



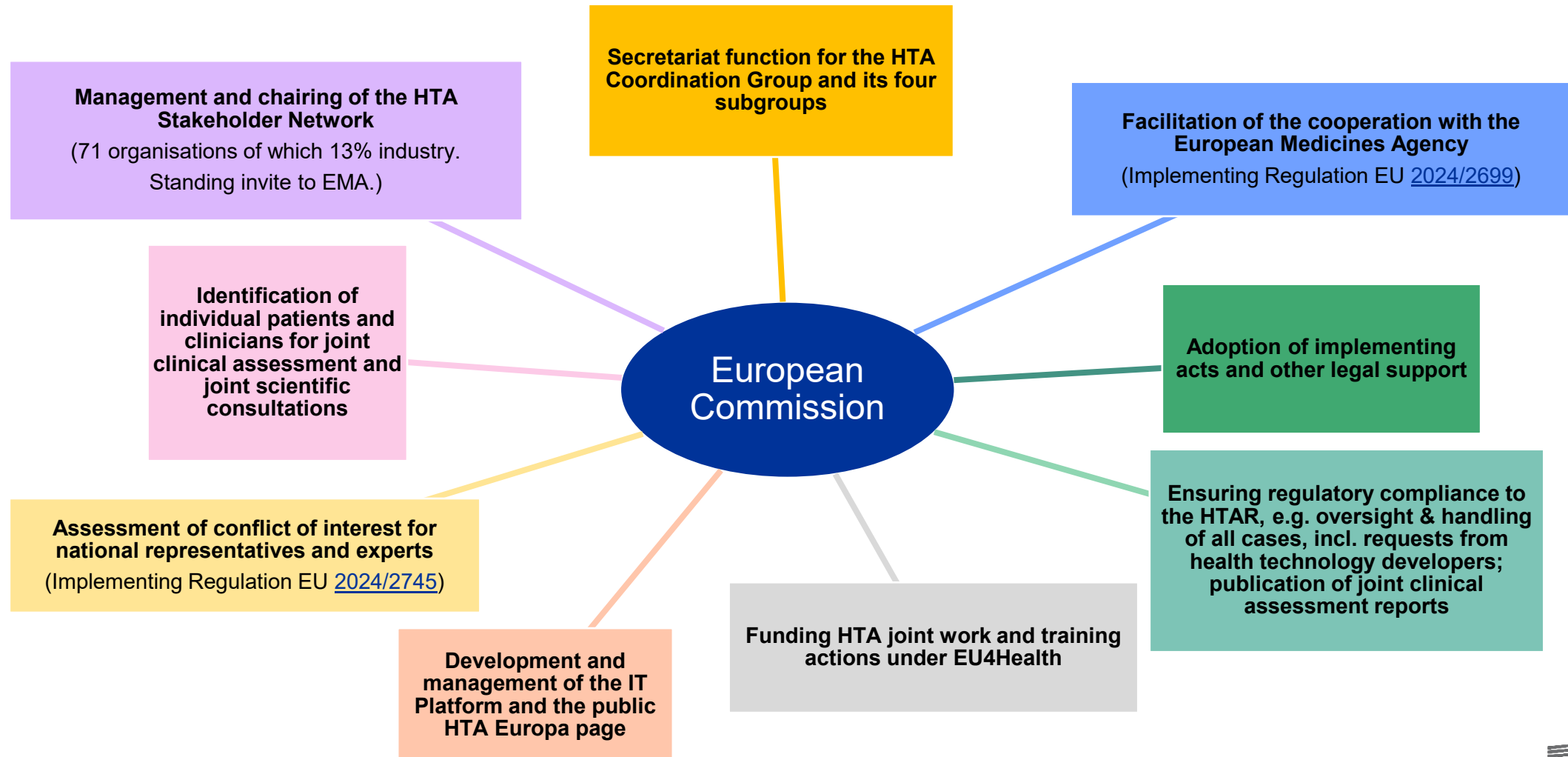
HTA Regulation

EMA 15th Industry Standing Group (ISG)
11 December 2025

A photograph of the European Union flag waving, held by two hands. The flag is blue with twelve yellow stars in a circle. The background is a blurred green landscape with trees.

Valentina Barbuto
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Directorate-General for Health and Food Safety, European Commission

Role of the HTA Unit in DG SANTE



The HTA Coordination Group

2 December 2025

Annual Work Programme 2026

28 November 2025

Health and Food Safety
Directorate-General



eNews



Health Technology Assessment – 2026 Work Programme adopted

On Friday 28 November, the annual HTA Work Programme for 2026 was adopted by the Member State Coordination Group on Health Technology Assessment (HTACG). The Work Programme outlines the key activities and strategic priorities of the group for the upcoming year.

