



Report from the CMD(h) meeting held on 20th and 21st February 2006

General Issues

CMD(h) Rules of Procedure

The European Commission has given a favourable opinion on the CMD(h) proposal for the Rules of Procedure for the Coordination Group for Mutual Recognition and Decentralised procedures – Human, as provided for in Article 27(3) of Directive 2001/83/EC, as amended.

The CMD(h) Rules of Procedure will be published on the website.

Role of the Vice-Chairperson of the CMD(h)

The CMD(h) has agreed on a document giving detailed instructions on the role of the Vice-Chairperson of the CMD(h), in accordance with Article 4(2) of the CMD(h) Rules of Procedure.

The document will be published on the website for information.

Functions and Tasks for the CMD(h)

Article 27 of Directive 2001/83/EC, as amended establishes the CMD(h) for the examination of any question relating to marketing authorisation of a medicinal product in two or more Member States in accordance with the Mutual Recognition and Decentralised procedures.

As this covers a variety of issues related to new applications, variations and renewals, the CMD(h) has agreed on a document to give further guidance on the functions and tasks for the CMD(h).

The document will be published on the website for information.

Procedure for adoption of lists of questions for Applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended

In order to make optimal use of the 60 days timeline in case of disagreement between Member States in a particular mutual recognition or decentralised procedure, the CMD(h) has agreed to follow a written procedure for adoption of the lists of questions. The lists of questions will be sent to the Applicant by Day 10 of the Procedure. The timeframe for Applicants to prepare a response document will remain 15 days.

The CMD(h) will work with the new timelines for a pilot period of 6 months. Review of the CMD(h) SOP – Disagreement in Procedures – Referral to CMD(h) will be considered after finalisation of the pilot phase.

CMD(h) Position on changing the Reference Member State

The CMD(h) has updated the Position on changing the Reference Member State, to consider the new decentralised procedure and to clarify that a change of the RMS cannot take place during a pending procedure.

It has also been agreed that the transfer of dossier/assessment reports and other relevant material to the new RMS should be done within 30 days. The new RMS will only be able to start new procedures when the requested information has been received.

E-mail addresses for submission of translations in Mutual Recognition and Decentralised procedures

The CMD(h) has agreed to publish a list of e-mail addresses for submission of translations in the mutual recognition and decentralised procedures.

Member States have agreed to accept text proposals for the SPC, PL and labeling in English with the submission of applications for marketing authorisation, type II variations and renewals in the MRP/DCP.

High quality translations of the agreed SPC, PL and labeling should be submitted at the latest 5 days after the end of the procedure.

For further information, please refer to Q&A 12 and 13 of the Questions and Answers document on the implementation of the new legislation, January 2006.

E-mail addresses for submission of electronic responses to the List of Questions for Applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended

In view of the short timeframe for the procedure in the CMD(h) in case of disagreement between Member States in a particular MRP or DCP, the CMD(h) recommends the submission of the response to the list of questions in electronic format and has agreed to publish a list of e-mail addresses for this purpose.

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

The CMD(h) has finalised on 30 January 2006 the first application for marketing authorisation referred to the CMD(h) for the 60-days procedure.

The application for Omeprazole, submitted in accordance with Article 10.1 (a)(iii) of Directive 2001/83/EC, was referred to the CMD(h) because potential serious health concerns were raised with regard to the available bioequivalence data for these specific formulations.

The Member States involved in the procedure were able to reach agreement on the authorisation of the medicinal product.

Please find below information on the Name of the product in the RMS, active substance, pharmaceutical form, procedure number, CMS, legal basis, grounds for referral to CMD(h), Day 60 and outcome of the procedure.

Name of the product in the RMS	Omeprazole 10mg, 20mg & 40mg Capsules
Active substance	Omeprazole
Pharmaceutical form	Gastro-resistant capsules
Procedure number	UK/H/799/01-03
CMS	AT, BE, CZ, DE, ES, EL, HU, LI, LU, NL, PL, PT, SK
Legal basis	Article 10.1 (a)(iii), Directive 2001/83/EC - Generic
Grounds for referral to CMD(h)	Different interpretation with regard to existing guidelines on the required bioequivalence data for the formulations
Day 60	30.01.2006
Outcome	Agreement reached

Meeting schedule

The next CMD(h) meeting will be held on 20th, 21st and 22nd March 2006.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **46** new Mutual Recognition Procedures were finalised during the month of January 2006. **8** Mutual Recognition Procedures for new applications were referred to CMD(h) in this period.

The status as of 31st January 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
2006	46	111	8 N.A.	--

16 Mutual Recognition Procedures (regarding **22** products) started in January 2006. The categories of these procedures are as follows:

1 new active substance classified as repeat use.

5 known active substances (already authorised in at least one member state).

9 abridged applications including **1** repeat use.

1 line extension application.

The new procedures started related to **2** full dossiers, **9** generics and **5** bibliographic applications.

The procedures consisted of **15** chemical substances and **1** Biological - Other¹.

15 of these procedures were prescription-only medicinal products in the reference Member State and **1** procedure was classified as Non-prescription (including OTC) medicinal product².

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 January 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	6
DK (1)	1
DK (4)	1
EE (2)	2
FR (1)	14
FR (1)	15
NL (3)	10
NL (1)	5
NL (1)	4
PT (1)	1
SE (1)	14
SE (1)	19
SE (1)	3
UK (1)	14
UK (1)	14
UK (1)	9

Decentralised Procedure

The CMD(h) noted that **21** new Decentralised Procedures (regarding **50** products) started in January 2006. The categories of these procedures are as follows:

18 abridged applications including **6** multiple applications.

3 known active substances (already authorised in at least one member state).

The new Decentralised procedures started related to **3** full dossiers, **14** generics and **4** for different use, route or dose.

The procedures consisted of **21** chemical substances³.

21 of these procedures were prescription-only medicinal products in the reference Member State⁴.

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 January 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (4)	12
AT (4)	6
AT (4)	8
AT (4)	1
DE (3)	1
DE (3)	1
DE (1)	7
DE (1)	25
NL (3)	20
NL (3)	8
NL (3)	8
NL (1)	23
NL (3)	15
NL (1)	12
NL (1)	2
NL (1)	17
NL (1)	3
NL (1)	1
NL (3)	1
UK (1)	20
UK (4)	3

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **316** type IA variations, **163** type IB variations and **93** type II variations were finalised during the month of January 2006. **16** renewals were finalised in this period.

The status as of 31st January 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	Arbitrations referred to CHMP
2006	316	163	93	16	--

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/>