

Report from the CMD(h) meeting held on 19th and 20th January 2009

Summary of CMD(h) Activities in 2008

The CMD(h) has agreed to publish on the website, for transparency reasons, a summary of the main activities carried out by the CMD(h) and its sub-groups/working groups in the areas identified as priorities for 2008 in the CMD(h) work plan. A list of new and revised CMD(h) documents and questions & answers developed by the CMD(h) in 2008 is included as an Annex to the document.

MRP/DCP statistics in 2008

Statistics regarding new applications in the MRP and DCP in 2008 according to the 5-level classification will be published on the website.

The statistics will also include information on the referrals to the CMD(h), addressing the referrals to the CMD(h) per type of procedure (MRP vs DCP), per type of product, per therapeutic area, per legal basis, per grounds and per outcome.

CMD(h) Work plan for 2009

The CMD(h) has agreed a work plan for 2009. The work plan will be published on the website, for transparency reasons.

The CMD(h) identified as new priorities for 2009, the contribution to the HMA Taskforce on resources, the discussion on how to implement a risk based assessment in MRP/DCP, the preparation for the new tasks of the CMD(h) in the new legislative proposals 'Strategy to better protect Public Health by strengthening and rationalising EU Pharmacovigilance', the implementation of eCTD in MRP and DCP, the implementation of Virtual product discussions, to enhance participation of Experts in discussions, etc.

The CMD(h) maintained as priorities for 2009, an active participation of all CMD(h) Members in CMD(h) and Work-sharing activities, the elimination of parallel assessment by CMSs, the increase in transparency on outcome of referrals to CMD(h) and CHMP, the reduction of national requirements, etc.

A list of documents to be developed and/or revised by the CMD(h) in 2009 is included as an Annex to the document.

List of medicinal products for SPC harmonisation – Outcome of consultation with Interested Parties

The CMD(h) has considered, at the meeting of the sub-group on harmonisation of SPCs, the comments received from Interested Parties on the list of medicinal products for SPC harmonisation, published on the website for an eight week period for public consultation.

The CMD(h) agreed to remove Noroxin (norfloxacin) and Oncovin (vincristine) from the list and will send the final list of products for SPC harmonisation to the EC, as foreseen in Article 30(2) of Directive 2001/83/EC, as amended.

The EC or a Member State, in agreement with the EMEA and taking into account the views of Interested Parties, may refer these products to the CHMP in accordance with Article 30(1) of Directive 2001/83/EC, as amended.

It is envisaged that prior to the start of the Article 30 referral procedures, the respective Marketing Authorisation Holders will be invited for pre-referral meetings.

CMD(h) meeting with representatives of Interested Parties

The report from the CMD(h) meeting on 16 December 2008 with representatives of AESGP, EFPIA and EGA was agreed and will be published on the website, for transparency reasons.

The CMD(h) has also agreed to publish the presentations given at the meeting.

CMD(h)/EMA Sub-Group on Paediatric Regulation

The list of active substances included in the second wave of the Article 45 work-sharing procedure will be published on the CMD(h) website.

Marketing Authorisation Holders are reminded that they should have the paediatric studies ready for submission to the appointed Rapporteur within one month of the request.

For studies not available in English, a summary of the study in English will be required.

The CMD(h) has agreed templates for the Rapporteur's Assessment Report for paediatric studies submitted in accordance with Article 45 and 46 of the Regulation (EC) No 1901/2006, as amended.

The templates will be published on the CMD(h) website, under Templates, AR, Paediatric data.

Question and Answer – Article 5 of Regulation (EC) No 1234/2008

The CMD(h) has agreed a Q&A to clarify that Article 5 of Regulation (EC) No 1234/2008, applicable as of 1st January 2009, can only be used to request the provision of a recommendation on the classification of a variation according to Commission Regulation (EC) No 1234/2008 and not according to the Commission Regulation (EC) No 1084/2003, in force until 31st December 2009.

Cover letter for Variation applications in MRP

The CMD(h) has agreed on a template for a cover letter for variation applications submitted through MRP, prepared by the Working group on Validation issues/National requirements.

The CMD(h) has agreed that the use of the template for the cover letter is voluntary and will publish it on the CMD(h) website.

Procedural advice on repeat-use

The CMD(h) has agreed a revised version of the Procedural advice on repeat-use, in accordance with Directive 2001/83/EC, as amended. The document addresses repeat-use following a decentralised procedure, withdrawal of the application during an earlier procedure, harmonisation of the labelling and package leaflet, renewals, updating of the dossier & repeat-use of "old dossiers", updating of the assessment report, etc.

The revised procedural advice on repeat-use will be published on the website.

