

Collaboration at the regulatory/HTA interface

Progressing parallel Joint Scientific Consultations – experience from the first call and preparation of the second one

Presented by Antje Behring (G-BA) and Thorsten Olski (EMA)

Are we on track? What do we consider a success?

- Understanding of each others' roles, alignment of perspectives and using a common language for the understanding of science and methodology but with possible differences in application
- Avoid delays in evidence generation by early exchange on population, endpoints, comparator, overall package for efficacy and safety and other study design characteristics
- Building synergies, promote convergence in HTA tools and methodologies
- Reduce duplication of efforts for HTA bodies and industry
- Uptake of joint outputs in Member States

Long path for HTA collaboration

- Over 10 years of experience of collaboration between EMA and EUnetHTAs; SEED, parallel Scientific Advice, Early Dialogue since 2010
- facilitated through coordination of HTA bodies in EU-financed Joint Actions, **JA1:** 2010-2012, **JA2:** 2012-2015, **JA3:** 2016-2021
- 31 completed PCCs and 28 completed PCIs to date, 2 Parallel Consultations on registry qualification (1 HTA body as observer, 1 HTA body substantive), Parallel consultation on the qualification of an IMI (Innovative Medicines Initiative) project (HTA bodies as observers and substantive)
- Demand from developers exceeded the capacity by EUnetHTA members (adequate financial resourcing necessary)
- Reviewing templates and procedures allowed to implement some HTAs requirements



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



eunetha
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Before 2020	2020-2021	since Dec 2021
Monthly submissions accepted/ denied by EDWP	1 Call for interest 4 products selected by EDWP	2 Calls for interest 3 products selected by CSCQ (1 st round) 5 products scheduled for 2 nd round
PCI (individual pathway) PCC (consolidated pathway)	PCC (individual pathway no longer available)	JSC (individual pathway no longer available)
F2F meeting for every procedure	F2F or written format	F2F (written format suspended)

JSC – key points

- Joint guidance documents
- Open Calls; First Open Call for 3 products launched in November 2021; First JSC in March 2022; current Open Call for the remaining 5 JSCs in June 2022
- Presubmission TC only in exceptional circumstances, continued involvement of HCPs, clinical experts; simultaneous notification to EMA and EUnetHTA
- Organization of the Briefing Book in terms of PICO; Additional section on PLEG and increased requirements on PROs
- Regular review of work to allow transitioning into a process for “Parallel (EMA/HTA) Joint Scientific Consultation”, in line with the requirements of Regulation (EU) 2021/2282 applicable from January 2025

which applications do we wish to see?

JSC CSCQ selection criteria

- phase II/II not started yet
- new mode of action, first in class
- unmet medical need
- Significant cross-border dimension
- Major Union-wide added value or EU research priorities
- targets a life-threatening/chron. debilitating disease
- Breakthrough technology

Reflections

- Disclaimer added: "As the selection criteria are applied for the first time in this Open Call, the specification of the selection criteria, their operationalisation and applicability will be further developed in the course of EUnetHTA 21."
- Oncology products and ATMPs are given preference

