Conference on the New Regulation on HTA

What's next?

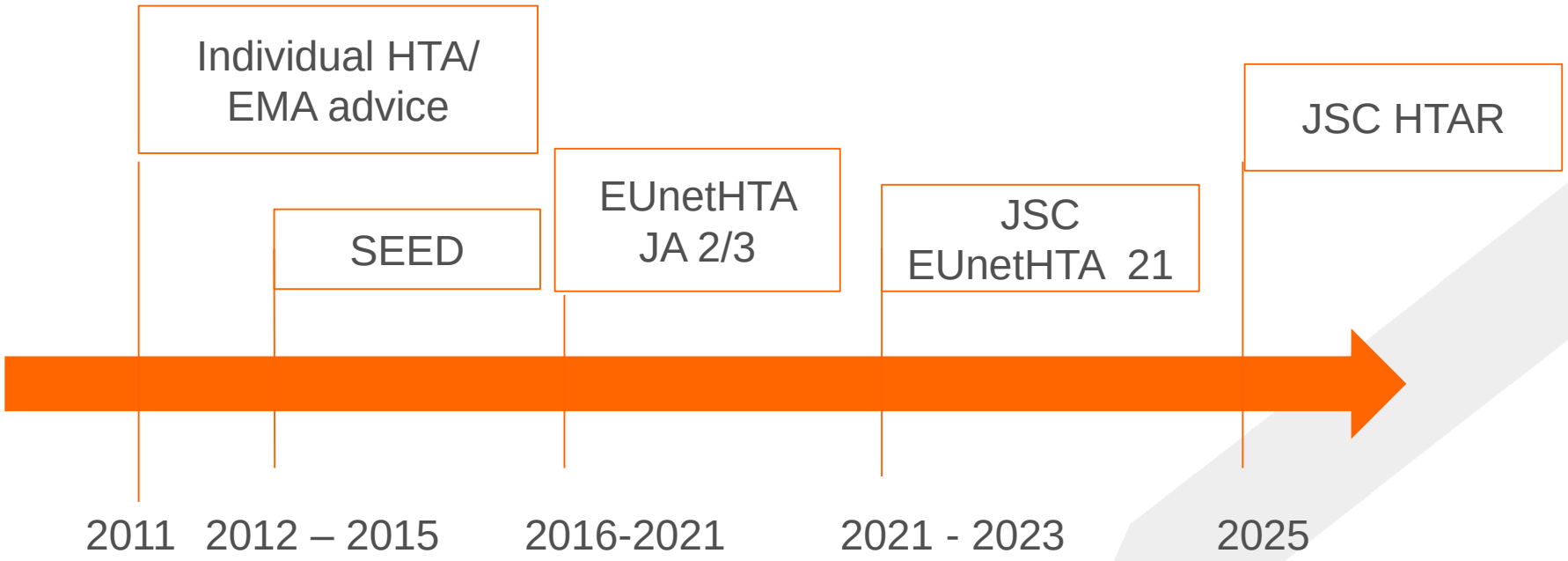
22.06.2022, Brussels

Joint scientific consultation

AGENDA

- History of HTA - advice
  Current developments in EUnetHTA 21
- i.Outlook on JSC system as of 2025
- i.Importance of collaboration amongst HTABs and equally between HTABs and EMA

Timeline of Joint Scientific advice (HTA)

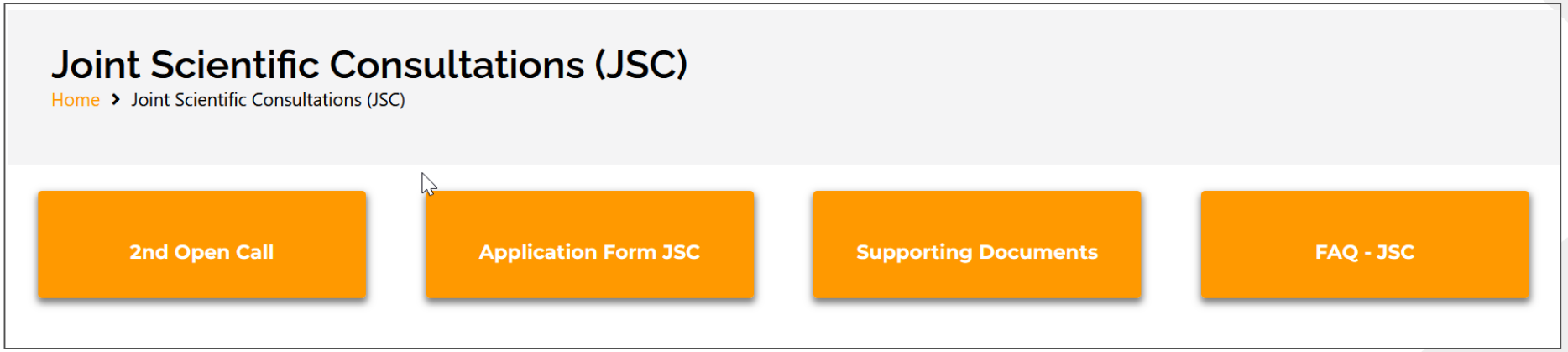


MS= member state, JCA= Joint clinical assessment, JSC= Joint scientific consultation, CG = coordination group; EDWP= Early Dialogue working party, CSCQ= Committee for scientific consistency and quality; HTAR= HTA Regulation; HTD = health technology developers

Advances of previous HTA - consultation formats that are being built upon:

