Engaging stakeholders in EUnetHTA

A summary of external stakeholder engagement activities in EUnetHTA Joint Action 3

Produced by the EUnetHTA Secretariat in May 2021

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1.Abbreviations

Please find below a list of abbreviations referenced throughout the document.

Abbreviation	Full word
AETS-ISCIII	Agencia de Evaluación de Tecnologías Sanitarias del Instituto de Salud Carlos III, Spain
AIHTA	Austrian Institute for Health Technology Assessment (formerly known as LBI-HTA)
COI	Conflict of Interest
COIC	Conflict of Interest Committee
CRO	Contact Research Organisation
DOI	Declaration of Interest
EBMT	The European Society for Blood and Marrow Transplantation
EC	European Commission
ECA	EUnetHTA Confidentiality Agreement
ED	Early Dialogue
EDC	Early Dialogue Committee
EDWP	The Early Dialogues Working Party
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EPAR	European Public Assessment Report
EPF	European Patients Forum
EPL	EUnetHTA Prioritisation List
EU	European Union
EUnetHTA	European Network for Health Technology Assessment
EURORIDIS	European Organisation for Rare Diseases
EXB	EUnetHTA Executive Board
F2F	Face-to-face
FAQ	Frequently asked questions
FMC-HTA	Future Model of Cooperation
GA	Grant Agreement
G-BA	Gemeinsamer Bundesausschuss
HCP	Healthcare Providers
HTA	Health Technology Assessment
HTAb	Health Technology Assessment bodies
HTAi	Health Technology Assessment International
INAHTA	International HTA Database
ISPOR	The Professional Society for Health Economics and Outcomes Research Company
JA3	Joint Action 3
LVAD	Left ventricular assist device
NICE	National Institute for Health and Care Excellence
P&C	Patients & Consumers
P&C/HCP	Patients, Consumers, and Health Care Professionals
PC	Parallel Consultation
PICO	Population Intervention Comparative Outcomes
PLEG	Post Launch Evidence Generation
PMG	EUnetHTA Project Management Group

REA	Relative Effectiveness Assessments
REQueST tool	Registry Evaluation and Quality Standards Tool
SDAT-PHARMA	Submission Dossier and Assessment Template (Subgroup)
TG	Task group
TISP	Topic Identification, Selection and Prioritisation
WP	Work package

2.General introduction and purpose of paper

2.1.Introduction and purpose of this paper

Broad and sustainable stakeholder involvement is a continued priority for EUnetHTA.

The aim of this document is to:

- Focus on external stakeholders.
- Bring together product-related progress on stakeholder engagement.
- Provide a snapshot of all stakeholder-related activities throughout the course of Joint Action 3 (JA3).

2.2.Types of stakeholder groups

The JA3 Grant Agreement (GA) identifies the following as the types of stakeholder groups with whom EUnetHTA should interact (in alphabetical order):

- Healthcare providers and organisations (including healthcare professionals and hospitals).
- HTA organisations (those outside the EUnetHTA consortium).
- Industry (technology producers, manufacturers).
- Patient and consumer organisations.
- Payers and policymakers.
- Regulators (pharmaceuticals and medical devices, EU and national).
- Research and academia.

Note. The above list is non-exhaustive. There may be other groups of stakeholders with whom EUnetHTA interacts and endeavours to engage that are not specifically listed.

2.3.Types of participation

Participation defines who and how individuals, groups and organisations are to be involved in HTA cooperation.

The involvement of external stakeholders in EUnetHTA Joint Action 3 is organised through:

- Participation in the EUnetHTA Forum.
- Participation in work packages (subject to guidance from the Executive Board).
    - Public consultations on select deliverables.
    - Facilitation of the provision of specific subject matter, information/knowledge on specific technical questions, i.e. a more targeted consultation approach.
    - Participation in joint production.

3.EUnetHTA Secretariat

The EUnetHTA Secretariat has endeavoured to involve stakeholders in its activities through a variety of methods, drawing upon its coordinating function to bring partners and stakeholders together over the course of JA3.

3.1.Meetings

Meetings are a vital part of keeping stakeholders up-to-date, managing expectations, and brainstorming ideas for further collaboration. Throughout JA3, a number of meetings were held, all of which aimed to enhance the way EUnetHTA involved stakeholders in its HTA processes.[1] Table 1 presents an overview of the meetings held between June 2016 and June 2021.

Date	Stakeholder	Title of meeting	Description
13.06.2016	Industry	Meeting with MEDTECH stakeholders	One of the first meetings of the Joint Action, this meeting intended to present the aims and objectives of the project to medical technology stakeholders and obtain their feedback on the project's plans.
19.10.2016 – 21.10.2016	All	EUnetHTA Forum	The first Forum of the Joint Action brought together stakeholders and the newly formed EUnetHTA work packages for a day of discussion on the project's aims and objectives.
08.03.2017	Patients and consumers	Consulting meeting with stakeholders representing European patient and consumer organisations	Led by the Secretariat, this meeting served as a general exchange between EUnetHTA and stakeholders representing patient and consumer organisations.
14.09.2017	All	2017 EUnetHTA Forum	During the 2017 Forum, stakeholders were provided with an update on the progress of JA3 as well as information on stakeholder involvement to date. Two panel sessions were held, with one on horizon scanning and topic selection, and another on the use of additional data from clinical practice for HTA. Stakeholders both contributed to the agenda (identification and invitation of speakers for specific sessions) and participated in the day's proceedings. The update, together with the interactive panel sessions, thus allowed stakeholders to be involved and take stock of the project's progress.

[1] Please note: Only large-scale meetings have been listed in this table. Several smaller meetings have also taken place over the course of the Joint Action, and these were organised by partners as they sought to involve stakeholders within the individual EUnetHTA products on which they lead.

20.10.2017	Industry	Technical Meeting	The annual meeting with EFPIA is an opportunity for EUnetHTA to gain feedback from industry representatives, and vice versa.
26.01.2018	Patients and consumers	Consulting meeting with stakeholders representing European patient and consumer organisations (TG)	A meeting was held with a number of different stakeholders representing European patient and consumer organisations. Work packages two, four, and five provided updates and a brief discussion ensued where Patient and Consumers organisations could share their proposals about engagement in Early Dialogues and Joint Assessments.
24.05.2018 – 25.05.2018	All	2018 EUnetHTA Forum	Four panel sessions were held during the 2018 EUnetHTA Forum. Issues discussed included: the relevance, timeliness and quality of EUnetHTA's work, preparing for disruptive innovation, synergies between Joint Assessments and Early Dialogues, and the changing landscape of European HTA. Stakeholders were approached for agenda suggestions (identification and invitation of speakers for specific sessions) at the beginning of the process and participated in the numerous panel sessions. All four sessions were well received and contributed to the ongoing dialogue between EUnetHTA and its stakeholder community.
29.05.2018	Regulators, Notified Bodies	1st Workshop for Coordinated Activities on HTA and Medical Device Authorities	Hosted by AIHTA (Austria). The EUnetHTA workshop intended to explore the possibilities of a permanent exchange and cooperation between EUnetHTA, Competent Authorities responsible for medical devices, and Notified Bodies.
11.12.2018	Industry	EUnetHTA 2018 Technical Meeting with Industry	The annual meeting with EFPIA is an opportunity for EUnetHTA to gain feedback from industry representatives, and vice versa.

16.01.2019	All	HTA Network Stakeholder Pool Meeting	The meeting was split into two parts, part a and part b. Part A: Patient and health care professional experts involvement This part of the meeting focused on the principled involvement of patients and clinical experts in the HTA process. Criteria to identify patient and clinical experts were also discussed both for current and possible future EU cooperation. Part B: Cooperation on identification and prioritisation of health technologies for joint work The discussion focused on possibilities for information sharing between industry and EUnetHTA with the objective of early identification of relevant technologies for Joint Assessments. On pharmaceuticals, a short presentation was followed by a discussion during which all sides exchanged their current experiences.
14.02.2019	Payers	EUnetHTA – Payers Meeting	This exchange between payer representatives and EUnetHTA focused on work package updates, a discussion on progress so far (in regard to payer involvement), and an update on the HTA legislation.
21.03.2019 – 22.03.2019	Healthcare providers and professionals	EUnetHTA - Health Care Providers and Health Care Professionals	This meeting with healthcare providers and professionals served as a 'check-in' to take stock of progress and exchange relevant updates. There was also a first presentation of the EUnetHTA policy on managing conflicting interests for external stakeholders.

