



eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

European HTA Collaboration Proposal Years 2009+

Overview of public consultation

Background

The EUnetHTA Project was established in 2006, with funding for three years from the European Commission. The Project aims to establish an effective and sustainable European network for health technology assessment (HTA) that informs policy decisions. To achieve this it is creating an open network, developing practical tools to share scientific evidence and frameworks for HTA among Member States. This cross border collaboration will help reduce duplication of effort, saving time and resources of Member States when health technologies are assessed for new or continued use in national/regional health care systems.

Funding for the EUnetHTA Project ceases at the end of 2008. To ensure that the work of the Project is continued to create a truly sustainable European HTA collaboration, a proposal document has been developed. The 'European HTA Collaboration Proposal' outlines the strategic framework, functions and organisational structure of such a permanent collaborative network for HTA, called the 'EUnetHTA Collaboration'.

The proposal was developed during 2007 by the EUnetHTA Project Secretariat, Executive Committee and the Associated Partners.

Process of consultation

The proposal document dated 'November 2007' was issued for consultation on 1 November 2007, with an invitation for comments on any part of the proposal.

The consultation was announced in the EUnetHTA News (e-newsletter) that was sent to 370 subscribers on 1 November 2007. It was published on the public part of the EUnetHTA website and distributed to international HTA organisations and a selection of European umbrella healthcare organisations, as shown in Annex 1.

The deadline for feedback was originally 1 December 2007, but this was extended to 20 December 2007 due to requests for an extension. The new date was communicated on 19 November via the news section of the EUnetHTA public website and through the regular EUnetHTA Members' Update distributed to all EUnetHTA members.

The invitation to comment on the proposal document stated that feedback from respondents would be made public and that respondents would receive further feedback. All responses were published on the EUnetHTA website on 15 January and this overview provides feedback to members of EUnetHTA, interested parties and the public.

Respondents

The majority of responses¹ were received after the second deadline of 20 December, with the last arriving on 25 January. All responses have been included in this overview.

As table 1 shows, 17 responses were received. Six were from EUnetHTA collaborating partners, four from industry umbrella organisations, two from Ministries of Health, two from pharmaceutical companies, one from an HTA Agency that is not a partner in EUnetHTA, one from two umbrella organisations for patients and one from an international HTA network. All but two of the responses were from Europe.

Table 1. Respondents to public consultation

Organisation	Country	Group
Ministry of Health/ZonMW	Netherlands	Ministry/Associated Partner
Department of Health (DoH)	England	Ministry
European Genetic Alliances' Network (EGAN) and European Organisation for Rare Disorders (Eurodis)	Europe	Umbrella Patient Organisations
Eucomed	Europe	Umbrella Organisation for Medical Technology Companies
Advanced Medical Technology Association (AdvaMed)	USA	Umbrella Organisation for Medical Technology Companies
European Association for Bioindustries (EuropaBio)	Europe	Umbrella Organisation for Biotech Companies
European Federation of Pharmaceutical Industries and Associations (efpia)	Europe	Umbrella Organisation for Pharmaceutical Companies
GSK	International	Pharmaceutical Company
Eli Lilly	International	Pharmaceutical Company
International Network of Agencies for HTA (INAHTA)	International	International HTA network
NHS Quality Improvement Scotland (NHS QIS)	Scotland	European HTA Agency not in EUnetHTA
Agency for HTA in Poland (AHTAPol)	Poland	Collaborating partner
Agenzia per i Servizi Sanitari Regionali (AssR)	Italy	Collaborating partner
Directorate of Health, Austurströnd	Iceland	Collaborating partner
Gesundheit Österreich	Austria	Collaborating partner
National Institute for Health and Clinical Excellence (NICE)	England/Wales	Collaborating partner
Center for Medical Technology Policy (CMTP)	USA	Collaborating partner

¹ Eucomed, Europabio, efpia, GSK, INAHTA, DoH Iceland, NICE, CMTP

All responses are available in full at:

http://www.eunetha.net/Communication/Press_Releases/EUnetHTA_public_consultation_-_original_responses/

The consultation was intended to give all those who wished to comment an opportunity to do so. As may be expected, responses were received from organisations that had an interest-based perspective in HTA. Six of the responses came from collaborating partners who are involved in the EUnetHTA Project and so their views may be different from other stakeholders who might be expected to respond in a 'public' consultation. This needs to be borne in mind in the distillation of consultation views presented in this overview and so they have been identified as collaborating partners in this overview.

