EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
e-Health and Health Technology Assessment

Brussels, 15 April, 2015

HTA NETWORK REFLECTION PAPER ON "REUSE OF JOINT WORK IN NATIONAL HTA ACTIVITIES"

ADOPTED BY THE HTA NETWORK, APRIL 2015

HTA NETWORK REFLECTION PAPER ON REUSE OF JOINT WORK IN NATIONAL ACTIVITIES

1. BACKGROUND – WHY "REUSE"?

From the HTA Network Multiannual work programme:

"Adoption of a reflection paper on the conditions to facilitate take up and reuse at national level of joint HTA production including information and joint assessments Timing: 1st half 2015"

To enable the move from piloting to long term sustainability of "Joint Work"[1] and more broadly the cooperation at EU level on HTA, it is essential to ensure the usefulness of the cooperative work.

The usefulness of the cooperation is also reflected by the extent to which Joint Work, i.e. the "products" of the cooperation are valued and used by national and regional HTA bodies as well as by other stakeholders, for example patients, healthcare providers, payers (statutory health insurance) and industry. Only if national/regional HTA bodies and stakeholders can benefit from joint work in their national activities will they continue to invest resources in the cooperation after EU funding from the Health Programme ends. If the reuse is not happening to the desired extent, there is the risk that the EU cooperation remains an interesting exercise but with limited value for national/regional HTA activities. Thus it will not be meeting the final objectives set out in Directive 2011/24 including, supporting Member States in providing "*objective, reliable, timely, transparent comparable and transferable information on the relative effectiveness[…]*[2]*" and avoiding duplication of assessments"* (Art 15.2).

The HTA Network, aware of the importance of this issue, in the process of drafting its strategy, listed a number of "facilitating factors" which could enable reuse of Joint Work in national/regional activities (see section 2.2 "Synergies and complementarity of European activities with national activities").

This paper should be seen as an instrument to support the implementation of the HTA Strategy, specifically section 2.2. It also aims at contributing to the design and content definition of the forthcoming Joint Action on HTA, which will have a key role in facilitating a smooth and efficient transition from a "project approach" to a permanent model of cooperation between HTA bodies.

Building on these "facilitating factors" identified by the HTA Network Strategy and on the experience gained within EUnetHTA Joint Actions, the SEED project and other cooperation efforts in the area of HTA, this paper **aims to**:

- Provide concrete recommendations on how Joint Work shall develop to make it easier for national and regional HTA bodies to reuse it in national activities. The commitment to reuse Joint Work shall not be understood as legally binding and shall respect the different levels of voluntary engagement in the scientific and technical cooperation on HTA. However, once engaged in specific activities the parties involved, which have made a voluntary commitment, have the obligation to deliver the task assigned to them.

[1] "Joint work" see Annex – Definition agreed by the HTA Network *"Strategy for EU cooperation on HTA – Glossary"*

- Provide recommendations on how national/ regional HTA bodies could address some of the facilitating factors which could enable reuse of Joint Work in national activities and

- Provide recommendations on how to facilitate the reuse of national/regional work produced in another country/region.

A general consideration should be made in relation to the Medical Device sector. The HTA Network has clearly indicated the need to keep a broad scope of cooperation on HTA, including Medical devices and other technologies. Collaborative efforts, within EUnetHTA and in other EU co-funded projects[3] will shortly provide indications on specific methodological challenges. However, as the European Legislation is currently under revision, it is difficult at this stage to identify concrete mechanisms of cooperation for specific activities with the regulators of the sector. Specific examples are early dialogues with manufacturers or the development of submission templates or other tools. Therefore, the issue may need to be reassessed once the new legislation is in place.

It should be noted that while the recommendations aim at facilitating reuse of Joint Work in national/regional HTA activities, these recommendations shall not interfere with *Member States's competence in deciding on the implementation of Health Technology Assessments conclusions and shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibility of Member States for the organisation and delivery of health services and medical care* (Art 15.7 of Directive 2011/24).

To facilitate the reading and understanding of the paper, it is useful to recall a few definitions set out in the HTA Network Strategy paper (Annex 3, Glossary), and in the Annex-Definitions.

