EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Regulatory/HTA interface under the HTA Regulation (HTAR) – Update on implementation activities

10th Industry Standing Group (ISG) meeting, 21 November 2024

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# Focus of today's update

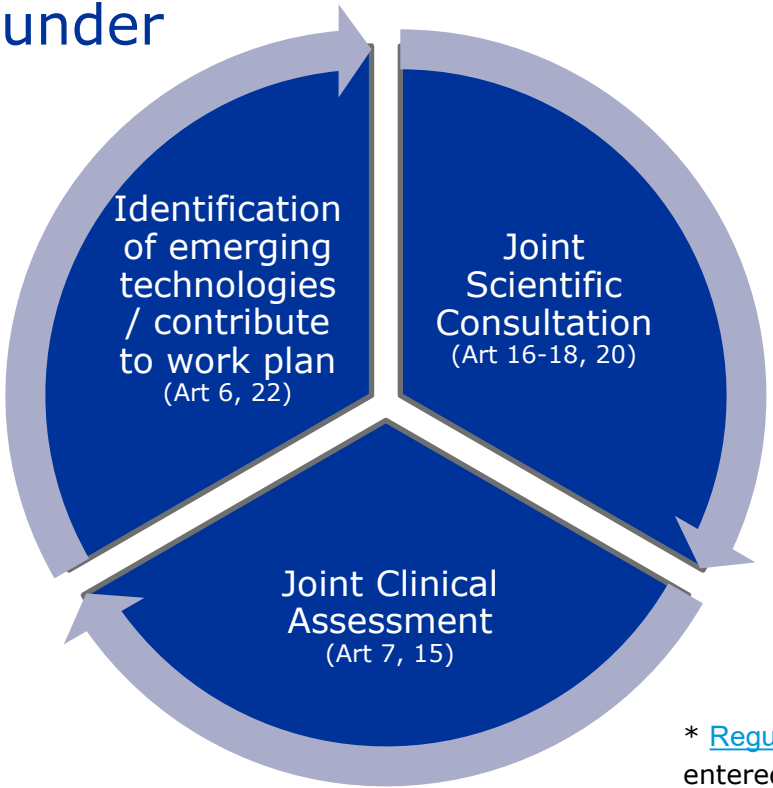
1. Operational aspects of the parallel notification processes for marketing authorisation application and joint clinical assessment
2. Framework for sharing of information between EMA and the HTA secretariat and the HTACG (incl. subgroups)

Outlook: Update in 1Q25 to focus on Joint Scientific Consultation

# Collaboration with EMA under the HTA Regulation*

Further details through Implementing Acts
to be adopted by the EC (Art 15, 20)

Transversal elements in the Regulation to facilitate such work, supported by the European Commission, include the sharing of confidential information




**Notes:**

- "Joint" refers to collaborative work amongst HTA bodies
- Activities cover medicinal products and medical devices / IVDs

* Regulation (EU) 2021/2282, entered into force in Jan 2022 and applies as of Jan 2025

# EC Implementation rolling plan – Implementing Acts to be adopted by 2025 (status: *November 2024*)

| | | |
|---|---|---|
| 1st | Procedural rules for **JCA of medicinal products** | Adopted 23 May 2024 |
| 2nd | Procedural rules on **cooperation with the EMA** | Adopted 18 October 2024 |
| 2nd | Procedural rules for the **management of conflicts of interest** | Adopted 25 October 2024 |
| 4th | Procedural rules for **JSC of medicinal products** | Under written consultation until 22 November 2024 |
| 5th | Procedural rules for **JSC of medical devices and IVD medical devices** | Published for public feedback until 26 November 2024 |
| 6th | Procedural rules for **JCA of medical devices and IVD medical devices** | In preparation |

**Finalised** - adopted by the European Commission

**In preparation** – pending adoption by the European Commission

# Operational aspects of the parallel notification processes for marketing authorisation application and joint clinical assessment