Extraction of comments

The consultation invited open comments on any part of the proposal and did not include a list of questions. Some respondents commented on all elements in detail, others focused only on specific areas of interest. Hence there was no clear a priori framework for analysis of responses, so comments have been extracted (Annex 2) according to the judgement of the reviewer into the following seven categories:

- 'Initial statement'
- EUnetHTA 'information sharing'
- EUnetHTA 'stakeholder' involvement
- 'Levels of collaboration'
- 'Process of collaboration'
- Collaboration 'funding'
- Collaboration 'governance'.

This overview summarises the comments from each respondent and draws out key themes. These will be used alongside other comments from the EUnetHTA Steering Committee submitted in autumn 2007, to develop the proposal for the EUnetHTA Collaboration.

Several consultation responses also included comments about general issues related to HTA. As these are not directly related to the proposal document that was consulted upon, they are not summarised here. However, they will be used to inform other EUnetHTA Project work (www.eunetha.net/Work_Packages/).

Overview of comments

The comments provide important information for development of the EUnetHTA Collaboration proposal. They highlight elements that are valued, areas where there are reservations about the proposed approach, misunderstandings of the proposals and areas that require further discussion.

Initial statement

The majority of respondents made clear statements that welcomed the work undertaken by EUnetHTA to develop common methods for HTA that should lead to consistent, robust, high quality, transparent HTA processes across Europe. Several (particularly the collaborating partners) expressed a desire to collaborate more and offered practical examples of how this could be achieved. The remaining respondents did not make any general opening statement.

EUnetHTA information sharing

Several welcomed the information sharing initiative as the method to support common standards and procedures, providing access to more high quality, relevant HTA information thus reducing duplication. One suggested that draft reports could be shared and one that the database could be extended to include HTA recommendations and resulting policy decisions.

A few respondents stated the need to define target audiences for information that are consistent with stakeholder groups and consider the connection to industry. Furthermore, if information is to be made available to the public, mechanisms for appropriate communication need to be considered and processes created for handling confidential content.

A few respondents stated the importance of using common terminology or suggested that the HTA glossary (*presumably from INAHTA*) could be updated.

EUnetHTA stakeholder involvement

One collaborating partner indicated that Social Insurance Institutions and Health Care Administrations should be listed as stakeholders in the EUnetHTA Collaboration proposal document.

Most other comments on stakeholder involvement came from Industry.

Several raised concerns that industry and other stakeholders (such as patients and clinicians) were only involved in the stakeholder forum and are thus limited to an advisory role. It was felt that this would only allow a limited opportunity to contribute to shaping the goals, process and outcome and that there were no assurances that the views of the stakeholder forum needed to be acted upon.

One respondent noted that the open forum website cannot be considered as a sufficient method for effective stakeholder involvement, a formal process is required that recognises the importance of collaboration throughout the whole HTA process.

Some indicated that there should be open dialogue with industry and other stakeholders. There were requests for the stakeholders to be fully involved in the Steering Committee, Executive Committee and the shell, to act as real partners and ensure that the stated values of EUnetHTA are upheld. One respondent noted it would be a critical weakness if this was not the case.

Several respondents stated the need to involve industry in work relating to horizon scanning and monitoring emerging technologies.

One respondent felt that the impact of HTA collaboration on stakeholders should be assessed regularly and that tools for collecting and integrating stakeholder input were needed.

Levels of collaboration

There was a wide range of views about the desirable level of collaboration.

One Ministry responder felt that often only collaboration at level 0 would be appropriate and one stakeholder felt that collaboration should also remain at level 0. Two stakeholders suggested that collaboration should be limited to levels 0 or 1 for three years; one suggested

that level 2 could then be considered. One stakeholder and one non EUnetHTA HTA Agency supported collaboration at levels 0-2.

In relation to the joint actions/collective decisions at level 3, several stakeholders raised concerns about transparency, transferability, accountability and the possibility of creating common outcomes and decisions instead of common methods. It was felt that this related more to making policy than informing policy.

