HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Regulation on HTA: A new reality for Access to Innovation in Europe

Regulation (Eu) 2021/2282 on Health Technology Assessment (HTAR)

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Co-Chair, HTA Member State Coordination Group (HTACG), EU

The European Health Strategies

MD and IVD Regulation

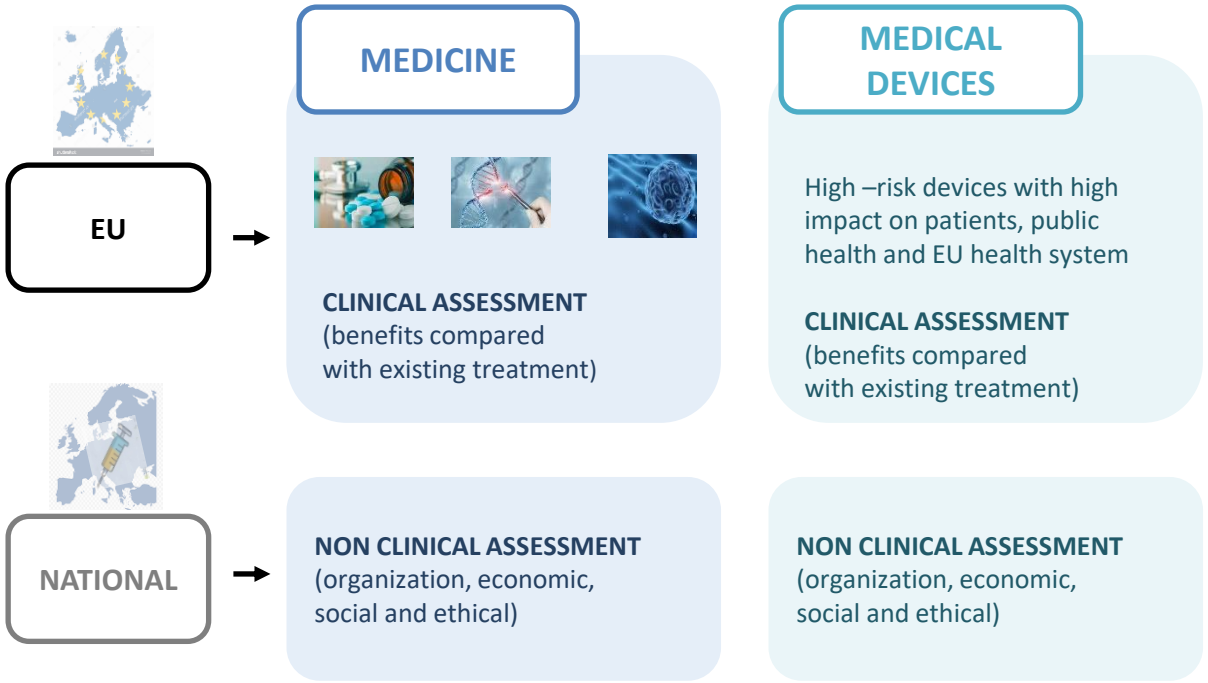
HTA Regulation

European Health Data Space

AI Regulation

New Pharmaceutical Legislation

What is joint HTA at the EU level?



Nearly 600 people are working hard across all European HTA agencies to implement HTAR between HTACG and its subgroups

Article 7

Health technologies subject to joint clinical assessments

1. The following health technologies shall be subject to joint clinical assessments:

(a) medicinal products as referred to in Article 3(1) and Article 3(2), point (a), of Regulation (EC) No 726/2004, for which the application for a marketing authorisation is submitted in accordance with that Regulation after the relevant dates set out in paragraph 2 of this Article, and for which that application is in compliance with Article 8(3) of Directive 2001/83/EC;

(b) medicinal products authorised in the Union for which a joint clinical assessment report has been published, in cases where an authorisation is granted pursuant to the second subparagraph of Article 6(1) of Directive 2001/83/EC for a variation to an existing marketing authorisation which corresponds to a new therapeutic indication;

(c) **medical devices classified as class IIb or III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion** in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation, and subject to selection pursuant to paragraph 4 of this Article;

(d) **in vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views** in the framework of the procedure pursuant to Article 48(6) of that Regulation, and subject to selection pursuant to paragraph 4 of this Article

What are key activities for whom?

EMA

- Single licensing system
- EU legislation
- Well-defined and agreed assessment criteria

EU HTA Regulation

- Joint framework for clinical assessment
- Common methodology and approach for clinical assessments and scientific consultations

NATIONAL

- Use of joint clinical assessment in national decision-making
- Non-clinical assessments
- Decision making on pricing and reimbursements

