Status review: implementation of the HTA Regulation

EAA Convention
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Key actions for the Commission

- **Secretariat function** for the HTA Coordination Group and its four subgroups
- Adoption of implementing acts and other **legal** support
- Supervision of the **procedures**, incl. requests to the health technology developer
- Decisions on **conflict of interest** for national representatives and experts
- Identification of **individual experts**
- Management of the **IT Platform and HTA Europa page**
- Facilitation of the **cooperation with the European Medicines Agency**

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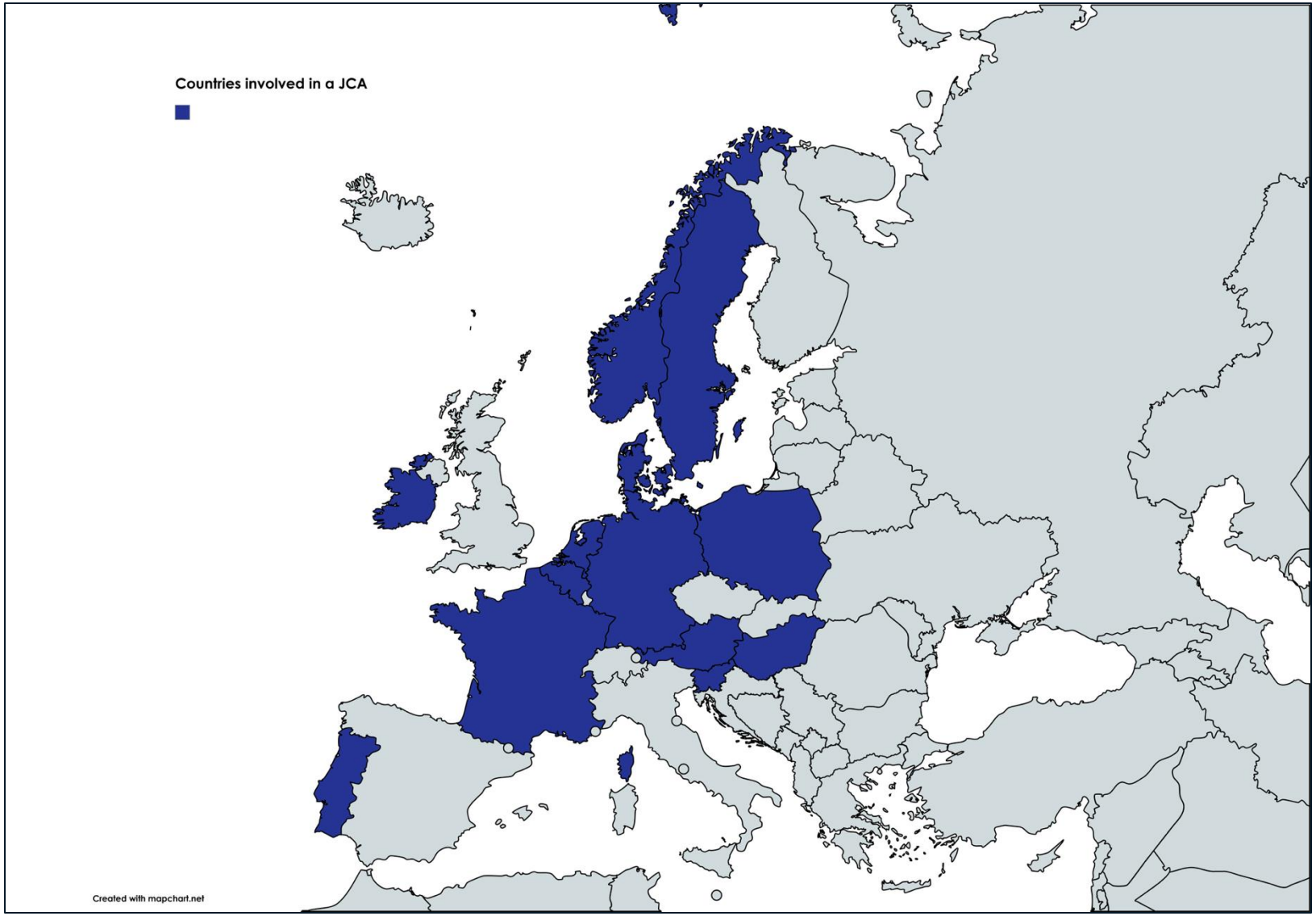
Implementing Regulations on HTA