One stakeholder explicitly stated that level 3 collaboration created confusion between assessment and appraisal and there needed to be a limit to the 'centralisation' of HTA activities, recognising the need for the national context. One stakeholder noted that centralised assessments could cause delays in access to technologies.

Most collaborating partners did not comment on the level of collaboration, so it could be assumed that they were happy with the proposals. However, one noted that 'mandatory' in figure 1 could be misinterpreted.

Process of collaboration

One respondent noted that the benefits of HTA collaboration could be speed and robustness of national assessments, faster access to innovative technologies, improved patient outcomes and positive stakeholder feedback. Another noted that the EUnetHTA Collaboration needs to demonstrate that added value can be delivered for national HTA organisations and stakeholders compared with less formal networking.

Several respondents stressed the difference between assessment and appraisal, with the latter requiring a variety of considerations relating to the national context.

One asked for consideration of the impact of the EUnetHTA Collaboration on decision making and speculated that a negative finding may be adopted more often than a positive finding and another requested that the impacts of collaboration on stakeholders be taken into account.

Several respondents requested complete transparency – with industry needing to know the process (methods, evidence reviewed), timelines, how decisions would be made (including disclosure of internal discussions) and with a mechanism for efficient, independent appeal.

One respondent asked what the incentives/sanctions for compliance/non compliance with collaboration requirements would be.

INAHTA supported the development of HTA institutions but asked for more details of EUnetHTA's plans in this area and suggested that INAHTA could contribute to this work. They also noted that having one contact point for HTA in Europe would be useful, but that the work needs to continue with broad input from around the world. They propose that a plan is created outlining how INAHTA can collaborate with EUnetHTA.

One HTA Agency outside EUnetHTA noted the benefits and risks of a sustainable network. The risks included erosion of INAHTA, influence of strong agencies, slow bureaucratic EU systems, and duplication of functions of other organisations (e.g. the HTA database).

Two collaborating partners made similar comments about the need to develop the work relating to identification and monitoring of emerging technologies in the EUnetHTA Collaboration. The priority should be to develop methods and processes to encourage 'bridging research' for high impact technologies, to enable generation of new information, whilst allowing controlled introduction of new technologies (coverage with evidence

development). It was suggested that the EUnetHTA Collaboration could bring together all those working in this field to share ideas, develop common study protocols, create a database of studies and facilitate collaborative studies.

Collaboration funding

Several respondents noted that the proposals for funding mechanisms were unclear and needed to be developed. One Ministry respondent expressed concern about 'double charging' as they already fund their national HTA Agency.

One stakeholder noted that funding may influence the organisational structure. Another stated that funding should be independent of any undue financial conflicts that may influence HTA outputs, but that a wide range of options should be considered including public-private partnerships.

Collaboration governance

One collaborating partner stated the importance of the legal identity, particularly for the function of being a single reference point for HTA in Europe.

One stakeholder asked for clarification of the relationships with the European Commission and other networks. This stakeholder also wanted to know the Member States' views about the proposal. Another stakeholder said that for credibility the EUnetHTA Collaboration should be independent of the European Commission. This stakeholder expressed a preference for a membership organisation, then an independent organisation with formal links to the European Commission and lastly to the EUnetHTA Collaboration being part of the European Commission.

One collaborating partner asked for more open discussion of the pros and cons of various models for the organisational structure.

One stakeholder asked for clearer descriptions of the functions of the Steering Committee, Executive Committee and Secretariat. One collaborating partner stated that Steering Committee members should only be selected from the nucleus and that they should be completely publicly funded. There were no other comments about the nucleus and shell from the collaborating partners.

Several respondents expressed the need for quality assurance and audit mechanisms and that outcomes (e.g. reduction in duplication) should be measured. One suggested that annual objectives and performance indicators should be published. Two stakeholders asked to whom EUnetHTA was accountable and one noted that accountability was particularly important if level 3 collaboration was to be considered.

Discussion

It is likely that the consultation comments were based not only on review of the EUnetHTA Collaboration proposal, but also on views formed from EUnetHTA public presentations during the first two years of the Project and the release of the first common core HTA for consultation in summer 2007.

