evidence).

Figure 1: The “Spectrum of Collaboration”



4. Organisation of the EUnetHTA Collaboration

The EUnetHTA Collaboration is a collaboration that has overarching principles for the common good (section 2.1). It is not merely a membership organisation. It hopes to create synergies from linking together HTA agencies and institutions in European countries to promote and enhance HTA across Europe through effective partnership collaboration.

The organisation of the Collaboration depends on formal conditions, practical considerations, and the views and interests of the partners, governments, stakeholders, and the EU Commission when establishing the EUnetHTA Collaboration. It needs to provide a structure that supports good governance in the country in which it is registered, receive funds, administer funds, employ staff, undertake legal negotiations (e.g. intellectual property rights) and be recognised in countries represented by partners as having the mandate for these tasks,

The Executive Committee of the EUnetHTA Project reviewed the organisational structure of several European health related organisations and societies but could not determine whether the Collaboration should be

- i) a separate organisation that is established as a legal entity, i.e. a not-for-profit organisation such as an association, that can meet the requirements listed above, or
- ii) a separate organisation that is NOT established as a legal entity and by itself does not have status to act as a legal entity but will have to be established in a way that allows another (hosting) legal entity to act on its behalf, taking over the legal responsibilities for financial and employee transactions and other legal obligations inside that organisation's financial and other systems (such as in the case of INAHTA hosted by SBU).

Both alternatives described above would allow for the EUnetHTA Collaboration Secretariat to be hosted in an existing organisation, however, in case of not being established as a legal entity, the EUnetHTA Collaboration must be hosted by an existing organisation.

Initial advice from lawyers has indicated that this decision should not be made until further information about the form of the Collaboration has been agreed. So this will need to be decided by the organisations that take forward this proposal to implementation. As outlined in section 6.1 these organisations will be called the 'founding partners'. In particular the following must be decided:

- where the organisation will be established and applicable law
- form of organisation (e.g. an association)
- whether country/region representation is required
- parties' responsibilities in the structure
- exact sources of finance
- any specific requests from founding partners to be considered in the creation of the statutes/bye-laws/articles of association.

It is clear that whatever mechanism is used to create the EUnetHTA Collaboration, it must NOT be possible to evolve into a 'European agency'. It is intended to be a membership organisation and never intends to make central European decisions about a technology.

The structure of the current EUnetHTA Project with its Steering Committee, Executive Committee and Secretariat and the governance principles of the project can serve as one model for consideration to develop agreement on the governance structure of the EUnetHTA Collaboration.

However, different names are proposed for these groups to stress that they support a permanent collaboration, not a time-limited project. Also, an Advisory Council is added (Figure 2).

The Plenary Assembly will take a strategic overview of the work of the EUnetHTA Collaboration including functions such as:

- approving strategic plans, work plans, annual reports, budgets
- agreeing changes to statutes
- appointing members for the Management Board
- advising on future developments.

The Management Board is a sub-group of the Plenary Assembly that is chosen by the Plenary Assembly to serve for a fixed term.

The Management Board will be responsible for supervising operational aspects and will monitor the management of the EUnetHTA Collaboration:

- supervising Secretariat
- preparing strategic plans
- preparing work plans and monitoring outcomes
- reviewing the performance of the Collaboration
- reviewing finances
- appointing a managing director.

The organisation will establish standing committees to oversee the functions and governance and provide assurance to the Management Board. Each committee will have a formal remit defined at the point of their establishment. Each committee may setup short-life working groups to take forward specific projects or tasks.

As some countries may have many organisations that are eligible to be partners of the EUnetHTA Collaboration, consideration should be given to the voting rights of partners on the Plenary Assembly. The members of the EUnetHTA Project Steering Committee had differing views about the mechanism for voting and so the following three options for the voting structure of the Plenary Assembly are proposed:

- i) all Partners have one vote
- ii) one Partner per country can vote
- iii) one Partner per health region can vote.

If the Collaboration decides upon options ii or iii, with country or region representation, it will be at the discretion of the partners in the country/region in consultation with the relevant government to decide who should be the representative.