[3] http://www.advance-hta.eu/; http://www.medtechta.eu

2. "JOINT WORK" (JW) - WHAT TO REUSE –

This chapter aims to provide some recommendations on how and what Joint Work shall develop to facilitate national and regional HTA bodies reuse of it in national/regional HTA activities. The main targets of these recommendations are the national/regional authorities responsible for HTA and HTA bodies. It aims to support their collaborative efforts to develop Joint Work, for example when participating in current and possibly future Joint Action on HTA and/or in other collaborative efforts at European and/or international level.

2.1. GENERAL RECOMMENDATIONS

For the purpose of this exercise the following activities are considered Joint Work:

(1) Joint Assessments Reports

(a) Rapid Relative Effectiveness Assessments

(b) Full/Comprehensive HTA

(2) Tools

(a) The HTA Core Model (important for Joint Assessments Reports and national/regional assessment reports)

(b) Submission templates (important for Joint Assessments Reports and national/regional assessment reports)

(c) Methodological standards for HTA

(d) Training material

(e) ICT tools (including Databases, web based solutions etc.)

(3) Support of (initial and additional) Evidence Generation initiatives appropriate for HTA purposes

(a) Early Dialogues

(b) Coordination of additional evidence generation

It should be noted that the development of Joint Work is an ongoing activity with different levels of maturity for different products. For example, initiatives on the coordination of additional Evidence Generation, while well acknowledged in the HTA Network strategy as important to implement the “life cycle approach” to technologies, are activities which are not yet well established in all countries nor the subject of intensive cooperation efforts. Therefore, the impact of the relevant recommendations may be seen in a longer term perspective when compared to other types of Joint Work.

In addition, for these specific activities, referring to “reuse" of Joint Work may not be fully appropriate, as some of them are not always applicable or compatible with current national legal frameworks or practices. For example not all HTA bodies perform initiatives to facilitate evidence generation like early dialogues or additional evidence generation.

Therefore in this context the concept of "re-usability" in national HTA activities shall be understood as "usefulness" for National HTA activities.

It should be noted that the recommendations below are largely applicable to all products of the cooperation; therefore they will not be repeated as specific recommendations under each section.

The HTA Network recommends that the cooperation on HTA and more specifically a possible third Joint Action on HTA should:

- Keep the focus on improving Joint Work and facilitate its reuse in national/regional activities. Therefore, it should devote sufficient resources to facilitate the transfer and uptake of Joint Work in national activities, including its adaptations to local needs.

- Devote sufficient resources to implement a professional project management process, including quality assurance and a mechanism for monitoring the progress of Joint Work and implement corrective measures as needed, to adjust the process to the needs of the cooperation.

- Implement a mechanism, including where possible, Standard Operating Procedures for a transparent topic selection and prioritization process, to ensure that the process meets the strategic priorities defined by the HTA Network and at the same time the needs of national/regional HTA bodies. Early information sharing of work plans (including use of relevant ICT tools), as well as reports on the reuse of Joint Work and/or of HTA work from other national/regional bodies, shall be given specific attention.

- Implement a process that facilitates clustering expertise to ensure high quality products and facilitates capacity building. For example, specific bodies leading the activities in specific type of technologies/conditions; ensuring that any process aiming at Joint Work involves any necessary additional expertise from independent experts, and appropriate stakeholders involvement.

- Implement an evaluation process to measure the benefits at national/regional level of Joint Work, for example by measuring the added value of European cooperation through increases in efficiency, quality, timelines and capacity building.

Any measurements of benefit shall not be contradictory to Art 15(7) of Directive 2011/24 and the statement of the HTA Network Strategy paper which points out to fully respect MS' responsibilities to organise and deliver health services and medical care.

2.2. SPECIFIC RECOMMENDATIONS ON JOINT WORK [4]

2.2.1 JOINT ASSESSMENT REPORTS

Timely adaptation and production of national/regional HTA Reports, based on joint assessment reports (Rapid REA and Full/Comprehensive HTA) can only be ensured if these reports are fit for purpose, of high quality, of timely availability, and covering the whole range of health technologies (beyond pharmaceuticals and medical devices). Therefore Joint Assessment Reports should be based on scientific, transparent, timely and efficient predefined project management processes, with appropriate stakeholders' involvement. Common understanding and possibly agreement on key methodological approaches is needed, to be inclusive enough to meet demands of individual countries as well.

