Brussels, 14 February 2018

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LIMITE

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WORKING PAPER

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INFORMATION

From: General Secretariat of the Council
To: Working party on Pharmaceuticals and Medical Devices (HTA)
N° Cion doc.: 5844/18
- Presentation

Delegations will find enclosed the presentation on the above mentioned topic by the Commission at the meeting of the Working Party on Pharmaceuticals and Medical devices on 14 February 2018.
Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

Brussels, 31.1.2018
COM(2018) 51 final
2018/0018 (COD)

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

Working Party on Pharmaceuticals and Medical Devices
14 February 2018, Brussels
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).

**HTA Core Model Domains**

1. Health problem and use of current technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Cost and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Patient and social aspects
9. Legal aspects
The two main components of HTA: Assessment and Appraisal

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
HTA across EU

Differences in:
- Procedural framework
- Methodology

Scope
- Medicinal products
  → 26 MS and NO
- Medical devices
  → 21 MS* and NO
- Under development
  → 2 MS

Key: N=31 countries with England, Scotland and Wales counted separately; red = no current HTA procedure; blue = pharmaceuticals only; yellow = both pharmaceuticals and non-pharmaceuticals

* In Wales HTA on medical devices is under development

(EUnetHTA, WP7 report, 2017)
Why an HTA initiative?

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)
Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

Chapter I  General Provisions

Chapter II  Joint Work on HTA at Union Level

Joint clinical assessments  Joint scientific consultations  Emerging health technologies  Voluntary cooperation On HTA

Chapter III  Rules for Clinical Assessments

Chapter IV  Support Framework

Chapter V  Final Provisions
Legal basis

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU).

In line with Article 114(3) (TFEU), a high level of human health protection has been considered in the preparation of the proposal which is expected to improve the availability of innovative health technologies for EU patients.
Chapter I  General Provisions

Article 1 - Subject Matter

1. This Regulation establishes:
   (a) a support framework and procedures for cooperation on health technology assessment at Union level;
   (b) common rules for the clinical assessment of health technologies.

2. This Regulation shall 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.
Chapter I  General Provisions

Article 2 - Definitions
(a) 'medicinal product'
(b) 'medical device'
(c) 'health technology'
(d) 'health technology assessment'
(e) 'clinical assessment'
(f) 'non-clinical assessment'
(g) 'collaborative assessment'

Make reference to definitions in other EU directives/Regulation
Chapter I  General Provisions

Article 3 - The Member State Coordination Group on Health Technology Assessment

-> composition
-> working methods
  • Sub-groups -> type of joint activities
  • Configurations -> type of health technologies
-> tasks

Article 4 - Annual Work Programme and Annual Report
HTA Coordination Group (CG)

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

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)

Stakeholder Network

Articles 3-4

Joint work carried out by MS experts

LEGAL PROPOSAL

Articles 3-4
Chapter II  Joint Work on HTA at Union Level

**SECTION 1**
JOINT CLINICAL ASSESSMENTS (*Art 5-11*)

**SECTION 2**
JOINT SCIENTIFIC CONSULTATIONS (*Art 12-17*)

**SECTION 3**
EMERGING HEALTH TECHNOLOGIES (*Art 18*)

**SECTION 4**
VOLUNTARY COOPERATION ON HTA (*Art 19*)
Chapter II   Joint Work on HTA at Union Level

Article 5 - Scope of Joint Clinical Assessments

1. The Coordination Group shall carry out joint clinical assessments on:

(a) medicinal products subject to the authorisation procedure provided for in Regulation (EC) No 726/2004, including where an amendment has been made to the Commission Decision to grant a marketing authorisation based on a change in the therapeutic indication or indications for which the original authorisation was granted, with the exception of medicinal products authorised under Articles 10 and 10a of Directive 2001/83/EC;

(b) medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation;

(c) in vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation.
Chapter II Joint Work on HTA at Union Level

Article 5 - Scope of Joint Clinical Assessments

2. The Coordination Group shall select the medical devices referred to in paragraph 1 points (b) and (c) for joint clinical assessment based on the following criteria:

(a) unmet medical needs;
(b) potential impact on patients, public health, or healthcare systems;
(c) significant cross-border dimension;
(d) major Union-wide added value;
(e) the available resources.
Chapter II

Article 6 – Preparation of Joint Clinical Assessment Reports

Health technology developer → Coordination Group → Joint clinical assessment (JCA)SG

Assessor & co-assessor
- Analyse the data submitted
- Incorporates input from stakeholders (patients, healthcare professionals)
- Prepare draft report of JCA

JCA SG
- Provides comments to draft report

Coordination Group
- Submits final draft report

Approves final JCA report

On request from assessors:
• Provides additional data
• Provides comments to draft JCA report

EC publication
Chapter II Joint Work on HTA at Union Level

Article 8 – Use of JCA Reports at Member State Level

1. Member States shall:
   (a) 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;
   (b) apply joint clinical assessment reports, in their health technology assessments at Member State level.