11.04.2019	All	2019 EUnetHTA Forum	The 2019 Forum saw the introduction of breakout sessions to better facilitate the viewpoints of a greater and more diverse number of stakeholders. Five were held in total, ranging from bridging the gap between EUnetHTA and healthcare providers, to discussing the uptake of pharmaceutical JAs on a national level. A standard panel session, discussing unmet medical needs, was also held. A journal article summarising the day's findings was published in early 2020. The article was authored by the Secretariat and the day's participants, and was published in the International Journal of Technology Assessment in Health Care.
27.05.2019	Industry	EUnetHTA Meeting with MedTech Europe	This meeting focused on how industry and EUnetHTA can work better together, using past experiences to plan for the future.
28.05.2019	Regulators, Notified Bodies, industry, health care providers, patients and payers.	2nd Workshop for Coordinated Activities on HTA and Medical Device Authorities	Hosted by AIHTA (Austria), this meeting focused on the perspectives of different stakeholders on collaboration on medical devices in light of the medical device regulation. The meeting featured voices from the HTA community, industry (MedTech Europe), payers, and patients (EPF).
06.06.2019	Patients and consumer organisations	EUnetHTA - Patient & Consumer Organisations	This meeting was the second step of the inclusion of the Patients and Consumers organisations from the HTA Network Stakeholder Pool in the work of the EUnetHTA Task Group on Patient Involvement.
03.12.2019	Industry	EUnetHTA 2019 Technical Meeting with Industry	The annual meeting with EFPIA is an opportunity for EUnetHTA to gain feedback from industry representatives, and vice versa.
03.02.2020	Industry	EFPIA/HTA WG Meeting	Meeting with EFPIA and representatives from GBA/HAS to present the status of the Early Dialogue Financing Mechanism.
04.11.2020	Regulators, Notified Bodies, industry (speaker), healthcare providers	3rd Workshop for Coordinated Activities on HTA and Medical Device Authorities (online)	Hosted by AIHTA (Austria). Besides an update on the progress in implementation of the MDR/IVDR and on the status quo of the proposal for a regulation on health technology assessment in the European Union, a dialogue on the evaluation of software as a medical device was initiated.

12.11.2020	Industry	Industry feedback workshop – PTJA	The second industry feedback meeting brought together industry representatives who have worked on a EUnetHTA assessment for half a day of feedback and information exchange.
01.12.2020	Industry	EUnetHTA 2020 Technical Meeting with Industry	The annual meeting with EFPIA is an opportunity for EUnetHTA to gain feedback from industry representatives, and vice versa.
04.12.2020	All	EUnetHTA Stakeholder Meeting	The meeting brought together stakeholders in a half-day session where: 1. Work packages provided updates, 2. NICE provided an update on the Future Model of Cooperation White Paper and 3. The draft document "Engaging stakeholders in JA3" (this document) was presented. Stakeholders had the opportunity to ask questions and provide verbal feedback.
15.04.2021	All	2021 EUnetHTA Forum	The final Forum of EUnetHTA JA3 hosted three stakeholder-orientated panel sessions: Session 1: Challenges to a lifecycle approach to EUnetHTA's work: Lessons learned from the current Joint Action Session 2: Research needs in HTA: What is needed today and what we will need tomorrow Session 3: EUnetHTA: The past, the present and the future - Lessons learnt and recommendations The agenda was developed in order to provide stakeholders with the opportunity to reflect as well as provide feedback for the future.

Table 1 An overview of all meetings with stakeholders from June 2016 to June 2021.

3.2.Coordination

3.2.1.Stakeholder List

The Secretariat also ensures stakeholder involvement in EUnetHTA by maintaining a list of stakeholder contacts. This list, originally created by the lead partner for Dissemination (Work Package 2 - AETS-ISCIII, Spain) contains information on stakeholders from the different groups EUnetHTA works with. The list is regularly updated and is used by partners as well as the Secretariat as a reference point for conducting consultations, or any other activities where stakeholder feedback is required.

The list has evolved throughout Joint Action 3 and now contains details of more than 50 representatives from a variety of healthcare and related organisations.

Please note: This list is separate from the HTA Stakeholder Pool, which is a stakeholder list of the 'HTA Network' managed by the European Commission.

3.2.2.Contribution to meeting agendas

The EUnetHTA Forum is a key annual event whereby EUnetHTA hosts more than 250 delegates for a day of discussion on trending topics in the HTA community. The event is also used as an opportunity to take stock of EUnetHTA's progress and update a global audience on the successes, achievements and barriers over the past year.

Throughout JA3, the agenda for the day has been co-created by the Secretariat and stakeholders. Stakeholders are the first group approached for topic suggestions (speaker identification for dedicated sessions), and the Secretariat endeavours to ensure opinions are taken into account to develop a dynamic agenda which serves the interests of both EUnetHTA partners and EUnetHTA's stakeholders. The agendas from previous years show that the event generates enthusiasm from across the spectrum of stakeholders – from patients to healthcare professionals, and from industry to payers. The event's success over the past years shows that collaboration in this area is vital and is one of the major successes of JA3.

3.2.3.Collaboration with the HTA Network Pool

Next to EUnetHTA is the HTA Network, a separate but linked network that focuses its activities on strategic issues relevant to EU cooperation on HTA. It provides strategic recommendations to the scientific and technical cooperation mechanism of EUnetHTA JA3. The HTA Network has a specific Stakeholder Pool managed by the European Commission. EUnetHTA JA3 collaborates closely with the EC to ensure that members of the HTA Network Stakeholder pool are informed about and included in activities of EUnetHTA JA3. EUnetHTA addressed the HTA Network Stakeholder Pool (respectively, patients and consumers, health providers, industry etc…) to participate or contribute to some structured and ad-hoc EUnetHTA activities on a voluntary basis (e.g. identification of patients for Early Dialogue and Joint Assessment).

*3.2.4.*Participation in conferences and events

Over the course of Joint Action 3, stakeholders have been regularly invited to attend EUnetHTA-organised meetings, and vice versa. This informal 'mutual platform provision partnership' has allowed both parties to facilitate thought-provoking panel sessions and debates on advances and trends in the HTA community and, on some occasions, capacity-building, for example participation in mutual learning sessions like the EURORDIS Summer School.

Working together on academic debate within HTA also provides the public with unique opportunities to scrutinise all parties. This consequently helps increase accountability and transparency for the benefit of the ultimate stakeholder, the patient.

3.2.5.Collaboration with EMA

The European Medicines Agency (EMA) is a decentralised agency of the European Union and is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union.[2]

Since 2010, EUnetHTA and EMA have been in regular contact to exchange information and discuss various issues of mutual interest.

[2] European Medicines Agency. Retrieved in October 2020 from the EUnetHTA website. Link: https://www.eunethta.eu/ema

Cooperation started with a project on EPARs. The joint EMA-EUnetHTA project responded to a political recommendation to consider how the assessment of the favourable and unfavourable effects of a medicine, as contained in the EMA's European Public Assessment Reports (EPARs), can best be used to inform the assessment of the relative effectiveness of new medicines for HTA purposes in EU Member States.[3]

In JA3, this was followed by discussions and concrete cooperation on the following topics via the EUnetHTA-EMA Work Plan:

- Databases for post-licensing studies;
- New EU pharmacovigilance legislation;
- Significant benefit for orphan medicinal products;
- EUnetHTA's rapid model for Relative Effectiveness Assessment of Pharmaceuticals (pilot and future developments, i.e. possibilities to streamline the timelines of EUnetHTA Joint Assessments with EMA assessments);
- Early scientific advice, EMA-HTA scientific advice;
- Regulatory and HTA methodological guidelines.

Discussions take place at the bi-annual meetings between EUnetHTA and EMA representatives, via participation of EMA as observer in relevant activities of the EUnetHTA Joint Actions, through regular meetings regarding the conduct of parallel consultations (Early Dialogues conducted by HTA bodies in collaboration with EMA), and by mutual commenting on specific documents produced by either of the organisations.

EUnetHTA and its members also participate in the EMA-supported ENCePP network.

A number of formal EUnetHTA-EMA Bilateral meetings have been held throughout JA3 and these are listed below:

Meeting date	**Meeting location**
07.12.2016	London, United Kingdom
15.12.2017	London, United Kingdom
07.12.2018	London, United Kingdom
04.07.2019	Diemen, The Netherlands
21.11.2019	Diemen, The Netherlands
13.07.2020	Virtual
16.12.2020	Virtual
28.04.2021	Virtual

Table 2 List of EUnetHTA-EMA Meetings over JA3.

Minutes from all meetings are co-produced and published on the EUnetHTA and EMA website.

