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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)

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.
Identification of emerging health technologies

⇓

Input for annual work programme

Joint scientific consultations (JSC)

⇓

JSC reports

Joint clinical assessments (JCA)

⇓

JCA reports

Identification of emerging health technologies

⇓

Input for annual work programme

Voluntary Cooperation

⇓

Collaborative assessments / non-clinical domains

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

HTA Coordination Group (CG) – High Level

EC Secretariat

Stakeholder Network

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)
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.
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