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

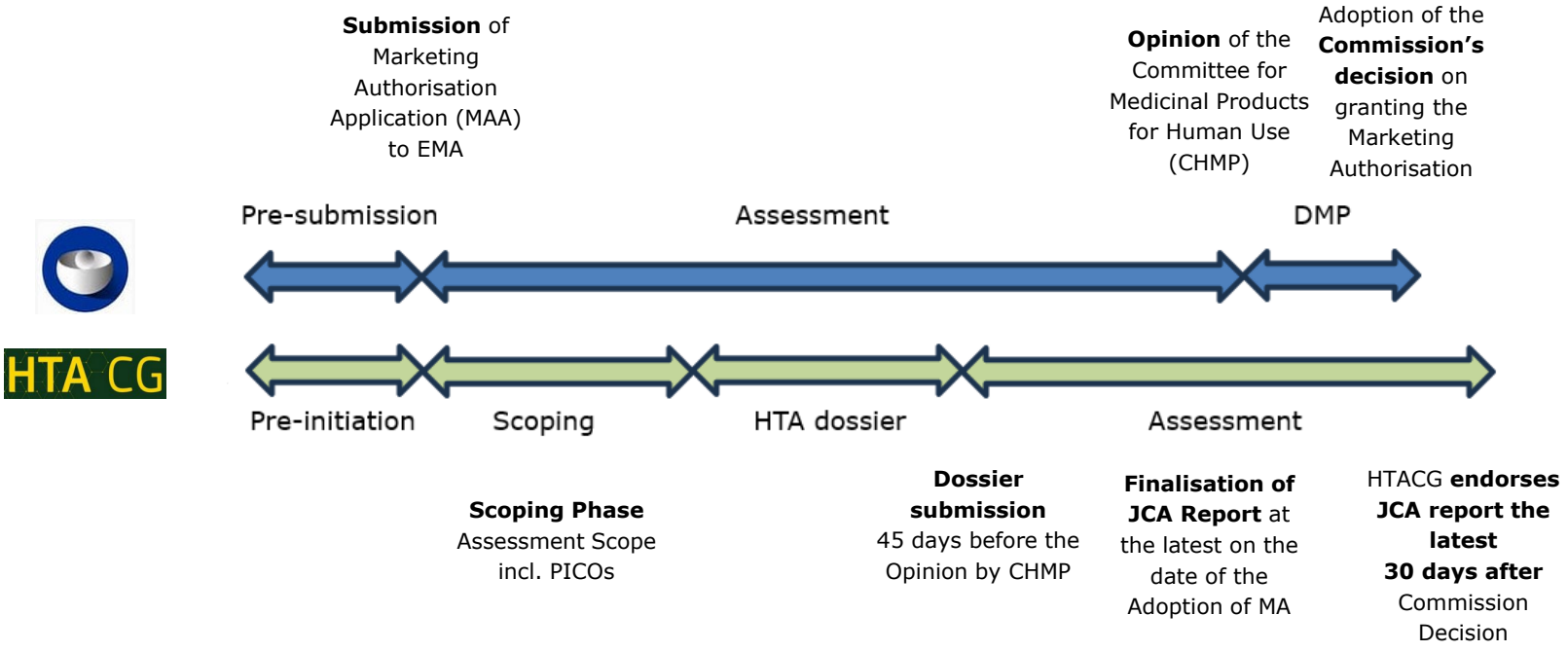
**Exchange of information with EMA (acc to Article 3)**

- 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

# Preparation is key for all parties involved



# Identification of upcoming MAAs in scope of JCA production

**New standard process**

- **Parallel guidance** for applicants on declaring products in the scope of Joint Clinical Assessment (JCA) under the HTAR released on **21 June 2024**

**Transition support**

- **Historic review** of 160+ LoIs in EMA systems reviewed, retrospectively (submitted before June 2024).
- **Communication** through EMA mailings to prospective applicants based on business pipeline data (coverage: until Q3 2025; 57 applicants in total)

**Harmonised notification process:** EMA and HTA secretariat agreed to use the same form to notify the intention to submit an application.

**Compliance rate** (*as of 11/11/24*):

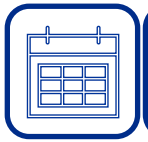
- 89% of "positive" notifications correctly identified by the applicant
- 62% correctly identified applications also sent to the HTA secretariat

# Framework for sharing of information between EMA and the HTA secretariat and the HTACG (incl. subgroups)

# Implementing Act on cooperation with the EMA

- The second of six acts released (adopted by the European Commission on October 18th).
- Provides the foundation for cooperation between EMA and the HTA secretariat / HTA network for European level work.
- Recognises the value of a long-standing collaboration, based on the experience since 2010, and codifies it in (tertiary) legislation.
- Sets a robust framework for ensuring the protection of confidential information.

## Rules on the information EMA shares/facilitates:

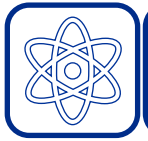


for **planning/forecasting** of joint clinical assessments (JCA) and joint scientific consultations (JSC) for medicines/devices

***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***

# Article 2 *at a glance*: Information exchange for JCA and JCS (medicines/medical devices)

**Medicinal Products:**

- By April 30 each year, the EMA provides the HTA secretariat with:
  - Upcoming submissions for marketing authorisation.
  - Variations to existing marketing authorisations for new therapeutic indications.
  - Estimated number of advice procedures under Regulation (EC) No 726/2004.

**Medical Devices/IVDs:**

- By April 30 each year, EMA provides information on:
  - Ongoing and finalised advice procedures for MDs.
  - Estimated future requests for advice by manufacturers.

**Key Elements:**

For medicinal products:
- *active substance name,*
- *health technology developer,*
- *therapeutic indication summary,*
- *eligibility for CP and PRIME scheme,*
- *expected submission date.*

For MDs/IVDs:
- *device type,*
- *intended purpose,*
- *development phase.*

# 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