EUROPEAN MEDICINES AGENCY

Medicinrådet

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

agena.s.
AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI

NNGYK
NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY

agencia española de medicamentos y productos sanitarios

AIFA
AGENZIA ITALIANA DEL FARMACO

MINISTRY OF SOCIAL AFFAIRS AND HEALTH

HAS
HAUTE AUTORITÉ DE SANTÉ

Ministry of Health, Republic of Cyprus

NIHO National Institute for Value and Technologies in Health Care

Gemeinsamer Bundesausschuss

SÚKL

TLV

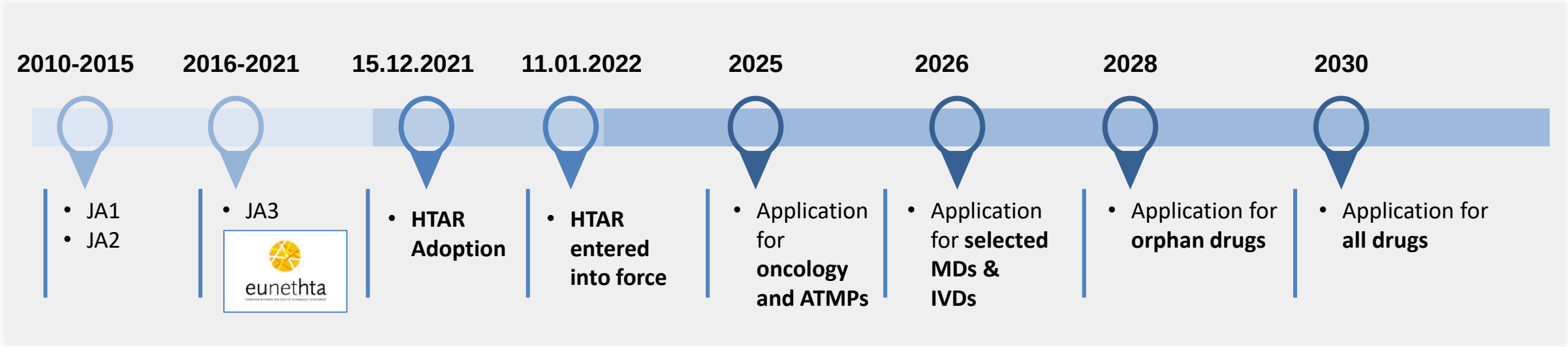
fimea

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

HALMED

EU HTAR entered into force in 2022, building on a decade cross-borde HTA experience in the EU

IMPLEMENTATION TIMELINES AND SCOPE



SUPPORTED BY EU AND NATIONAL HTAR READINESS PROGRAMS

EU HTAR Implementing Acts

Procedural rules for JCA of medicinal products	ADOPTED
Procedural rules for the management of conflict of interest	ADOPTED
Rules on cooperation by exchange of information with the EMA	ADOPTED
Procedural rules for JSC of medicinal products	**Q4 2024 –Public consultation will close on October 2024**
Procedural rules for JSC of medical devices and IVD medical devices	**Q4 2024**
Procedural rules for JCA of medical devices and IVD medical devices	**Q4 2024**

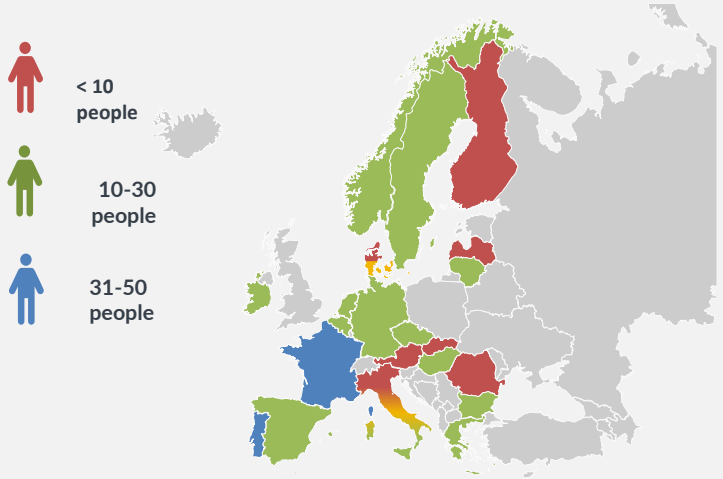
Guidance Documents

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 for the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations	28 November 2024
Procedural guidance for joint scientific consultation on medicinal products	28 November 2024
Guidance for the selection of joint scientific consultations for medicinal products	28 November 2024
Format and template (Medicinal Products) of requests from health technology developers for joint scientific consultation, the dossier submitted by the health technology developer and the outcome document for JSC.	28 November 2024

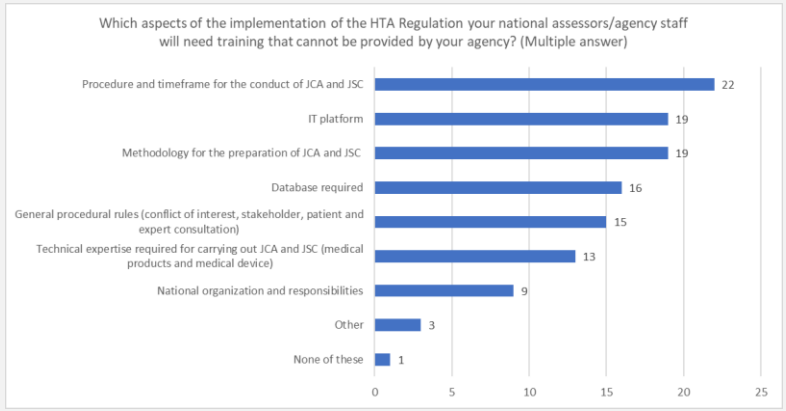
EU4Health | To build a long-term capacity and knowledge for the HTAR implementation

