

Report from the CMD(h) meeting held on 15th and 16th December 2008

Requirements on electronic submissions for Renewals and Variations within MRP, DCP or national procedures

Further to the work carried out by the Working Group on Validation issues/National requirements, the CMD(h) has agreed to publish on the website a table listing the number of electronic copies requested by each National Competent Authority for renewals and variations within MRP, DCP or national procedures.

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

The CMD(h) has agreed a list of active substances for the second 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 (i.e. by mid of February 2009).

The list of active substances included in the second wave of the Article 45 work-sharing procedure will be published on the CMD(h) website, with the report from the January 2009 CMD(h) meeting.

CMD(h) meeting with representatives of Interested Parties

The CMD(h) held a meeting on 16 December 2008 with representatives of AESGP, EFPIA and EGA.

The topics discussed included Member States' resources in the Mutual Recognition and Decentralised Procedures & CMD(h) contribution to the Task force on resources, a report on the status of the on-going Article 45 and 46 work-sharing procedures, electronic submissions and information on the Variation Regulation Sub-group & overview of documents to be developed/revised.

A report from the meeting will be published on the website, for transparency reasons.

Angiotensin Converting Enzyme (ACE) inhibitors and Angiotensin II Receptor Antagonists (AIIRAs): Use during pregnancy & lactation

Following review by the Pharmacovigilance Working Party of available data regarding the use of Angiotensin Converting Enzyme (ACE) inhibitors and Angiotensin II Receptor Antagonists (AIIRAs) during pregnancy and lactation, the PhVWP has agreed pregnancy and lactation wordings for the SmPC and package leaflet that should be used for ACE inhibitors and AIIRAs.

The recommended SmPC and package leaflet wordings will be published on the CMD(h) website, under 'PhVWP, PhVWP recommendations'.

Recommendation on submission dates for Applicants of the Decentralised Procedure (DCP)

The CMD(h) has adopted an updated recommendation on submission dates for Applicants of the Decentralised Procedure (DCP) in order to facilitate planning of submission dates for new applications in the DCP in 2009.

Change in the EU-Presidency

The December 2008 CMD(h) meeting was the last one under the French Presidency of the Council of the European Union. Czech Republic will take over the presidency in January 2009. Mrs. Monika Kišacová will be the Vice-Chairperson of the CMD(h), for the Czech Presidency of the Council of the European Union.

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 27.11.2008 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 **12** Mutual Recognition Procedures were finalised during the month of November 2008. **No** Mutual Recognition Procedures was referred to CMD(h) in this period. There was **1** Mutual Recognition Procedures referred to CHMP in this period.

The status as of 30th November 2008 of procedures under Mutual Recognition is as follows:

Year	New applications finalised ¹	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	422	96	37	7	25	1	2	9

39 Mutual Recognition Procedures (regarding **97** products) started in November 2008. The categories of these procedures are as follows:

28 abridged applications, including **2** multiple and **8** repeat use applications.

9 known active substance applications.

2 new active substance applications, which were repeat use applications.

The new procedures started in November 2008 related to **2** full dossier, **26** generic, **8** bibliographic, **1** informed consent and **2** hybrid applications.

All of these procedures consisted of chemical substance products.

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.'

35 of these procedures related to prescription-only medicinal products and **4** procedure related to a non-prescription medicinal product in the reference Member State².

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

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
CZ (1)	1
CZ (1)	1
DE (4)	12
DE (1)	9
DE (2)	10
DK (1)	15
DK (6)	1
DK (5)	15
DK (6)	1
DK (6)	1
DK (5)	1
DK (6)	2
DK (4)	3
DK (6)	3
FI (2)	14
FI (2)	6
FI (1)	12
FR (3)	12
IE (1)	1
IS (1)	5
NL (1)	3
NL (1)	2
NL (1)	7
NL (2)	21
NL (3)	7
NL (1)	2
NO (1)	5
PT (2)	6
PT (2)	3
PT (4)	6
PT (4)	3
PT (3)	8
PT (2)	8
PT (1)	6
PT (1)	8
SE (1)	1
SE (1)	4
SE (1)	7
UK (1)	10

Decentralised Procedure

The CMD(h) noted that there were **55** Decentralised Procedures finalised with a positive outcome during the month of November 2008. **4** Decentralised Procedures were withdrawn after day 120. **4** Decentralised Procedures were referred to the CMD(h) in this period. There were **no** Decentralised Procedures referred to the CHMP in this period.

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.

