1st Open Call for EUnetHTA 21 Joint Scientific Consultations (JSC)

From November 8, 2021 to December 7, 2021

BACKGROUND

In February 2021, a call for tender was launched to foster joint HTA 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 purpose of the contract is to provide 8 joint scientific consultations (JSCs) (formerly referred to as Early Dialogues) for medicinal products or at least, not less than 6 JSCs, allowing for the continuation of one of the most successful products of the EUnetHTA JA3. These will be consultations in parallel to European Medicines Agency (EMA) scientific advice and hence focus on medicinal products.

The primary selection of the first four medicinal products subject of JSC, will be carried out within 2 weeks following the application deadline in order to resume JSC activities from December 2021 at the latest. The EUnetHTA 21 partners will continue to work with the EMA to improve the consultation processes in order to meet the demand for consultations while ensuring the best scientific quality.

HOW TO APPLY

Two calls are planned for the EUnetHTA 21 period. The first open call will remain open from November 8, 2021 through December 7, 2021. The second open call will follow approximately one year after the first call in Q3 2022.

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

The Applicant's request for a 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 Committee for Scientific Consistency and Quality (CSCQ) JSC members will review the applications.

All Applicants will be informed of the CSCQ JSC decision two weeks after the deadline of the call. Promising products that could not be selected will be considered for a waiting list.

Due to the ongoing pandemic most meetings will likely be held virtually. The option of a physical meeting, held at EMA premises in Amsterdam, will be explored for all F2F meetings and the applicants will be informed accordingly.

EUNETHTA 21 JOINT SCIENTIFIC CONSULTATIONS

JSC provides 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 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 studies) 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 future HTA EU regulation. All JSCs will be conducted in parallel with EMA.

EUNETHTA 21 JSC SELECTION CRITERIA

Due to the tender specifications in EUnetHTA 21, the number of products to be selected for the JSC is limited. As the number of applicants is expected to exceed the number of slots, a selection of products will be necessary. With regard to the future HTA regulation, EUnetHTA 21 will apply the same selection criteria as defined in the EU HTA regulation. A prerequisite for a JSC is that the clinical trial (phase II/ or III) has not yet started.

Promising candidates are selected in two steps. Firstly, products have to meet all of the following essential criteria to be considered relevant.

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

Secondly, for the purpose of this call, EUnetHTA21 will prioritise the selected products by applying the following additional criteria to support the selection process:

g) targets a life-threatening or chronically debilitating disease; and
h) breakthrough technology[1]

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.

As the selection criteria are applied for the first time in this open call, the specification of the selection criteria, their operationalisation and applicability will be further developed in the course of EUnetHTA 21.

In the event that the call is over-subscribed, products which meet all of the listed criteria will be taken into consideration.

EUNETHTA 21 JSC FORMAT

All 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 JSC CSCQ 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 3.5 months in duration starting from receipt of the Draft Briefing Book.

The table below provides estimated dates[2] of final EUnetHTA 21 recommendations according to date of Draft Briefing Book Submission. The EUnetHTA 21 Final Written Recommendation represents the HTA bodies' final output.

[1]Breakthrough technology: Preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint (could include impact on a surrogate or clinical intermediate endpoint or pharmacodynamic biomarker that strongly suggests the potential for a clinically meaningful effect on the underlying disease; improved safety profile or quality of life) or a substantial improvement in practicality or convenience of use or care pathways (organizational impact).

[2] 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

Estimated Timelines for EUnetHTA 21 Final Recommendations

Draft Briefing Package Written submission	Estimated F2F Meeting date	EUnetHTA 21 Final Recommendations
10 Jan 2022	04 - 07 April 2022	22 Apr 2022
07 Feb 2022	02 - 05 May 2022	20 May 2022
07 Mar 2022	07 - 10 June 2022	24 Jun 2022
04 Apr 2022	04 - 07 July 2022	22 Jul 2022
02 May 2022	29 Aug - 01 Sept 2022	16 Sep 2022

ADDITIONAL INFORMATION

Further information regarding EUnetHTA 21 JSC, including guidance documents and templates, can be found on the EUnetHTA website and will be updated shortly. Any inquiries regarding this call or the JSC process itself should be directed to the EUnetHTA 21 JSC Secretariat (EUnetHTA21-JSC@g-ba.de).