EUnetHTA

ASSEMBLY & FORUM

2020

FOREWORD

I would like to welcome everyone to this year's event.

Due to the precautionary measures we have taken to lessen the impact of COVID-19, this year's Assembly is a virtual experience. While I miss the chance to meet you all in person, we are lucky that we can all adapt to this format to participate effectively and make this year an online success.

Last year I concluded that the European cooperation on HTA had seen a lot of development since the previous Assembly and Forum. That is definitely true also for this past year. In 12 months, almost everything we do as a network has been under discussion.

Most important is, of course, the ongoing political process of bringing forward the European Commission proposal on a future model for HTA cooperation. Several countries have spent their presidency meetings trying to bring this proposal to a decision, but still, the details of the future remain veiled for us on the technical level. Whichever decisions result will be very important to EUnetHTA and all our partners. However, for the time being it is not for us to come with our opinion on the political processes, but to continue our work in as productive a fashion as possible.

During the last year, EUnetHTA has applied for and been granted a one-year prolongation, and the project will hence run until May 31, 2021. During this extra year, focus should especially be on the production of EUnetHTA Assessments and Early Dialogues, the details, priorities, and consequences of which are continuously being discussed in the Executive Board.

A newly installed but highly important task group of EUnetHTA is the group working to formulate a Future Model of Cooperation on HTA (FMC-HTA). The aim is to define a platform for how the joint HTA work can be organised in more detail than what is covered in the political process stemming from the European Commission proposal. Work is being undertaken with the main questions:

- What shall be preserved from EUnetHTA?
- What needs to be changed or improved? and;
- What is missing?

The focus areas in which these questions are answered are: 1. Science, 2. Procedures, 3. Infrastructure, and 4. Evaluation.

The regional initiatives for HTA cooperation between a smaller number of countries continue their work, although some have partly changed direction. A new emphasis has been placed on joint horizon scanning in the International Horizon Scanning Initiative (IHSI), where several Member States are now part of the work.

Internally, EUnetHTA has continued the work to adapt and improve the changes in governance structure for the network that were initiated early 2018. One measure to accomplish this is to organise part of the work into subgroups that can handle issues that are influencing more than one or two work packages, but are also of importance to the whole Joint Action.

EUnetHTA Assessments remain a major focus of our activities. After the successful launch of the EUnetHTA Prioritisation List (EPL) in dialogue with the pharmaceutical industry, an EPL-2 has been published and is now leading to new letters of intent for upcoming pharma products. The high interest for Early Dialogues has also continued. The implementation reports from WP 7 show us that the uptake of EUnetHTA assessment reports is increasing.

Broad and sustainable stakeholder involvement is a continued priority for EUnetHTA and interaction with, among others; patients, healthcare providers, pharma and non-pharma industry, and payers, is something EUnetHTA aims to prioritise.

The EUnetHTA website now provides a “EUnetHTA one-stop shop” for HTA collaboration in Europe and sets the tone for a sustainable working environment for the future.

As we move forward, expanding upon our catalogue of EUnetHTA Assessments & Early Dialogues and encouraging national uptake, we are confident that EUnetHTA is equipped with the expertise and tools to continue fostering progressive, cross-country partnerships.

I would like to express my thanks to everyone who has participated and shown interest in the day's proceedings.

Niklas Hedberg
Chair of EUnetHTA Executive Board

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SAVE THE DATE!

Due to the prolongation, the EUnetHTA Secretariat will host an additional Assembly & Forum in 2021. The event will be held from 14-15 April 2021. More details will be confirmed via our website in due course.

THE STORY OF ZORGINSTITUUT NEDERLAND

As employees of the National Healthcare Institute, we are fully committed to providing access to high-quality and affordable care for over 17 million Dutch people.

Our government organisation actively promotes this vital issue.

SOLIDARITY AS A MOTIVE

Our motivation is that everyone must be assured of good care, no more than needed and no less than required. With that in mind, we implement the principle of solidarity in the healthcare system. Rich and poor, young and old, healthy and sick, in the Netherlands we all have access to the same affordable care. Everyone contributes to this through premiums and taxes. Whether you need a lot of care or a little, we are all responsible for each other. This solidarity cannot be taken for granted. A prerequisite is that people can be confident that their premium payments are spent wisely and prudently, and that they understand the choices behind it, which is exactly what we try to achieve every day.

PROVIDING DIRECTION, CONNECTING AND INSPIRING

We advise the Minister of Health about which care should or should not be reimbursed under the basic healthcare insurance. We also connect and inspire parties in the healthcare sector to jointly improve the quality of care and to pay more attention to sensible care. Together we work on, among other things, innovations in the field of responsible data use and eHealth. Finally, we manage the cash flows for the Health Insurance Act and the Long-Term Care Act.

QUALITY, ACCESSIBILITY AND AFFORDABILITY

What does a treatment add to what is already there? How much value does this have for a patient? What are the costs in relation to the expected effect? We have the expertise and commitment to thoroughly investigate these types of questions and translate the answers into practical advice, opinions, and other products. We do not determine which care is good or bad. What we do, however, is to review healthcare against the trinity of quality, accessibility, and affordability.

This takes place within clear assignments and frameworks. Politicians determine how much money is spent on healthcare. Healthcare providers, patients and health insurers together determine the right care within the requirements laid down by law. Only when they cannot resolve the matter do we ensure that a decision is made.

THE POWER OF TOGETHER

On behalf of society, we sometimes make difficult decisions about the composition of the basic healthcare package and the minimum quality of care. Our advisory committees help us achieve this. We believe in the power of doing things together and we look outside for input. In our deliberations, we take into account insights from the healthcare sector, science and society, both at home and abroad. There is a continuous dialogue with our environment to place our ideas in a broad context and to receive feedback on them.

This enables us to stay connected to what is going on in healthcare and society. We are transparent and explain our considerations and choices as clearly as possible, ensuring that everyone can understand them. Together with patients, healthcare providers and health insurers, we ensure that everyone in our country has access to high-quality and affordable healthcare. Now and in the future. That is our commitment!

Tiana van Grinsven
Member of the Board

AN UPDATE FROM THE EUNETHTA SECRETARIAT

Objectives

- Provide scientific and technical coordination support for European collaboration activities in HTA to the integration of the HTA activities in the whole life cycle of technologies.
- Provide coordination support to the network and the JA3 activities that increase the use, quality, and efficiency of joint HTA work at the European level to support evidence-based, sustainable, and equitable choices in healthcare and health technologies, and to ensure re-use in regional and national HTA reports and activities in order, notably, to avoid duplication of assessments.
- Ensure dialogue with EUnetHTA's stakeholders through coordinated communication and interaction.

CORE ACTIVITIES

The coordination of several key governance groups and events forms a major part of the Secretariat's activities:

THE EXECUTIVE BOARD

The Executive Board elects a Chair and two supporting Vice-Chairs from its voting members. It is comprised of organisations representing the work package lead and co-lead partners (13 consortium partners), elected member organisations of the EUnetHTA Assembly (five consortium partners), and non-voting observers (DG SANTE, CHAFEA, Chair and Vice-Chair of the Assembly). Together with the Chair of the Board, the Secretariat manages the coordination of the various face-to-face and electronic meetings throughout the calendar year. This includes content preparation, following up on decisions and actions of the Board, and identifying topics of strategic importance for the Board's consideration.

The Board has taken a number of key decisions over the past year which continue to shape the project in line with its strategic agenda.

- In **May 2019**, the Board approved the EUnetHTA governance proposal, which led to the creation of subgroups. These are cross-work package groups that work on issues which impact the project as a whole and prepare decisions for the Executive Board and the Heads of Agencies. More information is provided later in this section.
- In **May 2019**, the Board authorised the prolongation of EUnetHTA Joint Action 3 by one year.

- In **July 2019**, the Board agreed that inviting experts from the European Medicines Agency as external experts for the review of methodological guidelines should be considered so EUnetHTA has an enhanced level of expertise at a more advanced stage.
- In **July 2019**, the Board collaboratively developed and approved a text outlining EUnetHTA's understanding of HTA.
- After months of comments from numerous partners, in their **November 2019** meeting, the Board approved the international definition on HTA, an initiative led in a HTAi/INAHTA task group.
- The Board also discussed the objectives of and set up two subgroups over the course of the year. These include a subgroup on the PICO survey (PICO) and a subgroup on the Submission Dossier and Assessment Template (SDAT-PHARMA).

