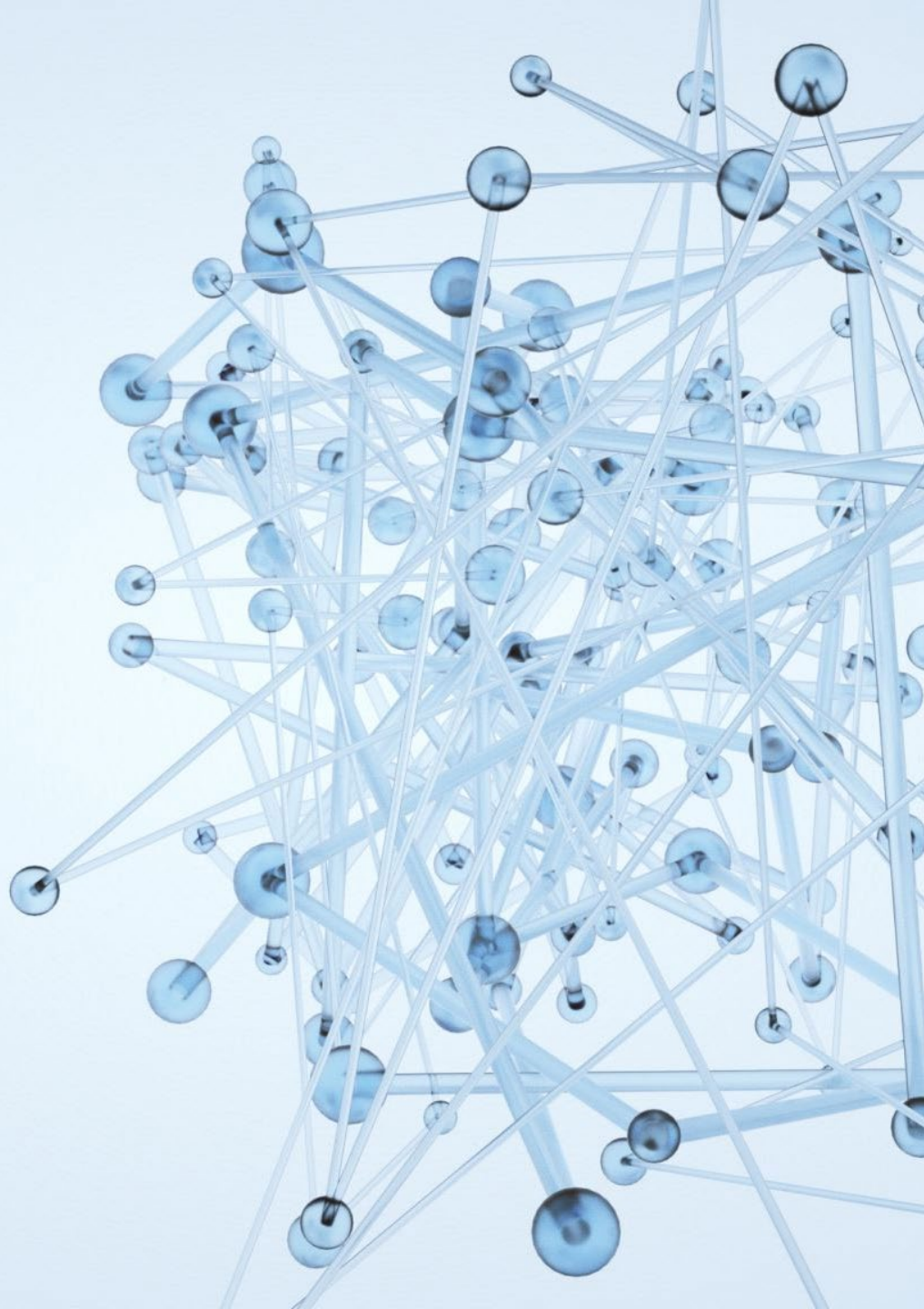
EMA
EUROPEAN MEDICINES AGENCY

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

ISG meeting, 31 March 2026

Presented by Michael Berntgen, Head of Scientific Evidence Generation (H-EG)



