

EUROPE: THE REVIVED SCHEME OF EUROPEAN SCIENTIFIC ADVICE – EUNETHTA 21 – ARE YOU PREPARED TO APPLY?

1. CONTEXT

- On 8 November EUnetHTA called for applications for joint scientific consultations (JSCs); the call is open until 7 Dec 2021.
- The call is for 8 JSCs (formerly referred to as Early Dialogues) for medicinal products.
- A second call will be in Q3 2022.

2. DETAILS

- Consultations will be in parallel with EMA consultations.
- The selection of the first 4 medicinal products should be within 2 weeks of application.
- 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, the following additional criteria will apply to support the selection process:

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

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.

3. CONCLUSIONS & POTENTIAL DIRECTION

Strategic: Given that Joint Clinical Assessments are soon applicable to cancer and ATMP medications, followed by orphan indications, JCS's can provide valuable strategic insights.

- Joint advice is specifically important for products where EMA and HTA evidence requirement discrepancies are expected. But requires commitment to change existing PH 3 plans.

Operational: Preparing advice needs to be planned early and needs to account for at least a 4mths process

- Consider carefully all EMA and HTA method requirements for developing evidence and map your questions for scientific advice against – you may find some solutions or allows informed modification of your questions.

Sources: EUnetHTA 21 JSC – open calls – EUnetHTA

Haute Autorité de Santé - HTA : la HAS actrice de la coopération européenne pour l'évaluation des technologies de santé (has-sante.fr)

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