[3] https://www.ema.europa.eu/en/documents/press-release/outcome-report-first-european-collaboration-between-regulators-hta-organisations-improving_en.pdf

3.2.6.Collaboration with other initiatives

As well as the European Medicines Agency, EUnetHTA has also collaborated closely with a number of other organisations and networks which include:

- Health Technology Assessment International (HTAi)
- The International Network of Agencies for Health Technology Assessment (INAHTA)
- The Professional Society for Health Economics and Outcomes Research Company (ISPOR)

3.2.7.Task groups and subgroups

3.2.7.1.Patients, Consumers, and Healthcare Providers (P&C/HCP) Task Group

The EUnetHTA task group on Patients, Consumers, and Health Care Professionals (TG P&C/HCP) was established by the EUnetHTA Secretariat to support the development of processes for Patient, Consumer, and Healthcare Provider involvement in EUnetHTA assessments and Early Dialogues (ED). TG P/C&HCP consisted of representatives from various work packages (WPs) within EUnetHTA JA3 and had weekly to monthly meetings with discussions on national experiences of stakeholder engagement, as well as on proposals on how to involve such stakeholders in Relative Effectiveness Assessments (REAs). Additionally, two face-to-face meetings took place with stakeholders representing European patient and consumer organisations, as well as with other organisations.

During JA3, the task group produced the following documents:

- Patient Input in Relative Effectiveness Assessments. The aim of this document is to reach a common understanding of patient input goals and preferred ways to engage with patients, and benefit from their inputs for the REA production within JA3. The document stems from consultation with the patient community and EMA. [4]

- EUnetHTA Patient Input Template. The form stems from the 'Patient Group Submission Template for HTA of Health Interventions', developed by HTAi, and it is intended to collect the views and experiences of patients and carers/care-givers to understand patients' unique perspective on the disease/condition of the health intervention which is being assessed. This template is available in all EU official languages. [5]

- A flyer for patients has been created to help healthcare professionals and organisations introduce EUnetHTA to patients and outline how they can get involved by submitting their own input in REAs.[6]

- Healthcare Professional Involvement in REAs. This document describes the process of gathering input from Healthcare Professionals in EUnetHTA REAs[7].

[4] https://eunethta.eu/wp-content/uploads/2019/06/Final_290519_Patient-Input-in-REAs.pdf

[5] https://eunethta.eu/stakeholders/patients/

[6] https://eunethta.eu/wp-content/uploads/2020/01/Electronic-Flyer-Patients.pdf

[7] https://eunethta.eu/stakeholders/health-care-providers/

3.2.7.2.Topic identification selection and prioritisation (TISP)

Stakeholders were invited to suggest possible topics for inclusion in the prioritisation exercise. Patient organisations submitted four suggestions for inclusion in TISP. Also, external stakeholders were invited to comment on the TISP recommendations during a public consultation. During the TISP pilot, a collaboration with the pharmaceutical regulator (EMA) was established. Due to the ongoing changes in the regulation of medical devices and in-vitro diagnostics, no such talks could be initiated with regulators in these fields. In a structured form and at predefined time points, EMA provided publicly available data on pharmaceuticals in the EMA process. This collaboration was extremely beneficial for the TISP work as it helped to conduct a feasibility assessment, and thus helped to identify which compounds could be excluded from the TISP work. Furthermore, the TISP recommendations states that Horizon Scanning supporting TISP should be open to proposals from the public.

3.2.7.3.Conflict of Interest (COI) Task Group

A EUnetHTA Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA Confidentiality Agreement (ECA) forms was developed to assess potential conflict of interest of individuals representing HTA bodies participating in a EUnetHTA task (internal) and experts (external). Each form is then assessed by the Conflict of Interest Committee (COIC) who evaluates the form and approves the individual for inclusion within a EUnetHTA joint product. The Committee is made up of individuals from the following organisations: ZIN, AIHTA, G-BA, HAS. The guidance, the DOI and ECA forms, FAQ and information on the DOI database can be found here: https://eunethta.eu/doi/.

3.2.7.4.Future Model of Cooperation on HTA (FMC-HTA) Task Group

As part of work on the Future Model of Cooperation on HTA, EUnetHTA is developing a White Paper. This aims to compile the outputs of JA3 into a paper that describes, in a single framework, the way EUnetHTA worked, what EUnetHTA has achieved, what has been learned, and what the project recommends for the future.

The White Paper was presented at a stakeholder meeting in December 2020 and stakeholders had the opportunity to ask clarifying questions. The paper also underwent a stakeholder consultation in April 2021.

3.2.7.5.Submission dossier and assessment template - SDAT-PHARMA Subgroup

In 2019, the Subgroup on Pharmaceutical Submission Dossier and Assessment Report Templates (SDAT-PHARMA) was established by the EUnetHTA Executive Board. This group comprises 17 experts from 13 EUnetHTA member organisations in 10 countries. The objectives of the subgroup are:

- To collect feedback from EUnetHTA partners on what information and data would be required in a future submission dossier template and, based on the received feedback, provide recommendations for a future (post-JA3) template.
- To evaluate the current EUnetHTA assessment report template (revised in March 2019), make minor changes to the template based on the received feedback, and share the rest of the feedback as recommendations for a future (post-JA3) template.

To meet the objectives above, the subgroup conducted two surveys among EUnetHTA partners in June-July 2020.

Due to the scope and timelines of the subgroup, it was not apt to involve stakeholders. However, after the subgroup outputs have been endorsed by the EUnetHTA Executive Board,

the recommendations for a future submission dossier template will be shared with EFPIA for their input. As agreed with EFPIA, their feedback will be included as an appendix to the recommendations.

3.3.Communications

3.3.1.EUnetHTA website

The website is the intended landing point for the majority of stakeholder engagement with EUnetHTA content. EUnetHTA communication channels serve to funnel users towards the site for access to latest publications, news, network information and history, plus everything else that explains the role EUnetHTA has played and continues to play within European HTA.

The site is WordPress-based and administered by the Communications Officer within the EUnetHTA Secretariat. The overarching aim is to maintain a location where stakeholders can easily navigate site pages to find the information they seek. This has required ongoing optimisation to suitably format the site for mobile devices as well as desktop, to ensure stakeholders can always get to where they need from wherever they are accessing the site.

Table 3 provides a summary of the dedicated website pages for each stakeholder.

Type of stakeholder	Description	Link to page
Patients and consumers	This page lists the outputs created for P&C involvement, such as the EUnetHTA questionnaire available in all official EU languages, calls for patient input and the patient leaflet.	Click here to access the page.
Healthcare professionals	This page lists the outputs created for HCP involvement.	Click here to access the page.
Payers	Payers are an integral stakeholder in the EUnetHTA network and documents pertinent to collaboration with them are captured here.	Click here to access the page.
Industry	The page includes information for companies who want to submit a compound for a EUnetHTA assessment.	Click here to access the page.

Table 3 An overview of the stakeholder sections available on the website.

3.3.2.EUnetHTA Magazine

The magazine provides a space where relevant HTA-related articles and content can be published via EUnetHTA member organisations and aligned partners. On a rolling basis, members and stakeholder groups are invited to submit articles for consideration so they may be scheduled accordingly in future issues. The magazine publishes quarterly, i.e. x4 issues per year that track the seasons. Publication is via the EUnetHTA website and channelled by social media news items.

Previously, the magazine was produced as a simple page numbered .pdf document for website/intranet publication and email dissemination. However, during 2019 this approach was shifted in favour of a web-based publication format called Foleon, to enable a more enjoyable user navigation, more effective cross-linkage to other EUnetHTA media, and user interaction tracking via embedded analytics. Additionally, this format provides more appealing graphical

elements and visuals, and formats specifically to user devices, whether mobile or desktop.

It should be noted that, due to the reassignment of priorities during 2020 around Covid-19 initiatives, the EUnetHTA Magazine has experienced interruptions in publication. As soon as partners are able to contribute, the magazine will publish accordingly.

For reference, access all prior issues of the magazine via this link.

3.3.3.Social media

EUnetHTA disseminates website-based publication and news information to a wider audience via LinkedIn and Twitter, with a current direct follower reach of 3,400 and 2,400 respectively. The role of social media platforms is to boost the window of visibility into EUnetHTA activity through brief, simple language that outlines the nature of a given news segment or specific publication, then to funnel the stakeholder to engage within the EUnetHTA website for further, more detailed information and content download.

LinkedIn and Twitter play an essential role in marking the progress of a EUnetHTA Assessment. Initially, a new assessment is announced to notify the HTA community of the project details, authoring team, and industry partners. Subsequent posts advertise a call for stakeholder participation, funneling candidates to website-based surveys, and provide links to an evolving website-based project page that lists the project plan, followed by the final assessment publication and related documents. Social media persistently call stakeholders back to specific developments in the assessment pathway and re-posts are published wherever a 'boost' is required.

