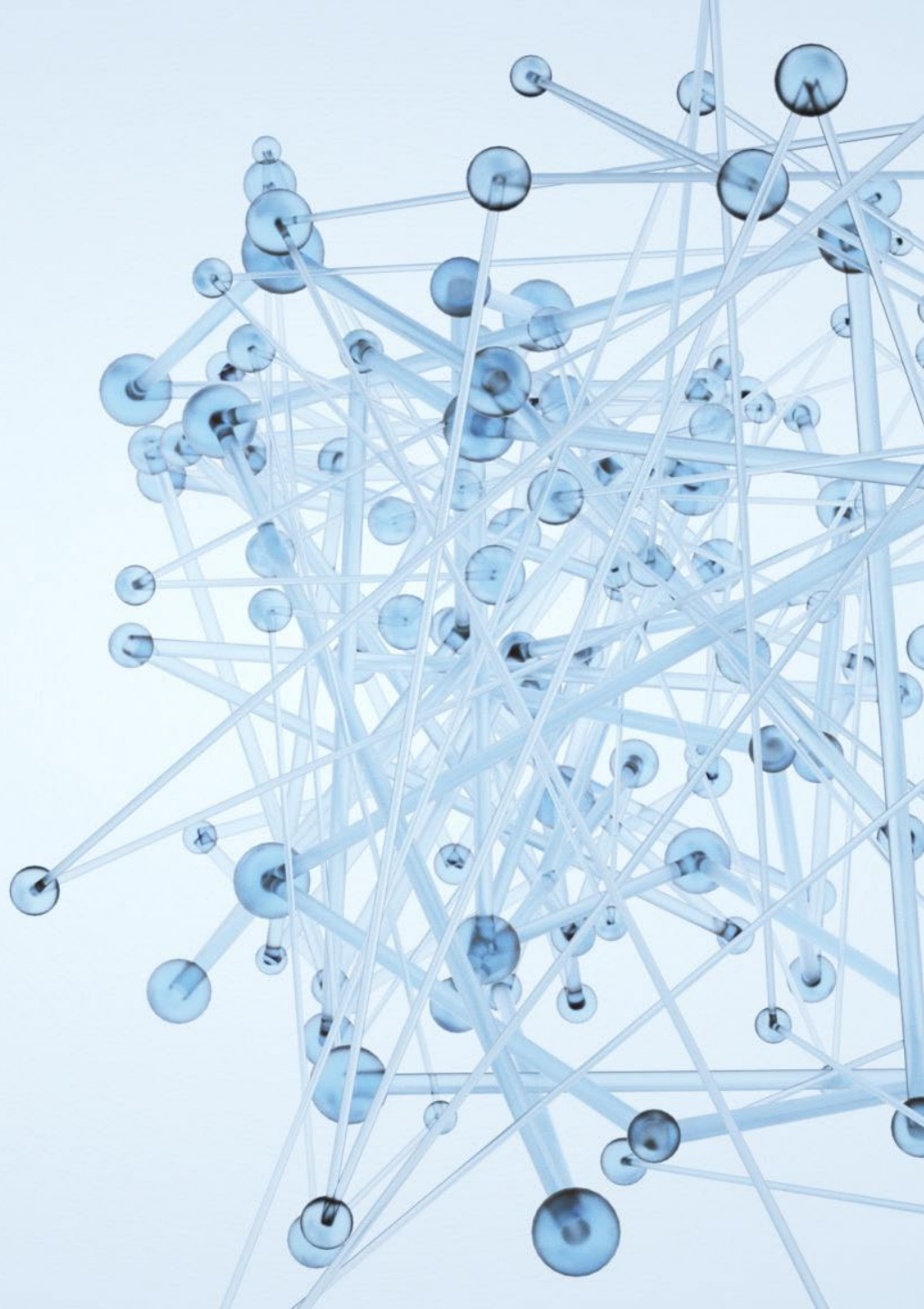
EMA
EUROPEAN MEDICINES AGENCY

Regulatory/ HTA interface under the HTAR – Update on implementation activities

ISG meeting, 30 September 2025

Presented by Michael Berntgen, Head of Scientific Evidence Generation Department



Focus of today's update

1. Operational aspects of the interface between Centralised Procedure (CP) and Joint Clinical Assessment (JCA)
2. Update on Joint Scientific Consultation (JSC) for medicinal products
3. Progress with sharing information for forecasting JCA and JSC

EC Implementation rolling plan

Procedural rules for **JCA of medicinal products**	Adopted 23 May 2024
Procedural rules on **cooperation with the EMA**	Adopted 18 October 2024
Procedural rules for the **management of conflicts of interest**	Adopted 25 October 2024
Procedural rules for **JSC of medicinal products**	Adopted 18 December 2024
Procedural rules for **JSC of medical devices and IVD medical devices**	Adopted 24 January 2025
Procedural rules for **JCA of medical devices and IVD medical devices**	HTA Committee vote 19 September 2025

Rules on the information EMA shares/facilitates:

for **planning/forecasting** of joint clinical assessments (JCA) and joint scientific consultations (JSC) for medicines/devices

Articles 2 & 3

for **identifying experts** (e.g., patients, clinical experts)

Article 5

on general **scientific and technical matters** related to HTA beyond assessments

Article 6

concerning the **security of sharing** and **protection of confidential information** exchanged

Articles 7 and 8

Identification of upcoming MAAs in scope of JCA production

Compliance rate (as of 15 September 2025):