An advisory mechanism to ensure engagement with stakeholders about the activities of the EUnetHTA Collaboration needs to be in place from the start. This could be in the form of an Advisory Council with broad and balanced stakeholder representation by European umbrella interest organisations from the identified stakeholder groups that can perform a consultative role for the Collaboration.

In section 2.2 the participants in the permanent EUnetHTA Collaboration were described (partners, governments, stakeholders) and some basic conditions for establishing the Collaboration were outlined.

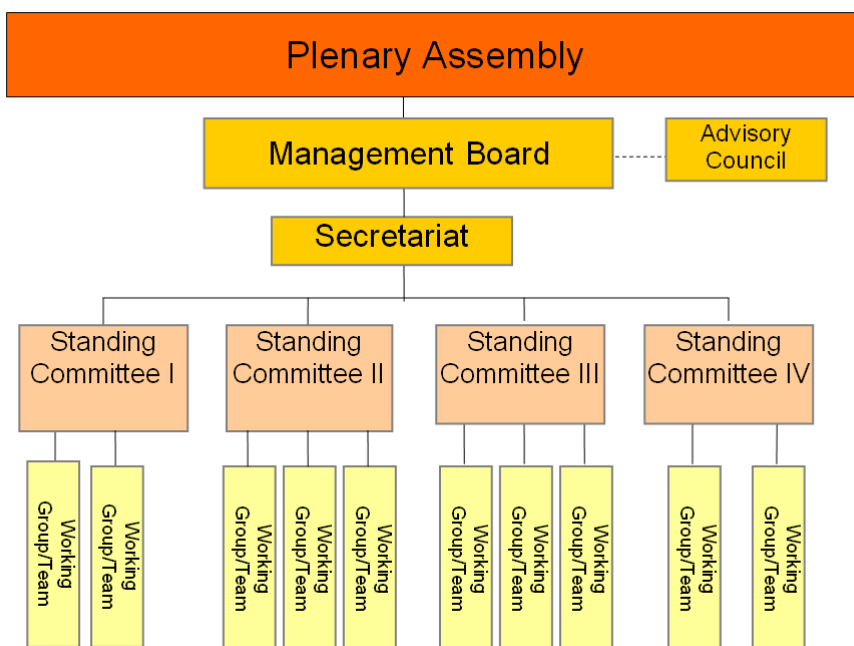
In addition some more formal requirements need to be met:

- a mechanism is agreed (registered legal entity vs. not registered as a legal entity) that allows the EUnetHTA Collaboration to operate legally (to receive and spend funds, employ staff) and administer matters (e.g. Intellectual Property Rights)
- a hosting organisation is identified for the first 2 – 3 years of the collaboration and that the Secretariat is in place, staffed and funded to be able to function from January 1 2009.
- an interim Plenary Assembly consisting of all partners can be convened in the first half of 2009
- an interim Management Board can be selected by the founding partners and Plenary Assembly by the first half of 2009
- statutes/partnership agreement is in place and supported by the founding partners of the EUnetHTA Collaboration
- a mechanism for effective stakeholder involvement is established.

The statutes/partnership agreement will be developed to be effective from day 1 of the EUnetHTA Collaboration. The EUnetHTA Collaboration will base its work on the functions described in section 2.3. These functions will be developed in phases so the composition and remits of the Plenary Assembly, Management Board and Secretariat will be changed over time to meet the requirements of the developing collaborative organisation.

The Statutes will describe the rights of partners, including voting rights in the Plenary Assembly, how elections to the Management Board will take place and the formal decision basis on where the Secretariat will be placed. The statutes should enable the flexible establishment of standing committees and ad hoc working groups. Formal links between members of the Management Board and working groups should be described. Individuals with specific expertise who do not belong to a partner organisation may be allowed to participate in ad hoc working groups/teams according to publication of potential conflicts of interests. In all cases, the majority of participants in such a working group should be partners.

