



Report from the CMD(h) meeting held on 23rd and 24th January 2006

General Issues

Guidance on Oral Explanations to CMD(h)

The CMD(h) has agreed on a Guidance on Oral Explanation to CMD(h), for applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended.

The Guidance document will be published on the website as an annex to the CMD(h) SOP – Disagreement in Procedures – Referral to CMD(h).

Questions and Answers on CMD(h) SOP - Disagreement in Procedures – Referral to CMD(h)

The CMD(h) has agreed on a Q&A document summarising the main comments received from Interested Parties on the draft SOP – Disagreement in Procedures – Referral to CMD(h). The Q&A document covers mainly the comments/questions that did not result in amendments to the SOP. The Q&A document will be published on the website and further Q&As will be added as they are developed.

New Questions and Answers on the implementation of the new Legislation

The CMD(h) has agreed 4 new Q&A to address the languages to be used for applications for variations and renewals to marketing authorisations granted via the Mutual Recognition or Decentralised procedures, PSUR submission when the time of marketing differs between MS and a Q&A to replace the document ‘Triggering of Mutual Recognition by Member States (Article 18 of Directive 2001/83/EC) Member States’ Standard Operating Procedure. The updated Q&A document will be published on the website.

Working document – Information to be submitted by the Member State of the European Reference Medicinal Product

The CMD(h) has agreed on a working document on the information to be transmitted by the Competent Authority of the Member State of the European reference medicinal product to the Competent Authority of the Member State where an application has been submitted, in accordance with Article 10(1) of Directive 2001/83/EC, as amended, when the reference medicinal product is not authorised in that Member State.

The working document will be published on the website for information.

The intention of the Group is to review the document within 6 months, in light of experience gained.

Best Practice Guide for the Public Assessment Report in the Decentralised and Mutual Recognition Procedure

The CMD(h) has finalised the Best Practice Guide for the Public Assessment Report in the Decentralised and Mutual Recognition Procedure, to comply with the requirements set out in Article 21(4) of Directive 2001/83/EC, as amended.

The Best Practice Guide takes account of the comments received following the consultation procedure and will be published on the website.

Recommendation on Implementation of Article 30 Decisions for Generic Products

The Recommendation on implementation of Article 30 Decisions for Generic Products has been updated, taking into account the changes following the new pharmaceutical legislation. The updated document will be published on the website.

Best Practice Guide EU Work Sharing Procedure in the Assessment of Paediatric Data

The CMD(h) has updated the Best Practice Guide for the EU Work sharing procedure in the assessment of paediatric data, mainly to give further clarification on the role of the Rapporteur and Co-Rapporteur in the procedure. The updated Best Practice Guide will be published on the website.

Report from the CMD(h) meeting held in January 2006

Sub-Group meeting on Harmonisation of SPCs

The Sub-Group on harmonisation of SPCs agreed on the criteria for selection of products for SPC harmonisation.

The proposed criteria were endorsed by the CMD(h) and will be published on the website.

List of CMD(h) Members – Professional Qualifications

An updated list of CMD(h) Members, to include a link to the respective professional qualifications, has been agreed by the CMD(h) and will be published on the website.

Contact Points for advice on Mutual Recognition and Decentralised Procedures

An updated list of Contact Points for advice on Mutual Recognition and Decentralised Procedures has been agreed by the CMD(h) and will be published on the website.

Summary of MRFG/CMD(h) Activities in 2005

The CMD(h) has agreed to publish on the website a summary of the main activities carried out by the former MRFG/ new CMD(h) and its sub-groups in 2005.

MRP statistics 2005

Statistics regarding new applications in the MRP in the year 2005 according to the 5-level classification will be published on the website.

Change in the EU-Presidency

The January 2006 CMD(h) meeting was the first one under the Austrian presidency. Mrs. Christa Wirthumer-Hoche is the Vice-Chairperson of CMD(h), for the Austrian presidency of the Council of the European Union.

Meeting schedule

The next CMD(h) meeting will be held on 20th and 21st February 2006.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **21** new Mutual Recognition Procedures were finalised during the month of December 2005. **9** Mutual Recognition Procedures for new applications were referred to CMD(h) in this period.

