

Report from the CMD(h) meeting held on 22nd, 23rd and 24th June 2009

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

Further to the evaluation of the functioning of the CMD(h), the CMD(h) agreed to make public the mandates and objectives of the various CMD(h) Sub-groups/Working Groups.

The CMD(h) has endorsed the mandate of the CMD(h)/EMEA Sub-group on Paediatric Regulation, which will be published on the CMD(h) website, under CMD(h) Sub-groups.

The CMD(h) has also agreed to publish, for transparency reasons, the CMD(h)/EMEA Paediatric Sub-group work plan 2009, including the proposed actions and deadlines to meet the identified work objectives.

The CMD(h) has agreed a question and answer to clarify that Article 7 of the Paediatric Regulation does not apply to informed consent or duplicate applications submitted after 26th July 2008 and which cross refer to a medicinal product for which an application for marketing authorisation was submitted before 26th July 2008. This Q&A will be added to the questions and answers on the Paediatric Regulation (Regulation (EC) No 1901/2006, as amended), published on the CMD(h) website, under Paediatric data assessment, Responsibilities from the paediatric regulation.

The CMD(h) has agreed a list of active substances for the fourth wave of the work-sharing for the assessment of paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation. Marketing Authorisation Holders will be requested to submit the paediatric studies to the appointed Rapporteur within one month of the request (i.e. by mid of August 2009). The list of active substances included in the fourth wave of the Article 45 work-sharing procedure will be published on the CMD(h) website.

EU Work-sharing Article 45 of the Paediatric Regulation – Public Assessment Report

The CMD(h) has agreed a public assessment report for paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation for naltrexone. The paediatric public assessment report will be published on the CMD(h) website, under Paediatric data assessment, Assessment reports on paediatric data. As no firm scientific conclusion can be drawn about the efficacy or side effects of naltrexone in children and adolescents from the studies submitted, there is no evidence for a change in the product information.

Question and Answer - Submission of translations following Article 29(4) referrals

The CMD(h) has agreed a Q&A to address submission of translations following Article 29(4) referrals when the CHMP opinion is that the valid SmPC, labelling and package leaflet are the final versions achieved during the CMD(h) procedure.

The CMD(h) has agreed that in order for Member States to be able to comply with the Commission Decision within 30 days following its notification, high quality translations of the summary of the product characteristics, package leaflet and labelling should be submitted at the latest 5 days after the Commission decision to the reference member state and concerned member states in the procedure.

The Q&A will be published on the CMD(h) website, under Questions & Answers, Post-referral phase.

Change in the EU-Presidency

The June 2009 CMD(h) meeting was the last one under the Czech Presidency of the Council of the European Union. Sweden will take over the presidency in July 2009. Mr. Christer Backman will be the Vice-Chairperson of the CMD(h) for the Swedish Presidency of the Council of the European Union.

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 04.06.2009 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 **28** Mutual Recognition Procedures were finalised during the month of May 2009. **4** Mutual Recognition Procedures were referred to CMD(h) in this period. There were **no** Mutual Recognition Procedures referred to CHMP in this period.

The status as of 31st May 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)		Withdrawn during CMD(h) referral	Applications referred to CHMP	
				For procedures referred in 2008	2009		For procedures referred to CMD(h) in 2008	2009
2009	145	82	9	2	2	0	0	1

32 Mutual Recognition Procedures (regarding **92** products) started in May 2009. The categories of these procedures are as follows:

26 abridged applications, including **1** multiple and **7** repeat use applications.

4 known active substance applications, including **3** repeat use applications.

2 Line Extension applications.

The new procedures started in May 2009 related to **1** fixed combination, **2** full dossier, **27** generic, **1** informed consent, and **1** hybrid application.

30 of these procedures consisted of chemical substance products, **1** procedure consisted of a biological vaccine product and **1** procedure consisted of a biological blood 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.'

31 of these procedures related to prescription-only medicinal products and **1** procedure related to a non-prescription medicinal product in the reference Member State².

New applications in Mutual Recognition procedure started in May 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria		9
Belgium		7
Bulgaria		7
Cyprus		4
Czech Republic		11
Denmark	5	13
Estonia		7
Finland		8
France	1	4
Germany	13	23
Greece		4
Hungary		12
Iceland		1
Ireland		7
Italy		8
Latvia		7
Lithuania		7
Luxembourg		5
Malta		4
Netherlands	6	13
Norway		7
Poland		15
Portugal		6
Romania		10
Slovak Republic	1	12
Slovenia		4
Spain		6
Sweden		10
United Kingdom	6	9

Decentralised Procedure

The CMD(h) noted that there were **119** Decentralised Procedures finalised with a positive outcome and **4** procedures finalised with a negative outcome. **1** Decentralised Procedure was referred to the CMD(h) in this period. There were **no** Decentralised Procedures referred to the CHMP in this period.

The status as of 31st May 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
2009	382	17	1837	7	8	0	0	1	3

104 Decentralised Procedures (regarding **225** products) started in May 2009. The categories of these procedures are as follows:

102 abridged applications, including **35** multiple applications.

1 known active substance application.

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.

1 new active substance application.

The new Decentralised procedures started in December related to **91** generic, **2** full dossier and **11** hybrid.

All of these procedures consisted of chemical substance applications.

99 of these procedures related to prescription-only medicinal products and **5** procedures related to non-prescription medicinal products in the reference Member State⁴.

New applications in Decentralised procedure started in May 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	14	47
Belgium		29
Bulgaria		22
Cyprus		6
Czech Republic	1	36
Denmark	9	32
Estonia	9	20
Finland		21
France	7	26
Germany	17	61
Greece		17
Hungary	3	31
Iceland	1	4
Ireland	1	18
Italy		35
Latvia		14
Lithuania		15
Luxembourg		18
Malta		4
Netherlands	31	53
Norway		17
Poland		47
Portugal	3	26
Romania		26
Slovak Republic		28
Slovenia		16
Spain		27
Sweden		25
United Kingdom	8	31

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **499** type IA variations, **274** type IB variations and **325** type II variations were finalised during the month of May 2009. **44** renewals were finalised in this period. There was **1** procedure referred to the CHMP in this period.

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.

The status as of 31st May 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
2009	2663	1422	1345	220	2

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>