

Report from the CMDh meeting held on 19th, 20th and 21st July 2010

List of medicinal products for SmPC harmonisation – Consultation with Interested Parties

The CMDh has agreed on a new list of medicinal products for which a harmonised SmPC should be drawn up, in accordance with Article 30(2) of Directive 2001/83/EC, as amended.

The list of medicinal products for SmPC harmonisation will be published on the website for an eight week period for public consultation.

Any comments on the list of medicinal products for SPC harmonisation should be sent to the CMDh secretariat (H-CMDhSecretariat@ema.europa.eu) by **Monday, 20 September 2010**, coordinated where possible by trade associations.

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

The CMDh has adopted revised versions of Chapter 1, 5 and 8 of the CMDh Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedure.

The CMDh has also agreed on new Questions & Answers on variations.

Questions & Answers and Best Practices Guides will be published on the CMDh website under “Procedural Guidance, Variation”.

The CMDh has agreed on further recommendations for classification of unforeseen variations. The recommendation will be published on the CMDh website under “Procedural Guidance, Variation, Article 5 recommendations”.

EU Work-sharing Articles 45 & 46 of the Paediatric Regulation – Public Assessment Reports

The CMDh has agreed on public assessment reports for paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation for amoxicillin, amoxicillin & clavulanic acid, propofol, mirtazapine, canis familiaris/felis domesticus (dog and cat hair allergen) and phleum pratense (grass allergen) including recommendations for the text to be included in SmPCs and package leaflets. The public assessment reports will be published on the CMDh website, under “Paediatric Regulation, Assessment reports”.

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

The CMDh has also agreed on a public assessment report for paediatric studies submitted in accordance with Article 46 of the Paediatric Regulation for Agopton and associated names (lansoprazole) and Famvir and associated names (famciclovir).

CMDh/EMA Sub-Group on Paediatric Regulation

The CMDh has agreed an updated Best Practice Guides on work-sharing procedures according to the Article 45 of Regulation (EC) No 1901/2006 and revised “Recommendations for implementing Commission Decisions following and Article 29 application under Regulation (EC) No 1901/2006” that have been aligned with variation regulation (EC) No 1234/2008 on variations.

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Both documents will be published on the CMDh website under “Paediatric regulation, Guidance documents”.

Camphor containing ointments and risk of unintended oral ingestion

The CMDh has endorsed the PhVWP report on ointments containing 400 mg and over of camphor per package and the risk of unintended oral ingestion and recommends the implementation of the PhVWP wording for the SmPC and PL for all ointments containing 400 mg and over of camphor.

The following timetable has been agreed by the CMDh and PhVWP for implementation of agreed SmPC and PL changes:

1 September 2010	Variation applications requested through CMDh
1 October 2010	Variation applications submitted by MA holders
1 November 2010	Variation applications approved by RMS

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

Isotretinoin for oral use and the risk of erythema multiforme, Stevens Johnson syndrome and toxic epidermal necrolysis – update of previous information

The CMDh has endorsed the PhVWP report on isotretinoin and the risk of erythema multiform and recommends the implementation of the PhVWP wording for the SmPC and PL for all isotretinoin containing products.

The following timetable has been agreed by the CMDh and PhVWP for implementation of agreed SmPC and PL changes:

1 September 2010	Variation applications requested through CMDh
1 October 2010	Variation applications submitted by MA holders
1 November 2010	Variation applications approved by RMS

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

Statistical information

The CMDh has agreed to publish statistical information on:

- MRP and DCP finalised and started in the first two quarters of 2010;
- the implementation of Regulation (EC) No 1234/2008 on variations;
- applications referred/concluded by the CMD(h) in the first semester of 2009, addressing referrals to CMDh.

This information will be published on the CMDh website under ‘Statistics’.

Template for validation of application for marketing authorization

The CMDh has adopted a template to be used by CMS (during validation in Mutual Recognition or Repeat Use MR procedure) or by RMS and CMS (during validation in DCP) to collect validation issues raised by Member States and to provide the applicants with clear guidance on whether or not these issues will prevent the procedure from starting and on deadlines for resolution of the pending issues.

Change in the EU-Presidency

The July 2010 CMDh meeting was the first one under the Belgian Presidency of the Council of the European Union. Belgium has taken over the presidency on 1st July 2010. Mrs Sophie Colyn is the Vice-Chairperson of the CMDh, for the Belgian Presidency of the Council of the European Union.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMDh noted that **42** Mutual Recognition Procedures were finalised during the month of June 2010. **No** Mutual Recognition Procedure was referred to CMDh in this period. **No** Mutual Recognition Procedures were referred to CHMP in this period.

The status as of 30th June 2010 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 2009	2010		For procedures referred to CMDh in 2009	2010
2010	149	78	6	2	3	0	0	2

14 Mutual Recognition Procedures (regarding **31** products) started in June 2010. The categories of these procedures are as follows:

- **6** abridged applications.
- **6** known active substance applications, including **3** repeat use applications.
- **2** line extension.

The new procedures started in June 2010 related to **2** full dossier, **8** generic, **3** bibliographic, **1** fixed combination.

12 of these procedures consisted of chemical substance products and **2** procedures 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.'

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

New applications in Mutual Recognition procedure started in June 2010.

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

Decentralised Procedure

The CMDh noted that there were **135** Decentralised procedures finalised with a positive outcome. There were **3** Decentralised Procedures with negative outcome and **1** procedure withdrawn after day 120. **No** Decentralised Procedure was referred to the CMDh in this period. **No** Decentralised procedures were referred to the CHMP in this period.

The status as of 30th June 2010 of procedures under Decentralised Procedure is as follows:

Year	New applications finalised ³	New applications withdrawn ³ (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 2009	2010		For procedures referred to CMDh in 2009	2010
2010	664	32	1685	2	0	0	1	1	0

92 Decentralised Procedures (regarding **224** products) started in June 2010. The categories of these procedures are as follows:

- **74** abridged applications, including **22** multiple applications.
- **16** known active substance applications, including **5** 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. For finalised procedures, this cumulative figure includes positive and negative procedures as well as those referred to CHMP.

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- **1** line extension applications.

- **1** new active substance applications.

The new Decentralised Procedures started in June 2010 related to **61** generic, **4** full dossier, **4** fixed combination, **2** informed consent, **10** bibliographic and **11** other generic.

90 procedures consisted of chemical substance applications, **1** consisted of biological blood product application and **1** consisted of Herbal application.

75 of these procedures related to prescription-only medicinal products and **17** procedures related to non-prescription medicinal products in the reference Member State⁴.

New applications in Decentralised procedure started in June 2010.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria		31
Belgium	1	28
Bulgaria		24
Cyprus		19
Czech Republic		29
Denmark	9	27
Estonia		23
Finland		27
France	4	27
Germany	13	35
Greece		23
Hungary		26
Iceland	2	10
Ireland		28
Italy		34
Latvia		20
Liechtenstein		1
Lithuania		24
Luxembourg		26
Malta		12
Netherlands	15	26
Norway		24
Poland		43
Portugal	3	30
Romania		29
Slovak Republic	1	28
Slovenia	6	17
Spain		38
Sweden	6	25
United Kingdom	32	14

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMDh noted that **220** type IA variations, **318** type IB variations and **218** type II variations were finalised during the month of June 2010. **70** renewals were finalised in this period. There were **no** 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.

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The status as of 30th June 2010 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
2010	1464	1729	1525	371	0

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>