[4] For each "type" of Joint Work

It should be noted that Joint Reports aim at facilitating work at national level but are not legally binding for national authorities.

To achieve these results, the HTA Network recommends:

- To strengthen cooperation on horizon scanning activities by exploring cooperation with existing initiatives at national or international level[5].

- To enable timely exchange of information between regulatory and HTA bodies both in the pre-marketing phase and post-marketing phase to facilitate timely production of Joint Work and avoid duplication of activities, as appropriate.

- To implement a well-defined workflow facilitated by professional project management which could enable, among others, early agreement on the scope and the participating HTA bodies; systematic and early identification of expertise (both on methods and clinical issues); transparency and effective quality assurance.

- To facilitate clustering expertise of national/regional HTA bodies according to the technology/disease indications (i.e. specific technologies assessed regularly by a set of bodies with expertise in the field).

- For Full/Comprehensive HTA, make a critical assessment on the amount of "transferable" (thus re-usable) information for non-clinical domains and adjust the process for Joint Work accordingly; implement the existing flexibility in the HTA Core Model Format.

- To facilitate appropriate stakeholders involvement in the production of Joint Reports.

- To gather support from technology developers in all stages of the assessment process.

- To recognise that a high degree of commitment and willingness to cooperate is needed, as well as investment in institutional connections, for building trust between participating HTA bodies.

- To acknowledge that systematically sharing the work plans of national/regional HTA institutions is essential to ensure that the subject of the joint activity meets the needs of the largest number of HTA Bodies, thus facilitates reuse.

- To conduct systematic search in the POP[6] database as a routine task, which is possibly included in national Standard Operating Procedures, in order to capitalise on the work done by others, to engage in Joint Work and to share work and results.

[5] For example INAHTA and the International Network Euroscan (http://euroscan.org.uk)

[6] See Annex-Definition

2.2.2 TOOLS TO FACILITATE INFORMATION SHARING AND JOINT WORK

To facilitate Joint Work and the reuse at national level of HTA work produced by other HTA bodies, it is essential that bodies and stakeholders involved in the HTA process can rely on "common" tools which respond as much as possible to the different information needs of HTA bodies and stakeholders. The common tools identified by the European cooperation, so far include: i) HTA Core Model, ii) Submission templates (important for Joint Assessment Reports and national/regional reports[7]), iii) Methodological standards for HTA, iv) Training material and v) ICT tools (including Databases, web based solutions etc.).

The HTA Core Model is a methodological framework for shared production and sharing of HTA information. Its applications will support European collaboration and more specifically Joint Work, as it provides a common reporting structure that enables standardised reporting of HTAs. As a broad methodological framework it should meet the needs of the HTA bodies working on the joint assessment and also the HTA bodies who want to use the model in their local (national/regional) work.

Submission templates cover evidence requirements for technology producers (manufacturers, companies, marketing authorisation holders or their representatives) across Europe. They are to be used to support submission files for national and joint assessments reports. These templates may include the evidence requirements of national/regional HTA bodies while simultaneously reflecting the HTA Core Model framework. Any Joint Work producing HTA information would be facilitated by a submission template that contains the most important evidence requirements of all countries that decide to participate. It should be recognised that evidence requirements will not be harmonised across all HTA bodies and therefore the submission template should be applicable to the greater number of countries. This will ensure the necessary freedom at national/regional levels to choose sections and questions that are relevant for their existing processes and to support requests for additional data to meet specific local requirements. Joint submission templates may also support efficiencies for technology producers.

Methodological standards for HTA should be continuously updated and adapted. However, developing new methodological standards, if needed, should be focused on facilitating re-usable Joint Work. It should be noted that cooperation with other international collaborative initiatives developing methodological guidance, should be foreseen to avoid duplication of efforts.

