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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 ➢ Implementing Act: JSC on medical devices and in-vitro diagnostic medical devices ➢ Implementing Act: JCA of medical devices and in-vitro diagnostic medical devices (DRAFT)

Guidance Documents by the Coordination Group

Methodological guidance documents

- Methodological guideline for quantitative evidence synthesis: direct and indirect comparisons (LINK)
- Practical guideline for quantitative evidence synthesis: direct and indirect comparisons (LINK)
- Guidance on outcomes for JCA (LINK)
- Guidance on reporting requirements for multiplicity issues and subgroup, sensitivitiy and post hoc analyses in JCA (LINK)
- Guidance on validity of clinical studies for JCA (LINK)

Procedural guidance documents

- Scientific specifications of medicinal products subject to JCA (LINK)
- Guidance on the scoping process (LINK)
- Procedural guidance for JCA medicinal products (LINK)
- Guidance for the appointment of assessors and co-assessors for JCA and JSC (LINK)
- Procedural guidance for JSC on medicinal products (LINK)
- Guidance for the selection of medicinal products for JSC (LINK)
- Procedural guidance for JSC on (in-vitro diagnostic) medical devices (LINK)
- Guidance for the selection of in-vitro diagnostic) medical devices for JSC (LINK)

Format and templates

- Guidance on filling in the JCA dossier template, dossier template, table template collection, technical specifications for dossier submission (LINK)
- Template for the JSC requests (LINK)
- Briefing document template for HTACG JSC (LINK)
- Briefing document template for Parallel HTACG/EMA JSC (LINK)
- Outcome document for JSC – medicinal products (LINK)
- Format and template of requests from HTD for JSC – medical devices (planned for Q1 2025)
- Outcome document for JSC – (in-vitro diagnostic) medical devices (LINK)
- Briefing document templates for JSC – (in-vitro diagnostic) medical devices (LINK, LINK)

The HTA secretariat can be contacted as follows:

General enquiries	SANTE-HTA@ec.europa.eu
Product-specific JCAs and for submission of early information for JCAs (to request access link to the HTA IT platform)	SANTE-HTA-JCA@ec.europa.eu
Submissions of requests for JSCs (to request access link to the HTA IT platform)	SANTE-HTA-JSC@ec.europa.eu
Technical support for the HTA IT platform	SANTE-HTA-IT-SUPPORT@ec.europa.eu