

Interinstitutional files: 2018/0018 (COD)

Brussels, 07 May 2018

WK 5461/2018 INIT

LIMITE

CODEC COMPET IA MI 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

## **Article 6 – Preparation of Joint Clinical Assessment Report**

### **Health technology developer (HTD)**

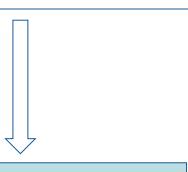
Obligatory submission of documentation (comprehensive evidence)

### **Coordination Group**

Joint clinical assessment (JCA) Sub-group



Assessor & co-assessor



- 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

**Coordination Group** 

**Approval** 

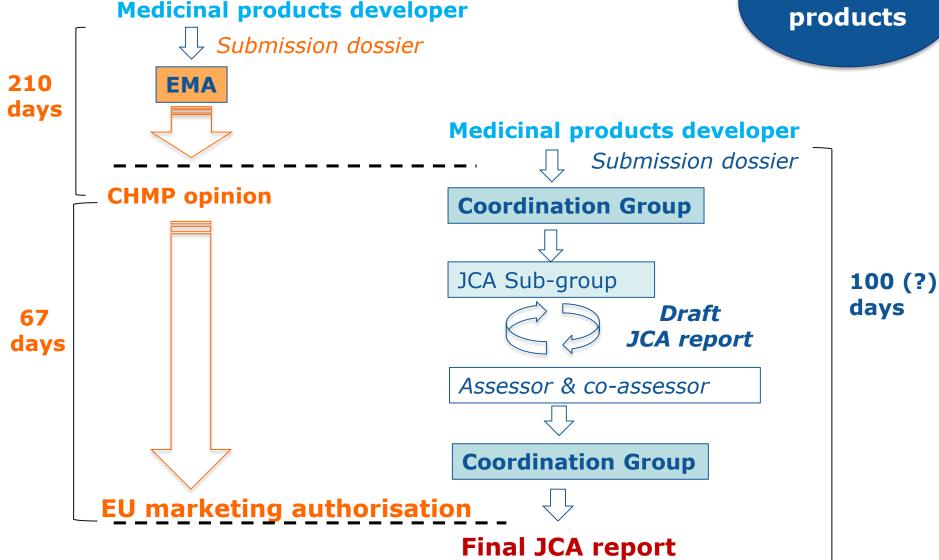




## Marketing authorisation

HTA (JCA)

Medicinal products





# **Conformity assessment**

HTA (JCA)

Selected Medical devices

#### **Medical devices developer**



Notified Body (NB) I Clinical evaluation assessment report

**Expert** panel

CE marking

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

**Flexible** 

Medical devices developer (MD selected by CG)

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

Coordination Group

JCA Sub-group

Draft
JCA report

Assessor & co-assessor

Coordination Group

Final JCA report

100 (?) days

