European Commission

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

DG SANTE - Health Systems and Products
Medical Products: safety, quality, innovation

9 February 2018

More than 10 years of cooperation: projects, joint actions

EUnetHTA JAs (2010–2020)

eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Research projects

SEVENTH FRAMEWORK PROGRAMME

AdhopHTA
MedtecHTA
INTEGRATE-HTA
ADVANCE-HTA

Key milestones

- **Inception impact assessment (IIA)**
    - Published 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

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HTA Network

Member States authorities

eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Executive Board

Pharmaceutical industry

Patients and consumers

Healthcare professionals

EUROPEAN COMMISSION

Brussels, 31.1.2018
COM(2018) 51 final

2018/0018 (COD)

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(Text with EEA relevance)

{SWD(2018) 41 final} - {SWD(2018) 42 final}

Medtech industry

Payers

More than 10 years of cooperation: projects, joint actions

ACHIEVEMENTS

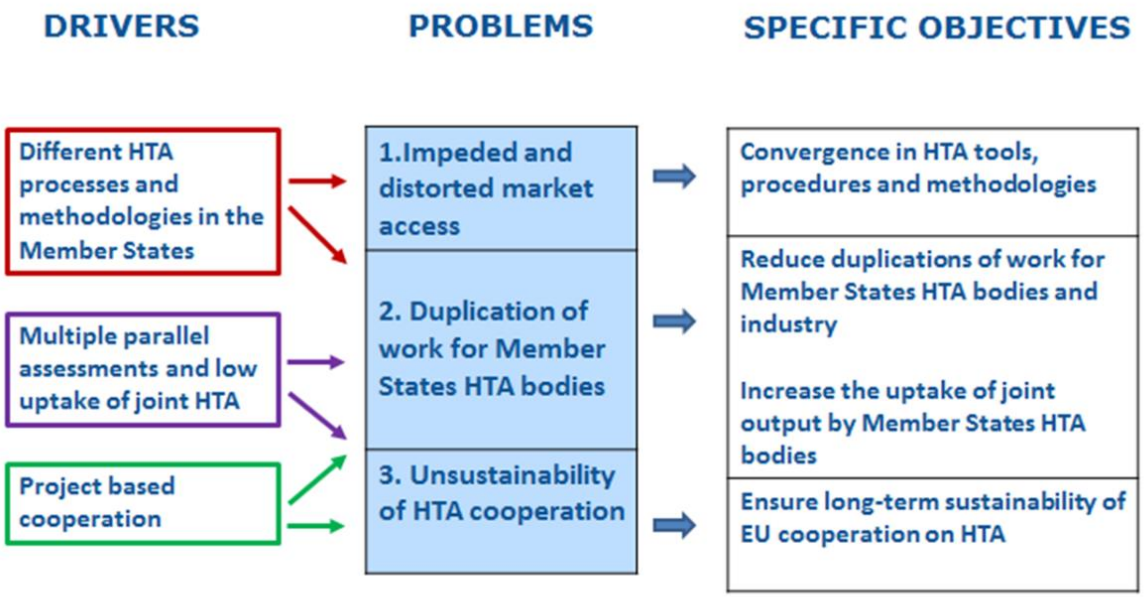
- **Trust** between HTA bodies
- **Capacity building**
- Development of **joint tools** (e.g. EUnetHTA Core Model, POP EVIDENT databases)
- Piloting **joint work** (e.g. early dialogues, joint assessments)

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

Operational objectives

- Promote convergence in HTA tools, procedures and methodologies
- Reduce duplication of efforts for HTA bodies and industry
- Ensure the uptake of joint outputs in Member States
- Ensure the long-term sustainability of EU cooperation



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)

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Chapter I General Provisions

Chapter II Joint Work on HTA at Union Level

Joint clinical assessments	Joint scientific consultations	Emerging health technologies	Voluntary cooperation
Section 1	Section 2	Section 3	Section 4

