

REPORT FOR RELEASE

Meeting of 12 – 13 March 2009

Start of harmonisation subgroup

In accordance with the work plan for 2009 the new subgroup on SPC harmonisation of nationally authorised products held its first meeting, and was given the following mandate:

1. To establish selection criteria and to propose to CMDv a prioritised list of products:
 - a. that may be used as reference product up to 2012 inclusive, with differences in the nationally authorised Summary of Product Characteristics (SPC) that could lead to a referral under article 34 or 35 of the Directive;
 - b. for which SPC harmonisation is important in relation to the protection of public health, even though they may not be necessarily referred as a result of generic application.
2. To develop and propose to CMDv alternative mechanisms for SPC harmonisation outside the scope of article 34(1) and 35 referrals.
3. To propose to CMDv a plan, including a time schedule, regarding the harmonisation of SPCs.
4. To have contact with the Committee for Medicinal Products for Veterinary Use (CVMP), the human Coordination Group for Mutual recognition and Decentralised procedures (CMDh) and interested parties, in an appropriate way and time, to ensure their views will be considered.

Laëtitia Le Letty from France was elected to chair the subgroup.

Global shortage of acetonitrile

The CMDv was informed of the global shortage of acetonitrile, a solvent which is widely used in the pharmaceutical industry for the analysis of active substances and for manufacturing medicinal products, among other possibilities. Marketing Authorisation holders of a veterinary medicinal product are reminded that they must maintain their dossier up to date. Consequently, using an alternative solvent or changing analytical methods will require the submission of variation applications together with appropriate supporting data.

Handling of Periodic Safety Update Reports (PSURs)

Marketing Authorisation Holders (MAHs) are required to systematically collect and evaluate information on safety data relating to their Veterinary Medicinal Products (VMPs) in accordance with Article 74 of Directive 2001/82/EC as amended.

In addition, MAHs should provide Competent Authorities with an update of the world-wide safety experience of a VMP. MAHs are expected to provide summary information on all adverse reactions and their causality assessment. They should address the benefit-risk balance of the product in the light of any new or changing pharmacovigilance information. This is necessary to ascertain whether further investigations need to be carried out and/or whether changes should be made to the SPC, or other product information.

In accordance with Article 75(5) of Directive 2001/82/EC as amended, MAHs shall submit PSURs at defined times post-authorisation.

The Best Practice Guide on handling of PSURs as published (<http://www.hma.eu/150.html>) has been prepared in order to define what should be done by the Reference Member State (RMS) and the Concerned Member States (CMS) regarding handling of PSURs for VMPs authorised via the MRP or DCP.

Restructuring of the Veterinary Mutual Recognition Product Index

The VMR-I website is currently out of order due to restructuring. CMDv apologises for any inconvenience this may cause. Meanwhile, information on products can be requested to the respective national authorities (<http://www.hma.eu/157.html>).

Annual report 2008 available on line

This report provides an overview of the work carried out by the CMDv in 2008: the realisation of planned activities following the CMDv Work Plan 2008 and new items that emerged along the way.

The year can be characterised by an ever growing number of procedures, particularly those made under the decentralised procedure,

	2008	2007	2006
MRP	79	76	70
DCP	70	26	4
Total	149	102	74

And an increasing number of referrals relating to environmental risk concerns,

	number of referrals to CMDv (and CVMP)			to CMDv as percentage of total products			to CVMP as percentage of total products		
	2008	2007	2006	2008	2007	2006	2008	2007	2006
MRP	9 (5)	4 (2)	7(6)	11%	5%	10%	6%	3%	9%
DCP	9 (4)	3 (2)	1 (0)	13%	12%	25%	6%	8%	0%
Total	18 (9)	7 (4)	8(6)	11%	7%	11%	6%	4%	8%

Although it had been anticipated that the DCP would attract less referrals because of the two phase assessment, the referral rate is equivalent to that in the MRP.

The success rate of resolving disagreements during the CMDv referral procedure increased:

2008, 50%	2007, 43%	2006, 25%
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More information on the progress made in processing generic applications, simplifying packaging requirements and reducing the number of validation issues and other matters discussed in 2008 are explained in the Annual Report document ([http://www.hma.eu/uploads/media/CMDv_annual_report_2008 - Final EMEA-CMDv-33261-2009.pdf](http://www.hma.eu/uploads/media/CMDv_annual_report_2008_-_Final_EMEA-CMDv-33261-2009.pdf)).

Product discussion

In March 2009, 1 product reached day 78 of the mutual recognition procedure and a further 9 products reached day 198 of the decentralised procedure. Out of these, 4 were discussed.

	MRP	DCP	Referrals
<i>Procedures</i>	1	11	0
Products	1	9	0
Immunological	1	0	0
Pharmaceutical	0	9	0
Discussed	1	3	0

It was noted that following the February 2009 meeting no agreement was reached on granting marketing authorisations for 3 products following the mutual recognition procedure. The products were consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

Information

CMDv documents are available on www.hma.eu/cmdv.html

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