Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

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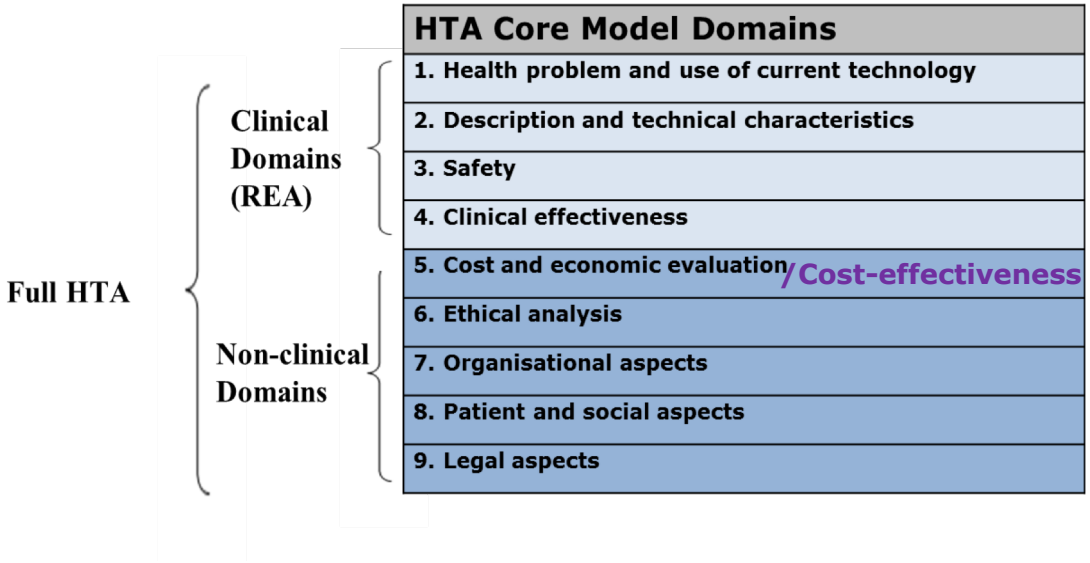
Background

HTA = "a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value" (as defined by EUnetHTA JA).



Why an HTA initiative?

More than 20 years of cooperation: projects, joint actions

ACHIEVEMENTS

- **Trust** between HTA bodies
- **Capacity building**
- Development of **joint tools** (e.g. EUnetHTA Core Model, POP EVIDENT databases)
- Piloting **joint work** (e.g. early dialogues, joint assessments)

LIMITATIONS

- **Low uptake of joint work** ⇒ duplication of work
- Differences in the **procedural framework** and administrative capacities of Member States
- Differences in national **methodologies**
- **No sustainability** of current cooperation model

Background

Key milestones

- **Inception impact assessment (IIA) -** September 2016
- **Consultation**
    - Online public consultation – Report May 2017
    - **Meetings with EUnetHTA JA3 and HTA Network**
    - Discussions with **stakeholders**
- **Studies** to support the IA process
- **Impact assessment –** finalised October 2017
- **Commission legal proposal –** 31 January 2018

Co-decision procedure – Council & European Parliament

Expected outcomes

Member States

- High quality and timely reports
- Pooling of expertise → specialisation of HTA bodies
- Better allocation of resources
- Savings in the long run, contribution to sustainability of healthcare systems

Patients

- Increased transparency
- Increased engagement in the HTA process at national and EU level
- Potential faster access across EU

Industry

- Positive impact on business predictability, competitiveness and innovation
- Savings (reduced duplication)

PROPOSAL

Article 1

Proposal for a

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- The Regulation establishes:
  - **support framework and procedures for cooperation** on health technology assessment at Union level
  - **common rules for clinical assessment** of health technologies

The Regulation **shall <u>not</u> affect** the rights and obligations of Member States with regard to the organisation and delivery of health services and medical care and the allocation of resources assigned to them.

Key elements (1)

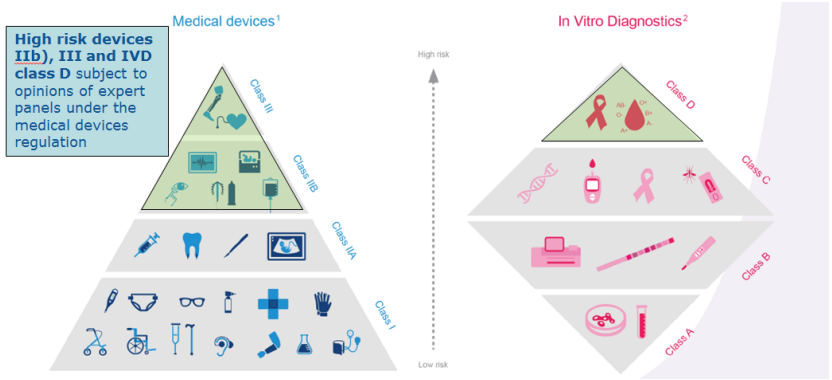
- **Provides support framework** and procedures for EU cooperation on HTA
- **Well defined scope** **Article 5**