EUnetHTA Executive Board, January 2020 (Diemen, Netherlands)

HEADS OF AGENCIES

This event pulls together all HTA agency heads from Member States represented in the Executive Board (voting and non-voting members) to discuss high-level strategic guidance to the Board. The Heads of Agencies meet face-to-face biannually over two days. The first day focuses on pharmaceuticals and the second on medical devices.

TRANSVERSAL GROUPS

There are two types of transversal groups within EUnetHTA; task groups and subgroups. Task group members focus on issues or areas of discussion, whereas subgroups are a newly created type of transversal group whose members specifically work on cross-work package issues and prepare recommendations for the Board and Heads of Agencies. More information on the creation of subgroups is mentioned under **Year Four Highlights**. More information on the individual remit of each transversal group is available later in this booklet under **An Overview of Transversal Groups**.

PROJECT MANAGEMENT GROUP

The Project Management Group (PMG) supports the coordination of project management tasks both at work package and cross-work package levels. The group meets remotely every month and face-to-face once a year. Chaired by the EUnetHTA Secretariat, the group focuses on the day-to-day challenges project managers face and is an arena for open discussion on progress and developments within work packages.

EUNETHTA ASSEMBLY & FORUM

The combined event has two focal points. The first, the Assembly, is the primary body representing the Consortium, and is comprised of one representative from each Consortium partner. The Secretariat is responsible for the coordination of the convention and helps facilitate discussion by creating the agenda in a way that maximises opportunities for work package updates and cross-partner discussion. The Forum offers the key opportunity for stakeholder interaction during the year.

MEETINGS WITH STAKEHOLDERS

The Secretariat also has a key role in coordinating various stakeholder meetings throughout the year. This includes the biannual EUnetHTA-EMA meeting – the agenda for which is jointly produced by the European Medicines Agency and the EUnetHTA Secretariat – and the EUnetHTA-EFPIA Technical Meeting, which brings our partners together with EFPIA representatives for a day of discussion on the progress of the project and emerging areas of interest.

YEAR FOUR HIGHLIGHTS

PROLONGATION OF THE JOINT ACTION

EUnetHTA Joint Action 3 has received official approval from CHAFEA for an extension of an additional 12 months without additional funding. This prolongation is meant to allow the finalisation of outstanding deliverables and, where possible, further prepare for a future European HTA system. The Executive Board is currently in the process of assessing and prioritising activities during these additional 12 months. Availability of budget and contractual obligations, such as outstanding deliverables, are primary factors that will inform such a decision. With the prolongation, EUnetHTA Joint Action 3 will now officially end in May 2021. All beneficiaries will receive a formal request to indicate whether they are willing to participate in the prolongation, or whether they would like to terminate their participation, as originally planned, on 31 May 2020.

GOVERNANCE DEVELOPMENTS

In their July 2018 meeting, the Executive Board requested that the Chairs of the Board, as well as the Secretariat, draft a proposal outlining the potential development of the Joint Action's governance structure. This proposal was sought in an attempt to address governance issues and gaps within the project, as well as to improve overall transparency and accountability.

The proposal was delivered by the Secretariat in May 2019 and, following a second revision, was consequently approved by the Board.

The proposal is based on a number of principles which aim to increase transparent decision-making capacity within the project:

- **Decision participation** – Within the limitations of a project-based approach, it is important to ensure for the Executive Board and the Heads of Agencies the broadest possible selection of countries in their composition.
- **Quality of decision** – An understanding was established that the Board, as well as the Heads of Agencies, do not necessarily have the capacity and resources to analyse every decision in full detail. Support from a specific group of experts is therefore necessary to ensure all decisions are of high quality and are based on a solid contextual foundation.
- **Decision-making** – Decisions, as they have been set up under the Joint Action mechanism, are taken by majority vote, based on expert opinion.
- **Decision application** – It is important that all partners abide by the decisions of the Board and the Heads of Agencies to ensure accountability and sustainability of the project.

Taking these principles into account, a number of mechanisms were established to further develop the governance structure within Joint Action 3.

- **Decisions of strategic value** – Decisions that have far reaching impact or are of strategic importance to EUnetHTA must be taken by the accountable decision-making bodies designated by the project.
- **The creation of subgroups** – Subgroups should be created to work on cross-work package issues. These groups should specifically prepare recommendations for the Executive Board and the Heads of Agencies and support them in the decision-making process. Subgroups are led by a rapporteur, appointed by the Board, and are comprised of EUnetHTA partners who possess the relevant expertise. The groups are set up in a way that allows for a highly inclusive approach and a transparent decision-making and appeal process. *For more information on the creation of subgroups, please contact the EUnetHTA Secretariat.*

As of March 2020, two subgroups have been established. One, led by NIPHNO (Norway) is working on the Pharmaceutical Submission Dossier and Assessment Template (SDAT-PHARMA), and another, led by RER (Italy,) is working on the PICO survey (PICO). An extensive update has been provided under **An Overview of Transversal Groups.**

DEVELOPMENT OF A FUTURE MODEL OF COOPERATION

One of the major deliverables of the EUnetHTA Secretariat is to develop a future model of cooperation on HTA. This model encompasses the work of the current and previous Joint Actions and is driven along the products that future HTA cooperation is expected to provide. Work on the model takes into account the current European Commission proposal for a HTA regulation, but primarily focuses on the scientific and technical aspects of HTA cooperation.

The activity is being led by the dedicated cross-partner Future Model of Cooperation (FMC-HTA) task group and is being extensively supported by NICE (UK). Work is divided into three phases with three specific outputs:

Phase	Title	Output
Phase I	Data mapping and analysis	A preparatory report detailing existing and missing elements, as well as those needing improvement.
Phase II	Roadmap and resource allocation	A roadmap detailing next steps to improve missing or underdeveloped elements.
Phase III	Production and implementation	A white paper defining a blueprint for collaboration on HTA post-2021.

As of March 2020, a preparatory report has been drafted which describes existing elements of a model of HTA cooperation and presents initial ideas on areas for improvement and missing areas. Following a discussion exercise within the Executive Board, the Project Management Group and the FMC-HTA task group, a roadmap will be developed which will make recommendations on areas of improvement.

COMMUNICATING EUNETHTA'S WORK

EUnetHTA Secretariat has continued to follow a simple communications strategy, that being to remove barriers to access for EUnetHTA products and content as it is made available to the public. The website, successfully migrated to an EU server to comply with GDPR regulations, is a repository for all EUnetHTA news, updates, assessment project documentation, and events access. Social media are used to provide supporting access lanes that drive users towards site content, while the EUnetHTA Magazine, now available in an online format, is better optimised for mobile devices as well as desktop reading, and offers a space for partner article submission as well as driving traffic to the EUnetHTA site.

Through these communications changes, general interaction rates with EUnetHTA content have been observed via social media, now reaching an average of 3000+ interactions or views per content-related post. Social media is also used to provide indirect support to certain aligned partner events, improving the potential for referral and dissemination of EUnetHTA messaging.

Additionally, Secretariat attendance at HTAi, ISPOR, and other HTA-related events has continued to provide visible representation for EUnetHTA, helping to solidify its place within the global HTA community.

AN OVERVIEW OF WHAT'S NEXT

FINALISING DELIVERABLES AND MILESTONES

As EUnetHTA enters its final year, the Secretariat's upmost priority is to support the finalisation of the project's deliverables and milestones as outlined in the Grant Agreement. It is estimated that most deliverables have now been completed and handed over to the Secretariat, so efforts during the final year will ensure that any unresolved tasks are completed and delivered.

FINALISING THE WHITE PAPER AS PART OF WORK ON THE FUTURE MODEL OF COOPERATION

Work on the future model of cooperation is an important WP1 deliverable, and the white paper (output of phase III) is an essential part of that. The model will not only feed into activities and priorities during the prolongation year, but will also set the stage for cooperation on HTA post-2021.

PREPARATION FOR HANDOVER

As part of finalising the project's deliverables and milestones, the Secretariat will also be working with partners to prepare the Joint Action for the next form of collaboration (details of which are still under discussion by the European Commission and Member States). This will mean verifying our IT platforms are sustainable and fit-for-purpose, and using the inventory created by the FMC-HTA task group to ensure all elements created throughout the Joint Action are captured and logged.