Chapter III Requirements for Clinical Assessments

Chapter IV Support Framework

Chapter V Final Provisions

Key elements (1)

1. Member State driven
   - **MS → scientific work**
2. Focus on clinical assessment
   - **no joint appraisal**
   - **no joint economic assessment**
3. High quality and timely output
4. Use of joint work → no duplication at national level
5. Fit for purpose → pharma vs medtech
6. Transparency → stakeholders' involvement

Key elements (2)

7. Areas of joint work
   - **Common tools and methodologies**
   - **Emerging new technologies/Horizon scanning**
   - **Joint scientific consultations (JSC)**
   - **Joint clinical assessments (JCA)**
8. Governance → stable secretariat
   - **Administrative support (e.g. meetings, planning)**
   - **Technical support (e.g. secretariat to assessors, quality management)**
   - **IT support (e.g. submission system, databases)**
   - **Support voluntary cooperation (e.g. notification, adaptation common tools)**
9. Pragmatic approach → phase-in approach

Key element 1 – Member State driven

→ HTA Coordination Group (CG)

- ✓ Member State-led -> members designated, one or more authority or body
- ✓ Will manage the overall governance of the joint work
- ✓ Will meet regularly to provide guidance and steer the cooperation.
- ✓ Will work based on an annual work programme developed and adopted by the Group

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HTA Coordination Group (CG)

Joint work carried out by MS experts

CG Sub-groups

Joint clinical assessments (JCA)
⇓
JCA reports
MP MD

Joint scientific consultations (JSC)
⇓
JSC reports
MP MD

Identification of emerging health technologies
⇓
Input for annual work programme
MP MD

Voluntary Cooperation
⇓
Collaborative assessments / non-clinical domains

Stake-holder Network

Preparation of the annual work programme/annual reports, updates of the common requirements and guidance documents

EC Secretariat

Administrative support
(e.g. meetings, planning)

Scientific/technical support
(e.g. scientific secretariat to rapporteurs, quality management)

IT support
(submission system, databases, intranet)

Support and monitor uptake
(notification, adaptation common tools/brokering).

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Key element 2 – Focus on clinical assessment (no appraisal, no economic assessment)

Scope of Joint Clinical Assessments (JCA)

- ***Medicinal products with central marketing authorisation:***
  - New active substances
  - New therapeutic indications for existing substances
- ***Medical devices classified as class IIb and III*** for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure
- ***In vitro diagnostic medical devices - class D*** for which the relevant expert panels have provided their views in the framework of the of the clinical evaluation consultation procedure
- Not **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 element 5
Fit for purpose → pharma vs medtech

Key element 2 - Focus on clinical assessment

Prioritisation of JCA

→ **For medical devices and IVDS**

→ **For medicinal products, but only in the transition period**

Key element 5 Fit for purpose → pharma vs medtech

Criteria:

- unmet medical needs;
- potential impact on patients, public health, or healthcare systems;
- significant cross-border dimension;
- major Union-wide added value;
- the available resources.

Key element 3 - High quality and timely output

-Build on already achieved work

-Synergies, but not delay or interfere with regulatory processes

-High quality and timely results

-Technical and scientific expertise

Key element 4 - Use of joint work
No duplication at national level

Member States shall:

- **not carry out a clinical assessment or an equivalent assessment process on a health technology included in the List of Assessed Health Technologies** or for which a joint clinical assessment has been initiated;
- **apply joint clinical assessment reports, in their health technology assessments at Member State level.**

+
Recital 16

Safeguard clause – applicable in exceptional circumstances (Article 34)

Key element 5 – Fit for purpose

Medicinal products

- "Aligned" with MA process (Recital 17)
- Prioritisation only during transition period (Article 10a.ii)
- Joint work carried out by MS experts – CG Sub-group dedicated to medicinal products (Article 3.9)
- Common procedural and methodological framework for CA, JCA, JSC (Article 20,22,23)

Medical devices

- At/After market launch (Recital 18)
- Prioritisation also after the transition period (Article 5.2)
- Joint work carried out by MS experts – CG Sub-group dedicated to medical devices (Article 3.9)
- Common procedural and methodological framework for CA, JCA, JSC (Article 11,22,23)

Recital 25
Where appropriate, distinct rules should be developed for medicinal products and medical devices.

