



Council of the European Union
General Secretariat

**Interinstitutional files:
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WK 5461/2018 INIT

LIMITE

**CODEC
COMPET
IA
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PHARM
SAN**

WORKING PAPER

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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



Assessor & co-assessor



Coordination Group



Final 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

Approval

Marketing authorisation

HTA (JCA)

Medicinal products

Medicinal products developer

Submission dossier

EMA

210 days

CHMP opinion

67 days

EU marketing authorisation

Medicinal products developer

Submission dossier

Coordination Group

JCA Sub-group

Draft JCA report

Assessor & co-assessor

Coordination Group

Final JCA report

100 (?) days

Conformity assessment

HTA (JCA)

**Selected
Medical
devices**

Medical devices developer



**Notified
Body (NB)**

**I Clinical evaluation
assessment report**



**Expert
panel**

**II 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 (MD selected by CG)



Coordination Group



JCA Sub-group



Assessor & co-assessor



Coordination Group



Final JCA report

**100 (?)
days**