

## **Report from the CMDh meeting held on 20<sup>th</sup>, 21<sup>st</sup> and 22<sup>nd</sup> September 2010**

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

The CMDh has agreed on new Question & Answer on variations. It 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”.

The CMDh has adopted a new timetable for requests for classification of unforeseen variations in 2011 as well as a new version of the template for recommendations following requests for classification of unforeseen variations.

Both documents will be published on the CMDh website under “Procedural Guidance, Variation, Article 5 recommendations” and under “Templates, Variations” respectively.

### **EU Work-sharing Article 45 of the Paediatric Regulation - Public Assessment Report**

The CMDh has endorsed public assessment reports for paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation for famciclovir, triptorelin, chondroitin sulfate, risedronate sodium and oxybutynin hydrochloride. The paediatric public assessment reports include recommendations for the text to be included in the SmPCs and package leaflets. They will be published on the CMDh website, under “Paediatric Regulation, Assessment reports”.

Marketing Authorisation Holders of medicinal products with the 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 Work-sharing procedure.

The CMDh has agreed a list of active substances for the 9<sup>th</sup> 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 (October 2010).

The list of active substances included in the 9<sup>th</sup> wave of the Article 45 work-sharing procedure will be published on the CMDh website.

### **Famvir – Implementation of the outcome of Article 30 referral procedure**

Following the Art.30 referral procedure for Famvir and associated names, it has been concluded that the 750 mg tablet strength is not any longer in line with the harmonised posology and was therefore de-registered.

In line with the agreed principles between CMDh and the pharmaceutical trade associations, concerned generic companies are requested to submit within 90 days a type IB variation (C.I.7.b), if applicable, or the corresponding national procedure to de-register their 750 mg strength accordingly and to keep the generic medicinal products in line with the reference medicinal product.

**Electronic submissions**

The CMDh would like to inform applicants and marketing authorisation holders that any question on e-CTD submissions or any comment on the Best Practice Guide on the use of eCTD in MRP/DCP, should be sent to the following email address: [eCTD@ema.europa.eu](mailto:eCTD@ema.europa.eu).

**Meeting between the EMEA/CMDh subgroup on Paediatric Regulation and Interested Parties**

The EMEA/CMDh subgroup met with Interested Parties on Monday 20 September 2010 to discuss their experiences with the implementation of Articles 29, 45 and 46 of the paediatric regulation.

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

The CMDh has adopted an updated guidance document with the timetables for MRP/DCP applications referred to the CMDh for the 60-days referral procedure for 2011. The updated guidance document will be published on the CMDh website under CMDh referrals.

**Revised CMDh procedural advice on validation issues/national requirements and common ground for invalidation**

The CMDh has updated its procedural advice on validation issues/national requirements and common ground for invalidation to reflect the latest discussions of the coordination group. The revised document will be published on the CMDh website under “Procedural Guidance, application for MA”.

**Revised CMDh recommendations on informed consent applications in mutual recognition and decentralised procedures.**

The CMDh has adopted a revised version of its recommendations on informed consent applications to give further guidance to the applicant regarding the authorisation route to be followed. The revised document will be published on the CMDh website under “Procedural Guidance, application for MA”.

**Revised template for Day 70 Quality Assessment Reports and creation of a template for Active Substance Master File Assessment Reports**

The CMDh has adopted a revised template for Day 70 Quality Assessment Reports and a new template for ASMF Assessment Reports so that the ASMF assessment is reflected in a stand alone document rather than being part of the general quality assessment report. The templates will be published on the website, under “Templates, assessment reports”.

**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 29.07.2010 will be available on the table with information on all applications referred to the CMDh, published under “CMDh-Referrals”.

**NEW APPLICATIONS**

**Mutual Recognition Procedure**

The CMDh noted that **73** Mutual Recognition Procedures were finalised during the months of July and August 2010. **2** 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 31<sup>st</sup> August 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			For procedures referred to CMDh in	
				2009	2010	2009	2010	
2010	<b>224</b>	<b>58</b>	<b>8</b>	<b>2</b>	<b>3</b>	<b>0</b>	<b>3</b>	

**46** Mutual Recognition Procedures (regarding **88** products) started in July and August 2010. The categories of these procedures are as follows:

- **32** abridged applications.
- **12** known active substance applications, including **4** repeat use applications.
- **1** line extension.
- **1** new active substance.

The new procedures started in July and August 2010 related to **9** full dossier, **31** generic, **4** bibliographic, **1** fixed combination and **1** other generic.

**45** 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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42 of these procedures related to prescription-only medicinal products and 4 procedures related to non-prescription medicinal products in the reference Member State<sup>2</sup>.

New applications in Mutual Recognition procedure started in July and August 2010.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria		11
Belgium		13
Bulgaria		13
Cyprus		10
Czech Republic	1	11
Denmark	4	11
Estonia		6
Finland	1	8
France	5	4
Germany	11	10
Greece		12
Hungary		13
Iceland		5
Ireland		9
Italy		10
Latvia	1	9
Liechtenstein		
Lithuania		8
Luxembourg		11
Malta		7
Netherlands	5	6
Norway		10
Poland		12
Portugal	4	15
Romania		8
Slovak Republic		10
Slovenia		10
Spain		12
Sweden	3	14
United Kingdom	11	5

## **Decentralised Procedure**

The CMDh noted that there were 72 Decentralised procedures finalised with a positive outcome. There was 1 Decentralised Procedure with negative outcome. There were 13 Decentralised Procedures withdrawn after day 120. No Decentralised Procedure was referred to the CMDh in this period. 1 Decentralised procedure was referred to the CHMP in this period.

The status as of 31<sup>st</sup> August 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	885	46	1820	0	0	0	1	1	1

345 Decentralised Procedures (regarding 674 products) started in July and August 2010. The categories of these procedures are as follows:

<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. For finalised procedures, this cumulative figure includes positive and negative procedures as well as those referred to CHMP.

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- **317** abridged applications, including **92** multiple applications.
- **16** known active substance applications, including **0** multiple applications.
- **12** line extension applications.

The new Decentralised Procedures started in July and August 2010 related to **279** generic, **12** full dossier, **4** fixed combination, **5** bibliographic and **45** other generic.

**344** procedures consisted of chemical substance applications, **0** consisted of biological blood product application and **1** consisted of Herbal application.

**330** of these procedures related to prescription-only medicinal products and **15** procedures related to non-prescription medicinal products in the reference Member State<sup>4</sup>.

New applications in Decentralised procedure started in July and August 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	9	61
Belgium	1	66
Bulgaria		53
Cyprus		26
Czech Republic	8	65
Denmark	52	48
Estonia	1	33
Finland		58
France	4	86
Germany	71	132
Greece		52
Hungary	4	65
Iceland	1	15
Ireland	1	57
Italy	2	103
Latvia		36
Liechtenstein		
Lithuania		48
Luxembourg		53
Malta	3	13
Netherlands	49	57
Norway	3	51
Poland		86
Portugal	42	70
Romania	1	68
Slovak Republic	4	66
Slovenia		39
Spain		130
Sweden	7	64
United Kingdom	83	63

## **VARIATIONS AND RENEWALS**

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

The CMDh noted that **572** type IA variations, **714** type IB variations and **350** type II variations were finalised during the months of July and August 2010. **100** renewals were finalised in this period. There were **no** procedures 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> August 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	2036	2443	1875	471	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>