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Key element 6 – Transparency

Stakeholder Network – Article 26

+ Article 22.a.iii

The Commission shall adopt **implementing acts** concerning procedural rules for the consultation of patients, clinical experts, and other stakeholders in clinical assessments.

Publication of reports – Article 7.6

- 'List of Assessed Health Technologies'
- JCA report + summary report

Conflict of interest – Article 22.a.i

The Commission shall adopt **implementing acts** concerning procedural rules for ensuring that HTA authorities and bodies carry out clinical assessments in an **independent and transparent manner, free from conflicts of interest**

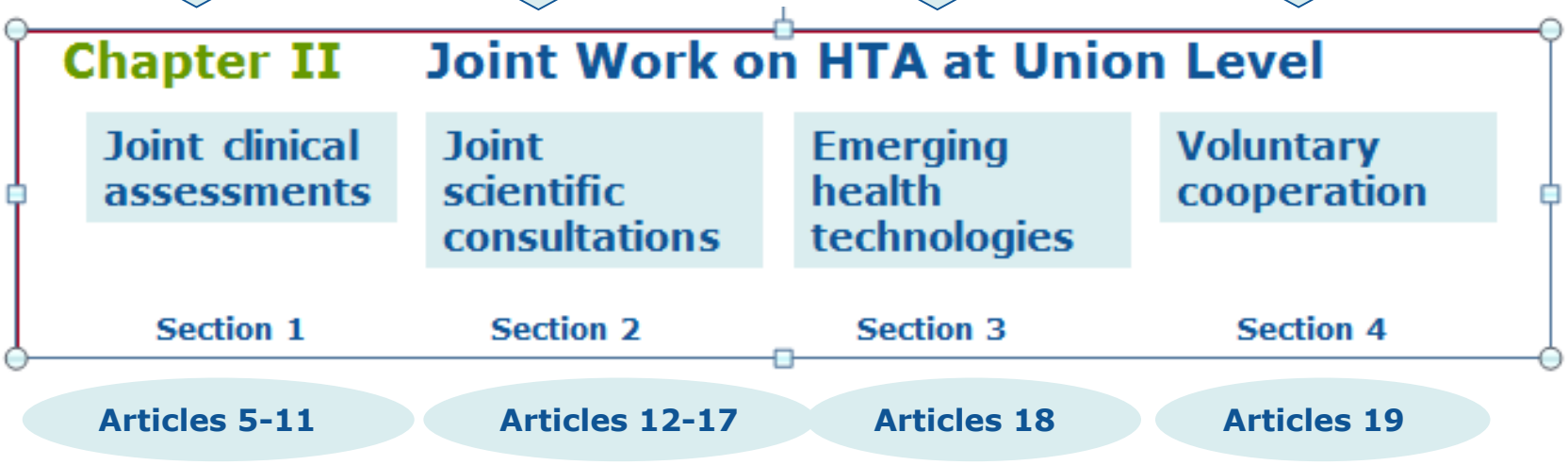
Key element 7 – Areas of joint work

WP 4
Joint REA

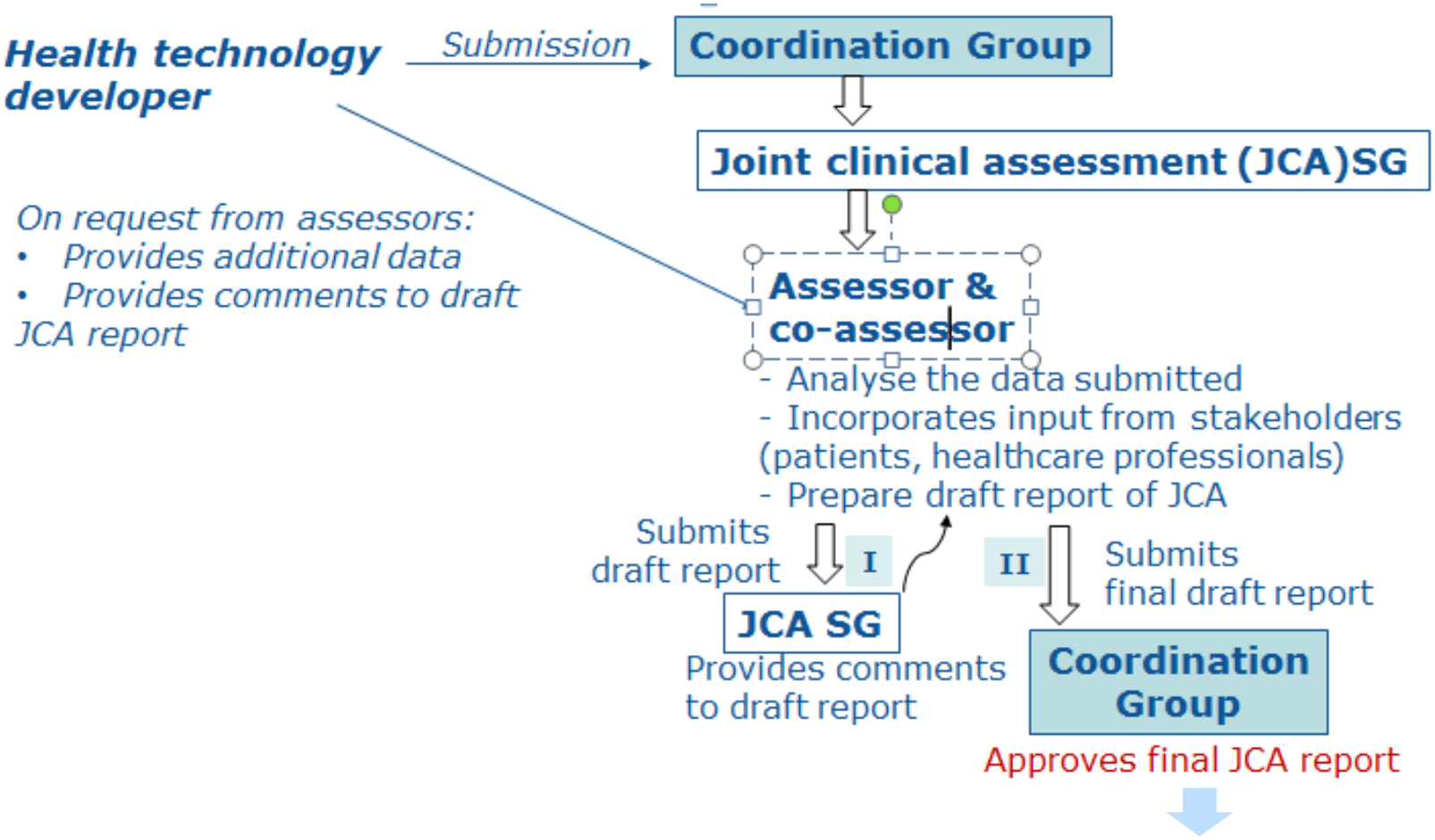
WP 5
Data generation

WP 4
Horizon scanning

WP 4
Collaborative assessments
Non-clinical assessments…



Preparation of Joint Clinical Assessment Reports



Preparation of Joint Clinical Assessment Reports

6.5. **The conclusions** of the joint clinical assessment report **shall be limited to** the following:

(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.

