Acronym: EUnetHTA JA 2

Title: European network for HTA Joint Action 2

Problem analysis including evidence base

Health Technology Assessment (HTA) aims at responding to decision-makers' information needs regarding the introduction, coverage, use or disinvestment of health technologies. Information needs often arise simultaneously across Member States (MS). A multiplicity of HTA agencies address such needs, leading to frequent duplication of efforts. For example, between 2005 and 2008 there were 7 HTA reports on Drug Eluting Stents and 6 reports on HPV vaccination published. HTA institutions vary across MS and though increased collaboration through e.g. EUnetHTA can be observed, more can be done to take full advantage of the added value of collaboration. This is due to lack of formal coordination and major differences in decision-making structures and requirements (time, quality of information, etc.) and in the level of implementation of HTA in MS. Previous European projects have demonstrated that collaboration and information sharing is facilitated with an organisational structure and common tools for HTA production. The EUnetHTA Joint Action (JA1) 2010-12 is currently refining the collaboration structure and tools with attention to global developments in the field. The Directive on cross-border healthcare (CBHC) to be transposed into MS legislation by October 2013 requires the establishment of a permanent network on HTA in Europe. Recently, health ministers and ministers of finance in the Council of the European Union have pointed out the need to strengthen activities aiming at ensuring financial sustainability of health systems while ensuring universal, equitable access to quality care. HTA is under the same financial pressure as the health systems and thus itself is required to use its resources efficiently. The need to enhance the use of HTA has also been pointed out by the European Commission and the HTA-scientific community. Participation in collaborative projects and JA1 has been shown to foster HTA in countries lacking an established HTA structure or capacity.

Target groups

The primary target group of the JA2 are the producers of HTA including those solely dedicated to drugs in the context of informing reimbursement and pricing decisions. The JA2 will foster capacity development and support their production processes. The activities of the JA2 arise from the premise that its pilot collaborative research and information sharing will be used to inform but not mandate the content of national / regional / institutional HTA and appraisal reports. MS and the Commission are prominent targets of this JA. The JA2 will provide input for the implementation of Article 15 of the Directive on CBHC. The recommendations regarding the design and running of a permanent European HTA cooperation and the demonstration of how collaboration works in practice are relevant to those who fund, commission or use HTA information, including MS without yet established HTA structure. Policy- and decision-makers of governments who will transpose the Directive into national legislation are a relevant target group since they will be in charge of ensuring the involvement of their own HTA institutions in the permanent voluntary network. Additional target groups are clinicians and patients, since the HTA information generated can also directly feed into decision-making at the individual level. Finally, manufacturers of health technologies are also a target group, since they are prominent in evidence generation and they are affected by decision-making in healthcare.

Methods and means

The JA2 will have two interrelated streams of activity. The "production" stream (WP4 and WP5) and the structure and methodological consolidation stream (WP2, WP6, WP7 and WP8). This JA2 builds upon the activities in the EUnetHTA Project 2006-08, EUnetHTA Collaboration 2009 and particularly on the evolving activities in the current JA1 (see www.eunethta.eu). More fundamentally, the work builds on the scientific background of relevant international research. A set of pilot assessments leading to national HTA reports will be performed in a collaborative manner based on the methodological developments and recommendations generated in the EUnetHTA Project and the JA1. To ensure collaboration, all partners have committed to actively contribute to one of the production WPs (except two partners from one MS). Collaboration models for the production of Core HTA (HTA covering 9 domains) or core information not covering all domains based on the HTA core model structure will be piloted in test assessments of currently relevant topics (i.e. topics for which information needs are identified by partners). Approaches are either the distribution of domains among participating partners (i.e. an agency would assess only one domain) or the assessment of each domain by researchers from several agencies. Similar models will be tested in the production of rapid assessments (WP5). The latter will also deal with assessment of evidence submitted by manufacturers. In the structure and methodological consolidation stream the information and knowledge management tools which were developed in the JA1 will be refined and finalized (WP6), methodologies, guidelines and models new developed and further refined (WP7, WP8), and specific training on their use will be provided for EUnetHTA partners and stakeholders. This stream facilitates the use of tools, methodologies, and information developed by the network in the pilot production of Core HTAs and core information for national HTA reporting. Besides, there will be maintenance, revision, and development of tools and methodologies and training according to needs. The experiences gained in the pilot production stream will feed directly into these activities, since this is required for developing the collaborative capacity of partners and enhancing their contribution to the collaborative assessments. Within the production WPs, data on the resources required and on the gains (i.e. faster production time, broader scope, and savings) will be collected in order to allow for a sound evaluation of the efficiency of collaboration. The governance structure and the approach to involve stakeholders that was developed in JA1 will be continued (see Annex 1c and d). Stakeholder views will continue to have an informative, non binding character and will be provided through the existing Stakeholder Forum and public consultations. Manufacturers will be specifically involved in the development of a submission template (WP5).