Selection during the transition period

- ***Medicinal products with central marketing authorisation***
  - New active substances
  - New therapeutic indications for existing substances

Selection permanent

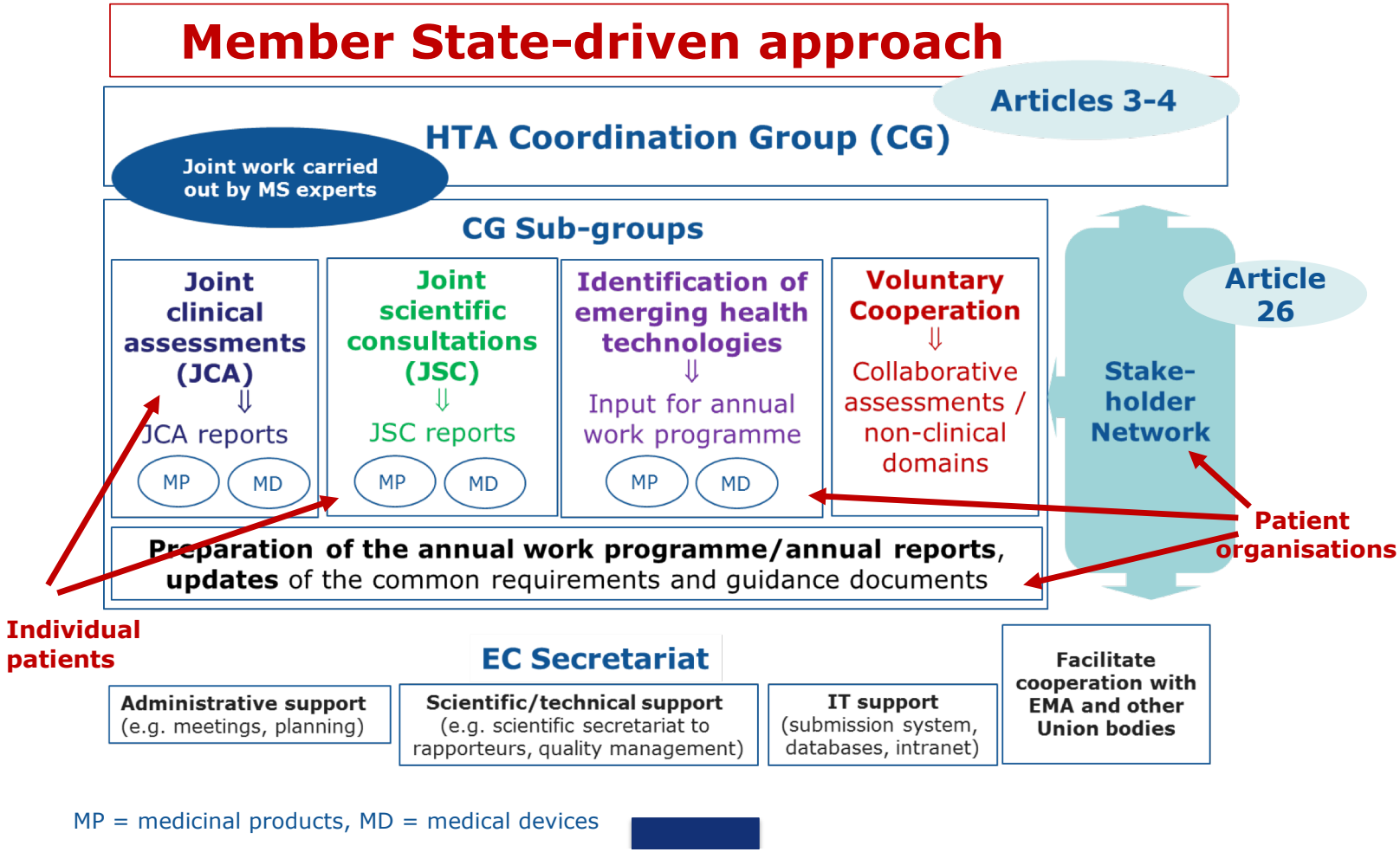
- ***Selection of medical devices & in vitro diagnostic medical devices***



Key elements (2)

- Focus on **clinical** aspects
- **Member States** driven approach
  - National agencies to do scientific work — **Articles 6, 13**
  - Annual programme decided by the Coordination group — **Articles 3-4**
  - Approval of joint reports by Coordination Group — **Articles 6, 13**
  - EC to provide secretariat (administrative, scientific, IT) — **Article 25**
  - EC to publish the joint reports — **Articles 7, 27**

PROPOSAL



MP = medicinal products, MD = medical devices

Key elements (2)

- Enable **synergies** between regulatory and HTA issues **Articles 11, 16**

- **Defined areas of join work**:
  - Joint clinical assessments/JCA (REA) **Articles 5-11**
  - Joint scientific consultations/JSC (early dialogues) **Articles 12-17**
  - Horizon scanning/Emerging health technologies **Article 18**
  - Voluntary cooperation **Article 19**