In general there was support for activities that seek to share methods and HTA information across Europe to promote consistency in standards, but a concern that the EUnetHTA Collaboration would also centralise decisions arising from HTA. Emphasis was placed on the

need to maintain Member State subsidiarity and to differentiate between assessment and appraisal.

Several respondents seemed to misunderstand the role of the network, expressing concerns about 'centralisation' of HTA activities and EUnetHTA 'decisions' or 'recommendations', implying pan European assessment. This seemed to stem from a misunderstanding arising from the presentation of the common core HTA on drug eluting stents (being misinterpreted as a complete HTA report, rather than the building blocks of core HTA information). There was also lack of knowledge about the work on adaptation and lack of clarity about activities planned for the different levels of collaboration. As a result the respondents that commented on the level of collaboration expressed concerns about the higher levels, particularly level 3.

There were requests to create transparent processes within the EUnetHTA Collaboration, but concern that the process for stakeholder involvement would not lead to effective engagement or partnership working. There were calls for stakeholder involvement at all levels of the EUnetHTA Collaboration. However, this view was not shared by all stakeholders (particularly collaborating partners).

The need to identify the added value and provide quality assurance of the work of the EUnetHTA Collaboration was stressed. A few respondents emphasized the need to clarify the funding, but only one respondent commented on the options for the organisational structure.

These comments will be considered alongside those received previously from the Steering Committee and the European Commission to produce a revised draft proposal for the EUnetHTA Collaboration for comment by the Executive Committee and Steering Committee.

Specific invitations to contribute to the consultation

International HTA organisations

The EUnetHTA Collaboration proposal document was sent to ISPOR, INAHTA, HTAi and EuroScan and they were asked to send it to their members. INAHTA provided an official response. HTAi placed the proposal document on their website and EuroScan discussed it during their annual meeting, but neither provided a written response. It is not known how ISPOR managed the document.

Umbrella healthcare organisations in Europe

The document was also sent to the following organisations:

Hospital policy makers

European Association of Hospital Managers
European Society of Quality in Health
European Hospital and Healthcare Federation

Patient organisations

European Patients' Forum
Citizen Participation in Science and Technology
European Parliamentary Technology Assessment
Alzheimer Europe

Healthcare professionals

European Union of Medical Specialists
Standing Committee of European Doctors
The European Forum of National Nursing and Midwifery Associations
and World Health Organisation
Council of European Dentists
European Federation of Nurses Associations
European Forum of Medical Associations
European Association of Senior Hospital Physicians

Industry

efpia
Eucomed
EuropaBio
Advanced Medical Technology Association
The European Association of Euro-Pharmaceutical Companies
European Diagnostic Manufacturers Association
European Generic Medicines Association

Annex 2

Extraction of public consultation comments

Respondent	Key points
MoH Netherlands/ ZonMw	<ul style="list-style-type: none">• Initial statement - supports proposal and stresses that national priority should be for further testing of tools in Dutch context to determine efficiency• Information sharing – willing to share information on EUnetHTA information system• Funding – need structural funding mechanisms
DoH England	<ul style="list-style-type: none">• Levels of collaboration – concern that higher levels are not always the best and often only collaboration at level 0 would be appropriate• Funding – need to provide information; concern about double charging given funding already provided for national HTA programme
EGAN/Eurodis	<ul style="list-style-type: none">• Initial statement - interested to cooperate in EUnetHTA's work• Stakeholders – note the growing influence of HTA on cost considerations and concern because patient organisations do not perceive health care as a cost issue. Progress in treatment of genetic and rare diseases is valued in a much more positive way than it currently seems to be valued in cost-effectiveness analyses.