Number of application forms for registration of homeopathic medicinal products

The CMD(h) has agreed to accept the submission of one application form for several dilutions of a homeopathic stock for a pharmaceutical form. This agreement is reflected in a Q&A, which will be published on the CMD(h) website, under Questions & Answers, Homeopathics.

Request for Marketing Authorisation Holders for medicinal products presented as pressurised metered dose inhalers (pMDI)

Marketing Authorisation Holders are requested to review dossiers to ensure that storage orientation studies have been performed and the results of these studies are included in the registered dossier. If the results of the storage orientation studies show that there is a possibility for dose decrease/increase after storage in certain positions, an appropriate recommendation for storage orientation and/or re-priming of the product should be included in the product information.

If MAHs establish that their dossiers need to be updated with respect to either of the above points, an appropriate variation application should be submitted.

Marketing Authorisation Holders are requested to carry out the review of their dossiers and submit any necessary variation applications as soon as possible and not later than 30th June 2010.

A letter detailing this request will be published on the CMD(h) website under 'Contacts with Representative Organisations.'

Reflection paper on advice to Applicants/Sponsors/CROs of Bioequivalence Studies

The CMD(h) would like to bring to the attention of Applicants/Sponsors/CROs of Bioequivalence Studies, the publication on the EMA website, under Inspections – Good Clinical Practices <http://www.emea.europa.eu/Inspections/GCPproc.html> of the reflection paper on advice to Applicants/Sponsors/CROs of Bioequivalence Studies.

This advisory document has been developed in order to underline the responsibilities of the parties involved, clarify expectations and reinforce steps taken by the applicants, sponsors and CROs themselves to ensure the quality of bioequivalence trials submitted in marketing authorisation dossiers.

Information on applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended

Information on the name of the product in the RMS, active substance, pharmaceutical forms, procedure number, CMS, legal basis, grounds for referral to CMD(h), Day 60 and outcome of the procedure, for the referrals to the CMD(h) finalised on 22.12.2008 will be available on the table with information on all applications referred to the CMD(h), published under 'CMD(h)-Referrals'.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **12** Mutual Recognition Procedures were finalised during the month of December 2008. **1** Mutual Recognition Procedures was referred to CMD(h) in this period. There was **1** Mutual Recognition Procedures referred to CHMP in this period.

The status as of 31st December 2008 of procedures under Mutual Recognition is as follows:

Year	New applications finalised ¹	New applications in process	Referred to CMD(h)	Agreement reached in the CMD(h)		Withdrawn during CMD(h) referral	Applications referred to CHMP	
				For procedures referred in 2007	2008		For procedures referred to CMD(h) in 2007	2008
2008	411	82	39	7	25	1	2	10

21 Mutual Recognition Procedures (regarding **36** products) started in December 2008. The categories of these procedures are as follows:

16 abridged applications, including **4** repeat use applications.

5 known active substance applications, including **2** repeat use applications.

The new procedures started in December 2008 related to **2** full dossier, **15** generic, **1** hybrid and **3** bibliographic applications.

20 of these procedures consisted of chemical substance products and **1** biological other product.

¹ Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised.'

All of these procedures related to prescription-only medicinal products in the reference Member State².

Number of countries involved in the new applications in Mutual Recognition procedure started in December 2008.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	2
DE (1)	3
DE (1)	14
DE (4)	8
DK (3)	9
DK (3)	2
DK (3)	2
FR (1)	3
FR (2)	3
FR (1)	23
LV (1)	2
LV (1)	2
PT (1)	3
PT (1)	5
PT (4)	6
PT (1)	3
SE (1)	4
SE (1)	14
SE (3)	5
SE (1)	2
UK (1)	12

Decentralised Procedure

The CMD(h) noted that there were **23** Decentralised Procedures finalised with a positive outcome and **1** with negative outcome during the month of December 2008. **No** Decentralised Procedures were referred to the CMD(h) in this period. There were **2** Decentralised Procedures referred to the CHMP in this period.

The status as of 31st December 2008 of procedures under Decentralised Procedure is as follows:

Year	New applications finalised ³	New applications withdrawn (After day 120)	New applications in process	Referred to CMD(h)	Agreement reached in the CMD(h)		Withdrawn during CMD(h) referral	Referred to CHMP	
					For procedures referred in 2007	2008		For procedures referred to CMD(h) in 2007	2008
2008	734	7	1709	43	2	28	1	2	5

100 Decentralised Procedures (regarding **193** products) started in December 2008. The categories of these procedures are as follows:

95 abridged applications, including **24** multiple applications.

3 known active substance applications.

2 line extension applications, including **1** multiple application.

The new Decentralised procedures started in December related to **85** generic, **1** bibliographic, **12** hybrid and **2** fixed combination.

