European Commission

Joint Clinical Assessment for Medicinal Products

January 2025 #HealthUnion

The Regulation on Health Technology Assessment (Regulation (EU) 2021/2282) HTAR establishes a framework for conducting Joint Clinical Assessments (JCA) at EU level. These assessments support member states in their national Health Technology Assessment (HTA) processes, providing a scientific analysis of clinical evidence on the relative effects of a health technology (a medicinal product or a medical device) on health outcomes. This analysis can inform decisions on the allocation of budgetary resources in the field of health, including on pricing or reimbursement of health technologies.

WHAT IS A JOINT CLINICAL ASSESSMENT?

The **HTA Regulation**, **Commission Implementing Regulations and Guidances** issued by the Member State Coordination Group on Health Technology Assessment (HTACG) lay out the rules, procedures and methodologies for Joint Clinical Assessments for medicinal products. The Joint Clinical Assessments will focus on clinical domains only, without any value judgements or conclusions on reimbursement. This will remain in the mandate of the Member States and to do this, they may add other information at national level, such as cost-effectiveness.

The **JCA subgroup** of the HTACG conducts the Joint Clinical Assessments. The subgroup appoints **an assessor and a co-assessor** from different Member States to conduct the assessment. The assessor, with the help of the co-assessor, prepares a draft Joint Clinical Assessment report based on the dossier submitted by the health technology developer. The dossier contains complete and up-to-date information, data, analyses, and other evidence on the medicinal product under assessment, requested in the assessment scope defined by the assessor and the co-assessor. **Patients, clinical experts and other relevant experts** are also involved in the assessments. The **draft joint clinical assessment** report is then reviewed and endorsed by the HTACG. This endorsement should happen no later than **30 days** after the Commission grants marketing authorisation for the given medicinal product. The report is then considered by the national authorities in their national health technology assessments and decision-making processes.

WHICH PRODUCTS DO THE JOINT CLINICAL ASSESSMENTS COVER?

Staggered approach toward all medicinal products seeking centralised Marketing Authorisation

12 January 2025	13 January 2028	13 January 2030
New oncology medicinal products and advanced therapy medicinal products		
New therapeutic indications for which a JCA report has been published		
New orphan medicinal products		
All new medicinal products		

WHO IS INVOLVED?

Seven key partners:

- HTA Coordination Group (HTACG)
- JCA Subgroup
- Health Technology Developers (HTDs)
- Individual Experts (patients, clinical experts and other relevant experts)
- HTA Secretariat in the European Commission
- European Medicines Agency (EMA)

EMA CENTRALISED PROCEDURE AND JOINT CLINICAL ASSESSEMENT OCCUR IN PARALLELL

EMA Centralised Procedure	Joint Clinical Assessment
Submission of Application for Marketing Authorisation to EMA	
	Scoping phase and finalisation of the assessment scope (PICO) 10 days after CHMP adopts its list of questions
Opinion of the Committee for Medicinal Products for Human Use (CHMP)	
	Dossier submission within 100 days (60 in some situations) after the request and at the latest 45 days before the Opinion by the CHMP
Adoption of the Commission decision granting the Marketing Authorisation (MA)	
	Finalisation of JCA report by the JCA Subgroup at the latest on the date of the granting of MA
	Endorsement of the JCA report by the Coordination Group no later than 30 days after the granting of a MA

Additional timelines of the JCA procedure are detailed in the Procedural guidance for JCA medicinal products
https://health.ec.europa.eu/publications/procedural-guidance-jca-medicinal-products_en

HOW DOES THE PROCESS WORK?

1. START OF JCA PROCESS

1. The **EMA notifies the HTA secretariat** of the receipt of a marketing authorisation application.
2. When submitting a marketing authorisation application to the EMA, the **HTD submits relevant information to the HTA secretariat**.
3. The JCA process formally begins upon the **appointment of assessor and co-assessor** by the JCA subgroup.

