HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Landing HTA Regulation: Insights into European Policies and Implementation in Southern Europe – Cases of Spain and Italy

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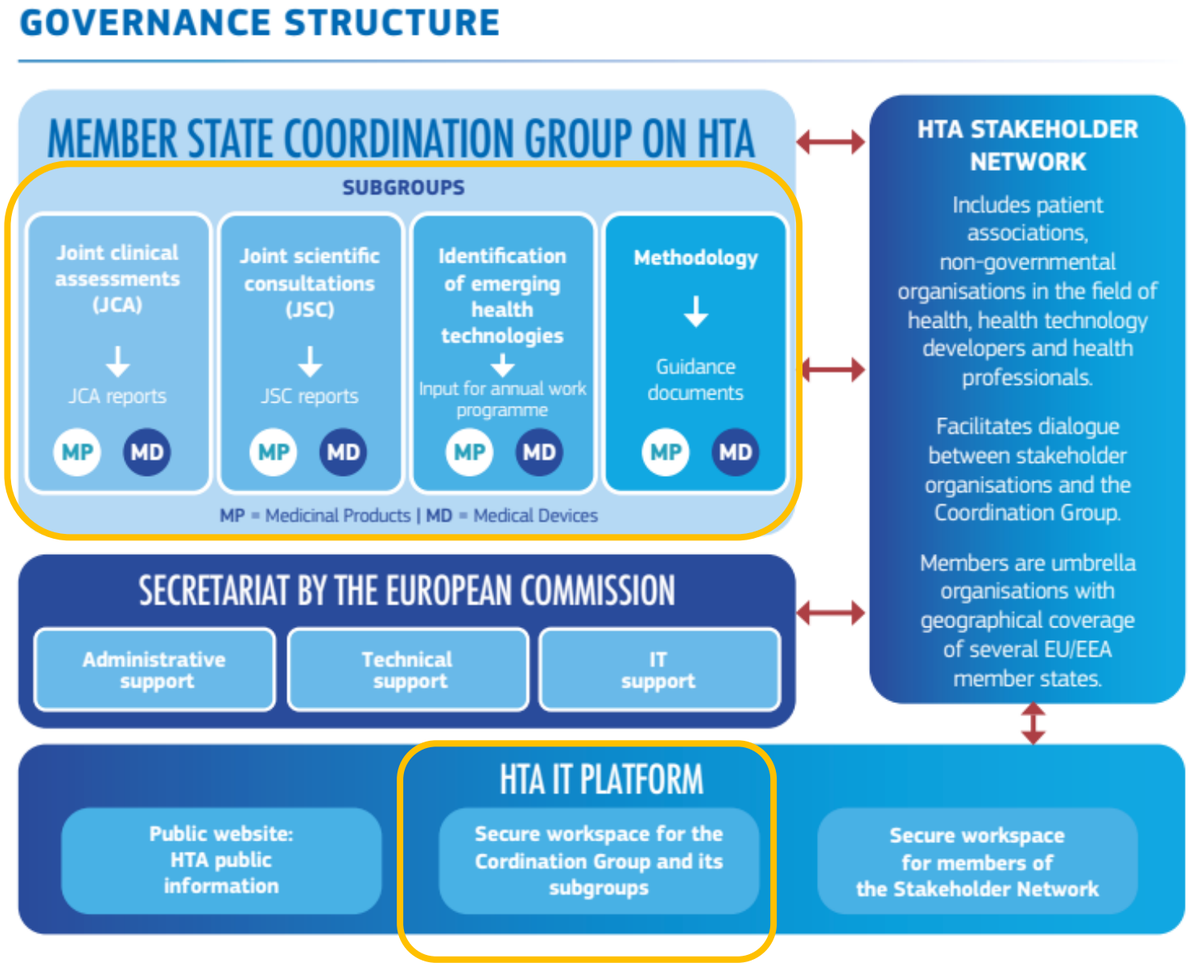
ISPOR Europe 2024 - 18 November 2024

