

## Report from the CMD(h) meeting held on 17<sup>th</sup>, 18<sup>th</sup> and 19<sup>th</sup> November 2008

### New three-year term of the Coordination Group for Mutual Recognition and Decentralised Procedures – CMD(h)

The November meeting was the first meeting of the second three-year term for the CMD(h).

Mrs. Truus Janse-de Hoog was re-elected Chairperson of the CMD(h), by an absolute majority of the CMD(h) Members, for a second term of three years.

### Sub-Group on Variation Regulation

The CMD(h) has endorsed the mandate for the Sub-group on Variation Regulation, set up together with the CMD(v) and the EMEA, to take forward the various activities arising from the revision of the Variation Regulation.

The mandate of the Sub-group will be published on the website, under CMD(h) Sub-groups, Variation Regulation.

### CMD(h)/EMEA Sub-Group on Paediatric Regulation

The CMD(h) has finalised the Procedural advice concerning submission of information on paediatric data according to Article 46 of the Paediatric Regulation, including a revised version of the cover letter and line listing, further to the comments received during the consultation procedure.

The final procedural advice will be published on the CMD(h) website.

The CMD(h) would like to recommend Marketing Authorisation Holders within the same Company to combine all national Marketing Authorisation Holders in one line listing indicating in which MS the product is authorised (one line per Member State).

The combined line listing should be submitted to all concerned National Competent Authorities and EMEA with one cover letter only.

The CMD(h) has revised Q&A 12 of the Questions and Answers on the Paediatric Regulation, to clarify that Marketing Authorisation Holders should submit information on the finalised studies only in the cover letter and line listing, as described in the procedural advice concerning submission of information according to Article 46 of the Paediatric Regulation. However, the paediatric data has to be available upon request.

The revised Q&A will be published on the CMD(h) website.

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

The Paediatric public assessment report for Valcyte (valganciclovir) will be made available on the CMD(h) website, under Paediatric data assessment, assessment reports on paediatric data.

### Implementation of Commission Decisions after Article 30 referral procedures

A link to the Commission decisions, including the SPC, package leaflet and labelling of the finalised Article 30 referral procedures for **cetirizine**, **ciprofloxacin**, **gemcitabine**, **losartan**, **losartan/hydrochlorothiazide** and **risperidone** has been published on the CMD(h) website.

Generic Companies are encouraged to contact the Reference Member State to harmonise the product information of the medicinal product authorised via MRP/DCP to conform to the Commission Decision, through submission of a Type IB Variation - 46, provided the conditions set up in the Commission Regulation (EC) No 1084/2003 are met.

#### Core Package Leaflet for Influenza Vaccines

The CMD(h) developed together with European Vaccines Manufacturers a core package leaflet for Influenza Vaccines, which reflects the results of consultation with target patient groups.

The core package leaflet should be implemented for the vaccination season of 2009/2010 and will be published on the CMD(h) website together with the current core SPC for Influenza Vaccines, under product information.

#### Oxycodone containing medicinal products – Labelling and Package leaflet warning – Taking alcohol

The CMD(h) has agreed to request Marketing Authorisation Holders of oxycodone containing medicinal products to include the following labelling warning and a corresponding warning relevant to the individual product in the package leaflet:

##### **Oxycodone labelling**

“WARNING – TAKING ALCOHOL

*Do not take these tablets/capsules with alcohol”*

##### **Oxycodone package leaflet**

*“These tablets/capsules should not be taken with alcohol. Alcohol use could increase serious side-effects of oxycodone, such as sleepiness and drowsiness and slow and shallow breathing. These tablets/capsules are designed to release a strong painkiller slowly over 12 hours. Alcohol may speed up the release of oxycodone from the tablet/capsule and this might result in increased side-effects.*

*Tablets/capsules should be avoided in patients with a history of or present alcohol and drug abuse.”*

#### Reference medicinal products for bioequivalence studies

Applicants are reminded that a medicinal product to be used as a reference in a bioequivalence study conducted in support of a generic/hybrid application must be a version of the original medicinal product that is authorised within the Community. Bioequivalence studies performed with a product not authorised within the EEA will not be considered acceptable.

