EU HTA Regulation – What, Why, When?

October 12th 2023

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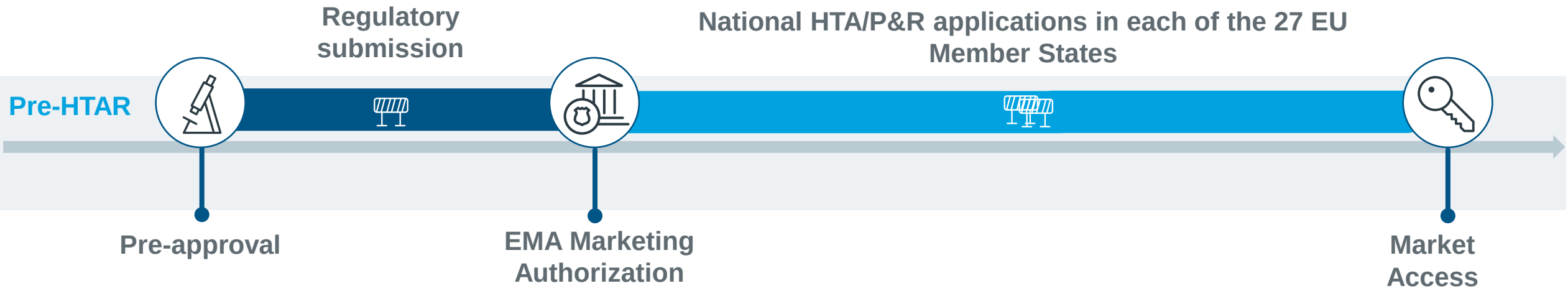
While regulatory decisions are centralised in the EU, each country has its own HTA process



