Training

EUnetHTA 21 & HTA Regulation

European Network for Health Technology Assessment
EC Service Contract | 2021-2023 & future HTA Regulation

Abbreviations used

See supporting document for more terminology used

COIC = Conflict of Interest Committee

DOI = Declaration of Interest

ECA = EUnetHTA 21 Confidentiality Agreement

EUnetHTA = European Network for Health Technology Assessment

HCP = Healthcare Professional

HTA = Health Technology Assessment

HTAb = Health Technology Assessment bodies

HTAR = Health Technology Assessment Regulation

HTD = Health Technology Developer

JCA = Joint Clinical Assessment

JSC = Joint Scientific Consultation

PICO = Population, Intervention, Comparator(s), Outcomes(s)

An introduction to HTA

HTA vs. Regulatory

Regulators (European Medicines Agency) - Authorization focus: Efficacy, Safety, Quality of the drug

- Does technology X work?
- Does the benefit of technology X outweigh the risks? Is technology X of sufficient quality?
- Are there any additional needs for technology X post-licensing?

HTA - Assessment focus: Benefit in comparison to current standard treatment

- How does technology X compare with technology Y?
  - Is technology X better than the current standard we already have (technology Y)?
    - Fewer harms, under what circumstances, for certain patient population?
  - Put in national context - What else needs to be considered? Underlying question: Is it worth paying for?

Current situation in the EU: Regulatory vs. HTA

EMA

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

National HTA

- All Member States have different HTA systems
- National legislations and procedures
- Different methodologies and assessment criteria

Situation under the HTA Regulation

EMA

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

HTA Regulation

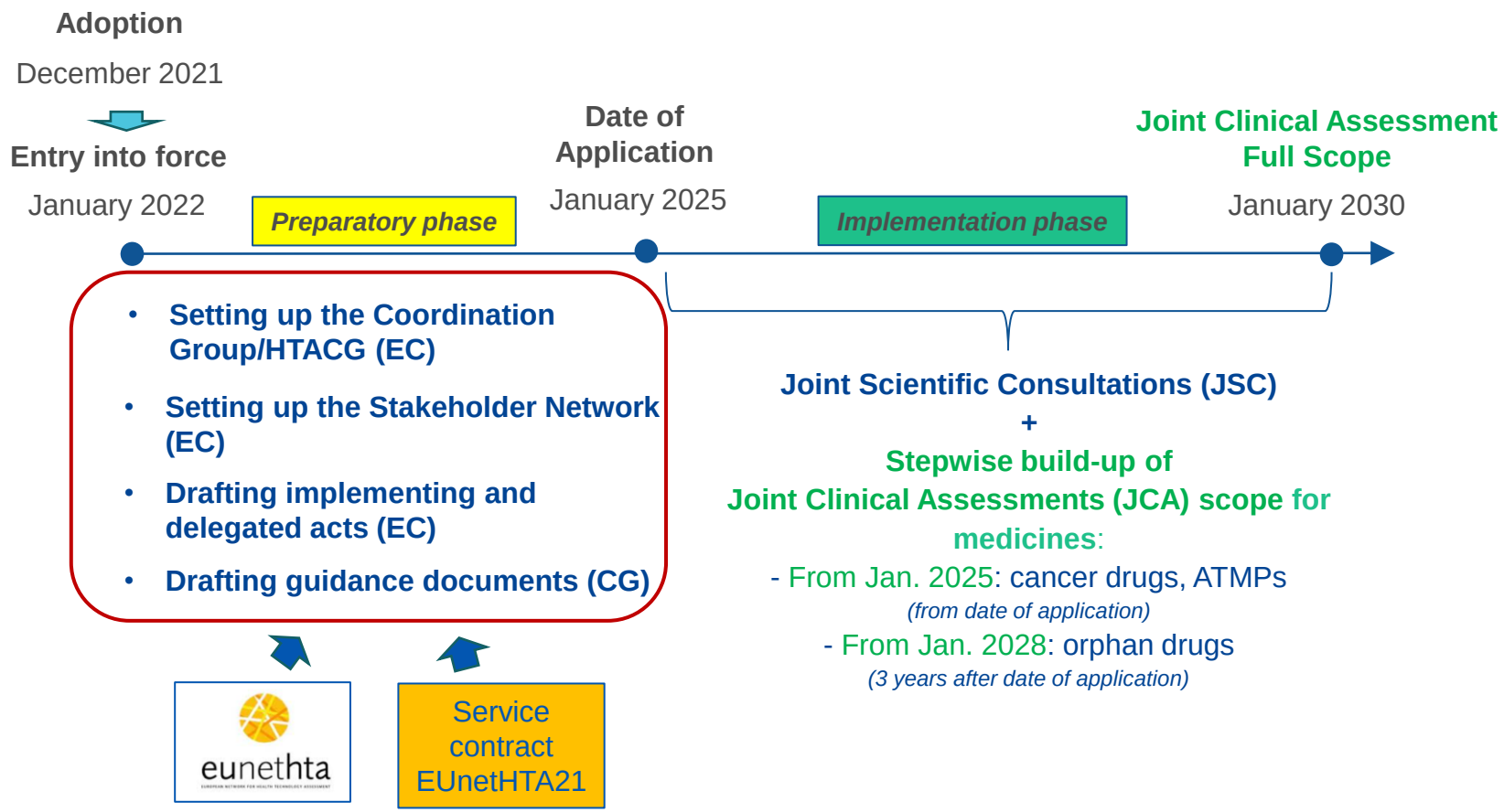
- EU regulation
- Common methodology and approach for JSC and JCA