Subgroups


GOVERNANCE STRUCTURE
MEMBER STATE COORDINATION GROUP ON HTA
SUBGROUPS
Joint clinical assessments (JCA)
JCA reports
MP
MD
Joint scientific consultations (JSC)
JSC reports
MP
MD
Identification of emerging health technologies
Input for annual work programme
MP
MD
Methodology
Guidance documents
MP
MD
MP = Medicinal Products | MD = Medical Devices
SECRETARIAT BY THE EUROPEAN COMMISSION
Administrative support
Technical support
IT support
HTA STAKEHOLDER NETWORK
Includes patient associations, non-governmental organisations in the field of health, health technology developers and health professionals.
Facilitates dialogue between stakeholder organisations and the Coordination Group.
Members are umbrella organisations with geographical coverage of several EU/EEA member states.
HTA IT PLATFORM
Public website: HTA public information
Secure workspace for the Cordination Group and its subgroups
Secure workspace for members of the Stakeholder Network

Subgroups

April 2023

The agendas and minutes are public https://health.ec.europa.eu/events_en

Subgroups members

Members of the subgroups

- Subgroup for joint clinical assessments
  - Medical devices
  - Medicinal products
- Subgroup for joint scientific consultations
  - Medical devices
  - Medicinal products
- Subgroup for the identification of emerging health technologies
  - Medical devices
  - Medicinal products
- Subgroup for the development of methodological and procedural guidance
  - Medical devices
  - Medicinal products

https://health.ec.europa.eu/health-technology-assessment/regulation-health-technology-assessment/member-state-coordination-group-hta-htacg_en

Subgroups representation

	MP	MD	MS represented in total (MP or MD)
SG JCA	27 Member States (65 representatives and alternates)	23 Member States (56 representatives and alternates)	27 Member States
SG JSC	25 Member States (56 representatives and alternates)	20 Member States (44 representatives and alternates)	25 Member States
SG MPG	27 Member States (62 representatives and alternates)	24 Member States (53 representatives and alternates)	26 Member States
SG EHT	26 Member States (57 representatives and alternates)	24 Member States (47 representatives and alternates)	25 Member States

+ EEA countries are broadly represented

Subgroups operation

	CHAIR AND CO-CHAIR	SPAIN*	
		MP	MD
JCA	HAS (FRANCE) ZIN (NETHERLANDS)	2	2
JSC	G-BA (GERMANY) AEMPS (SPAIN)	2	2
MPG	IQWIG (GERMANY) INFARMED (PORTUGAL)	2	2
EHT	DMA (DENMARK) AIFA (ITALY)	2	2

*AEMPS, RedETS and DGCCSSNSyF

Subgroups´ Rules of Procedures

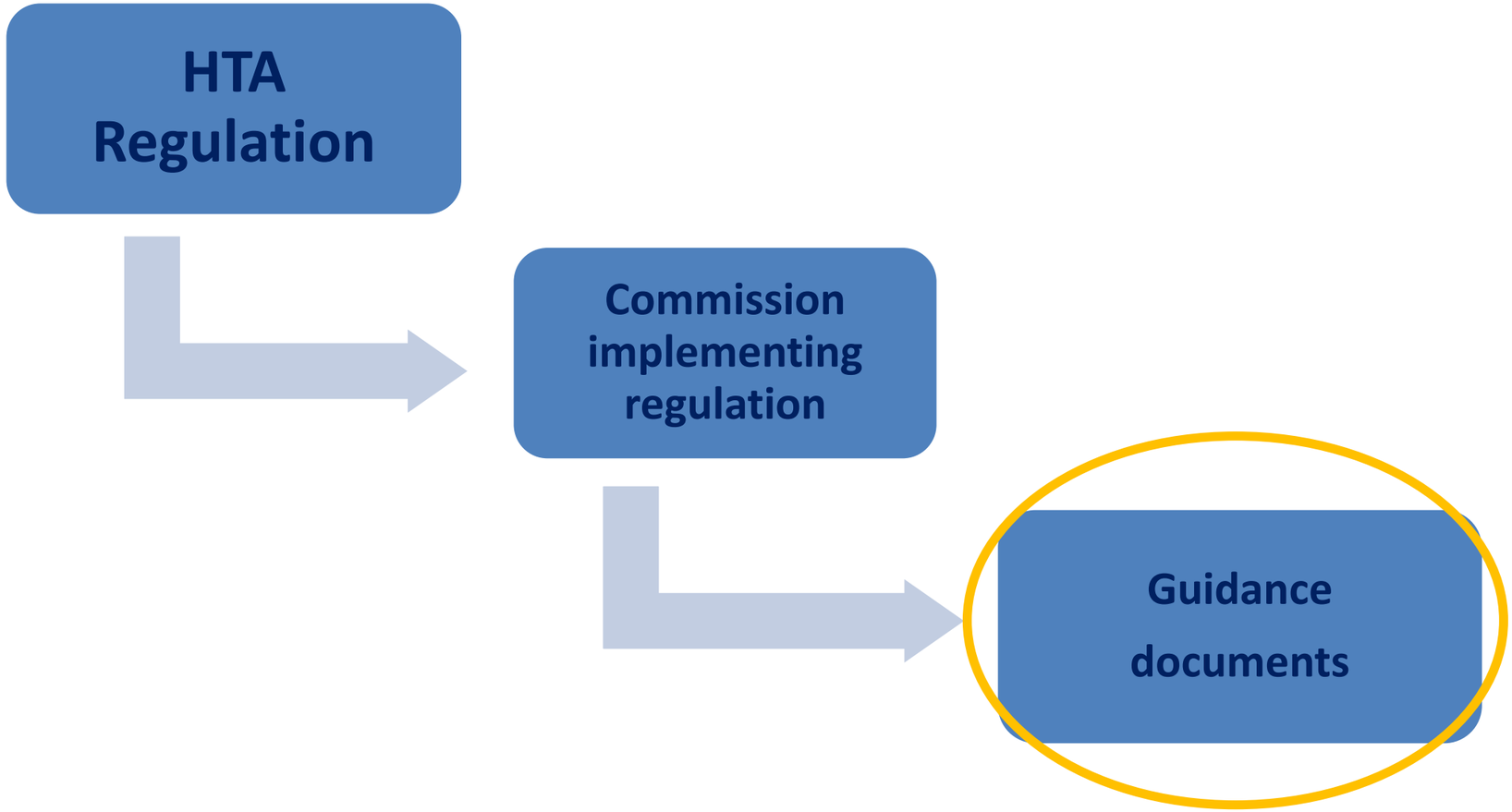
Common tasks → to assist the HTA CG in:

