EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Regulatory/HTA interface under the HTA Regulation (HTAR)

9th Industry Standing Group (ISG) meeting, 28 June 2024

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

Overview of implementation activities

European collaboration between regulators and HTA bodies

- Since 2010, **EMA and** the European Network for Health Technology Assessment (**EUnetHTA**) have been working closely on topics of mutual interest
  - Cooperation was facilitated through coordination of HTA bodies in EU-financed Joint Actions, and a subsequent tender for service (EUnetHTA ceased to exist in mid-September 2023)
- The new **HTA Regulation in Europe**, applicable from January 2025, recognizes the value of such collaboration
  - Current implementation period (see Towards a permanent collaboration framework for EMA and Health Technology Assessment bodies)
- The **aim of this regulatory/HTA cooperation** is to build synergies between regulatory evaluation and HTA along the medicine lifecycle

HTA Regulation – Key principles

- Joint work on common scientific, clinical aspects
- High-quality, timely scientific reports
- Better evidence-base, efficiency, non-duplication

- Joint work driven by Member States' HTA bodies
- Ensure use in national HTA processes

- Improved transparency and inclusiveness

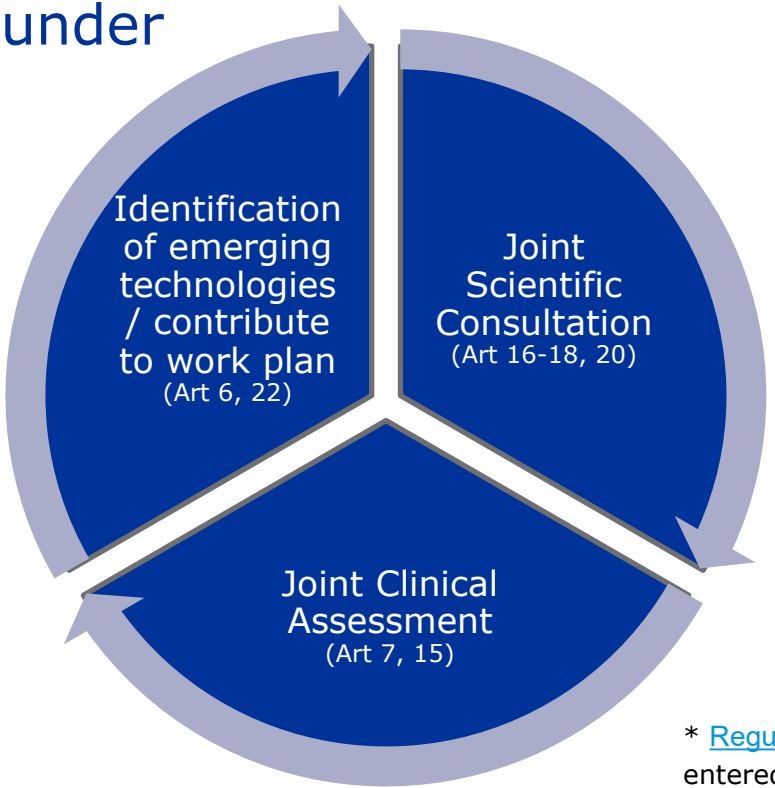
- Recognised value of regulatory/HTA collaboration along the medicines lifecycle to create synergies

- Stepwise implementation

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

HTA Regulation Implementation timeline

Adoption

December 2021

Entry into force

January 2022

Preparatory phase for implementation

Date of Application

January 2025

Application phase

Joint Clinical Assessment Full Scope

January 2030

- **Setting up the Coordination Group (HTACG) and its subgroups (EC)**
- **Setting up the Stakeholder Network (EC)**
- **Developing the IT platform (EC)**
- **Drafting implementing and delegated acts (EC)**

Joint Scientific Consultations (JSC)

+

Stepwise build-up of Joint Clinical Assessments (JCA) scope for medicines:

- From Jan. 2025: cancer drugs, ATMPs

(from date of application)

- From Jan. 2028: orphan drugs

(3 years after date of application)

- **Drafting guidance documents (CG)**

eunethta

Service contract EUnetHTA21

- **Workplan activities**

EUROPEAN MEDICINES AGENCY

European Commission

Concluding EMA/EUnetHTA bilateral meeting on 14.09.2023

"Celebrating joint achievements - progressing future collaboration"

[Minutes of the EMA EUnetHTA meeting 14.09.23]

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 September 2023
EMA/409236/2023
Media and Public Relations

News announcement

Towards a permanent framework for collaborative work in the context of health technology assessment in the EU

Over the past three years, EMA and the EUnetHTA 21 (European Network for Health Technology Assessment) consortium have delivered a number of milestones to prepare the EU for the entry into application of the Regulation on Health Technology Assessment. EUnetHTA 21, the successor of the former European Network for Health Technology Assessment (EUnetHTA), ceases to operate on 16 September 2023, but preparations will continue for the implementation of the Regulation, which will become applicable in January 2025, under the direction of the HTA Coordination Group.

