EMA
EUROPEAN MEDICINES AGENCY

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

ISG meeting, 28 March 2025

Presented by Michael Berntgen, Head of Scientific Evidence Generation Department, and Joao Ferreira, HTAR implementation lead

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. Expert identification in the context of JCAs and JSCs
4. Medical device related activities

EC Implementation rolling plan (status: *March 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**	In preparation

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)

Reminder: Requirements in the Implementing Act on Joint Clinical Assessment (medicinal products)

Exchange of information with EMA (acc to Article 3)

- Notification of HTA secretariat about MAA / EoI submission in scope of JCA
- Information about positive validation and timelines
- During the assessment, information about changes to timelines and substantial questions / outstanding issues impacting the therapeutic indication
- Provision of CHMP Opinion (AR and SmPC)

As of 13 January 2025, all medicinal products falling under the scope of Article 7 of Regulation (EU) 2021/2282, for which the applicant declares in its application for marketing authorisation that it contains a new active substance and the therapeutic indication is the treatment of cancer and those that concern ATMPs are subject to JCA.

MAA – Marketing Authorisation Application; EoI = Extension of Indications; AR = Assessment Report; SmPC = Summary of Products Characteristics

Identification of upcoming MAAs in scope of JCA production

Compliance rate (as of 3 March 2025):

- Since June 2024, **87%** of all "positive" notifications **correctly identified** by the applicant
    - In 2025 only one notification was incorrectly identified as being in scope hence by now good understanding by applicants
- **53%** correctly identified applications **also sent** to the HTA secretariat.
    - Only 31% of notifications in 2025 were also sent to the HTA secretariat hence this trend is concerning
    - Most frequently applicants do not send notifications of change of submission date in parallel

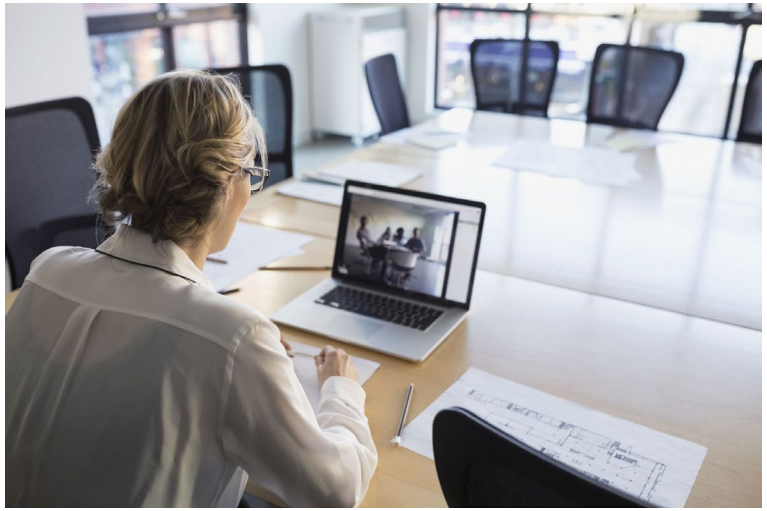
<u>Important to cascade standard process</u>:

- 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
- EMA/HTA secretariat monthly meetings
- Reminders sent to applicants, if needed

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)
- March 2025:
  - Two applications submitted, currently under validation.
  - Once assessment starts, those are included in ongoing MAA assessments listing (EMA website)
  - The HTA secretariat will publish list of JCA's in production
- Applications:
  - 1 new active substance for cancer treatment, 1 ATMP



EMA's first formal notification was sent to the HTA secretariat on 11 March 2025

Provision of information during the Centralised Procedure

EC/JCASG/EMA/CHMP working group on exchange of information at the CP/JCA interface

- Acc to 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.”
- Working group established and work is progressing

1.2.9. Provision of information to support Joint Clinical Assessment

Activity areas

The Regulation on Heath Technology Assessment (Regulation EU 2021/2282) will come into application in January 2025. One of the areas for regulatory/HTA collaboration under this Regulation concerns the provision of information from the regulatory assessment of an application for marketing authorisation or extension of indication for medicinal products to inform the respective Joint Clinical Assessment (JCA) for this technology performed by the Member State Coordination Group on HTA (HTACG) and its subgroups. The reason being that the assessment scope for JCA is based on the therapeutic indication of the medicinal product. Therefore, while preserving the separation of the respective remits of the Coordination Group and the European Medicines Agency, information shall be provided via the respective secretariats. The Implementing Regulation on JCA for medicinal products (Commission Implementing Regulation (EU) 2024/1381) specifies further the type of information provided.