DISSEMINATION

Partners: AETS-ISCIII, SU, NICE, AQuAS, UCSC Gemelli, AIHTA, HAS, SNHTA.

Objectives

- Support EUnetHTA in the dissemination of information on JA3.
- Collaborate in identifying and improving stakeholder engagement.
- Maintain oversight and coordinate the training strategy for JA3.
- Participate in the task group responsible for the development of a future model of cooperation on HTA (a key Secretariat deliverable focusing on the scientific and technical elements of cooperation).
- Explore and improve strategies for promoting EUnetHTA activities.

Activities and products

Dissemination (WP2) activities and products are split amongst three key areas:

- Communication
- Training
- Stakeholder engagement

CORE ACTIVITIES

PRODUCTS AND PUBLICATIONS

(collaboration with/supporting the Secretariat)

- EUnetHTA Communication Strategy/Dissemination Plan.
- EUnetHTA Graphical Guide.
- EUnetHTA Welcome Guide.
- EUnetHTA Magazine (external audiences) - published eight issues since autumn 2017.
- Newsletter (internal audiences) - published 10 newsletters since January 2017.
- Instructions on Authoring Rules and Copyright Issues-ARCI (WP2-WP4-WP6 collaboration).

THE DISSEMINATION REGISTRY

A total of 212 dissemination activities undertaken by EUnetHTA partners have been registered so far. The Dissemination Registry includes records of publications, event attendance, and other dissemination activities. The Registry is used to analyse and evaluate dissemination activities in EUnetHTA, identify gaps and make recommendations to improve the dissemination process. The analysis of four years of the Joint Action has shown that 159 records were related to events (e.g. congresses, workshops, and communications), 36 were scientific articles, and the rest were other types of activities.

INTERNATIONAL CONTRIBUTIONS

New HTA consensus definition. Over the past year, EUnetHTA has actively contributed to the working group defining the international definition of HTA (in collaboration with INAHTA, HTAi, HTAsiaLink, RedETSA, HTA Glossary, WHO and ISPOR). The Executive Board also recently endorsed the definition, marking a significant step in ensuring EUnetHTA is well represented within the global HTA community.

TRAINING

PRODUCTS

The JA3 Training Strategy summarises needs, methods and procedures for training actions.

CHANNELS

The Virtual Classroom (intranet) is an online repository available to all EUnetHTA partners that stores information on:

- Webinars.
- Electronic materials on guidelines.
- Training on joint and collaborative products.
- Information on authoring and methods.
- Implementation experiences.

STAKEHOLDER ENGAGEMENT

- Historical data on modes of stakeholder involvement in EUnetHTA have been presented during various conferences and via the Assembly and Forum.
- There is continuous collaboration with the EUnetHTA Secretariat to update the list of stakeholders for public consultations.
- Work package 2 continues to lead on stakeholder engagement activities through its participation in the Patients, Consumers, and Healthcare Provider Involvement Task Group (WP1, WP4, WP5 and WP6). This group explores ways to improve the engagement of patients, consumers, and healthcare professionals in Assessments and Early Dialogues. Our published products include Patient Input in Relative Effectiveness Assessments and an informative flyer to educate patients on the EUnetHTA process.

AN OVERVIEW OF WHAT'S NEXT

AETS-ISCIII, along with its partners, will continue to:

- Support the Secretariat and Executive Board in communication and dissemination activities.
- Continue the implementation of ARCI rules.
- Continue the implementation and alignment of training activities, supporting work on the future model of cooperation in the process.

EVALUATING OUR WORK

Partners: DVSV, TLV, HI, NKUA, SNHTA, ZIN.

Objectives

While evaluating EUnetHTA Joint Action 3, the evaluation team tries to answer the following questions:

- Is the project reaching its objectives?
- To what extent are the different parts of the project contributing to the common goals of the project?
- Are the different parts of the project being implemented as planned?
- What work is being done to facilitate future European HTA collaboration?

The purpose of looking into these questions is to promote collaboration, optimise resource use, and to enable the project as a whole to achieve its goals.

CORE ACTIVITIES

BI-ANNUAL EVALUATION REPORTS

Bi-annual Evaluation Reports are short, descriptive reports that aim to:

- Give an overview of how the different activities (deliverables and milestones) in EUnetHTA are progressing; and
- Monitor resources used.

Sections of different topics that are thought to be of value can be added to a bi-annual report.

BI-ANNUAL EVALUATION REPORT VI

The 6th Bi-annual Evaluation Report was finished in early summer 2019. It contains a brief summary and discussion of the 3rd EUnetHTA Implementation Report and an analysis concerning future European HTA collaboration based on interviews with some of EUnetHTA' s partners. It also contains sections that are standard in the Bi-annual Reports, namely: a section with a status update on the goals that were set out at the start of the project from December 2018 until May 2019, a section with a brief analysis regarding resources used from June 2016 to November 2018, and a section dedicated to the evaluation team's findings and recommendations.

BI-ANNUAL EVALUATION REPORT VII

During winter 2019/2020, the 7th Bi-annual Evaluation Report was written. It contains the three reoccurring sections as described for the 6th Bi-annual Report.

It also contains a section based on data gathered on interviews with end users of EUnetHTA assessments (decision-makers and/or payers). Furthermore, there is an analysis of the time and money spent to produce different EUnetHTA products that can be used to support discussions on further European collaboration on HTA.

YEARLY INTERIM EVALUATION REPORT

Yearly Interim Evaluation Reports aim to provide a more in-depth analysis of EUnetHTA. The analysis helps define the added value EUnetHTA activities can bring, includes responses from interviews and/or surveys with EUnetHTA partners or different stakeholders, and outlines the development of EUnetHTA.

3RD YEARLY INTERIM EVALUATION REPORT

In October 2019, the 3rd Yearly Interim Evaluation Report was completed. The report focuses on the project's third year and contains a section further exploring the data collected from an industry survey and interviews with partners regarding future HTA collaboration. The report also included a deeper analysis of resources used, both time and money spent, and a more exhaustive analysis of the different goals of the project, assessing how they have been achieved and how they may be completed. There is also a section where the evaluation team follows up on the findings and recommendations made in the different Evaluation Reports during the first three years of the project.

STAKEHOLDER ENGAGEMENT

The evaluation team has continuously had formal and informal contact with different stakeholders. During the fourth project year, the focus has been on interviews with end users. In addition, the evaluation team has interviewed a number of end users who are decision-makers and/or payers. If possible, the evaluation team would like to conduct a follow-up survey with all relevant stakeholders, and an additional stakeholder survey with a focus on the pharmaceutical and other technology industries during EUnetHTA' s fifth year.

AN OVERVIEW OF WHAT'S NEXT

After the end of the project, the evaluation team will write a Final Evaluation Report. The aim is to use data on time and money spent during the project, analyse what has been achieved, and the average costs of different activities. The final report should also evaluate the added value of EUnetHTA reports and use the experience of the project to evaluate the conditions for a sustainable European HTA network.
During the fifth year, the evaluation team will provide support for the ongoing activities as well as assist in the preparations for future HTA collaboration. This work will possibly be in the shape of one or two additional Bi-annual Reports.

JOINT PRODUCTION

Partners: NIPHNO, ZIN, NOMA, AIHTA and several others.

Objectives

- Production of Joint and Collaborative Assessments.
- Refine the production processes of jointly produced assessments based on lessons learned and experiences from Joint Action 2 and 3.
- Provide recommendations for horizon scanning, topic identification, selection and prioritisation.
- Facilitate the implementation of jointly produced assessments.
- Provide input for a sustainable model of European collaboration on jointly produced assessments after 2021.

PRODUCTION OF EUNETHTA ASSESSMENTS – STATUS

Pharmaceuticals	Other Technologies
9 assessments published 5 assessments ongoing	20 assessments published 5 assessments ongoing

You can access all ongoing and published EUnetHTA assessments on the EUnetHTA website and read more about the assessments here.

Joint Production (WP4) consists of around 60 non-profit partner organisations that produce or contribute to HTA.

WHY PARTICIPATE IN A EUNETHTA ASSESSMENT?

A European collaboration on HTA benefits companies, national HTA agencies, and ultimately patients. By participating in EUnetHTA assessments, companies have the opportunity to collaborate with EUnetHTA and shape the future of European HTA.