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

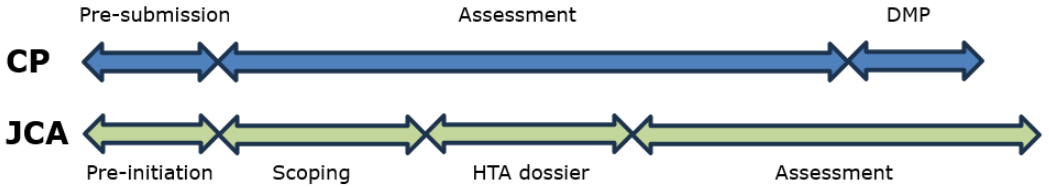
Adoption	**Public consultation finished**	HTAR Article 25.1(a)	Conflict of interest management	by Q3 2024	In preparation
Adoption	**Under public consultation**	HTAR Articles 15.1 (a) and (b); 20.1 (c) and (d)	Cooperation by exchange of information with the European Medicines Agency (EMA)	by Q3 2024	In 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

Operational aspects of the parallel processes for centralised procedure and joint clinical assessment

Concepts for the implementation of key processes: **Joint Clinical Assessment (JCA)** for human medicines

Key principles:

- Exchange with the HTACG secretariat during the CP assessment
- Exchanges at milestones – focused (relevant / necessary)
- Maintain the independence of Benefit/Risk assessment
- Administrative automation as much as possible



Implementation status:

- Identification of MA applications in JCA scope during pre-submission phase (from 06/2024)
- Development of operations under Article 3 of the Implementing Act on JCA-MP

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

Changes to the Letter of Intent (LoI)

General principle:

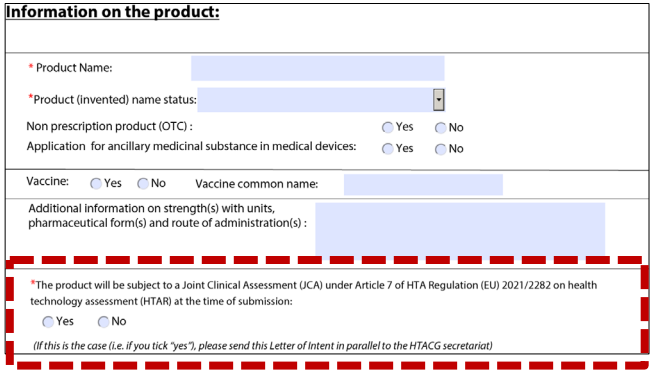
EMA and the secretariat of the Member State Coordination Group on HTA (HTACG) have agreed to use the same form (i.e. EMA LoI) for respective notifications.

Objective: connect regulatory and HTA procedures at pre-submission to facilitate and prepare respective assessments.

Instructions to applicants:

Applicants should declare in the LoI whether their application falls under the scope of Article 7 of Regulation (EU) 2021/2282 and, therefore, is subject to JCA.

Separate (submission) procedures: applicants send LoI in parallel to the HTA IT platform.



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)

EMA deliverables:

1. Update to LoI
2. Update to pre-authorisation guidance document (Q 2.4, 2.7, 2.10) and collapsable Q&As (EMA website)

Products in scope of JCA under the HTAR

Implementation Timeline: Three key milestones (in **2025**, **2028** and **2030**, respectively) with the dates referring to receipt of MAA submission by EMA

13 January 2025

Medicinal products with new active substances for **cancer** treatment

Advanced Therapy Medicinal Products (ATMPs)

14 January 2028

Orphan medicinal products

14 January 2030

All other medicinal products under Article 7 of Regulation 2021/2282

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

For more information on HTAR implementation, see here

Implementation of the Regulation on health technology assessment

PAGE CONTENTS

- Implementation rolling plan
- Member State Coordination Group on HTA (HTACG)
- HTA Stakeholder Network
- Implementing acts
- Latest updates
- 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