Figure 2: EUnetHTA Collaboration Organisational Structure



5. Funding the EUnetHTA Collaboration

The EUnetHTA Project was supported by the European Commission for three years and during this period the Associated Partners provided substantial funding from their own organisational budgets. Contributions to the EUnetHTA Collaboration from partners themselves alone will not be sufficient to cover core activities (Secretariat and other essential activities) and so joint funding from several sources will be needed.

Financial contributions would be accepted from:

- EU funding
- governments
- publicly funded statutory health insurance organisations
- international non-for profit organisations
- partners
- donations/grants from non-for-profit organisations.

Other sources may be accepted but would need to be approved by the Plenary Assembly. In all cases, grants should be unrestricted and conflicts of interests would be disclosed.

A budget for the initial year and a typical year in phase 1 of the EUnetHTA Collaboration is being created by the EUnetHTA Project Executive Committee according to the functions outlined in section 2. Once initial funding sources have been identified, it will be necessary to determine how receipts from funders will be balanced with membership contributions (in money and in kind) to undertake the functions of the Collaboration. The balancing of committed resources, intended functions and anticipated number of partners will determine the required fee for partnership and priorities of work.

It is expected that core funding (unrestricted) would be used to support the Secretariat and permanent activities. Some core funding would also be allocated to project work (limited-term) through the budget. These allocations would be decided on the basis of project descriptions including specification of deliverables, milestones, costs and resources available. It is anticipated that central budget allocations would only provide part funding for any project and that the remainder of financing would come from other funding sources (grants, in kind contributions etc).

6. The establishment and roll-out of the EUnetHTA Collaboration

6.1 Developing this proposal

The EUnetHTA Project Steering Committee encourages partners in the EUnetHTA Project and other interested European HTA organisations to establish a group that will implement this proposal. These 'founding partners' should include organisations that are highly experienced in undertaking HTA to inform policy, long established organisations contributing to such HTAs (e.g. doing systematic reviews, economic evaluations, etc) and smaller, newer HTA organisations.

The 'founding partners' will work from the summer of 2008 to bring about the formal establishment of the EUnetHTA Collaboration. A 'critical mass' of organisations is needed that is willing to commit resources and expertise to this work. Following the EUnetHTA Project Steering Committee

meeting on 29 May 2008, 12 partners* of the current EUnetHTA project have already indicated their willingness to act as a 'founding partner' to take this proposal to fruition.

The aim is that all founding partners will become partners in the Collaboration, but this will depend on acceptance of the underpinning statutes or bye-laws and the contribution of partnership fees. The work of all founding partners who established the Collaboration must be clearly recognised.

6.2 Phase 1 of the EUnetHTA Collaboration

The EUnetHTA Collaboration can start on 1 January 2009 if certain prerequisites, as listed in sections 2.2 and 4, are met. These will be considered by the 'founding partners' in their establishment of the Collaboration.

This proposal refers to priorities proposed for 'phase 1' of the Collaboration. The duration of phase 1 cannot be precisely defined and is not necessarily defined in time but is a result of:

- successful operation of the prioritised activities in the EUnetHTA Collaboration
- promoting and supporting collaboration in those prioritised activities at levels 0-2
- effective functioning of the governance structure.

The functions to be undertaken in the first years will depend upon the funding available and activities within functions will need to be prioritised according to available resources. Additional functions and activities are envisioned to take place after phase 1 as the Collaboration develops and identifies new needs.

7. Relations to the global HTA community and international health organisations

In the international HTA community there are a number of global organisations which are natural collaborators for The EUnetHTA Collaboration, such as the International Network of Agencies for HTA (INAHTA), HTA International (HTAi), Guidelines International Network (GIN), EUROSCAN and the Cochrane Collaboration. It is an explicit goal to avoid duplication of activities between the organisations and to seek synergies through coordination. The EUnetHTA Collaboration's focus on European added value and on decision-making in Europe separates the EUnetHTA Collaboration from the other organisations in the international HTA community. However, the activities of the organisations are linked in different ways and coordination and division of work is necessary to obtain the best possible synergies of the interaction with other international HTA organisations. The coordination will be accomplished through ongoing dialogue with the relevant organisations.