Training material shall be understood as activities and tools developed to train national/regional HTA bodies members to facilitate both the production of Joint Work and its reuse**.**

ICT Tools include the existing POP and EVIDENT Database, as well as the HTA Core Model online tool. Additional ICT tools may be necessary to facilitate Joint Work and its reuse, for example to enable the secure exchange of confidential information.

[7] In HTA submission templates can also be used, for example when asking input to patients' group, however these type of submission templates have not yet been the subject of EU cooperation.

To support the further development of the tools mentioned above the HTA Network recommends:

- To make the HTA Core Model more user-friendly to facilitate its uptake in current practices.

- To increase awareness and use of the HTA Core Model in Joint Work and local (national/regional) work, within HTA bodies.

- To increase awareness and use of submission templates developed in the framework of EU cooperation, within HTA bodies and within industry.

- To align the development of methodological standards by the EU cooperation to the specific needs of Joint Work, and explore synergies with relevant bodies and organisations developing methodological guidance.

- To establish close links and synergies with international organisations with the expertise and resources to develop general HTA training tools, including educational webinars, videos, handbooks, guidelines etc.

- To continue to focus on the development of training tools matching the activities and the needs of the EU cooperation, most specifically for Joint Work, and its reuse.

- To consider facilitating exchange programmes between HTA Bodies, active in the cooperation, to enable "on the job training".

- To optimise the usability of databases currently developed by the EUnetHTA cooperation (for example POP Database, EVIDENT Database, Core model online tool), notably by avoiding administrative hurdles to manually enter information and increase their user friendliness. For example, implement automatic links with other existing databases[8] and/or associate a centralised literature search facility.

- To increase accessibility, dissemination and communication on such databases and other tools with national and regional HTA bodies and other stakeholders, as appropriate. For example, to consider the development of a web portal as a single entry point to all key tools which could facilitate cooperation on HTA, including access to national/regional HTA databases and online tools.

- Explore ways to ensure sustainability and continue maintenance of ICT tools.

2.2.3 SUPPORT OF INITIATIVES TO PROMOTE EVIDENCE GENERATION (INITIAL AND ADDITIONAL) APPROPRIATE FOR HTA PURPOSES

These activities aims at reflecting the "life cycle" approach which is described in the HTA Strategy, namely that HTA cooperation can play an important role by strengthening activities from the horizon scanning process and the early development phase to the well-established use of technologies. This includes, for example, the generation of evidence appropriate for HTA purpose, over the pre and post launch period of new technologies. To enable such an approach and make it beneficial, closer interaction between HTA bodies, regulators, payers and providers of technologies will be essential.

[8] University of Southampton Database; INAHTA, national HTA databases etc.

Cooperation is clearly needed to prepare HTA bodies to agree on possible joint requirements for post-launch data collection. As an example, for pharmaceuticals, closer cooperation with regulators for Post Authorisation Efficacy Studies (PAES) would be desirable. In addition, new initiatives lead by the European Commission like the Safe and Timely Access to Medicinal Products Expert Group (STAMP) and the EMA pilot on adaptive pathways also call for closer cooperation with HTA bodies.

Early Dialogues, EDs (or early scientific advice) aim at providing prospective, transparent and timely advice by regulators and/or HTA body/bodies (multi-HTA scientific advice) or both (parallel scientific advice) to technology developers so that they may integrate the specific needs of both Regulators and HTAs in the product development.

For multi-HTA scientific advice aiming to improve initial evidence generation for health technologies two approaches can be combined:

1) Product specific approach: ED between HTA bodies and companies on the development of new drugs or medical devices[9].

2) Disease specific approach: development of guidelines for the technology developers. Disease-specific guidelines aim to give non-binding recommendations to technology developers about the type of data to be produced during the development of technologies (initial evidence generation) to support the relative effectiveness and cost-effectiveness assessments in a given condition. Besides comprehensive disease-specific guidelines, advice on some methodological issues regarding the development of a new technology should be considered (e.g. the use of a new endpoint, the use of a new or controversial statistical or methodological approach…) that may lead to the publication of advice from HTA bodies.

It should be noted that the aim of this activity is to improve the quality and appropriateness of the data produced during technology development. Its results cannot be expected before the end of the product development so no immediate reuse at a national/regional level is expected. In addition, a disease specific approach shall be considered as a longer term activity because cooperation in this area is currently at an initial phase. Intermediary products such as advice on new methodological approaches could be a more immediate topic for cooperation.