NEED ASSESSMENT SURVEY COMPLETED

~500 people to receive trainings



Procedural and methods are key need areas



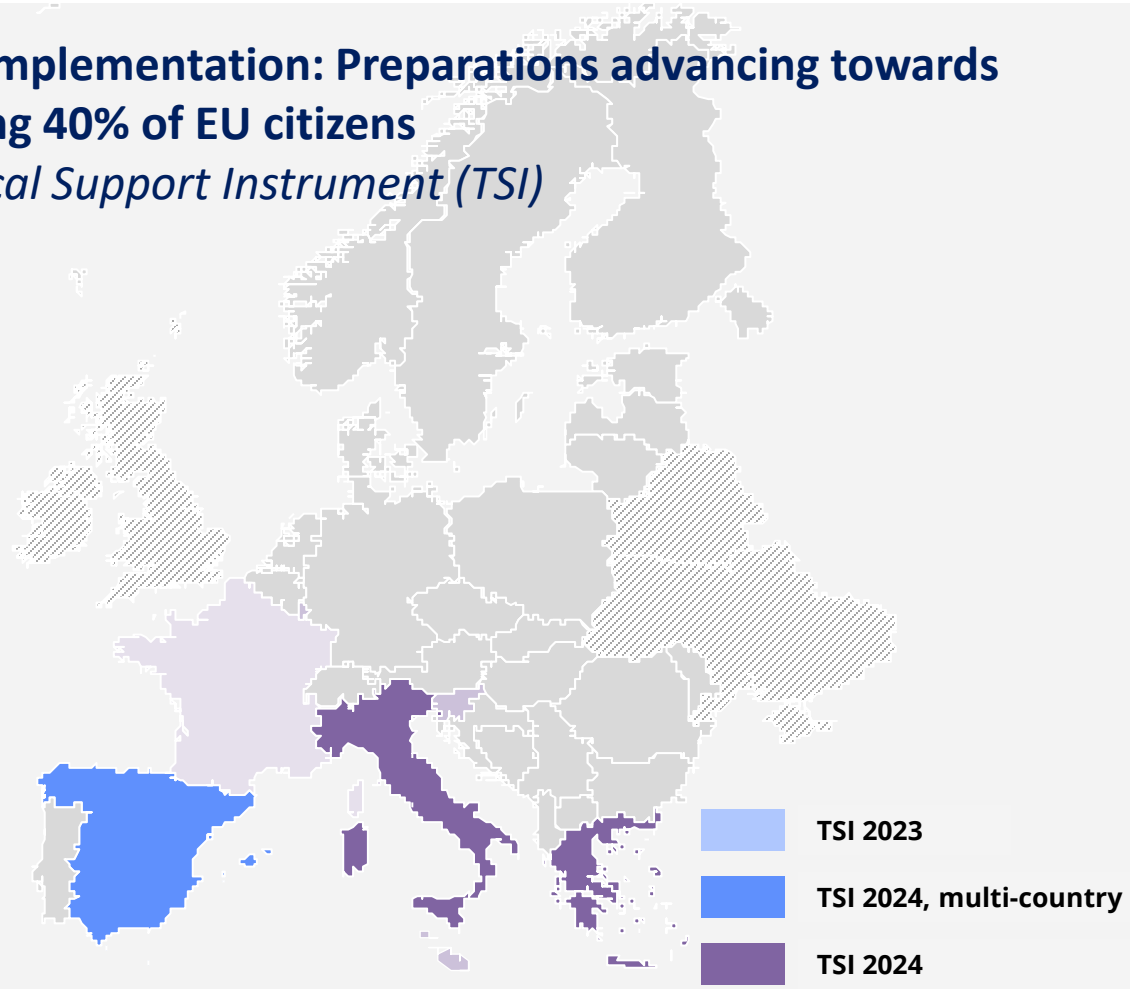
TRAINING PROGRAM FOR A LONG-TERM HTAR CAPACITY

HAG- INSIGHT
Head of Agencies Group Initiative for Knowledge and Skill Enhancement in Health Technology Assessment Regulation

HTAR Implementation national readiness programs

HTAR implementation: Preparations advancing towards covering 40% of EU citizens

Technical Support Instrument (TSI)



**Country sizes are readjusted for visibility, may not represent actual relative sizes (e.g. Malta), Some country distant islands may not be visible due to sizing adjustments.*

Supporting the successful implementation of the Regulation UE 2021/2282 on health technology assessment by HAS

Reorganization of Italian national governance

Strengthening the national framework for the implementation of the EU HTA Regulation 2021/2282: capacity building and harmonization

Supporting the successful implementation of the EU Health Technology Assessment Regulation by AEMP

Support for the implementation of the EU Health Technology Assessment Regulation
Implementation of the HTA Legislation in Malta
Supporting the establishment of HTA procedures to ensure a successful implementation of the Regulation UE 2021/2282 on health technology assessment

HTAR Readiness Italy – Medical Devices

Landing HTA Regulation:– Case of Italy Medical Devices

NATIONAL PROGRAM FOR HEALTH TECHNOLOGY ASSESSMENT FOR MEDICAL DEVICES

PNHTA 2023-2025

What's the PNHTA 2023-2025?

The National Health Technology Assessment Program for medical devices is a national initiative spanning three years, with the primary objective of critically assessing and integrating health technologies into the framework of the National Health Service (SSN).

