EU HTA – Legal Framework and Guidance Documents

Where to find the relevant information?

Legal Framework

Regulation (EU) 2021/2282	The legal framework for EU HTA is defined by the Regulation (EU) 2021/2282 on health technology assessment (HTAR). This framework covers joint clinical assessments (JCA), joint scientific consultations (JSC), the identification of emerging health technologies (EHT), and voluntary cooperation. The HTAR entered into force in January 2022 and applies as of January 2025. ➢ Regulation (EU) 2021/2282
Implementing Acts	The HTAR provides for certain aspects to be further developed and specified by means of Implementing Acts. Implementing Acts are adopted by the Commission in areas where uniform conditions for implementation are needed. These aspects include JCA, JSC, management of conflicts of interest, and exchange of information with the EMA. ➢ Implementing Act: JCA for medicinal products (incl. annex) ➢ Implementing Act: Cooperation with EMA by exchange of information ➢ Implementing Act: Conflicts of interest (incl. Annex) ➢ Implementing Act: JSC on medicinal products (DRAFT) ➢ Implementing Act: JSC on (in vitro diagnostics) medical devices (DRAFT)

Guidance Documents by the Coordination Group

During the implementation phase, the Coordination Group will publish several guidance documents. Already published guidance documents can be found below:

- Methodological guideline for quantitative evidence synthesis: direct and indirect comparisons
  Adopted on 8 March 2024
- Practical guideline for quantitative evidence synthesis: direct and indirect comparisons
  Adopted on 8 March 2024
- Guidance on outcomes for joint clinical assessments
  Adopted on 10 June 2024
- Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in joint clinical assessments
  Adopted on 10 June 2024
- Scientific specifications of medicinal products subject to joint clinical assessments
  Adopted on 10 June 2024
- Guidance on validity of clinical studies
  Adopted on 04 July 2024

Rolling Plan

The rolling plan sets out the key activities that the European Commission has already completed or plans to complete in preparation for the implementation of the HTAR. This plan is subject to regular review in order to ensure transparency and up-to-date information for relevant stakeholders.

➢ Rolling Plan

EUnetHTA 21 Deliverables

EUnetHTA 21 was a joint consortium of 13 European HTA agencies to support the European Commission in the implementation of the HTAR. During the EUnetHTA 21 contract period (2021 – 2023) several (procedural) guidance documents and templates have been developed and published, which formed the basis for the official EU HTA guidance documents developed by the Coordination Group.

➢ EUnetHTA 21 Deliverables