- the preparation of its **annual work programme** and **annual report**.
- establishing and regularly reviewing **standard operating procedures**.
- to establish a process to agree on the **outputs** of the Subgroup
- establishing **cooperation** relevant **Union level bodies**.

Specific tasks → to assist the HTA CG in the:

- SG JCA: preparation and update of **joint clinical assessments**
- SG JSC: selection and preparation of **joint scientific consultations**.
- SG MPG: preparation and update of **methodological and procedural guidance** on the joint work provided
- SG EHT: preparation of **reports** on emerging health technologies expected to have a major impact on patients, public health or healthcare systems

Rules and procedures



Adoption foreseen in the next HTA CG Meeting on 28Nov2024
+
Publication

Guidance Documents

Methodological Guidance	Adoption by CG
Methodological Guideline for Quantitative Evidence Synthesis: Direct and Indirect Comparisons	8 March 2024
Practical Guideline for Quantitative Evidence Synthesis: Direct and Indirect Comparisons	8 March 2024
Guidance on outcomes for joint clinical assessments	13 June 2024
Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in joint clinical assessments	13 June 2024
Scientific specifications of medicinal products subject to joint clinical assessments	13 June 2024
Guidance on the validity of clinical studies for joint clinical assessments	19 September 2024
Guidance on Scoping Process	28 November 2024
Guidance on procedural steps and timeframe for joint clinical assessments	28 November 2024
Guidance on filling in the joint clinical assessment (JCA) dossier template – Medicinal products and Table template collection for guidance on filling in the joint clinical assessment (JCA) dossier template – Medicinal Products	28 November 2024

Guidance Documents

Methodological Guidance to be adopted by the HTACG

Methodological Guidance	Description
1. Procedural guidance for joint scientific consultation on medicinal products	This guidance defines detailed **procedural steps and the timeframe for the conduct of JSC. It is the primary reference for HTDs and other stakeholders to comprehend key process steps and action points throughout the JSC procedure.** The document outlines the procedure for both formats: The HTACG JSC and the Parallel HTACG/EMA JSC. Information on the Parallel HTACG/EMA JSC procedures has been agreed with the EMA secretariat.
2. Format and template of requests from health technology developers for joint scientific consultation – medicinal products	Contains predefined fields to be completed as accurately as possible. The request for JSC should be submitted to the HTA Secretariat via the HTA IT platform
3. Guidance for the selection of joint scientific consultations for medicinal products	The selection of health technologies to be subject of a JSC follows a two-step procedure: the first step is the verification of eligibility according to Article 16(2) HTAR, - being likely to be the subject of joint clinical assessment pursuant of HTAR 78 Article 7(1) and; 79 - the clinical studies and clinical investigations are still in the planning stage. which is followed by a selection step according to Article 17(3) HTAR, if needed. The present guidance document aims to make the eligibility criteria and the selection criteria for JSC **explicit and to provide an interpretation** of these criteria for Medicinal Products (MP). This should help health technology developers (HTD) in the preparation of their JSC request and guide the Subgroup for JSC (JSC SG) in the selection, thus facilitating a transparent process.