Social media are also employed to create awareness of EUnetHTA member organisation activities, publications, or member representation of EUnetHTA activities at conferences, academic events, or with partner organisation interaction, such as with the European Commission, EMA, or EFPIA.

3.3.4.Other communications

EUnetHTA members are encouraged to regard the EUnetHTA website as the main landing point for stakeholder interaction with EUnetHTA work outputs and news. Therefore, members indirectly manage their respective areas of the website as they evolve via direct interaction with the Communications Officer, who administers the site in response to their requests.

Since there is a significant sense of respective 'ownership' of member-driven content on the site, members help the Secretariat to stay on top of site management through constant tracking of their respective areas.

For events specific documentation, news content, and graphical elements are created by the Secretariat for virtual or physical EUnetHTA gatherings, such as the annual Assembly & Forum Welcome Guide. Such publications aim to engage stakeholders with the relevant preparatory information to ensure collective awareness at events and to give a progress overview for the network. These involve input from various work packages, which is collated, edited, and formatted via the Secretariat team.

Finally, given the diverse international representation among EUnetHTA members and the fact that English is, more often than not, the second language of our membership, the Secretariat Communications Officer endeavours to provide a 'gate' for final editing and proofing of written language for work package deliverables. The aim is to ensure clarity of publication language for effective stakeholder engagement, while retaining the character and intent of the authoring teams' written styles.

4.Product-specific summary

4.1.Joint and Collaborative Assessments - Pharmaceutical and Other Technologies (WP4)

This section is split into the following four sections:

1) Patient engagement in EUnetHTA assessments
2) Healthcare professional involvement in EUnetHTA assessments
3) Plain language summaries
4) FAQ and other documents for industry involvement

In the development of these outputs, WP4 has interacted with the respective stakeholder group to discuss objectives, challenges, solutions and outcomes.

4.1.1.Patient engagement in EUnetHTA assessments

Recommendations on how to involve patients and patient representatives in EUnetHTA assessments have been finalised by EUnetHTA (click here to access the document *Patient Input in REAs* on the EUnetHTA website). 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 goal of patient contribution in assessments is 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.

EUnetHTA seeks to actively involve patients or patient representatives in assessments. This involvement is illustrated in Figure 1, in addition to the involvement of healthcare professionals. The numbers represent how many assessments have included each type of involvement.

For pharmaceutical assessments, it is mandatory to seek patient input. The project manager coordinates the identification process, facilitates the input approach, and documents this in a database. Two out of 18 assessments did not pursue patient engagement, due to the rapid nature of the specific COVID-19 Rapid Collaborative Assessments. The other 16 assessments did pursue patient engagement. For one of these, the online patient input template is still ongoing. 13 of 16 pharmaceutical assessments successfully involved patients (i.e. patients could be identified/recruited and/or the pursued approach was completed) (cut-off point: 18 November 2020). Pursued approaches were: one-on-one conversation (n=3) and use of online patient input template (n=13). Two assessments were unsuccessful in including patients (one-on-one conversation (n=1), online patient input template (n=1)). In one of the assessments where a one-on-one conversation was conducted, this approach occurred in a very late stage of the assessment phase and thereby limited the usability of the patient input. For two assessments where the online patient input template was used, no responses were received. However, for one of the assessments where no response was received to the online patient input template, the assessment team also had a one-on-one conversation with a patient.

In other technologies assessment, it is mandatory for the assessment team, together with the project manager, to discuss patient involvement. In case the assessment team, together with the project manager decide not to involve patients, a sound rationale needs to be given and

documented. 11 of 26 other technologies assessments successfully involved patients (i.e. patients could be identified/recruited and/or the pursued approach was completed) (cut-off point: 18 November 2020). For other technologies assessments, pursued approaches for patient involvement were: (online) patient input template (n=8), one-on-one conversation (n=5), group conversation (n=2), scoping e-/f2f meeting with patients/patient representatives (n=1), and other approaches (i.e. review of draft PICO, review of draft project plan or draft assessment report, involvement as a team member, use of national surveys, n= 13). In several assessments, more than one approach was used. However, if one approach was used multiple times within a single assessment, it was still counted as one. Not all led to successful patient involvement in assessments. This was the case for the use of the (online) patient input template (n=5), one-on-one conversation (n=1) and other approaches (review of scope, review of draft project plan or draft assessment report, or feedback on selection and importance of outcomes, n=7). Reasons for unsuccessful recruitment of patients included lack of response or unwillingness to participate, which was the case in seven assessments. Eight assessment teams did not plan for patient input due to tight timelines or lack of a specific patient group organisation.

Patient involvement was shown to be most useful in the scoping phase. Reasons for deviating methods in patient engagement between pharmaceutical and other technology assessments are around different nature of topics, timeframes, and the mode of project management. It is to be noted that upon request of the authoring team, different approaches or a combination of approaches can be used in both branches of assessment.

Currently, patient input is described in the method section of the report and there is a dedicated chapter where the teams include a summary (verified by the patients) of the one-on-one conversation, group conversation, scoping e-meeting, or key messages of the (online) patient input template results (if approved by the patient organisation that responded). However, more effort needs to be put into developing recommendations and guidance on how to use and implement patient input in assessment reports.

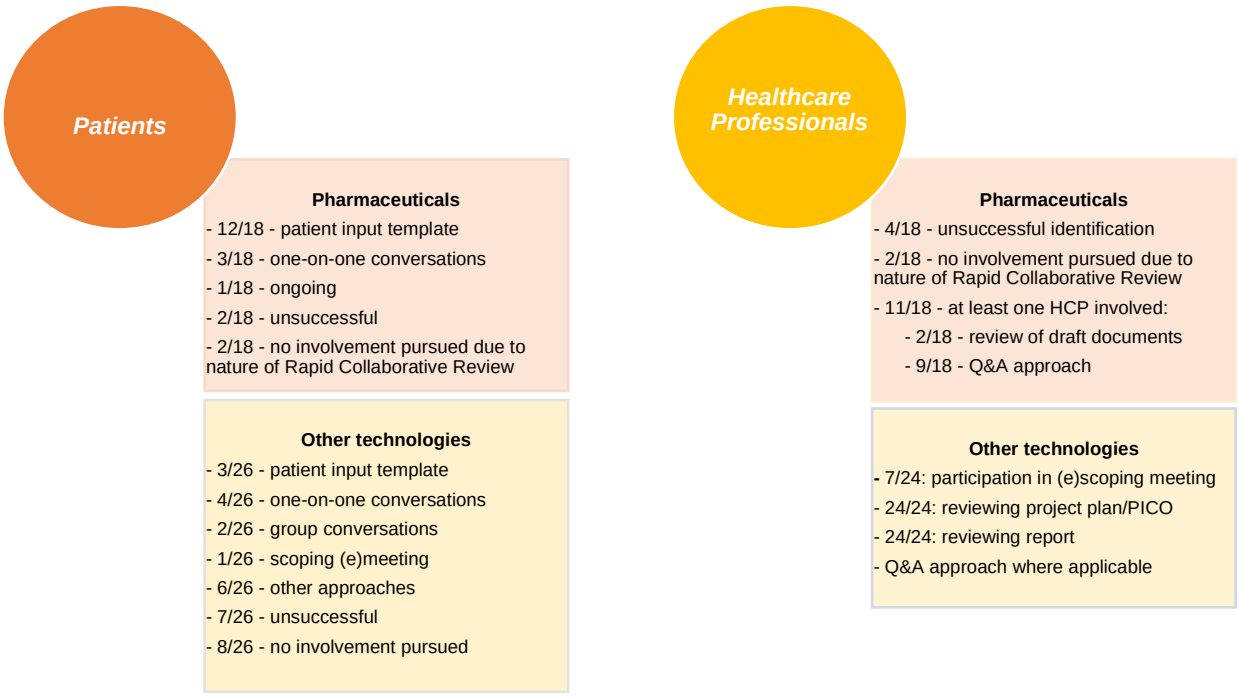

Figure 1 Successful engagement approaches for patient and HCP engagement. 'Successful' means that patients could be identified/recruited and/or the pursued approach was completed. 'Unsuccessful' means that no patients could be identified/recruited for any of the pursued approaches. It could be the case that more than one approach was used in one assessment.

The task group on Patients & Consumers and Healthcare Providers has developed the recommendations for patient input in REAs, the EUnetHTA Patient Input Template, an information flyer for patients (all available on the website[8]) and an evaluation questionnaire for patients. The EUnetHTA Patient Input Template has been translated in to 22 official EU languages in order to facilitate the completion of the template by patients/patient organisations[9]. The evaluation questionnaire for patients has been finalised recently and will be sent to individual patients and/or patient organisations that participated in a recent EUnetHTA assessment in JA3.