**Legislative decrees n.137 and n. 138 August 5 2022*
Ministry of Health decree 9 June 2023 "Adozione del Programma Nazionale HTA"

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NATIONAL PROGRAM FOR HEALTH TECHNOLOGY ASSESSMENT FOR MEDICAL DEVICES PNHTA 2023-2025

Main Objectives

Production of HTA report.

Transfer and implementation of the HTA results within the National Health Service.

Scope

Ensuring the efficiently allocation of healthcare resources, promoting equitable access to health technologies, and enhancing the quality of care.

PNHTA - Process steps

Process steps

Requirements/ procurement	Health Tecnology notification	Prioritization	Assessment *(use of JCA for clinical domain and assessment only not covered by JCA)*	Appraisal	HTA results implementation	Impact of HTA

JCA Medical Devices

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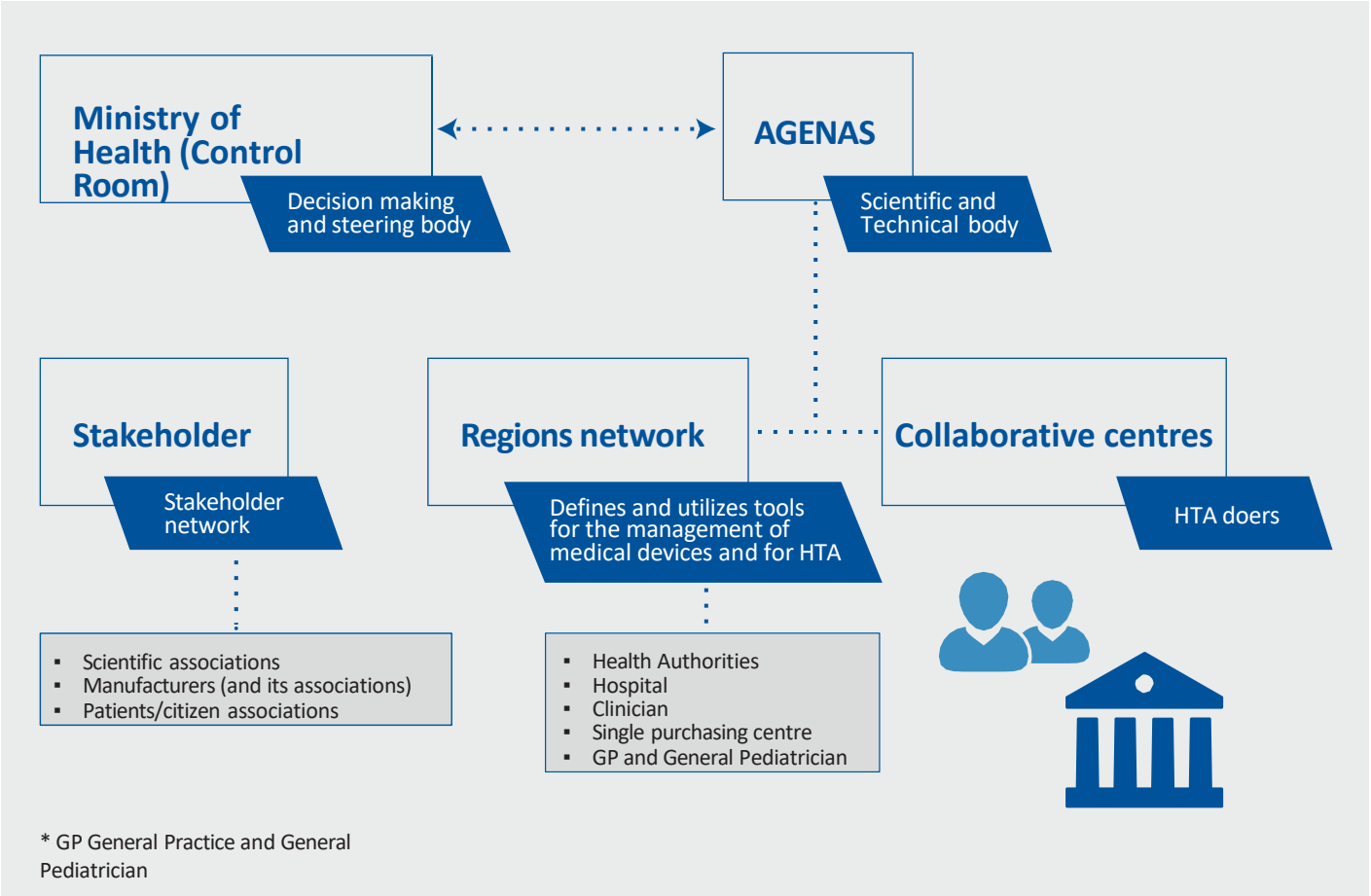
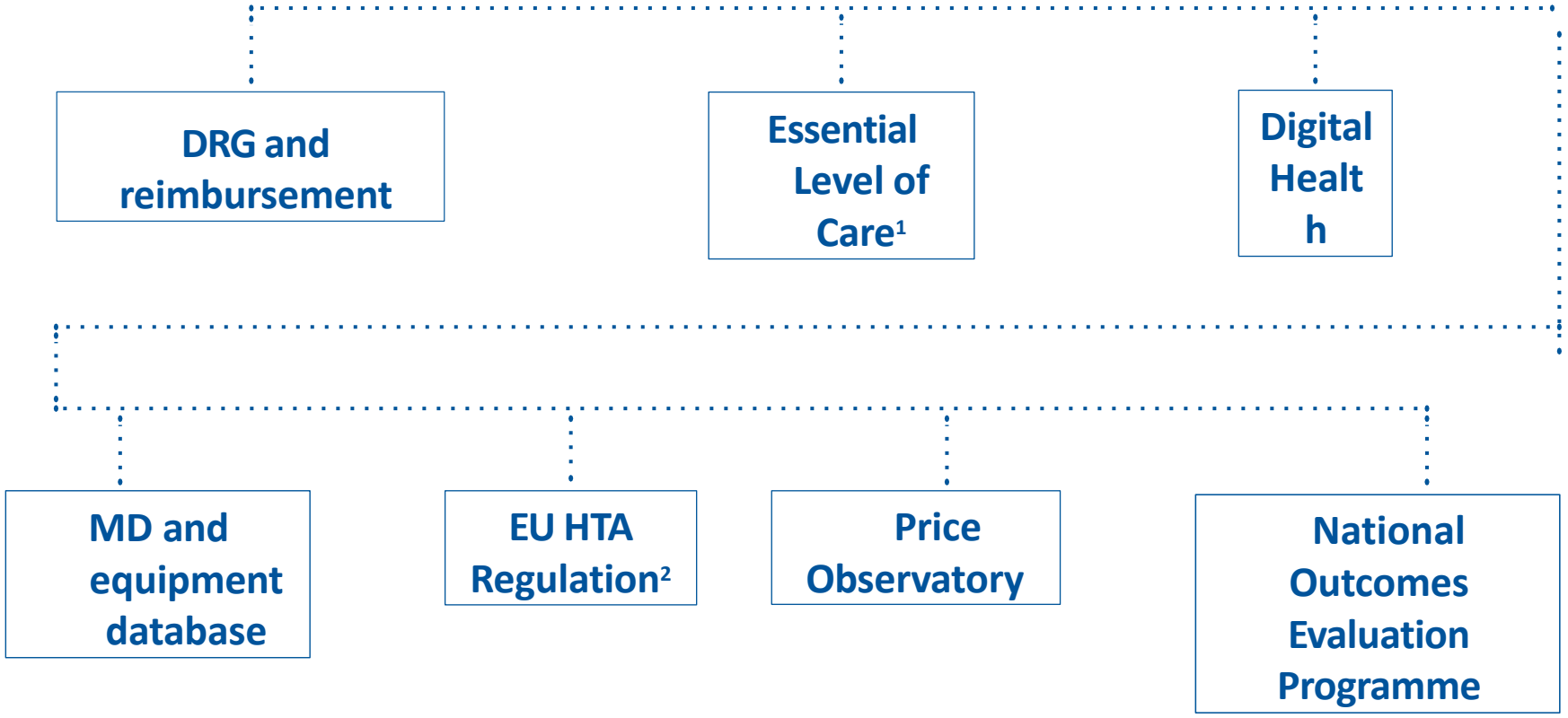
Governance Structure of the PNHTA 2023-2025