Expected Outcomes

The main outcome of the JA2 will be the implementation of the permanent network for HTA in Europe. This network shall be based on the principles of good governance including transparency, objectivity, independence of expertise and fairness of procedure. The production of specific HTA information (i.e. core HTA information and rapid assessments) will allow testing of the capacity for collaboration of national bodies and allow identifying appropriate models to make collaboration effective and worth its costs. The experiences and the information generated will feed into the process related to the implementation of the Directive on CBHC regarding cooperation in HTA.. The commitment by the MS by way of nomination of JA partners to build a permanent collaborative network of HTA agencies will be reinforced in the transposition and implementation of the Directive assuring long-term MS engagement in a permanent, voluntary European HTA Network supported by the Community. Exchange of information among agencies is further developed and unnecessary duplication of work in the field of HTA in Europe is reduced. The gains from and investments needed to participate in collaboration are known to HTA organisations across Europe. Based on this knowledge, agencies will introduce the HTA Core Model and the refined cooperation tools developed in this JA2 at appropriate stages in their work procedures and produce and share relevant parts of HTA information accordingly. Availability of Core HTAs and information allows agencies to redirect resources to methodologically sound assessment of

context-dependent aspects of the specific technology which will increase the responsiveness of HTA to the needs of decision-makers (i.e. ensuring timely provision of locally relevant information). A model for structuring industry submissions for rapid collaborative assessments in the context of reimbursement/coverage decisions according to the requirements of the transparency Directive will be developed building on the experiences and data generated from pilot production of rapid assessments. Both the capacity of conducting rapid assessments on drugs or devices (as it will be demonstrated in the JA2) and the availability of a common structure for reporting data by manufacturers can facilitate the establishment of an acceptable system for collaborative assessment of submissions. Collaborative assessments of information provided by manufacturers may be used with local context-specific information in rapid HTA reports for national decision-making (or appraisal) to reach rapid and robust context specific decisions on coverage / reimbursement. These outcomes contribute to the dissemination of health information and knowledge, thus improving policy-and decision-making in the health systems, which turns into protection of citizens against unsafe or ineffective technologies and improves access to high value health technologies. Ultimately this contributes to improved health of the populations

External and internal risk analysis and contingency planning

Risk (R): Change in key personnel in the Coordinator, WP-leaders (LPs) and/or Associated Partners (APs). Contingency (C): Most WPs have a LP and a co-LP which can substitute any time. More staff will work in Coordinating Secretariat. 3-year Work Plan and continuous monitoring of changes, constant communication through WP1 and updating of personnel. Standard Operating Procedures Manual produced by the Secretariat for rapid information of new staff.(R):Delay in reporting by APs. (C): Requirement of preliminary reporting at least 30 days prior to final reporting date. Separate Consortium Agreement signed by all the AP of the JA2 detailing responsibilities and repercussions of not performing according to the agreement.(R): Financial or management crises in one of the AP organisations. (C):Strong central coordination with assistance of WP LPs, good internal communication and distribution of tasks among partner organisations should contain the risk of WPs becoming diverted from focus or timetable. APs can substitute each other. Most APs are public bodies able to rapid crisis management and access to resources.(R): Consensus cannot be reached on vital issues. (C): A governance and Organisational structure was place since JA1. Intensive work by the Executive Committee and the Coordinator will be put into clarifying positions, regulatory and policy backgrounds for discrepancies and in consulting partners prior to developing common positions. Consensus that will allow the network to move forward towards its objectives should be pursued while accepting that conditions for national implementation may differ.(R): No sustainability of European network for HTA secured beyond the JA. (C):Close cooperation with the European Commission and relevant stakeholders for the application of Article 15 of CBHC Directive.