4.1.2.Healthcare professional involvement in EUnetHTA assessments

EUnetHTA has developed 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 were finalised at 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.

For pharmaceutical assessments, it is mandatory to seek involvement of clinical experts in the assessments, and this has been pursued for all assessments (n=16), but not for the Rapid Collaborative Assessments on COVID-19 compounds (data cut-off point: 18 November 2020). Clinical experts participated in 11 out of 16 assessments by means of reviewing the project plan and assessment report, (n=2) and Question and Answer approach (n=8). In one assessment, the identification is still ongoing. In four assessments, the identification was unsuccessful. Experiences in the pharma branch have shown that clinical experts are reluctant to partake in reviewing exercises due to resource constraints (most of the clinical experts are practicing medical doctors) and due to the low remuneration from EUnetHTA. In addition, half of the clinical experts that have expressed interest to participate were rejected due to a conflict of interest. Often, these experts had participated as Principal Investigator in the drug under assessment or a comparator drug.

For other technologies assessments, it is also mandatory to involve clinical experts. Several methods of involvement of clinical experts were applied and tested. In 24 out of 24 assessments, the clinical experts reviewed the preliminary PICO and/or the draft project plan, as well as the draft assessment. In seven out of 24 assessments, the clinical experts participated in a scoping (e-)meeting. Where applicable, the authoring team approached the clinical experts during the course of the assessment in order to pose questions or clarify any open issues (cut-off point: 18 November 2020). Dedicated SOPs with regard to the review of

[8] https://eunethta.eu/stakeholders/patients/ (Accessed 02.04.2020)

[9] https://eunethta.eu/eunethta-patient-input-template/

draft project plan and draft assessment, including checklists for clinical experts, were created. Experiences have shown that identification of experts can be difficult and time-consuming. In some instances, identified clinical experts needed to be rejected because of a conflict of interest. Looking for experts on the national level or via national databases proved to be most successful.

4.1.3.Plain language summaries

To facilitate the dissemination of EUnetHTA assessments, a template for plain language summaries of assessment reports has been developed. A structured consultation with selected HTA agencies, as well as the HTA Network Stakeholder Pool, were part of the development. Currently, the template is being tested for a variety of pharmaceutical and other technology assessments. The plain language summary aims to be understandable for patients and citizens.

4.1.4.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 industry and explain how manufacturers can be involved in assessments. The production procedure became more standardised as it evolved. In an attempt to keep track of changes in the procedure, templates and/or (methodological) guidelines, and ensure procedural fairness, an Industry Procedure Manual was developed. This manual gives detailed information about the production process tailored to the information needs of the (submitting) manufacturer.

4.2.Early Dialogues (WP5)

*4.2.1.*Patients

The methods by which EUnetHTA EDs involve patients was developed as a hybrid model. At the outset of JA3, patient experience within the EDWP members was minimal. The two exceptions were NICE and G-BA, although both used very different approaches. In that context we wanted to test multiple possibilities of patient involvement with different levels of engagement and expertise, and thus devised three approaches:

Approach	**Patient Deliverables**
Approach 1: Patient/ patient representative interviewed regarding the disease and their experience.	• Minutes of the interview • Patient contribution visible in final EUnetHTA recommendations • Feedback questionnaire and interview
Approach 2: Approach 1 + discussion with local HTAB regarding submission file (without applicant).	• Minutes of the interview • Patient contribution visible in final EUnetHTA recommendations • Feedback questionnaire and interview
Approach 3: Approach 2 + discussion with all participating HTABs regarding the submission file and participation in the F2F meeting with the applicant.	• Minutes of the interview • Patient contribution visible in final EUnetHTA recommendations • Share final EUnetHTA recommendations • Feedback questionnaire and interview

Table 4 Patient approaches and deliverables.

The approaches are based on a combination of those used across different HTAb. They were discussed within the EDWP and published on the EUnetHTA website.

In terms of recruiting patients, this is begun once the EDWP decision on eligibility is final. At that point, the EUnetHTA ED Secretariat begins contacting European and national associations to identify potential patient experts. Throughout JA3, the ED Secretariat tested centralising requests through a European network of associations and, in parallel, directly contacting national and European organisations. While patients were identified through both mechanisms, a significant majority of the patients were identified via direct contact with national and European patient associations. This result is due to a much faster response time by national associations (sometimes same day), and also due to a better acceptance regarding the compensation rules (no payment for services), Conflict of Interest, etc.

As soon as a patient is identified, which may take from a day or two to over a month, the ED Secretariat contacts them to schedule an introductory interview to discuss their potential involvement and to explain the following:

- EUnetHTA and what we do;
- The difference between HTAb and Regulators;
- What an ED is and what is expected of their participation;
- Answer any questions they may have regarding the process, EDs, etc.

The patient interview is generally conducted by the Scientific Coordinator and Rapporteur. However, it can also be coordinated by any of the participating HTAb, particularly if the interview is to be conducted in the national language. The interview may take place at any time from reception of the Final Briefing Book up until one week prior to the EUnetHTA e-meeting on draft positions (if written-only format) or the pre-F2F meeting (if face-to-face). Prior to the telephone interview, the patient receives a copy of the Patient Interview Guide. This allows them to know in advance the questions to be asked and, if desired, to pre-complete the guide. Following the interview, the patient/patient representative receives a draft of the minutes of the interview for validation and the finalised version is circulated to the entire EDC so that everyone is aware of the patient feedback. In addition, the minutes of the interview are included in the EUnetHTA Final Written Recommendations and (except for approach 1), the patient receives a copy of the EUnetHTA Final Written Recommendations. In all cases, the ED Secretariat shares a post-ED patient feedback questionnaire with the patients after the process has been completed, and conducts a final feedback interview with the patient(s) in order to receive their feedback on the process, but also in order to provide them any additional information or feedback.

Since Q2 2017, 122 requests for EDs have been received. Of these 122, 38 were accepted as ‘EUnetHTA’ EDs (PC or Multi-HTA). The patient involvement process officially began in Q1 2018 and, since then, 85% of the 39 ‘EUnetHTA' EDs have had patient participation (i.e. at least one approach used) and in several instances multiple approaches were used concurrently (up to three patients).

Approach	Number of EDs	Number of patients/ED
Approach 1 Individual patient - interviewed regarding the disease and their experience	6 EDs (3 with approach 1 & 2)	5 French patients 1 Spanish patient
Approach 2 Approach 1 + Discussion with local HTA body regarding submission file (without applicant)	18 EDs (4 with approach 2&3)	20 German patients 2 French patients 1 Italian patient 4 EU Representatives
Approach 3 Approach 1 + Discussion with all participating HTA bodies regarding the submission file and participation in the F2F meeting with the applicant	11 EDs (4 with approach 2&3)	8 EU Representatives 5 French patients

Table 5 Number of patients who have participated in an Early Dialogue.

4.2.2.Analyses of Patient Participation

Two types of analysis were conducted concerning the involvement of patients in EUnetHTA EDs. The first was an analysis of the feedback provided by all patients who participated during their feedback interview at the end of the ED procedure. This feedback helped shape how patients were recruited and informed, but also influenced the recommendations made by the ED Secretariat for post-EUnetHTA.

Following the conclusion of each ED, participating patients were interviewed based on a standardised feedback questionnaire. In total, 37 patients have been involved in the EDs completed during EUnetHTA JA3. Feedback was received from 23 of those participants.

Overall, the feedback was positive. Participants felt that the questionnaire used to guide the interview was helpful and led to real conversation. All patients responded that they felt that they had ample opportunities to express their opinion, and were happy to have the summary of their input included in the Final Written Recommendations. Nevertheless, participants signalled a continued need for training (e.g. BB very complex). A detailed analysis will be provided at a later date.

The second analysis was conducted as part of the overall qualitative analysis carried out by the Lead and Co-Lead partners on the first 21 EUnetHTA EDs (of which 16 included patients).

The overall high percentage of inclusion of patient input in the EUnetHTA Final Recommendations seen through this analysis proves the relevance of patient contribution to the ED process. The analysis assessed the main topics where patients/patient representatives contributed to the ED process and the reflection of their input in the EUnetHTA Final Written Recommendations. Their contributions mainly focused on: choice of population to be included (inclusion / exclusion criteria), comparator, and outcomes (almost in all ED). However, they also provided input on study duration and the intervention itself. Areas were also identified where their feedback was less often considered:

Potential difficulties of current/future treatment administration/usage (frequency of administration, acceptability of injection, convenience of oral treatment, etc.

Importance of specific symptoms primarily considered at the country-level (different national approaches of the HTAb to proactively provide list of patient relevant outcomes).

