

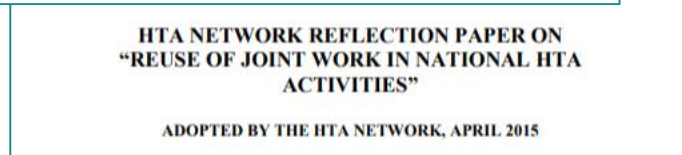
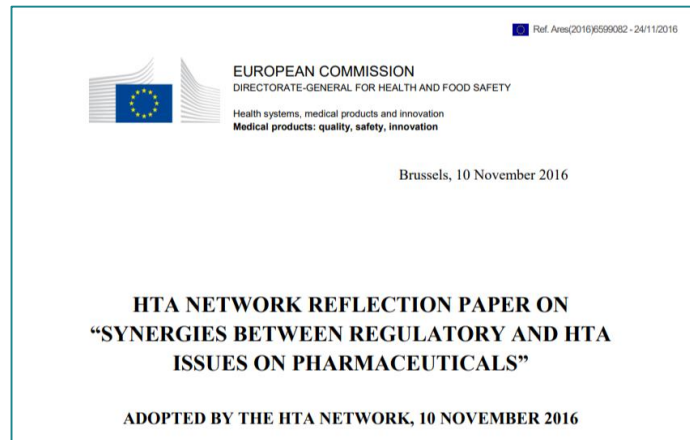


Topic 1. Recent developments and next steps regarding EU cooperation on HTA

DG SANTE

7 July 2021

Strengthening EU HTA cooperation



JA1 (2010 – 2012)
JA2 (2012 – 2015)
JA3 (2016 – 2021)



HTA Regulation

Co-decision procedure

- PT Presidency - Mandate to start negotiations with the European Parliament (informal trialogues) in March 2021. A second mandate to continue the trialogues was obtained in June 2021.
- 16 technical meetings
- 3 Political trialogues – 26 April, 31 May, 21 June
- Provisional agreement reached by co-legislators on 21 June
- Confirmed by the Committee of the Permanent Representatives of the Governments of the Member States to the EU/COREPER on 30 June (2 abstentions)

Co-decision procedure – Next steps

- European Parliament
 - Vote in ENVI Committee – 13 July 2021
 - Vote in Plenary – September 2021
- Final adoption
- Publication in the Official Journal

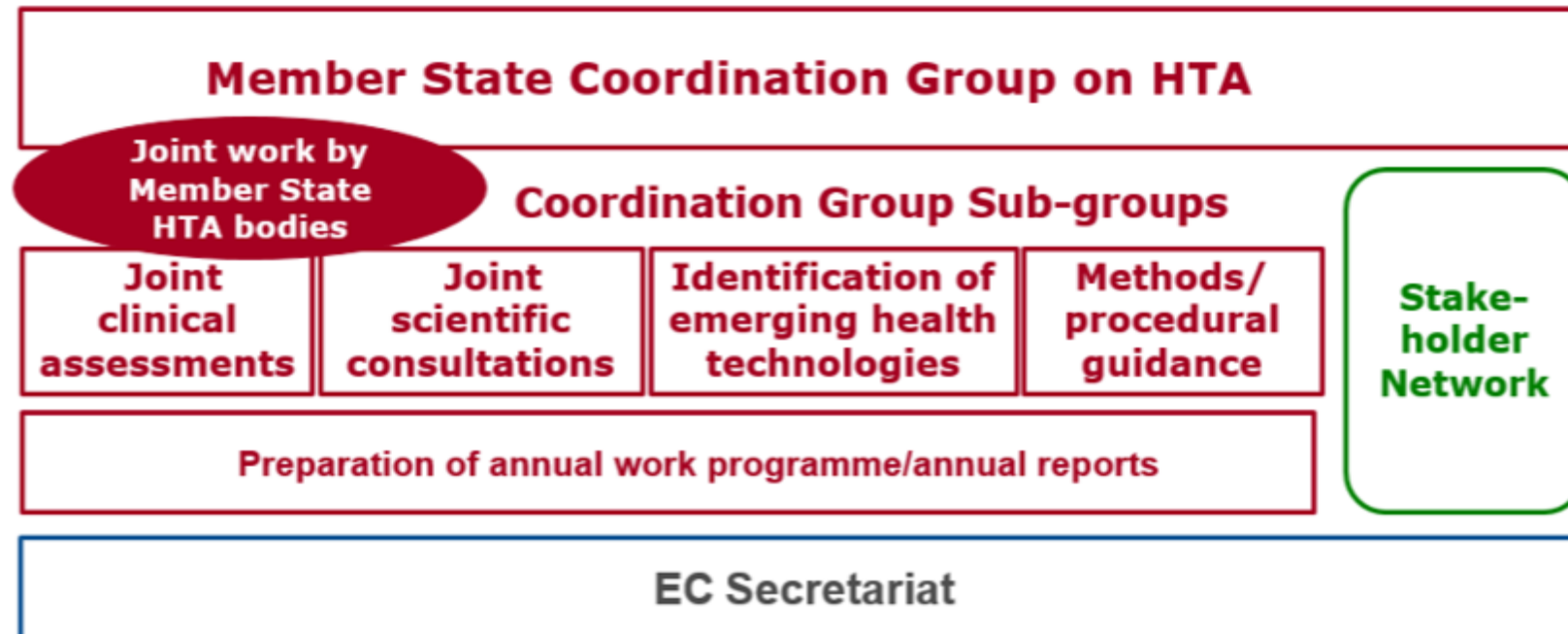
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Key principles

