



Report from the CMD(h) meeting held from 24th to 26th April 2006

General Issues

Sub-group meeting on Harmonisation of SPCs

There was a meeting of the Sub-Group on harmonisation of SPCs, mainly to consider the initial proposals from Member States for products for which a harmonised SPC should be drawn up.

The Sub-group considered also the number of products that may be referred to the CHMP for arbitration and future cooperation with Interested Parties.

The Sub-Group agreed to meet with Interested Parties as needed.

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.

List of Guidance documents in the Mutual Recognition Procedure under revision & Publication and consultation of MRFG/CMD(h) Guidance documents on the implementation of the new legislation

The CMD(h) has updated the lists of Guidance documents in the MRP under revision & Publication and consultation of Guidance documents on the implementation of the new legislation, to reflect the current status of the documents under revision/preparation by the CMD(h), in accordance with the new legislation.

Urgent Safety Restriction – Member States' Standard Operating Procedure

The CMD(h) has considered the comments received from Interested Parties on the Urgent Safety Restriction – Member States' Standard Operating Procedure. The updated SOP, agreed by the CMD(h) and PhVWP, 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 with regard to the content of the application and to give further clarification on the role of the Rapporteur and Co-Rapporteur in the procedure. The updated BPG will be published on the website.

Informal CMD(h) meeting

An informal CMD(h) meeting will be held in Vienna on 18-19 May 2006. The meeting will be mainly focused on Member States experience with the new legislation, including the new decentralised procedure, referrals to CMD(h) and the work within the CMD(h).

The transparency requirements of the new legislation, consultation with target patient groups, usage patents and harmonisation of package leaflets will also be on the Agenda for the meeting.

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 31 March 2006.

Name of the product in the RMS	Fostimon 75, 150 IU/ml
Active substance	urofollitropin
Pharmaceutical form	Powder and solvent for solution for injection
Procedure number	FR/H/282/01-02
CMS	AT, BE, CY, DE, DK, ES, FI, IE, LU, NL, NO, PT, SE, UK
Legal basis	Article 8(3), Directive 2001/83/EC – Full dossier
Grounds for referral to CMD(h)	Efficacy in the claimed indications and safety (immunogenicity).
Day 60	31.03.06
Outcome	Agreement Reached

Name of the product in the RMS	Glucomed
Active substance	Glucosamine hydrochloride
Pharmaceutical form	Tablet
Procedure number	SE/H/560/01
CMS	AT, BE, CY, CZ, DE, DK, EE, EL , ES, FI, FR, HU, IE, IS, IT, LT, LU, LV, NL, NO, PL, PT, SK, UK
Legal basis	Article 10.1(a)(ii), Directive 2001/83/EC - Bibliographic
Grounds for referral to CMD(h)	Different interpretation of the submitted quality data and existing bibliographic data concerning safety and efficacy.
Day 60	31.03.06
Outcome	Referred to CHMP for arbitration

Name of the product in the RMS	Alendros 70
Active substance	alendronic acid
Pharmaceutical form	Tablet
Procedure number	CZ/H/115/01
CMS	EE, HU, LT, LV, PL, SK
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	31.03.06
Outcome	Referred to CHMP for arbitration

Name of the product in the RMS	Doxazosin NM Pharma
Active substance	Doxazosin mesylate
Pharmaceutical form	Prolonged release tablet
Procedure number	SE/H/465/01
CMS	CZ, HU, NL, PL, SI, SK
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	31.03.06
Outcome	Agreement reached

Name of the product in the RMS	Doxazosin Retard "Arrow"	Doxazosin "Winthrop"
Active substance	Doxazosin mesylate	
Pharmaceutical form	Prolonged release tablet	
Procedure number	DK/H/431/01/E/01	DK/H/694/01/E/01
CMS	PT, SI, UK (wave 2) NO, SE, DE (wave 1)	DE, ES, HU, NL, PL, SK, UK (wave 2) CZ (wave 1)
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic	
Grounds for referral to CMD(h)	<ol style="list-style-type: none"> 1. Different views on the clinical consequences of deviation from the existing bioequivalence guideline. 2. One CMS for Doxazosin Retard "Arrow" raised concerns over the indication "Essential Hypertension". Agreement was reached in the CMD(h) on the wording of the indication. 	
Day 60	31.03.06	
Outcome	Referred to CHMP for arbitration	

Name of the product in the RMS	Ramipril Capsules 1.25, 2.5, 5, 10 mg	
Active substance	ramipril	
Pharmaceutical form	Capsule, hard	
Procedure number	UK/H/830/01-04	
CMS	BE, DE, IT, MT, NL, PT, SE	
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic	
Grounds for referral to CMD(h)	<ol style="list-style-type: none"> 1. Difference in approved indications between RMS SPC and CMS, such that the following indications are not included in the UK SPC: <ul style="list-style-type: none"> • Treatment of manifest non-diabetic glomerular nephropathy • Treatment of incipient diabetic nephropathy (microalbuminuria) in patients with type 2 diabetes mellitus and hypertension <p>The CMS considered that omission of these indications was a public health concern because all information in SPC and PIL for interchangeable generic products should be consistent.</p> <ol style="list-style-type: none"> 2. One CMS raised concern over interpretation of criteria for extrapolation of results from a bioequivalence study conducted with the 10mg strength capsules to the 1.25mg strength, based on linearity of ramipril/ramiprilat pharmacokinetics over this dose range. 	
Day 60	31.03.06	
Outcome	Agreement reached. Further action in the Sub-group on harmonisation of SPCs.	