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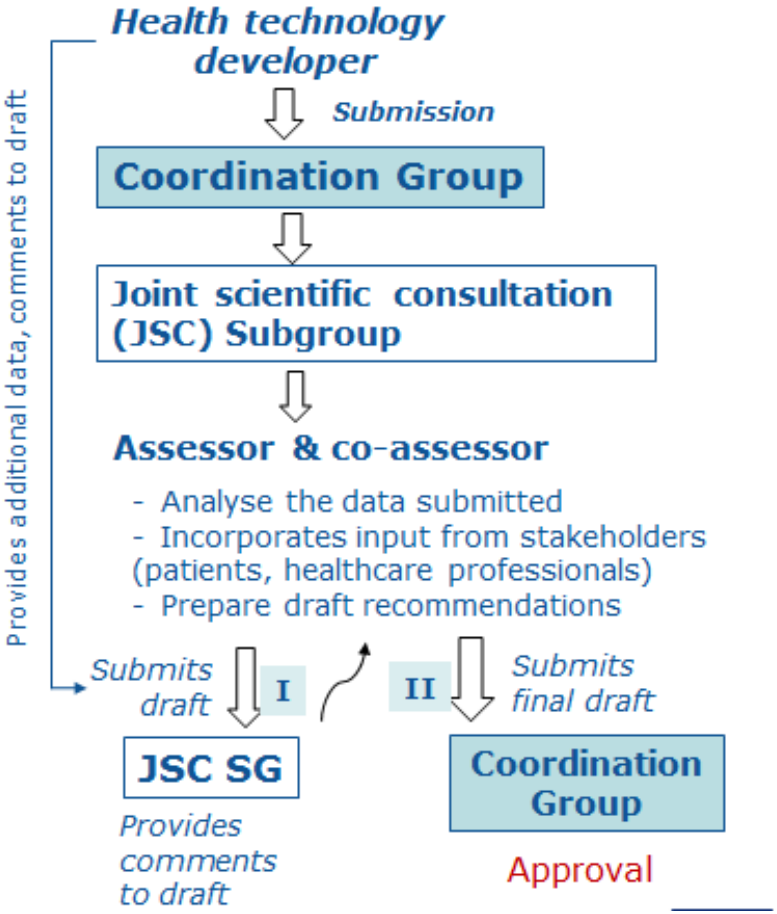
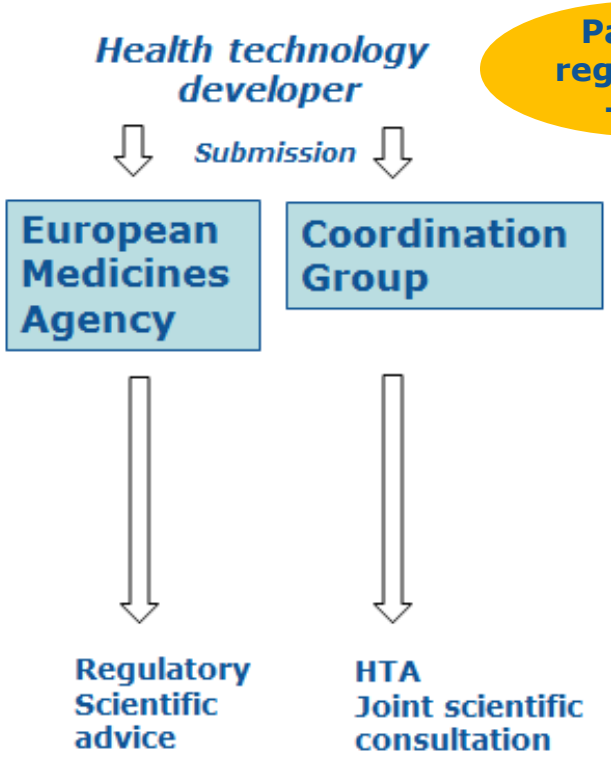
Joint Scientific Consultations

HTA only



Parallel regulatory -HTA



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Emerging Health Technologies