The status as of 31st December of procedures under Mutual Recognition is as follows:

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures referred to CMD(h)	Arbitrations referred to CHMP
2005	954	137	10 N.A.	2 N.A.

44 Mutual Recognition Procedures (regarding **81** products) started in December 2005. The categories of these procedures are as follows:

1 new active substance.

11 known active substances (already authorised in at least one member state) including **3** multiple applications and **1** repeat use.

30 abridged applications including **13** multiple applications and **2** repeat use.

2 line extension applications.

The new procedures started related to **9** full dossiers, **32** generics and **3** bibliographic applications.

The procedures consisted of **41** chemical substances, **2** Biological - Blood Product and **1** Biological - Vaccine¹.

44 of these procedures were prescription-only medicinal products in the reference Member State².

1. As considered by RMS.
 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.
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Number of countries involved in the new applications in Mutual Recognition procedure started in December 2005.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (1)	8
DE (1)	13
DE (1)	8
DE (1)	7
DK (3)	1
DK (1)	1
DK (3)	1
DK (2)	16
DK (1)	7
DK (1)	1
DK (1)	1
DK (1)	1
DK (1)	1
DK (2)	1
FI (1)	13
FI (1)	5
FI (1)	1
HU (2)	13

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
HU (2)	5
HU (2)	4
HU (2)	9
HU (2)	12
IT (1)	4
NL (3)	16
NL (1)	25
NL (1)	23
NL (1)	1
NL (1)	5
NL (1)	3
SE (3)	6
SE (3)	7
SE (1)	11
SE (5)	2
UK (1)	3
UK (1)	19
UK (1)	1
UK (4)	15
UK (6)	17
UK (1)	15
UK (2)	1
UK (3)	4
UK (3)	2
UK (3)	2
UK (3)	1

Decentralised Procedure

The CMD(h) noted that **9** new Decentralised Procedures (regarding **22** products) started in December 2005. The categories of these procedures are as follows:

9 abridged applications including **4** multiple applications.

The new Decentralised procedures started related to **9** generics.

The procedures consisted of **9** chemical substances³.

7 of these procedures were prescription-only medicinal products in the reference Member State and **2** procedures were classified as a Non-prescription (including OTC) medicinal products⁴.

3. As considered by RMS.

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.

Number of countries involved in the new applications in Decentralised procedures started in December 2005.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (2)	9
DE (4)	5
DE (4)	3
DE (4)	1
DE (4)	1
NL (1)	9
NL (1)	1
NL (1)	6
NL (1)	3

VARIATIONS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **414** type IA variations, **166** type IB variations and **154** type II variations were finalised during the month of December 2005. **1** arbitration from variations was referred to the CHMP in this period.

The status as of 31st December of variations 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	Arbitrations referred to CHMP
2005	4044	1944	1509	7 Var.

The global status since 1st January 1995 is as follows (further detailed statistics can be found at the MRFG website):

YEARS	PROCEDURES FROM NEW APPLICATIONS FINALISED	PROCEDURES FROM TYPE I VARIATIONS FINALISED	PROCEDURES FROM TYPE IA VARIATIONS FINALISED	PROCEDURES FROM TYPE IB VARIATIONS FINALISED	PROCEDURES FROM TYPE II VARIATIONS FINALISED	PROCEDURES REFERRED TO CMD(h)	ARBITRATIONS REFERRED TO CPMP
1995	10	16			17		1 N.A.
1996	84	49			73		1 N.A. and 1 variation
1997	146	101			163		1 N.A. and 1 variation
1998	182	339			222		1 N.A. and 4 variations
1999	228	671			301		2 N.A. and 2 variations
2000	306	1007			320		3 N.A. and 2 variations
2001	443	1487			474		1 N.A. and 3 variations
2002	420	2104			527		2 N.A. and 7 variations
2003	529	2473	230	94	754		5 N.A. and 3 variations
2004	760	43	3240	1998	1083		9 N.A.
2005	954	N/A	4044	1944	1509	10 N.A.	2 N.A. and 7 variations
1995-2005	4062	8290	7514	4036	5443	10 N.A.	28 N.A. and 30 variations

All documents mentioned in this press release can be found at the CMD(h) website at the European Medicines Authorities Windows 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 the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*

<http://heads.medagencies.org/>