Horizontal Work package - Description of the work

Work package number 1

WP1 title: Coordination and sustainable network implementation. Coordinator (Coor) answering to the Plenary Assembly (PA) (consisting of APs,, main policy setting body) and being a member of the Executive Committee (EC) (Consisting of Lead Partners (LPs), 3 elected Aps, PA Chair (non-voting position) and DG SANCO representative (observer, no voting); main executive body, strategic leadership) will act as the JA2 operational contact for the EAHC and APs for technical, administrative,

financial matters & monitoring (operational leadership). WP LPs will be responsible for coordination of activities in the WPs and assist Coor with timely reporting and providing information on request. The JA1 SOP manual (with details on management/governance, procedures & forms) will be adjusted and a 3-year JA2 Work Plan will be developed and updated as needed. Reports to the EAHC will be prepared to ensure rigorous quality assurance of JA2. WP1 is responsible for organising 3 annual Plenary Assembly (PA) and 6 WP1 meetings in different MS. Representatives of DG SANCO, EAHC, DG RTD and other relevant EU-bodies (eg, EMA, CIE) and representatives of the JA2 Stakeholder Forum will be invited to the PA meeting and at the level of work packages where appropriate and at their own expense.. PA will decide the JA's working and management plan, provide opportunity for JA participants to meet and strengthen JA dynamics. JA2 EC will be responsible for potential conflict resolutions between the partners and stakeholder involvement activities. The Governance Guiding Principles and the Stakeholder Involvement Policy adopted for JA1 will continue to apply in JA2. The business model delivered during JA1 will be further developed for sustainable HTA network implementation in the light of Article 15 of the Directive on CBHC. The JA2 EC and Coordinator will lead the sustainable network implementation work including responsibility for stakeholder involvement to ensure coherence with the processes and achievements in and across the JA2 WPs. Continuous dialogue with DG SANCO (and other relevant EU institutions) will be ensured through regular communication (e-mail/phone/e-meeting). WP1 will use public consultation to solicit input into the development of recommendations for the implementation of the European HTA network from a wide audience of JA2 target groups. WP2 will facilitate communication of the interim and final results of the work.
The Governance Guiding Principles as well as the Stakeholder Involvement Policy and Standard Operating Procedures as applied during the EUnetHTA Joint Action (JA1) 2010-2012 will continue to apply during JA2 as agreed by the EUnetHTA JA2 partners (Complementary Annexes).

Work package number 2

WP2 Title: Dissemination and capacity building. Aim: Increase awareness and understanding of the usefulness of the EUnetHTA tools, methods and results among EUnetHTA partners and stakeholdersWP2 builds on the work done by WP2 and WP8 in JA1, including activities and content described in the 3 year work plan. Necessary updates of the informational material to be done for JA2 with focus on online communication. WP2 continues to facilitate communication; with Coordinator and other partners providing content and structure of both internal and external communication. WP2 extends its scope into capacity building, training and networking activities. Capacity building and training in EUnetHTA tools is connected to the processes and tools built in the EUnetHTA 2006-2008 project, collaboration (2009) and the JA1. The targets for training are EUnetHTA partners and stakeholders (specifically patients and healthcare professionals). The EUnetHTA JA1 WP8 survey on "HTA capacity building and training needs" identified learning needs and barriers to the use of EUnetHTA tools. The planned capacity building is based on the findings from this survey and emerging needs identified by the end of JA1. Capacity building on HTA methods and sharing of good practice for implementation of HTA results are new areas for training and support. "Training the trainers" is essential and future trainers will transfer knowledge and know-how to other HTA agency staff and Stakeholders at national level. Both in-person and e-learning training tools are employed. The roles of LP and Co-LP WP2 and Coordinator: LP and Co-LP work closely on all tasks. KCE (Co-LP) will take the main responsibility for the communication and networking and NOKC (LP) will take the main responsibility for the capacity building and training. Coordinator provides daily support including coordination of JA2 external and internal communication Collaboration with academic institutions WP2 will aim to involve academic institutions that are currently providing education and research in HTA.
Communication and networking