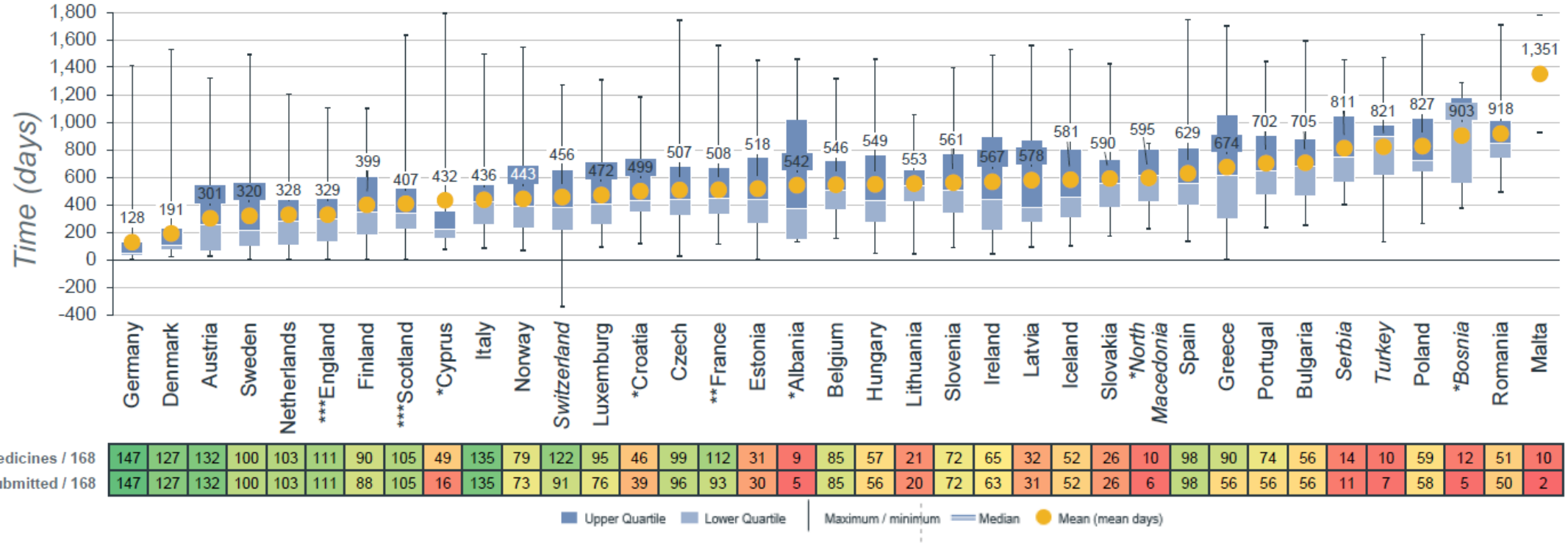
DEFINITION

- Health technology assessment (HTA) is a systematic and multidisciplinary evaluation of the properties of health technologies and interventions covering both their direct and indirect consequences
- It aims to determine the value of a health technology and to inform guidance on how these technologies can be used in health systems
- Recommendation for decision makers and other stakeholders to support the decision-making process at the policy level by providing evidence about the technology

Source: https://www.who.int/health-topics/health-technology-assessment

HTA methods and processes vary by country leading to differences in time to patient access in the EU

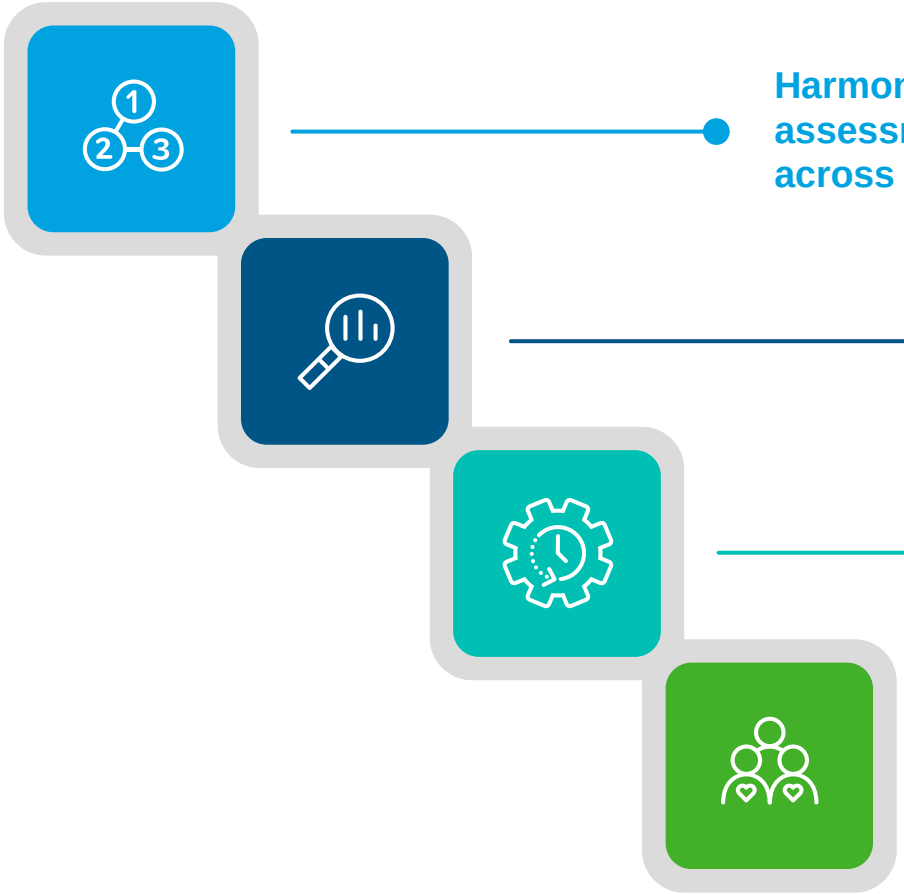
Time from central approval to availability (2018-2021, all products)



Note: the **time from central approval to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list). The marketing authorisation date is the date of central EU authorisation throughout. EUaverage: 517 days (mean %) (Note: Malta is not included in EU27 average as only 2 dates were submitted in total) † In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative **For France, the time to availability (508 days, n=93 dates submitted) does not include products under the ATU system for which the price negotiation process is usually longer. ***In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines

