Strengthening the regulatory/HTA interface: Update on the support to the HTA Regulation implementation

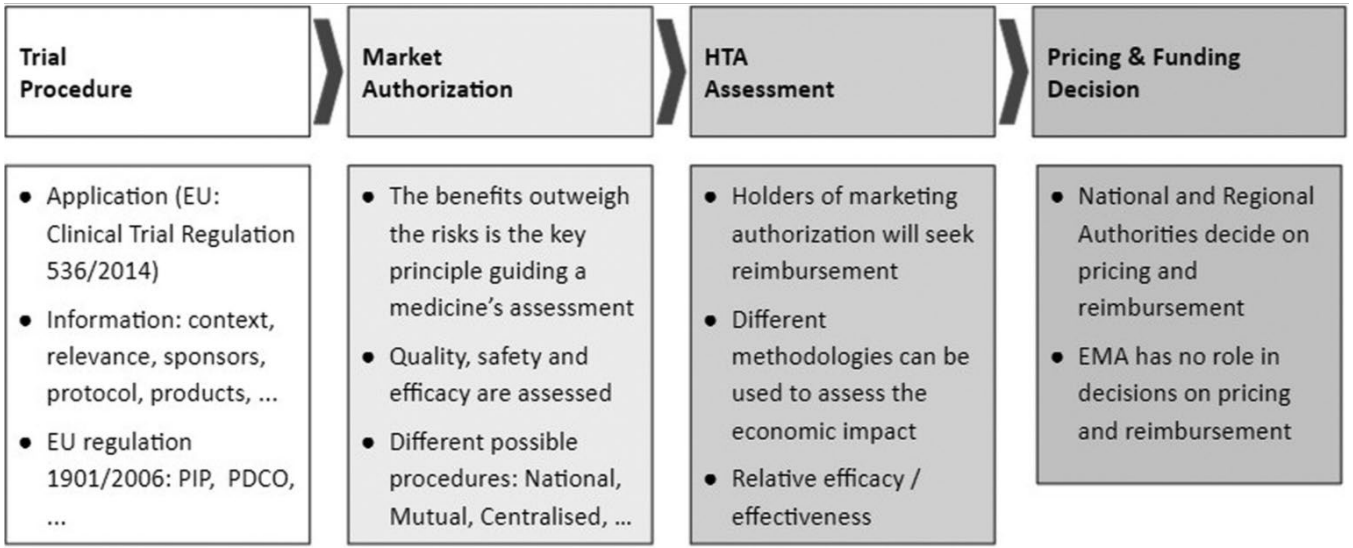
PCWP/HCPWP and all eligible organisations meeting

14 November 2023

Presented by Michael Berntgen and Francesca Cerreta,
Scientific Evidence Generation Department

An agency of the European Union

Ecosystem of decision making towards access for patients



Moretti et al, Br J Clin Pharmacol. 2022; 88:5052–5059

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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 for 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

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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

European Commission

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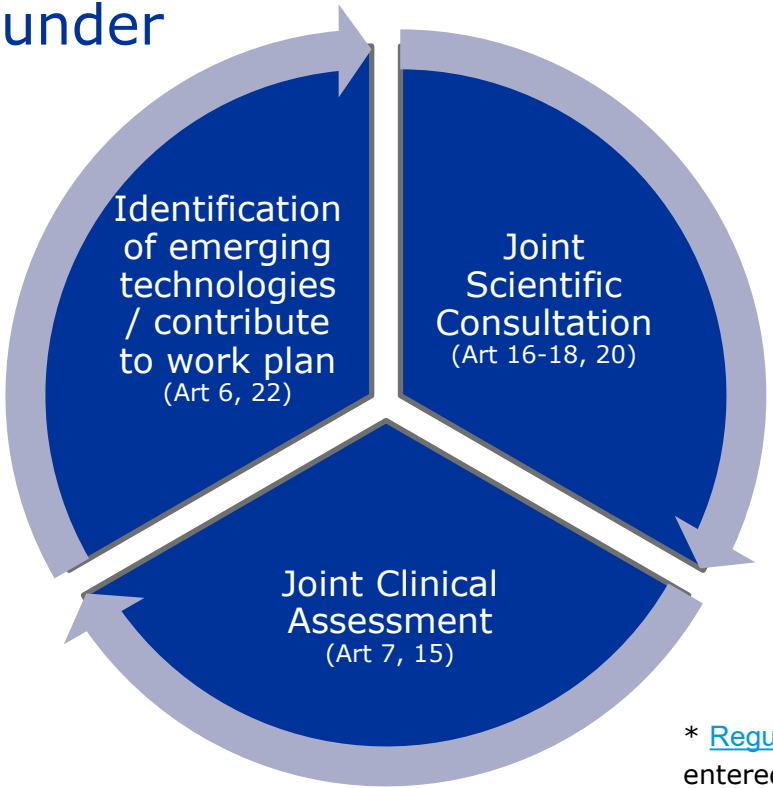
Collaboration with EMA under the HTA Regulation*

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



Note: "Joint" refers to collaborative work amongst HTA bodies

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

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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

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Concluding EMA/EUnetHTA bilateral meeting on 14.09.2023

"Celebrating joint achievements - progressing future collaboration"

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.

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Implementation rolling plan – Implementing Acts

HTAR Articles 15.1(a) and (c); 25.1(b); 26.1	Joint Clinical Assessments for medicinal products	by Q4 2023	In preparation
HTAR Article 25.1(a)	Conflict of interest management	by Q1 2024	In preparation
HTAR Articles 15.1 (a) and (b); 20.1 (c) and (d)	Cooperation by exchange of information with the European Medicines Agency (EMA)	by Q1 2024	In preparation
HTAR Article 20.1	Joint Scientific Consultations for medicinal products	by Q2 2024	Planned
HTAR Article 20.1	Joint Scientific Consultations for medical devices	by Q3 2024	Planned
HTAR Articles 15.1 (b) and (c); 25.1(b); 26.1	Joint Clinical Assessments for medical devices	by Q4 2024	Planned

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Making it real: some examples

Cooperation on RWE / DARWIN

- HTA / payer representatives in the DARWIN Advisory Board and the BDSG
- Workshop on identification of use cases / studies ongoing

Oncology-specific interactions

- Involvement of HTAs in the Cancer Medicines Forum
- Invitation to the EAA Fall Convention "Oncology as pacemaker"

Challenges in evidence needs

- Deep-dive on ATMP product assessments together with CAT
- Collaboration to analyse access to innovation (incl. PRIME, CMA)

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Activities are multi-dimensional and complementary …

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Evolving opportunities for interactions and collaborations between regulators, HTAs and payers

Building blocks to improve future interactions/collaborations

Early scientific advice
Enhance the process, flexible and iterative; increase capacity, speed up admin process, informal interaction, PLEG discussion

Alignment of evidence requirement
Identification of commonality of evidence requirement, transparent and agreed methodology

Regulatory- HTA interactions
Development of pilots at local, regional and global levels of new models of collaborative working, more integrated process

Reg/Reg, HTA/HTA interactions
Capacity building, Information sharing, Joint assessments, Work sharing, Reliance model

Collaborative approach among all stakeholder
Horizon scanning of new technology ; proactive joint planning with all the stakeholders for emerging technologies

Regulatory, HTA and payer interactions and collaborations: optimising their use and outcome success, CIRS workshop 10-11th March 2021 (workshop report)

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