Focus of today's update

1. Operational update on the interface between Centralised Procedure (CP) and Joint Clinical Assessment (JCA)
2. Status update on parallel Joint Scientific Consultation (JSC) for medicinal products and medical devices
3. Collaboration on scientific and technical topics of horizontal nature

12 January 2026: First anniversary of the application of the HTA Regulation

Highlights from the first year of operation at the regulatory / HTA interface

First **initial MAAs in scope of JCA production** submitted in March 2025

Since July 2025, **provision of information** from ongoing Centralised Procedures to support JCA

Evidence planning for three medicinal product developments progressed in **parallel Joint Scientific Consultation**

First **comprehensive forecast reports (business pipeline)** covering medicinal products and medical devices provided to the HTA secretariat

Joint EMA/HTAb **position paper on evidence and uncertainty management** published

Numerous implementation **updates provided to stakeholders** (e.g. at ISG meetings)

All Implementing Acts (IA) under the HTAR adopted (EMA provided technical support)

Successful **SANTE/EMA workshop on experience with the operations** at the regulatory/HTA interface held in September 2025

Identification of upcoming MAAs in scope of JCA production

Compliance rate (as of 11 March 2026):

- Still notifications **not sent** to the HTA secretariat although overall better compliance
  - Reminders had to be sent to applicants for **37%** of 2025-2026 notifications
  - Currently still not followed up by applicants for around **18%** of these unsatisfactory notifications

Important to cascade standard process:

- Parallel guidance for applicants on declaring products in the scope of Joint Clinical Assessment (JCA) under the HTAR
- Harmonised notification process: use of the same form (i.e. Letter of Intent) to notify the intention to submit an application.
- Important for applicant (HTD) to provide information to EMA and HTA secretariat in parallel, also for change of dates

Simplification from January 2026: when sending to the applicant a reminder regarding the need of parallel submission of an LoI for an MAA declared as being in JCA scope, EMA will CC the HTA Secretariat for awareness and follow-up, as required

Provision of information from the Centralised Procedure to inform Joint Clinical Assessment

Principles: 1/ respect of separate remits; 2/ exchange **through secretariats** only; 3/ information to be appropriate and relevant

After CHMP adoption of questions, EMA to provide to the HTA secretariat:

- Clinical major objections or clinical other concerns that might impact the therapeutic indication(s) of the medicinal product proposed by the applicant
- Clinical major objections related to non-full marketing authorisation (e.g conditional marketing authorization or marketing authorisation under exceptional circumstances)

Identification of such questions is without prejudice to the final outcome of the regulatory assessment as well as of the HTA assessment.

Updates on timelines based on the adopted timetables.

Review: after 12 months of experience (including usefulness and efficiency)

Continued experience since July 2025, with EMA providing:

- an extract from adopted documents, acc. to principles
- information on next procedural timelines.

All information is based on what the applicant received as part of the ongoing procedure.

