

## **Report from the CMDh meeting held on 15<sup>th</sup> and 16<sup>th</sup> February 2010**

### **Information on national timeslot booking systems for Decentralised Procedures**

As discussed at the HMA Taskforce on Resources meeting and in order to make timeslot booking more transparent for Applicants, Member States agreed to provide a summary of national booking systems and policy for publication on the CMDh website. The table currently published under “Procedural Guidance, Application for MA, DCP” and containing links to NCA webpages will be updated with the summaries.

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

The CMDh has agreed on further Questions & Answers that will be published on the CMDh website to answer general questions in relation with the implementation of Regulation (EC) No 1234/2008.

### **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 Gentamicin and Amikacin including recommendations for the text to be included in the SmPC. The Public Assessment Reports will be published on the CMDh 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.

### **New Q &As on suspensions of marketing authorisation following a referral according to Article 29(4) of Directive 2001/83/EC**

The CMDh has agreed three Q & As regarding suspensions of marketing authorisations following a referral according to Article 29(4) of Directive 2001/83/EC addressing actions that can possibly be undertaken by applicants. These Q&As will be published on the CMDh website under “Questions and Answers, Post-referral phase”.

## **NEW APPLICATIONS**

### **Mutual Recognition Procedure**

The CMDh noted that **5** Mutual Recognition Procedures were finalised during the month of January 2010. **No** Mutual Recognition Procedure was referred to CMDh in this period. **No** Mutual Recognition Procedure was referred to CHMP in this period.

The status as of 31<sup>st</sup> January 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	5	70	0	1	0	0	0	

**19** Mutual Recognition Procedures (regarding **37** products) started in January 2010. The categories of these procedures are as follows:

- **11** abridged applications, including **8** repeat use applications.
- **7** known active substance applications.
- **1** line extension application which is a repeat-use application.

The new procedures started in January 2010 related to **5** full dossier, **11** generic, **2** bibliographic and **1** hybrid applications.

**18** of these procedures consisted of chemical substance products and **1** procedure consisted of a biological (blood) product.

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<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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**18** of these procedures related to prescription-only medicinal products and **1** procedure related to a non-prescription medicinal product in the reference Member State<sup>2</sup>.

New applications in Mutual Recognition procedure started in January 2010.

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

### **Decentralised Procedure**

The CMDh noted that there were **92** Decentralised procedures finalised with a positive outcome and **2** procedures were finalised with a negative outcome. **1** Decentralised Procedure was withdrawn after day 120. **No** Decentralised Procedure was referred to the CMDh in this period. **No** Decentralised procedure was referred to the CHMP in this period.

The status as of 31<sup>st</sup> January 2010 of procedures under Decentralised Procedure is as follows:

Year	New applications finalised <sup>3</sup>	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 2009	2010		For procedures referred to CMDh in 2009	2010
2010	94	1	1708	0	0	0	0	0	0

**110** Decentralised Procedures (regarding **209** products) started in January 2010. The categories of these procedures are as follows:

- **97** abridged applications, including **22** multiple applications.

<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.

<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. This cumulative figure includes positive and negative procedures as well as those referred to CHMP.

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- **9** known active substance applications, including 4 multiple applications.
- **3** line extension applications.
- **1** new active substance application.

The new Decentralised Procedures started in January 2010 related to **82** generic, **4** full dossier, **4** fixed combination, **3** bibliographic, **2** informed consent and **15** hybrid applications.

**110** of these procedures consisted of chemical substance applications.

**105** of these procedures related to prescription-only medicinal products and **5** procedures related to non-prescription medicinal products in the reference Member State<sup>4</sup>.

New applications in Decentralised procedure started in January 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	4	27
Belgium		28
Bulgaria		18
Cyprus		11
Czech Republic		27
Denmark	7	23
Estonia	1	15
Finland	2	30
France		36
Germany	25	46
Greece		17
Hungary		27
Iceland	1	12
Ireland	6	25
Italy		37
Latvia		15
Lithuania		15
Luxembourg		22
Malta	7	7
Netherlands	17	35
Norway	1	16
Poland		33
Portugal	2	35
Romania	3	27
Slovak Republic		27
Slovenia		14
Spain		41
Sweden	12	21
United Kingdom	22	23

## **VARIATIONS AND RENEWALS**

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

The CMDh noted that **403** type IA variations, **247** type IB variations and **251** type II variations were finalised during the month of January 2010. **46** renewals were finalised in this period. There was **no** procedure referred to the CHMP in this period.

<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.

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The status as of 31<sup>st</sup> January 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	403	247	251	46	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>