- Guidance for HTD to generate evidence from clinical trials needed to address HTA needs for (joint) assessments and across multiple countries
- Standing committee with open discussion of different points of view
  - Bringing together different experiences and expectations of HTA-bodies
  - Identification of commonalities and differences between member states.
- Parallel advice with EMA leading to mutual learnings and alignment of procedures, hence establishing mutual trust
- Develop different approaches to patient involvement
- Testing different formats of consultation (HTA only, written only)
- Continuous improvement of coordination

JSC in EUnetHTA 21?



https://www.eunethta.eu/jsc/

- formation of a new standing committee.
  - EDWP → CSCQ JSC
  - 11 HTA organisations, at least 6 participating in each JSC
    - NOR, SWE, IRL, ESP, PRT, FRA, IT, BEL, NLD, HUN, D
  - Monthly meetings

Conduction of JSC

Pre JSC

- Open Call
- Application
- Selection and information of HTD

internal

- Setting up hands on group for JSC (min. 6 HTAs)
- Appointing assessor and co - assessor

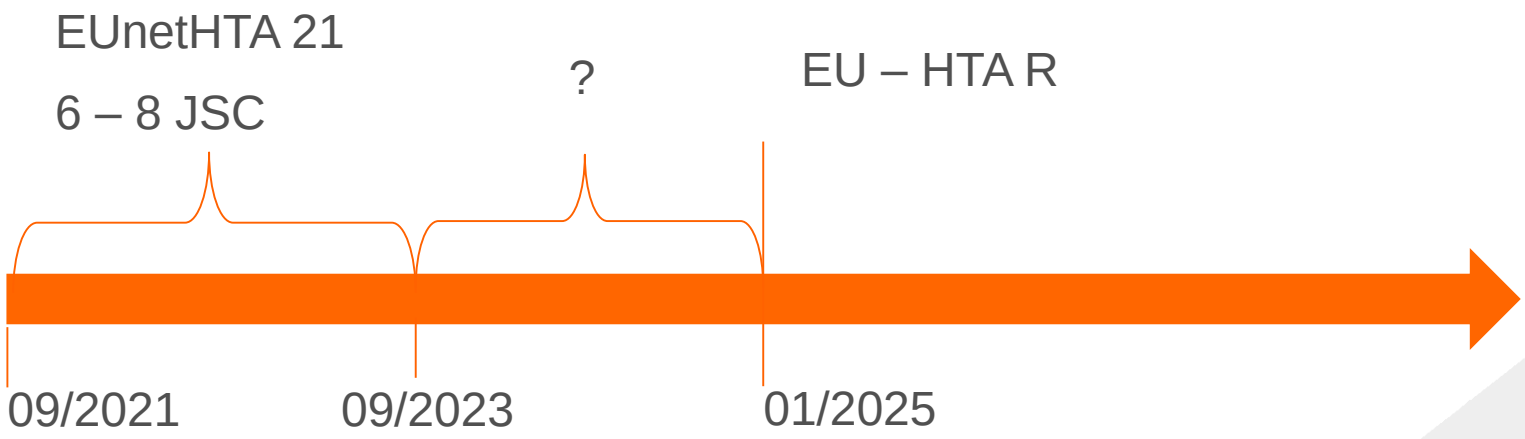
JSC

- According to procedural guidance
- Involvement of experts (patients and HCP)
- F2F meeting (virtual) with EMA and HTD
- Validation of the final recommendation by the CSCQ JSC (11 HTAs).

JSC in EUnetHTA 21?

- non-binding scientific advice
- parallel consultations with the EMA
- Update of procedures, Briefing book, templates, FAQ, selection criteria
- First open call for JSC
  - Feedback received to improve 2nd open call
- First 3 JSCs started (oncology, orphan drugs)
- 2nd Open Call open from June 6th to August 31st
  - 5 JSC are planned
  - In case of any questions: EUnetHTA21-JSC@g-ba.de

JSC beyond 2023: infrastructure & resources



How to meet the need for advice between 2023 and 2025?

- National advice possible in some countries
- Additional multinational or simultaneous national Scientific Advice on a voluntary basis
- Participation of member states depending on resources

Comparison

EUnetHTA JA 2/ 3

- individual MS - position
- Learning and Exchange of Information
- Adaptation of procedure
- participation of HTAb depending on resources
- Review of content only by few MS
- Patient involvement
- Advice also possible for health economic questions
- Written and F2F format

EUnetHTA 21/ HTAR

- Focus on future JCA
- MS - specific opinions will be kept
- fixed number of participants in EUnetHTA 21, Assessor & Co-assessor
- Endorsement/ validation of written recommendation of CSCQ | CG
- Expert involvement (patients & HCP)
- Selection criteria according to the regulation
- "… clinical study design aspects, incl. comparators, interventions, outcomes and patient populations"
- "… shall include a meeting with the health technology developer"

Collaboration HTA ←→ HTA and HTA ←→ EMA

- HTA | HTA : Different areas of responsibility at national level depending on the health system
- HTA | EMA: Different requirements for decision-making
- coordination of procedure (selection of products, time frame, participants, meeting process)
- Exchange on patient and HCP involvement.
- Standardised exchange on clinical development issues throughout the process
- No harmonization of requirements, but
  - mutual support when similar challenges are identified.
  - early identification for additional evidence needs (filling post-approval evidence gaps)
  - Acceptance of different requirements for evidence generation and exchange of positions