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DDPS declaration form/Guidance document

CMDh meeting with representatives of Interested Parties 20 June 2011

Declaration form approved DDPS

- **Published December 2010 under “Procedural Guidance, Application for MA”**
- **To be used as of 1 February 2011 for new applications (DCP/MRP)**
- **March 2011: revised version also applicable to type IB variation applications (C.I.8.b) and publication guidance document**

Current situation - used when/how?

- **New applications MRP/DCP**
 - **DDPS applicant**
 - **DDPS future MAHs different from applicant**
 - **signed by applicant **or** future MAH**
 - **Not possible to include future MAHs with DDPS not approved by CA**
 - **Submission on day 0**
 - **Module 1.8.1**
 - **Change future MAH **during procedure only once per MS** on day 60 (MRP), day 106 or 160 (DCP)**
 - **Change MAH during national implementation phase in consultation with respective MS**

Current situation – type IB variation application

- **Type IB Variation application C.I.8.b**
 - **signed by applicant**
 - **Submission on day 0**
 - **Module 1.8.1**

Declaration form – new proposal

- **New applications MRP/DCP **one form** to be signed by applicant (on behalf of future MAHs) only**
- **Section 5 table to include information on future MAHs**
- **Section 6: only one signature**

Questions received

What is meant with approved by CA?

- CA = all EU MS including Iceland, Norway, Liechtenstein and EMA (not necessarily RMS DCP/MRP)
- No need to submit document/proof
- Q&A 3.12 variations has been amended accordingly

Questions received

Applicant is company X/NL

Future MAH in AT is company X/AT (same mother company)

Do I have to fill in section 5.1 of the declaration form?

No, unless these companies use a different DDPS.

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▶ DDPS Declaration form