Eucomed	<ul style="list-style-type: none"> • Initial statement - support values and mission, recognising tools already developed • Stakeholders <ul style="list-style-type: none"> ○ only advisory role planned, but industry and professional societies making essential contributions to HTA and so should be included in shell to ensure stated values are upheld ○ no formal process for stakeholder involvement, open forum website is insufficient, stakeholders need to be integral to collaboration throughout the whole HTA process (from scoping) ○ collaboration with industry could discuss appropriateness of clinical evidence and input to horizon scanning ○ need open dialogue among all stakeholders to develop this work. • Levels of collaboration <ul style="list-style-type: none"> ○ should be limited to 0, 1 for next 3 years, then level 2 may be considered • Process of collaboration <ul style="list-style-type: none"> ○ must have transparency - currently stakeholders do not have access to all WP newsletters, eg those for WP7 and WP8 ○ manufacturers need to know how decisions will be made, steps involved and timelines need independent, 'formal appeal process (for decisions) to resolve any disagreements on EUnetHTA output' ○ what would the incentives/sanctions for compliance/non compliance be? • Funding <ul style="list-style-type: none"> ○ considers key purpose of document is to raise funds, but the document provides no details of actual implementation, this needs clarification ○ need to recognise that the funding sources may influence the organisational model and not just vice versa • Governance <ul style="list-style-type: none"> ○ need quality assurance – e.g. to measure quality of outputs ○ outcomes – unsure that reduced duplication can be achieved ○ publish annual objectives and performance indicators ○ who will audit?
---------	--

AdvaMed	<ul style="list-style-type: none"> • Initial statement - addresses valuable need to determine latest methods and support sustainable sharing of assessment information • Information sharing <ul style="list-style-type: none"> ○ seeks to promote information sharing and communication among members, but without sufficient connection to industry • Stakeholders <ul style="list-style-type: none"> ○ database for monitoring upcoming and existing technologies would be challenged without cooperation of industry ○ involvement only in the forum and not the shell prohibits involvement in recommendation of appropriate evaluation approaches for classes of technologies ○ exclusion of patient groups, physician groups and industry from Steering and Executive committees is 'a critical weakness' (examples from NICE and MedCAC of involvement in advisory committees) • Levels of collaboration –there should be no 'joint actions' without a better evolved structure and more transparent process • Process of collaboration <ul style="list-style-type: none"> ○ EUnetHTA as a direct influencer of health policy within national decision-making bodies, should have a fully transparent process with complete disclosure of internal discussions, methods, evidence reviewed, considerations made with respect to HTA recommendations and deliberations of its Committees ○ Need independent appeals process for parties that disagree with 'EUnetHTA recommendations' • Governance - need external audit
EuropaBio	<ul style="list-style-type: none"> • Initial statement - strongly supports a sustainable collaboration to advocate and facilitate robust, transparent and predictable, HTA analysis • Stakeholders – all stakeholders need to be involved in the decision making process of the EUnetHTA Collaboration, particularly in the Steering Committee

Efpia	<ul style="list-style-type: none"> • Initial statement - Efpia looks forward to working constructively with EUnetHTA to improve use of HTAs in healthcare policy decision-making to benefit of European patients. However, this consultation period was too short, so current response is preliminary. • Stakeholders <ul style="list-style-type: none"> ○ no guarantee that stakeholder views will be taken into consideration as they are apart from the process and structure does not allow for true involvement • Level of collaboration <ul style="list-style-type: none"> ○ sceptical about practical feasibility and desirability of moving beyond levels 0 and 1 collaboration due to: <ul style="list-style-type: none"> ▪ confusion between assessment and appraisal suggested by level 3 collaboration (appraisal involves value judgements which may not be shared) ▪ agreement on common methods would be helpful but no agreement on gold standard ▪ needs to be a limit to 'centralisation' of HTA activities – merit in collaboration to share generalisable data (e.g. meta-analyses, safety and efficacy assessments), but assessments are linked to national health care environment and infrastructure. In a different national context comparators, treatment practices, patient management, societal values (impacting utility weights), resource use and costs may be different. • Process of collaboration <ul style="list-style-type: none"> ○ European HTA collaboration should not interfere with national responsibility and competence for organisation of health care and must allow national decisions that take account of national differences and priorities in accordance with subsidiarity ○ consider likelihood of output having impact on decision making - negative HTA finding more likely to be adopted regardless of appropriateness by those with financial constraints, whereas positive findings may be considered not applicable ○ no guarantee of efficient and independent handling of appeal • Governance <ul style="list-style-type: none"> ○ to whom is EUnetHTA accountable?
-------	--