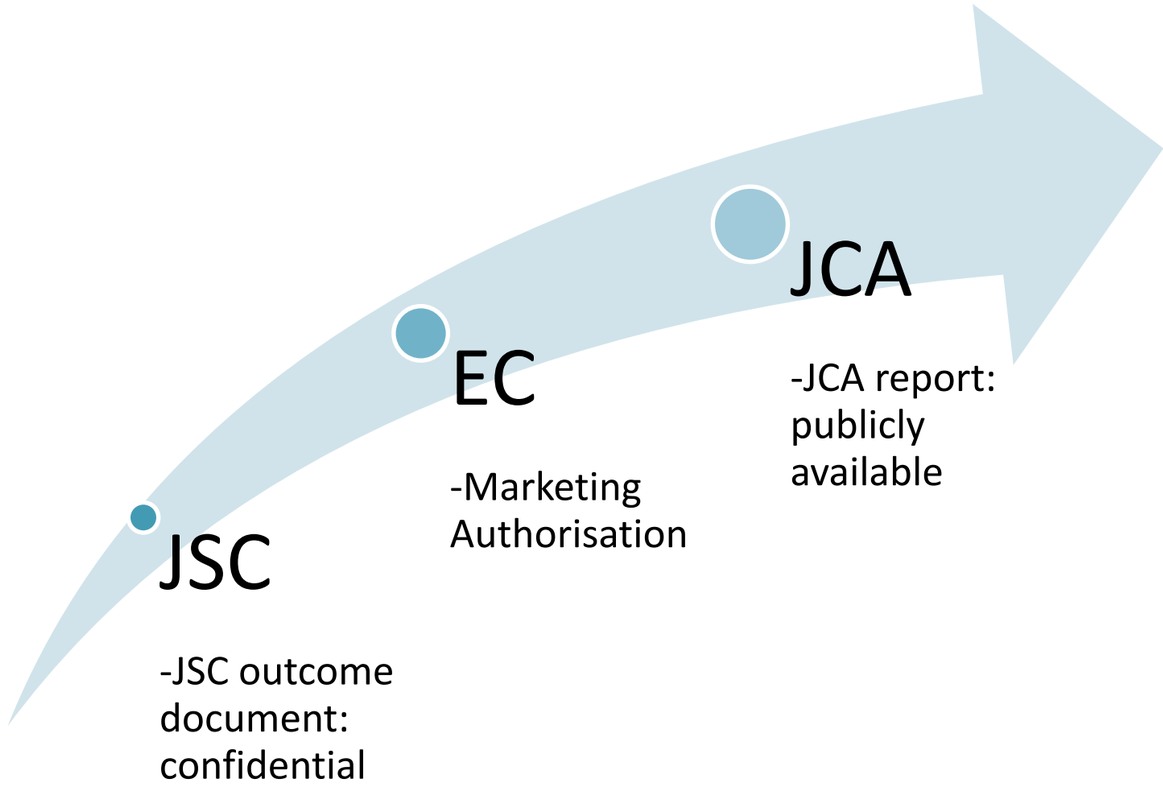
Guidance Documents

Methodological Guidance to be adopted by the HTACG

Methodological Guidance	Description
4. Format and template for the dossier submitted by the health technology developer for joint scientific consultation - medicinal products	The briefing document with annexes and references constitutes the briefing package. The use of this **briefing document template** is mandatory and standard headings in the template should be used. It is important to follow the template as the document forms the basis of the advice procedure.
5. Format and template for the joint scientific consultation outcome document medicinal products	Template for the final common recommendations + additional MS recommendations.
6. Guidance for the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations	Defines the procedure for the appointment of assessor and co-assessor; ets minimum requirements for the appointment of the assessor and co-assessor 56 for JCAs and JSCs for medicinal products (MPs) and medical devices (MDs) and in vitro diagnostic medical devices (IVD).