Additional evidence generation describes the additional studies or any kind of additional data collection requested or recommended by HTA bodies following HTA on the health technologies.

While recognising that some of these activities may have a longer term approach, the HTA Network recommends to:

- Maintain and clarify different options to perform ED. For example i) ED between national HTA bodies and technology developers, ii) ED between HTA bodies and Technology developers at European level (currently performed by EUnetHTA and the SEED-consortium), iii) ED between HTA bodies, technology developers and regulators at European level (for pharmaceuticals, currently performed by EMA as "parallel scientific advice" and for both pharmaceuticals and other medical technologies by the SEED Consortium as "parallel early dialogues"). Maintaining and possibly clarifying the different options for

[9] It has to be reminded that early dialogues are non-binding and confidential.

performing these activities seems to be the most effective way to meet the needs and the capacities of both HTA bodies and technology developers.

- Strengthen interactions with regulators and define one single framework/process to perform ED involving both HTA bodies and regulators at European level, building on existing experiences. Specific attention shall be given to ED for Medical Devices, considering the different regulatory framework and market access pathways compared to pharmaceuticals.

- Implement a process for ED that facilitates clustering expertise to ensure high quality products and facilitate capacity building. Involve any necessary additional expertise from independent experts, and appropriate stakeholders involvement.

- Consider a possible mechanism that could enable feeding the results of the ED into the future development of disease specific guidelines, provided that such guidelines are used by relevant stakeholders.

- Establishing closer cooperation between HTA bodies in coordination of cross-border data collection and evaluation, including implementing specific pilots, taking into accounts Member States' legal frameworks.

- Establishing closer interaction with initiatives that evaluates the use of patients' registries, develop methods for analysis of registry data possibly in cooperation with the registry holders or other relevant stakeholders, to create synergies and avoid duplications.

- Exploring coordinated approaches and possibly further cooperation with pharmaceutical regulators on post-authorisation data collection, such as possible parallel advice. Explore the possibility of developing or testing methodologies for post-authorisation data collection on pharmaceuticals (PAES) that are relevant to support regulatory and HTA activities (phase IV studies and observational data collection). While acknowledging the difference in regulatory frameworks and market access pathways, similar approaches shall be considered for medical devices, to facilitate closer monitoring of the safety and the effectiveness of the technologies.

- Explore possible funding and organisational models to make these activities self-sustainable, including the possibility of collecting fees. Attention should be paid to the specific needs and concerns of some national/regional realities and to SMEs.

- The HTA network will further examine these proposals in light of the upcoming proposal from the SEED consortium on a permanent model for the conduct of early dialogues for medicines and medical devices as well as the experience from the Pilot EMA-HTA Scientific Advice.

3. "JOINT WORK" (JW) - HOW TO REUSE

This chapter aims at providing some recommendations on how national/ regional HTA bodies could address some of the factors which may facilitate the reuse of Joint Work and the reuse of national/regional work performed by other bodies. The main targets of these recommendations are national/regional authorities responsible for HTA and HTA bodies in their activities of organising and performing national HTA work.

These recommendations shall respect national responsibilities of Member States and their HTA bodies to define their national/regional legal framework and working practices for implementing HTA, and thus exclude aspects related to pricing and reimbursement issues.

3.1. GENERAL RECOMMENDATIONS

From existing experience, it was noted that Joint Work could be more often and better used in national/regional activities, if certain factors are addressed. Such factors can be grouped into three broad categories: **1) Legal** (i.e. evidence requirements written in legal ordinance rather than submission templates); **2) Organisational** (i.e. process, time, resources) and **3) Scientific** (i.e. methodological challenges).

To facilitate reuse of Joint Work the HTA Network recommends to:

- Consider reviewing explicit legal requirements that may prevent the use of Joint Work in national/regional activities, as appropriate.

- Increase transparency on national HTAs process and reports.

- Introduce flexibility and explore opportunities to use English has the working language, to share output of the national/regional HTA production process, for example by making available summaries of national Reports in English.