STAKEHOLDER ENGAGEMENT

PATIENT ENGAGEMENT IN EUNETHTA ASSESSMENTS

Recommendations on how to involve patients and patient representatives in EUnetHTA assessments have been finalised by EUnetHTA. EUnetHTA deems patient involvement very important in the production of assessment reports, and recognises that patients and those who support them have unique knowledge about what it is like to live with a specific disease or medical condition. Patient input is therefore considered essential to inform the scope (research question) of the assessment.

The goals for patient contribution in assessments are to gain better insights into the disease/condition and current available treatments, as well as the outcomes that are important from the patients' perspective. For patients, involvement in assessments may provide insight into the HTA method. A EUnetHTA Patient Input Template has been developed to capture these experiences and views from patients. This form is used for the open calls for patient input on the EUnetHTA website, and is a modified version of the HTAi patient group submission form. Translation of the patient input template to all EU languages is anticipated in the coming year to facilitate use and ensure a proper understanding of the form. Both the recommendations and the patient input template can be found here.

EUnetHTA seeks to actively involve patients or patient representatives in assessments. This involvement is illustrated in the below graphic in addition to the involvement of healthcare professionals. The numbers represent how many assessments have included each type of involvement.

Patients/Patient Representatives	Healthcare Professionals
Pharmaceuticals • 2/14: One-on-one interview • 11/14: Patient input template • 1/14: Unsuccessful	**Pharmaceuticals** • 2/14: Reviewing report • 7/14: Q&A approach • 4/14: Ongoing identification • 1/14: Unsuccessful
Other Technologies • 4/22: One-on-one-conversation • 2/22: Group conversation • 5/22: Patient input template • 4/22: Other • 4/22: Unsuccessful	**Other Technologies** • 22/22 (often more than one approach used)

HEALTHCARE PROFESSIONAL INVOLVEMENT IN EUNETHTA ASSESSMENTS

EUnetHTA is now developing recommendations on how to engage with healthcare professionals in EUnetHTA assessments. The input of healthcare professionals is deemed essential when developing the scope of an assessment, helping to ensure that key factors relevant for clinical practice are considered during the EUnetHTA assessment process. In addition, healthcare professionals play an important role during the production of a EUnetHTA assessment by helping the EUnetHTA team understand clinical practice and answer any questions they may have, for example on clinical pathways or procedures. These recommendations were under consultation by selected stakeholders during the beginning of 2020 and are planned to be finalised by the end of spring 2020.

EUnetHTA is also testing different methods of engagement for healthcare professionals. Currently, engagement is performed by one or more of the following activities; reviewing the scope of the assessment (research question), answering specific clinical questions to define the scope, participating in a scoping e-meeting, reviewing the draft project plan/draft assessment report and/or answering specific clinical questions during the production of the assessment.

CORE ACTIVITIES AND HIGHLIGHTS

TOPIC IDENTIFICATION, SELECTION AND PRIORITISATION (TISP) AND THE EUNETHTA PRIORITISATION LIST (EPL)

A working group consisting of members from several Joint Production partners have developed "Recommendations for Horizon Scanning, Topic Identification, Selection and Prioritisation for European Cooperation on Health Technology Assessment". will be available here. The preparation of the recommendations have been informed by a question and answer approach, selected background literature, collaboration with the European Medicines Agency (EMA), stakeholder input to draft recommendations, and pilots on voluntary Topic Identification, Selection and Prioritisation (TISP) processes. As part of the pilot, stakeholders were invited to suggest topics for EUnetHTA assessments. The outcome of the pilot was the EUnetHTA Prioritisation List (EPL), one for pharmaceuticals and one for other technologies. Experiences from the pilot have informed the final recommendations.

In the pharmaceutical branch in 2018 there was a need to strengthen the production of pharmaceutical Joint Assessments. To comply with this need, the EUnetHTA Prioritisation List 1.0 was published in October 2018. The EPL 2.0, based on the TISP process, was published after the pilot, in July 2019. The EPL for pharmaceuticals is available here. The EPL for other technologies is available here.

CONTINUOUS UPDATES ON THE PRODUCTION PROCESS OF ASSESSMENTS

The production process of assessments is continuously being improved, based on feedback from the assessment teams involved with previous EUnetHTA assessments and input from partners. EUnetHTA also collects feedback from manufacturers who have been involved in the process. This valuable information is used to further improve processes and templates.

SUMMARY OF ONGOING ACTIVITIES IN OR RELEVANT FOR THE TWO BRANCHES

Pharmaceuticals

- Procedural revisions to ensure timely publication after Market Authorisation.
- PICO survey to ensure relevant PICO definition(s) for the EUnetHTA assessment.
- Revisions of templates to ensure better readability and usability.
- Creation of the EUnetHTA Prioritisation List (EPL) to ensure relevant Joint Assessments.

Other Technologies

- Decentralised project management of Collaborative Assessments.
  - Training and support to Activity Centre Department Leads.
- Revision of procedures in the production process.
- Revision of documents and templates.
- PICO survey will be considered for a pilot.

Joint Production works closely with Quality Management (WP6) partners to produce Standard Operating Procedures (SOPs) which are continuously integrated in the Companion Guide. The tools, templates and guidelines that support production of assessments are also accessible there (although not fully populated yet).

Please see the **Quality Management section** for more information about SOPs and the Companion Guide.

PLAIN LANGUAGE SUMMARIES

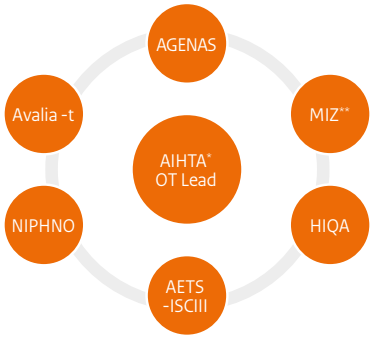
To facilitate the dissemination of EUnetHTA assessments, we are working on a template for plain language summaries to be used in the assessment reports. The template is currently being developed and tested. The plain language summary aims to be understandable aims to be understandable for patients and citizens. As soon as the plain language summary pilots are available, we will engage in a structured consultation with the HTA Network Stakeholder Pool.

FAQ FOR INDUSTRY AND SUBMISSION REQUIREMENTS

The FAQ for other technologies and FAQ for pharmaceuticals have been published on the EUnetHTA website to direct enquiries from the industry and explain how manufacturers can be involved in the assessments. Submission requirements have been published for other technologies and pharmaceutical technologies, specifying the citation and publication policy. In both cases, the authoring team is free to cite the submission dossier without redaction. At the time of publication of the final assessment report, EUnetHTA will also publish the submission dossier as completed by the manufacturer. For other technologies, the entire submission dossier will be published, whereas for pharmaceuticals, only the core submission dossier will be published and the attachments of the submission dossier (e.g. CSR reports) will not be published as a stand-alone document. However, assessment teams are free to cite from the attachments without redaction. For more information, you can find the submission requirements for other technologies here and for pharmaceuticals here.

DECENTRALISED PROJECT MANAGEMENT OF COLLABORATIVE ASSESSMENTS: ACTIVITY CENTRE DEPARTMENT LEADS IN OTHER TECHNOLOGIES

The Activity Centre Department Leads perform project management for many of the Collaborative Assessments. The purpose of this model is to generate a designated pool of agencies with established roles and growing experience in sustainable collaboration, which should facilitate the continuation of joint work after 2021. To date, 13 other technologies assessments were project managed with a decentralised approach by the activity center department leads.



AIHTA (Austrian Institute for Health Technology Assessment) was the Ludwig Boltzmann Institute for Health Technology Assessment (Other Technologies)

**MIZ (Ministry of Health of the Republic of Croatia) was the Agency for Quality and Accreditation in Healthcare and Social Welfare (AAZ)*

VISION PAPER FOR COORDINATED ACTIVITIES ON HTA AND MEDICAL DEVICE AUTHORITIES

A 2nd Workshop of the EUnetHTA Task Force on HTA and Medical Devices took place on 28 May 2019 in Vienna. The aim of the workshop was to explore the synergies (Early Dialogue (ED)/ Scientific Advice (SA); Post-Launch Evidence Generation (PLEG)/ Post Market Clinical Follow-Up (PMCF)) between EUnetHTA and Competent Authorities (regulators) responsible for medical devices, while encouraging stakeholders to participate. A report of the meeting can be found here.