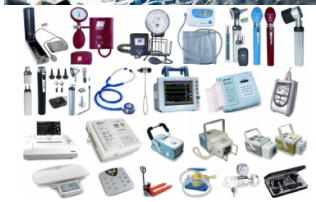
Joint clinical assessments (JCA)

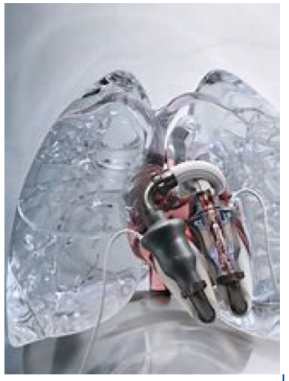
- Based on obligatory submission by industry to the Coordination Group
- Analysis by the JCA Sub-group, led by Assessor and Co-assessor chosen based on their expertise and experience
- **Patients and clinical experts asked to provide input**
- Draft report submitted by assessor to the Coordination group
- Approval by the Coordination Group
- **Publication by EC of the full report on the IT Platform**

Joint scientific consultations (JSC)

- Based on request from company interested in receiving advice on study design + data to be collected for (regulatory and) HTA purposes (*for medicinal products 6-8 years before application for marketing authorisation*)
- Analysis by the JCA Sub-group, led by Assessor and Co-assessor chosen based on their expertise and experience
- **Patients and clinical experts asked to provide input**
- Draft report submitted by assessor to the Coordination group
- Approval by the Coordination Group
- Overview of JSCs published in the annual report of the Coordination Group

Horizon scanning/ Emerging new technologies





Potential candidates for joint clinical assessments

- Annual report prepared by the Coordination Group
- Input from stakeholders

Assessment vs appraisal

Article 6, 8, and Recital 16

Joint clinical assessment **EU**

Conclusions limited to:

(a) an analysis of the **relative effects** of the health technology being assessed on the patient-relevant **health outcomes** chosen for the assessment

(b) the **degree of certainty** on the relative effects based on the available evidence.

1

NATIONAL APPRAISAL **NATIONAL**

of joint clinical assessment and additional context-specific considerations (e.g. number of patients affected in MS, how patients are currently treated in the healthcare system, costs) +/- economic, ethical organisational, legal

Conclusions on added value

(e.g. added therapeutic value, cost-effectiveness…)

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NATIONAL DECISION MAKING (e.g. P&R)

European Commission

Key elements (4)

- **High quality** – Member States experts
- **Timely output**
  - **For medicinal products –** by the time of publication of the EC Decision granting marketing authorisation
  - **For medical devices** → flexible timeline (at or after market launch)

Recitals 17-18

- **Transparency and independence**
  - Publication of reports
  - Conflict of interest procedures
  - Clear procedures for involving stakeholders

Article 22.1.

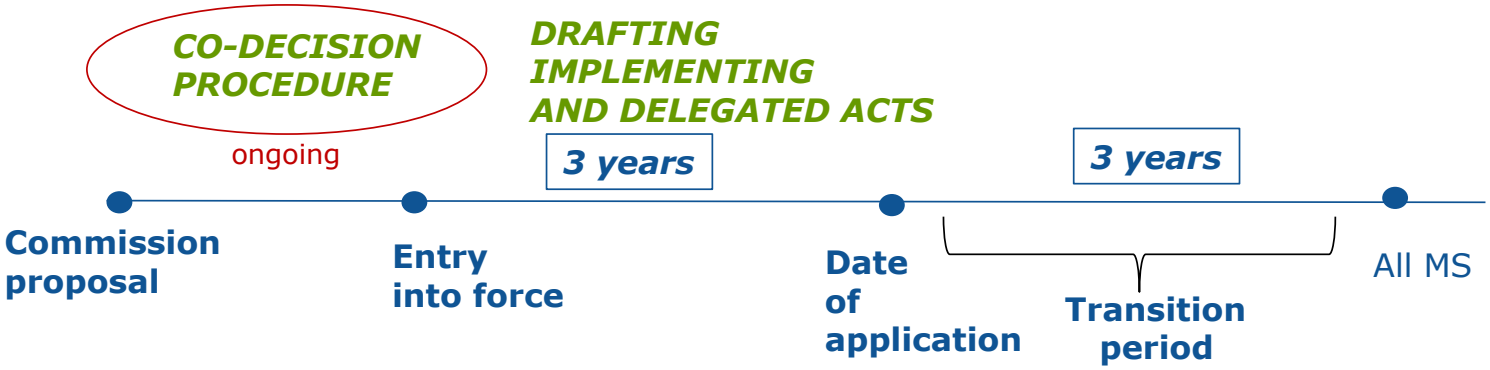
- Pragmatic **phase-in** approach

Articles 33, 36

Articles 33, 36

Phase-in approach

Timeline



+ Recitals 29-30

- Member States **may delay their participation** in the system of JCA and JSC until **3 years after the date of application**
- **Prioritization** of health technologies subject to JCA, JSC

Thank you!

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