Source: EFPIA Patients W.A.I.T. indication survey 2022. https://www.efpia.eu/media/s4qf1eqo/efpia_patient_wait_indicator_final_report.pdf

The HTA Regulation aims to improve and accelerate patients' access to new health technologies in the EU



Harmonize health technology assessment methodologies across 27 EU member states

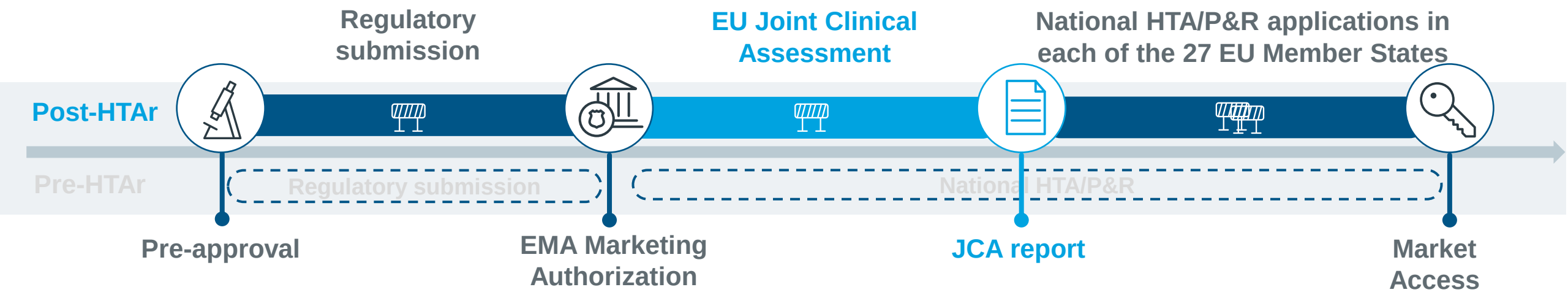
Establish predictability of HTA outcomes

Avoid duplication of effort when submitting and reviewing the dossier

Accelerate patients' access to new medicines

Source: Regulation (EU) 2021/2282. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282

With the implementation of a pan-EU process, JCA could become the standard pathway for access



The EUnetHTA collaboration has defined two key elements: scientific advice and assessment of clinical effectiveness & safety on an EU level

Joint Scientific Consultation (JSC)

JSCs will provide **non-binding scientific advice** from at least 2 HTA bodies, before the start of pivotal clinical trials, on MS expectations for submissions, including the following:

- Study design (choice of comparator, relevant outcomes, quality of life, patient groups)
- Evidence generation (pivotal trials & post-launch evidence generation)

Joint Clinical Assessment (JCA)

New products launching in the EU will need to submit an HTA dossier focusing on **clinical effectiveness** at the EU level no later than 45 days ahead of the anticipated CHMP opinion

The new EU HTA process introduces an EU-level HTA but will not replace national HTA processes

DOMAINS OF THE CORE HTA MODEL

Health problem and current use of technology	**Description and technical characteristics**	**Safety**
Clinical effectiveness	Cost and economic considerations	Ethical analysis
Organizational aspects	Patient and social aspects	Legal aspects

In scope *Out of scope*

In compliance with HTA Regulation 2021/2282 (HTAR) Article 9.1:

- The JCA report will not contain any value judgement or conclusions on the overall clinical added value
- It will analyze the relative effects of the health technology against parameters within assessment scope
- It will evaluate the degree of certainty of the relative effects considering the strengths and limitations of available evidence

