2nd Open Call for Parallel EMA/EUnetHTA 21 Joint Scientific Consultations (JSC)

From 6 June, 2022 to 31 August, 2022

BACKGROUND

In February 2021, a call for tender was launched to foster joint work supporting EU cooperation on health technology assessment (HTA) beyond May 2021 (when the EU co-funded EUnetHTA Joint Action 3 (JA3) ended), thus providing relevant input to the new legal framework on HTA.

The contract was awarded to the EUnetHTA 21 Consortium in September, 2021. One deliverable of the service contract is to provide at least 6 up to a maximum of 8 Joint Scientific Consultations (JSCs - formerly referred to as Early Dialogues) for medicinal products, allowing the procedural and scientific preparation of JSCs under the HTA Regulation. These JSC will be consultations in parallel to European Medicines Agency (EMA) scientific advice (parallel EMA/EUnetHTA 21 JSC) and hence focus on medicinal products.

The EUnetHTA 21 partners will continue to work with the EMA to improve the consultation process in order to meet the demand for consultations while ensuring the best scientific quality.
Two Open Calls are planned for the EUnetHTA 21 period. The first Open Call has been conducted in November/December 2021. The second Open Call, which is the subject of this document, will remain open from 6 June, 2022 to 31 August, 2022.

EMA/EUNETHTA 21 JOINT SCIENTIFIC CONSULTATIONS (JSC)

The JSCs provide 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 health technology developers (HTD) in view of future HTA assessment/re-assessment.

Parallel EMA/EUnetHTA 21 JSCs should enable an exchange between the applicant and HTA agencies and regulators (EMA) at an early stage in the development process in order to allow the integration of

the different requirements across multiple European Member States (e.g. choice of comparators, relevant outcomes, quality of life, patient groups) in the study design (pivotal trials & post-launch evidence generation (PLEG)) and the economic evidence generation plan. However, when consensus is not possible, the views of participating HTA bodies will be made known to the applicant.

Our medium-term goal is to establish a regular, legally acceptable procedure in view of the HTA regulation. All JSCs will be conducted in parallel with EMA and hence focus on medicinal products.

JSCs primarily focus on the pivotal trials and therefore questions regarding the pivotal (phase II/III) study design are mandatory. Discussions on PLEG can only be facilitated when contextualized with clinical data from the pivotal (phase II/III) studies. Also, when seeking advice on PLEG an information set regarding the envisaged PLEG plan is needed, as stated in the Briefing Book template which can be found on the EUnetHTA 21 website. Furthermore, the applicant should follow the proposed order of JSC topics according to the Briefing Book template.

EMA/EUNETHTA 21 JSC SELECTION CRITERIA

Due to the tender specifications, the number of products to be selected for JSCs in EUnetHTA 21 is limited. As the number of applicants is expected to exceed the number of slots, a selection of products will be necessary. A prerequisite for a JSC is that the clinical studies (phase II/III) and clinical investigations are still in the planning stage. Furthermore, EUnetHTA 21 will apply the same selection criteria as defined in the EU HTA regulation. The criteria for selecting from eligible JSC requests for medicinal products are:

a) Unmet medical needs (no treatment or only unsatisfactory treatment available);
b) First in class;
c) Potential impact on patients, public health, or healthcare systems;
d) Significant cross-border dimension;
e) Major Union-wide added value; or
f) Union clinical research priorities

Oncology products and/or ATMPs and indications for which there is no established guidance for clinical development (i.e. in absence of recent HTA evaluation in similar indication) are also given preferred consideration.

The specification of the selection criteria, their operationalisation and applicability will be further developed in the course of EUnetHTA 21.
More information can also be found in the JSC Frequently Asked Questions (FAQ) section of the EUnetHTA 21 website.

Please note that there is no option for a follow-up consultation with EUnetHTA 21 during the project phase. All relevant questions must be submitted in a single request under the Open Call.

EUNETHTA 21 JSC FORMAT AND SLOTS

All parallel EMA/EUnetHTA 21 JSCs are supported by the EUnetHTA 21 JSC Secretariat, thereby benefiting from HTA scientific and administrative coordination, consolidated HTA comments, a concerted effort to find agreement among the Committee for Scientific Consistency and Quality (CSCQ) JSC regarding specific issues as well as a consolidated document containing EUnetHTA 21's Final Written Recommendations. Opportunities for close discussion amongst HTA bodies, and with Regulators, with mutual understanding are maximized.

The JSC procedure will be approximately 4.5 months in duration starting from receipt of the Draft Briefing Book.

The table below provides estimated dates of EUnetHTA 21 Final Written Recommendations according to the date of the Draft Briefing Book submission. The EUnetHTA 21 Final Written Recommendation represents the HTA bodies' final output.

Estimated dates[1] for the start of the procedure (receipt of the Draft Briefing Package), F2F Meetings and EUnetHTA 21 Final Written Recommendations:

Draft Briefing Package submission	Estimated F2F Meeting date	EUnetHTA 21 Final Written Recommendation
24 Oct 2022	6 – 9 Feb 2023	8 Mar 2023
5 Dec 2022	13 – 16 Mar 2023	12 Apr 2023
9 Jan 2023	11 – 14 Apr 2023	10 May 2023
13 Feb 2023	10 – 12 May 2023	7 Jun 2023
13 Mar 2023	5 – 8 Jun 2023	5 Jul 2023

HOW TO APPLY

In order to apply for a JSC, health technology developers (HTD) of medicinal products should complete the EUnetHTA 21 JSC application form available on the EUnetHTA 21 website or upon request (EUnetHTA21-JSC@g-ba.de) and submit their application and annexes (if applicable) preferably via Eudralink to the EUnetHTA 21 JSC Secretariat (EUnetHTA21-JSC@g-ba.de).

The applicant's request for a parallel EMA/EUnetHTA 21 JSC should provide sufficient information to substantiate the claimed basis of selection and follow the guidance notes provided with the form.

In all cases, the submitted applications must comply with the selection criteria described below. Once the call is closed, the members of the Committee for Scientific Consistency and Quality (CSCQ) JSC will review the applications.

A maximum of five JSC will be selected in this second Open Call. All applicants will be informed of the CSCQ JSC decision within 15 working days after the Open Call has been closed.

ADDITIONAL INFORMATION

Further information regarding parallel EMA/EUnetHTA 21 JSC, including guidance documents and templates, can be found on the EUnetHTA 21 website. Please also check regularly for updates to the relevant documents. Any inquiries regarding this Open Call or the JSC process itself should be directed to the EUnetHTA 21 JSC Secretariat (EUnetHTA21-JSC@g-ba.de).

[1] 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 21 and EMA websites later this year.