

Patient Involvement: The EUnetHTA Early Dialogues Perspective

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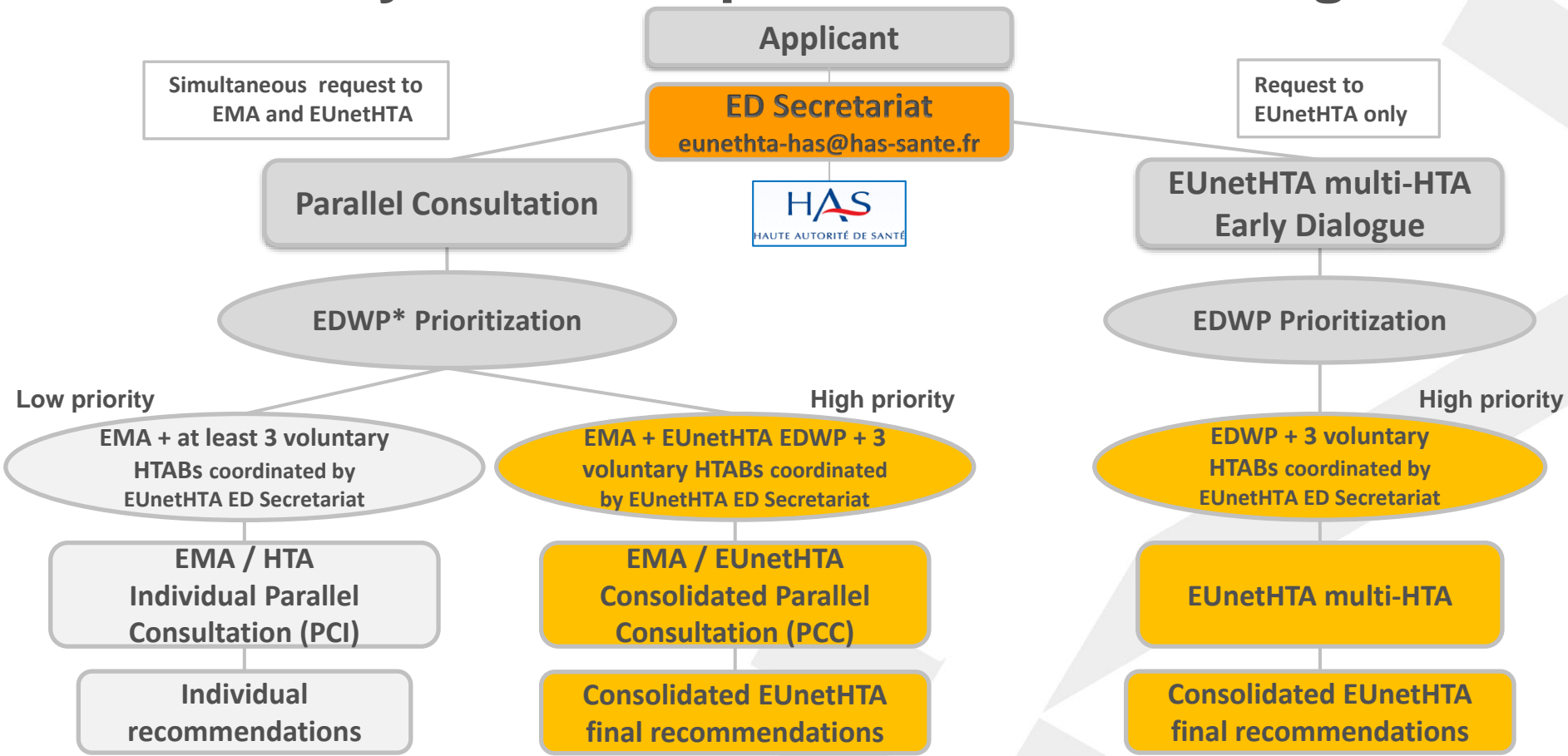


What is an Early Dialogue?

EUnetHTA defines an Early Dialogue (ED) as:

A non-binding scientific advice, before the start of pivotal clinical trials (after feasibility / proof of concept study), in order to improve the quality and appropriateness of the data produced by the developers in view of future HTA assessment / re-assessment.

One Gateway for all ED procedures involving HTAbs



Legend: EUnetHTA Procedure Non-EUnetHTA procedure

*EDWP: Early Dialogues Working Party

Graduated approach to Patient Involvement – Early Dialogues (Pharma and MD)

Approach	Patient Deliverables
Approach 1: Patient/ patient representative interviewed regarding the disease and their experience.	<ul style="list-style-type: none">• 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).	<ul style="list-style-type: none">• 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.	<ul style="list-style-type: none">• Minutes of the interview• Patient contribution visible in final EUnetHTA recommendations• Share final EUnetHTA recommendations• Feedback questionnaire and interview

Identifying and Preparing Patients

1. Once the EDWP decision is final, the EUnetHTA ED Secretariat begins contacting associations to identify potential patient experts
2. As soon as a patient is identified, the ED Secretariat contacts them to schedule an introductory interview to discuss
 - EUnetHTA and what we do
 - the difference between HTAb and Regulators
 - what an ED is
 - what is expected of their participation
 - answer any questions they may have regarding the process, EDs, etc.

Timeline of current patient involvement – Early Dialogues (Pharma & MD)

~ 4,5 months total

timeline

ED Secretariat begins **contacting associations and identifying patients**; Administrative procedures initiated in case of Approach 3

Patient Interviews

Can occur from reception of the Final Briefing Book up until 1 week prior to the EUnetHTA pre-F2F Meeting.

D -55 EDWP/EDMDWP Decision

D 0 Reception of Final Briefing Book

D +30 EUnetHTA e-Meeting on List of Issues*

D +60 EUnetHTA pre-F2F meeting*
F2F meeting with Applicant (+ EMA if Parallel)*

D +75 EUnetHTA Final Recommendations*

D +80 Feedback Questionnaire and Interview

*possible patient participation
(according to patient background and availability)



Patient Involvement in EUnetHTA EDs to Date

82 requests for EDs since Q1 2017 (Parallel procedure launched Q3 2017)

- 28/82 have been “EUnetHTA” EDs (PCC or Multi-HTA)
- 3/82 are still awaiting EDWP decision

Patient involvement process established Q1 2018

- 26/28 “EUnetHTA” EDs have had patient participation (at least 1 approach was used)
- In 6 instances multiple approaches used (up to 3 patients)

Impact of Patient Involvement

Within EUnetHTA Early Dialogues, input received from patients often has a large impact.

- Changes in clinical endpoint(s) based on description of clinical burden or patients' expectation from drug
- Adaptation of inclusion and exclusion criteria to capture evidence in relevant subgroup, taking into account population heterogeneity
- Input on comparator arm - in particular acceptance of placebo arm/open design

Going Forward: Further Research on PROs and Patient Preference in Early Dialogues

More science before interviews in order to further discuss:

1. Choice of SCALE
2. WHEN the data is collected
3. PREVENTION of missing data

Sources:

- Applicant should submit preliminary research on PROs and rationale for final proposed scales
- ED Secretariat reviews recommendation ICHOM, COMET...

Thank you

For more information:

<https://www.eunethta.eu/services/early-dialogues/>

**Contact the EUnetHTA ED Secretariat:
eunethta-has@has-sante.fr**

