

## **Report from the CMDh meeting held on 13<sup>th</sup>, 14<sup>th</sup> and 15<sup>th</sup> December 2010**

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

The CMDh would like to inform Marketing Authorisation Holders that although some Member States already apply the variation classification guideline (Guideline on the operation of the procedures laid down in Chapters II, III and IV of Commission Regulation (EC) No 1234/2008) to medicinal products registered through national procedures, it will not be possible to include these national products in variation worksharing procedures until the scope of Regulation (EC) No 1234/2008 is extended to include products authorised through national route.

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

### **Assessment of Detailed Description of Pharmacovigilance System during MRP/DCP**

The CMDh would like to inform the applicants that in order to avoid the assessment by RMS of DDPSs already approved by other competent authorities, as of **1<sup>st</sup> February 2011** the applicants will be asked to submit the information regarding previous assessments together with the DDPS, using a Declaration Form that should be annexed to the application form.

The “Declaration Form for the submission of DDPS already approved by a competent authority” to be used by applicants will be published on the CMDh website under “Procedural Guidance, Application for MA”.

### **CMDh/EMA Sub-Group on Paediatric Regulation**

The CMDh has agreed a list of active substances for the tenth wave of the worksharing 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 February 2011).

The list of active substances included in the tenth wave of the Article 45 work-sharing procedure will be published on the CMDh website.

The CMDh has revised the “List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation” in order to include information on which parts of the SmPC are impacted by the outcome of the worksharing procedures.

The updated list will be published on the CMDh website under Paediatric Regulation, Article 45 and previous worksharing”.

### **Treaty between Liechtenstein and Austria allowing automatic recognition by Liechtenstein of Marketing Authorisations granted by Austria**

The Treaty between Liechtenstein and Austria about automatic recognition of the Marketing Authorisations granted via MRP or DCP has entered into force on 1st Dec 2010.

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This allows Liechtenstein to use Marketing Authorisations granted by Austria **provided the applicants have identified Liechtenstein as CMS in the application form** submitted with MRP or DCP applications. At the end of the procedures, Austria will grant authorisations that will be recognised by Liechtenstein.

## **Risk of psychiatric adverse drug reactions to inhaled and intranasal corticosteroids and risk of non-psychiatric systemic adverse drugs reactions to intranasal corticosteroids**

The CMDh has endorsed the PhVWP report on the risk of psychiatric adverse drug reactions to inhaled and intranasal corticosteroids (beclomethasone, betamethasone, budesonide, ciclesonide, dexamethasone, flunisolide, fluticasone, mometasone, prednisolone, tixocortol, triamcinolone), and the risk of non-psychiatric systemic adverse drugs reactions to intranasal corticosteroids. The CMDh recommends the implementation of the PhVWP wording for the SmPC and PL for all products containing the concerned corticosteroids.

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

<b>18 February 2011</b>	Variation applications requested through CMDh
<b>18 April 2011</b>	Variation applications submitted by MA holders
<b>15 October 2011</b>	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”.

## **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 remifentanyl, metronidazole, metronidazole + spiramycin, mepivacaine, honey bee venom and vespula venom, 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 public assessment reports for paediatric studies submitted in accordance with Article 46 of the Paediatric Regulation for Adartrel (ropinirole), Seretide Diskus/Seretide Eudraler and associated names (salmeterol xinafoate + fluticasone propionate), Nexium (esomeprazole) and Aricept (donepezil/donepezil hydrochloride).

## **EU Work sharing Project – Assessment of paediatric data**

The CMDh has agreed to publish the paediatric public assessment report from the previous paediatric worksharing (before the entry into force of Regulation (EC) No 1901/2006) the procedure for Cozaar (losartan) will be made available on the CMDh website, under “Paediatric regulation, Assessment reports, Previous worksharing project”.

## **Data requested for Variations and/or Renewal Applications in the MRP/DCP**

For transparency reason, the CMDh has agreed to publish the list of data requested for variations and/or renewal applications in the MRP/DCP which are not stated in the current EU legislation and/or in Volume

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2B, Presentation and format of the dossier Common Technical Document (CTD) and/or in the EEA approved guidelines/ recommendation papers.

The new document will be published on the CMDh website under “Procedural Guidance, Variation”.

## Revised CMDh procedural advice on common grounds seen for invalidation/delaying day 0 for variations

The CMDh has updated its procedural advice on validation issues/national requirements and common ground for invalidation/delaying day 0 for variations to reflect the experience gained with implementation of Regulation (EC) No 1234/2008.