#### CMD(h) Best Practice Guide on the use of eCTD in the mutual recognition and decentralised procedures

The CMD(h) would like to remind Interested Parties that it is still possible to send comment on the above mentioned best practice guide, published on the CMD(h) website in April 2008 for a consultation period until the end of 2008.

The aim of the BPG is to facilitate and encourage the use of eCTD as the submission format in the MRP and DCP.

Any comments should be sent to the attention of the CMD(h) Secretariat ([H-CMDhSecretariat@emea.europa.eu](mailto:H-CMDhSecretariat@emea.europa.eu)) until the end of 2008.

#### Implementation of Sunset Clause provision & Changes of Reference Member State

Marketing Authorisation Holders are requested to use, where possible, the same Reference Member State for multiple marketing authorisations, including the various strengths and pharmaceutical forms, in case of changes of Reference Member State, due to the implementation of the sunset clause provision in the original Reference Member State.

Please consider on this regard the CMD(h) position on changing the reference member state.

#### Joint DIA-EMEA-CMD(h) Workshop on User Testing, 5 December 2008, London, UK

A joint DIA-EMEA-CMD(h) Workshop on User Testing, aimed at discussing EMEA and MSs experience in the assessment of user tests and give recommendations how the test can contribute to improve the quality of a package leaflet will be held in London on 5 December 2008.

Information on applications referred to the CMD(h) 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 CMD(h), Day 60 and outcome of the procedure, for the referrals to the CMD(h) finalised on 30.10.2008 will be available on the table with information on all applications referred to the CMD(h), published under 'CMD(h)-Referrals'.

**NEW APPLICATIONS**

**Mutual Recognition Procedure**

The CMD(h) noted that **74** Mutual Recognition Procedures were finalised during the month of October 2008. **1** Mutual Recognition Procedures was referred to CMD(h) in this period. There were **6** Mutual Recognition Procedures referred to CHMP in this period.

The status as of 31<sup>st</sup> October 2008 of procedures under Mutual Recognition is as follows:

Year	New applications finalised <sup>1</sup>	New applications in process	Referred to CMD(h)	Agreement reached in the CMD(h)		Withdrawn during CMD(h) referral	Applications referred to CHMP	
				For procedures referred in 2007	2008		For procedures referred to CMD(h) in 2007	2008
2008	406	70	37	7	25	1	2	9

**22** Mutual Recognition Procedures (regarding **39** products) started in October 2008. The categories of these procedures are as follows:

**15** abridged applications, including **1** multiple and **6** repeat use applications.

**7** known active substance applications, including **2** repeat use applications.

The new procedures started in October 2008 related to **5** full dossier, **14** generic, **2** bibliographic and **1** hybrid application.

**21** of these procedures consisted of chemical substance products and **1** biological other product.

---

<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.'

**21** 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>.

Number of countries involved in the new applications in Mutual Recognition procedure started in October 2008.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
CZ (1)	3
CZ (1)	5
DK (2)	1
DK (2)	1
DK (1)	5
DK (3)	1
ES (1)	6
FI (2)	9
FI (2)	5
FR (1)	8
NL (2)	16
NL (1)	12
PT (1)	8
PT (4)	1
PT (1)	11
PT (1)	10
SE (2)	2
SE (2)	5
UK (1)	11
UK (2)	16
UK (4)	4
UK (2)	14

### **Decentralised Procedure**

The CMD(h) noted that there were **83** Decentralised Procedures finalised with a positive outcome and **1** with negative outcome during the month of October 2008. **7** Decentralised Procedures were referred to the CMD(h) in this period. There were **2** Decentralised Procedures referred to the CHMP in this period.

The status as of 31<sup>st</sup> October 2008 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 CMD(h)	Agreement reached in the CMD(h)		Withdrawn during CMD(h) referral	Referred to CHMP	
					For procedures referred in 2007	2008		For procedures referred to CMD(h) in 2007	2008
2008	672	7	1525	37	2	22	1	2	3

**123** Decentralised Procedures (regarding **252** products) started in October 2008. The categories of these procedures are as follows:

**112** abridged applications, including **34** multiple applications.

**2** known active substance applications.

**5** line extension applications, including **3** multiple applications.

**4** applications for a new active substance.

<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.