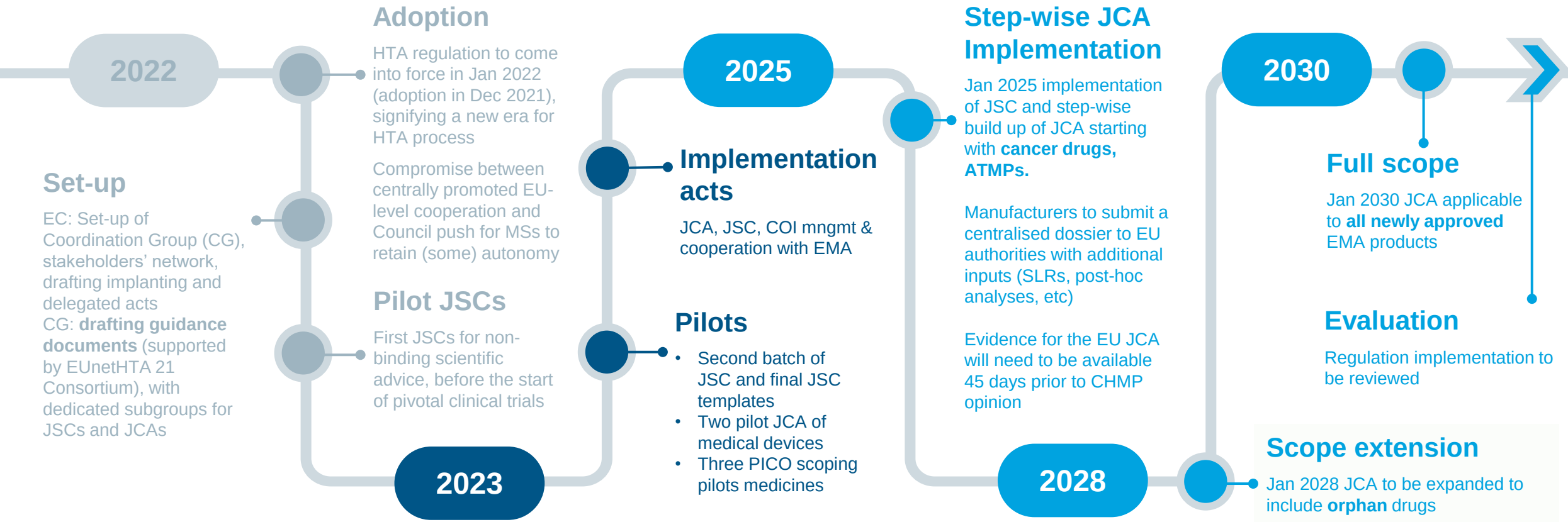
JCA **"given due consideration":** report should be part of the documentation and should be considered by national HTA bodies, however content should not be binding

Obligation on Member States **not to request at national level the same information**, data, analyses or other evidence that has been already submitted at EU level. However, they may request clarification

Member States remain responsible for drawing conclusions on the 'added value' for their health systems and pricing and reimbursement decisions

Source: Regulation (EU) 2021/2282. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282

We have reached the midway point between EU HTA Regulation adoption in 2021 and its first implementation in 2025



Abbreviations: EC: European Commission; CG: Coordination Group; JSCs: Joint Scientific Consultations; JCAs: Joint Clinical Assessments; MS: Member State (of the EU); ATMPs: Advanced Therapy Medicinal Products; SLR: Systematic Literature Review; CHMP Committee for Medicinal Products for Human Use

Three different coordination committees have been put in place to support implementation

EUnetHTA 21

- Joint consortium of 13 agencies based on a service contract signed on September 17, 2021
- Governance structure: Consortium executive board, Committee for Scientific Consistency and Quality, Hands-on-groups, Conflict of Interest Committee
- >60 deliverables including methodological guidance, 8 JSC, 2 JCA etc
- Operation ceased on September 16th 2023

Heads of Agency Group

- Leaders or directors of 32 national HTA agencies in different European countries
- Meet 3 times a year
  - Support the development of the basis for joint work on all HTA activities
  - Prepare national systems and capacities for the adoption of the Regulation.
  - Support the joint work at the technical and scientific level
  - Advise policy makers

Member State Coordination Group on Health Technology Assessment (HTACG)