The background of this initiative is the effort of HTA agencies to reduce the evidence gap between market approval (CE marking) and market access (reimbursement and coverage decisions) for high risk medical devices (class IIb and III, IVD: C and D). An alignment of requirements for evidence generation between regulators and HTA, as far as is possible, can contribute to the early market access of safe and effective medical devices for patients, maintain low costs for healthcare systems, and ease the burden of manufacturers when complying with varying requirements across European countries.

Aim of Vision Paper

To develop coordinated activities between the Competent Authorities, Notified Bodies and EUnetHTA (supported by the EU-Commission and in cooperation with stakeholders).

Final Aim

To reduce the evidence gap between market approval (CE marking) and market access (reimbursement and coverage decisions).

PROCESS FOR THE IMPLEMENTATION OF EUNETHTA ASSESSMENTS IN NATIONAL AND REGIONAL PRACTICE

Joint Production works to ensure the timely availability and usability of assessments. Collaboration with National Implementation and Impact (WP7) is thus essential as they collect data about whether and how EUnetHTA assessments are being used in national, regional and local contexts, the decisions that the assessments are informing, and factors that limit national/regional use of assessments. Promotion of EUnetHTA assessments and support for uptake is formalised in the Implementation Network.

AN OVERVIEW OF WHAT'S NEXT

In the JA3 prolongation year, Joint Production will seek to continue the generation of jointly produced assessments. We will also support the development of a future model of cooperation of European HTA.

EARLY DIALOGUES

Partners: HAS, G-BA and several others.

Objectives

- Conduct Early Dialogues.
- Develop and test a fee-for-service mechanism for HTA body (HTAb) involvement in Early Dialogues.

CORE ACTIVITIES

The core focus over the past year has been the completion of the planned 33 EUnetHTA Early Dialogues and the creation of the pilot fee-for-service model.

CONDUCT EARLY DIALOGUES (EDS)

Since 2017, EUnetHTA has been offering Early Dialogues. Up until January 2020, the EUnetHTA ED Secretariat has received 95 requests for EDs (table 1). During 2019, the EUnetHTA ED Secretariat received and processed 46 requests. Of these, 36 were requests for pharmaceutical parallel consultations, with 13 following the Consolidated Parallel Consultation (PCC) pathway. In the same period, seven pharmaceutical Multi-HTA requests were received, for which one was completed. One request was received for a Multi-HTA ED for a medical device. After initial review and comment by the Scientific Coordinator, it was returned to the applicant for a revised and final briefing document. Finally, two requests for qualification were received. Despite interest from multiple HTAb, EUnetHTA did not accept the requests due to resource constraints. 27 of the 46 requests (59%) included questions on the economic model. Orphan drugs comprised 13 of the pharmaceutical requests, with four being accepted for Multi-HTA or PCC procedures. Table 1 below provides an overview of all requests received since the beginning of EUnetHTA JA3.

TABLE 1: A TOTAL OF 95 REQUESTS HAVE BEEN RECEIVED FOR EUNETHTA EARLY DIALOGUES. A BREAKDOWN IS PRESENTED BELOW.

TOTAL REQUESTS FOR EARLY DIALOGUES

EUnetHTA Early Dialogues			
Therapeutic Field *(indication)*	MULTI-HTA EARLY DIALOGUES *(17 requests)*		PARALLEL CONSULTATIONS *(76 requests)*
	Pharmaceutical Products *(4 requests)*	**Medical Devices** *(3 requests)*	**PCC** *(27 requests)*
	19 refused requests (non-compliance with procedure, non-eligibility for PCI or for multi-HTA, resource constraints, outside EDWP members' remit)		
Auto-immune disease/ dysfunction	1 *(refused)*		1 *(refused)*
Cancer	1 *(completed)* 1 *(refused)*	1 *(completed)*	9 *(completed)* 1 *(withdrawn by applicant)* 8 *(refused)*
Metabolic disorders		1 *(awaiting applicant decision)*	
Neuro-degenerative disorder	1 *(completed)*		3 *(completed)* 1 *(refused)*
Viral disease	1 *(on-going)* 2 *(refused)*		1 *(completed)*
Other	2 *(completed)* 4 *(refused)*	1 *(withdrawn by applicant)*	14 *(completed)* 9 *(refused)*

** The total number of requests includes two inquiries for EMA qualification procedures.*

FEE-FOR-SERVICE MODEL

The final, outstanding deliverable for WP5A is the piloting of a financing mechanism for Early Dialogues. The pilot mechanism, which should launch Q1 2020 and continue until Q2 2021, should pave the way for a future sustainable mechanism. During the pilot period, the mechanism will focus on EDs for pharmaceutical products only. The ED procedure itself will remain essentially unchanged, with transparent priority-setting (selection criteria) and a clear decision-making procedure among EDWP partners.

The EDFM pilot will operate on a flat fee and use the EUnetHTA Grant Agreement as a legal basis to establish a General Framework Agreement to be signed by all participating parties, including HTAb that do not intend to receive fees. The Framework Agreement will define all roles and procedures, as well as costs. It has been written in collaboration with European legal experts and business case consultants. A fixed number of pilots to be conducted prior to the end of JA3 will be established in the Framework Agreement, with all signatories participating in all EDs unless the request is outside of agency remit. The EDFM structure will provide for financing with no direct link to industry payment for any single ED, and will be cost neutral to HTAb (covering all costs: staff, travel, ED & EDFM Secretariats).

STAKEHOLDER ENGAGEMENT

PATIENTS

Since the first EUnetHTA EDs a concerted effort has been made to involve experts, with a particular focus on patients and patient representatives. This effort will continue during the prolongation of JA3 and has been integrated into the EDFM framework.

The EUnetHTA ED Secretariat begins contacting associations as soon as the EDWP decision is final to identify potential patient experts. In parallel, national agencies follow their national procedure of recruitment (primarily G-BA, HAS, and NICE).

As soon as a patient is identified, the ED Secretariat contacts them to schedule an introductory interview to:

- Present HTA & EUnetHTA, as well as what we do.
- Explain what an Early Dialogue is.
- Explain what is expected of their participation and what they can expect throughout the process.
- Respond to any questions they may have regarding the process, EDs and administrative tasks.
- Present the briefing book content at high level, as well as preliminary discussions between HTAb, if needed.

Next, they will be interviewed by EDWP members and are given the option to contribute to HTAb discussions on the dossier. As of December 2019, 32 patients have been involved in EUnetHTA EDs. Table 2 provides an overview of the distribution of their participation.

TABLE 2: PATIENT INVOLVEMENT IN EUNETHTA EDS BY APPROACH

Approach	Number of EDs	Number of Patients/ ED
Approach 1 Individual patient – interviewed regarding the disease and their experience	3 EDs (1 with both approach 1&2)	7 patients
Approach 2 Approach 1+ discussion with local HTA body regarding submission file (without applicant)	18 EDs (2 with approach 1 & 2 and 5 with approach 2 & 3)	13 German patients 1 French patient 2 EU representatives 5 ED with 2 patients
Approach 3: Expert Approach 1+ discussion with all participating HTA bodies regarding the submission file and participation in the F2F meeting with the applicant	7 EDs (5 with approach 2&3)	9 patients

HEALTHCARE PROFESSIONALS (HCPS)

The involvement of HCPs is primarily carried out at the national level by the participating HTAb. This allows them to collect information regarding national specificities. Implications on a European level (closer to approach 3 for patients) need to be further developed.

AN OVERVIEW OF WHAT'S NEXT

EARLY DIALOGUE FINANCING MECHANISM (EDFM)

The key focus over the next year will be the piloting of the EDFM. This pilot phase will be followed by an audit which will allow us to modify the mechanism as needed in order to launch a sustainable mechanism going forward (i.e. post-JA3).

QUALITATIVE ANALYSIS OF COMPLETED EARLY DIALOGUES

WP5A lead (HAS) and co-lead (G-BA) intend to complete a qualitative analysis on EDs conducted in addition to the quantitative presentation. The main objective is to analyse the alignment between the HTAb positions throughout the EDs. Common findings will be summarised with a target to publish a positioning paper on common HTAb expectations, including clear common statements. A detailed methodology has been developed, allowing for a specific and detailed analysis of not only the PICO domains, but also PLEG, economic evaluation, and the overall development plan as additional aspects to consider. The evaluation will be done in a peer review process facilitated by WP5A lead and co-lead, HAS and G-BA. At least 21 EDs will be included in the analysis. The publication is planned for 2020.

