



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

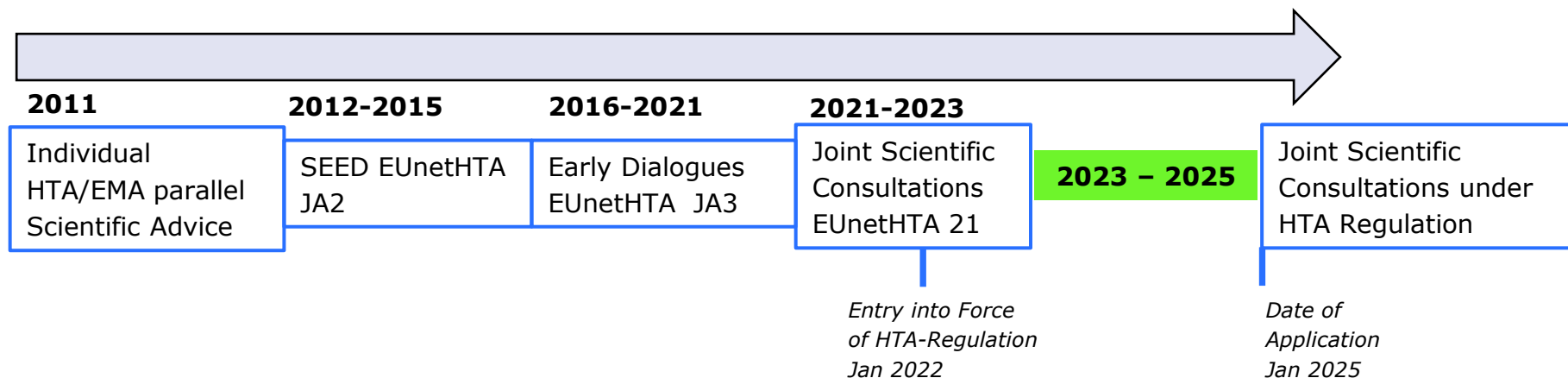
# Cooperation at the HTA/regulatory interface

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Update and opportunities for future dialogue

Presented by Stephanie Said (G-BA) and Thorsten Olski (EMA)





- Follow-up actions from the last (9<sup>th</sup>) Stakeholder Platform (Dec 2022): EMA and HTA counterparts to consider **options** for discussion on evidence planning involving regulators and HTAs after EUnetHTA21 and **before the new arrangements** under the HTA Regulation become applicable; “**interim period**”

## Procedure:

- Named “**parallel EMA/HTA body (HTAb) Scientific Advice**”
- Modeled after the EUnetHTA JA3 individual parallel consultation (Parallel Consultation Individual, PCI)
- Detailed guidance published on [EMA](#), [EUnetHTA 21](#) and [G-BA](#) websites

## Framework:

- **Not under** EUnetHTA. It is a voluntary initiative. Call for participation in EUnetHTA 21 CSCQ JSC, HAG, and HTA subgroup on JSC
- **Not to be confused** with **current JSC** (EUnetHTA 21) or **upcoming JSC** (HTA-Regulation)

## Key elements:

- Acceptance of applications on a rolling basis upon initiative by applicants (no Open Call)
- Selection criteria of the HTA-Regulation apply
- G-BA (HTA Coordination Contact) to coordinate the involvement of HTAbs throughout the procedure
- Allocation depending on available resources. Applicants will not be able to choose participating HTAbs.
- A minimum of 2 active HTAbs per procedure is foreseen. If the minimum number of active HTAbs is not reached, the request will continue as EMA-only scientific advice. Participation of HTAb will not be limited to previous EUnetHTA members, but extend to all HTAbs volunteering
- Output will be individual Written Recommendations by HTAbs as well as the EMA Advice Letter

## Timeline and practical aspects

### Parallel EMA/HTA Scientific Advice

- Applicants should flag their interest to G-BA as the HTA Coordination Contact and copy EMA
- HTA Coordination Contact (G-BA): [Interimadvice.hta@g-ba.de](mailto:Interimadvice.hta@g-ba.de)
- Centralised recruitment of HTAbs
- Distinction between active participants and observers
- Procedure length will be ~4,5 months
- Discussion meetings with applicants foreseen for all procedures
- Outcome documents of the procedure: EMA Scientific Advice Letter + individual Written Recommendations (**non-consolidated**) separately by each of the participating national HTAbs

## Timeline and practical aspects

- Official announcement on webpages including the info package (guidance, templates etc.; 03-Jul-2023)
- Applicants should request such parallel scientific advice three months before the standard submission deadline
- Supported by the European Commission in preparation for the application of the HTA-Regulation



# Q & A

## Further information

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