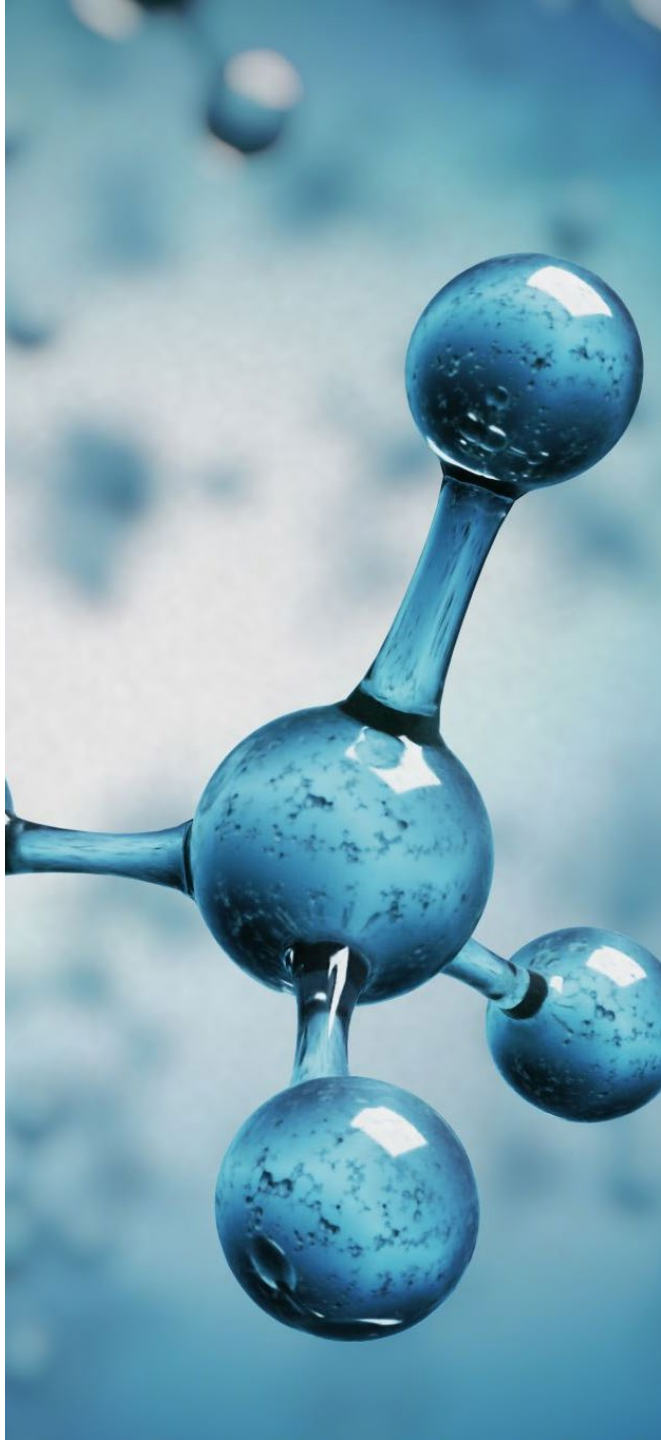
List of MAAs with JCA production requiring exchange of information **Based on the HTA secretariat listing Joint Clinical Assessments** (02/03/2026)

International non-proprietary name (INN) / Common Name	Indication - Summary	Substance type
Autologous melanoma-derived tumor infiltrating lymphocytes, ex vivo-expanded	Treatment of melanoma	ATMP
Tovorafenib	Treatment of paediatric low-grade glioma (LGG)	Chemicals
Onasemnogene abeparvovec	Treatment of 5q spinal muscular atrophy (SMA)	ATMP
Lurbinectedin	Maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)	Chemicals
Camizestrant	Treatment of adults with locally advanced or metastatic breast cancer	Chemicals
Tarlatamab	Treatment of extensive-stage small cell lung cancer	Biologicals
Catequentinib	Treatment of synovial sarcoma or leiomyosarcoma	Chemicals
Senaparib	Maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer	Chemicals
Relacorilant	Treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer	Chemicals
Ensartinib	The treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	Chemicals
Zopapogene imadenovec	Treatment of respiratory papillomatosis in adults	ATMP
Sintilimab	Treatment of non-squamous non-small cell lung cancer in adults	Biologicals
Sonrotoclax	Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)	Chemicals