- Established by the Regulation: 1 for medicinal products and 1 for devices
- Representatives from the HTA agencies of EU MS, health ministries, EMA and EC
- Chairs: NCPE, TLV, AGENAS
  - Subgroup for JCA (HAS, ZIN)
  - Subgroup for JSC (G-BA, NIPN)
  - Subgroup for the Identification of Emerging Health Technologies (DMA, AIFA)
  - Subgroup for the Development of Methodological and Procedural Guidance (IQWiG, INFARMED)

EUnetHTA 21 developed guidance to harmonize the pan-EU HTA process in preparation for 2025 implementation

Methodological Deliverables*

D4.2: Scoping Process

D4.3: Comparators and Comparisons
- 4.3.1: Practical guideline
- 4.3.2: Methodological guideline (final version published)

D4.4: Endpoints

D4.5: Applicability of Evidence

D4.6: Validity of Clinical Studies

Joint Clinical Assessment (JCA)/Collaborative Assessments (CA)

D5.1: JCA/CA Submission Dossier Template

D5.2: JCA/CA Assessment Report Template

D5.3: Procedural Guidelines for Appointment of Assessors
- 5.3.1 Appointment of assessors/co-assessors
- 5.3.2 HTAb Technical Expert Working Groups

D5.4: Production of JCA/CA (medical devices) + timelines

Joint Scientific Consultations (JSC)

D6.1: Production JSC†

D 6.2/3: Template Briefing Book and JSC Report

D6.4: Procedural Guidance JSC

Transversal Activities

D7.1: HTA/HTD Interaction
- 7.1.1 Guideline for interaction
- 7.1.2 Factual accuracy check
- 7.1.3 Handling commercial in confidence data

D7.2/3: Patient and Expert Interaction
Guidance on templates for stakeholder input

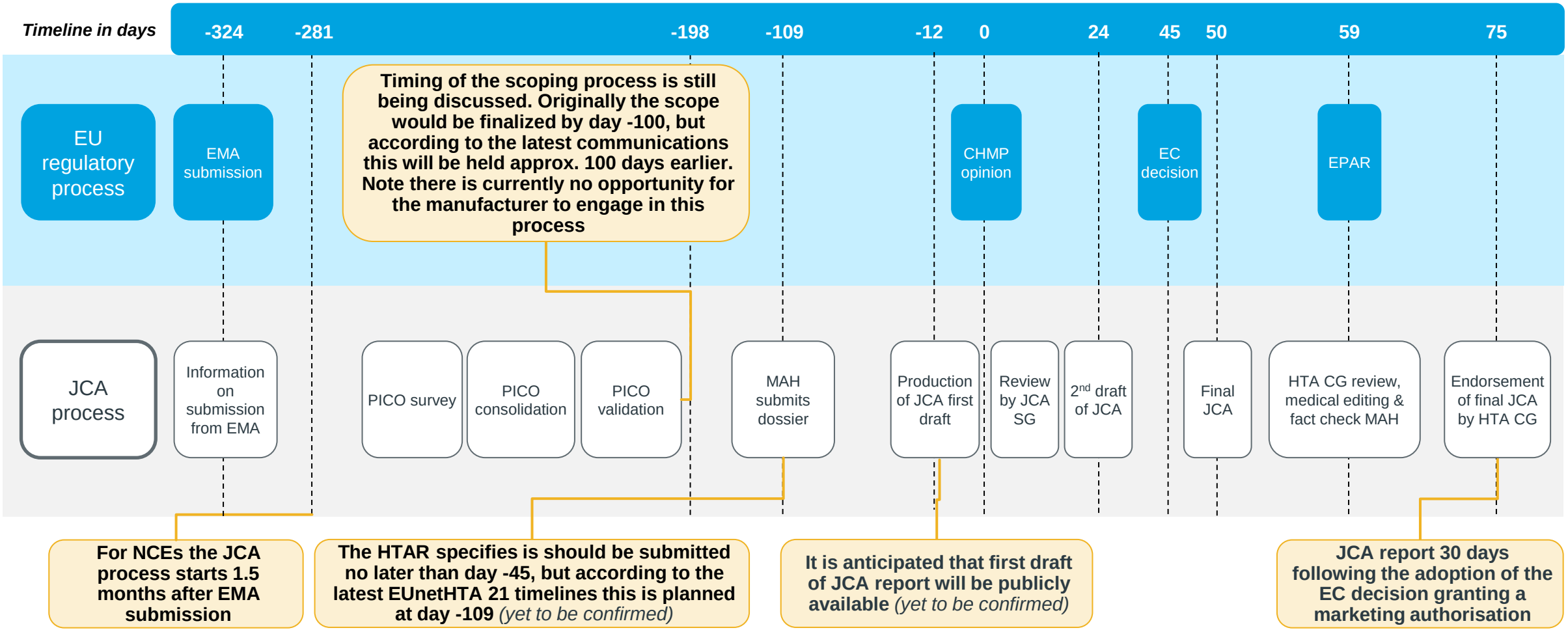
D7.5: Identification and Handling of Conflict of Interest guidance and forms

