



# Status overview: EU HTA Regulation

**EAA Spring Convention  
16 April 2026**

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# After EAA fall convention 2025



- ❖ 12 January 2026: 1 year of the HTA Regulation !

From EAA fall convention:

- ❖ 2 Coordination Group (HTACG) meetings, 16 subgroups meetings
- ❖ 2 webinars for developers of medical devices on 12 Dec 2025 and for patients on 6 Feb 2026 (recordings available)
- ❖ Publication of HTACG Work Programme 2026
- ❖ Publication of first HTACG Annual report for 2025
- ❖ Publication of public Emerging Health Technology report

# Joint Clinical Assessments (15 ongoing)




15 EU/EEA countries involved in at least one joint clinical assessment

- ❖ Close to finalisation of first JCA
- ❖ Work on medical devices to start in 2026

# Joint Scientific Consultations



- ❖ **2025: 7 products selected**, of which 4 in parallel with EMA scientific advice
  - 6 Joint Scientific Consultations  **Completed**
- ❖ **2026: 4 [requests periods](#)** (the second is currently open until 29 April 2026)

# Identifications of experts - State of play

**40 patients/carers and clinicians** provided input to assessment scope

**> 300 patients/carers and clinicians** invited to fill in a Declaration of Interest

**> 50 patients/carers and clinicians selected** for Joint Clinical Assessments and Joint Scientific Consultations

**New Europa website page** on involvement of patients and clinicians

**Consultation with the HTA Stakeholder Network** on the JSC and JCA templates for individual expert input

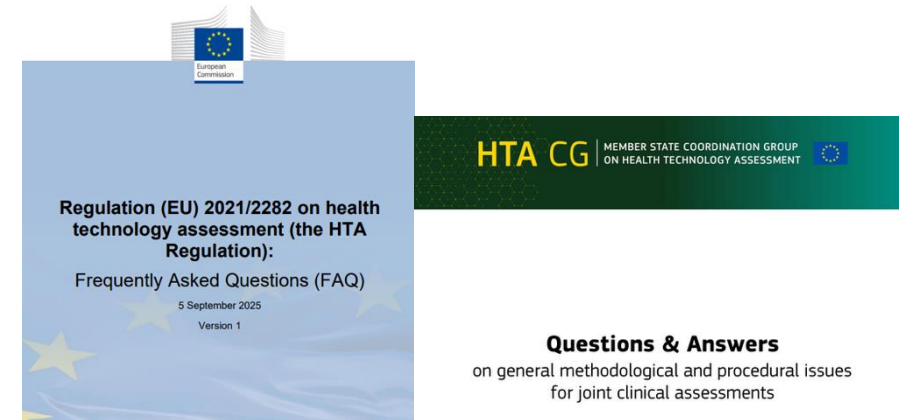
# HTA-IT-Platform – State of play

- **1070 – Unique Users** of the HTA-IT-Platform (01/04/2026).
- **5000-6000 – Hits** per month (2026 monthly average).
- **118 – Health technology developers (HTDs)** secure spaces created.
- **582 – Declarations of interests** checked, and individuals onboarded.
- **14 - Training** sessions given so far.

**Constant updates** based on users' feedback (next version 5.1.2)

# HTA website on Europa

- **Up-to-date information** [https://health.ec.europa.eu/health-technology-assessment\\_en](https://health.ec.europa.eu/health-technology-assessment_en)
  - **Ongoing**, discontinued, completed **JCAs**
  - HTACG [Annual report](#) and [Annual Work Programme](#)
  - Key docs – legal acts, guidance, agendas, minutes
  - Frequently asked questions



- **Announcement and recording of events**

- Webinars (**next one:** 24 April 2026 [The EU HTA Regulation: Webinar for health technology developers of medicinal products - Public Health](#))
- **Dedicated page for experts** [Opportunities for patients, carers and clinicians - Public Health](#)
- **Dedicated page for health technology developers** (**upcoming**)

# Evaluation of the HTA Regulation

- Article 31(1) of the HTA Regulation

By 13 January 2028, the Commission will present a report to the European Parliament and to the Council on the application of the HTA Regulation incl. on:

- (a) **added value for Member States (MSs) of the joint work [...]** in particular, whether the health technologies subject to JCAs and the quality of JCAs meet the needs of MSs
- (b) **non-duplication of the request of information**, data, analyses and other evidence for JCAs for MSs and health technology developers
- (c) **functioning of the support framework [...]** and, potential need to introduce a fee-paying mechanism

- Based on the findings of the report, the Commission can present a legislative proposal to update the Regulation



# Steps to the evaluation report

- **Evaluation Working Group** within the **HTA Stakeholder Network** (recently met on 15 April 2026)
- Close work with the **Heads of HTA Agency Group** on national reporting
- Call for evidence to be expected in 2026, followed by public consultation
- **Reality checks** planned mid 2026-mid 2027

# Looking ahead and next steps



- ❖ Learning from first JCAs
- ❖ Optimise as we go, integration of short-term learnings via **feedback** from assessors and experts
- ❖ Continued collaboration with EMA at the interface **regulatory/HTA**
- ❖ Raising awareness about HTA Regulation especially SMEs and manufacturers (for medical devices)

# Thank you for your attention

## *Any comments/questions?*

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