JSC - Challenges and way forward

Addressing demands and challenges

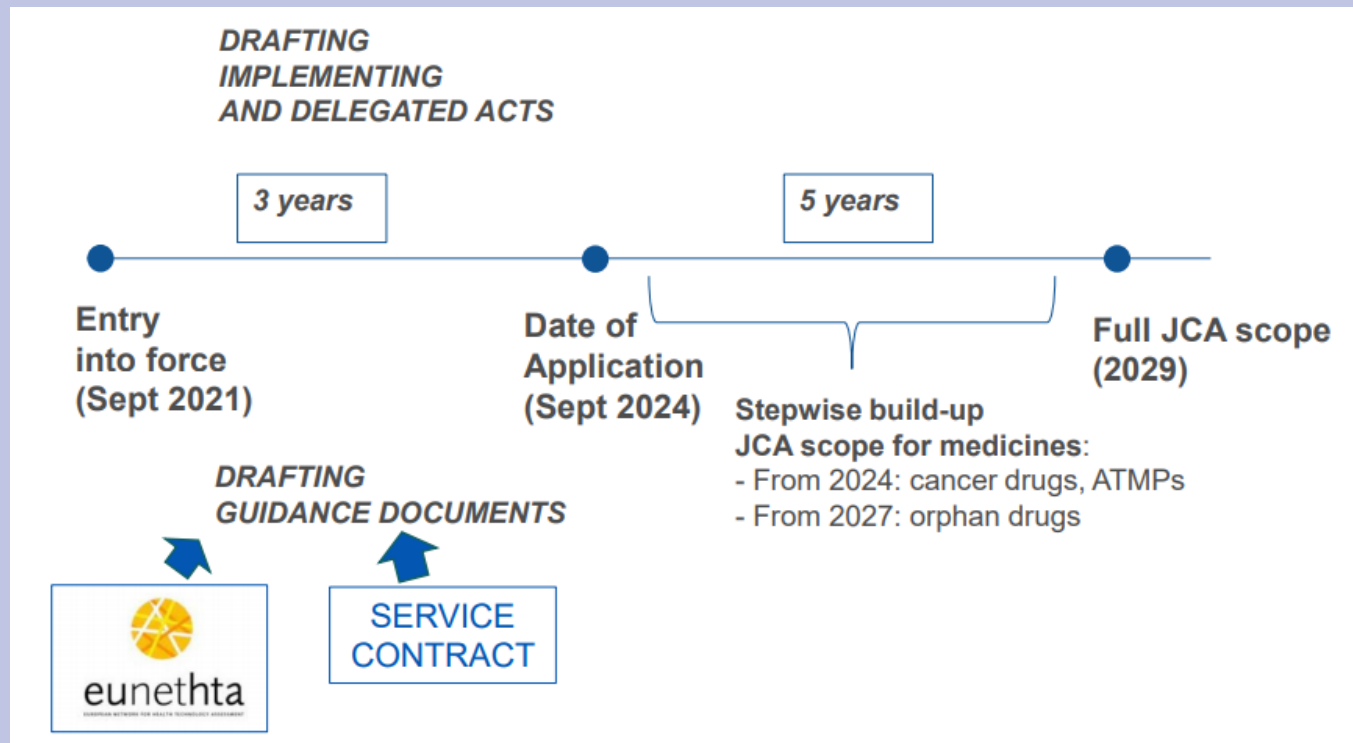
- Number of procedures: recent tender 8 procedures
- Demand primarily for face-to-face-meetings. Procedure focuses on F2F-meetings
- Shorter procedure not a primary concern but quality of input and involvement of HTAbs. Long discussion meetings (3 hours) and broad involvement of HTAbs

Way forward

- Good practices: centralised HTA recruitment, single submission, secretarial centralisation, streamlined logistics, greater HTA coordination, multi-stakeholder, EMA and EUnetHTA as equal partners, procedure is kept as lean as possible
- Work on implementation of the HTA-Regulation at the EC is ongoing

JSC - way forward

HTA Regulation



HTA-Regulation in a nutshell

- Selection of procedures according to criteria (phase II/III not started, new MoA, first in class, unmet medical need, significant cross-border dimension, Union-wide added value or EU research priorities, life-threatening/chron. debilitating disease, breakthrough technology)
- JSC practices: centralised HTA recruitment, single submission, secretarial centralisation, streamlined logistics, greater HTA coordination, multi-stakeholder, procedure is kept as lean as possible; F2F-meetings
- MSs remain responsible for drawing conclusions on added value, pricing, reimbursement
- Coordination Group being established, as well as subgroups focussing on specific topics, like the JSC subgroup, which may nominate members as well as according to expertise
- Horizon Scanning; JCA; Medical Devices

Priorities for EMA HTA collaboration post JA

- **Product-specific** work (JSC, exchange of information, evidence planning and assessment for advanced medicinal products)
- **Methodological** work (real-world evidence, patient relevant data , extrapolation)
- **Operational** work: (continuous optimisation of regulatory outputs, methodologies for engagement of pts and HCPs; practices in the context of companion diagnostics; horizon scanning and preparedness of HTA and regulatory systems; development of guidance and advice mechanisms for regulatory and health care system uptake of innovative medicines; review of experience with the Orphan Medicines Assessment Report (OMAR) by HTAs in order to continuously improve this output; development of guidance, optimising information on subpopulations labelling and EPARs)

Take home messages

- The joint technical work of the EMA/EUnetHTA cooperation has been the foundation for establishing mutual trust and understanding
- The fact that decade long voluntary work has now translated into a regulation is a clear demonstration of its value
- Priority areas for future collaboration between regulators and HTA at European level have been developed and they inform the implementation of the HTA Regulation
- Early discussion and preparation for development plans will be important in view of the application of the legislation in 2025 (JSC and JCA)