

Report from the CMD(h) meeting held on 16th and 17th February 2009

Correction to MRP/DCP statistics in 2008

The statistics for new applications in the MRP and DCP in 2008 according to the 5-level classification have been corrected with regard to the new active substance decentralised procedures finalised in 2008.

Common request form for reference member state in a decentralised procedure

The Heads of Medicines Agencies have, in cooperation with the CMD(h), developed a common request form to be used by Applicants when requesting National Competent Authorities to act as Reference Member State in a decentralised procedure.

The common request form will be published on the CMD(h) website, together with a link to National Competent Authorities Webpages where recommendations for requests to act as RMS are published.

Evaluation of the functioning of the CMD(h) – Outcome of questionnaires to CMD(h) Members and Interested Parties

The CMD(h) agreed, as a priority for 2008, to evaluate the functioning of the CMD(h) and consider how further improvements in the operation of the Group can be achieved.

The CMD(h) has agreed to publish a report with a summary of the responses to the various sections of the questionnaires to CMD(h) Members and Interested Parties and the main actions proposed to address the issues raised. The action plan will be followed up at regular CMD(h) meetings.

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

As requested in the CMD(h) meeting with representatives of Interested Parties, the CMD(h) has agreed an early publication of the list of active substances to be included in the third wave of the Article 45 work-sharing procedure.

Marketing Authorisation Holders will be requested in April 2009 to submit the paediatric studies for the active substances in the third wave to the appointed Rapporteur within one month of the request, with a view to starting the work-sharing procedure as of May 2009.

The CMD(h) has agreed a document with Recommendations for implementing Commission decisions following an Article 29 application under the Paediatric Regulation. The document will be published on the CMD(h) website.

The CMD(h) has also agreed a revised version of the Best Practice Guide Article 45, EU Work sharing procedure, to include information on the numbering system for the work-sharing procedure. The revised BPG will be published on the website.

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.

EU Work sharing Project – Assessment of paediatric data

The Paediatric public assessment reports for Lamictal (lamotrigine) will be made available on the CMD(h) website, under Paediatric data assessment, Assessment reports on paediatric data.

CMD(h) Best Practice Guide on the use of eCTD in the mutual recognition and decentralised procedures

The CMD(h) has agreed to extend the period for consultation on the above mentioned document until the end of June 2009.

Any comments should be sent to the attention of the CMD(h) Secretariat (H-CMDhSecretariat@emea.europa.eu) until the end of June 2009.

The aim of the BPG is to facilitate and encourage the use of eCTD as the submission format in MRP and DCP and is available for immediate use by Applicants.

Informal CMD(h) meeting – Prague, Czech Republic

An informal meeting will be held in Prague on 9-10 March 2009. The meeting will include a joint session with CHMP to discuss, amongst other topics, interaction between the different Committees/Groups, the Pharmaceutical package, etc.

The CMD(h) will discuss risk-based assessment in MRP/DCP and avoiding full parallel assessment, handling of requests to be RMS in National Competent Authorities, Paediatric Work-sharing, Implementation of the Variation Regulation at national level, etc.

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 26.01.2009 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 **24** Mutual Recognition Procedures were finalised during the month of January 2009. **2** Mutual Recognition Procedures was referred to CMD(h) in this period. There were **no** Mutual Recognition Procedures referred to CHMP in this period.

The status as of 31st January 2009 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) For procedures referred in		Withdrawn during CMD(h) referral	Applications referred to CHMP For procedures referred to CMD(h) in	
				2008	2009		2008	2009
2008	24	94	2	1	0	0	0	0

17 Mutual Recognition Procedures (regarding **26** products) started in January 2009. The categories of these procedures are as follows:

13 abridged applications, including **1** multiple and **5** repeat use applications.

3 known active substance applications.

1 Line Extension application.

The new procedures started in January 2009 related to **1** full dossier, **14** generic and **2** bibliographic applications.

All of these procedures consisted of chemical substance products.

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.

New applications in Mutual Recognition procedure started in January 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria		8
Belgium		5
Bulgaria		5
Cyprus		1
Czech Republic	2	9
Denmark	1	4
Estonia		1
Finland		5
France	1	2
Germany	1	6
Greece		7
Hungary		6
Iceland		2
Ireland		2
Italy		5
Latvia		2
Lithuania		2
Luxembourg		
Malta		2
Netherlands	3	6
Norway		3
Poland		10
Portugal	4	9
Romania		6
Slovak Republic		7
Slovenia		3
Spain		8
Sweden	3	6
United Kingdom	2	6

Decentralised Procedure

The CMD(h) noted that there were **72** Decentralised Procedures finalised with a positive outcome. **1** Decentralised procedure was withdrawn after day 120 during the month of January 2009. **No** Decentralised Procedures were referred to the CMD(h) in this period. There was **1** Decentralised Procedure referred to the CHMP in this period.

The status as of 31st January 2009 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 2008	2009		For procedures referred to CMD(h) in 2008	2009
2008	72	1	1736	0	8	0	0	1	0

94 Decentralised Procedures (regarding **238** products) started in January 2009. The categories of these procedures are as follows:

88 abridged applications, including **15** multiple applications.

4 known active 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.

2 line extension applications.

The new Decentralised procedures started in December related to **2** full dossier, **84** generic, **2** bibliographic, **4** hybrid and **2** fixed combination.

All of these procedures consisted of chemical substance applications.

93 of these procedures related to prescription-only medicinal products and **1** procedure related to a non-prescription medicinal product in the reference Member State⁴.

New applications in Decentralised procedure started in January 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	2	26
Belgium	2	27
Bulgaria		32
Cyprus		11
Czech Republic	1	30
Denmark	14	40
Estonia		19
Finland		22
France	2	25
Germany	11	43
Greece		14
Hungary	2	28
Iceland		4
Ireland		20
Italy		32
Latvia		19
Lithuania		20
Luxembourg		13
Malta		5
Netherlands	10	29
Norway		15
Poland		40
Portugal	3	26
Romania		29
Slovak Republic		29
Slovenia		13
Spain		24
Sweden	6	27
United Kingdom	41	51

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **455** type IA variations, **178** type IB variations and **172** type II variations were finalised during the month of January 2009. **35** renewals were finalised in this period. There were **no** procedures referred to the CHMP in this period.

The status as of 31st January 2009 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	455	178	172	35	0

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.

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:

*Mrs. Truus Janse-de Hoog
College ter Beoordeling van Geneesmiddelen
Kalvermarkt 53
NL – 2500 Den Haag , The Netherlands
CMD(h) Secretariat*

*Phone: + 31 70 356 74 08
Fax: + 31 70 356 75 15
E-mail: gm.janse@cbg-meb.nl
E-mail:
H-CMDhSecretariat@emea.europa.eu*

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

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