



HTA Regulation – experience from the first year of implementation

PCWP/HCPWP joint meeting
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EU Regulation on Health Technology Assessment

In application since **12 January 2025**

Common framework and procedures for cooperation of Member States on health technologies at EU level

High-quality, evidence-based decision-making
Transparency and **inclusiveness**

Joint activities driven by Member States

- Joint Clinical Assessment
- Joint Scientific Consultations
- Horizon Scanning
- Methodologies and procedures

HTA Stakeholder Network

73 patient organisations, health professional organisations, health technology developer associations and other health-related NGOs **informing the work of the Coordination Group**

- **Two meetings** in June and October 2025
- **Topics discussed:**
 - Updates on the **implementation of the EU HTA Regulation**
 - Consultation on the **HTA Coordination Group 2026 work programme**
 - Measuring **performance under the EU HTA Regulation**
 - **Members' presentations**
 - **Breakout sessions** on joint work on medical devices and in vitro diagnostic medical devices; identification of patients and clinicians; joint scientific consultations on medicinal products

State of play – Joint Clinical Assessments



13 ongoing joint clinical assessments



15 EU/EEA countries currently involved in at least one JCA as assessor/co-assessor



30 patients/carers and clinicians contributed to the assessment scope so far

State of play – Joint Scientific Consultations



2 request periods in 2025; 4 request periods in 2026

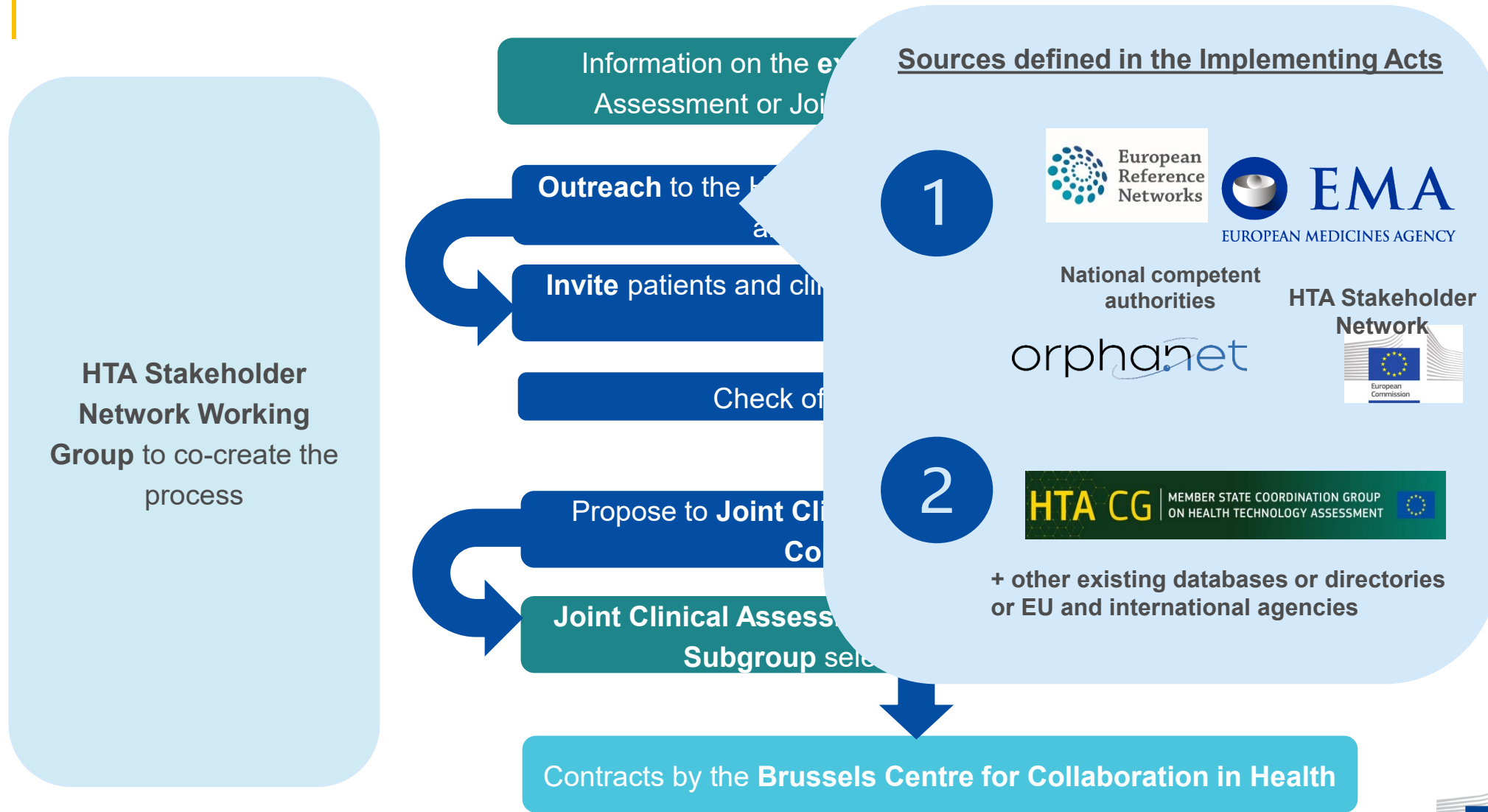


7 joint scientific consultation initiated (4 concluded, 1 withdrawn, 2 ongoing)



10 patients/carers and clinicians contributed so far

Identification and selection of patients and clinicians in joint work



State of play – Identification



5 meetings of the HTA stakeholder network working group on identification of patients and clinicians



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



New dedicated IT helpdesk for patients and clinicians



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

Lessons learnt so far



- **Engagement** from multiple Member States
- **Close collaboration with subgroups** to fine-tune processes
- **Increase awareness of the HTA Regulation** and related processes among companies, patients, and clinicians
- **System in place enabling patients and clinicians to contribute** to consultations
- Need to **provide ongoing support to experts** throughout the process
- **Learning from the EMA**

HTA website on Europa

- **Up-to-date information**
 - [Ongoing](#) joint clinical assessments
 - HTACG Annual Work Programme
 - Key documents – legal acts, guidance, agendas, minutes
 - Frequently asked questions
- **Announcement and recording of events**

**Upcoming webinar
for patients and
clinicians**

**Friday 6 February 2026,
12:00 - 14:00 (CET)**

Looking ahead



- **Learning from the experience** with first JCAs and JSCs
- **Evaluation of the Regulation:**
 - HTA Stakeholder Network Evaluation Working Group to collect feedback
 - Commission report for the European Parliament and the Council: 13 January 2028

Thank you

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