CHMP Opinion adopted

Parallel Joint Scientific Consultation (JSC) for medicinal products

- From the 2025 intake, **3 parallel JSCs** (aka parallel EMA/HTA scientific advice) have been completed
  - One parallel JSCs concerned an oncologic condition, and the other two non-oncologic rare diseases.
- For 2026, in the first request period **2 parallel JSC on medicinal products** have been confirmed to proceed
  - One in an oncologic condition and one for a non-oncologic rare disease.
- For more information:
  - 2026 Work Programme for the request periods
  - Parallel scientific advice and special development aspects or product types
  - Dates of 2026 SAWP-H meetings and submission deadlines



Looking forward on collaborative work on Medical Device

In the context of the **joint scientific consultations*** on medical devices:

- Possibility for **parallel advice to medical device manufacturers by the Expert Panels** according to Timetable 2026
- The expert panels advise on intended clinical development strategies and clinical investigation proposals, in line with Article 61(2) of the MDR for:
  - Class III medical devices
  - Class IIb active medical devices intended to administer or remove medicines from the body.

*refer to the HTACG workplan

Collaboration on scientific and technical topics of horizontal nature

HEADS OF HTA AGENCIES GROUP

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 April 2025
EMA/115125/2025

Joint HTAb-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions

Outcome of a workshop series between HTA bodies and regulators

[Position paper]

FUTURE WORK

- Establish a **methodology network** in the EU HTAb community
- Publish **guidance documents and reflection papers** on key methodological issues arising in the workshops, including
  - Adaptive randomised designs (e.g. platform trials)
  - Pragmatic trials
  - The estimand framework
  - External controls
- Joint regulatory-HTA **assessors' discussion forum** to discuss learnings from completed assessments and identify future priorities

[ISPOR 2025 abstract]

Participation of HTAs in workshops, e.g.

Workshop on the Use of External Controls for Evidence Generation in Regulatory Decision-Making

3 November 2025, 10:00 – 17:30 (CET/CEST)
Virtual meeting/ EMA, Amsterdam – room 1D

Patient Registry workshop on Alzheimer's disease

15 December 2025, 09:00 – 17:30 (CET/CEST)
In-person at the EMA building, Amsterdam (Room 1D) + virtual enabled

Representatives in governance bodies

e.g. DARWIN EU Advisory Board, NDSG Advisory Board, ACT EU MSP

Michael Berntgen • You
Head of Scientific Evidence Generation Department, European Medic...
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- "Bridge the evidence gap in development programmes."
- "Develop an integrated evidence plan."
- "Importance of one European voice in global evidence planning."
- "Not necessarily more evidence, but cleverly planned evidence."

These and many more forward-looking perspectives were shared in this morning's session on "Addressing Evidence Needs for #Regulatory and #HTA Decision Making" at #DIAEurope2026 in Rotterdam.

[LinkedIn post]

Complementary work plans for 2026 to establish scientific/technical work

HTACG Annual Work Programme 2026

The HTACG and its subgroups Chairs and co-Chairs will aim to meet on a biannual basis with the European Medicine Agency to discuss methodological developments and other horizontal issues of scientific nature related to the implementation of the HTAR.

CHMP work plan 2026 / CAT work plan 2026

Scientific consultations involving other decision makers to facilitate optimisation of clinical evidence generation in drug development programmes

Clinical evidence generated during drug development is intended to serve different decision making. It is therefore desirable that evidence requirements do address regulatory needs as well as those of other down-stream decision makers.

Key objective:

- To engage with other decision makers in multi-stakeholder consultations on evidence generation planning.
- To prospectively identify post-licensing evidence needs considering the expected evidence available at time of initial decision making by regulators and HTAs, respectively.

Activities in 2026:
Collaborate with the Member State Coordination Group on HTA (HTACG) on evidence requirements and management of uncertainties for different types of developments, to inform prospective evidence planning for development programmes.
Engage with the HTACG on opportunities for collaboration on scientific and methodological guidelines.
Explore with healthcare payers opportunities for sharing views on prospective evidence planning, focusing on post-licensing evidence needs.

For more on HTAR implementation and contact information, see here

Implementation of the Regulation on health technology assessment

PAGE CONTENTS

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