GSK	<ul style="list-style-type: none"> • Initial statement - support added value from EUnetHTA (as outlined in proposal) to: <ul style="list-style-type: none"> ○ facilitate use of HTA at national level in line with best practice principle ○ encourage good governance among national HTA agencies, including manner for stakeholder involvement through entire HTA process ○ promote more consistency in standards and methods ○ be a European resource centre for independent, expert advice and provide tools ○ be a European hub for exchange of information, data and methods • Stakeholders <ul style="list-style-type: none"> ○ Stakeholder Forum will only provide limited opportunity for industry to feed into the process ○ medical sector, patients and industry should have at least advisory function • Level of collaboration should remain at level 0 due to the following issues: <ul style="list-style-type: none"> ○ transferability of HTA assessments – limitations should be recognised and only undertaken when non-binding agency cooperation (as outlined in ‘support added value’) has been proven of added value ○ extent of European collaboration should be guided by feasibility, ability to eliminate redundancies, impact on making national assessment process more efficient and potential to add value over existing arrangements ○ level 3 collaboration would fail to meet requirements of transferability and accountability • Process of collaboration <ul style="list-style-type: none"> ○ needs to demonstrate that it can deliver added value to national HTA organisations and other stakeholders compared with less formal networking arrangements ○ assessment and appraisal needs to be a clear two-step process ○ appraisal determinations and other activities (such as scoping of appraisals, economic evaluations, financial impact, equity of access, capital investment requirements, training, local dissemination of results, reviews, design of follow-up studies) must be addressed at national level ○ need independent appeals process ○ need transparency • Governance <ul style="list-style-type: none"> ○ unclear to whom the network should be accountable – particularly important to determine for level 3 collaboration that includes collective decision-making ○ nature of relationship with EC needs to be clarified ○ how would the proposed network fit with existing European/international networks? ○ want to know MS’s position towards the network
-----	--

Eli Lilly	<ul style="list-style-type: none"> • Initial statement <ul style="list-style-type: none"> ○ supports efforts to bring greater clarity and agreement among HTA stakeholders about expected data requirements, standards for stakeholder engagement and transparency, including a holistic view of what constitutes benefit and value in a treatment of patients, providers and society ○ supports EUnetHTA's efforts to improve and practice of HTA throughout Europe • Information sharing (function 6.2.1) <ul style="list-style-type: none"> ○ need to define target audiences for information to be made available that are consistent with defined stakeholder groups ○ if data are available to public need to determine how it will be effectively communicated and what will remain commercial in confidence • Stakeholders <ul style="list-style-type: none"> ○ add role of stakeholders in shaping goals, process and outcome of HTA and indicate that they are partners in developing an HTA ○ impact of increased HTA collaboration on stakeholders should be assessed at regular intervals ○ need tools for collecting and integrating stakeholder input ○ industry should be in stakeholder forum, but need accountability that opinions of the Forum will be taken on, so to establish true partnership, stakeholders should have representation on the Steering or Executive Committee • Levels of collaboration <ul style="list-style-type: none"> ○ support levels 0-2, as level 3 may propagate common outcomes as opposed to common methods and 'collective decisions' appears to relate to policy making rather than informing policy • Process of collaboration <ul style="list-style-type: none"> ○ need to clarify that benefits of HTA are characterised by process (speed and robustness of national HTA assessments) and outcomes (timely access to innovations, patient satisfaction and stakeholder impact assessments) ○ consider timing of assessment and possible delays in access if a centralised assessment is performed ○ process of collaboration should be sensitive to potential impact on stakeholders ○ functions 6.2.3/6.2.5 <ul style="list-style-type: none"> ▪ rather than standardisation and common practices, encourage <u>good</u> HTA practices that allow for advancements in assessment methods ▪ report limitations of assessment findings • Funding <ul style="list-style-type: none"> ○ should be independent of any undue financial conflicts that may influence HTA outputs, but should consider a wider range of options including public-private partnerships • Governance <ul style="list-style-type: none"> ○ for credibility should be clear separation and independence from EC so preference is for membership organisation, then independent organisation with formal links to EC, lastly as part of EC ○ need more detailed descriptions of functions of Steering Committee, Executive Committee and Secretariat
-----------	--