Name of the product in the RMS	Lamotrigine 25, 50, 100, 200mg	
Active substance	lamotrigine	
Pharmaceutical form	Tablets	
Procedure number	UK/H/827/01-04	
CMS	BE, CZ, DE, DK, EL, HU, IE, PL, SI	
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic	
Grounds for referral to CMD(h)	Difference in approved indications between innovator SPC in RMS and CMS, such that the indication for bipolar disorder is not included in the RMS SPC. One CMS considered that omission of this indication was a potential serious risk to public health because all of the information in the SPC and PIL for interchangeable generic products should be consistent.	
Day 60	31.03.06	
Outcome	Agreement reached. Further SPC activity proposed.	

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **82** new Mutual Recognition Procedures were finalised during the month of March 2006. **7** Mutual Recognition Procedures for new applications were referred to CMD(h) in this period. **7** Mutual Recognition Procedures for new applications were referred to CHMP in this period.

The status as of 31th March 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)	Agreement reached in the CMD(h)	Arbitrations referred to CHMP
2006	152	103	32 N.A.	11	7

60 Mutual Recognition Procedures (regarding **128** products) started in March 2006. The categories of these procedures are as follows:

2 new active substances, including **1** repeat use.

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

32 abridged applications including **2** multiple applications and **3** repeat use.

16 line extension applications.

The new procedures started related to **11** full dossiers, **39** generics, **5** hybrid applications, **2** fixed-combinations and **3** bibliographic applications.

The procedures consisted of **56** chemical substances and **4** biological blood products.

59 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.

- As considered by RMS.
- 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 March 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
CZ (3)	4
CZ (2)	2
CZ (1)	4
DE (1)	10
DE (1)	15
DE (1)	5
DE (3)	1
DE (4)	9
DE (4)	9
DE (4)	9
DE (4)	5
DK (1)	17
DK (1)	3
DK (1)	8
DK (2)	6
DK (2)	2
DK (2)	4
DK (4)	1
DK (2)	16

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (2)	1
DK (2)	8
DK (1)	8
DK (1)	3
FI (2)	8
FI (2)	4
FI (2)	1
FI (2)	1
FI (2)	9
FI (2)	11
FI (1)	3
FI (2)	5
FI (2)	1
FI (2)	1
FI (1)	8
FR (1)	17
FR (1)	12
HU (4)	5
IT (2)	4
NL (2)	3
NL (3)	4
NL (3)	4
NL (3)	5
NL (2)	4
NL (2)	4
NL (6)	2
NL (6)	4
NL (6)	2
NO (2)	2
PT (1)	3
SE (2)	3
SE (1)	6
SE (3)	9
UK (4)	23
UK (1)	1
UK (2)	8
UK (1)	4
UK (1)	18
UK (1)	7
UK (1)	2
UK (1)	2

Decentralised Procedure

The status as of 31th March of procedures under Decentralised Procedure is as follows:

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures referred to CMD(h)	Agreement reached in the CMD(h)	Arbitrations referred to CHMP
2006	--	86	--	--	--

25 Decentralised Procedures (regarding **45** products) started in March 2006. The categories of these procedures are as follows:

18 abridged applications including **8** multiple applications.

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

2 line extension applications, including **1** multiple applications.

The new Decentralised procedures started related to **5** full dossiers, **11** generics, **2** similar biologicals and **7** hybrid applications.

The procedures consisted of **25** chemical substances³.

All 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 March 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (3)	14
DK (3)	3
DK (3)	3
DK (2)	12
DK (2)	3
FI (4)	5
FR (2)	24
FR (2)	14
FR (2)	2
NL (1)	18
NL (1)	3
NL (1)	1
NL (1)	1
NL (1)	6
NL (1)	4
NL (1)	4
NL (2)	12
NL (2)	14
NL (2)	5
NL (3)	13
SE (1)	1
SE (2)	3
SE (1)	6
SE (1)	2
SE (1)	1

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **377** type IA variations, **234** type IB variations and **167** type II variations were finalised during the month of March 2006. **32** renewals were finalised in this period.

The status as of 31th March 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	992	532	420	77	--

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*.

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

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