EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

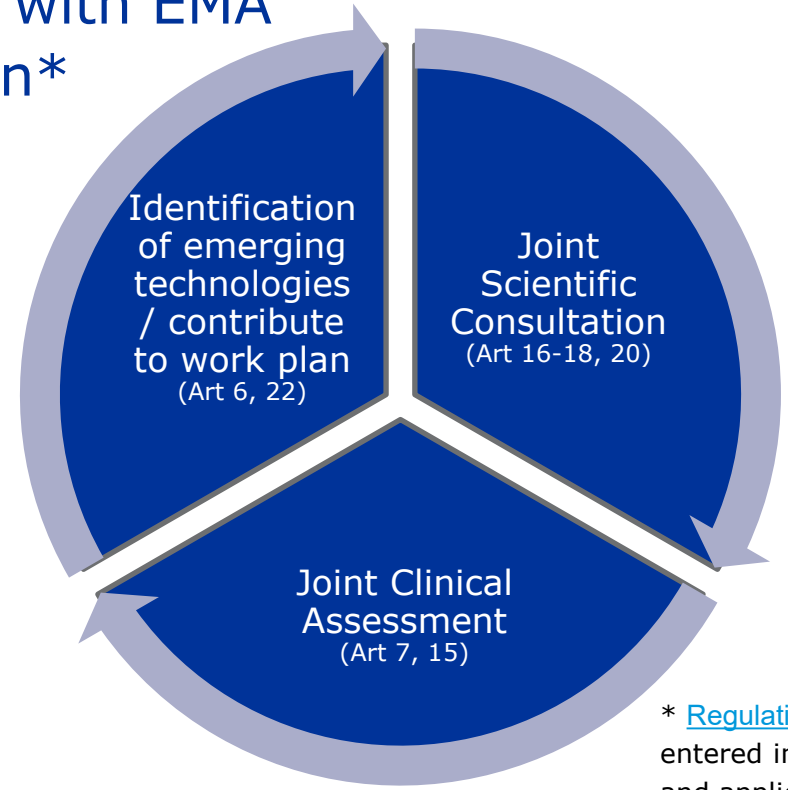
10th Industry Standing Group (ISG) meeting, 26 September 2024

Presented by
Michael Berntgen, Head of Scientific Evidence Generation Department

Reminder: 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

Implementation rolling plan – Development of Implementing Acts (status June 2024)

Implementing act for joint clinical assessments	HTAR Articles 15.1(a) and (c); 25.1(b); 26.1	Commission Implementing Regulation (EU) 2024/1381 of 23 May 2024 laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level, as well as templates for those joint clinical assessments	Adopted 23 May 2024

Adoption **Public consultation closed**	HTAR Article 25.1(a)	Conflict of interest management	by Q3 2024	In preparation
Adoption **Public consultation closed**	HTAR Articles 15.1 (a) and (b); 20.1 (c) and (d)	Cooperation by exchange of information with the European Medicines Agency (EMA)	by Q3 2024	In preparation
Adoption	HTAR Article 20.1	Joint Scientific Consultations for medicinal products	by Q3 2024	In preparation
Adoption	HTAR Article 20.1	Joint Scientific Consultations for medical devices	by Q4 2024	Planned
Adoption	HTAR Articles 15.1 (b) and (c); 25.1(b); 26.1	Joint Clinical Assessments for medical devices	by Q4 2024	Planned

Update on the notification process for Marketing Authorisation Applications (regulatory) in scope of Joint Clinical Assessment (HTA)

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

Parallel EC/EMA communication on 21st June 2024

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
State of Health, European Semester, Health technology assessment

Joint clinical assessment of medicinal products: Submission of early information by health technology developers

After 12 January 2025, medicinal products falling under the scope of Article 7(2), point (a) of Regulation (EU) 2021/2282 (the HTA Regulation) will be subject to a Joint Clinical Assessment (JCA). Initially, the JCA will concern medicinal products with new active substances for which the therapeutic indication is the treatment of cancer as well as advanced therapy medicinal products. As of 13 January 2028, all medicinal products designated as orphan medicinal products and, as of 13 January 2030, all other medicinal products falling under the scope of Article 7 of Regulation 2021/2282 are also subject to JCA.