JSC vs JCA

Joint Scientific Consultation (JSC)	Joint Clinical Assessment (JCA)
DEFINITION	
- Scientific advice - provided jointly by HTA bodies - Can be in parallel with regulators - To HTD on the clinical development	- Joint HTA reports, produced by 2 EU MS - On HTD submission dossier - HTD cannot submit data again on national level - Focussing on the **clinical domains** - **Without value judgements** - MS to give due consideration
AIM	
To generate evidence that satisfies the needs of HTA bodies during their assessment and ultimately facilitates patient access	To avoid duplications of work at the national level, increase consistency and quality of assessments and ultimately facilitate patient access
RELEVANT ARTICLES IN THE HTA REGULATION	
Art. 16 – Art. 21 Covering principles of JSC; Requests for JSC (& selection criteria); Preparation of JSC; Approval of JSC; Format and template for JSC	**Art. 6 – Art. 15** Covering annual work plan; Health technologies subject to a JCA; Initiation & PICO development; Obligations of HTD; Assessment process; Obligations Member States; Update of JCA



Joint Scientific Consultations (JSC)

Number of JSC will be communicated in the work programme at the latest by 30 November of each year

- For 2025: ~ 10 JSC planned with the aim to continuously increase capacities in the coming years
- 2 request periods planned for 2025: 3.2.-3.3.2025 + 2.-30.6.2025

To apply: Request template must be submitted during a request period and justify eligibility and fulfilled selection criteria

Submission of Briefing package in case of selection:

- Briefing document template:
  - PICO (Population, Intervention, Comparator and Outcomes)
  - Post Licensing Evidence Generation (PLEG) only in conjuction with study design
  - Health Economic Assessment (voluntary cooperation)

JSC Subgroup

Selection process will be laid down in the Guidance on JSC selection:

- Step-wise approach: Eligibility criteria → selection criteria → number of JSC scheduled for the request period

Feedback loop during the process: List of Issues (LoI) for HTD and Written response to LoI by HTD

Direct exchange: Discussion meeting with HTD

Outcome of the JSC procedure: JSC Outcome Document with common position + individual positions by MS in an annex (further specifications)

- Not legally binding but should reflect the state of the art of medical science at the time of the JSC

JSC MP governance

Joint Scientific Consultations in parallel with Scientific Advice

	Regulatory	Health Technology Assessment
Secretariat	EMA	**European Commission**
Approval and decision adoption	CHMP (Committee for Medicinal Products for Human Use) Members are national regulatory agencies	HTA CG (Member State Coordination Group on Health Technology Assessment) Members are national HTA authorities and bodies; and Ministry of Health
Technical Work	SAWP (Scientific Advice Working Party)	**JSC SG** (Subgroup for Joint Scientific Consultations)
Legal Basis	Regulation (EC) No 726/2004 (…) Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency	REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2021 on HTA and amending Directive 2011/24/EU

JSC MD governance

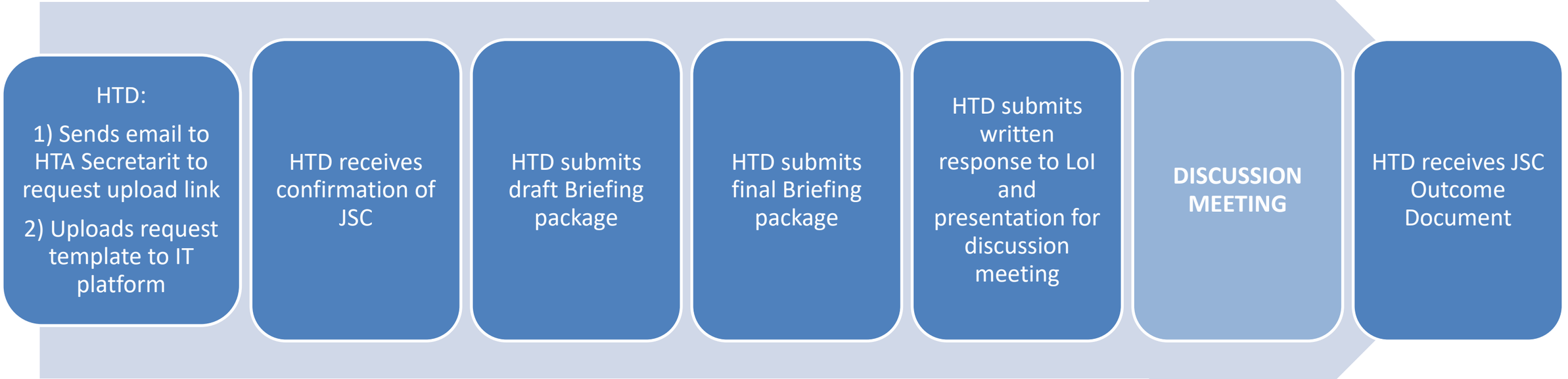
Joint Scientific Consultations in parallel with Expert Panel Consultation

