



Report from the CMD(h) meeting held from 20th to 22nd March 2006

General Issues

Meeting on Harmonisation of SPCs with Interested Parties

The Sub-Group on Harmonisation of SPCs met with Interested Parties to hear their views on future harmonisation of authorisations for medicinal products authorised in the Community.

The CMD(h) Sub-Group on Harmonisation of SPCs will continue its work, with a view to laying down a list of medicinal products for which a harmonised SPC should be drawn up, taking into account the proposals from all Member States, in accordance with Article 30(2) of Directive 2001/83/EC, as amended.

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

The CMD(h) has agreed 2 new Q&A to address submission of ‘new data’ and format of the response document for applications referred to the CMD(h) for the 60 days referral procedure.

The updated Q&A document will be published on the website.

Best Practice Guide on Break-out Sessions

The CMD(h) has agreed an updated Best Practice Guide on Break-out Sessions, mainly to consider the new decentralised procedure and to take account of initial comments received from Interested Parties.

Any comments on the updated Best Practice Guide on Break-out Sessions should be sent by 20 April 2006, coordinated where possible by trade associations, to the CMD(h) secretariat (sonia.ribeiro@emea.eu.int).

Consultation with target patients groups for the package leaflet

Applicants are reminded that the submission of the results of consultation with target patient groups, in accordance with Article 59(3) of Directive 2001/83/EC, as amended, or justification for its absence is required with the submission of applications for marketing authorisation via the mutual recognition procedure.

For applications submitted via the decentralised procedure this is also a requirement; however, applicants should consider the need and timing of consultation with target patients groups within the procedural timeframe.

For further information on the timing of user consultation, submission and assessment within the evaluation procedure in the mutual recognition or decentralised procedure, please refer, respectively, to the Best Practice Guide for the Mutual Recognition Procedure and to the Decentralised procedure – Member States SOP, available on the Heads of Medicines Agencies website.

Submission of Detailed description of the Pharmacovigilance and Risk Management Systems

Applicants are reminded that the submission of a detailed description of the pharmacovigilance and, where appropriate, of the risk-management system which the applicant will introduce is required with the submission of applications for marketing authorisation via the mutual recognition or decentralised procedures, in accordance with Article 8.3(ia) of Directive 2001/83/EC, as amended.

Applicants, which have already a national marketing authorisation and have planned to start a mutual recognition procedure soon, are advised to contact the RMS to discuss the possibility of a transitional period. The transitional period is limited to a maximum of 6 months.

For further information, please refer to the Guideline on Risk Management Systems for medicinal products for human use, published on the EMEA website.

Report from the CMD(h) meeting held in March 2006Notifications to the EMEA/CHMP in the Mutual Recognition/Decentralised Procedures

The above mentioned document has been updated to take account of Directive 2004/27/EC.

Applicants are no longer requested to inform the EMEA of the submission of applications for marketing authorisation via the mutual recognition or the new decentralised procedure.

Only in the event of arbitration for applications for marketing authorisation or variations to marketing authorisation, the EMEA should receive the dossier for the respective procedure.

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

Please find below information on the Name of the products in the RMS, active substances, pharmaceutical forms, procedure numbers, CMS, legal basis, grounds for referral to CMD(h), Day 60 and outcome of the procedures, for the referrals to the CMD(h) finalised on 3 March 2006.

Name of the product in the RMS	Epratenzide Plus 600/12.5 mg
Active substance	eprosartan, hydrochlorothiazide
Pharmaceutical form	Film-coated tablet
Procedure number	DE/H/538/01
CMS	FR, PT, SE
Legal basis	Article 10.1(b), Directive 2001/83/EC – Fixed combination
Grounds for referral to CMD(h)	Efficacy of the combination product in comparison with eprosartan as monotherapy. Inconsistent information in SPC section 4.6 (Pregnancy and lactation) in comparison to other medicinal products with angiotensin-II antagonists in combination with hydrochlorothiazide.
Day 60	03.03.2006
Outcome	Agreement reached

Name of the product in the RMS	Cardoreg	Doxagamma
Active substance	doxazosin mesylate	
Pharmaceutical form	Prolonged release tablet	
Procedure number	DK/H/429/01/E01	DK/H/624/01/E01
CMS	CZ, HU, PL, SK, UK (wave 2) DE, ES, NO, SE (wave 1)	UK (wave 2) DE, NO, SE (wave 1)
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic	
Grounds for referral to CMD(h)	Different views on the clinical consequences of deviation from the existing bioequivalence guideline.	
Day 60	03.03.2006	
Outcome	Referred to CHMP for arbitration	

Name of the product in the RMS	Doxastad
Active substance	doxazosin mesylate
Pharmaceutical form	Prolonged release tablet
Procedure number	SE/H/469/01
CMS	DE, EE, ES, LT, LV, NL, UK
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic
Grounds for referral to CMD(h)	Different views on the clinical consequences of deviation from the existing bioequivalence guideline.
Day 60	03.03.2006
Outcome	Referred to CHMP for arbitration