• Maintain and further develop the promotional and communication strategy for the results of EUnetHTA project and joint actions in collaboration with WP1.
• Facilitate and contribute to further development of the EUnetHTA Members Only web site and the external web site (including social media) in collaboration with WP1 and WP6.
• Establish a network for exchange of communication methods and best practices among EUnetHTA partners on how to enhance the impact of their products (i.e. HTA reports) to facilitate actual implementation by decision makers
• Facilitation of access to national HTA reports based on the HTA Core Model and Core HTAs on the EUnetHTA website.
• Organise one workshop for the network of communicators, with exploring and more frequent regular use of online solutions for meetings

Capacity building and training in EUnetHTA tools and methods (EUnetHTA members and stakeholders)

• Coordinate production of training material for the EUnetHTA tools and methods together with WP lead partners (handouts, webcasts, e-learning material, manuals).
• Organise training courses (face-to-face, webinars, e-learning) to EUnetHTA partners on the proper use and implementation of EUnetHTA tools and methods.
• Develop and pilot HTA capacity building and education activity for specific stakeholder groups (in cooperation with the Stakeholder Forum) to enhance stakeholder understanding of HTA, its implications, and how HTA can contribute in the resource allocation process within each member state.
WP2 LP will work closely with the Coordinator and the other LPs.

Work package number 3

WP3 title: Evaluation and data collection on costs and efficiency
WP3 will identify to what extent the individual WPs enable the JA2 to meet its objective. In addition WP3 will collect and analyze data on costs and resources used from other WPs – especially WP4 and WP5. This information shall be used to develop the recommendations for a sustainable EUnetHTA collaboration after the end of JA2. Evaluation activities will accompany all WPs using (adapted versions) of JA1 evaluation questionnaires and structured interviews of all partners. For WP4 and WP5 there will be collection of data on costs and resource use. The data on costs and resource use will as far as possible be drawn by the JA partners from their routine accounting information and analysed by WP3. Resources are allocated for this data collection. Other efficiency gains enabled by EUnetHTA across WPs will also be described. Information on the quality of the HTA core information will be derived from the quality assessment applied within each pilot in WP4, WP5, and WP7. The results will be summarized in the evaluation report. Outline of an evaluation plan According to the ISO 9000/2000 model adapted to the structure of EUnetHTA and its work in JA2 the JA2 WPs are distributed like this: Management (WP1) Production of core HTA information (WP4, WP5) Marketing / dissemination (WP2) Research & development (WP7, WP8) Infrastructure (WP6) Controlling (WP3) The evaluation plan will follow a strategy of 3 different evaluation levels and a quality assessment.WP3 will contribute to the Specific objective 1

Core Work Package - Description of the work

Work package number 4

WP4 title: Testing collaborative production of HTA information for national adaptation and reporting
WP4 develops systematic networking to jointly produce HTA information (eg, full core HTA) for national reporting while piloting the application of EUnetHTA tools. 1) Methods to identify potential partners (clusters of agencies/ researchers) for establishing a working collaboration to be defined on the basis of the results of the evaluation by JA1 WP3 and of the experience of JA1 WP4/B. An IT-supported method to be pursued in collaboration with WP5 and WP6 to make the selection process for clusters and topics systematic, easy and fast. 2) HTA Topics to be selected among the planned projects posted from partners in the POP database, 1) not identified by themselves for rapid assessment according to participants' own local needs, or 2) notified as important by partners, while taking into account European perspective. One topic may be suggested by DG SANCO. Close attention to be paid to defining topic selection and prioritisation procedure to capture common interest with the aim to facilitate assessments by the partners without overloading them.3) Clusters of agencies/researchers to be organised based on the preferences and specific expertise so that all partners can be involved. Lessons learned in JA1 will form the cornerstone of methods for JA2 activities. 4) Collaborative clusters will produce Core HTAs and Core HTA structured information (three Core HTAs are envisioned, with 20 national HTA reports developed based on the produced Core HTAs). The electronic online Tool&Service for producing, publishing, storing and retrieving HTA information (deliverable of JA1) to be applied and feedback and experience to be collected for improvement and update of the tools (in collaboration with WP8)5) A simultaneous pilot production of local/national reports using Core HTAs and core HTA information produced to be carried out to combine core information with locally produced information. Core HTA protocols to be defined by each cluster of agencies, according to quality assurance criteria. Quality assurance of core HTAs and HTA structured information to be carried out. Data on costs associated with the collaborative production to be collected according to a shared framework.
Taking into account the experience accrued during the JA1 a number of clusters of partners will be organised to produce core HTA structured information on topics prioritised by themselves using the electronic online Tool and Service for producing, publishing, storing and retrieving HTA information and core model applications available. Furthermore, the integration of core HTA information with locally produced information will be piloted for local reporting. By the end it is expected the improvement of core HTA structured information available for all the partners and the improvement of the HTAs production by Member States due to the workload distribution.