Guidance documents developed by EUnetHTA 21 are not final and may change as the European Commission develops the implementation acts

Source: https://www.eunethta.eu/
IQVIA - NVTAG symposium | EU HTAR | Oct 2023

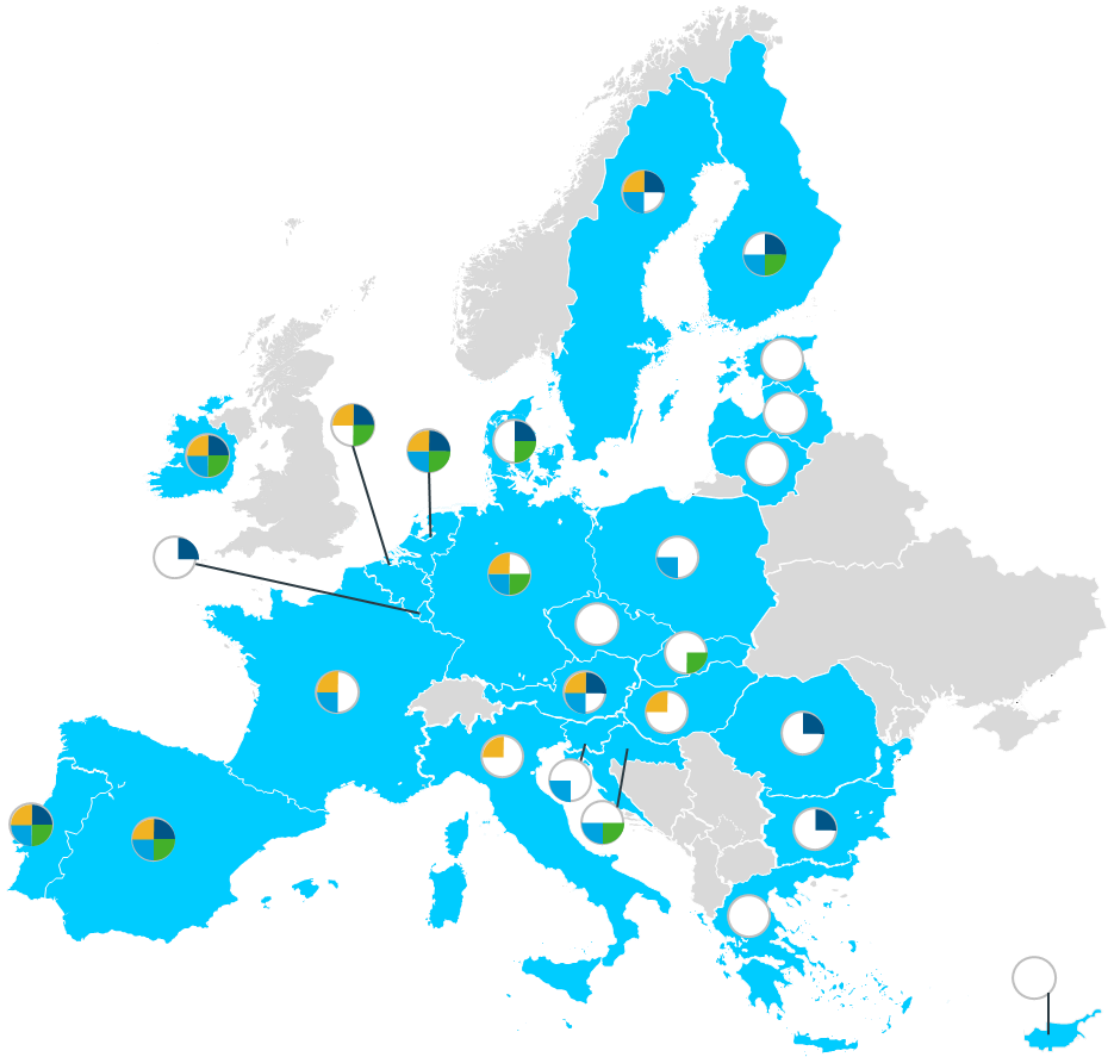
HTAb: Health Technology Assessment body; HTD: Health Technology Developer
*EUnetHTA 21 has also produced medical devices guidelines not depicted here †No generic guidance to be published

