

Question & Answer N. 1/2006

Repeat use – Clarification on BPG003

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QUESTION

Further clarification is requested on the document CMD(v)/BPG/003 (previous VRMF/053/98).

The following hypothetical procedures are being followed for a certain product by a company:

MRP Procedure I: RMS: A; CMS's: B and C.
Procedure has been successful resulting in SPC-1;

MRP Procedure II: (repeat use procedure): RMS: A; CMS's: D and E.

Option A:

The second procedure is successful and results in SPC-1.
No problems will arise.

Option B:

The second procedure is successful and results in SPC-2.
SPC –1 and SPC-2 need to be “harmonised”; no major problems exist.

Option C:

The second procedure is unsuccessful. A referral to CMD(v) is initiated by CMS E; no agreement is reached and the application is referred to CVMP for arbitration. CVMP agrees with CMS E and no SPC can be drawn up.

In this latter case, what will happen to the original marketing authorisation in the RMS A?

What will happen to the marketing authorisation of the CMS's B and C based on SPC-1?

ANSWER

At the end of the MR procedure, the SPC should be identical in all MS involved. If an arbitration procedure is initiated following the identification of an issue of potential serious risk to human or animal health or the environment during the repeat use procedure, the outcome of the arbitration procedure will apply to the marketing authorisations granted for that product in the RMS and all CMS.