2. SCOPING PHASE

4. The assessor and co-assessor draft an **assessment scope proposal** detailing research questions for the JCA. This is known as PICO (Patient or Population Intervention Comparison or Control Outcome).
5. To ensure that the assessment scope reflects the needs of the Member States, the **members of the JCA subgroup are invited to comment** on the suggested scope from their national perspective. In addition, individual experts are invited to provide their input on the assessment scope.
6. The **assessment scope is finalised by the JCA subgroup** and is shared with the HTD in the Commission's initial request for the submission dossier. This is done within **10 days** after the Committee for Medicinal Products for Human Use (CHMP) adopts its list of questions, or at the latest **75 days** after the EMA validation of the marketing authorisation application in accelerated procedures and for variations to the terms of an existing marketing authorisation.
7. The HTD can request an assessment scope explanation meeting with the JCA Subgroup.

3. DOSSIER SUBMISSION

8. The HTD submits a **comprehensive dossier**, including clinical and safety evidence, to the HTA secretariat in digital format within **100 days** of the Commission's initial request (reduced to **60 days** in accelerated procedures and for variations to the terms of an existing marketing authorisation).
9. The assessor and co-assessor can ask the HTD to submit additional information via the HTA secretariat.
10. The HTA secretariat shares all the information received from the HTD with the assessor and co-assessor and the JCA subgroup.

4. DRAFT JCA REPORT

11. The assessor and co-assessor prepare a **draft JCA report and a summary report** with input from the JCA subgroup and the individual experts.
12. The draft JCA and summary reports are **shared with the HTD** to check technical or factual inaccuracies, and to comment on any information the HTD considers to be confidential.
13. The HTD may provide, on their initiative, new relevant information, data, analyses and other evidence to the HTACG via the HTA secretariat.

5. FINALISATION OF JCA REPORT

14. The JCA subgroup **discusses and finalises the draft JCA report** and summary report in a meeting. Individual experts may be invited.
15. The finalised report is submitted to the HTACG for endorsement. The HTACG must endorse the reports no later than **30 days** following the adoption of the Commission Decision granting the marketing authorisation for the medicinal product under assessment.
16. After the Commission's procedural check, the **JCA report and summary report endorsed by the HTACG is published**.

Please note that the Joint Clinical Assessment is to be discontinued, for example, where an application for a marketing authorisation or for a variation to the terms of an existing marketing authorisation is withdrawn, or where the outcome of the centralised procedure is negative.

SUBMISSION OF EARLY INFORMATION BY HEALTH TECHNOLOGY DEVELOPERS

Although the marketing authorisation application triggers the JCA process, the preparation for it starts earlier, to ensure the timely conduct of the process. Therefore, HTDs are invited to share their letters of intent, sent to the EMA, with the HTA secretariat. The HTA secretariat will use the information from the letter of intent to prepare for the JCA and to identify patients, clinical experts and other relevant experts to be involved in the JCA. Submission of early information by health technology developers will also help the JCA subgroup to identify an assessor and a co-assessor.

In order to ensure that patients, clinical experts and other relevant experts take part in Joint Clinical Assessments in an independent and transparent manner, free from conflict of interest, they will only be selected and involved in Joint Clinical Assessments after the Commission has assessed their declarations of interest.

USE OF THE JCA REPORT

National authorities have the obligation to give due consideration to the published JCA reports in their national HTA and to annex both the dossier submitted by the HTD and the published JCA report in their own national HTA documentation.

Moreover, the Member State authorities must provide information to the HTACG on the outcome of the national HTA that has been subject to a JCA, including how the JCA report was considered when carrying out a national HTA. Based on this information, the European Commission produces a **yearly report summarising the uptake of the JCA reports in HTAs in Member States.**

MORE INFORMATION

Implementation of the EU Regulation on Health Technology Assessment

https://health.ec.europa.eu/health-technology-assessment

Heath Technology Assessment Regulation

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282

JCA Implementing Regulation

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202401381

Guidance Documents

https://health.ec.europa.eu/health-technology-assessment/key-documents_en?f%5B0%5D=topic_topic%3A227

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