The JCA process will run in parallel to the existing EU regulatory processes, starting approx. 320 days prior to CHMP opinion



Note: process for NCE based on average duration of clock-stops (120 days). Abbreviations: CG: Coordination Group; EMA: European Medicines Agency; EPAR: European public assessment reports; EU: European Union; HTA: JCA: Joint clinical assessment; MA: Marketing authorisation; MAH: Marketing authorisation holder; PICO: Population, intervention, comparator, outcome; SG: subgroup

As of today, there is limited information as to how MS will implement regulation, align processes and incorporate JCA



PICO scope is predefined

Belgium, Croatia, Denmark, Finland, Germany, Ireland, Netherlands, Portugal, Slovakia, Spain

EUnetHTA 21 members

Austria, Belgium, France, Germany, Hungary, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden

Author of EUnetHTA JA report

Austria, Croatia, Finland, France, Germany, Ireland, Netherlands, Poland, Portugal, Slovenia, Spain, Sweden

Involved in other collaborations

- **BeNeLuxA**: Austria, Belgium, Ireland, Luxembourg, Netherlands
- **Romanian-Bulgarian IFA**: Romania, Bulgaria
- **NLF**: Finland, Iceland, Norway, Sweden, and Denmark
- **FINOSE**: Finland, Sweden, Norway
- **Iberia Partnership**: Portugal, Spain

Some key uncertainties remain with regards to the scoping process, MS input into JCA and local implications

JCA dossier
- Comprehensiveness & robustness
- Usability
- Impact

Scoping
- Consolidation MS input
- Adjustments to implementation act

Product
- Alignment between EMA label and study population
- Combination products, biomarkers
- Parallel processes
- Early access

MS input
- Capability and capacity building
- Engagement with patient and clinical organizations

National dossiers
- Incorporation of JCA
- Complementary analyses
- Alignment of processes and timelines

Thank you for your time

References to IQVIA's thought leadership on EU HTA

- The future of EU HTA. How pharmaceutical companies can prepare for the new process
- ISPOR issue panel: EU Joint Clinical Assessment – One for All and All for One?
- The Pharmaceutical Reimbursement and Access Pathways in the 27 EU Member States: Who Is Ready for Joint EU HTA?
- Impact of Additive PICOs in a European Joint Health Technology Assessment. a Hypothetical Case Study in Lung Cancer
- EU HTA: Business as usual for market access strategy or time for change?
- How Emerging Biopharma Companies Can Prepare for EU HTA
- What you need to know about the EU HTA regulation before deadline
- HTA Accelerator