The EMA published guidance on 21 June 2024 to applicants/health technology developers on how to declare in the EMA Letter of Intent (via the Pre-submission request form) whether their application falls under the scope of the Health Technology Assessment Regulation ((EU) 2021/2282 Article 7) and, therefore, is subject to JCA. The Member State Coordination Group on Health Technology Assessment published a document entitled "*Scientific specifications of medicinal products subject to joint clinical assessments*" to support identification of products subject to JCA from 2025.

Pre-authorisation guidance

2.4.1.2 Declaring a product in scope of Joint Clinical Assessment (JCA) under the HTA Regulation (Regulation (EU) 2021/2282) in the Letter of Intent NEW June 2024

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. As of 14 January 2028, all medicinal products designated as orphan medicinal products and, as of 14 January 2030, all other medicinal products falling under the scope of Article 7 of Regulation (EU) 2021/2282 are also subject to JCA.

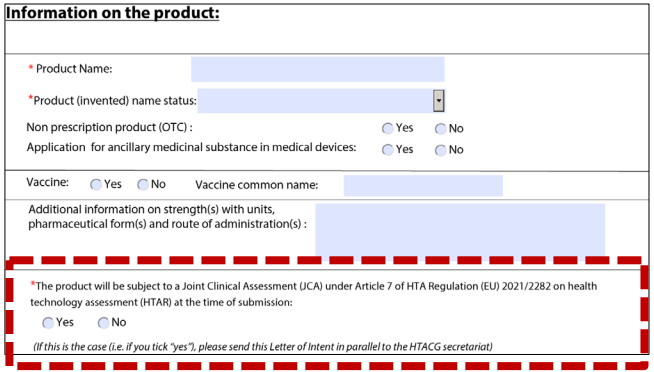
To facilitate and prepare the respective assessments, EMA and the secretariat of the Member State Coordination Group on HTA (HTACG) have agreed to use the same form for respective notifications. Therefore, on the basis of the type of submission for a marketing authorisation application and the planned submission time, applicants should declare in the Pre-submission request form whether their application falls under the scope of Article 7 of Regulation (EU) 2021/2282 and therefore is subject to JCA. This declaration shall be made alongside the request under section 1.1.1 (when selecting the indent "Intent to submit MA").

See Joint clinical assessment of medicinal products: Submission of early information by health technology developers - European Commission and Pre-authorisation guidance | European Medicines Agency

"Letter of Intent" notifications *Background and experiences*

EMA and the HTA secretariat agreed to use the same notification form

- Facilitation of preparation for respective processes
- Coordination amongst secretariats for parallel work
- Reduced administrative burden on the applicants
- Clear guidance to applicants on submission modalities



Information on the product:

* Product Name:

*Product (invented) name status:

Non prescription product (OTC) : Yes No

Application for ancillary medicinal substance in medical devices: Yes No

Vaccine: Yes No Vaccine common name:

Additional information on strength(s) with units, pharmaceutical form(s) and route of administration(s) :

*The product will be subject to a Joint Clinical Assessment (JCA) under Article 7 of HTA Regulation (EU) 2021/2282 on health technology assessment (HTAR) at the time of submission:

Yes No

(If this is the case (i.e. if you tick "yes"), please send this Letter of Intent in parallel to the HTACG secretariat)

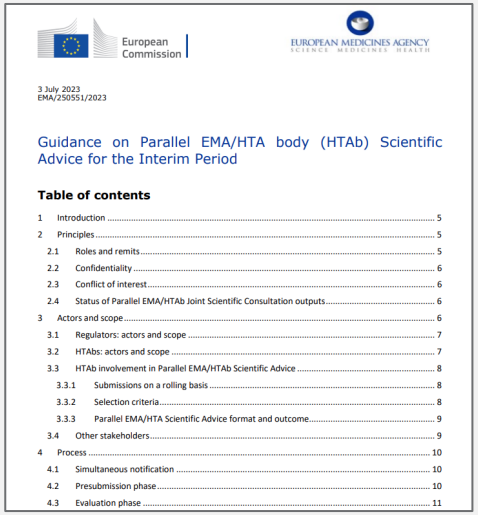
Experience to-date

- Notifications received for both initial LoI and update due to delay of submission
- 81% of "positive" notifications correctly identified by the applicant
- Only 50% of correctly identified MAAs were also sent to the HTA secretariat