- By now almost all "positive" notifications **correctly identified** by the applicant
    - In 2025 only four notification incorrectly identified as being in scope (e.g. biosimilars)
- Continued issue that correctly identified applications **are not sent** to the HTA secretariat
    - Reminders had to be sent to applicants for 51% of notifications in 2025
    - Currently still not followed up by applicants for around 43% of these unsatisfactory notifications
        - *Applicants continue to show limited responsiveness to reminders to submit to HTA secretariat*

<u>Important to cascade standard process</u>:

- Parallel guidance for applicants on declaring products in the scope of Joint Clinical Assessment (JCA) under the HTAR released on 21 June 2024
- Harmonised notification process: EMA and HTA secretariat agreed to use the same form (i.e. Letter of Intent) to notify the intention to submit an application.
- Important for applicant (HTD) to provide the information to EMA and HTA secretariat in parallel, also for change of submission dates
- Responsiveness by applicants to reminders to be increased; if not enhanced need to identify alternatives

Frequently asked questions about joint clinical assessments

NEW

1. Scope of medicinal products are subject to JCA
2. Meaning of “stepwise approach”
3. Specific scenarios for new marketing authorisation application
4. Non-Article 8 submissions
5. Medicinal products subject to JCA as of January 2025
6. Orphan medicinal product for the treatment of a rare cancer
7. Outcome of new active substance claim
8. Coformulations/combinations
9. Definition of the terms
10. Orphan medicinal product is removed from the Register
11. Difference between the specific type of a variation
12. Specific scenario for extension of indication
13. Application of Article 8
14. Case of a conditional MA
15. Assessment of companion diagnostics

HTA Regulation: Frequently Asked Questions (FAQ)

First MAAs with JCA production in parallel hence requiring exchange of information

Based on the list of ongoing Joint Clinical Assessments published by the HTA secretariat (status: 2 September 2025)

International non-proprietary name (INN) / Common Name	Indication - Summary	Substance type (classification)
Autologous melanoma-derived tumor infiltrating lymphocytes, ex vivo-expanded	Treatment of melanoma	ATMP
Tovorafenib	Treatment of paediatric low-grade glioma (LGG)	Chemicals
Sasanlimab	Treatment of bladder cancer	Biologicals
Onasemnogene abeparvovec	Treatment of 5q spinal muscular atrophy (SMA)	ATMP
Lurbinectedin	Maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)	Chemicals
Camizestrant	Treatment of adults with locally advanced or metastatic breast cancer	Chemicals
Tarlatamab	Treatment of extensive-stage small cell lung cancer	Biologicals
Catequentinib	Treatment of synovial sarcoma or leiomyosarcoma	Chemicals
Senaparib	Maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer	Chemicals

Provision of information from the Centralised Procedure to inform Joint Clinical Assessment

Principles: 1/ respect of separate remits; 2/ exchange through secretariats only; 3/ information to be appropriate and relevant

After CHMP adoption of questions, EMA to provide to the HTA secretariat:

- Clinical major objections or clinical other concerns that might impact the therapeutic indication(s) of the medicinal product proposed by the applicant
- Clinical major objections related to non-full marketing authorisation (e.g conditional marketing authorization or marketing authorisation under exceptional circumstances)

Identification of such questions is without prejudice to the final outcome of the regulatory assessment as well as of the HTA assessment.

Updates on timelines based on the adopted timetables.

Review: after 12 months of experience (including usefulness and efficiency)

First experience in July 2025:

Provision of information from two adopted List of Questions

- Information selected acc to principles
- Outlook of next procedural timelines

Implementation of parallel JSC process

- Following the two open calls for JSC requests in 2025, the JSCSG has selected **4 requests for parallel JSC** (aka parallel EMA/HTA scientific advice) out of the total of 7 JSCs accepted for 2025
    - Two parallel JSCs concern oncologic conditions, and the other two non-oncologic rare diseases.
    - The first parallel JSC is progressing well with the joint SAWP/JSCSG discussion meeting in 4Q25.

<u>To note for applicants:</u>

- In case of parallel JSC the applicant is advised to immediately contact EMA and register the consultation on the IRIS platform to ensure EMA participation.
- The HTA Secretariat and the EMA should receive the briefing package simultaneously by the stated deadline. For submission to EMA, please use the IRIS platform.

Information for forecasting JCA and JSC (medicines/medical devices)

Medicinal Products:

- Upcoming submissions for marketing authorisation.
- Variations to existing marketing authorisations (new indications).
- Estimated number of advice procedures.

Medical Devices/IVDs:

- Ongoing and finalised advice procedures.
- Estimated future requests for advice.

EMA sent the first ever **forecast report** to the HTA secretariat by end of April 2025 and provided and update on medicinal products in September 2025

Quarterly reports to support the **selection of medical devices and IVDs** for joint clinical assessment were provided in April and July

For more on HTAR implementation and contact information, see here

Implementation of the Regulation on health technology assessment

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The Regulation (EU) 2021/2282 on health technology assessment (HTAR) entered into force on 11 January 2022 and will apply from 12 January 2025.

In the preparatory phase for the implementation of the HTAR (January 2022 – January 2025), this webpage aims at informing national authorities, health technology developers and stakeholders about the development of implementing legislation in accordance with the powers conferred to the Commission by the co-legislators.

In the implementation phase of the HTAR (beyond January 2025, when joint HTA work will start), this webpage will include all the information required by Article 30.3 of the HTAR.

– Factsheet on implementation of the Regulation