- **Joint work** on common **scientific, clinical aspects** of HTA
- Joint work **driven by Member State HTA bodies**
- Ensure **high quality, timeliness and transparency**
- Ensure **use of joint work in national HTA processes**
- **Member States** remain responsible for:
 - Drawing **conclusions on added value** for their health system
 - Taking **decisions on pricing & reimbursement**
- **Progressive implementation**

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Organisational framework



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Main areas of joint work

- **Joint clinical assessments** (medicines, medical devices)
- **Joint scientific consultations**
(advice to health technology developers on clinical study design;
parallel HTA-EMA advice for medicines)
- **Identification of emerging health technologies**
("horizon scanning")
- **Voluntary cooperation in other areas**
(e.g. on other health technologies or non-clinical HTA aspects)

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Joint Clinical Assessments: medicines

- **Centrally authorised new medicines:**
 - *Step 1 (3 years): cancer drugs, ATMPs*
 - *Step 2 (2 years): orphan drugs*
 - *Step 3: full scope*
- For those medicines that have already undergone a JCA:
extensions of therapeutic indication (variations)

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Joint Clinical Assessments: medical devices

- **Medical devices (class IIb and III)**
with scientific opinion under the clinical evaluation consultation procedure
(Regulation (EU) 2017/745)
- **In vitro diagnostic medical devices (class D)**
with expert panel view under the clinical evaluation consultation procedure
(Regulation (EU) 2017/746)
- **Selection by Coordination Group** (from within above outer scope):
based on defined criteria (e.g. unmet medical needs, impact on public health)

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Involvement of external experts and stakeholder organisations