All of these procedures consisted of chemical substance applications.

² In this category products are classified as prescription-only or Non-prescription (OTC) products when the RMS has approved them accordingly, although the legal status is not part of the Mutual Recognition Procedure.

³ Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. This cumulative figure includes positive and negative procedures as well as those referred to CHMP.

98 of these procedures related to prescription-only medicinal products and 2 procedure related to non-prescription medicinal products in the reference Member State⁴.

Number of countries involved in the new applications in Decentralised procedures started in December 2008.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (1)	27
AT (1)	1
AT (2)	11
AT (2)	5
AT (2)	2
DE (2)	17
DE (1)	6
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	1
DE (2)	1
DE (2)	1
DE (2)	1
DE (1)	1
DE (1)	1
DE (1)	1
DE (4)	5
DE (4)	2
DK (2)	11
FR (1)	3
FR (2)	3
FR (2)	2
FR (2)	1
FR (2)	2
FR (2)	2
FR (2)	1
FR (2)	2
FR (2)	1
FR (2)	1
FR (2)	1
FR (1)	4
FR (4)	4
FR (4)	9
HU (1)	8
HU (1)	1
IE (3)	10
IE (3)	7
IE (3)	1
IE (3)	2
IE (3)	11
NL (2)	14
NL (2)	1
NL (2)	2
NL (2)	4
NL (1)	14
NL (5)	14
NL (5)	11
PT (2)	3
PT (3)	5
PT (3)	8
PT (3)	1
PT (2)	5
PT (1)	9
PT (1)	10

⁴ In this category products are classified as prescription-only or Non-prescription (OTC) products as applied for in the RMS, although the legal status is not part of the Decentralised Procedure.

PT (3)	4
PT (3)	4
PT (3)	4
SE (1)	4
SE (2)	7
SE (1)	14
SK (1)	6
UK (1)	1
UK (3)	11
UK (1)	1
UK (1)	1
UK (2)	2
UK (1)	3
UK (1)	19
UK (3)	4
UK (1)	1
UK (1)	8
UK (1)	8
UK (2)	8
UK (4)	18
UK (1)	1
UK (1)	1
UK (1)	1
UK (4)	1
UK (2)	21
UK (2)	6
UK (2)	4
UK (3)	5
UK (1)	5
UK (2)	5
UK (1)	5
UK (2)	5
UK (1)	5
UK (2)	5
UK (1)	7
UK (2)	7
UK (1)	11
UK (3)	1
UK (3)	1
UK (1)	4
UK (1)	4
UK (1)	5
UK (1)	4

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **213** type IA variations, **114** type IB variations and **91** type II variations were finalised during the month of December 2008. **18** renewals were finalised in this period. There were **no** procedures referred to the CHMP in this period.

The status as of 31st December 2008 of variations and renewals under Mutual Recognition is as follows:

Year	Procedures from Type IA variations finalised	Procedures from Type IB variations finalised	Procedures from Type II variations finalised	Renewals finalised	Applications referred to CHMP
2008	6275	2590	2642	443	0

YEARS	MRP NEW APPLICATIONS FINALISED	DCP NEW APPLICATIONS FINALISED	TYPE I VARIATIONS FINALISED	TYPE IA VARIATIONS FINALISED	TYPE IB VARIATIONS FINALISED	TYPE II VARIATIONS FINALISED	MRP /DCP REFERRED TO CMD(H)	ARBITRATIONS REFERRED TO CHMP
1995	10		16			17		1 N.A.
1996	84		49			73		1 N.A. and 1 variation
1997	146		101			163		1 N.A. and 1 variation
1998	182		339			222		1 N.A. and 4 variations
1999	228		671			301		2 N.A. and 2 variations
2000	306		1007			320		3 N.A. and 2 variations
2001	443		1487			474		1 N.A. and 3 variations
2002	420		2104			527		2 N.A. and 7 variations
2003	529		2473	230	94	754		5 N.A. and 3 variations
2004	760		43	3240	1998	1083		9 N.A.
2005	954		N/A	4044	1944	1509	10 N.A.	2 N.A. and 7 variations
2006	535	57	N/A	4524	2209	1916	105 N.A.	22 N.A.
2007	441	392	N/A	5640	2298	2167	69 N.A.	22 N.A. and 8 variations
2008	411	734	N/A	6275	2590	2642	82 N.A.	19 N.A.
1995-2008	5449	1183	N/A	23953	11133	12168	266 N.A.	91 N.A. and 38 variations

All documents mentioned in this press release can be found at the CMD(h) website under the heading *Press Releases*.

Information on the above mentioned issues can be obtained from the chair of the CMD(h) or from the CMD(h) Secretariat:

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Or you could visit the CMD(h) web site at:

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