

WORK SHARING VARIATIONS

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- Look at a few numbers
- A reminder of the process
- A couple of tips

HIGH LEVEL MESSAGE

- It's Working!



**THANK YOU FOR
LISTENING**

A Few Statistics

- In 2012 – 35 work share applications
- In 2013 – 52 work share applications
- In 2014 – 59 work share applications
- In 2015 – 12 work share applications, so far

SCOPE

- Article 20 – single application: the same IB or the same Type II variation (or same group of variations listed in Annex III of regulation)
- Can include CAP, DCP, MRP or National.
- If CAP included then EMA will take the lead.
- If DCP / MRP then RMS will take the lead. CMDv will decide / endorse applicant proposal if more than one RMS.
- National only products in more than one Member State - CMDv will decide / endorse applicant proposal if more than one RMS.

PROCEDURE

- MAH to discuss intent with preferred reference authority.
- Then submit the letter of intent to CMDv Secretariat.
- CMDv will discuss / endorse appointment of reference authority and also confirm proposed classification(s).
- Reference authority will confirm with MAH and allocate procedure number after the CMDv meeting.
- Procedure run on Type II timetable.

REMEMBER

- Article 20 (10) of Regulation 1234/2008 as amended by 712/2012 states that:

“ Where harmonisation of a section of the summary of product characteristics of a purely national marketing authorisation has been achieved through a worksharing procedure, any subsequent variation submission affecting the harmonised section shall be transmitted simultaneously to all member states concerned”

TIPS & POINTERS

- Submit letter of intent in good time to the Secretariat – bear in mind that the first meeting mailing is circulated two weeks prior to the meeting.
- If you are positively excluding a member state from a procedure, explain why in letter of intent – stops question from being asked at CMDv.
- Think about timing – have had examples where letters of intent are submitted months ahead of the actual planned submission and then amendments put forward.

AND FINALLY

- Are there more worksharing applications?
- We receive many around quality aspects – but what about others e.g. changes to withdrawal periods?
- Only a few MAH seem to take up this opportunity – why?
- It works!

***THANK YOU AND ANY
QUESTIONS?***