Key objectives

- To provide relevant and necessary information from the regulatory assessment to support the preparation of Joint Clinical Assessments led by the HTACG.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

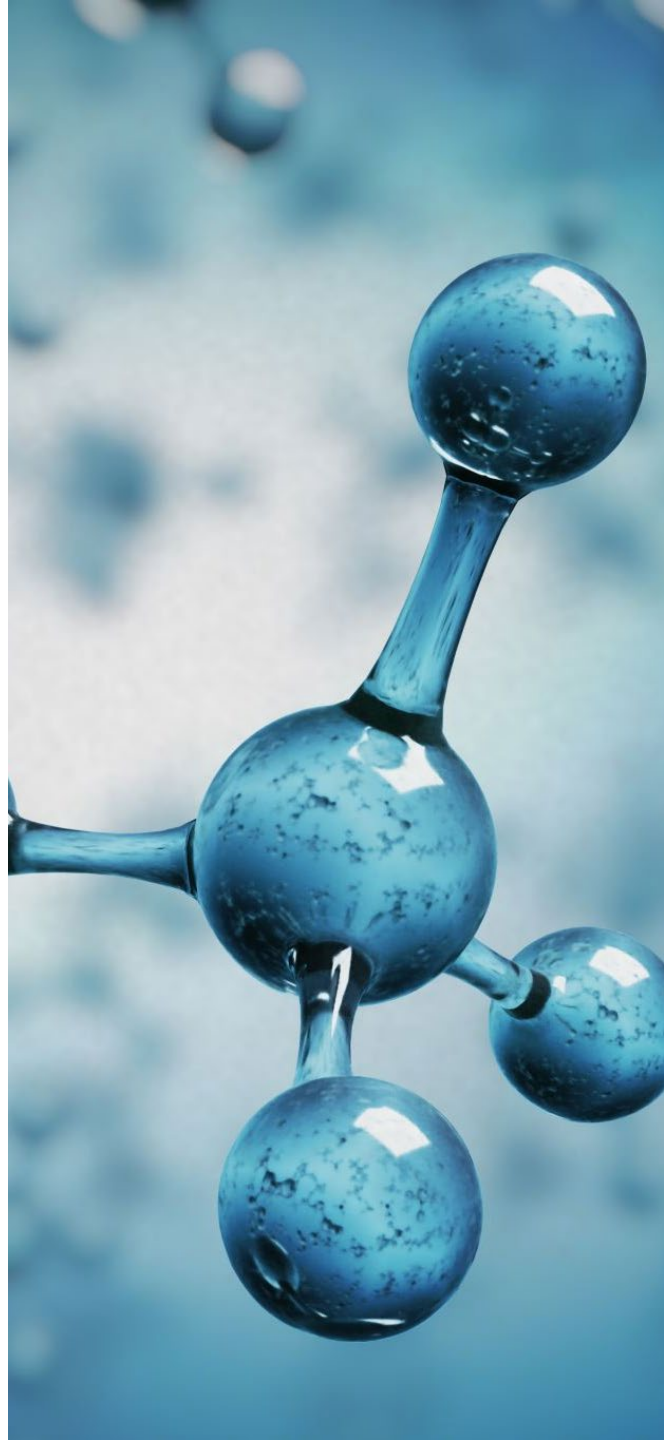
- Development of guidance on provision of information on substantial questions or outstanding issues from the CHMP review that might impact the JCA assessment scope, in collaboration with the HTA secretariat and the JCA Subgroup.