As with the feedback analysis, this analysis confirmed that participating patients should ideally have expertise on the disease and some knowledge of the clinical development process to provide significant input during the ED process.

As with all ED participants, patient experts must also complete the EUnetHTA DOI and confidentiality forms. In only one instance, a patient was refused due to a conflict of interest (in that case the person had assisted in the product development). It should be noted also that sometimes it was very difficult to identify a patient to participate and, at other times, although one was identified, they decided not to participate (time constraints, administrative burden, low monetary compensation). Finally, we do not pay experts (of any type) for their participation in EUnetHTA EDs. Instead, they receive a minimal amount in compensation for the time they spend on the ED, based on the approach through which they are involved.

We have started to draft and recommend further to develop guidance documents around patient involvement in Early Dialogues. This guidance could take different forms (i.e. information sheets, short videos, online presentations) and includes topics such as:

- What are EDs and why participate?
- Revise and customise on an ED basis the interview guide used by SC/R when interviewing patients.
- Guidance regarding the recruitment of patients.
- Patient guidance for participating in both virtual and F2F meetings.
- Revision of patient feedback collection.

4.2.3.Healthcare Professionals

The involvement of Healthcare Professionals (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. During JA3, our experience in HCP involvement is limited to the one ED for a medical device.

4.3.Post-Launch Evidence Generation (WP5)

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.

4.4.Methods (WP6)

The activities on EUnetHTA's methods in JA3 comprise a major revision of the methodological guideline on information retrieval processes and the development of a new guideline on the critical assessment of economic evaluations. For both guidelines, public consultations of draft guideline versions have been conducted in autumn 2019 to collect feedback from stakeholders and all other interested parties.

EUnetHTA has further established a permanent feedback form that allows input on all EUnetHTA guidelines. The form is available on the EUnetHTA website here.

5.Findings from internal reporting

The evaluation team in EUnetHTA WP3 has produced 10 evaluation reports, of which seven have been shorter bi-annual reports. These reports have contained both reoccurring updates on resources spent and deliverables met, as well as specific topics such as results from partner and stakeholder interviews, etc.

Three interim evaluation reports have also been published, and the evaluation team has tried to take a more analytic approach and present findings and reflections over time. Below are the most important findings on stakeholder involvement and interaction identified in the interim evaluation reports.

5.1.Interim Evaluation Report 1

In the first interim evaluation report from 2017, the evaluation team found that one of the major external concerns about EUnetHTA work was connected to stakeholder involvement. Interviews and other interactions with parties suggested that EUnetHTA JA3 was not fully perceived as open and easy-to-access.

The high-level meeting in June 2017, where some stakeholders were present, was a positive experience and, in the second bi-annual report, the evaluation team recommended that EUnetHTA should increase its efforts to involve stakeholders. Stakeholder communication then became the main focus at the EUnetHTA Assembly and Forum in September 2017. Despite there being more work to do, this step in the right direction reiterated EUnetHTA's commitment to increasing stakeholder involvement, as a result of concerns raised in the interim report.

A lot of stakeholders also shared the perception that common HTA assessments in the EU would be a vital step towards transparent information about benefit, safety, and cost-effectiveness of pharmaceuticals and other interventions. They hoped that after the previous technical and methodologically-focussed Joint Action 1 and Joint Action 2, it was time to prove that there would be added value in the form of national uptake of the assessment reports.

EUnetHTA work package two also prepared a document, building on the Grant Agreement and on previous experiences with stakeholder involvement, called "Stakeholder Analysis". This document was published in November 2017 and provides some guidance and lessons learned regarding stakeholder involvement.

Overall, in the 2017 report, the evaluation team concluded that - amongst a broad group of stakeholders - there was commitment to the goals of the EUnetHTA project and a willingness to contribute when invited to do so. EUnetHTA recognised the different perspectives and important contributions that stakeholders could make, and that involving stakeholders at different phases of the work is a matter of legitimacy.

5.2.Interim Evaluation Report 2

When the second Interim Evaluation Report was published in 2018, one of the main findings for consideration was the low production rate of joint assessments for pharmaceutical products.

Because of this, EUnetHTA focused on continuing to improve dialogue with industry, predominantly pharmaceutical. This was done primarily to increase the number of letters of intent for joint assessments, but also to manage expectations on continued Early Dialogues.

The approach to reach out to companies with interesting products was good, but more efforts needed to be made. Therefore, the heads of agencies commissioned EUnetHTA to become more proactive in its work. As a response to this, EUnetHTA set up and circulated a list of the most relevant pharmaceutical products for partners to consider. That list was later transformed into the EUnetHTA Prioritisation List (EPL).

Points of contact with other stakeholders during this project year included: different meetings through the work packages, and the EUnetHTA Forum and the stakeholder interviews conducted by the evaluation team with a selection of 10 stakeholders.

Throughout the interviews, a number of stakeholders mentioned that knowledge and information-sharing could still be improved.

One way to measure a specific kind of stakeholder interaction is to study implementation of EUnetHTA reports, e.g. how many payers or other end users have implemented the joint assessment reports. The joint work (WP1, WP3, WP6 and WP7) to develop a metric tool (later renamed implementation feedback form) was successfully completed and, based on the early feedback, the first Interim Evaluation Report could be published in May 2018.

One way to summarise the findings in Interim Evaluation Report 2 is to say that, because of the low number of joint assessments and letters of intent for pharma products, the continued dialogue with industry was a priority during this project year.

At the same time, while external publications such as the EUnetHTA Magazine and the Welcome Guide (distributed prior to the annual Forum) were launched and proved successful, structures for communication with other stakeholders needed further improvement if they were to be sustainable in the long-term.

5.3.Interim Evaluation Report 3

Although it was a finding in project year 2, year three had the most pronounced stakeholder interaction with the pharmaceutical industry. Both the work on EPL 1, EPL 2, a new submission template and the implementation rates of the published joint assessments, were subjects of intense discussions.

The updated EUnetHTA website and other measures improved external communication.

In January 2018, the report also found that an increasing number of stakeholders were unsure about the status of the HTA Network as well as the importance of the political process around the European Commission proposal on HTA.

Overall, it was clear that stakeholder inclusion in EUnetHTA was an ongoing process.

6.Appendix A: Stakeholder comments on this paper

Note. Due to changes in the document following the stakeholder comments, the page and line numbers may no longer align with the contents of this file.

From	**Type**	**Page no.**	**Line and section no.**	**Comment and rewording suggestion**	**Character of comment** *This may be (1) major, (2) minor or (3) linguistic*	**Response from EUnetHTA**
Eurordis	Patients	General		The **target** of this Report may need to be clarified upstream: professional stakeholders only / general public information? That will impact the structure of the Report as well as the wording. The structure: some parts may look like an activity report, instead of a stakeholder engagement Report. The engagement of stakeholder is not the common ground of all the activities/deliverables/accomplishment listed. The wording: the language of the report is accessible to experts only, general public will hardly learn more about how is it possible to engage in HTA. In many chapters the link with the external stakeholder engagement is not clear or is fragmented: for instance, many of the activity listed have actually just one link with stakeholders and that's to have been submitted to a public consultation, nonetheless they are spread out in different chapters. E.g. many Reports, Guidelines and Papers have been submitted to public consultation and that is their one and only common ground in terms of stakeholder engagement. Authors can decide to put all documents that underwent a public consultation under the same chapter or to keep the structure based on the activities, but with the focus	Major	Many thanks for your comment. The purpose of the document is to present the ways EUnetHTA Joint Action 3 has engaged stakeholders and the draft paper is structured by work package.

From	Type	Page no.	Line and section no.	Comment and rewording suggestion	Character of comment *This may be (1) major, (2) minor or (3) linguistic*	Response from EUnetHTA
				on the stakeholder link, so: activity "x" (with only essential details) -> type of stakeholder engagement (with relevant details) *See below as examples (§3 Methods; Interim Evaluation Reports).* *EUnetHTA has a WP on methodology. Instead of focusing on what this WP has done, the true information is: EUnetHTA produced xx guidelines on, xx of them have been submitted to public consultation (and perhaps: which type of stakeholder showed interest for this and replied, what impact did they have, all this is available *here*… etc).* *e.g. Interim reports paragraph* *the key of these reports seems to be they contain an analysis of the interaction EUnetHTA was developing with stakeholder. That could be the (one and only) focus: interim report 1 listed some concerns about… interim report 2 registered improvement in … etc. All the rest may fall out this Report scope*		
Eurordis	Patients	5	13-14	Even though one of the aims of the Report is to "Define overreaching principles of external stakeholder management and interaction", we can find no principles presented in this Report.	Major	Following the creation of the Future Model of Cooperation on HTA White Paper – which also went for consultation to stakeholders in April 2021 – this aim will be removed as the White Paper captures principles and recommendations for stakeholder engagement. Apologies for the confusion.
Eurordis	Patients	7	Table	(2017 EUnetHTA Forum) "Stakeholders both contributed to the Agenda **(*identification and invitation of speakers for specific sessions)*** and participated in the day's proceedings."	Minor	Many thanks. We have made this change in the document.