Eli Lilly continued	<p>Detailed textual changes suggested to the proposal relating to:</p> <ul style="list-style-type: none"> • concern about HTA being defined as policy analysis • emphasis on broad definition of health technology • Need to consistently apply the notion that HTA does not interfere with national responsibility and competence throughout the document • Vision – to support timely access • Mission – development of HTA to take account of needs of stakeholders and transparency of HTA • Aims – different perspectives for value of technology should be appropriately represented, breadth of technologies reiterated, good practice to support local context • Values – additional concepts added to broaden responsibilities for Collaboration • Functions and levels of collaboration – as above plus <ul style="list-style-type: none"> ○ good not 'best practice' for HTA ○ for development of HTA institutions, recommend alignment with international standards for HTA established through professional organisations such as ISPOR, HTAi, INAHTA ○ when providing contact point for Europe need to clarify national decision making roles and input of HTA amongst other factors ○ process indicators for pilots should be related to impacts on patients as well as process indicators
------------------------	--

INAHTA	<ul style="list-style-type: none"> • Initial statement - developing and improving common processes for doing and reporting HTA is an important area for collaboration, but non European INAHTA members have not seen the results from the EUnetHTA Project and this limits comments • Information sharing <ul style="list-style-type: none"> ○ providing an increasing volume and quality of relevant HTAs and reduced duplication is important ○ agreement to share draft versions of reports for limited, internal use would facilitate information sharing and reduce duplication • Process of collaboration <ul style="list-style-type: none"> ○ facilitating development of HTA Institutions is important, but the process should be more specific and indicate how extensive the input from EUnetHTA could be; INAHTA could contribute ○ EUnetHTA providing contact point in Europe seems reasonable ○ tackling barriers caused by language is helpful and harmonising HTA methods and concepts needs to continue with broad input from around the world ○ INAHTA and EUnetHTA should become collaborative partners. A detailed and specific collaborating plan should be presented to both networks
NHS QIS	<ul style="list-style-type: none"> • Stakeholders – could build more productive links with industry and healthcare providers rather than just involving them as stakeholders • Level of collaboration – support involvement to level 2 • Process of collaboration <ul style="list-style-type: none"> ○ Advantages of sustainable network <ul style="list-style-type: none"> ▪ sharing of information (particularly information not in a major European language) ▪ more commonality of healthcare systems in Europe than other parts of the world ▪ geographical distances allow more frequent face-to-face interaction ▪ small agencies would welcome access to tools and knowledge ○ Disadvantages <ul style="list-style-type: none"> ▪ INAHTA might be eroded and relationships with agencies in America and Oceania lost ▪ strong agencies may overly influence HTA development and impact healthcare decision making in Europe ▪ European structures may be bureaucratic, resource intensive and hinder progress ▪ HTA information system would duplicate functions of HTA database, HTAi vortal

AHTAPol	<ul style="list-style-type: none"> • Initial statement - fully support developing and improving common processes for performing and reporting HTA, particularly staff exchange schemes • Information sharing <ul style="list-style-type: none"> ○ desire to share more than primary evidence, would like to have access to recommendations and decisions made in other countries, recognising that national value judgements would still be needed ○ propose database called Reimbursement Information Sharing Clearinghouse (RISC) including core HTAs, full national HTAs, national recommendations – with justification, decisions with prices and limitations ○ RISC would help test credibility of proponents of technology who say it is widely used in Europe and help monitor implementation of HTA results • Governance <ul style="list-style-type: none"> ○ legal identity crucial, particularly in relation to function ‘provide a single reference point/body on matters concerning HTA’. Question is how to organise such formal institutional institution-creating collaboration in order to maintain sufficient national identity. ○ how should the efficient, financially sustainable organisational structure be achieved? ○ need more open discussions to discuss pros and cons of organisational options <p>Suggested textual changes to proposal document:</p> <ul style="list-style-type: none"> • on page 14, interventions should read diagnostic interventions • query re sentence about association between Board membership and Secretariat management
AssR	<ul style="list-style-type: none"> • Initial statement - strongly endorse continuation and development of EUnetHTA methods for producing and disseminating relevant high quality HTA information • Information sharing <ul style="list-style-type: none"> ○ formation and development of a net using common standards and procedures has highest priority ○ need more emphasis on common language • Governance <ul style="list-style-type: none"> ○ nucleus members should be completely publicly funded ○ Steering Committee members should only be selected from nucleus