1st	Procedural rules for JCA of medicinal products	2024/1381	Adopted 23 May 2024
2nd	Procedural rules on the cooperation with the EMA	2024/2699	Adopted 18 October 2024
3rd	Procedural rules for the management of conflicts of interest	2024/2745	Adopted 25 October 2024
4th	Procedural rules for JSC of medicinal products	2024/3169	Adopted 18 December 2024
5th	Procedural rules for JSC of medical devices and IVD medical devices	2025/117	Adopted 24 January 2025
6th	Procedural rules for JCA of medical devices and IVD medical devices	2025/2086	Adopted 17 October 2025

Joint Clinical Assessments (10 ongoing)



13 EU/EEA Countries currently involved in at least one JCA

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Joint Scientific Consultations

- **2025**: 2 requests periods (3 February to 3 March and 2 to 30 June)
- **7 products selected** and companies informed
  - 4 parallel consultations with EMA
  - 2 Joint Scientific Consultations Completed
- Request periods for 2026 will be published in the HTA Coordination Group 2026 Work programme and on the Europa website

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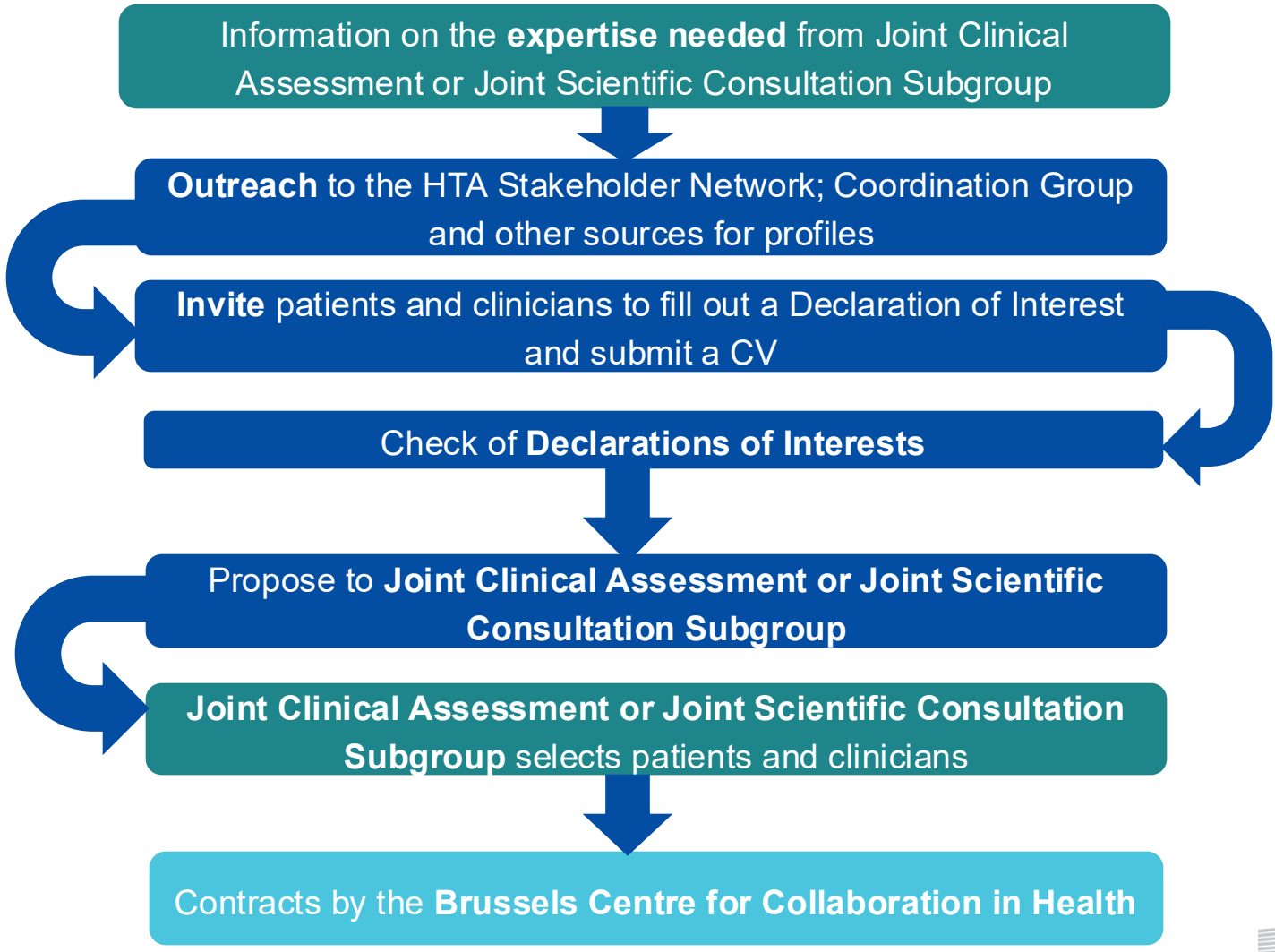
Identification and selection of patients and clinicians in joint work