Some international organisations related to health are of particular interest to the EUnetHTA Collaboration. These include:

- The European Commission
- The Council of Europe
- WHO Regional Office for Europe

The longstanding interest and support from the European Commission Directorate SANCO will be stimulated to enable the EU to support the EUnetHTA Collaboration, which will facilitate HTA to inform health policy in Member States and other countries across Europe.

In addition, consideration will be given to links with international organisations such as the Organisation for Economic Co-operation and Development (OECD).

* As of June 16, 2008

Annex 1.

The policy background in Europe for EUnetHTA Collaboration

European health initiatives

The proposal from the EUnetHTA Steering Committee outlines the strategic framework, functions and organisational structure of a permanent collaborative network for HTA, called the 'EUnetHTA Collaboration'.

The potential of using HTA as a tool in decision making in relation to policy decisions on health interventions and technologies has caught the interest in many parts of the world and international governmental organizations such as the World Health Organization, OECD and World Bank. The European Commission and Member States are expressing support to the development of a sustainable collaboration and organizations for HTA at the Member State level.

The Executive Board of the World Health Organization⁶ has on its thirteenth meeting, 29 January 2007 forwarded to the World Health Assembly a suggestion to urge the Member States to collect, verify, update and exchange information on health technologies as an aid to their prioritization of needs and allocation of resources.

In the European Union (EU), HTA is recognised as an essential element in improving the quality of healthcare in the health systems of Member States in the EU. This is in line with the Common Values and Principles⁷ that underpin all health care systems in Europe. The overarching values of universality, access to good quality care, equity, and solidarity have been widely accepted in the work of the different EU institutions. Together they constitute a set of values that are shared across Europe. Universality means that no-one is barred access to health care; solidarity is closely linked to the financial arrangement of national health systems and the need to ensure accessibility to all; equity relates to equal access according to need, regardless of ethnicity, gender, age, social status or ability to pay. EU health systems also aim to reduce the gap in health inequalities, which is a concern of EU Member States; closely linked to this is the work in the Member States' systems on the prevention of illness and disease by inter alia the promotion of healthy lifestyles

During discussions in the informal meeting of EU Health Ministers in Aachen, Germany, on 20th of April 2007 on EU Strategy for Health Services the Trio presidencies of the EU (the German, Portuguese and Slovenian Presidencies, (January 2007 until June 2008)) provided a document called *Health care across Europe: Striving for added value*. The document related to values and policies by noting that:

"In line with the value of access to good quality care and the principle of patient safety, we can improve the healthcare quality standards across the different health systems in the EU through the following:

- evidence-based medicine, health technology assessments, cost-benefit-analyses"⁸

An international study "Financing Sustainable Healthcare in Europe: New Approaches for New Outcomes"⁹ was endorsed and presented to the European Commission, in February 2007. This so-called Cox report states that:

⁶ WHO Resolutions and decisions, EB120.R21, Health technologies, 29 January 2007

⁷ Official Journal of the European Union, C 146, Volume 49, June 22 2006

⁸ Notes of the Trio Presidency – Health care across Europe: Striving for added value, Aachen, 20th April 2007

⁹ FINANCING SUSTAINABLE HEALTHCARE IN EUROPE

ENSURING VALUE FOR MONEY IN HEALTH CARE - THE ROLE OF HTA IN THE EUROPEAN UNION
Corinna Sorenson, Panos Kanavos, Michael Drummond, 2007

- HTA can play a valuable role in health care decision making, but the process must be transparent, timely, relevant, in-depth and usable
- assessments need to use robust methods and be supplemented by other important criteria
- by maximising the potential of HTA, decision-makers will be better able to implement decisions that capture the benefits of new technologies, overcome uncertainties, and recognise the value of innovation, all within the constraints of overall health system resources

The permanent EUnetHTA Collaboration is also in line with the Programme of Community action in the field of health 2008-13 which states that:

(27) In order to ensure a high level of coordination between action and initiatives taken by the Community and Member States in the implementation of the Programme, it is necessary to promote cooperation between Member States and to enhance the effectiveness of existing and future network in the field of public health. The participation of national, regional and local authorities at the appropriate level in accordance with the national systems should be taken into account in regards to the implementation of the Programme.

