

REPORT FOR RELEASE

Meeting of 8-9 November 2007

Work plan 2008

In pursuit of continuous improvement of the functioning of the co-ordination group and the conduct of mutual recognition and decentralised procedures, CMD(v) discussed what items should be included in work plan for the coming year. Issues that have been identified for further action in 2008 include for example the handling of generic applications, harmonisation of packaging requirements and validation.

CMD(v) will be pleased to consider any idea or suggestion from industry, veterinarians, animal keepers or other stakeholders. Comments should be sent to the CMD(v) secretariat by 6 December 2007 at the latest.

Expiry of antigen storage period

CMD(v) considered the situation where an antigen, of which the authorised storage period had expired, was used in a vaccine production.

It is understood that from time to time minor manufacturing deviations from the details set out in the marketing authorisation occur, which carry no risk to the animal health. These one-off issues should be dealt with in accordance with a procedure and on a case-by-case basis. In case of a one-off deviation the following should be followed by the manufacturer / marketing authorisation holder:

- The final decision must be taken under the responsibility of the Qualified Person.
- The decision must be supported by documentation as required by Good Manufacturing Practice and made available to the competent authority.
- Quality risk principles must be applied and an assessment should be performed by the manufacturer to support a conclusion that the occurrence is a minor quality deviation and does not affect the safety and efficacy of the product.
- The antigen/active substance and finished product should comply with the specifications.
- The risk assessment should assess the need for inclusion of the affected batches in the on-going stability program as required by Chapter 6 of the GMP Guide.
- All such deviations must be reviewed as part of the annual product quality review as required by Chapter I of the GMP Guide.

It should be stressed that the above only applies to one-off deviation. Recurrent deviations are changes and variations to the affected marketing authorisation are necessary.

Best Practice Guide

The Best Practice Guide for Automatic Validation of Applications in the Mutual Recognition / Decentralised Procedures was revised. For the Decentralised Procedure the agreed automatic validation of 14 days was included. The updated version will be published on the CMD(v) website.

Product discussion

Six products reached day 78 of the mutual recognition procedure in November 2007. Out of these 6 were discussed at the meeting. Also discussed was a product referred to CMD(v) under Article 33(1) of Directive 2001/82/EC, as amended. The applicant took the opportunity to express their point of view in a hearing.

	MRP	DCP	Referrals
<i>Procedures</i>	7	0	1
Products	6	0	1
Immunological	4	0	0
Pharmaceutical	2	0	1
Discussed	5	0	1

It was noted that agreement was reached on all procedures that reached day 90 in October.

Information

CMD(v) documents are available on www.hma.eu.

For further information, please contact the secretariat at the European Medicines Agency, for the attention of Wim Riepma, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK wim.riepma@emea.europa.eu