# HTA Joint Scientific Consultations

## How to get most out of Scientific Advice?

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# What’s happening right now?

- **EUnetHTA 21 is close to ceasing its operations**
  - The service contract will expire as of 16th of September 2023.
  - There are still deliverables related to JSCs coming out:
  - Revised external guidance, briefing document template, timelines being published (rather minor revisions)
  - Handover procedure to the Commission (and HTACG) in progress
- **HTACG – SG on JSCs established**
  - We are setting up our internal processes (+liase with other SGs)
  - Work plan + mapping exercise on experience with scientific advice
  - Entering an interim period until 12th of January 2025.

# Joint Scientific Consultations (JSC)

**What is a JSC?**

- Early scientific advice for HTDs before the start of pivotal clinical trials on initial evidence generation for Marketing Authorisation Application/HTA assessment, and Post Licensing Evidence Generation (PLEG, only in conjunction with a request for discussion of pivotal trial design)

**What is the aim of a JSC?**

- Promotes optimal and robust evidence generation fit-for-purpose for HTA (and Regulators), ultimately bringing benefits for public health by enabling access to medicines which are effective to European patients as the ultimate goal
- Discussions are structured around PICO (comparators, interventions, health outcomes and patient populations) and health economic assessment

# EUnetHTA 21 JSCs (Pharma)

**EUnetHTA 21 service contract (2021 – 2023): 6-8 JSCs were foreseen,**
**7 JSCs were conducted during EUnetHTA 21**; selection criteria of the HTAR applied.

| EUnetHTA 21 JSCs | | |
|---|---|---|
| **Open Call** | # of JSCs selected | Characterization of JSCs selected |
| **1st Open Call (2021)** | 3 | 2 oncological and 1 non-oncological product:<br>▪ 3x First in class (FC)<br>▪ 2x Orphan designation (OD)<br>▪ 1x PRIME |
| **2nd Open Call (2022)** | 4 | 3 oncological and 1 non-oncological product:<br>▪ 4x First in class (FC)<br>▪ 1x Orphan designation (OD)<br>▪ 2x ATMP<br>▪ 1x PRIME<br>▪ 1x SME |

# **EUnetHTA 21 JSCs (Pharma)** cont'd

- Overall all **11 partners of the EUnetHTA 21 Committee for Scientific Consistency and Quality (CSCQ) JSC** have been involved in the JSCs
- The roles of **Assessors and Co-Assessors** were taken on by a total of **6 different HTAbs**
- For the **7 JSCs** in total: **6 patient experts and 4 clinical experts have been involved at European level.** Additionally, partners involved national experts on national level according to their national procedure.
- **Guidelines and templates** were revised and updated at the beginning of EUnetHTA 21, have been revised internally in the mid-term of the project and now underwent a final round of revision including a **public consultation in July 2023**, the CEB approved the updated versions on the 6th of September 2023.
- The current versions of all publicly available JSC documents can be found on the EUnetHTA 21 website: https://www.eunethta.eu/jointhtawork/

# EUnetHTA 21 JSCs (Medical Devices, MD)

**EUnetHTA 21 service contract (2021-2023): No JSC MD**

- According to service contract no JSC on Medical Devices (MD) foreseen for the EUnetHTA 21 project phase
- During EUnetHTA JA3: 1 Pilot Early Dialogue on MD had been conducted

Thus experiences are limited in this field.

# JSC Roles and Responsibilities Matrix

- **Requested by Heads of HTA Agencies Group (HAG)**
- **Developed by EUnetHTA 21 JSC Secretariat**
- Aiming to provide a clear overview of the JSC process and steps:
  - Tasks linked to the JSC framework and process under the HTA Regulation,
  - How the work is shared and who is responsible,
  - Which steps are derived from HTA Regulation articles or EUnetHTA 21 recommendations.
- Enables for an analysis of procedural requirements and informs resource allocation

# Interim period (Apr 2023 – Jan 2025)

- Examining EUnetHTA 21 deliverables for uptake
- Getting a picture of SG members
  & getting every member on the same page with how we will work
  - It seems that more members have experience with joint scientific consultations than with national processes
- Within- and between group procedures to be set up
- Implementing act in Q2 2024

…and the cherry on top: voluntary advice.

# Voluntary Interim Advice #1

- HTAbs needed to flag their interest in participating in Parallel EMA-HTA body Scientific Advice for the interim period **until 2nd June 2023, as well as the number of consultations they wish to take part.**
- HTAbs interested in active participating must have **national rules and procedures in place to avoid conflict of interest situations and maintain confidentiality**. These are a national responsibility and will not be managed centrally. In terms of an observer status only maintenance of confidentiality needs to be ensured.
- HTAbs may **participate actively** or as an **observer.**

# Voluntary Interim Advice #2

**Framework**

- Voluntary initiative: European HTAb (EUnetHTA 21 CSCQ JSC, HAG and HTA subgroup on JSC) consulted for expression of interest

**Key elements**

- Rolling approach upon Applicant's initiative: dependent on available HTAb resources
- HTA R selection criteria apply
- Participation of HTAbs: active or as observers - minimum of 2 active HTAbs per procedure
- In case less than two HTAb are available, the request will continue as EMA-only scientific advice.
- Output: EMA Advice Letter + Individual Recommendation Letters of the participating HTAbs (non-consolidated recommendations, but joint e-meetings will still enable for a common understanding and exchange)

# Voluntary Interim Advice #3

- **Official announcement in July 2023** on both HTAb and EMA webpages including the info package (External guidance, Application form and Briefing document template)
- Coordination of HTAb involvement by G-BA (HTAb coordination contact): Applicants are invited to flag their interest for a parallel scientific advice to EMA (when applying for EMA Scientific Advice) or to G-BA (HTA coordination contact)
- Expected work load: Usual effort of a national consultation + joint meetings
- **Approx. 3 procedures foreseen in total** for the interim period (one interim procedure takes ~4 months)

# Synergies with EU legislation

- Two possible synergies with the recent efforts to revise the legislation on pharmaceuticals:
  - **Unmet medical need**: the legislative proposal of the European Commission proposes to grant additional market exclusivity conditional on the medicinal product addresses UMN. The EMA sets scientific guidelines for the application of the relevant article & initiates conulstation process.
  - **More alignment with EMA timelines**: the legislative proposal envisages shortening EMA scientific assessment timelines, so meeting the expectations on more engagement with the HTDs and also more aligment with EMA timelines is going to be difficult for HTAbs.

# How to get most out of Scientific Advice…

## …in the interim period?

- Be responsive to advice
- Get used to sharing more information – it is the HTD's responsibility of sharing information that is sufficient for answering their questions
  - Discussing UMN is not a priority, neither are extensive discussions aroud SLRs or NMAs
- Follow up on updates (HTA SN) and engage in voluntary consultations

## …beyond 2025?

- Engage with the European Commission's consultation procedure on the implementing act on JSCs (see the Implementation Rolling Plan for draft timelines)

**Thank you** for your attention!