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WORKING PAPER

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (HTA)
Subject:	Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

Delegations will find enclosed the presentation on Articles 3 and 6 of HTA proposal given by the Commission at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 11 July 2018.

HTA Coordination Group (CG) – High Level

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

Set-up

Article 3

HTA Coordination Group (CG) – High Level

- MS designate **1+** national HTA authorities / bodies as **members**
- **Members** appoint their **representatives**
- Meetings co-chaired by Commission and elected co-chair
- CG **may** meet in different configurations
- Decisions by **consensus** or, where necessary, by **simple majority**
- 1 vote per Member State (not per member)

Tasks

Article 3

HTA Coordination Group (CG) – High Level

- Adopt RoP (e.g. tasks of assessors, co-assessors, subgroups, procedures for adoption of documents)
- Establish sub-groups (min. 5 sub-groups)
- Coordinate and approve the work of its sub-groups
  - **Annual work programme**
  - **Annual report**
  - **JCA / JSC reports**

CG – Sub-Groups

- MS designate **1+** national HTA authorities / bodies as **members**
- **Members** appoint their **representatives**
- **Standing** sub-groups carry out work on:
  - **Joint Clinical Assessments**
  - **Joint Scientific Consultations**
  - **Identification of Emerging Health Technologies**
  - **Voluntary Co-operation**
  - **Horizontal sub-group** (prep annual work programme/annual reports, update working documents/guidelines)
- May meet in different configurations.
- Send docs for approval to CG.

Joint Clinical Assessments

Article 6

In practice: CG – SG - Assessor interaction for JCAs

- CG initiates JCA by designating sub-group
- Sub-group:
  - **agrees on the scope of the JCA = PICO (Patient Populations, Intervention, Comparators, Clinical Outcomes)**
  - **appoints assessor and co-assessor**
  - **requests the submission of dossier (mandatory submission of data & evidence)**
- Assessor with co-assessor:
  - **check contents of submission**
  - **consults**
    - External experts (patients, clinical experts)
    - health technology developer (fact-checking)
    - sub-group
    - Commission
  - **incorporates comments**
  - **submits draft report to sub-group**

In practice: CG – SG - Assessor interaction for JCAs

- Sub-group peer reviews the draft report
- Assessor prepares the final draft report
- CG approves the final draft report
- Assessor removes any commercially sensitive information
- CG sends the approved report to the Commission and the health technology developer