HTA Stakeholder Network Working Group to co-create the process



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Identifications of experts - State of play

17 patients/carers provided input to assessment scope

> 200 patients/carers and clinicians invited to fill in a Declaration of Interest

> 40 patients/carers and clinicians selected for Joint Clinical Assessments and Joint Scientific Consultations

New dedicated IT helpdesk for patients and clinicians

Additional **communication material and guidance on conflict of interest**

Upcoming **new Europa website page** on involvement of patients and clinicians

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IT Platform – State of play

- **9 – JCA workflows** open.
- **6 – JSC workflows** open.
- **77 – Health technology developers (HTDs)** secure spaces created.
- **515 – Declarations of interests** checked, and individuals onboarded.
- **11 – Training** sessions given so far.

Constant updates based on users' feedback (next version 4.3.0)

HTA website on Europa

Any other suggestion?

- **Up-to-date information** https://health.ec.europa.eu/health-technology-assessment_en
  - Ongoing JCAs
  - Implementation rolling plan
  - HTACG Annual Work Programme
  - Key documents – legal acts, guidance, agendas, minutes
  - Frequently asked questions

- **Announcement and recording of events**
  - HTA - Conference 2 July EU health technology assessment: Advent of a new era of collaboration - Public Health
  - Webinars (latest 17 October 2025 The EU HTA Regulation: Webinar for health technology developers of medicinal products - Public Health)
- **Dedicated pages for experts and HTDs *(in preparation)***

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Evaluation of the HTA Regulation

- Article 31(1) of the HTA Regulation

No later than 13 January 2028, the Commission shall 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

Steps to the evaluation

- Preparation work to start early 2026
- Establishment of an **Evaluation Working Group** within the **HTA Stakeholder Network**
- Co-creation of the **HTAR evaluation framework**
- Close work with the **Heads of HTA Agency Group** on national reporting

Looking ahead and next steps

- **Communication and raise awareness**
- **Optimise interaction with HTDs**
- **Learnings** from the first JCAs and JSCs, together with experts and stakeholders
- Start **planning for the evaluation** of the HTA Regulation
  - Member States report by Jan 2027
  - Commission report by Jan 2028
- Positioning of **HTA in EU health priorities**

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Thank you for your attention

Any comments/questions?

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