The new Decentralised procedures started in October related to **113** generic, **1** bibliographic, **4** hybrid and **5** full dossier.

**122** of these procedures consisted of chemical substance applications and **1** procedure consisted of a homeopathic substance application.

**122** 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>4</sup>.

Number of countries involved in the new applications in Decentralised procedures started in October 2008.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (1)	8
AT (1)	2
CZ (3)	7
DE (4)	4
DE (1)	3
DE (1)	10
DE (1)	10
DE (1)	1
DE (2)	6
DE (12)	4
DE (4)	1
DE (2)	1
DE (1)	7
DE (1)	9
DE (1)	24
DE (1)	2
DE (1)	1
DE (1)	11
DE (4)	1
DE (4)	1
DE (4)	2
DE (4)	1
DE (2)	5
DE (2)	4
DE (2)	20
DE (1)	5
DE (1)	4
DE (1)	1
DE (1)	3
DE (1)	1
DE (4)	4
DE (3)	1
DE (3)	2
DE (3)	1
DE (3)	1
DE (1)	2
DE (2)	12
DE (2)	4
DE (2)	1
DE (4)	7
DE (4)	4
DE (4)	1
DE (1)	13
DE (1)	1
DE (1)	3
DK (1)	9
DK (2)	6
DK (1)	9
DK (3)	9
HU (1)	4

---

<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.

HU (1)	7
HU (1)	1
NL (2)	7
NL (2)	7
NL (1)	18
NL (1)	1
NL (1)	1
NL (1)	2
NL (4)	12
NL (4)	1
NL (4)	22
NL (3)	1
NL (4)	3
NL (4)	1
NL (3)	1
NL (4)	5
NL (3)	21
NL (3)	1
NL (3)	1
NL (3)	1
NL (3)	1
NL (3)	2
NL (1)	6
NL (1)	2
NL (1)	3
NL (1)	4
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	2
NL (1)	3
NL (3)	4
NL (3)	2
NL (3)	2
NL (3)	14
NL (3)	1
NO (3)	3
PL (1)	4
PL (1)	3
PL (1)	9
PL (1)	8
PT (3)	8
PT (3)	6
SE (1)	15
SE (4)	14
SE (3)	13
SI (1)	8
SI (1)	1
SI (1)	4
UK (1)	6
UK (2)	15
UK (2)	14
UK (2)	7
UK (2)	5
UK (1)	7
UK (2)	2
UK (1)	1
UK (1)	1
UK (1)	23
UK (1)	8
UK (1)	6
UK (1)	4
UK (2)	9
UK (1)	1
UK (1)	6
UK (2)	14
UK (2)	4

UK (1)	1
UK (1)	4
UK (3)	23
UK (1)	10
UK (1)	5
UK (1)	6

## **VARIATIONS AND RENEWALS**

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

The CMD(h) noted that **534** type IA variations, **245** type IB variations and **229** type II variations were finalised during the month of October 2008. **39** renewals were finalised in this period. There were **no** procedures referred to the CHMP in this period.

The status as of 31<sup>st</sup> October 2008 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
2008	5587	2276	2329	383	2

**All documents mentioned in this press release can be found at the CMD(h) website under the heading *Press Releases*.**

*Information on the above mentioned issues can be obtained from the chair of the CMD(h) or from the CMD(h) Secretariat:*

*Mrs. Truus Janse-de Hoog  
College ter Beoordeling van Geneesmiddelen  
Kalvermarkt 53  
NL – 2500 Den Haag , The Netherlands  
CMD(h) Secretariat*

*Phone: + 31 70 356 74 08*

*Fax: + 31 70 356 75 15*

*E-mail: [gm.janse@cbg-meb.nl](mailto:gm.janse@cbg-meb.nl)*

*E-mail:*

*[H-CMDhSecretariat@emea.europa.eu](mailto:H-CMDhSecretariat@emea.europa.eu)*

*Or you could visit the **CMD(h) web site** at:*

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