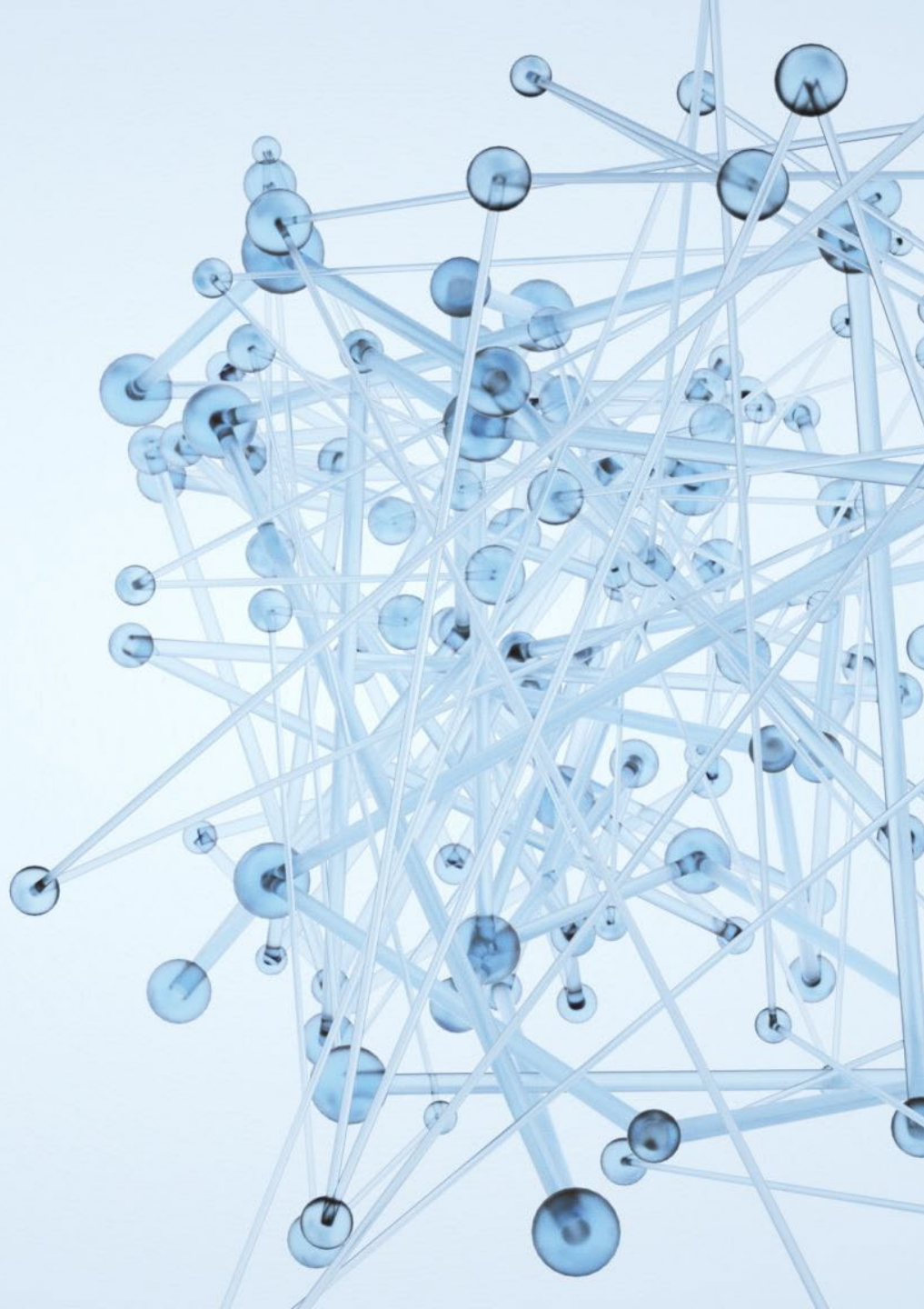
EMA
EUROPEAN MEDICINES AGENCY

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

ISG meeting, 30 June 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. Other activities as result of the new interface
4. Joint HTAb/regulatory position paper on evidence and uncertainties

EC Implementation rolling plan *(status 25.06.2025)*

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**	Public consultation on the draft closed

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

Operational aspects of the interface between Centralised Procedure (CP) and Joint Clinical Assessment (JCA)

Identification of upcoming MAAs in scope of JCA production

Compliance rate (as of 3 March 2025):

- By now almost all “positive” notifications **correctly identified** by the applicant
    - In 2025 only two notification incorrectly identified as being in scope
- Continued issue that correctly identified applications **are not sent** to the HTA secretariat
    - Only 54% of notifications in 2025 were also sent to the HTA secretariat hence this needs addressing
- Responsiveness to reminders is **variable**
    - In around 42% of cases applicants do not react on reminders to submit to the 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

NEW

- Responsiveness by applicants to reminders to be increased; if not enhanced need to identify alternatives