CHMP Workplan 2025

Update on Joint Scientific Consultation for medicinal products

Preparation for the first parallel JSC request

- 1st request period closed on 3 March 2025 and applicants have been informed by the HTA secretariat of the outcome.
- 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.
- 2nd request period scheduled for 2-30 June 2025
    - Important for developers intending to receive parallel JSC to first make a request



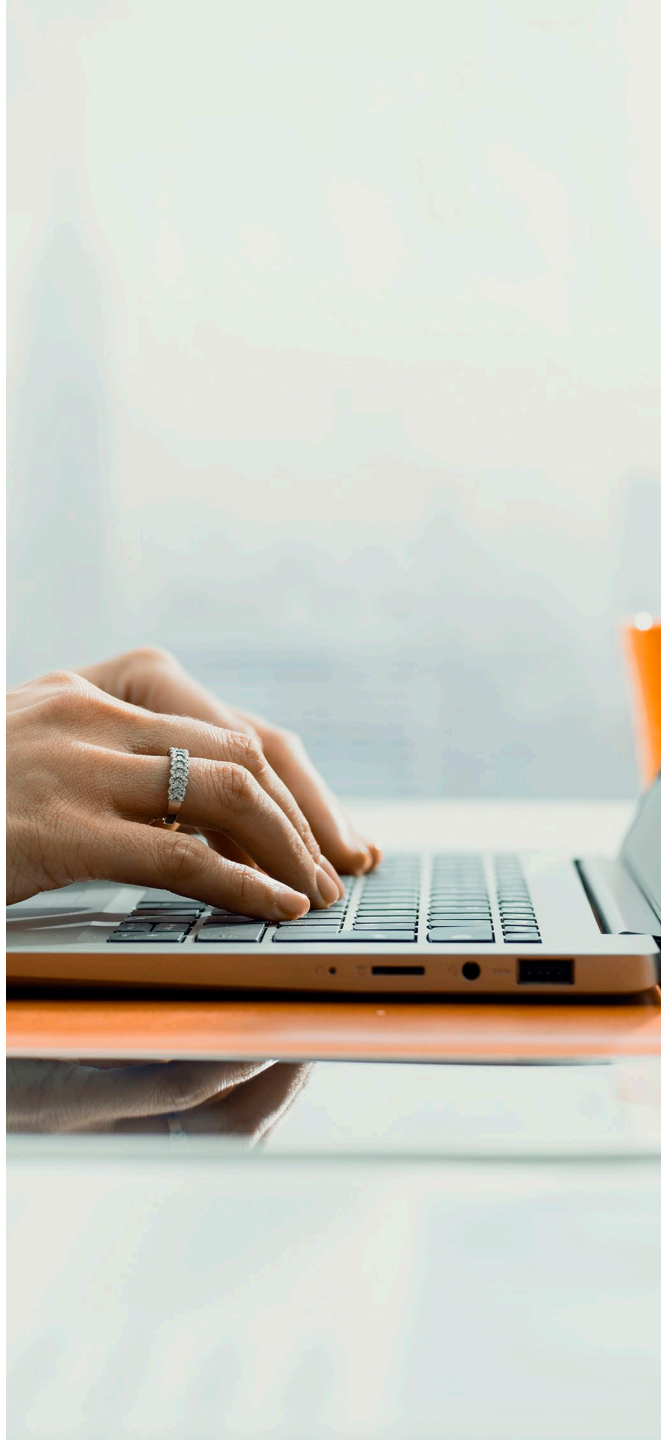
Expert identification in the context of JCAs and JSCs

Expert consultations

Requirement (Art. 5) of Implementing Act on cooperation with the EMA):

EMA will provide 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.	The personal data provided will be **limited** to the individual experts' names, contact details, and areas of expertise.

EMA is working with the HTA Secretariat on the process to support the expert identification



Medical device related activities

Overview of HTAR implementation activities for MDs/IVDs

Supporting development of future parallel JSC operations:

- Ongoing advice procedures with HTA bodies in observation (*presented under agenda item 3.).*
- Review of parallel JSC briefing document template

Upcoming forecasting report activities:

- Acc the *Implementing act of exchange of information with EMA*, preparing documentation under:
  - Art. 2 for the forecast of JCA/JCS for MD/IVDs (yearly submission)

Assisting selection of MD/IVDs for JCA (quarterly reports):

For more information on HTAR implementation, 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

Regarding the publication of the list of ongoing joint clinical assessments, please refer to the EC Europa website.