

Variation Regulation Subgroup & Overview of developed and revised documents

CMD(h) meeting with Interested Parties

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CMD(h)-(v)Subgroup on Variation Regulation

- Representatives from CMD(h) and CMD(v)
- Chaired by Susanne Winterscheid (BfArM), Gavin Hall (MHRA) and Sandra Kruger (MEB)
- EMEA is also present

Mandate

- (1) Prepare proposals for**
 - a. new CMD guidance and documents to the revised Variation Regulation, and**
 - b. adaptation of existing CMD guidance and documents to the revised Variation Regulation**

These proposals will be forwarded to the CMD(h) and CMD(v) for endorsement.
- (2) Input to EC proposals, e.g. for Guidelines**
- (3) Common interpretation of the revised Variation Regulation in order to ensure a consistent approach with variation procedures in the future.**

For common topics such as recommendations on classification of unforeseen variations and work sharing, a joint discussion with the EMEA should take place in the subgroup.

Transitional period

- Art. 27 of Variation Regulation 1234/2008: “Regulations 1084/2003 & 1085/2003 shall continue to apply to valid notifications or applications for variations which are pending on 1 January 2010“
- CMD and EMEA agreed on the same principle: the date of submission is relevant
 - Variations submitted to RMS and CMS **before** 1/1/2010 will be handled according to the current system
 - Variations submitted to RMS and CMS **after** 1/1/2010 will be handled according to the new system

Best Practice Guides

Publication of revision 6 of the Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedure, taking into account Commission Regulation No 1234/2008, is published as a draft document

<http://www.hma.eu/96.html>

Best Practice Guides

- Will be updated after publication of Commission Guidelines (expected before end November)
- Further update of CMD(h) BPG is planned after some months of experience with new Variation Regulation

Application form

- Publication is expected in the week 16-20 November
- User Guide is still under preparation

What is a Marketing Authorisation?

- There is no harmonised definition for “one marketing authorisation” → each Member State may have a different way of granting their national marketing authorisation according to their own national procedures
 - a marketing authorisation for one medicinal product may include all strengths and pharmaceutical forms of that product, or
 - a different marketing authorisation may be granted for each strength and pharmaceutical form of that same medicinal product

Agreement

- Agreement needed on what is considered one Marketing Authorisation to define Grouping (and Worksharing)
- All strengths and pharmaceutical forms of a medicinal product are considered to belong to one Marketing Authorisation ([AT/H/0123/001-00n](#))

Grouped application procedure numbering in MRP

$$\frac{c \quad B \quad G}{M \quad E \quad B}$$

CC/D/nnnn/QQ/vvvv/g

Where:

- CC = two letter country code of the RMS
- D = Domain (H or V)
- nnnn = product counter (if 1 MA) / xxxx (if >1 MA)
- QQ = qualifier (e.g. IA, IB, II, X)
- vvvv = sequential variation counter
if 1 MA: next available.
If >1 MA: new counter (for Type IA only)
- g = Grouping qualifier (G)

Examples: [AT/H/0236/II/0027/G](#) (for 1 (same) MA)
[AT/H/xxxx/IA/0004/G](#) (for >1 MA)

Grouped application procedure numbering in MRP

If 1 MA is included in grouping:

- number is composed of the RMS code, domain, product counter (nnnn=1234) and the next available variation sequence (vvv)
 - e.g. [AT/H/0753/IB/0070/G](#)
 - MAH can determine this number himself

Grouped application procedure numbering in MRP

If >1 MA is included in grouping

- for Type IA Variations, more than one MA may be grouped. In that case the product counter is replaced by a placeholder (nnnn='xxxx') followed by the grouping qualifier and a new grouping variation counter

➤ e.g. [AT/H/xxxx/IA/0002/G](#))

➤ Number must be obtained from RMS prior to submission

Worksharing procedure numbering

[CC/D/nnnn/QQ/vvvv](#)

Where:

CC = two letter country code of the Reference authority

D = Domain (H or V)

nnnn = placeholder : xxxx (is literally meant as 'xxxx')

QQ = qualifier for worksharing: WS

vvvv =sequential variation counter (four number digit)

Example: [AT/H/xxxx/WS/007](#)

Worksharing procedure numbering

AT/H/xxxx/WS/007

- The number is not product related
- Sequential variation counter ('007') is a new counter starting from 1 for each Reference Authority
- Number must be obtained from Reference Authority prior to submission

Q&As on CMD website

- The current list of Q&As will be revised, on the basis of
 - **Questions sent to CMD(h)**
 - **Questions discussed at DIA/EMEA/CMD meeting 26 October**
 - **Questions put forward by members of the Variation Subgroup**

After 1 January 2010

Subgroup continues to

- Share experience
- Identify areas for further discussion
- Agree update of BPG and Q&A