HTA collaboration – parallel EMA/ HTA Joint Scientific Consultation

7th Industry Stakeholder Platform on Research and Development support

23 November 2021

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HTA collaboration

- 10 years of experience of collaboration between EMA and EUnetHTAs
- Objectives remain to promote convergence in HTA tools and methodologies, reduce duplication of efforts for HTA bodies and industry, uptake of joint outputs in Member States
- EU-financed Joint Actions, **JA1:** 2010-2012, **JA2:** 2012-2015, **JA3:** 2016-2021
- 32 completed PCCs during JA3 and 28 completed PCIs to date; PCC = parallel EMA – HTA consultation; PCI = parallel EMA and individual HTA consultation
- 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

Most recent changes during JA3

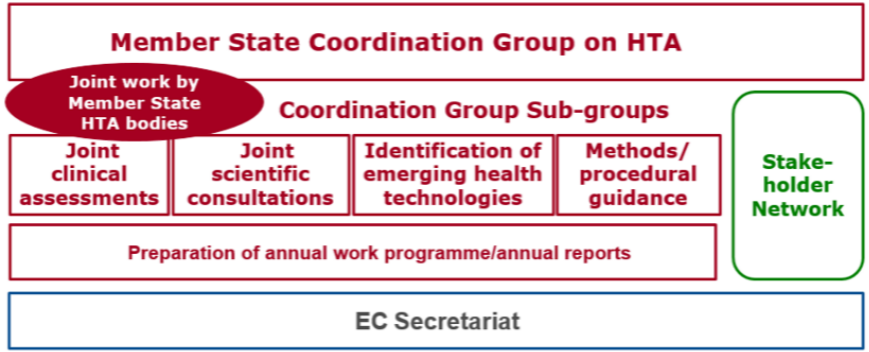
- One Call for Interest
- All applicants getting consolidated feedback from HTAb
- Introduction of Written-Only Format
- Shortening of procedure by 1 (F2F) or 2 (written) months
- Organization of the Briefing Book in terms of PICO
- Additional section on PLEG and increased requirements on PROs

Reflections

- Strong demand for Discussion Meetings (F2F or virtual)

Next step – Joint Scientific Consultations

- EC launched call for tender; EUnetHTA21 under ZIN leadership won the *Service Contract for the Provision of Joint Health Technology Assessment (HTA) Work Supporting the Continuation of EU Cooperation on HTA*
- 8 procedures (4 per year) until 2023



Reflections

- MSs remain responsible for drawing conclusions on added value, pricing, reimbursement

- Ideally, number of procedures to be increased in the future

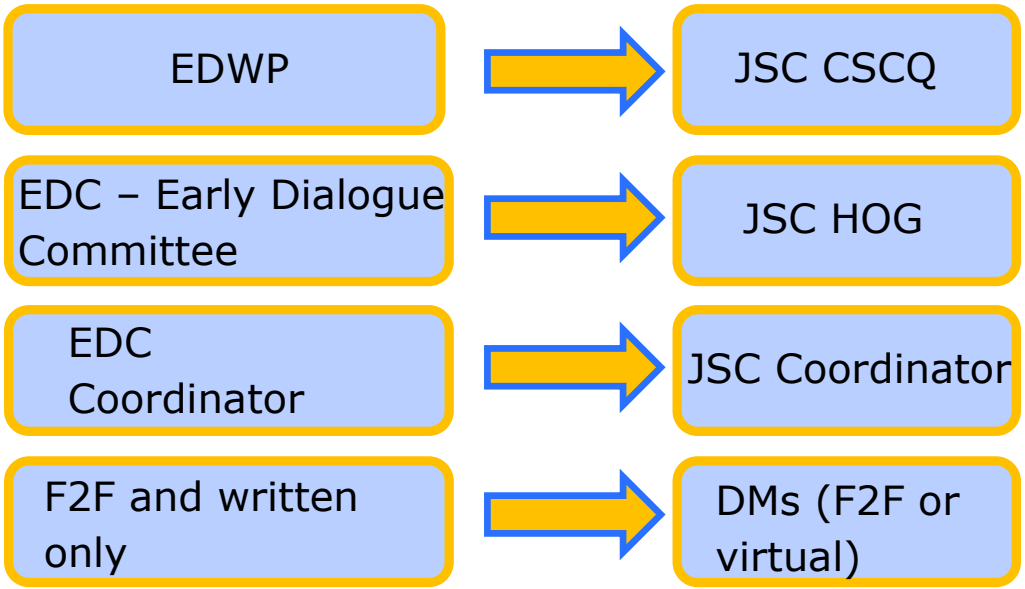
JSC – What remains the same

- Simultaneous notification to EMA and EUnetHTA
- Joint guidance documents
- Presubmission TC only in exceptional circumstances
- Open Calls with selection (HTA)
- Continued involvement of HCPs, clinical experts

Reflections

- EUnetHTA operating with Eudralink
- Procedure is kept as lean as possible

JSC – What is new



Reflections

- Re-focus on Discussion Meetings (F2F or virtual)
- At least 6 HTAbs participate in each JSC
- Focus on future assessment of products (HTA- Regulation).

JSC – What is new

- New name: Joint Scientific Consultation
- Discontinuation of the written-only procedure; All consultations take place in the Discussion Meeting format (F2F or virtual)
- The EDWP (at EUnetHTA) has been replaced by the JSC CSCQ [Composition of the JSC CSCQ: AIFA (Italy), AEMPS (Spain), G-BA (Germany), HAS (France), INFARMED (Portugal), KCE/KCE-NIHDI (Belgium), NCPE (Ireland), NIPN (Hungary), NOMA (Norway), TLV (Sweden) and ZIN (Netherlands)]
- Leadership by G-BA

<u>Reflections</u>

- Re-focus on Discussion Meetings (F2F or virtual)
- The challenge remains to involve more HTAb;
- Discussion ongoing to offer meetings besides the Discussion Meetings

JSC – 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

- "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 – next immediate steps

- Open Call launched on 8th of November
- **Deadline for applications 7th of December**

(https://eunethta.eu/services/jsc/)

- Selection to be done by mid-December
- First JSC around March 2022
- 4 JSCs in 2022
- Next Open Call in October 2022

Challenges and way forward

Challenges/ Improvements

- single call and number (4) of procedures per call
- Stakeholders demand primarily F2F-meetings
- Guaranteed number of participating HTAb

Way forward

- Increase in number of procedures to meet stakeholder demands
- Keep F2F a priority
- Focus on stakeholder value (quality of output; level of interaction)
- Competency building
- Work on methodology
- Lessons learned: during F2F more time for discussion is needed

Summary, Reflections and way forward

- the "Service Contract for the Provision of Joint Health Technology Assessment (HTA) Work Supporting the Continuation of EU Cooperation on HTA" is instrumental as a restart of the work between EMA and EUnetHTA
- Building on successes and experiences previous initiatives (PSA, SEED, PC)
- positive aspects are kept (centralised HTA recruitment, single submission, secretarial centralisation, streamlined logistics, greater HTA coordination, multi-stakeholder, EMA and EUnetHTA equal partners, working together, benefits patient access and public health)
- priority areas for future collaboration between regulator and HTA at European level have been developed to continue future collaborative work