- Increase awareness of Joint Work and facilitate changes in the routine working process, including adapting national/regional SOPs, to facilitate the reuse of Joint Work and/or make national/regional scientific and technical outputs more useable by other HTA bodies; for example by using common tools (e.g. POP/Evident databases, HTA Core Model framework, common templates etc.), and/or by improving accessibility to Joint Work within National HTA bodies.

- Promote the collection and dissemination of information on the added value of Joint Work to the decision/policy makers both at national/regional levels.

- Allocate sufficient resources to support collaborative project management of Joint Work, and integrate these collaborative efforts in national resource planning.

- Promote communication and information transfer between assessors involved in EU cooperation efforts and those responsible for national production.

3.2. SPECIFIC RECOMMENDATIONS ON JOINT WORK [10]

3.2.1 JOINT ASSESSMENT REPORTS

In developing and testing joint products and in particular Joint Assessment Reports, as well as in the efforts to facilitate reuse of HTA work produced by other bodies, a number of barriers have been identified. These barriers include: format and content of submission templates and/or of HTA Reports defined in national legislations, thus preventing updates to reflect, among other, developments within Joint Work; different information requirements about the procedure for medical devices; limited transparency on submitted data and lack of publication of national reports; the working language defined in legislation; limited awareness of Joint Work or national/regional work done by other agencies in national activities; lack of clarity on the multiple actors involvement in the assessment process; non-alignment of timing of Joint Work in comparisons with national priorities; limited information sharing at an early phase of assessment; differences in formatting between national assessment reports and an assessment report produced with the Core Model/Guidelines; differences in methodological standards.

To overcome the barriers mentioned above the HTA Network recommends to:

- Prefer flexible mechanisms to define submission templates and/or national/regional HTA Report's templates so that changes can be easier, including possible use of "common-core template/format".

- Further increase scientific cooperation on methodological issues between HTA bodies, for example on the choice of the end points, comparators, indirect comparisons etc.

- Further increase scientific and methodological cooperation beyond HTA bodies for example to payers, regulators and stakeholders.

3.2.2 TOOLS TO FACILITATE INFORMATION SHARING AND JOINT WORK

Regarding increasing the use and further development of common tools for HTA purposes, some possible barriers have been identified. These include: difficulty in balancing specificity of methodological standards (that make them more usable) with their acceptability by different countries (agreement more easily reached if guidance remains general); limited expertise within national/regional bodies to use some parts of the common guidelines; differences in language, limited funding devoted to cooperation efforts, limited (if any) awareness/accessibility to common tools for national assessors; different practices/teaching models for training material; different levels of confidentiality for data in different countries.

To overcome the barriers mentioned above the HTA Network recommends:

- To foster convergence on what to share, with whom, and for which purpose when performing HTA activities.

- To allocate sufficient resources to feed into and populate common databases with national activities, for example by contributing to POP and EVIDENT.

[10] For each "type" of Joint work

- To promote the training of assessors within national/regional HTA bodies on common tools which could facilitate Joint Work.

3.2.3 EVIDENCE GENERATION (INITIAL AND ADDITIONAL) INITIATIVES APPROPRIATE FOR HTA PURPOSES

Some potential barriers to strengthening cooperation in the evidence generation (initial and additional) process, appropriate for HTA purposes, include: non-existence of legal basis (in some countries) or diversity of legal basis (when existing); diversity of requirements; lacking of model to ensure financial and organisational sustainability; uncertainty on new regulatory framework for medical devices; diversity of players allowed/involved in conducting additional evidence generation; differences in privacy regulations; lack of cross border capacity for data collection; limited (or no) funding; limited capacities of data collection and sharing; unclarity on the various stakeholders within a country involved in the HTA process; different positions on the opportunity to use observational data for assessments of effectiveness and relative effectiveness and safety; choice of different timing (in lifecycle of technology) for data collection; differences in comparators and standard of care; different types of management entry agreements and therefore different possible outcomes.

It is well noted that some of the barriers listed above, are directly linked with the national responsibilities on the organisation and delivery of healthcare, for example the diversity of management entry agreements and the different players involved in the decision making process. These are listed as they have an impact on the development of the Joint Work however it is not the objective of these recommendations to propose to remove such provisions, rather to see how the cooperation in evidence generation can be developed taking these factors into account.

