

Report from the CMD(h) meeting held on 23rd and 24th June 2008

Updated versions - Application forms for marketing authorisation of medicinal products and for variations

Applicants/Marketing Authorisation Holders are informed that updated versions of application forms for marketing authorisation of medicinal products for human use and for variations to marketing authorisation, to take account of the requirements according to Regulation (EC) No 1901/2006 ('Paediatric Regulation') are available, respectively, in Volume 2B and Volume 2C of the Notice to Applicants http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol2_en.htm.

The updated applications forms should be used, where possible. The CMD(h) has agreed to accept the use of the previous applications forms at the latest by 1st October 2008. In such cases, Applicants/Marketing Authorisation Holders are requested to address the requirements according to Regulation (EC) No 1901/2006 ('Paediatric Regulation') for applications for marketing authorisation of medicinal products for human use, submitted as of 26 July 2008.

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

A first wave of the work-sharing for the assessment of paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation is expected to start in September 2008.

Marketing Authorisation Holders are, therefore, requested to have the paediatric studies ready for submission to the appointed Rapporteur within one month of the request (i.e. by mid October 2008).

The CMD(h) has agreed a procedural guidance to facilitate the submission of paediatric data according to Article 46 of the Paediatric Regulation.

Marketing Authorisation Holders should submit, within 6 months of completion of the paediatric studies, a cover letter and a line listing to each Competent Authority(ies) where the medicinal product is authorised in electronic format only, with a copy to the EMA.

The list of addresses to be used for the submission of paediatric information for each Competent Authority and the EMA is published on the CMD(h) website, under 'Contact Points.'

The CMD(h) will follow a work-sharing procedure for the evaluation of paediatric studies submitted according to Article 46 of the Paediatric Regulation.

Any comments on the procedural guidance should be submitted within one month, i.e. by 30 July 2008, to the attention of the CMD(h) secretariat (H-CMDhSecretariat@emea.europa.eu).

EU Work sharing Project – Assessment of paediatric data

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

Informal CMD(h) meeting - Kranjska Gora, Slovenia

The CMD(h) convened for an Informal meeting on 10th and 11th June 2008 in Kranjska Gora, Slovenia, held as part of a programme of events organised under the Slovenian Presidency of the Council of the EU.

The main topics discussed at the meeting included a joint session with the CHMP, to discuss experience on Article 29(4) referrals, how to increase transparency on the outcome of referrals and the Paediatric Regulation.

The CMD(h) discussed also the role of the CMD(h) after revision of the Variation Regulation and a work planning for the various activities involving the CMD(h) (e.g. referrals for Type II variations, recommendation on classification of unforeseen variations, worksharing, etc), validation issues in the framework of variations and renewals and an overview of the duration of 'clock-stop' by some RMSs.

The main part of the meeting was dedicated to the evaluation of the functioning of the CMD(h), with the aim of discussing how further improvements in the operation of the Group can be achieved.

Most of the issues discussed at the informal meeting will be taken forward at regular CMD(h) meetings, such as, the work planning in relation to the revision of the Variation Regulation, the evaluation of the functioning of the CMD(h) and transparency on the outcome of CMD(h) and CHMP referrals.

Information on applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended

With the aim of increasing transparency on the outcome of CMD(h) and CHMP referrals and to facilitate search of information by Interested Parties, the CMD(h) has agreed to publish a table with information on all applications referred to the CMD(h) and, where they resulted in a CHMP referral, to include the date of the CHMP opinion and a link to the respective Commission Decision.

The table will be updated on a monthly basis and be available on the CMD(h) website, under 'CMD(h)-Referrals'.

Change in the EU-Presidency

The June 2008 CMD(h) meeting was the last one under the Slovenian Presidency of the Council of the European Union. France will take over the presidency in July 2008. Mr. Alban Dhanani will be the Vice-Chairperson of the CMD(h), for the French Presidency of the Council of the European Union.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **30** Mutual Recognition Procedures were finalised during the month of May 2008. **11** Mutual Recognition Procedures were referred to CMD(h) in this period. There were **no** Mutual Recognition Procedures referred to CHMP in this period.

The status as of 31st May 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	169	141	23	7	7	--	2	1

41 Mutual Recognition Procedures (regarding **95** products) started in May 2008. The categories of these procedures are as follows:

1 known active substance (already authorised in at least one member state) application.

37 abridged applications, including **12** multiple and **2** repeat use applications.

3 line extension applications, which were **all** repeat use applications.