Work package number 5

WP5 title: Applying the HTA Core Model for Rapid Assessment for national adaptation and reporting
Fourteen pilot rapid assessments containing structured core HTA information based on the HTA Core Model to be produced jointly with several European Agencies. In addition to ten rapid relative effectiveness assessments (REA) for pharmaceuticals, four rapid assessments for other health technologies (eg, medical devices, interventions, diagnostics) will be produced. Additionally, thirty local/national reports based on the HTA information from the pilot assessments will be generated. WP5 will critically review the applicability of the work already accomplished by JA1 WP5 and WP7B in 2010-2012. The production of the pilot rapid assessments in JA2 will build on the experiences with the model for rapid REA of pharmaceuticals in WP5 of JA1and the hands-on experience with a number of assessments on pharmaceuticals and medical devices that were produced as a spin-off of the work on the POP database.WP5 will be organised in sub-groups of APs that have similar work-profiles and carry out rapid technology assessments regularly before reimbursement or incorporation of technologies in practice. The structure and workload/tasks/budget availability to each participating partner in the

subgroups will influence the level of involvement of each participating partner (active/less active); eg less-active APs can contribute in reviewing the rapid assessments produced by active APs. Quality assurance will be applied to all assessments. The basis for the selection of a pharmaceutical for a rapid REA is often a European market authorisation for a new chemical entity or a new indication of an existing pharmaceutical. Since not all pharmaceuticals can be assessed the LPs and APs need to define a prioritisation procedure which will also relate to their respective need for national production of rapid assessments. Based on the proportion of European market authorizations of pharmaceuticals for orphan diseases, WP5 will select 2-3 orphan pharmaceutical for a pilot assessment. The need of at least two APs (based on POP database) who plan to do national reporting on a specific health technology will be the starting point for the selection procedure of non-pharmaceutical technologies.

Work package number 6

WP6 title: Information Management Infrastructure and Services (IMIS)
In JA2, an efficient Information Management System will continue to be a central building block of the EUnetHTA network, just as it was in JA1. WP6 will build on, further develop and consolidate the work done by WP6 of the JA1. Some tools hosted by other JA1 WPs will be transferred to JA2 WP6 where possible. WP6 will closely collaborate with other developers of EUnetHTA tools to ensure interoperability. The objective is to set up comprehensive Information Management Infrastructure and Services. Hence, tasks of JA2 WP6 are divided into "Tools" and "Services" , according to the first draft of the forthcoming business model.
Tools: WP6 will provide an IT environment to support tasks and team work of JA2 partners: • New Website, Intranet and Work rooms will be implemented, based on JA1 WP6 recommendations (current CMS version is not "any browser" compliant and support will end with JA1).• The single authentication system , the Planned and Ongoing Projects database and the contact database developed during JA1 will be maintained and a new release will be provided • The document repository and mailing lists server provided by JA1, and a Web conferencing tool will be maintained • An e-learning platform will be explored with other WPs wishing to create and disseminate online courses (coordinated by WP2).
Services : WP6 will • Monitor content of, communicate about, and offer support and technical training for the tools maintained / developed by WP6.• Provide active brokering for collaboration on identical topics identified through the POP database.• Maintain interoperability standards between EUnetHTA tools, including those hosted by other WPs; and promote interoperability with HTA tools outside EUnetHTA where possible • Provide a helpdesk for users of the Intranet and of other team work supporting tools. • Provide aggregated newsletter to partners and associates based on single institution newsletters • Surveys: EUnetHTA partners will be surveyed on needs at the beginning of the joint action, and satisfaction at the end (with WP3)