This analysis will be complemented with feedback systematically solicited from patients/patient representatives and industry at the conclusion of each ED.

POST-LAUNCH EVIDENCE GENERATION AND REGISTRIES

Partners: HAS, AIFA , avalia-t , NICE, TLV and several others.

Objectives

The objective is to set up and consolidate common activities on Post-Launch Evidence Generation, as this has become a significant issue requiring attention:

- Piloting joint work on defining requirements for Post Launch Evidence Generation (PLEG), for specific products or data sources registries, (PLEG pilots).
- Developing a tool to support HTA organisations in guiding and evaluating registry quality towards effective usage in HTA (REQueST®).

CORE ACTIVITIES

PRODUCT-SPECIFIC PLEG PILOTS

In year four, this work stream has been finalising three PLEG pilots for real world evidence (RWE) needs, for the following products:

- Spinraza® in spinal muscular atrophy, in a situation of uncertainty;
- Ibrance® in metastatic breast cancer in order to check the real world use of the drug and;
- Left ventricular assist devices (LVAD), a medical device as destination therapy in end-stage heart failure.

All three pilots were based on proposals made by partner agencies and arose from evidence gaps identified in respective **national assessments**.

There was consistent agreement among participating agencies on a common dataset for real world evidence generation for the products in question. Moreover, the LVAD pilot was specifically conducted using the REQueST® tool to define the quality requirements for the registries to be set up.[1]

1 *The two other pilots started before the final version of REQueST® was available.*

More information on the pilots and the available reports can be found on the EUnetHTA website.

In parallel, this work stream has been updating general pilot templates and procedures for product-specific pilots. Moreover, table templates have been developed in collaboration with WP4 in order to disseminate information on PLEG needs identified in **EUnetHTA Joint Assessments**, and consequently allow a link to be made between joint production and PLEG work. The tables in the REA reports allow additional evidence generation needs to be structured in a harmonised manner. The tables can therefore serve as a starting point for PLEG pilots, in which further requirements for PLEG (i.e. common dataset, quality requirements) would be defined.

REGISTRY-SPECIFIC PLEG PILOTS

This work stream has also carried out one PLEG pilot, which assessed the suitability of an existing data source for PLEG purposes. The pilot was performed in collaboration with the European Society for Blood and Marrow Transplantation (EBMT) Registry. Its aim was to provide advice, from participating agencies, on the quality and the usability of the EBMT Registry for post-launch follow-up of CAR T therapies, to inform HTA re-assessment at a national level. The quality assessment of the EBMT Registry was performed using the REQueST® tool.

More information on the pilot and the available report can be found on the EUnetHTA website.

REQUEST® TOOL

This work stream published the final version of the REQueST® tool. REQueST® aims to support HTA organisations, as well as other actors, in guiding and assessing the quality of registries, with a view to the effective use of registry data. It is designed to be a simple tool that is based on international published guidance on registry methodology and sits alongside it as a tool for implementation. The tool can be used by both evidence developers to assess the quality of their registry, and international or national organisations considering whether to use registry data for HTA and regulatory purposes.

The standards set out in the tool are universal and essential elements of good practice and evidence quality, which are therefore applicable to different types of registries.

Accompanying the tool is a 'Vision paper' which explores the options for the long-term delivery, use, and sustainability of REQueST® beyond Joint Action 3.

Further to its publication, REQueST® has been used in two EUnetHTA PLEG pilots in year four, as well in several individual national PLEG activities.

The tool can be accessed and used from https://eunethta.eu/request-tool-and-its-vision-paper/.

Evidence developers interested in collaborating with EUnetHTA regarding the quality requirements for their registry are invited to contact the WP5 lead at eunethta-has@has-sante.fr.

STAKEHOLDER ENGAGEMENT

This work stream has involved stakeholders in the development of the REQueST® tool and its vision paper. In year four, 13 external organisations, including (in alphabetical order) academia, CRO representatives, health professionals, INAHTA member agencies, industry, patient representatives and regulators, have responded to the public consultation on the tool and the vision paper. The views shared helped prepare the final version of these outputs and make them as useful as they can be for various actors.

Similarly, WP5B is continuously exploring possibilities to collaborate with various stakeholders when conducting PLEG pilots. In addition to the aforementioned collaboration with EBMT in the framework of the registry-specific pilot, one of the product-specific pilots (on LVAD) included a specific round of involvement of external independent experts, in order to gather their feedback on the proposed common dataset for real world evidence generation for these devices.

AN OVERVIEW OF WHAT'S NEXT

- Conduct product-specific PLEG pilots arising from REA (Joint Production).
- Further promote the use of REQueST® and improve the tool based on experiences and feedback.
- Gather lessons learned from PLEG pilots, along with developed tools and templates, into the final work stream output ("Recommendations and Tools for PLEG"), in order to indicate best practices for cross-border collaboration on PLEG.

QUALITY MANAGEMENT, SCIENTIFIC GUIDANCE AND TOOLS

Partners: IQWIG, KCE and several others.

Objectives

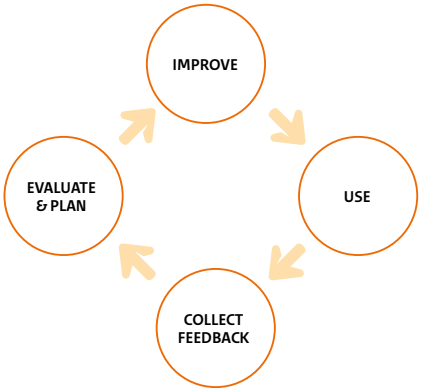
- Establishment of a sustainable quality management system (QMS) for EUnetHTA.
- Launch and maintenance of the EUnetHTA Companion Guide, a comprehensive online repository providing relevant support and guidance for the production of HTA reports to assessment teams and project managers.
- Development, evaluation and maintenance of all components of the Companion Guide: QMS concept, process flows, Standard Operating Procedures (SOPs), templates, guidelines, POP Database, Evidence Database and other IT tools, recommendations, and further guidance documents.

YEAR 4 ACHIEVEMENTS – CONTINUOUS DEVELOPMENT, EVALUATION AND MAINTENANCE OF THE QMS

EVALUATION AND IMPROVEMENT OF THE QUALITY MANAGEMENT SYSTEM

Based on findings and feedback received from multiple sources (surveys for assessment teams, project managers, workshops, case studies, and direct input, etc.), a “List of measures for improvement of the QM system” for processes, templates, methodological guidelines and tools was compiled.

A revision of the already finalised parts of the QMS, based on change requests received is currently ongoing.



EUNETHTA COMPANION GUIDE

After being piloted on the first assessments, a user test of the EUnetHTA Companion Guide has been conducted among WP4 partners with a focus on the user-friendliness of the tool.

Enhancements introduced with the EUnetHTA Companion Guide 2.0

- Addition of a visual navigation menu on the start page to facilitate quick identification of relevant content.
- Generation of the menu item "Knowledge Centre" to facilitate identification of standard terms listed under the "List of Terms" and training material.
- Creation of an updated training module on the use of the Companion Guide 2.0.
- Addition of several internal and external links to facilitate navigation between related contents (e.g. adjacent SOPs and guidelines, training materials).
- Provision of all templates that are required throughout the assessments in one place.
- Generation of dedicated pages for process-related guidance documents for other technologies (OT) and pharma that have been developed by cross-WP task groups (e.g. DOICU form, ARCI Guidance, recommendations on patient input).

SOPS, METHODOLOGICAL GUIDELINES, AND HTA CORE MODEL

The production of SOPs continued. The vast majority of around 40 SOPs describing all process steps of Rapid REA Pharma and Rapid REA OT are now available in the Companion Guide. The SOPs in use have been revised based on the feedback received from assessment teams and project managers.

The Methodological Guideline on 'Process of Information Retrieval for Systematic Reviews and Health Technology Assessments on Clinical Effectiveness' has undergone a major revision and version 2.0 is now publicly available. The update of the guideline 'Comparators & Comparisons: Direct and Indirect Comparisons' is underway.

A new EUnetHTA guideline on the critical assessment of economic evaluations was published in early 2020, while the development of further new guidelines on the critical assessment of clinical evidence is still ongoing. All of these activities included public consultations of draft guideline versions.

The **HTA Core Model** reporting structure has been revised. A template for a full HTA of OT is currently under development comprising all nine domains and links to guidelines, SOPs and other EUnetHTA guidance.

