



eunethta  
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

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# Open Call for EUnetHTA Parallel Consultations and Multi-HTA Early Dialogues

July 3, 2020

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## BACKGROUND

The EUnetHTA Executive Board has recognized the interest to continue to offer Early Dialogues (ED) through the EUnetHTA prolongation period (through May 31, 2021). For that purpose, additional EUnetHTA budget will be allocated for the ED activity to be reopened.

EUnetHTA will aim to conduct 1 ED per month with a maximum 8 EDs during the EUnetHTA prolongation period. Primary selection of products, based on an open call to industry, will be carried out during the summer in order to restart ED activities in September 2020. The WP5 Lead and Co-Lead partners are working together with EMA on a more efficient procedure while ensuring the best scientific quality and coordination.

Fees may apply for the participation of some HTA bodies in EDs if the attendance is wished by the industry<sup>1</sup>.

## HOW TO APPLY

The open call will remain open from July 3, 2020 through to August 15, 2020. Once candidates have been selected for the 8 available EDs, additional applications may be considered for a 'reserve' list.

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<sup>1</sup> Applicants should contact the EUnetHTA ED Secretariat for information regarding fees.

## HOW TO EXPRESS YOUR INTEREST?

### Parallel Consultation

Sponsors/developers of health technologies should complete the EUnetHTA Early Dialogue Request Form available on the [EUnetHTA website](#) and submit their completed dossier to the EUnetHTA ED Secretariat ([euneththa-has@has-sante.fr](mailto:euneththa-has@has-sante.fr), cc: [scientificadvice@ema.europa.eu](mailto:scientificadvice@ema.europa.eu)) via Eudralink for Parallel Consultations.

### Multi-HTA ED

Applicants should complete the EUnetHTA Early Dialogue Request Form available on the [EUnetHTA website](#) and submit their completed dossier to the EUnetHTA ED Secretariat through a secure messaging service. If one is not available to the Applicant, they should contact the [EUnetHTA ED Secretariat](#) as early as possible so that a secure link can be provided.

In all cases, the submitted request must comply with the indications described below (General aspects of the procedure – Letter of Intent).

All Applicants will be notified of the EDWP decision the first week of September for EDs running from September 2020 through May 2021).

Parallel Consultation F2F meetings will be held at EMA premises (Amsterdam).

Multi-HTA EDs will be held at HAS (Paris) or G-BA (Berlin).

The option of e-meetings will be explored for all F2F meetings and the Applicants will be informed accordingly.

## EUNETHTA EARLY DIALOGUES

EUnetHTA defines an Early Dialogue 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.

EUnetHTA EDs should enable to exchange between the Applicant and HTA agencies at an early stage in the development process in order to allow for the integration of HTA requirements (e.g. choice of comparators, relevant outcomes, quality of life, patient groups) in the study design (pivotal trials & post-launch studies) and the economic evidence generation plan. The main objective of EUnetHTA EDs is to gather and provide the common recommendations on how the drug or device could be developed in order to fill HTA requirements across multiple European Member States. However, when consensus is not possible, the views of participating HTA bodies will be made known to the Applicant.

## EUNETHTA EARLY DIALOGUE SELECTION CRITERIA

In a context of resource constraints in JA3, there is a limit to the number of products to be selected for Parallel Consultation or Multi-HTA ED.

The product should aim to bring added benefit to patients i.e. by:

A new mode of action for the indication

AND targeting a life-threatening or chronically debilitating disease

AND responding to unmet need (no treatment or only unsatisfactory treatment available)

EUnetHTA aims for a diverse selection of EDs and therefore selected EDs should represent a wide array of topics, therapeutic areas etc. (e.g. orphan, ATMPs, anti-infectives, oncology). The Applicant's request for a EUnetHTA Early Dialogue should provide sufficient information to substantiate the claimed basis of selection and follow the guidance notes provided with the form.

## EUNETHTA EARLY DIALOGUE FORMAT

### TYPES OF ED AVAILABLE

While both Parallel Consultations and Multi-HTA EDs remain available during this period requests for Parallel Consultation will be prioritized in order to maximize impact. Regardless of the type of ED, there is one single procedure; however, there are two different formats the consultation can take, following selection of a product: Written-only format and F2F meeting format.

All EUnetHTA EDs are supported by the EUnetHTA ED Secretariat, thereby benefiting from HTA scientific and administrative coordination, consolidated HTA comments, a concerted effort to find agreement among the EDWP regarding specific issues as well as a consolidated document containing EUnetHTA's Final Written Recommendations. In the case of Parallel Consultations, opportunities for closed discussion amongst HTA, and with Regulators, with mutual understanding are maximised.

Regardless of the format of a parallel consultation the HTA bodies' final output remains the EUnetHTA Final Written Recommendation.

For Parallel Consultations, a preliminary exchange on procedure format and associated organisational topics will take place during the monthly Administrative discussion between EUnetHTA and EMA.

### *EUnetHTA decision criteria for procedure format*

The decision as to which format the procedure will follow will be decided by the EDWP after review of the Applicant's Draft Briefing Book. This decision will be based on:

- PRIME products
- Complexity of development
- Need for an in-depth discussion with the applicant about the development plan, e.g. in case of unclear development plan or unexperienced companies
- Major issues with the development plan that would benefit from discussion with the Applicant.

The Applicant will be informed of the decision on the procedure format upon reception of the Final Briefing Book by EUnetHTA.

Procedures that *do not* require a F2F meeting will be approximately 2,5 months in duration starting from reception of the Draft Briefing Book.

Procedures that *do* require a F2F meeting will be approximately 3,5 months in duration starting from reception of the Draft Briefing Book.

The table below provides estimated dates<sup>2</sup> of final EUnetHTA recommendations according to date of Draft Briefing Book Submission.

<sup>2</sup> The table within this document provides only an estimate of the dates in question. The official dates will be those published simultaneously on the EUnetHTA and EMA websites

### Estimated Timelines for EUnetHTA Final Recommendations

Draft Briefing Package submission	EUnetHTA Final Written Recommendations (Written-only format)	EUnetHTA Final Written Recommendations (F2F Meeting format)
4 Sep 20	25 Nov 20	11 Dec 20
2 Oct 20	22 Dec 20	29 Jan 21
30 Oct 20	10 Feb 21	26 Feb 21
27 Nov 20	10 Mar 21	30 Mar 21
15 Jan 21	7 Apr 21	27 Apr 21
12 Feb 21	5 May 21	25 May 21

## ADDITIONAL INFORMATION

Further information regarding EUnetHTA Early Dialogues, including guidance documents and templates, can be found on the [EUnetHTA website](#). Candidates should direct any inquiries regarding this call or the ED process itself to the EUnetHTA ED Secretariat ([eunetha-has@has-sante.fr](mailto:eunetha-has@has-sante.fr)).