Integration area with the PNHTA 2023-2025



HTAR Readiness Italy – Medicinal products

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AIFA
AGENZIA ITALIANA DEL FARMACO

HTA-R PREPARATION IN THE ITALIAN MEDICINES AGENCY

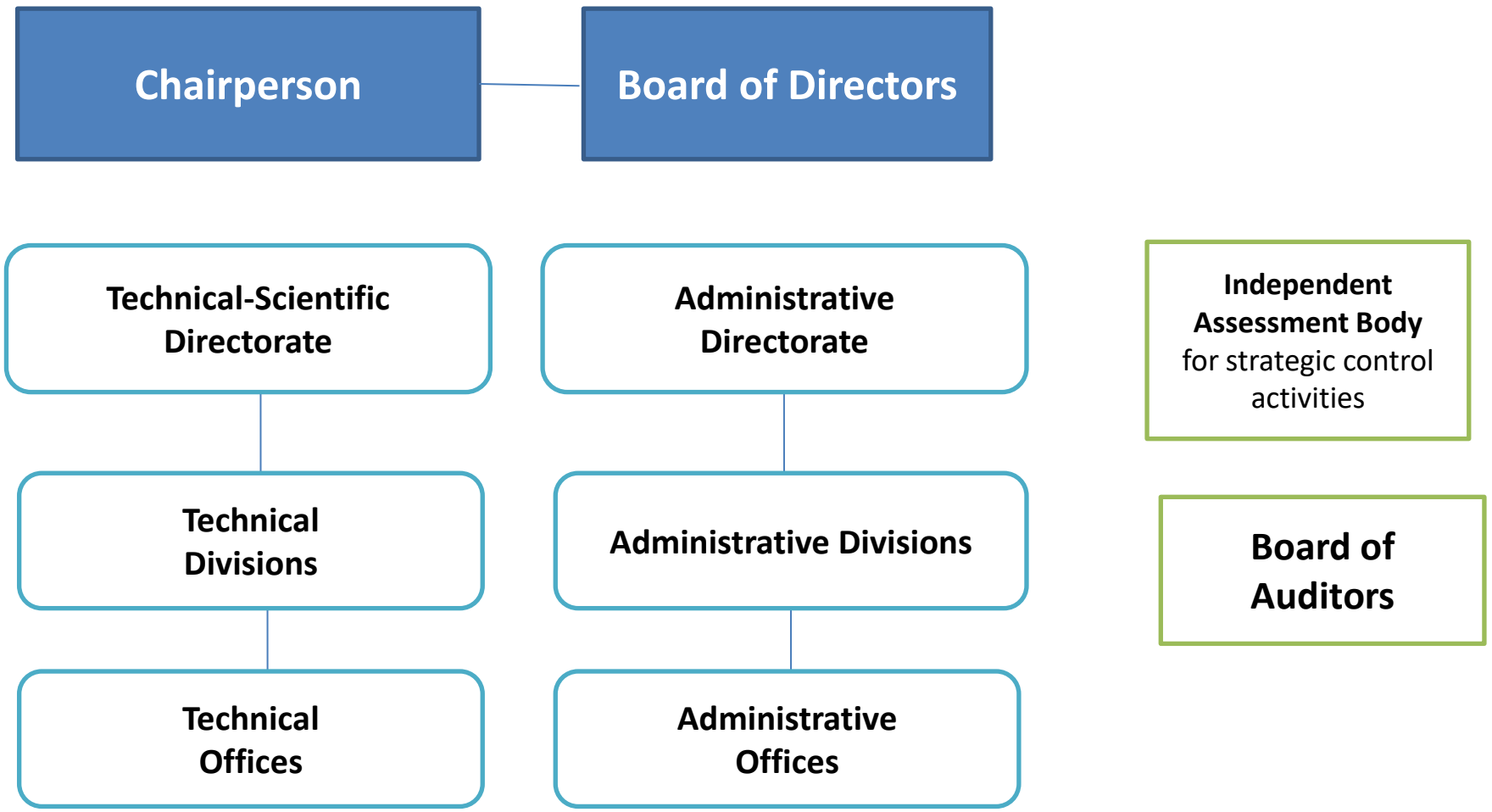
Number of HTAs per year: 150/year (NCEs, OMPs, Therapeutic Extension)
Scope of HTAs (all NCEs, Orphan Medicines, Therapeutic Extensions)