Name of the product in the RMS	Formoterol Novolizer 6 µg, 12 µg
Active substance	formoterol
Pharmaceutical form	Inhalation powder
Procedure number	DE/H/571/01-02
CMS	AT, BE, ES, FR, IE, IT, LU, NL, PT, UK
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Last paragraph
Grounds for referral to CMD(h)	Different interpretation of the submitted data concerning safety and efficacy of the medicinal product.
Day 60	03.03.2006
Outcome	Agreement reached

Name of the product in the RMS	Lansoprazole Vetiquima 15 mg, 30mg	Lansoprazole Suprazol 15 mg, 30mg
Active substance	lansoprazole	
Pharmaceutical form	Gastro-resistant capsule, hard	
Procedure number	PT/H/113/01-02	PT/H/114/01-02
CMS	DE, IE, IT, NL, SE, UK	BE, DE, DK, FI, IT, NL, NO, SE, UK
Legal basis	Article 10.1 (a)(iii), Directive 2001/83/EC - Generic	
Grounds for referral to CMD(h)	Choice and composition of meal content used in the fed bioequivalence study and risk of dose dumping related to food intake. Discussion on clinical relevance of a lower C _{max} for the test product.	
Day 60	03.03.2006	
Outcome	Agreement reached	

Name of the product in the RMS	Nurofen Junior Zäpfchen 60 mg
Active substance	ibuprofen
Pharmaceutical form	Suppository
Procedure number	DE/H/0433/01
CMS	AT, BE, CZ, ES, EL, FR, LU, PL, PT, SK
Legal basis	Article 10.1(a)(ii) - Bibliographic
Grounds for referral to CMD(h)	Different interpretation of the existing bibliographic data.
Day 60	03.03.2006
Outcome	Agreement reached

Name of the product in the RMS	Alfuzosin Stada
Active substance	alfuzosin
Pharmaceutical form	Prolonged release tablet
Procedure number	SE/H/559/01
CMS	AT, CZ, DE, DK, ES, HU, IE, IT, NO, PL, SK, UK
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic
Grounds for referral to CMD(h)	Deficiencies in the study design to fully evaluate the influence of food on the formulation.
Day 60	03.03.2006
Outcome	Agreement reached

Meeting schedule

The next CMD(h) meeting will be held on 24th, 25th and 26th April 2006.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **24** new Mutual Recognition Procedures were finalised during the month of February 2006. **17** Mutual Recognition Procedures for new applications were referred to CMD(h) in this period.

The status as of 28th February 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	70	89	25 N.A.	--

27 Mutual Recognition Procedures (regarding **61** products) started in February 2006. The categories of these procedures are as follows:

6 known active substances (already authorised in at least one member state), including **1** repeat use.

20 abridged applications including **3** multiple applications and **3** repeat use.

1 line extension application.

The new procedures started related to **3** full dossiers, **18** generics, **2** generics-other and **4** bibliographic applications.

The procedures consisted of **27** chemical substances.

26 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.
-

Number of countries involved in the new applications in Mutual Recognition procedure started in February 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	25
DE (1)	16
DK (4)	14
DK (1)	5
FI (1)	6
FI (2)	6
FI (2)	9
FI (5)	14
FI (5)	1
FI (5)	1
FR (3)	21
HU (1)	11
IT (1)	4
NL (2)	5
NL (2)	11
NL (2)	5
PT (2)	5
SE (2)	13
SE (1)	18
SE (5)	21
SE (1)	7

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

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
SE (3)	1
SE (1)	15
SE (3)	1
UK (1)	13
UK (1)	6
UK (2)	7

Decentralised Procedure

The CMD(h) noted that **31** new Decentralised Procedures (regarding **39** products) started in February 2006. The categories of these procedures are as follows:

22 abridged applications including **4** multiple applications.

2 known active substances (already authorised in at least one member state), including **1** multiple application.

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

The new Decentralised procedures started related to **5** full dossiers, **25** generics and **1** generic-other.

The procedures consisted of **31** chemical substances³.

30 of these procedures were prescription-only medicinal products in the reference Member State and **1** procedure was classified as Non-prescription (including OTC) medicinal product⁴.

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 February 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (4)	3
DK (1)	1
DK (1)	2
DK (1)	6
DK (1)	1
DK (1)	4
DK (1)	1
DK (1)	1
DK (1)	4
DK (1)	2
DK (1)	1
DK (3)	5
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	1
NL (4)	14
NL (1)	14
NL (1)	1
NL (1)	21
NL (1)	1
NL (1)	1
SE (1)	2
SE (1)	1
SE (1)	2
SE (1)	4
SE (1)	1

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
UK (1)	10
UK (1)	7
UK (1)	8
UK (1)	1

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **299** type IA variations, **135** type IB variations and **160** type II variations were finalised during the month of February 2006. **29** renewals were finalised in this period.

The status as of 28th February 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	615	298	253	45	--

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):

Mrs. Truus Janse-de Hoog

Phone: + 31 70 356 74 08

College ter Beoordeling van Geneesmiddelen

Fax: + 31 70 356 75 15

Kalvermarkt 53

E-mail: gm.janse@cbg-meb.nl

NL – 2500 Den Haag , The Netherlands

*Or you could visit the **CMD(h) web site** at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*

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