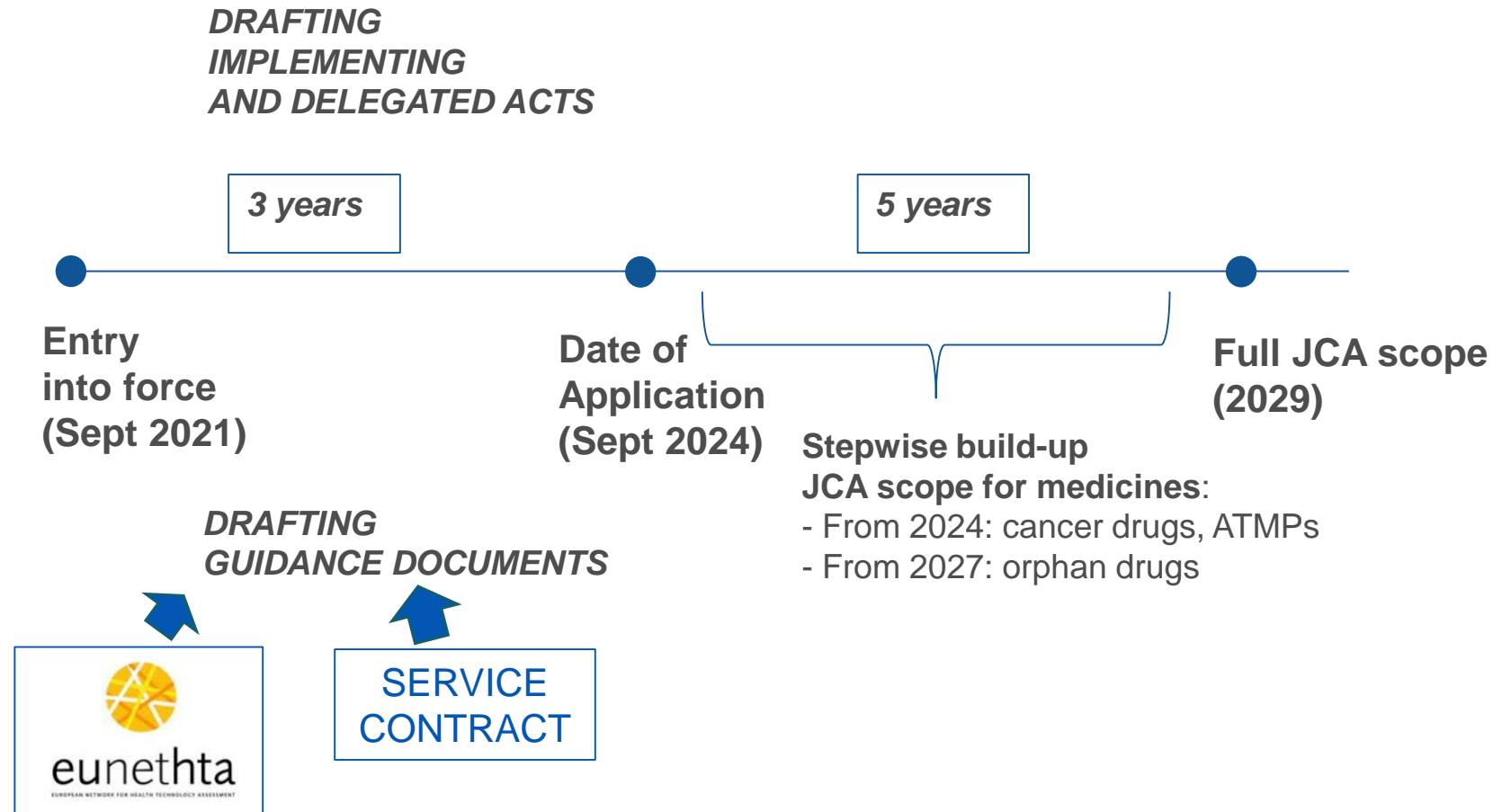
- **External experts** (patients, clinical and other relevant experts):

*Provide input based on their specialised expertise (e.g. therapeutic area) during **Joint Clinical Assessments** and **Joint Scientific Consultations***

- **Stakeholder organisations** (e.g. healthcare professional organisations, insurers/payers, industry associations, patient groups, scientific societies):
 - *Provide input on horizontal and strategic issues*
 - *Regular meetings between Stakeholder Network and Coordination Group*

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Timeline of implementation



Health Programme 2020 WP - Call for tender

EU cooperation on HTA (1)

Scope of the procurement

Title:

Service contract for the provision of joint Health Technology Assessment (HTA) work supporting the continuation of EU cooperation on HTA

Reference number: CHAFEA/2020/HEALTH/04

Short description:

The subject of this call for tenders is to address methodological issues to foster joint HTA work supporting EU cooperation in this area. The service is expected to cover the following key :

(1). Advance development of HTA methodology to be applied when carrying out joint work (i.e. Joint Clinical Assessments (henceforth "JCA") and Joint Scientific Consultations (henceforth "JSC")). (1). Joint HTA work including:

(a). 8 JSC for medicinal products or at least, not less than 6 and not more than 12 JSC; and (b). 2 JCA for medicinal products or 4 collaborative assessments (CA) for medical devices, not less than 1 JCA for medicinal products or 2 CA for medical devices and not more than 2 JCA or 4 CA respectively.

Estimated total value

Value excluding VAT: 3.000.000 EUR

Health Programme 2020 WP - Call for tender EU cooperation on HTA (2)

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- **Interaction (meetings / events / other forms of consultations proposed by the tenderer) with stakeholders** - including sharing of information and improvement of procedures and guidelines which require stakeholders' input (e.g. patients, health professionals, industry), based on the procedures developed by EUnetHTA JAs and other relevant internationally agreed guidelines. The tenderer shall propose a feasible mechanism to ensure appropriate contribution from patients and clinical experts to the joint HTA work;

Stakeholder Pool members -> contacted after the kick-off of the contract with details about the tenderer and relevant activities

Award decision – mid-July

Potential timeline – September 2021 -> September 2023

Thank you