Article 34 - Safeguard clause – applicable in exceptional circumstances

"[...] on grounds related to the need to protect public health in the Member State concerned and provided the measure is justified, necessary and proportionate as regards achieving that aim."
Chapter II Joint Work on HTA at Union Level

Article 9 – Updates of JCA

- in case of conditional central marketing authorisation of medicinal products;
- when an initial joint clinical assessment report specified the need for an update once additional evidence for further assessment is available;
- when requested by one or more of the CG members.

Article 10 – Transitional arrangements for JCA

Article 11 – Adoption of Detailed Procedural Rules for JCA
Chapter II Joint Work on HTA at Union Level

Article 12 - Requests for Joint Scientific Consultations (JSC)

- **Health technology** developers may request a joint scientific consultation with the CG for the purposes of obtaining scientific advice concerning data and evidence likely to be required as part of a JCA.

- For medicinal products, JCA can be carried out
  - Only by the CG
  - By the CG and EMA, in parallel – "parallel JSC"
Chapter II

Article 13 – Preparation of Joint Scientific Consultations

**Health technology developer**

*Submission*

**Coordination Group**

**Joint scientific consultation (JSC) Subgroup**

**Assessor & co-assessor**
- Analyse the data submitted
- Incorporates input from stakeholders (patients, healthcare professionals)
- Prepare draft recommendations

I. **JSC SG**
   - Provides comments to draft

II. **Coordination Group**
   - Submits final draft

**Parallel regulatory - HTA**

**Health technology developer**

*Submission*

**European Medicines Agency**

**Coordination Group**

**Regulatory Scientific advice**

**HTA Joint scientific consultation**

**Legal Proposal**
Chapter II  Joint Work on HTA at Union Level

**Article 18 - 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.
Chapter II  Joint Work on HTA at Union Level

Article 19 - 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 used to facilitate the cooperation
• May be carried out using the common rules and procedures and shall be included in the annual work programmes
Chapter III  Rules for Clinical Assessments

Article 20 - Harmonised Rules for Clinical Assessments

The common procedural rules and methodology apply to:

- **Joint** clinical assessments
  
  **AND**

- Clinical assessments of medicinal products and medical devices *carried out by Member States.*
Chapter III   Rules for Clinical Assessments

Article 21 - Clinical Assessment Reports -> national HTA reports

• MS have to provide the Commission the national clinical assessment reports and summary reports at the latest 30 working days after the completion of the health technology assessments.

• The Commission shall publish the summary reports of national HTA reports and make the clinical assessment reports available to other Member States through that IT platform.
Chapter III  Rules for Clinical Assessments

Article 22 - Common Procedural Rules and Methodology

Implementing acts to be developed by Commission:

- procedural rules for:
  - ensuring that HTA authorities and bodies carry out clinical assessments in an independent and transparent manner, free from conflicts of interest;
  - the mechanisms for the interaction between HTA bodies and health technology developers during clinical assessments;
  - the consultation of patients, clinical experts, and other stakeholders in clinical assessments.

- methodologies used to formulate the contents and design of clinical assessments.
Chapter IV – Support Framework

Article 25 - Commission Support for the Coordination Group

- host 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
- facilitate cooperation with the relevant Union level bodies on the joint work on medical devices
Chapter IV – Support Framework

Article 26 - Stakeholder Network

- The Commission shall establish a **stakeholder network** through an open call for applications.
- The Commission shall **publish the list of stakeholder organisations** included in the stakeholder network.
- The Commission shall **organise ad-hoc meetings between the stakeholder network and the CG** in order to:
  (a) update stakeholders on the work of the group;
  (b) provide for an exchange of information on the work of the CG.
- At the request of the CG, the Commission shall **invite** healthcare professionals and patients nominated by the stakeholder network to attend meetings of CG as observers.
- Shall support the CG in the identification of patient and clinical expertise for the work of its sub-groups.
Chapter IV– Support Framework

**Article 27 - IT Platform**

The Commission shall develop and maintain an IT platform containing information on:

(a) planned, on-going, and completed joint clinical assessments and Member State health technology assessments;

(b) joint scientific consultations;

(c) studies on emerging health technologies;

(d) results of the voluntary cooperation between Member States
Chapter V – Final provisions

Timeline

- **Commission proposal**
- **Entry into force**
- **Date of application**
- **Transition period**
- **All MS**

**CO-DECISION PROCEDURE**

**DRAFTING IMPLEMENTING and DELEGATED ACTS**

- **3 years**
- **3 years**

- Member States **may delay their participation** in the system of JCA and JSC until **3 years after the date of application**

- **Selection** of health technologies subject to JCA, JSC

+ Recitals 29-30
Thank you!