Work package number 7

WP7 title: Methodology development and evidence generation: Guidelines and pilots production
JA 2 WP 7 is developed on the basis of actions of JA1 WP7 and WP5 with a view to support and complement JA1. • The JA1 WP7 EVIDENT (formerly "Eiffel") database containing information on evidence generation on new technologies to be actively used to foster cross-border collaboration on shareable data collection for required additional studies. EVIDENT will be maintained and further developed according to needs. In the field of pharmaceuticals collaboration with the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) will be explored. • Tools

(guidelines and templates) will be developed on the basis of the HTA Core Model to facilitate and help standardising technology developers' data files for submissions of dossiers for rapid HTAs (standardising the presentation of data, completeness of submitted data). • New developments to improve the robustness and efficiency of HTA comprise actions and measures to support and guide the generation of higher quality and more appropriate evidence for initial assessment "upstream" in the technology "pipeline" where innovations undergo research and development before introduction to healthcare practice. Mapping the future needs of HTA producers, getting an overview of those actions, as well as piloting early dialog and disease specific guidelines will be done. • According to stringent clarification and common agreement on general needs WP7 will update/complement methodological guidelines for the assessment of pharmaceuticals produced by JA1 WP5 and develop new guidelines for distinct methodological issues in the assessment of health technologies in general. • Quality assurance will be applied across activities. The main operational tasks are

- Pilot implementation of data collection for additional evidence generation by using EVIDENT database and core datasets (including common core study protocol for a technology of interest)

- Develop general methodological guidelines for HTA and templates for submissions of data by technology developers for rapid HTAs (in cooperation with WP5)
- Develop pilot actions to facilitate the production of appropriate data for new technologies, in the view of making available adequate data for the application of the HTA Core Model at the time of initial assessment of technologies (early dialogue, disease-specific guidelines for technology developers)
- Develop new guidelines for distinct methodological issues where such documents are necessary to support the production of core HTA Information by JA2 WPs 4 and 5

Roles :
- LP: general coordination, update of JA1 WP5 guidelines if necessary and directly responsible for the development of disease specific guidelines, guidelines to improve evidence generation and early dialogue
- CoLP: support LP, coordination and development of general guidelines for distinct methodological issues in the assessment of health technologies in general
- NICE: development of template for manufacturer's file
- Active APs: development of or active participation in guidelines production
- Less active APs: review of production and participation in surveys

Work package number 8

WP8 title: Maintenance of HTA Core Model infrastructure to support shared production and sharing of HTA information
HTA CORE MODEL ONLINE:• Maintenance of Online Tool & Service (including database of core HTA information) produced within JA1, to support information production in JA2 WPs 4 and 5 • Further development of Online Tool & Service, with particular emphasis on facilitating the piloting of a) production of structured HTA information, core HTAs and rapid HTAs, and b) use of already existing information in the Core HTA database to support production of local reports, including adaptation of findings from structured HTA information, core HTAs and rapid HTAs as developed in JA1 WP4. CORE HTA DATABASE: • Maintenance of the database of structured HTA information and core HTAs developed within JA1 to support storage, publishing and further utilization of information produced within JA2WP4 and 5. Updating already existing applications: • Updating the HTA Core Model applications developed during EUnetHTA project 2006-2008 and JA1 with particular emphasis on harmonising the methodological guidance across models and bringing it up-to-date. Current applications supporting full core HTAs cover the following themes: medical and surgical interventions, diagnostic technologies and screening technologies.• Support to the updating of the REA model for

pharmaceuticals (in close collaboration with WP5) developed by WP5 of JA1 into a model that supports production of full core HTAs of pharmaceuticals, i.e. adding the domain on economics and updating (wherever needed) the contents of other domains. SUPPORT FOR TRAINING AND IMPLEMENTATION: • Persons involved in the development of various parts of the Core HTA Structure will participate in training sessions and workshops organised by WP2. This includes personnel of LP and 3 other active APs who are invited to participate in a "training task force" to support training of trainers. This can include actual training in workshops etc, or producing training materials and guides. In addition WP8 will organise training specifically for the online tool.