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INFORMATION

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 - Presentation by the Commission

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 7 May 2018.
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

7 May 2018
Article 6 – Preparation of Joint Clinical Assessment Report

Health technology developer (HTD)

- Obligatory submission of documentation (comprehensive evidence)

Coordination Group

Joint clinical assessment (JCA) Sub-group

Draft JCA report

- Verify completeness of documentation: if needed request additional information from HTD
- Analyse the documentation submitted
- Incorporate input from the other members of the SG in the preparation phase (e.g. comparators, patient populations, endpoints)
- Consult and incorporate input from external experts (patients, clinical experts)
- Prepare JCA draft report, incorporating comments from the other members of the SG
- Submits final JCA report to the CG

Assessor & co-assessor

Coordination Group

Final JCA report

Approval
Conformity assessment

Medical devices developer

Notified Body (NB)

Submission

Clinical evaluation assessment report

Expert panel

Scientific opinion on the clinical evaluation assessment report (max 60 days)

CE marking

Flexible

(in line with the annual programme adopted by the CG)

Medical devices developer

Submission dossier

Coordination Group

JCA Sub-group

Draft JCA report

Assessor & co-assessor

Coordination Group

Final JCA report

Selected Medical devices

HTA (JCA)

100 (?) days

European Commission