National

- JCA to be used in national decision-making
- National consultations possible

HTA Regulation & key products

HTA Regulation - Implementation timeline



What is EUnetHTA 21?

- EUnetHTA 21 is an EC service contract aiming to
  - Support the implementation of the HTA Regulation (HTAR), after its adoption in December 2021

- All output is joint output, with all consortium partners around the table

- Focus on developing methodological and transversal guidelines, templates and procedures
  - Also conducting joint products: Joint Scientific Consultation and Joint Clinical Assessment

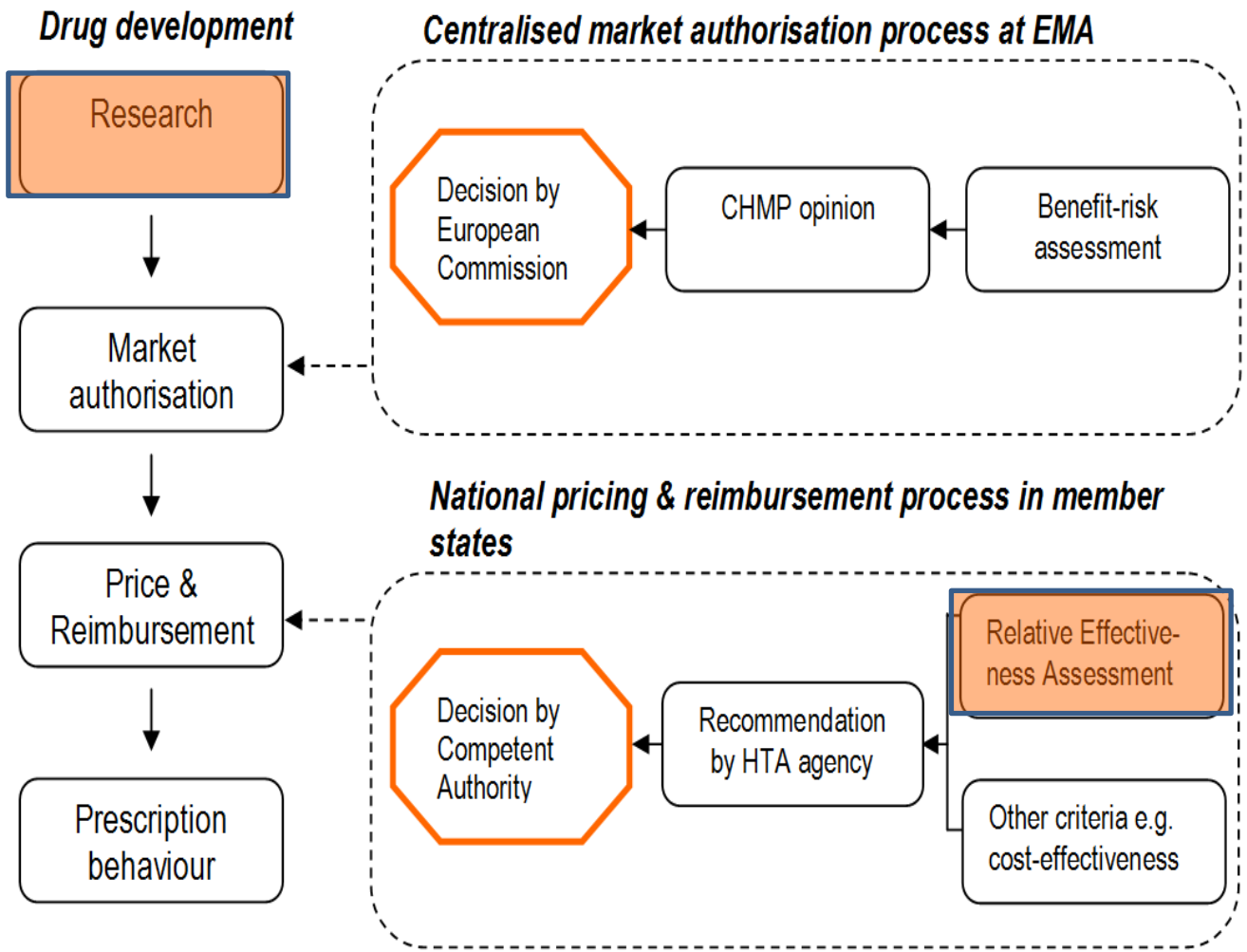
More info on: https://www.eunethta.eu/jointhtawork/

Key products under the HTAR

Joint Scientific Consultation (JSC)	Joint Clinical Assessment (JCA)
DEFINITION	
Scientific advice provided jointly by HTA bodies to manufacturers on the clinical development. Can be in parallel with regulators	Joint HTA reports produced by multiple European Member States, focussing on the clinical domains
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

Where would EU-HTA come in?

Joint Scientific Consultation (JSC)



Joint Clinical Assessment (JCA)

Joint Scientific Consultation in EUnetHTA 21

Abbreviations:
HTAb = HTA bodies
HTD = Health Technology Developer

Briefing Book

- Application and Selection of candidates
- Submission Draft Briefing Book
- Review by HTA bodies (HTAb)
- Final Briefing Package

JSC Recommendations

- EMA and HTAb to evaluate Briefing Book → *Share List of Issues*
- HTD to submit written response
- "Face-to-Face" Meeting between EMA, HTAb and HTD
- Final Written Recommen-dations

~3 months

Joint Clinical Assessment in EUnetHTA 21

Abbreviations:
PICO = Patient population, intervention, comparator and outcome
HCP = Healthcare Professional
HTAb = HTA bodies
HTD = Health Technology Developer

Scoping phase

- Topic identified
- Create assessment team
- Define scope/PICO
  - Involve patients and HCP
  - HTD submits dossier based on PICO