Development of the framework for parallel Joint Scientific Consultation for medicinal products

Evidence planning for medicinal products involving regulators and HTAs

Current framework: EMA/HTAb parallel scientific advice



European Commission

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 July 2023
EMA/250551/2023

Guidance on Parallel EMA/HTA body (HTAb) Scientific Advice for the Interim Period

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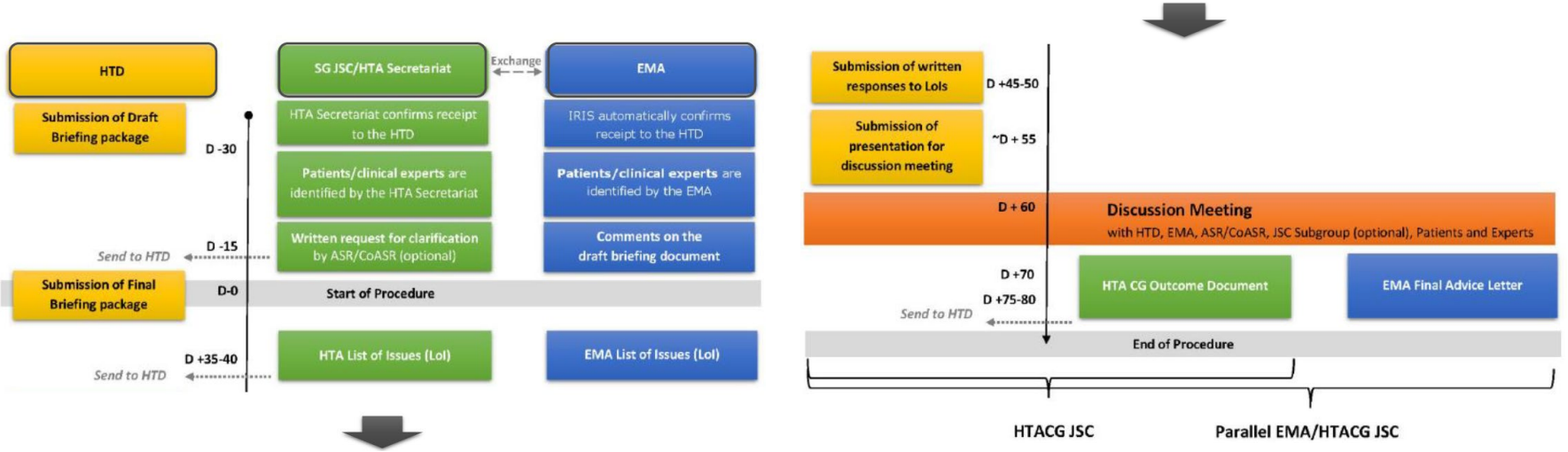
Future framework: parallel JSC under the HTA Regulation

1. Development of the **procedural guidance** led by the JSC subgroup with contribution – on parallel JSC aspects – from EMA
   - Adoption by HTACG planned for 11/2024
2. Establishment of an **Implementing Regulation** led by the European Commission

Procedural guidance: one guidance, two formats (HTACG-only and in parallel with EMA)

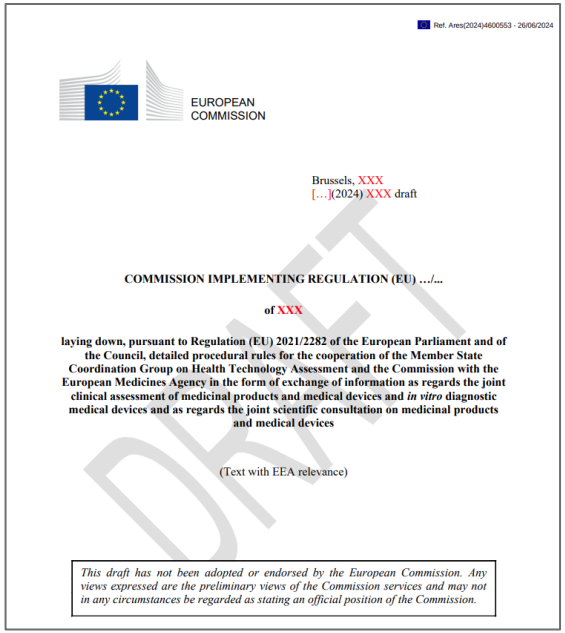


Exchange of Information with EMA

Outline of dedicated Implementing Regulation on cooperation by exchange of information (draft)