INFORMATION SPECIALISTS NETWORK

An information specialists network has been established in order to support assessment teams with expertise in information retrieval on an ad-hoc basis and to identify an information specialist if this is missing in the assessment team.

Moreover, the network provides training sessions and collaborates on information retrieval methodology and processes.

INVOLVEMENT OF WP6 IN CROSS-WP ACTIVITIES

EUnetHTA governance bodies

- Executive Board.
- Project Management Group.
- WP4-WP6 Coordination Group (comprised of leads and co-leads of WP4 and WP6).

Other work package cooperation

- Cooperation with WP2 on training activities.
- Cooperation with WP7 on the uptake of EUnetHTA guidelines and tools.

Task groups and subgroups

- Authorship Rules and Copyrights Issues (ARCI).
- Common Phrases and GRADE.
- Future Model of Cooperation (FMC-HTA).
- Patient/Consumer and Healthcare Provider (P/C&HCP).
- Pharma Submission Dossier and Assessment Report Templates (SDAT-PHARMA) subgroup.
- PICO subgroup.

IMPLEMENTATION

Partners: NICE , Agenas and several others.

Objectives

The objectives of Work Package 7 (Implementation) are to:

- Provide technical support about implementation issues to enable the development of an HTA cooperation mechanism that successfully takes implementation issues at national, regional and local (hospital) levels into account.
- Facilitate uptake and implementation in national, regional and local settings of EUnetHTA tools and jointly produced HTA information in EUnetHTA (from previous joint actions and as well as in Joint Action 3) and the reuse of HTA reports produced by Member States.

CORE ACTIVITIES

IMPLEMENTATION NETWORK

WP7 supports agencies to (1) identify feedback issues on the use of EUnetHTA products (2) engage in EUnetHTA activities, and (3) resolve implementation issues. The implementation network provides implementation reports every six months.

The fourth and final implementation report was published in November 2019. Further implementation data will continue to be collected for our final deliverable (evaluation report).

As of the start of February 2020, a total of 24 Joint or Collaborative Assessments have been published under JA3 for which implementation data are available, of which four are for PT and 20 are for OT. WP7 implementation data (as reported at February 2020) shows:

- 242 examples of use of JA3 assessments have been reported.
- 64 uses of the 4 PT assessments.
- 178 uses of the 20 published OT assessments.
- 127 uses are in assessment procedures (PT = 53, OT = 74).
- 115 uses were dissemination of the assessments (PT = 11, OT = 104).

The data show:

- Increase in the use of assessments.
- Use of PT assessments is higher than JA2.
- Use of OT assessments is comparable with JA2.
- An increase in countries using JA3 assessments compared with JA2.

As part of the network, WP7 has developed an implementation strategy. The strategy includes a set of principles, responsibilities and activities that have been identified by partners as being important to supporting implementation in JA3 and post-2021.

The implementation strategy was incorporated into the 3rd Implementation report, published in May 2019.

WP7 has been hosting a series of implementation webinars to enable partners to share their implementation experiences. The webinars are recorded and are made available in the virtual classroom on the EUnetHTA intranet.

To better understand the tools required by partners to support implementation, WP7 developed a short paper outlining the options for further development of the HTA Adaptation Toolkit. We consulted partners on the paper as part of the consultation on the 4th implementation report.

Publicly Available Documents
4th Implementation report (November 2019)
https://eunethta.eu/wp-content/uploads/2019/12/Implementation-Report-Nov-2019_Final-27112019-for-Internet.pdf

CASE STUDIES

Agencies are interviewed to explore their experiences of joint working and use of joint products, and the context in which HTA cooperation will have to be implemented.

In Year 3, WP7 worked with WP6b to undertake a case study on the use of EUnetHTA tools and guidelines in agency procedures and the effect of choosing different tools and methods on uptake of joint REAs. The case study was undertaken through an online survey sent to all WP7 partners and 10 follow-up interviews were undertaken with selected cases. The findings of the case study were incorporated into the 3rd Implementation report (publication May 2019).

Publicly Available Documents
Year 3 Case study on use of EUnetHTA tools and methodology guidelines
https://eunethta.eu/wp-content/uploads/2019/06/May-2019-Implementation-report_appendix_case-study-interview-summaries_Final-May-2019.pdf

FINAL DELIVERABLE – EVALUATION REPORT

WP7 is working on our final deliverable *"an evaluation report with the outcomes of the changes to assessment procedures against adoption metrics and including the Member States' experiences"*.

The report is being compiled through analysis of existing EUnetHTA datasets and interviews and new data collection and interviews. We will be consulting on the draft report in May 2020, in advance of final publication in June 2020.

The report will address the following research questions:

- Compared with Joint Action 2 (JA2), has there been an increase in JA3 in the number and uptake of EUnetHTA Joint and Collaborative Assessments?
- What is the relationship between changes in uptake and changes in EUnetHTA Joint and Collaborative Assessment processes, including:
  a. changes that were implemented between JA2 and JA3, and;
  b. changes that were implemented in JA3?
- To what extent are the structures, methods and processes being implemented "fit for purpose", meeting the individual needs of relevant Member States in terms of timeliness, relevance, transparency, inclusivity and scientific rigour?
- What are the key scientific and procedural features that need to be put in place by EUnetHTA, Member States, and where relevant industry stakeholders, to maximise implementation of Joint and Collaborative Assessments in a future model of HTA cooperation?
- What support for implementation (e.g. implementation advisers, mechanisms for shared learning, measurement and evaluation of implementation) should be built into a future model of HTA cooperation?

TECHNICAL SUPPORT FOR THE DEVELOPMENT OF A MODEL OF HTA COOPERATION

WP7 is supporting WP1 to develop the scientific and technical mechanism for sustainable HTA cooperation. The focus of the model is on related recommendations at the scientific and technical level, emphasising the governance, participation, coordination, processes and infrastructure required to produce outputs and implement tools and services that will support ongoing HTA collaboration.

This activity is ongoing. The first stage of the work was to audit existing elements of a model of HTA cooperation. Work packages provided information about existing documents, tools and templates, and identified areas that are missing or require improvement. This information is being used to develop discussion papers that will identify key missing elements or areas requiring improvement, and the next steps to addressing these.

STAKEHOLDER ENGAGEMENT

Through the implementation network, WP7 continues to reach out to HTA users and producers who are not part of EUnetHTA to support awareness of EUnetHTA and use of EUnetHTA assessments and tools more widely. A stakeholder consultation is planned for our final deliverable.

AN OVERVIEW OF WHAT'S NEXT

- Produce a final evaluation report with implementation outcomes from EUnetHTA JA3 (May 2020) and recommendations for developing a permanent model of HTA cooperation (May 2021).
- Continue to provide technical support to WP1 for a model of HTA cooperation.

AN OVERVIEW OF TRANSVERSAL GROUPS IN EUNETHTA

Update for the Assembly & Forum – April 2020

TASK GROUPS

FUTURE MODEL OF COOPERATION ON HTA (FMC-HTA)

Chaired by Marcus Guardian, ZIN

OBJECTIVES

- Develop a complete blueprint for future European collaboration on HTA post-EUnetHTA JA3.
- The focus of this model and related recommendations will be primarily at the technical level, emphasising elements of HTA products and the coordination of European-level efforts. The orientation of these efforts will be output-driven alongside products and services HTA bodies are expected to provide.
- Such a model will take into consideration the achievements of current and former Joint Actions, as well as the Legislative Proposal on a European HTA framework, currently under discussion before Parliament and Council.

UPDATE

- EUnetHTA partners were asked to comment on a preparatory report describing existing elements of a model of HTA cooperation, together with initial ideas about areas for improvements and missing elements.
- Using the comments on the report, an initial sifting exercise was coordinated by NICE within the task group to agree on which areas to take forward for discussion.
- A series of three papers have been produced by NICE to support further discussion on the agreed areas. These primarily revolve around 1) strategy, governance and participation (Executive Board), 2) procedures, infrastructure and evaluation (Project Management Group) and 3) scientific guidance (FMC-HTA Task Group).

- The discussions resulted in priority areas which were taken to the Board for further scrutiny before forming the basis of:
  - a report that summarises the elements of a model of HTA cooperation that have already been defined within the Joint Action, and which elements of a model of HTA cooperation should be improved, abandoned, or are missing, and;
  - a roadmap, recommending next steps in order to improve or develop the elements identified in the first stage.
- The report is currently being drafted by NICE and will be made available as part of a EUnetHTA-wide partner consultation in Q2 2020.

