

London, 15 December 2005

REPORT OF THE CMD(v) MEETING – FOR RELEASE

Meeting of 8-9 December 2005

ASSESSMENT ISSUES	DECISIONS
Outcome of Veterinary Mutual Recognition Procedures	Two immunological and eight pharmaceutical products were discussed at the November meeting. The Marketing Authorisations for seven applications have been recognised by all of the individual CMS. Points of disagreement for two products are to be referred from the CMD(v).
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for seven pharmaceutical products and three immunological products had reached Day 78 at this meeting.
ORGANISATIONAL ISSUES	
CMD(v) SOP –Disagreement in procedures-referral from CMD(v)	The document was adopted and would be made public.
Best Practice Guide for Type IA variations	The document was adopted and would be made public.
Best Practice Guide for Type IB variations	The document was adopted and would be made public.
Best Practice Guide for Repeat use procedures	The document was adopted and would be made public.
Best Practice Guide for DCP	The document was adopted and would be made public. In response to suggestions brought forward by interested parties, it was made clear that the withdrawal of an application does not necessarily prevent referral from the CMD(v) to the CVMP.
Best Practice Guide for procedure for automatic validation of MRP.	The document was adopted and would be made public.
Best Practice Guide for the RMS	This BPG would be discussed finally after adoption of the BPG for MRP and DCP.

Best Practice Guide-For the processing and assessing labelling and packaging provided in support of mutual recognition and decentralised application	The document was adopted and forwarded to IFAH Europe and EGGVP for information and comments.
Best Practice Guide for The Production of Publicly Available Assessment Reports	The document was adopted and would be made public.
GENERAL	
Where to find Best Practice Guides	Adopted Best Practice Guides would be published after finalisation on the website of the Heads of Medicine Agencies (vet), www.hevra.org
Date of next Meeting	The next CMD(v) meeting is scheduled to take place in London on 19-20 January 2006. Esther Werner will chair the meeting.