	Regulatory	Health Technology Assessment
Secretariat	EMA	**European Commission**
Approval and decision adoption	Expert Panel	HTA CG (Member State Coordination Group on Health Technology Assessment)
Technical Work	Expert Panel	**JSC SG** (Subgroup for Joint Scientific Consultations)
Legal Basis	Regulation (EU) 2017/745 on medical devices	REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2021 on HTA and amending Directive 2011/24/EU

Process overview: HTD action points

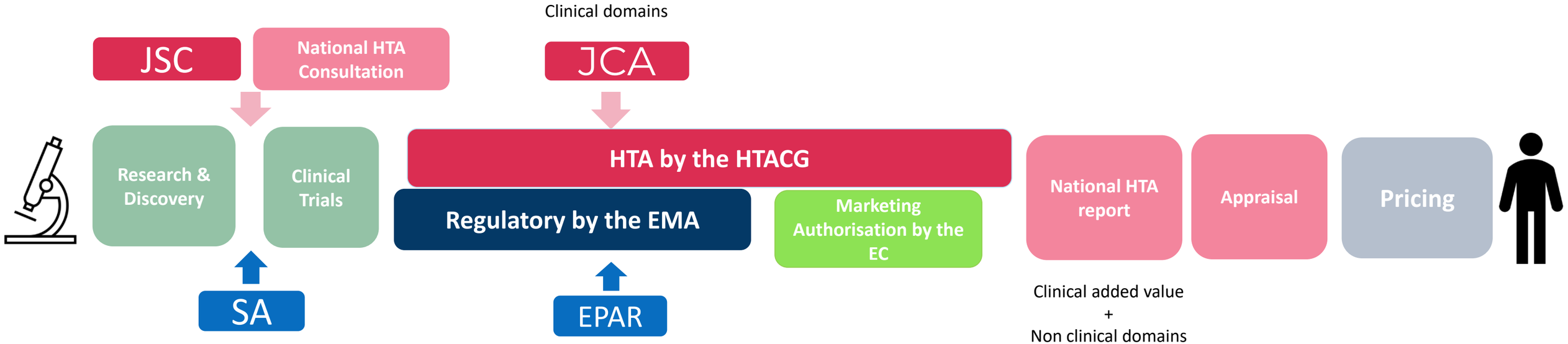
During the request period

Duration: approximately 4.5 months, from the receipt of the draft Briefing package



- Within 15 working days after the end of each request period, the Coordination Group shall inform the requesting health technology developer whether it will engage in the joint scientific consultation

New European scenario in 2025



JSC: Joint Scientific Consultation
SA: Scientific Advice
HTD: Health Technology Developer
JCA: Joint Clinical Assessment
HTACG: Member State Coordination Group on Health Technology Assessment
EMA: European Medicines Agency
EPAR: European Public Assessment Report
EC: European Commission

Subgroups Work in 2024

Monthly meetings.
Working Groups set up.

- SG JCA: PICO exercises, resource planning, development of guidance documents, collaboration in IT Platform set up.
- SG JSC: interim advice, resource planning, feedback to IA JSC, development of guidance and templates documents, collaboration in IT Platform set up.
- SG MPG: development of guidance and templates, collaboration in IT Platform set up.
- SG EHT: mapping of systems, work streams, resource planning.

Subgroups Work in 2025

What to expect?

- SG JCA: start of JCA for products for cancer treatments and ATMPs.
- SG JSC: limited number of JSCs for MP and MD – ensure HTA needs are met.
- SG MPG: review of guidance documents as needed.
- SG EHT: development of EHT reports.

HTA CG

MEMBER STATE COORDINATION GROUP
ON HEALTH TECHNOLOGY ASSESSMENT

Thank you