From	Type	Page no.	Line and section no.	Comment and rewording suggestion	Character of comment *This may be (1) major, (2) minor or (3) linguistic*	Response from EUnetHTA
Eurordis	Patients	7	Table	(Consulting meeting with stakeholders representing European patient and consumer organisations) "Work packages two, four, and five provided updates and a brief discussion ensued ***where Patient and Consumers Organisation could share their proposals about engagement in Early Dialogues and Joint Assessment."***	Minor	Many thanks. We have made this change in the document.
Eurordis	Patients	7	Table	(2018 EUnetHTA Forum) "agenda suggestions, ***identification and invitation of speakers for specific sessions."***	Minor	Many thanks. We have made this change in the document.
Eurordis	Patients	9	Table	(EUnetHTA HealthCare Providers and HealthCare Professionals) ***First presentation of the EUnetHTA policy on managing conflicting interests for external stakeholders.***	Minor	Many thanks. We have made this change in the document.
Eurordis	Patients	9	Table	(EUnetHTA Patient Consumer Organisations) This meeting was the second step of the inclusion of the Patients and Consumers organisations from the HTA Network Stakeholder Pool in the work of the EUnetHTA Task Group on Patient Involvement.	Minor	Many thanks. We have made this change in the document.

From	Type	Page no.	Line and section no.	Comment and rewording suggestion	Character of comment *This may be (1) major, (2) minor or (3) linguistic*	Response from EUnetHTA
Eurordis	Patients	10	§ 2.2.1 Stakeholder Inventory	Can the author specify the term of the creation and inclusion for this Stakeholder Inventory? Has that been feed based on the opportunities of interactions? Or was it something stakeholders could/can apply for? (was is similar to a Registry?).	Minor	Thank you for your comment. We are happy to clarify this issue. The Stakeholder List was created on the basis of the HTA Stakeholder Pool of the European Commission and contacts in JA2. The file was also continuously updated during JA3. Regrettably, we were not able to create an official registry but this is something that we have included within the proposal for the Future Model of Cooperation on HTA.
Eurordis	Patients	10	26	"Successes, achievements ***and barriers*** over the past year".	Minor	Many thanks. We have made this change in the document.
Eurordis	Patients	11	2	"Stakeholders are the first group approached for topic suggestions and ***speakers identification for their dedicated sessions***"	Minor	Many thanks. We have made this change in the document.
Eurordis	Patients	11	5-6	The Forum was also meant to fill the void of structured interaction with stakeholders, as no framework for interaction for European Organisations were established. That also showed some limits of the Forum: a one-day meeting was quite short to update and discuss over one-year work.	Major	This has been noted. Many thanks.

From	Type	Page no.	Line and section no.	Comment and rewording suggestion	Character of comment *This may be (1) major, (2) minor or (3) linguistic*	Response from EUnetHTA
Eurordis	Patients		2.2.3. Collaboration with the HTA Network Pool	This paragraph is technically correct (the Pool and EUnetHTA are to different things), but then is not clear why this is mentioned. EUnetHTA JA3 collaborates closely with the EC to ensure that members of the HTA Network 16 Stakeholder pool are informed about and included in activities of EUnetHTA JA3. ***EUnetHTA addressed the HTA Network Stakeholder Pool (respectively, patients and consumers, health providers, industry etc…) to participate or contribute to some structured and ad-hoc EUnetHTA activities on a voluntary basis (e.g. identification of patients for Early Dialogue and Joint Assessment).***	Major	Many thanks. We have made this change in the document.
Eurordis	Patients	12-13	2.2.7.1. Patients, Consumers, and Healthcare Providers (P&C/HCP) Task Group	Here a link with external stakeholder is missed: the three texts has been submitted (in their final version) to a public consultation. (contribution came from the following categories of stakeholders…)	Major	This has been noted. Many thanks.

From	Type	Page no.	Line and section no.	Comment and rewording suggestion	Character of comment *This may be (1) major, (2) minor or (3) linguistic*	Response from EUnetHTA
Eurordis	Patients	13	2.2.7.2. Topic identification selection and prioritisation (TISP)	1. Why is that under task group and subgroups? Isn't a WP3 activity on its own? 2. This paragraph is very dense, listing a lot of activities, which differs by nature and link with different stakeholders "Stakeholders were invited to suggest possible topics for inclusion in the prioritisation exercise". ***"The mechanism of participation for stakeholder than… (e.g. patients organisation) in topic selection not being defined from the start:*** ***a. Upon request of patient organisations, the official template has been modified and made available to patient organisations***	Major	1. While technically a WP4 activity, the Executive Board decided to list TISP as a task group as it was felt the group had a strategic mandate and thus regular reporting was required. Therefore, for consistency, it has also been listed as a task group in this document too. 2. This has been noted. 3. This has been noted.

From	Type	Page no.	Line and section no.	Comment and rewording suggestion	Character of comment *This may be (1) major, (2) minor or (3) linguistic*	Response from EUnetHTA
				b. to submit specific technologies for Joint Assessment xx/all of them has been submitted to the (*member states? / specific work package*?). xx has been included. Also, external stakeholders (as defined in section 1.2) were invited to comment on the TISP 26 recommendations during a public consultation. It could be useful to specify when and how this exercise was performed and add the results (xx answers and xx selections: final outcome: TPL).		

From	Type	Page no.	Line and section no.	Comment and rewording suggestion	Character of comment *This may be (1) major, (2) minor or (3) linguistic*	Response from EUnetHTA
Eurordis	Patients	13	2.2.7.3. Conflict of Interest (COI) Task Group	That's a great EUnetHTA outcome, but no involvement to report here: did external stakeholder contributed to this work?	Major	This activity was listed as the development of the new COI form and associated guidance facilitated stakeholder input in JA3.
Eurordis	Patients	14	2.2.7.4. Future Model of Cooperation on HTA (FMC-HTA) Task Group	Isn't worth to add that a public consultation will be held on March 2021 on the White Paper?	Major	Many thanks. We have made this change in the document.

From	Type	Page no.	Line and section no.	Comment and rewording suggestion	Character of comment *This may be (1) major, (2) minor or (3) linguistic*	Response from EUnetHTA
Eurordis	Patients	17	8-10	"1) Recommendations on how to involve patients and patient representatives" Patients and patients representatives are the same: A Patients is also a representatives (of other patients). IF "patient representatives" means someone acting on behalf of a Patient Organisation, then better to say explicitly "Patient Organisations": So, we would suggest one of these two options: "***patients and Patients Organisations***" "*Patient representatives and Patient Organisations*" "1) Recommendations on how to involve patients and patient representatives 2) Recommendations on how to involve healthcare professionals in EUnetHTA assessments." The Report doesn't contain any recommendation, neither about principles nor procedures.	Major	We have changed the section names (line 8 and line 10) to the following for clarity: 1. Patient engagement in EUnetHTA assessments 2. Healthcare professional involvement in EUnetHTA assessments
Eurordis	Patients	17	21-22	"Recommendations on how to involve patients and patient representatives in EUnetHTA assessments have been finalised by EUnetHTA" Is there any future Report yet to come on this?	Major	The document is available here: https://eunethta.eu/the-final-version-of-patient-input-in-relative-effectiveness-assessments-is-now-available/.

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Eurordis				On the last two comments, see previous answer and what patient Organisations published on this subject: "Why should Patients be involved in HTA" (endorsed by 14 European Organisations): http://download2.eurordis.org.s3.amazonaws.com/hta/FINAL%20_Patient_Organisations_Joint_Statement_HTA_Cooperation.pdf - "Principles of Patients and Consumers Engagement" (endorsed by the HTA Network Stakeholder Pool – presented at the 9th February 2018 HTA Network) https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20180209_co04_en.pdf - "A framework of engagement for patients, consumers, and health providers Organisations in EUnetHTA Joint Action 3 European cooperation" (Letter to the EUnetHTA Board and General Assembly endorsed by 8 European Organisations).		This has been noted. Many thanks.