- The CG shall prepare **annually a study on emerging health technologies** expected to have a major impact on patients, public health or healthcare systems.
- In the preparation of the study, the CG shall consult:
  - health technology developers;
  - patient organisations;
  - clinical experts;
  - the EMA;
  - the Medical Devices Coordination Group
- The conclusions of the studies shall be summarised in the CG's annual reports + **taken into account for the annual work programmes.**

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Voluntary Cooperation on HTA

- The Commission shall support and **facilitate cooperation** and the exchange of scientific information among Member States on:
  - (a) **non-clinical assessments** on health technologies;
  - (b) **collaborative assessments on medical devices**;
  - (c) health technology assessments on **health technologies other than medicinal products or medical devices**;
  - (d) the provision of **additional evidence** necessary to support health technology assessments.
- The CG shall be used to facilitate the cooperation
- May be carried out using the common rules and procedures and included in the work programmes

Key element 8 – Governance

EU funding

- For the financing of the work of the CG and its sub-groups and activities in support of that work involving its cooperation with the Commission, with the EMA, and with the stakeholder network
- Shall include funding for the participation of MS' designated HTA authorities and bodies in support of the work on JCA and JSC.

  → **Assessor and co-assessors shall be entitled to a special allowance compensating them for their work on JCA and JSC in accordance with internal Commission provisions.**

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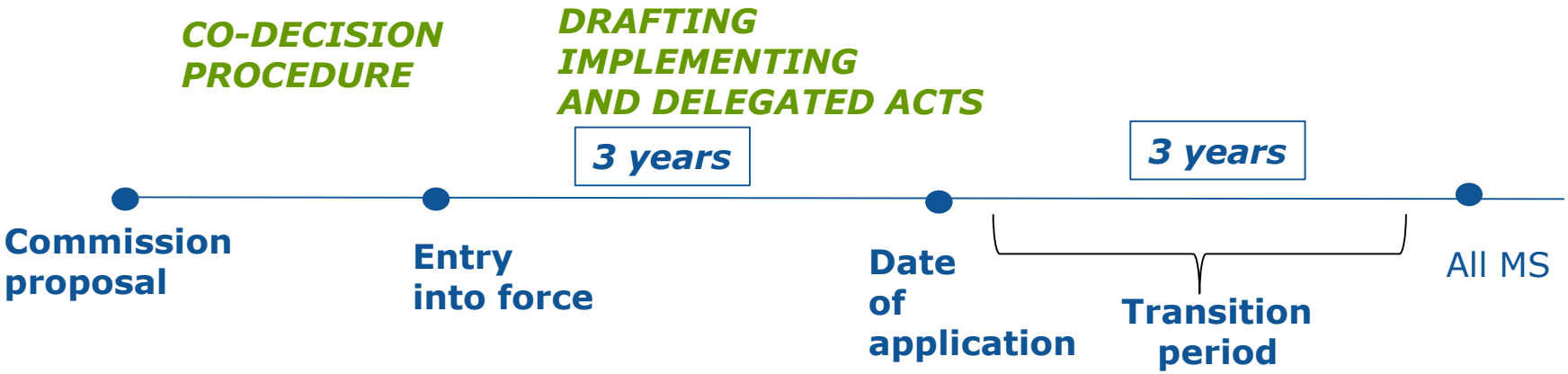
Key element 8 – Governance

Commission Support for the Coordination Group

- **host** on its premises and co-chair the meetings of the CG;
- provide the **secretariat** for the CG and provide **administrative, scientific and IT support**
- **publish on the IT platform** the CG's annual work programmes, annual reports, summary minutes of its meetings, and reports and summary reports of joint clinical assessments;
- **verify** that the work of the CG is carried out in an **independent and transparent manner**;
- **facilitate cooperation with the EMA** on the joint work on medicinal products including the sharing of confidential information;
- **facilitate cooperation with the relevant Union level bodies** on the joint work on **medical devices** including the sharing of confidential information.

Key element 9 – 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
- **Expected number of JCA/JSC per year =** up to 65/40 by the end of the transition period