

Interinstitutional files: 2018/0018(COD)

Brussels, 12 July 2018

WK 8585/2018 INIT

LIMITE

CODEC COMPET IA MI PHARM SAN

WORKING PAPER

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

WORKING DOCUMENT

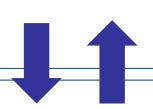
From: To:	General Secretariat of the Council Working Party on Pharmaceuticals and Medical Devices (HTA)
Subject:	Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

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.

DG LIFE.2.C LA/ns

EN





HTA Coordination Group (CG) - High Level

CG Sub-groups

Joint clinical assessments (JCA)

JCA reports

MP

MD

Joint scientific consultations (JSC)

JSC reports

MD

Identification of emerging health technologies

Input for annual work programme

Voluntary Cooperation

Collaborative assessments / non-clinical domains

Stakeholder Network

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



MP

EC Secretariat



Set-up



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 cochair
- CG may meet in different configurations
- Decisions by consensus or, where necessary, by simple majority
- 1 vote per Member State (not per member)

Tasks



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.



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



Joint Clinical Assessments



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