

HTA CG

MEMBER STATE COORDINATION GROUP OF
HEALTH TECHNOLOGY ASSESSMENT



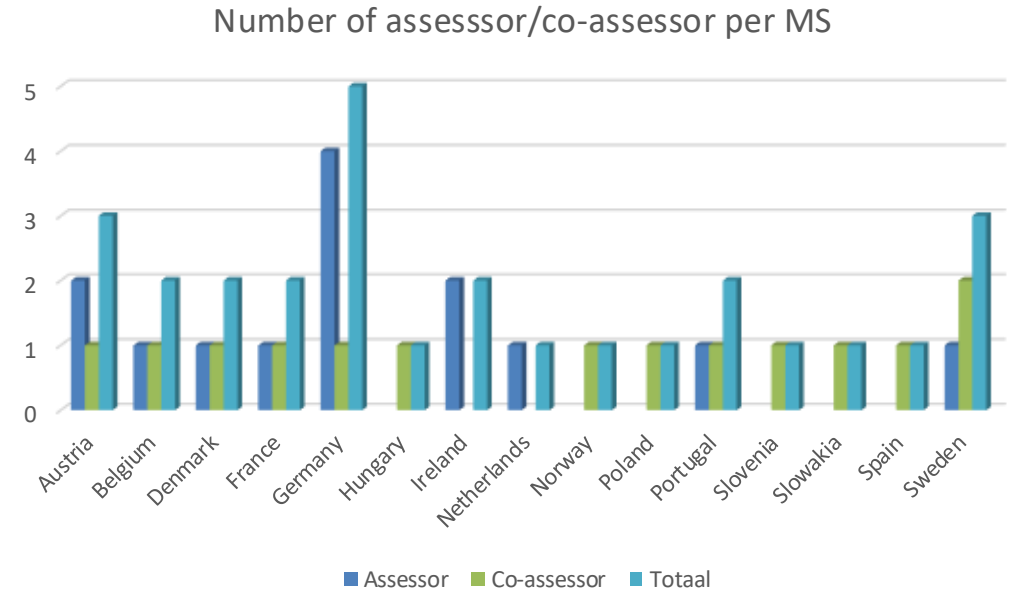
Joint Clinical Assessment Process of Medicinal Products

Anne Willemsen
Chair of the JCA Subgroup
EAA, April 2026

Ongoing JCA of Medicinal Products – statistics

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

- Until January '26, 14 JCA were initiated
 - 23% is ATMP
 - 54% is Orphan Designation
- 15 different MS took assessor and co-assessor roles
 - **17 different HTA bodies!**
- Status of JCA production:
 - **First JCA finalisation expected soon!**
 - About half in assessment phase
 - Rest is awaiting dossier
 - 1 discontinued due to EMA withdrawal
- Trend in JCA submissions
 - Gradually increased during the quarters in 2025.
 - Based on Letters of Intent received so far, anticipate high scaling up of JCAs



Lessons learned so far

- Letter of Intent (LOI)
 - For the ongoing JCA: 57% were delayed compared to planned submission date from LOI
 - Timely LOI and updates aids capacity planning & scoping work
- Timely submission of Clinical Overview and draft SmPC
- Changes made to the format of the assessment scope explanation meeting
 - Still, it cannot be used to discuss appropriate methods for the dossier; nor will it lead to changes to the PICO
- General dossier expectations:
 - Complete **every part** of the dossier template, in accordance with the IR 2024/1381, Annex I
 - Carefully follow all HTACG adopted guidances,
 - In particular the one on how to fill in the submission dossier
 - For **every PICO** conduct a Systematic Literature Search (according to section 4.2.1 of Annex I).
 - Report both the search strategy and the results
 - Also in the absence of evidence
- Short deadlines for additional requests
- Include all available evidence in the initial dossier submitted to address Commission's first request

Key take aways

MAA process and JCA run in parallel, yet separate procedure

- submit Letters of Intent and provide updates in a timely manner
- Submit **at same time** as you submit to EMA the SMPC and clinical overview

Sufficient competences & resources for developing the dossier

- Start early on your submission dossier and map the PICO landscape

Communication between Regulatory and Market Access departments

Follow the regulations (HTAR and IR) and guidance carefully!

HTA CG

Subgroup Joint Clinical Assessment