The revised document will be published on the CMDh website under “Procedural Guidance, Variation”.

## Information on applications referred to the CMDh 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 CMDh, Day 60 and outcome of the procedure, for the referrals to the CMDh finalised on 25.11.2010 will be available on the table with information on all applications referred to the CMDh, published under “CMDh-Referrals”.

## Change in the EU-Presidency

The December 2010 CMDh meeting was the last one under the Belgian Presidency of the Council of the European Union. Hungary will take over the Presidency in January 2011. Mrs. Katalin Varsanyi will be the Vice-Chairperson of the CMDh, for the Hungarian Presidency of the Council of the European Union.

## NEW APPLICATIONS

### Mutual Recognition Procedure

The CMDh noted that **19** Mutual Recognition Procedures were finalised during the month of November 2010. **No** Mutual Recognition Procedure was referred to CMDh in this period. **1** Mutual Recognition Procedure was referred to CHMP in this period.

The status as of 30<sup>th</sup> November 2010 of procedures under Mutual Recognition is as follows:

Year	New applications finalised <sup>1</sup>	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	<b>284</b>	<b>51</b>	<b>10</b>	<b>2</b>	<b>5</b>	<b>0</b>	<b>0</b>	<b>5</b>

**21** Mutual Recognition Procedures (regarding **40** products) started in November 2010. The categories of these procedures are as follows:

- **11** abridged applications, including **7** abridged repeat use applications.

<sup>1</sup> 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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- **9** known active substance applications, including **7** repeat use applications.
- **1** New Active Substance applications.

The new procedures started in November 2010 related to **6** full dossiers, **11** generic and **4** Bibliographic.

**19** of these procedures consisted of chemical substance products.

**19** of these procedures related to prescription-only medicinal products and **2** procedures related to non-prescription medicinal products in the reference Member State<sup>2</sup>.

New applications in Mutual Recognition procedure started in November 2010.

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

## **Decentralised Procedure**

The CMDh noted that there were **112** Decentralised procedures finalised with a positive outcome. **4** Decentralised procedures were withdrawn after day 120 in this period. **1** Decentralised Procedure was referred to the CMDh in this period. **No** Decentralised procedures were referred to the CHMP in this period.

<sup>2</sup> 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 30<sup>th</sup> November 2010 of procedures under Decentralised Procedure is as follows:

Year	New applications finalised <sup>3</sup>	New applications withdrawn <sup>3</sup> (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	<b>1245</b>	<b>53</b>	<b>1881</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>1</b>

**220** Decentralised Procedures (regarding **553** products) started in November 2010. The categories of these procedures are as follows:

- **198** abridged applications, including **58** multiple applications.
- **17** known active substance applications.
- **4** Line extension applications.
- **1** New Active Substance applications.

The new Decentralised Procedures started in November 2010 related to **189** generics, **17** bibliographic, **2** informed consent, **1** full dossier and **11** hybrid.

All procedures consisted of chemical substance applications.

**210** of these procedures related to prescription-only medicinal products and **10** procedures related to non-prescription medicinal products in the reference Member State<sup>4</sup>.

New applications in Decentralised procedure started in November 2010.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	3	42
Belgium	3	31
Bulgaria		36
Cyprus		14
Czech Republic	6	51
Denmark	20	25
Estonia	2	23
Finland	1	27
France	1	33
Germany	47	78
Greece		25
Hungary		48
Iceland		10
Ireland		24
Italy		58
Latvia		22
Liechtenstein		
Lithuania		29
Luxembourg		34
Malta	5	13
Netherlands	63	31
Norway		18
Poland	2	76
Portugal	21	35
Romania		56
Slovak Republic		50
Slovenia		18
Spain	2	61
Sweden	11	26
United Kingdom	33	45

<sup>3</sup> 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.

<sup>4</sup> 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.

## **VARIATIONS AND RENEWALS**

### **Mutual Recognition and Decentralised Procedures**

The CMDh noted that **592** type IA variations, **390** type IB variations and **89** type II variations were finalised during the months of November 2010. **69** renewals were finalised in this period. There were **no** procedures referred to the CHMP in this period.

The status as of 30<sup>th</sup> November 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	2764	3560	2261	679	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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**<http://www.hma.eu/cmdh.html>**