Special programs: Innovative Medicines and access to dedicated funding

Legislation (all NCEs, Orphan Medicines, Therapeutic Extensions are assessed + re-assessment + new packages, etc)
process steps to follow)

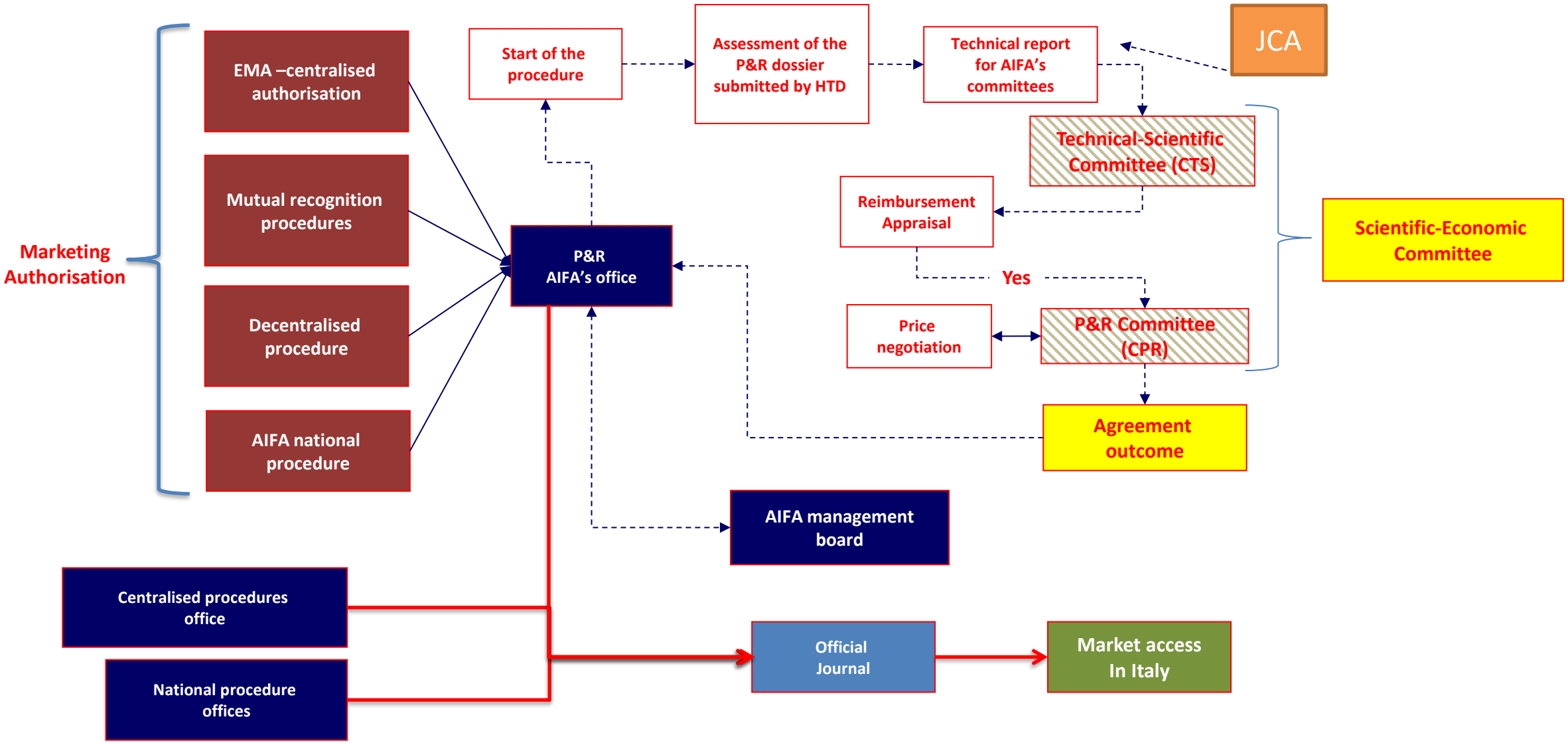
Informing the process:
For HTD by IT platform, available for tracking the status of the procedure and for generating the e-dossier

