

Variations - progress in worksharing CMDv comments

**EMA/IFAH-Europe Info Day
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Variations - progress in worksharing

Worksharing requests to CMDv

	2010	2011	2012	2013
Requests to CMDv	24	26	30	52

CMDv guidance documents

- **CMDv/BPG/018 on worksharing**

http://www.hma.eu/uploads/media/Nov13_BPG-018-03_Worksharing.pdf

- **Worksharing – applicant's letter of intent**

<http://www.hma.eu/163.html>

- **Update on handling worksharings for variations involving products authorised via MRP/DCP and purely-nationally authorised products (NAPs)**

http://www.hma.eu/uploads/media/Worksharing_procedural_update_Nov_2013.pdf

Worksharing procedure of the same MA holder

- more than one purely national MA in more than one MS (also one purely national MA in more than one MS)
- more than one mutual recognition MA
- one or several purely national & mutual recognition MAs(s)

Reference authority: one of the MSs

Confirmation by CMDv

Reference Authority (RA)

- **MAH choose a NCA to act as RA**, except for worksharing with the same RMS.
- **MAH contacts chosen RA & discuss** an upcoming worksharing procedure before notifying to the CMDv by submitting draft letter of intent to RA.
- **NCA agrees to act as RA & confirms** that proposed variation classification(s) & any grouping(s) are acceptable (**same variations** for all involved products).

This will ensure a smooth discussion at CMDv

Pre-submission notification (letter of intent)

- **MAH submits final letter of intent to RA**, copying CMDv secretariat – 15 days in advance of CMDv meeting
- Discussion at CMDv meeting
- **RA replies directly to the MAH** after CMDv meeting
 - confirming CMDv's (non)acceptance of the worksharing
 - providing the procedure number
- **MAH includes RA reply in variation documentation**

Letter of intent

- Applicant details
- Application details
 - a) List of marketing authorisations concerned
(MRP/DCP + **proceudre no.**, national authorised + **MA no.**)
 - b) Description of the changes (according Classification GL,
description in words, justification grouping)
 - c) Preferred Reference Authority
 - d) Justification why a worksharing procedure is suitable

Letter of intent

- Application details
 - e) Intended submission date
 - f) Explanation that all MAs concerned belong to the same MAH
 - g) If applicable, details of submission/approval/rejection of the same variation(s) in any Member State(s)
 - h) If applicable, details of any MAs (MR/DC or purely national) that have been excluded

Thank you very much for listening!

Any questions / comments?