International evidence based networks

The EUnetHTA Collaboration aims to reach a high level of cooperation between European countries and enhance work on HTA in order to serve the needs of national governments.

The role of international interest organisations in the field of HTA are primarily to inform about the role that HTA can play in informing decisions and in prioritization of resources for health care service.

The mission of the International Network of Agencies for Health Technology Assessment (INAHTA) is to provide a forum for the identification and pursuit of interests common to health technology assessment agencies.

Health Technology Assessment International's (HTAi) mission is to support the growth of the HTA community by providing a forum for the exchange of information, methods and expertise amongst partners of the HTA community.

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) ISPOR promotes the science of pharmacoeconomics (health economics) and outcomes research (the scientific discipline that evaluates the effect of health care interventions on patient well-being including clinical outcomes, economic outcomes, and patient-reported outcomes) and facilitates the translation of this research into useful information for healthcare decision-makers to ensure that society allocates scarce health care resources wisely, fairly and efficiently.

In the World Health Organisation Regional Office for Europe the Health Evidence Network (HEN) is conceived as network of technical partners and financial partners, involving United Nations agencies with a mandate related to health, organizations working with evidence-based health policy and health technology assessment, other institutions and governments. HEN gives rapid access to independent and reliable health information and evidence by providing:

- answers to policy questions in the form of evidence-based reports and summaries;
- easy access to evidence and information from a number of web sites, databases and documents; and
- in conjunction with the European Observatory on Health Systems and Policies, policy briefs focused on health systems and of relevance to the European Region's Member States.

Annex 2.

Health Technology Assessment

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 technology¹⁰. 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 health policies to provide patients with equitable and timely access to safe, effective, high quality health technologies that achieve best value.

Assessment and appraisal

HTA is increasingly used in formal policy processes across Europe. HTA informs policy but does not define policies or make decisions.

It is important to know where HTA (which is defined as policy analysis) stops, and policy making takes over – or at least where the zone of transfer is - in the process of setting up policies and making decisions. This clarity should be asked from any HTA organisation / regulatory body. Only the word “assessment” should be used when describing the HTA work. “Appraisal” should be used when and if one wants to describe processes that take HTA and other information into steps towards issuing policies (e.g. NICE Guidance in England and Wales) and decisions. Assessment and appraisal have the same meaning in daily language. One should therefore be explicit on the nature of the information: informing policy / or making decisive recommendations for policy / decisions. In some institutions there may be a division of work between units / departments / groups that a) make the HTA and b) make the recommendations / decisions. In such cases the “product” coming out of b) should not be called HTA. They are based on HTA but often take into account other kinds of information and influence (such as local values or available resources).

HTA information is fed into (complex) decision-making together with other sorts of reflection that HTA cannot include in the work – without ending up being policy making or decisions on policies. That is why there are people doing HTA and people doing policy making, and why the distinction should be as clear as possible for everybody involved – irrespective of any close collaboration between them.

Here is an illustrative example: There is a clear distinction in England between assessment (a scientific process and the role of the HTA Programme) and appraisal (the role of policymakers, like the National Institute for Health and Clinical Excellence (NICE) (Walley, 2007). The HTA Programme supports all NICE technology appraisals by commissioning independent assessments of the evidence, accompanied by economic evaluation and a review of manufacturers’ submissions. These are provided to NICE’s appraisal committees to inform its decisions, and are made publicly available once NICE has reached its preliminary decisions. The assessment does not make a recommendation to the committee.

¹⁰ www.inahta.org/HTA (accessed 25 February 2008)

The distinction between assessment and appraisal may work well in the governance of England and Wales National Health Service (NHS), but will not per se carry the same clarity outside the NHS.

What is considered to be part of HTA reporting in one country such as stating policy options and their consequences followed by a recommended choice may not be seen as HTA in another, where only stating the policy options would be HTA and the recommendations be policy making. Thus European collaboration in HTA today must be flexible enough to cover some of the range between “pure” research information and giving advice and recommendations. However, in each report and each institution there should be clarity and transparency on these matters.