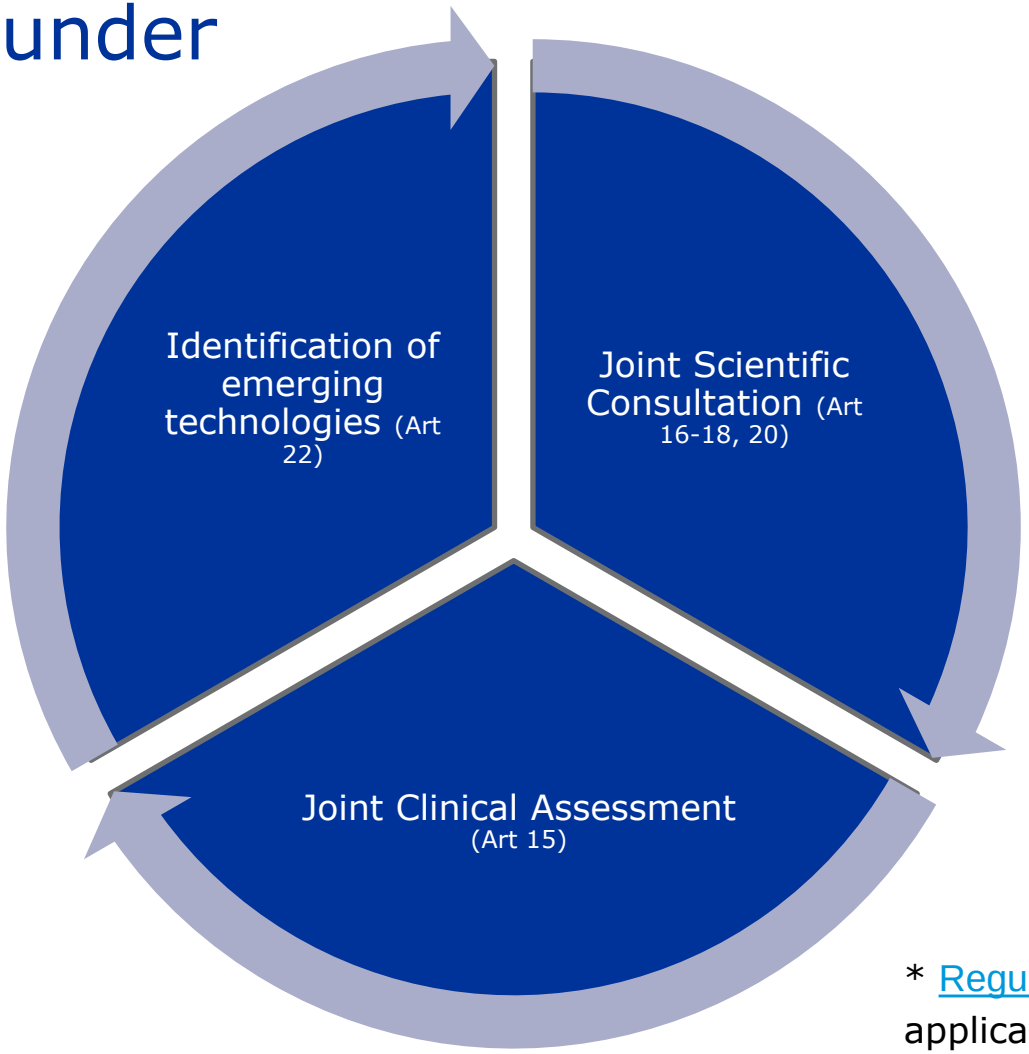
Assessment phase

- First draft
- Review all HTAb
- Fact. Check: HTD
- Publication; followed by MS appraisal

~3 months

Collaboration with EMA under the HTA Regulation*

Further details through Implementing Acts



Note: "Joint" refers to collaborative work amongst HTA bodies

Transversal elements in the Regulation to facilitate such work, supported by the European Commission, include the sharing of confidential information

* Regulation (EU) 2021/2282, applicable from January 2025

Contribution through the joint EMA/EUnetHTA21 work plan

Joint scientific consultation on evidence generation, including PLEG	Study methods and guide-lines of real-world evidence, including for registries	Generation of patient relevant data / information to support decision making
Exchange of information on the respective assessments of medicinal products by regulators and HTA bodies	Methodologies for engage-ment of patients and HCPs	Practices in the context of companion diagnostics
Continuous optimisation of regulatory outputs	Extrapolation / evidence transfer as tool to support assessment in smaller populations	Horizon scanning and preparedness of HTA and regulatory systems

- Oversight through biannual EMA/EUnetHTA 21 bilaterals (most recent on 17th June 2022)
- In addition, exchange on selected EUnetHTA 21 deliverables