Patient and HCP input: on a case-by-case approach

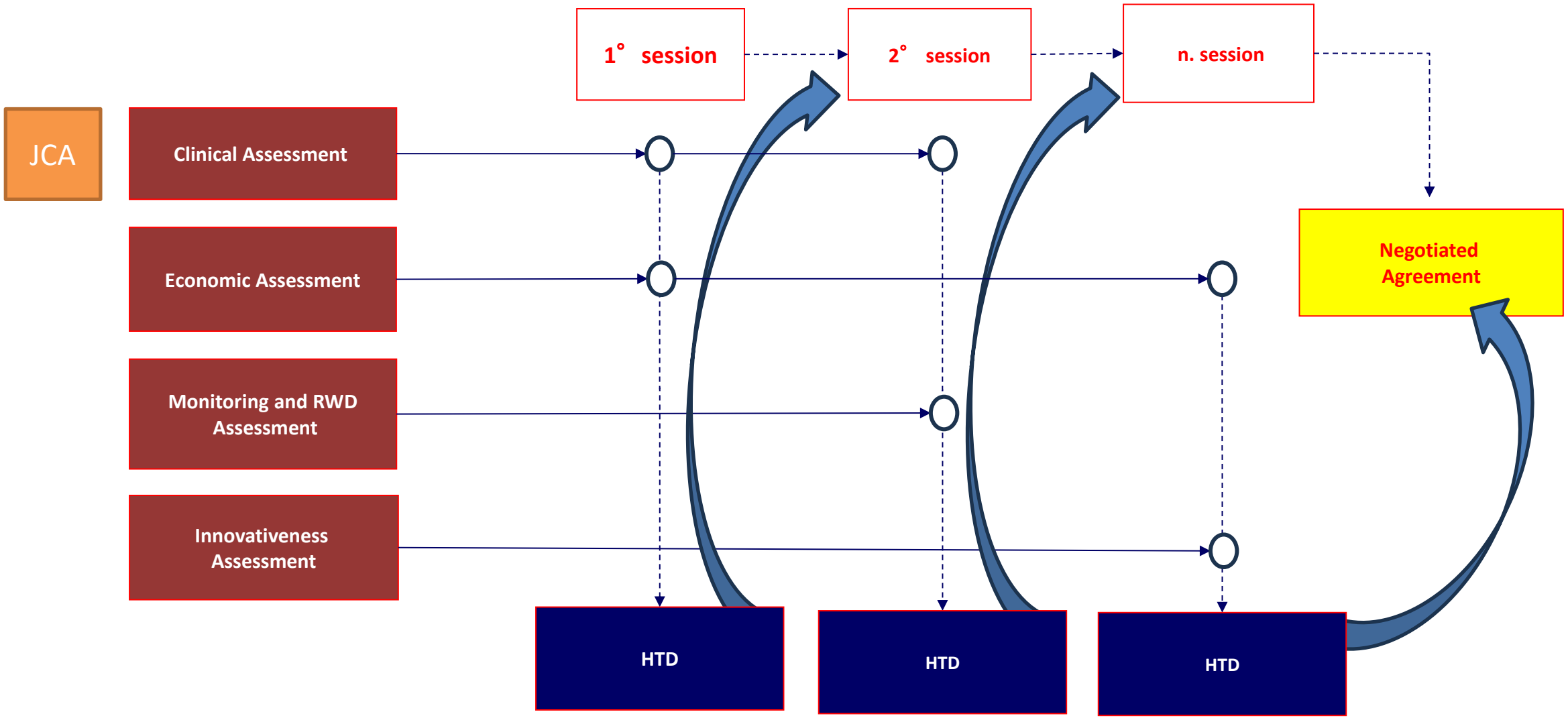
AIFA (CURRENT) ORGANIZATION AND FUNCTIONING REGULATION