In 2026, the HTA Coordination Group estimates

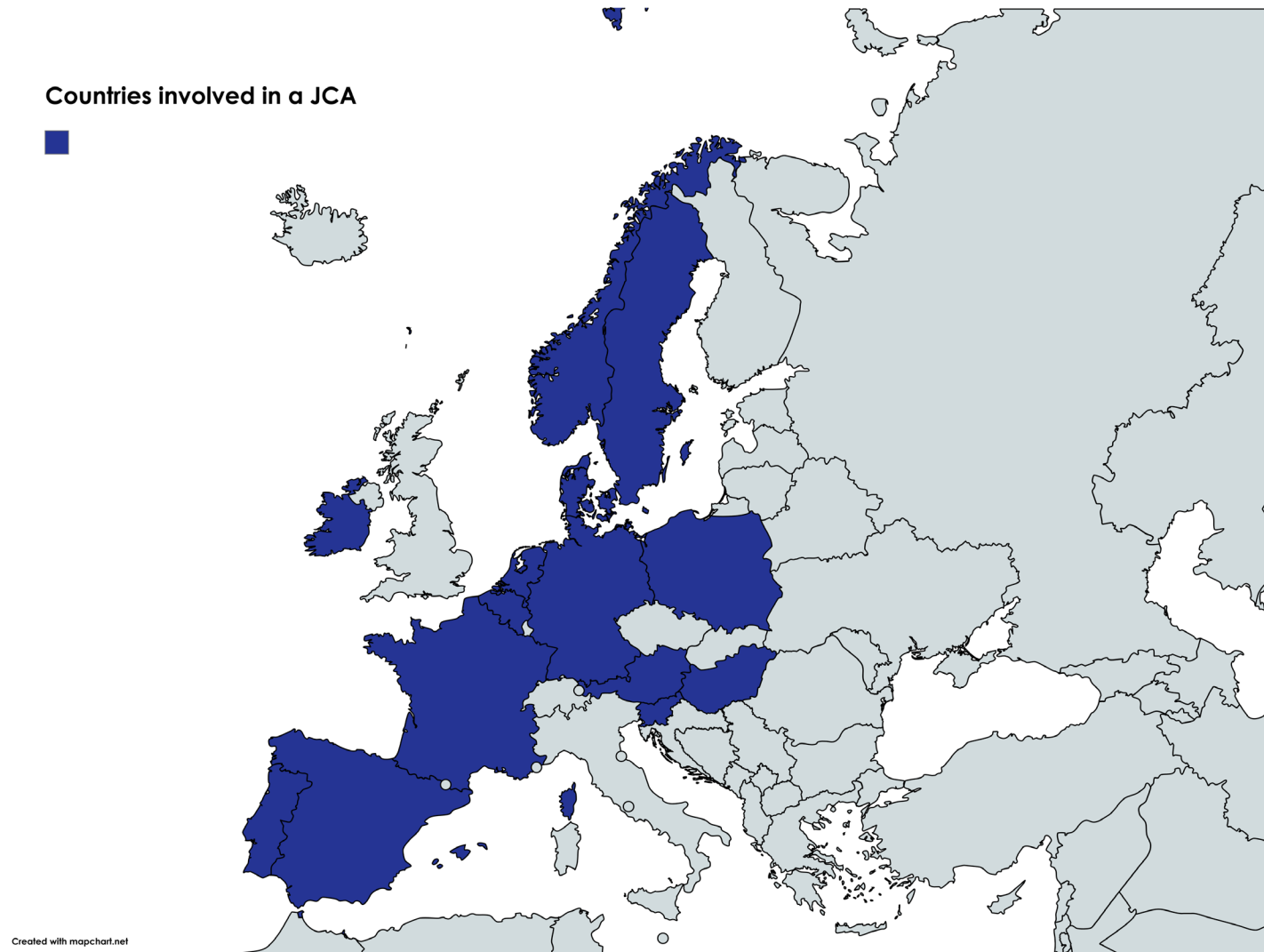
- ❖ ≈ 50 joint clinical assessments of medicines.
- ❖ ≈ 5 joint clinical assessments of medical devices.

The Coordination Group commits to meet with the health technology associations in the HTA Stakeholder Network to ensure the smooth implementation of the HTAR.

Biannual meetings with EMA to discuss methodological developments relevant for the HTAR will also be introduced.





Joint Clinical Assessments (12 ongoing)



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



Joint Scientific Consultations (JSCs)

- ❖ In 2025, the JSC Subgroup selected 7 products. 4 of these, concern joint scientific consultations in parallel with EMA scientific advice.
- ❖ 3 joint scientific consultations 
- ❖ In 2026, max 12 requests for medicines and 5 requests for medical devices.  **no fees**
- ❖ Request periods are now public on [the Europa website](#) :

- 07 January to 04 February 2026
- 01 to 29 April 2026
- 03 June to 01 July 2026
- 23 September to 21 October 2026



HTA website on Europa

Any other suggestion?

- **Up-to-date information** https://health.ec.europa.eu/health-technology-assessment_en
 - **Ongoing joint clinical assessments**
 - 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](#)) **Tomorrow first one on medical devices!**
- **Dedicated pages for experts and health technology developers** (**in preparation**)

IMPLEMENTATION ROLLING PLAN
REGULATION (EU) 2021/2282 ON HEALTH TECHNOLOGY ASSESSMENT

This rolling plan outlines the key activities that the Commission has undertaken or plans to undertake in relation to the implementation of Regulation 2021/2282 on Health Technology Assessment (HTAR). The plan is regularly reviewed and updated to ensure that national authorities and stakeholders have access to the latest information.

The HTAR entered into force on 11 January 2022. It is applicable as of 12 January 2025.

Latest update: 8 December 2025

All actions - year 2025

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Member State Coordination Group on Health Technology Assessment (HTACG) and its subgroups HTAR Article 3				
Meetings of the HTACG	HTAR Article 3	Member State Coordination Group on HTA (HTACG) - European Commission	28 February, 22 May, 30 June, 25 September, 23 October, 28 November	Completed



Thank you for your attention

Any comments/questions?

To reach the SANTE HTA team, please write to:

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