To overcome the barriers mentioned above the HTA Network recommends:

- To strengthen cross-border cooperation on evidence data collection (initial and additional), in line with national legislation and working practices.

- Increase coordination between different stakeholders involved in the activity to better defines roles and responsibilities.

- Following the adoption of the new regulatory framework on medical devices, explore effective ways to increase cooperation between different stakeholders.

ANNEX – DEFINITIONS

(Mainly from ANNEX 3 HTA Network Strategy)

Additional evidence generation: Additional studies or any kind of additional data collection requested or recommended further by HTA bodies following HTA on any health technologies.

Disease-specific guidelines: Aim to give non-binding recommendations for the technology developers about the type of data to be produced during the development of technologies (initial evidence generation) to support relative effectiveness and cost-effectiveness assessment in a given condition.

Early Dialogue (or early scientific advice): Aims to provide prospective, transparent and timely advice by regulators or HTA body/bodies (multi-HTA) or both (parallel) to product sponsors so that they may integrate their specific needs in the product development and generate evidence appropriate for HTA purposes.

Evidence generation: Initial evidence generation (early dialogues and disease specific guidelines) and **additional evidence generation process** (additional studies or any kind of additional data collection requested or recommended further by HTA bodies following HTA on any health technologies).

EVIDENT Database: The Evidence database on new technologies (EVIDENT Database) (http://www.eunethta.eu/evident-database) allows sharing and storage of information on the reimbursement/coverage and assessment status of promising technologies and on additional studies requested or recommended further to a HTA.

Health technology: Any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes the pharmaceuticals, devices, procedures and organizational systems used in health care.

HTA Core Model Domains: The HTA Core Model® consists of nine domains indicating the different areas of assessments such as safety and effectiveness and also including organizational aspects, social and ethical aspects.

HTA Report: An HTA report is an independent, objective, and transparent collection of HTA information to inform policy. Depending on the specific context, it may address all aspects (domains) within the HTA process.

Initial evidence generation: Improving initial evidence generation for health technologies combining two approaches: 1) Product specific - ED between HTA bodies and companies on the development of new drugs or medical devices and 2) Disease specific: development of disease specific guideline for the technology developers.

Joint Work: Activities in which countries and/or organisations work together in order to prepare shared products or agreed outcomes. These may include, for example, literature reviews, structured information for rapid or full HTAs, early dialogues or scientific advice on R&D planning and study design. Joint Work aims at supporting Member States in providing objective, reliable, timely, transparent, comparable and transferable information and enables an effective exchange of this information.

Parallel early dialogue/scientific advice: At the same time point/location, but not necessarily together, scientific advice of regulators and HTA organisations on the prerequisites for phase III trials that are going to be initiated by the manufacturer for market registration and reimbursement.

PAES (Post-authorization efficacy studies): According to the new European pharmacovigilance legislation, post-authorisation efficacy studies (PAES) may be imposed by regulatory authorities to pharmaceutical companies at the time of authorisation of a new product, where concerns related to some aspects of the efficacy of the medicinal product can be resolved only after marketing and at any time after product approval where there are indications that previous efficacy evaluations might have to be revised significantly. PAES may be aimed at collecting data to enable the assessment of efficacy of medicinal products in everyday medical practice.

POP Database: The EUnetHTA Planned and Ongoing Projects (POP) database (*http://www.eunethta.eu/pop-database*) allows HTA bodies to share information with each other on planned and on-going projects conducted at the individual agency. The aim of the database is to reduce duplication and facilitate collaboration among HTA bodies.

Submission templates: Templates that cover evidence requirements from industry (manufacturers, companies, marketing authorisation holders or their representatives) across Europe to be used to support national HTA process in European countries and joint assessments reports; those for joint assessment reports includes the evidence requirements from European organisations responsible for reimbursement, while reflecting the HTA Core Model framework.

Topic selection and prioritization process: Process used by HTA doers for applying the selection criteria to filter topic suggestion as well on the scoring, ranking and prioritization of topics for Joint Work, which should be defined by SOP.

END