

Report from the CMD(h) meeting held on 21st, 22nd and 23rd September 2009

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

The CMD(h) has adopted a recommendation to the Member States on how to issue the compliance statement within the marketing authorisation to smooth the application of Article 36(3) of Regulation (EC) No 1901/2006.

The “Recommendation for implementation of compliance statement for the agreed completed PIP” will be published on the CMD(h) website, under “Paediatric regulation, Guidance documents”.

The CMD(h) has agreed a list of active substances for the fifth 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 November 2009).

The list of active substances included in the fifth 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 oxazepam including a recommendation for the text to be included in the SmPC and package leaflet. The Public Assessment Report will be published on the CMD(h) website, under “Paediatric Regulation, Assessment reports”.

Marketing Authorisation Holders of medicinal products with the same active substance and pharmaceutical form are requested to include this information in their SmPCs and package leaflets within 90 days of publication of the public assessment report, in accordance with the Best Practice Guide – Article 45, EU Work-sharing procedure.

Meeting between the EMEA/CMD(h) subgroup on Paediatric Regulation and Interested Parties

The EMEA/CMD(h) subgroup met with Interested Parties on Monday 21 September 2009 to discuss the experience with Articles 45 and 46 work-sharing procedures, the published CMD(h) recommendation on PUMA and the CMD(h) recommendation for implementation of compliance statement for the agreed completed PIP.

Ceftriaxone and the risk of precipitation when given with calcium-containing solutions

The CMD(h) has endorsed the PhVWP report on ceftriaxone and the risk of precipitation when given with calcium-containing solutions and recommends the implementation of the PhVWP wording for the SmPC and PL for all ceftriaxone containing products.

The following timetable has been agreed by the CMD(h) and PhVWP for implementation of agreed SmPC and PL changes:

12 October 2009	Variation applications requested through CMD(h)
19 November 2009	Variation applications submitted by MA holders
18 December 2009	Variation applications approved by RMS
18 March 2010	Updated SmPC/PL into new production batches

The PhVWP recommended SmPC and package leaflet wording will be published on the CMD(h) website, under “Product information, PhVWP recommendations”.

Revision of the Core SmPC/PL for trivalent influenza vaccines

The CMD(h) agreed on a revised Core SmPC/PL for trivalent influenza vaccines. The core SmPC and package leaflet should be implemented for the vaccination season of 2010/2011 and will be published on the CMD(h) website under “Product information”.

Timetables for MRP/DCP applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended

The CMD(h) has adopted an updated guidance document with the timetables for MRP/DCP applications referred to the CMD(h) for the 60-days referral procedure for 2010. The updated guidance document will be published on the CMD(h) website under CMD(h) referrals.

Additional Data requested for New Applications in MRP and DCP

The CMD(h) has adopted a revised version of the document named “Additional Data requested for New Applications in the Mutual Recognition and Decentralised Procedures” that will be published under “Procedural Guidance, Application for MA”.

DIA/EMEA/CMD(h) joint conference on variations

A DIA/EMEA/CMD(h) joint conference meeting on variations will be held in London on the 26 October 2009. CMD(h) and EMEA representatives shall discuss the new procedures following the implementation of the Variation Regulation (EC) No 1234/2008. For more information, visit the DIA website: www.diahome.org.

CMD(h) Pandemic Plan

The CMD(h) has agreed on a pandemic plan. The CMD(h) pandemic plan is published on the CMD(h) website under “Procedural Guidance”. This plan outlines a framework for maintenance of core and critical business functions within CMD(h) in the event of an outbreak of the pandemic influenza according to the WHO pandemic phase system. The plan will not be implemented until a decision is taken to trigger the plan, according to provisions defined in the pandemic plan. An announcement that the plan has been triggered will be given on the website.

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 30.07.2009 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 **61** Mutual Recognition Procedures were finalised during the months of July and August 2009. **1** 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 August 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	244	63	10	2	5	0	0	1

51 Mutual Recognition Procedures (regarding **96** products) started in July and August 2009. The categories of these procedures are as follows:

33 abridged applications, including **10** repeat use applications.

10 known active substance applications, including **7** repeat use applications.

7 Line Extension applications, including **6** repeat use applications.

1 new active substance application, which is a repeat use application.

The new procedures started in July and August 2009 related to **12** full dossier, **28** generic, **2** bibliographic, **2** fixed combination and **7** hybrid applications.

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

47 of these procedures related to prescription-only medicinal products and 4 procedures related to non-prescription medicinal products in the reference Member State².

New applications in Mutual Recognition procedure started in July and August 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	1	11
Belgium		7
Bulgaria		10
Cyprus		9
Czech Republic		17
Denmark	5	14
Estonia		12
Finland	1	12
France	3	12
Germany	2	15
Greece		13
Hungary		17
Iceland		7
Ireland		14
Italy		9
Latvia		11
Lithuania		11
Luxembourg		6
Malta		9
Netherlands	12	21
Norway		12
Poland		16
Portugal	3	12
Romania		11
Slovak Republic		17
Slovenia	1	9
Spain		13
Sweden	15	24
United Kingdom	8	16

Decentralised Procedure

The CMD(h) noted that there were **199** Decentralised Procedures finalised with a positive outcome and **13** procedures finalised with a negative outcome. **5** Decentralised Procedure was 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 August 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	701	18	1794	15	8	3	3	1	4

196 Decentralised Procedures (regarding **452** products) started in July and August 2009. The categories of these procedures are as follows:

159 abridged applications, including **45** multiple applications.

27 known active substance applications, including **16** multiple 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.

7 line extension applications.

3 applications for a new active substance.

The new Decentralised procedures started in December related to **145** generic, **8** full dossier, **20** bibliographic, **4** fixed and **19** hybrid.

178 of these procedures consisted of chemical substance applications, **17** procedures consisted of herbal products and **1** procedure consisted of a biological other product.

173 of these procedures related to prescription-only medicinal products and **23** procedures related to non-prescription medicinal products in the reference Member State⁴.

New applications in Decentralised procedure started in July and August 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	6	47
Belgium	2	42
Bulgaria		32
Cyprus		10
Czech Republic	10	54
Denmark	21	54
Estonia	1	32
Finland		34
France	13	43
Germany	38	112
Greece		21
Hungary	2	47
Iceland	3	12
Ireland		33
Italy	2	57
Latvia		33
Lithuania		36
Luxembourg		41
Malta		3
Netherlands	23	55
Norway	1	32
Poland		60
Portugal	10	44
Romania		39
Slovak Republic	4	48
Slovenia		24
Spain		53
Sweden	11	42
United Kingdom	49	75

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **1383** type IA variations, **610** type IB variations and **413** type II variations were finalised during the month of July and August 2009. **92** renewals were finalised in this period. There were **3** procedures 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 August 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	4732	2328	2006	367	5

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>