<u>Scope:</u> Exchange of information as regards the JCA of medicinal products and medical devices and in vitro diagnostic medical devices and as regards the JSC on medicinal products and medical devices

- planning and forecast of JCA and JSC
- identification of patients, clinical experts and other relevant experts (‘individual experts’)
- general scientific and technical matters
- security of sharing and protection of confidential information



Ref. Ares(2024)4600553 - 26/06/2024

EUROPEAN COMMISSION

Brussels, XXX
[…](2024) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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laying down, pursuant to Regulation (EU) 2021/2282 of the European Parliament and of the Council, detailed procedural rules for the cooperation of the Member State Coordination Group on Health Technology Assessment and the Commission with the European Medicines Agency in the form of exchange of information as regards the joint clinical assessment of medicinal products and medical devices and *in vitro* diagnostic medical devices and as regards the joint scientific consultation on medicinal products and medical devices

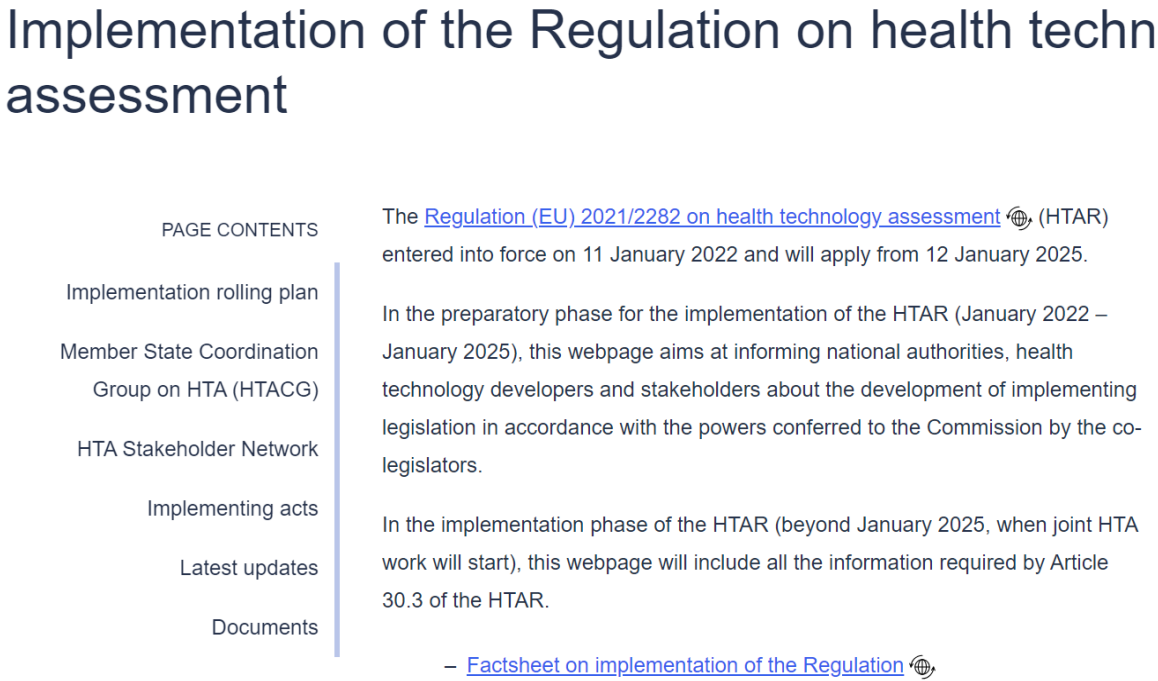
(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

DRAFT

Draft for public consultation

For more information on HTAR implementation, see here



Implementation of the Regulation on health technology assessment

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- Documents

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