CONFLICT OF INTEREST (COI)

Chaired by Giovanni Tafuri, ZIN

OBJECTIVES

- Ensure consistent understanding and application of the EUnetHTA DOI procedure.
- Check in: What is working well? What needs to be clarified/improved?
- Identify limitations of the DOI procedure and tool (i.e., template).
- Develop new adapted procedures and tools.

UPDATE

- In year four, the task group established a committee for the assessment of potential conflict of interest related to the involvement of patients or healthcare professionals in the activities of Joint Assessments, Early Dialogues, or PLEGs. The committee consists of representatives from the EUnetHTA Secretariat, WP4, and WP5. Since the creation of the committee, assessments are being conducted according to the EUnetHTA procedure guidance for handling declarations of interest and confidentiality issues. The full procedure and form is available on the EUnetHTA website under Declaration of Interest (DOI).

PATIENTS, CONSUMERS, AND HEALTHCARE PROVIDERS (P&C/HCP)

Chaired by Giovanni Tafuri, ZIN

OBJECTIVES

- To define a common/consistent strategy for P&HCP contribution to EUnetHTA WP4&5 activities and to facilitate the deliverables, namely of WP4 and WP5, with respect to how patients/consumers (P&C) and healthcare providers (HCP) will be involved at the project level.

UPDATE

- In year four, following the paper on 'Patient Input in Relative Effectiveness Assessments' previously produced by the task group, a similar document is being finalised in relation to the involvement of healthcare professionals in the EUnetHTA REA process.

HTA AND MDR/IVDR- MEDICAL DEVICES

Chaired by Claudia Wild, AIHTA

OBJECTIVES

- To explore possible synergies between EUnetHTA activities on Medical Devices and in-vitro diagnostics, and the regulators (Competent Authorities supported by EU Commission (DG GROW) in implementing the MDR/ IVDR) – similar to EMA-EUnetHTA collaboration in the area of medicinal products.

UPDATE

- Two workshops on synergies were held in May 2018 and May 2019 (output documentation available on the EUnetHTA website).
- A third workshop will be held in November 2020.

EUNETHTA COMMON PHRASES AND GRADE (ECP-GRADE)

Chaired by Rudy Dupree, ZIN

OBJECTIVES

- To avoid the use of sentences/words in an assessment report which may unintentionally imply or predetermine reimbursement decisions in some jurisdictions.
- To recommend on the use or non-use of GRADE or other internationally adopted rating systems in Joint Assessments.
- To provide a scenario-based set of standardised formulations regarding the textual presentation of results and conclusions in PT & OT Joint Assessments for increased consistency.

UPDATE

- The subdeliverable 'negative list' was submitted to the Executive Board for information. The 'negative list' contains phrases the task group agreed on should be refrained from being used in Joint Assessments.
- The positive list is strongly dependent on whether or not an evidence grading system is used. Therefore, the task group will wait on creating a positive list of phrases until the decision/choice of grading system has been made.
- We have completed a scoping study of existing international evidence grading systems. A meeting with the task group and the GRADE working group will be arranged in March to explore obstacles and discuss ways to facilitate the further use of GRADE. Findings and statements will be presented to the Board.

SUBGROUPS

SUBMISSION DOSSIER AND ASSESSMENT TEMPLATE - PHARMACEUTICALS (SDAT-PHARMA)

Chaired by Sari Susanna Ormstad, NIPHNO

OBJECTIVES AND UPDATE

(of the submission dossier template work)

- To collect feedback from EUnetHTA partners on what information and data would be required in a future template. Based on the feedback, provide recommendations on a future template (ongoing activity).
- If needed, make minor but necessary amendments to the current (JA2) template, based on the outputs and recommendations of other EUnetHTA subgroups and task groups.

OBJECTIVES AND UPDATE

(of the assessment report template work)

- To compare the current EUnetHTA assessment report template (revised in March 2019) with national HTA templates to identify areas of improvement (completed activity).
- To collect feedback on the current template from authoring teams and EUnetHTA partners (ongoing activity).
- To collaborate with and use the output of other EUnetHTA subgroups and task groups (ongoing activity).
- To make minor changes to the current template and provide recommendations for improvement to a future template. This activity will be based on the input received on objectives 1, 2 and 3.

Timeframe: The subgroup started its work in November 2019, and will finalise its deliverables by the end of May 2020.

PICO (PICO)

Chaired by Luciana Ballini, RER

OBJECTIVES

- To develop an official document providing guidance on the scoping process and the development of research question(s), i.e. PICO(s), to be reported in the Project Plan (PP) and developed in the Relative Effectiveness Assessment (REA).
- To develop a document applicable to both pharmaceuticals and other technologies, addressing and highlighting specific issues where necessary.
- To state which elements of methods must be reported in the Project Plan/Protocol.

UPDATE

Meetings:
The kickoff meeting was held on 17 January 2020, during which the following was agreed:

- The subgroup will cooperatively liaise with and maintain regular contact with the Submission Dossier and Assessment Template Subgroup (SDAT-PHARMA), the GRADE and Common Phrases Task Group (ECP-GRADE), the HTA Core Model Task Group, and the Early Dialogue Working Party (EDWP).
- The development of research questions will be based on the assessment of policy questions (for example, what are the benefits of an intervention within standard care?), rather than on the availability of data.

A subgroups coordinators meeting was also held on 11 February, during which a discussion took place on:

- The pros and cons of the development of research questions based on policy questions relevant for all agencies, vis-a-vis basing the REA only on the pMAH's proposal of PICO.
- Developing consistency between the Joint Assessment approach in developing PICO(s), and the Early Dialogues' approach on advising on the research questions and prerequisites for HTA bodies.

Next Steps:
The SDAT-PHARMA Subgroup will work on a list of issues and questions which they would like addressed and share this with the PICO Subgroup.

OTHER CROSS-WORK PACKAGE GROUPS

HTA CORE MODEL

Chaired by IQWiG

OBJECTIVES

- The main objective of the group is the revision of the Core Model to provide a clear and easy way to handle structure, and to provide scientific guidance which can easily fit to new scientific results, as well as to provide support for the scientists working on Joint Assessments through the integration of the HTA Core Model into the EUnetHTA Companion Guide.
- The first aim is to adapt the reporting structure of the Core Model by developing a set of templates for the project plan, and for the assessment reports of different applications of the HTA Core Model.
- The second aim is to outsource methodological guidance from the HTA Core Model into separate Methodological Guidelines and identify any additional guidelines that may be required.

UPDATE

- The Core Model Working Party is currently working on a template for a full HTA of Other Technologies (OT) that is comprised of all nine domains and links to guidelines, SOPs, and other EUnetHTA guidance.

TOPIC IDENTIFICATION, SELECTION AND PRIORITISATION (TISP)

Chaired by Vigdis Lauvrak, NIPHNO

OBJECTIVES

- To develop and refine a system of horizon scanning, topic selection and prioritisation in close collaboration with the relevant work packages.

UPDATE

- The Joint Production Lead Partner and a working group, consisting of members from several WP4 partners, have developed recommendations for Horizon Scanning and Topic Identification, Selection and Prioritisation (TISP) processes in the context of European cooperation on HTA.
- The EurosScan toolkit, background literature, collaboration with the European Medicines Agency (EMA), stakeholder input, and two pilots have informed discussions of the authors leading to the recommendations. The pilots resulted in the EUnetHTA Prioritisation Lists (EPLs). The EPLs consist of individual compounds/ technologies that are of significant interest to national HTA agencies. The EPLs stand complementary to the already well-established mechanism for the voluntary submission of topics. The recommendations, EPLs, and the TISP pilot evaluation reports can be accessed on the EUnetHTA website.
- The recommendations are from the perspective of HTA assessors involved in EUnetHTA relative effectiveness assessments (REAs). The recommendations are generic in the sense that they are valid for different models of European cooperation on HTA. The main conclusion is that transparent, unbiased and efficient horizon scanning services should inform the prioritisation of European cooperation on HTA. Due to uncertainties regarding future models for cooperation and legislative regulation, we (the TISP group) were not able to do provide recommendations on the ownership and financial responsibilities for horizon scanning and the TISP process, nor detailed criteria for selection and prioritisation. These are important areas that remain to be defined.