

Report from the CMDh meeting held on 14th, 15th and 16th December 2009

Implementation of Regulation (EC) No 1234/2008 on variations

The CMDh has adopted an updated Cover Letter for Variation Applications. It will be published on the CMDh website under “Procedural Guidance, variation”.

An updated Question & Answer document will be published on the CMDh website to answer general questions in relation with the implementation of Regulation (EC) No 1234/2008.

Applicants are informed that the draft application form published on the EC website (http://ec.europa.eu/enterprise/sectors/pharmaceuticals/better-regulation-variations-regulations-developments_en.htm) should already be used for variation applications under Regulation (EC) No 1234/2008 applying to submissions as of 1st January 2010.

CMDh/European Medicines Agency Sub-Group on Paediatric Regulation

The CMDh has adopted “Recommendations on submission and assessment in paediatric worksharing” for assessors and Marketing Authorisation Holders. This document will be published on the CMDh website, under “Paediatric regulation, Guidance documents”.

The CMDh has agreed a list of active substances for the sixth 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 Rapporteurs within one month of the request (i.e. by mid of February 2010). The list of active substances included in the sixth wave of the Article 45 work-sharing procedure will be published on the CMDh website.

The CMDh has also agreed to publish a list of active substances for which data according to Article 45 of the Paediatric Regulation has been submitted. The list will be published on the CMDh website under “Paediatric Regulation”.

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

The CMDh has agreed two public assessment reports for paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation for colestyramine and bisacodyl. The documents will be published on the CMDh website, under “Paediatric Regulation, Assessment reports”.

The public assessment report on bisacodyl includes a recommendation for the text to be included in the SmPC. 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.

Revised SOP on Decentralised Procedures

The CMDh has agreed on a revised SOP on DCP. Further guidance is given to the applicants for timeslot booking and submissions. The revised version aims at improving and clarifying the DCP process and fosters early discussions at CMDh level on disagreements that may arise during the procedures.

The revised document will be published on the website, under “Procedural Guidance, Application for MA”.

Revised Best Practice Guide on Break-out Sessions

The CMDh has agreed on a revised Best Practice Guide on Break-out Sessions to introduce the use of Vitero web conferencing. The revised document will be published on the website, under “Procedural Guidance, Application for MA”.

Revised Public Assessment Report template

The CMDh has agreed on a revised public assessment report template. This will be published on the website, under “Templates”.

Working Party on the future of CMDh

The CMDh Working Party on the future of CMDh has held its first meeting on 15th December 2009 to discuss the scope for the CMDh in the future taking into account existing tasks and the extended responsibilities foreseen in coming legislation.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMDh noted that **12** Mutual Recognition Procedures were finalised during the month of November 2009. **2** Mutual Recognition Procedures were referred to CMDh in this period. There was **1** Mutual Recognition Procedures referred to CHMP in this period.

The status as of 30th November 2009 of procedures under Mutual Recognition is as follows:

Year	New applications finalised ¹	New applications in process	Referred to CMDh	Agreement reached in the CMDh		Withdrawn during CMDh referral	Applications referred to CHMP	
				For procedures referred in 2008	2009		For procedures referred to CMDh in 2008	2009
2009	324	74	20	2	7	3	0	3

31 Mutual Recognition Procedures (regarding **54** products) started in November 2009. The categories of these procedures are as follows:

- **19** abridged applications, including **1** multiple and **2** repeat use applications.
- **10** known active substance applications, including **4** repeat use applications.
- **2** line extension applications.

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.’

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The new procedures started in November 2009 related to **6** full dossier, **17** generic, **6** bibliographic and **2** hybrid applications.

30 of these procedures consisted of chemical substance products and **1** procedure consisted of biological other products.

28 of these procedures related to prescription-only medicinal products and **3** of these procedures related to non-prescription medicinal products in the reference Member State².

New applications in Mutual Recognition procedure started in November 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria		12
Belgium		11
Bulgaria		8
Cyprus		3
Czech Republic	1	10
Denmark	4	12
Estonia		3
Finland	1	9
France	1	10
Germany	1	17
Greece		7
Hungary		9
Iceland		4
Ireland	1	11
Italy		12
Latvia		2
Lithuania		3
Luxembourg		6
Malta		
Netherlands	8	14
Norway		7
Poland		17
Portugal	3	13
Romania		11
Slovak Republic		10
Slovenia		5
Spain	1	14
Sweden	5	16
United Kingdom	5	14

Decentralised Procedure1

The CMDh noted that there were **95** Decentralised procedures finalised with a positive outcome and **no** procedures finalised with a negative outcome. **2** Decentralised procedures were withdrawn after day 120. **No** Decentralised procedure was referred to the CMDh in this period. There were **no** Decentralised procedures referred to the CHMP in this period.

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.

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The status as of 30th November 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 CMDh	Agreement reached in the CMDh		Withdrawn during CMDh referral	Referred to CHMP	
					For procedures referred in 2008	2009		For procedures referred to CMDh in 2008	2009
2009	1109	21	1685	18	8	8	1	1	7

100 Decentralised Procedures (regarding **220** products) started in November 2009. The categories of these procedures are as follows:

- **92** abridged applications, including **26** multiple applications.
- **4** known active substance applications, including **1** multiple application.
- **3** line extension applications.
- **1** new active substance application (multiple application).

The new Decentralised procedures started in November related to **79** generic, **3** full dossier, **1** fixed combination, **4** bibliographic and **13** hybrid.

97 of these procedures consisted of chemical substance applications, **1** procedure consisted of biological blood product and **2** procedures consisted of a biological vaccine product.

85 of these procedures related to prescription-only medicinal products and **15** procedures related to non-prescription medicinal products in the reference Member State⁴.

New applications in Decentralised procedure started in November 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	16	40
Belgium		32
Bulgaria		18
Cyprus		6
Czech Republic		34
Denmark	6	31
Estonia		18
Finland		31
France		28
Germany	22	54
Greece		14
Hungary		30
Iceland		4
Ireland		23
Italy	2	35
Latvia		19
Lithuania		24
Luxembourg		24
Malta	1	5
Netherlands	13	38
Norway		23
Poland	4	38
Portugal	3	25

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.

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.

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Romania		22
Slovak Republic	1	30
Slovenia		10
Spain		30
Sweden	4	28
United Kingdom	28	45

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMDh noted that **522** type IA variations, **328** type IB variations and **239** type II variations were finalised during the month of November 2009. **50** renewals were finalised in this period. There was **1** procedure referred to the CHMP in this period.

The status as of 30th November 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	6387	3343	2742	512	6

All documents mentioned in this press release can be found at the CMDh website under the heading *Press Releases*.

Information on the above mentioned issues can be obtained from the chair of the CMDh or from the CMDh Secretariat:

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*Or you could visit the **CMDh website** at:*

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