Notification of submitted MAAs in scope of JCA production

EMA Notification to HTA Secretariat

- Requirement:
  - EMA to provide HTA secretariat with information on JCA applications received and validation outcomes (Article 3 (1) of IA on JCA of medicinal products)
- Transparency measures:
  - On EMA website included in the listing Medicines for human use under evaluation
  - NEW The HTA secretariat published List of ongoing joint clinical assessments

International non-proprietary name (INN) / Common Name	Indication - Summary	Substance type (classification)	Accelerated Assessment (Art. 14(9) Reg 726/2004)	Revert to standard Time Table (MM/YY)	Variation to the terms of an existing MA	Orphan product	Date of EMA validation of the MAA	Assessor	Co-assessor
Autologous melanoma-derived tumor infiltrating lymphocytes, ex vivo-expanded	Treatment of melanoma	ATMP	N		N	N	27/03/2025	National Authority for Health, France	Agency for Health Technology Assessment and Tariff System, Poland
Tovorafenib	Treatment of paediatric low-grade glioma (LGG)	Chemicals	N		N	Y	27/03/2025	National Centre for Pharmacoeconomics, Ireland	Institute for Quality and Efficiency in Health Care, Germany
Sasanlimab	Treatment of bladder cancer	Biologicals	N		N	N	22/05/2025	Dutch National Health Care Institute, The Netherlands	Danish Medicines Council, Denmark

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

Legal basis:

Article 3 of the Implementing Act on JCA of medicinal products: "The main steps for the exchange of the information referred to in the first subparagraph, as well as the exact content of the information to be communicated at those steps, shall be agreed upon by the European Medicines Agency, the HTA secretariat and the JCA Subgroup."

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)

Update on Joint Scientific Consultation for medicinal products

Implementation of parallel JSC process

- 2nd request period for 2025 closes today (30 June)
  - Important for developers intending to receive parallel JSC to first make a request
  - Applicants will be informed by the HTA secretariat of the outcome.
- Parallel JSC from 1st request period in processing
- 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.

Guidance on the EMA website

Single documents on JSC also covering parallel JSC:

- Procedural Guidance for Joint Scientific Consultations (JSC) on Medicinal Products (MP)
- Request template for HTACG JSC and Parallel HTACG/EMA JSC for Medicinal Products (MP) (PDF version, Word version)

Parallel joint scientific consultations with the Member State Coordination Group on HTA (HTACG)

Regulation (EU) 2021/2282 on health technology assessment (HTAR) established a framework for **joint scientific consultations** (JSC) at EU level.

The Member State Coordination Group on HTA (HTACG) carries out these joint scientific consultations.

Under this regulation, medicine developers may request **scientific advice** from EMA in parallel with the joint scientific consultations that the coordination group provides.

The **parallel consultation** aims to allow developers to obtain feedback from regulators and and health technology assessment (HTA) bodies in EU Member States on their evidence-generation plans. This supports decision-making on marketing authorisation and reimbursement of new medicines.

As an outcome of the procedure, developers receive a **scientific advice letter** from EMA and an **outcome document** from HTA bodies.

Developers wishing to apply for a **parallel joint scientific consultation** procedure must first contact the European Commission's HTA secretariat to obtain access to their HTA IT platform. Developers then need to submit their request form during the request periods that the coordination group publishes in its annual work programme.

The coordination group selects applications in line with the selection criteria and other related information that the Commission makes available:

- Guidance for the selection of Medicinal Products (MP) for Joint Scientific Consultations (JSC)
- Procedural Guidance for Joint Scientific Consultations (JSC) on Medicinal Products (MP)
- Briefing document template for Parallel HTA Coordination Group (HTACG)/European Medicines Agency (EMA) Joint Scientific Consultation (JSC) for Medicinal Products (MP)
- Joint Scientific Consultations

For more information on EMA's role in HTA processes, see:

- Health technology assessment bodies
- Dates of 2025 Scientific Advice Working Party (SAWP) meetings and submission deadlines for scientific advice, protocol assistance, qualification of novel methodologies and HTACG/EMA parallel Joint Scientific Consultation (JSC) requests

Other activities as result of the new interface

Implementing Act on cooperation with the EMA

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 report to the HTA secretariat by the deadline (30 April 2025)

Expert identification in the context of JCAs and JSCs

- EMA provides the HTA secretariat with information on suitable individual experts upon request and if the information is available
- These experts can be proposed to relevant subgroups as patients, clinical experts, or other relevant experts for JCAs or JSCs
- Different modalities are currently being explored by the HTA secretariat

Joint HTAb/regulatory position paper on evidence and uncertainties

- Strong preference for randomised evidence
- Opportunities to complement pre-licensing data
- Estimand framework as valuable, shared language
- Improving outcome collection / analysis / reporting
- Availability of individual participant data
- Effect estimation by indirect comparisons
- Complement clinical trial data with real-world data
- Decision making under uncertainty

HEADS OF HTA AGENCIES GROUP

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 April 2025
EMA/115125/2025

Joint HTAb-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions

Outcome of a workshop series between HTA bodies and regulators

Position paper

EMA

For more information on HTAR implementation, see here

Implementation of the Regulation on health technology assessment

PAGE CONTENTS

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