HTA CG | MEMBER STATE COORDINATION GROUP O
HEALTH TECHNOLOGY ASSESSMENT

Status on Joint Clinical Assessment

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Regulatory (EU)

EMA

Regulatory approval

- Does technology X work?
- Does the benefit of technology X outweigh the risks?
- Are there any additional needs for technology X post-licencing?

Single licensing system; one EU legislation

Health Technology Assessment

HTAR

In JCA: relative assessment of Technology X vs. Technology Y (and others)

- How does it compare to what we already have (fewer harms, in whom etc)

Relative effectiveness and relative safety

Clinical domain only!

- No value judgements
- No conclusions on added value or reimbursement
- Common methodology and approach

National

Appraisal phase

- e.g. cost effectiveness to be added
- Other considerations?
- Weighing arguments; decision making/reimbursement advice

JCA should be given due consideration in national decision-making

Ongoing JCA of Medicinal Products

https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en

JOINT CLINICAL ASSESSMENT (JCA)
DEFINITION
- Joint HTA reports, produced by 2 EU MS - On HTD submission dossier - HTD cannot submit data again on national level - Focussing on the **clinical domains** - **Without value judgements** - MS to give due consideration
AIM
Avoid duplications of work, increase consistency & quality of assessments; ultimately facilitate patient access
SCOPE UNDER HTAR
Medicinal Products - From Jan '25: New active substance Onco & ATMP - From Jan '25: + JCA on Orphan - From Jan '30: full scope - Includes Type II variation once JCA has been published on the initial indication Medical Devices - High risk MD, Type IIb/III and IVD (as of 2026)

ONGOING JCA		
SUMMARY INDICATION	**ASSESSOR/CO-ASSESSOR**	**STATUS**
Melanoma	France/Poland	Confirmation check dossier
Paediatric low-grade glioma	Ireland/Germany	
Bladder cancer	Netherlands/Denmark	Scope finalized – HTD informed of final assessment scope and assessment scope explanation meeting took place
SMA	Ireland/France	
Small cell lung cancer	Germany/Portugal	
Breast cancer	Austria/Belgium	
Small cell lung cancer	Germany/Hungary	
Synovial sarcoma or leimoyosarcoma	Sweden/Norway	
Ovarian, fallopian tube or peritoneal cancer	Germany/Slovenia	Scope finalized – HTD informed of final assessment scope

JCA timelines in parallel to EMA

a) Standard procedure for New Chemical Entities
b) Type II variation (Extension of Indication) and accelerated procedure
c) re-initiation of JCA or update of JCA without a new scope
d) Update of JCA with a new scope
e) To be followed by adopted CG

Letter of Intent
- Letter of Intent to both EMA and the HTA Secretariat
- **Please be realistic and provide updates**

HTD shall submit
- SmPC
- clinical overview section
- New therapeutic indication (if applicable)

Final consolidated PICO*
- a) D87
- b) D50

** As per JCA procedural guidance*

HTD submission Dossier
As of the sharing of the scope:
- a) 100 days
- b) 60 days

EC completeness check:
- a) 15 working days
- b) 10 working days

Missing information HTD
- a)15 days
- b)10 days
- 7 days for minor info

Clarifiying/additional info (asked by asr/co-asr)
- 7 to 30 days

HTD to submit new evidence
- No later then 7 days after CHMP

HTD fact check:
- a) 7 days
- b) 5 days

Finalize JCA[e]
- The latest on the day of EC decision granting MA
- c) 180 days
- d) 330 days

JCA	Start JCA at submission to EMA	Scoping phase	Submission dossier	Drafting JCA	Final JCA
EMA	Start MAA	D120 LOQ		CHMP	CD

Involvement of experts in JCA

- Co-creation of effective patient and clinical experts involvement is key ;
- Working group on the identification of patients and clinical experts launched within the Health Technology Assessment Stakeholder Network ;
- Identification of individual experts and CoI check by the HTA Secretariat (EC) ;
- Selection of experts by the JCA SG ;
- Experts comment the consolidated scope before finalization and the revised draft report (*IR JCAs for medicinal products*) ;
- Fifth meeting of the SN held on 1 July 2025 in Brussels;

Health technology assessment: Webinar for patients and clinical experts - Public Health

Key take aways for health technologies developers

- Submit Letters of Intent and provide updates
- Submit at same time as you submit to EMA the SMPC and clinical overview
- Familiarize with all guidances and the legislation
- **Prepare yourself:** start mapping the PICO landscape in Europe
- Increase communication within company, between regulatory and market access
- JCA runs in parallel to EMA process, yet it is a separate procedure and different dossier!