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Eurordis	Patients	17	28-32	"The goal of patient contribution in assessments is to gain ***a broader perspective on the technology and its impact both and patients and the healthcare system. That might include*** the knowledge ***of the*** disease/condition***, the*** current available treatments, as well as the outcomes that are important from the patients' perspective ***and the society, including costs***. For patients, ***it is of upmost importance to contribute in assessing something that would have an impact on their lives, while expanding their knowledge by participating into the HTA process. With patients in the assessment, the whole civil society can better trust the process and the consequent decision-making."***	Major	Many thanks for your comment. This has been noted. For further information, please refer to page 3 "Goals for direct patient input in REA" in the following "Patient input in REAs" document: https://eunethta.eu/the-final-version-of-patient-input-in-relative-effectiveness-assessments-is-now-available/ This discusses further goals of patient involvement.
Eurordis	Patients	18	1--19	"Reasons for unsuccessful recruitment …" Add: - adjustement of the procedures over time - differencies in methods/procedures/approaches among different agencies/countries/authors - the timing - the topics selected and its interest/non-interest for the patient community - the network and the relationship to be built with patients or consumers organisations to be involved	Major	This has been noted. Many thanks.

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Eurordis	Patients	18	24	"approaches" A reference to the section of the Report on the different approaches could be helpful.		For further information, please refer to page 4-5 "Preferred methods for patient input" in the following "Patient input in REAs" document: https://eunethta.eu/the-final-version-of-patient-input-in-relative-effectiveness-assessments-is-now-available/
Eurordis	Patients	24	Chapter 3.4 Methods (WP6)	1. better specify that is not "methods of stakeholder engagement" but "HTA methodology" 2. This paragraph could focus more on the aspects of the public consultations held on this methodological guidelines OR includes this paragraph in the same sections with other deliverables that did undergo a public consultation (and keep the focus on the topic of stakeholder engagement)	Major	This has been noted. Many thanks.
Eurordis	Patients	24-25	4 – Findings from internal reporting	Better summarise and shorten the content of the paragraph on Internal Reports by keeping the focus on stakeholder engagement, otherwise it's hard to find a clear message in these lines.	Minor	This has been noted. Many thanks.

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Eurordis	Patients	24	39	"A list of Stakeholder" This is a broad and unclear term. If those stakeholders expressed this opinion publicly there should not be problem to mention them and to mention the context of their remarks (where and how).	Major	This has been noted. Many thanks.
Eurordis	Patients	24	46	The Stakeholder Analysis paper was submitted to a public consultation too: in our opinion that should be the focus, more than the technical reference to the Grant Agreement (which is understandable only by experts).	Major	This has been noted. Many thanks.
Eurordis	Patients	25	25	"How many payers or other end users have implemented the joint 25 assessment reports". What does "implement" mean in this context? We are not sure that "to implement" is the right term for the joint assessments produced by EUnetHTA. Anyway, the question about the payer that used EUnetHTA work for their decision-making is an interesting question.	Major	This has been noted. Many thanks.
HAI	Patients	10	Final line of Table 1	Date of April meeting should be 2021 not 2020	3	Many thanks. We have made this change in the document.
HAI	Patients	11	2.2.4, line 21	We were not invited to an event or meeting for 18 months (June 2019- Dec 2020) so I suggest removing 'regularly'	2	This has been noted. Many thanks.

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HAI	Patients	18	Lines 18-19	HAI is non-disease specific patient and consumer group and was available to participate in the technologies assessment where there was no patient input. EUnetHTA should consider reaching out to more organisations, not just disease specific groups, before determining that no patient input is available. Therefore would suggest clarification that JA3 did not reach out to enough organisations, or a similar conclusion that can be positively built upon.	2	This has been noted. Many thanks.
EPF	Patients	11	1-2 2.2.2	Involvement of stakeholders was random and with limited follow up. I would suggest a more realistic rewording.	3	This has been noted. Many thanks.
EPF	Patients	11	16-17 2.2.3	Sharing of information with the Stakeholder pool is very limited and random.	1	This has been noted. Many thanks.
EPF	Patient	19	7-14 3.1.1	The draft communications tools could have been shared with Patient and Consumers representatives for validation.	2	This has been noted. Many thanks.
EPF	Patients	21	21-25 3.1.5	The message here looks contradictory on identification through national and European associations.	3	This has been noted. Many thanks.
EPF	Patients	22	12-16 3.2.1	Figures of numbers of patient involved in EDs are not included and replaced by an X. The same applies to table 5. Hope the text will be updated.	1	Apologies, this information was not included in the draft version of the document. The relevant section has now been updated.
UEMO European Union of General Practitioners Family Doctors	HCP	20	1-2	We appreciate the mention of clinical pathways and procedures. HCP can inform during the assessment about the practical use of a new technology and about the feasibility.		This has been noted. Many thanks.

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UEMO		20	18-20 and 33-34	Stakeholders organisations such s.as UEMO can help for identification of experts.		This has been noted. Many thanks.
UEMO		20	44-45	From the point of view of general practitioners, the shared decision process during the consultation is the key moment of HTA in the real life. The discussion between HCP and patient has to be based on plain language summaries clearly explaining the advantages and risks. "First do not harm" remains the central principle during the shared decision process.		This has been noted. Many thanks.
UEMO		23	36-40	Important to develop further. HCP stakeholders organisations such UEMO can help to find HCP for interviews.		This has been noted. Many thanks.
European Hematology Association (EHA)	Healthcare Professionals	11	20-21	EUnetHTA's participation in two meetings at the EHA Annual Congress in June 2019 – a panel session on access to innovative therapies, as part of a joint symposium of EHA and patient organisations, and a dedicated session on HTA as part of the Capacity Building Program for patient advocates – was received well and contributed to awareness of EUnetHTA activity and HTA among hematologists as well as patients.	Major	This has been noted. Many thanks.
European Hematology Association (EHA)	Healthcare Professionals	11	15	For information, as the member list on the EC website dates from 2018: EHA participated in the HTA Network Stakeholder Pool meeting for HCPs of April 2019 and applied for formal membership of the Pool in 2020.	Minor	This has been noted. Many thanks.

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European Hematology Association (EHA)	Healthcare Professionals	13	21	Footnote 7, list of HCP members of the HTA Network Stakeholder Pool on the EUnetHTA site: see previous comment.	Minor	This has been noted. Many thanks.
European Hematology Association (EHA)	Healthcare Professionals	19-20	Section 3.1.2.	P20, line 20-23, expert rejections due to COI to P.I. roles: Currently, after we identify, contact and nominate experts, we are not kept informed in a structural manner about how many of them are contacted, respond, get involved or are rejected – and if rejected, for what reasons. We therefore rely on informal feedback from our experts (who don't always take the time to keep us informed in detail). While we plan to conduct a survey of all experts nominated by EHA for assessments by EunetHTA so far, it would be helpful to get feedback from EUnetHTA itself. Good and comprehensive feedback helps us (or other medical societies) to assist EUnetHTA (or other bodies) in the best possible way.	Major	This has been noted. Many thanks.

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European Hematology Association (EHA)	Healthcare Professionals	General	General	EHA strongly supports the conduct of joint clinical assessments of pharmaceuticals as developed by EUnetHTA and foreseen in the EC proposal for EU-level HTA. A major challenge in our experience is to get the top experts involved, due to stringent COI policies. EHA and other HCP organizations need to be involved in discussions about pragmatic application of COI policies, to help find the right balance between avoiding harmful COI and the need to benefit from the best possible expertise. This challenge is particularly acute when it comes to orphan medicinal products, with few or no experts without COI. EHA is also interested in being part of discussions on HCP involvement in EDs and Post-Launch Evidence Generation.	Major	This has been noted. Many thanks.
ESC	HCPs	5	1.2 L 28	Research and Academia were not considered as separate Stakeholder Group for EUMetHTA. ESC emphasizes the importance of the distinction between healthcare providers and academia , justifying the need to create a separate stakeholders group for learned societies, as "evidence providers" for the process of Joined HTA (as opposed to healthcare services providers - "evidence users").	1	This has been noted. Many thanks.
ESC	HCPs	12	2.2.7.1	ESC as a part of HCPs group was not involved in Early Dialogues.	1	This has been noted. Many thanks.
ESC	HCPs	20	3.1.2 L12 and on	Experts in their own capacity rather than Academia/Learned Societies were involved in the assessments. There was no established formal pathway for the involvement of the Academia.	1	This has been noted. Many thanks.

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ESC	HCPs	23	3.2.1	ESC continuesly scans for the new technologies that may potentially influence clinical practice, updatring its clinical guidelines. Therefore ESC strongly supports involvment of HCPs/Academia in the Early Dialogues as so far this involvment takes place at a national level only.	1	This has been noted. Many thanks.
ESC	HCPs	23	3.3	ESC strongly supports Research and Academia involvement in post-launch evidence generation.	1	This has been noted. Many thanks.