<p>Directorate of Health, Iceland</p>	<ul style="list-style-type: none"> • Initial statement - proposal close to flawless and hope that EUnetHTA Collaboration will be established now, not in the future with means for permanency <p>Suggested changes to drafting of document:</p> <ul style="list-style-type: none"> • Chapter 1 could include consideration that products of EUnetHTA may become outdated if ongoing work is not secured, coordinated and led and emphasize that many Agencies value the continued external assistance and leadership • Chapter 5 <ul style="list-style-type: none"> ○ Values title is vague and could be replaced with 'responsibilities and dedication' ○ it is the only section to state the need to be 'responsive to the needs of decision makers' ○ explain that single reference point relates to methodological issues and other specific issues • Chapter 6 – too wordy with interplay of policy and decision
<p>Gesundheit Österreich</p>	<ul style="list-style-type: none"> • Initial statement - very interested in establishment of sustainable European HTA Collaboration and wish to be more involved in the future • Information sharing - include update of HTA glossary in function 6.2.1 • Stakeholders - Stakeholder Forum should include representatives of Social Insurance Institutions and Health Care Administration • Process of collaboration – add further development and standardisation of economic evaluation methods in function 6.2.3

NICE	<ul style="list-style-type: none"> • Initial statement - Looking forward with other partners to support the network's aims and objectives • Levels of collaboration – mandatory in figure 1 could be misinterpreted. • Process of collaboration <ul style="list-style-type: none"> ○ for WP7 (horizon scanning to identify and monitor emerging technologies) <ul style="list-style-type: none"> ▪ high priority to work with international partners to manage balance between timely access and evidence, based, cost-effective diffusion ▪ EUnetHTA should build on experience of EUROSCAN and other horizon scanning initiatives to identify new technologies ▪ work towards development of methods, processes and communication policies for 'coverage' decisions encouraging generation of new information whilst allowing controlled introduction of new technologies ▪ EUnetHTA could provide a platform for bringing together policy makers, researchers, professionals and public representatives from different countries (Italy, Netherlands, France, UK, USA, Canada) who are experimenting with innovative ways for the controlled introduction of new technologies to share experiences ▪ establish an electronic database of case studies from partner organisations ▪ encourage and coordinates launch national or international pilots of controlled introduction of new technologies and assesses success ▪ EUnetHTA has an important role to play in bridging research, policy and practice for new technologies where the evidence base is weak ○ differentiate activities that relate to methods vs those that relate to policy/strategy <p>Text change to document: alter 'mandatory' in figure 1.</p>
------	--

<p>CMTF</p>	<ul style="list-style-type: none"> • Initial statement - Fully endorses mission of supporting delivery of high quality, safe and efficient care through coordinated HTA • Process of collaboration <ul style="list-style-type: none"> ○ for WP7 (horizon scanning to identify and monitor emerging technologies) <ul style="list-style-type: none"> ▪ provides platform for additional efforts to ensure that these technologies undergo adequate and timely evaluation ▪ for those technologies likely to have great impact, work could be collaboratively pursued to define the comparative effectiveness and cost-effectiveness evidence to be developed to ensure that decision makers apply technology appropriately and efficiently ▪ this evidentiary framework would be most helpful for specific technologies ▪ could work towards development of methods, processes and communication policies for reimbursement decisions that would support development of evidence needed by decision makers, this could link in with a variety of initiatives in this field working on conditional reimbursement/coverage with evidence development ▪ EUnetHTA could provide a forum to develop common study protocols that could be conducted simultaneously or collaboratively – this could be a level 3 collaboration
-------------	--

Filnavn: Overview of public consultation final03042008
Bibliotek: F:\EMTV\Ansattes Mapper\JUCH\EUnetHTA
Project\WP1\EUnetHTAStructure\From November 2007 and on\Public Consultation
Skabelon: H:\Office2003\Normal.dot
Titel: 2nd Draft
Emne:
Forfatter: Karen Facey
Nøgleord:
Kommentarer:
Oprettelsesdato: 04-03-2008 09:14:00
Versionsnummer: 2
Senest gemt: 04-03-2008 09:14:00
Senest gemt af: SST.DK
Redigeringstid: 12 minutter
Senest udskrevet: 04-03-2008 09:57:00
Ved seneste fulde udskrift
Sider: 20
Ord: 5.600 (ca.)
Tegn: 34.161 (ca.)