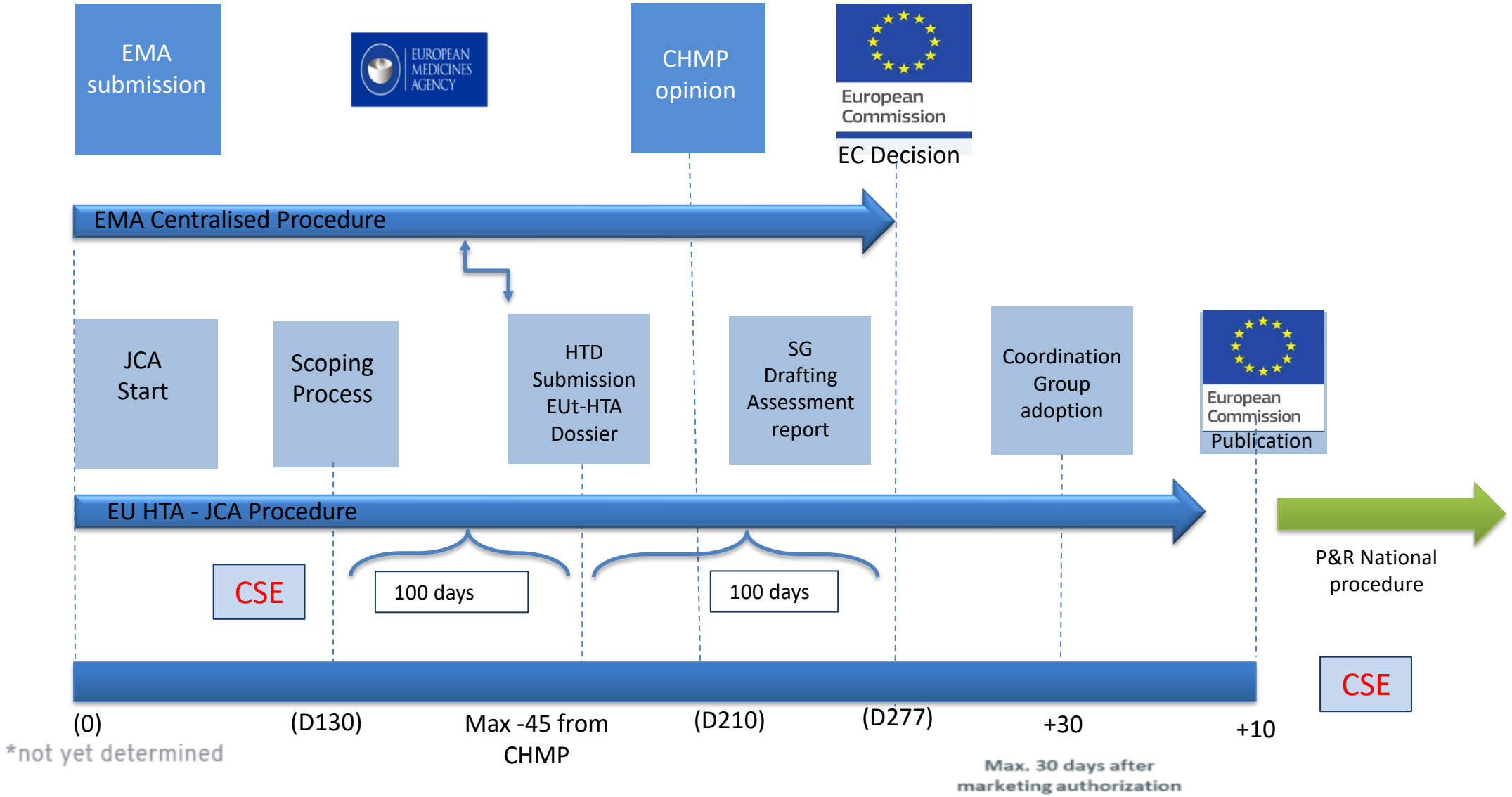
THE PRICING AND REIMBURSEMENT PROCEDURE



SCIENTIFIC AND ECONOMIC COMMITTEE



JCA TIMELINE AND CSE ROLE



Regulation containing rules on the organization and functioning of the Scientific-Economic Pharmaceutical Committee of the Italian Medicines Agency

Art. 8. Tasks

The Commission carries out the tasks assigned to it by article 48, paragraph 5, letters d), e) and l) of the legislative decree of 30 September 2003, n. 269

(….)

In particular, it expresses the following mandatory opinions of a non-binding nature:

(…)

*f. expresses an opinion, **limited to the national healthcare context, in relation to the parameters for the joint clinical evaluation and the evaluation of the Joint Clinical Assessment**, subsequently published in implementation of European Regulation no. 2282 of the European Parliament and of the Council of 15 December 2021, published in the Official European Journal of 22/12/2021;*

Metrics of Agency: 670 is the whole AIFA staff

HTA Activities: **Pharmaceutical Economics and Strategy Division**

- **Pharmaceutical Economics Department:**
  - **Health Economic Evaluation Office**
  - **Monitoring Registries Office**
  - **Pharmaceutical Budget Monitoring Office**

P&R and national HTA Assessment (73)

49 Multidisciplinary expertises:

- 22 Pharmacists assessors,
- 6 Medical assessors,
- 3 Biologists assessors,
- 9 Health economists,
- 5 Statisticians
- 4 Health tecnician

+

- 3 Legal officiers
- 21 Administrative officiers

In cooperation with:

- Medical assessors/Clinical experts, statisticians from other Divisions/Departments

+

- **External experts when necessary**

+150 units: under evaluation (budget bill 2025)

Thank you

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