The new procedures started in May 2008 related to **1** full dossier, **35** generic and **5** hybrid applications.

These procedures consisted of **40** chemical substance products and **1** homeopathic product.

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.

38 of these procedures related to prescription-only medicinal products and **3** procedures 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 May 2008.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
CZ (4)	2
CZ (3)	2
DE (2)	1
DE (2)	2
DE (2)	19
DE (1)	10
DE (2)	7
DE (2)	2
FI (1)	8
FI (2)	1
FI (2)	2
FI (2)	1
FI (2)	2
FI (2)	1
FI (2)	1
FI (2)	2
FI (5)	8
FI (5)	1
FI (5)	2
FI (5)	3
FI (1)	5
HU (4)	3
IS (2)	2
IS (3)	6
IS (3)	3
IS (3)	2
IS (3)	1
IS (3)	6
IS (3)	6
NL (1)	1
NL (2)	4
NL (2)	5
NL (1)	1
NL (2)	1
NL (1)	2
NL (1)	6
NL (1)	1
NL (1)	1
NL (1)	4
NL (2)	1
NL (2)	1

Decentralised Procedure

The CMD(h) noted that there were **61** Decentralised Procedures finalised with a positive outcome during the month of May 2008. **2** 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 31st May 2008 of procedures under Decentralised Procedure is as follows:

Year	New applications finalised ³		New applications withdrawn ⁴	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	
	Positive outcome	Negative outcome				2007	2008		2007	2008
2008	300	4	1	1209	14	2	8	1	2	--

104 Decentralised Procedures (regarding **239** products) started in May 2008. The categories of these procedures are as follows:

90 abridged applications, including **35** multiple applications.

6 known active substance applications, including **1** multiple application.

7 line extension applications.

1 new active substance application.

The new Decentralised procedures started in May related to **87** generic, **5** bibliographic, **8** hybrid and **4** full dossiers.

103 of these procedures consisted of chemical substance applications and **1** procedure consisted of a biological blood product.

103 of these procedures related to prescription-only medicinal products and **1** to a non-prescription medicinal product in the reference Member State⁵.

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

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
CZ (1)	7
CZ (1)	1
DE (2)	28
DE (1)	4
DE (5)	16
DE (5)	1
DE (5)	1
DE (4)	8
DE (3)	1
DE (3)	1
DE (1)	3
DE (4)	10
DE (1)	12
DE (3)	1
DE (3)	1
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	12
DK (1)	12
DK (1)	4
DK (1)	2
DK (2)	16

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.

⁴ After day 120.

⁵ 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.

DK (6)	13
DK (6)	1
DK (6)	1
DK (6)	1
DK (6)	13
DK (4)	10
DK (4)	6
DK (3)	1
DK (4)	1
DK (3)	1
DK (2)	10
DK (6)	1
DK (1)	3
DK (1)	2
DK (1)	3
FI (3)	8
FR (1)	8
HU (1)	21
HU (2)	4
HU (2)	8
HU (2)	1
IT (5)	14
IT (5)	1
IT (1)	1
IT (3)	3
IT (3)	2
IT (5)	1
IT (5)	1
IT (2)	1
IT (2)	1
IT (3)	5
IT (5)	3
NL (1)	16
NL (1)	26
NL (1)	10
NL (1)	7
NL (1)	6
NL (1)	5
NL (1)	20
NL (1)	14
NL (2)	10
NL (1)	11
NL (1)	10
NL (1)	1
NL (2)	9
NL (1)	13
NL (1)	4
NL (3)	12
NO (5)	2
PT (1)	1
SE (2)	13
SE (1)	18
SE (1)	21
SK (4)	7
SK (4)	4
UK (1)	9
UK (1)	3
UK (1)	5
UK (2)	2
UK (3)	17
UK (2)	6
UK (1)	11
UK (1)	6
UK (1)	3
UK (1)	5
UK (3)	8
UK (2)	1

UK (1)	11
UK (5)	3
UK (1)	5
UK (4)	3
UK (1)	9
UK (1)	1
UK (1)	8
UK (1)	1
UK (2)	1
UK (1)	1
UK (1)	5
UK (1)	7
UK (1)	1
UK (1)	1

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **572** type IA variations, **205** type IB variations and **244** type II variations were finalised during the month of May 2008. **39** renewals were finalised in this period. There were **2** procedures referred to the CHMP in this period.

The status as of 31st May 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	2670	1053	1160	165	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):

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

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