The status as of 30th November 2008 of procedures under Decentralised Procedure is as follows:

Year	New applications finalised ³	New applications withdrawn (After day 120)	New applications in process	Referred to CMD(h)	Agreement reached in the CMD(h) For procedures referred in		Withdrawn during CMD(h) referral	Referred to CHMP For procedures referred to CMD(h) in	
					2007	2008		2007	2008
2008	733	11	1632	41	2	27	1	2	3

176 Decentralised Procedures (regarding **388** products) started in November 2008. The categories of these procedures are as follows:

167 abridged applications, including **57** multiple applications.

5 known active substance applications, including **2** multiple applications.

4 line extension applications.

The new Decentralised procedures started in November related to **141** generic, **3** bibliographic, **29** hybrid and **3** full dossier.

All of these procedures consisted of chemical substance applications.

172 of these procedures related to prescription-only medicinal products and **4** procedures related to non-prescription medicinal products in the reference Member State⁴.

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

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (1)	1
AT (1)	7
AT (1)	27
AT (1)	3
AT (4)	14
AT (4)	1
AT (3)	8
AT (3)	2
AT (3)	1
AT (3)	1
AT (3)	1
AT (3)	1
AT (3)	1
DE (1)	8
DE (1)	2
DE (1)	10
DE (2)	6
DE (5)	4
DE (5)	6
DE (2)	2
DE (4)	3
DE (4)	9
DE (4)	1
DE (2)	1
DE (2)	1
DE (2)	1
DE (4)	1
DE (4)	1

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

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.

DE (4)	1
DE (1)	1
DE (1)	1
DE (6)	1
DE (6)	1
DE (6)	1
DE (6)	1
DE (6)	1
DE (6)	1
DE (5)	1
DE (6)	3
DE (5)	4
DE (2)	20
DE (4)	7
DE (4)	2
DE (4)	2
DE (4)	3
DE (3)	2
DE (3)	4
DE (3)	4
DE (1)	17
DE (2)	18
DE (1)	8
DE (1)	2
DE (1)	16
DE (1)	1
DE (3)	1
DE (3)	1
DE (2)	5
DK (6)	10
DK (6)	1
DK (4)	15
DK (4)	11
DK (4)	10
DK (11)	6
DK (4)	2
DK (1)	8
DK (1)	22
DK (1)	1
DK (1)	1
DK (1)	5
DK (1)	11
DK (1)	27
DK (1)	7
DK (1)	1
DK (1)	7
DK (1)	5
DK (1)	2
DK (1)	11
DK (1)	9
DK (1)	1
DK (1)	4
DK (1)	3
DK (1)	1
DK (1)	1
DK (1)	1
DK (1)	1
DK (1)	3
DK (4)	9
DK (2)	1
DK (1)	1
FI (1)	9
FR (1)	3
FR (1)	1
FR (1)	4
HU (4)	24
IT (1)	5
IT (1)	1

IT (5)	6
MT (2)	23
NL (2)	10
NL (5)	2
NL (5)	2
NL (1)	20
NL (1)	1
NL (1)	1
NL (1)	11
NL (1)	2
NL (1)	1
NL (5)	11
NL (2)	15
PT (1)	7
PT (1)	3
PT (3)	1
PT (3)	1
PT (3)	7
RO (1)	9
SE (2)	7
SE (1)	9
SE (2)	3
SE (1)	1
SE (1)	1
SE (1)	2
SK (3)	8
UK (1)	20
UK (4)	5
UK (2)	1
UK (2)	1
UK (2)	7
UK (2)	1
UK (2)	1
UK (2)	21
UK (2)	9
UK (1)	8
UK (1)	7
UK (1)	1
UK (2)	12
UK (1)	24
UK (2)	15
UK (1)	2
UK (1)	2
UK (1)	4
UK (1)	4
UK (1)	4
UK (1)	4
UK (1)	4
UK (2)	4
UK (2)	8
UK (2)	1
UK (1)	6
UK (4)	17
UK (2)	6
UK (1)	7
UK (2)	8
UK (1)	6
UK (1)	7
UK (1)	1
UK (1)	2
UK (1)	3
UK (1)	6
UK (5)	9
UK (1)	3
UK (3)	5
UK (1)	4
UK (1)	4
UK (1)	11

UK (1)	2
UK (1)	4
UK (1)	4
UK (1)	4
UK (1)	2
UK (2)	7
UK (1)	2
UK (1)	2
UK (2)	4
UK (1)	15
UK (1)	1
UK (2)	4
UK (2)	7
UK (3)	3
UK (1)	1

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **475** type IA variations, **200** type IB variations and **222** type II variations were finalised during the month of November 2008. **42** renewals were finalised in this period. There were **no** procedures referred to the CHMP in this period.

The status as of 30th November 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	6062	2476	2551	425	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:

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