



Report from the CMD(h) meeting held on 16th, 17th and 18th October 2006

EU Work Sharing Project - Assessment of paediatric data

Applicants are reminded that after finalisation of the EU work-sharing project – assessment of paediatric data, they should submit a Type II variation procedure (or extension application, as appropriate), via the appropriate mutual recognition or national procedure, to implement the agreed text for inclusion in the SPC.

CMD(h) Annotated QRD Template for MR/DC Procedures

The CMD(h) has agreed an updated QRD template for MR/DC procedures, to address in the Labelling – information in Braille, the situations where a justification for not including Braille, provided in module 1.3.6, has been agreed by National Competent Authorities.

Type II Variation Assessment Reports Template

The CMD(h) has agreed templates for the preliminary and final Type II variation MRP Assessment Reports. The templates will be published, for transparency reasons, on the website.

Informal CMD(h) meeting, 10-11 October 2006, Helsinki, Finland

The CMD(h) convened for an Informal meeting on 10th and 11th October 2006 in Helsinki, Finland, held as part of a programme of events organised under the Finnish Presidency of the EU, in parallel to the Informal CHMP and COMP.

There was a joint session with the CHMP to discuss the Referrals according to Article 29 of Directive 2001/83/EC and consider the Guideline on the definition of a potential serious risk to public health in the context of Articles 29(1) and (2) of Directive 2001/83/EC.

The co-ordination of data sharing for paediatric medicines available in Europe, including the follow-up of the EU work-sharing for paediatric data after implementation of the Paediatric Regulation were also discussed.

The informal CMD(h) meeting was mainly focused on MSs experience with the DCP, transparency issues, including communication of outcome of referrals in the CMD(h) and some practical issues concerning the harmonisation of the package leaflet and user consultation.

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 25 September 2006.

Name of the product in the RMS	Tarka Tablets
Active substance	trandolapril/verapamil hydrochloride
Pharmaceutical form	Tablet
Procedure number	NL/H/107/05-06/MR
CMS	DE, DK, IT
Legal basis	Article 10b, Directive 2001/83/EC - Fixed combination
Grounds for referral to CMD(h)	One of the Member States is of the opinion, that the clinical program submitted cannot support the proposed indications. Demonstration of a superior blood pressure lowering of the 240/2 and 240/4 mg dose strengths compared to the approved 180/ 2 mg dose strength has not been demonstrated.
Day 60	25.09.06
Outcome	It was noted that the NfG on clinical investigation of medicinal products in the treatment of hypertension – Fixed combinations,

	<p>does not address line extensions of fixed-combinations and does not require demonstration of a superior blood lowering pressure effect to the approved fixed combination.</p> <p>The clinical studies performed demonstrated superiority of the fixed combination over placebo and the individual compounds. This is reflected in a new wording of the indication.</p> <p>Agreement reached.</p>
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Name of the product in the RMS	Cefuroximaxetil 125, 250, 500mg		
Active substance	cefuroxime		
Pharmaceutical form	Film-coated tablet		
Procedure number	NL/H/556/01/E01	NL/H/556/02/E01	NL/H/556/03/E01
CMS	AT, CZ, HU, IE, LT, LV, PL, SK (Wave 1) EE, EL, ES (Wave 2)	AT, BE, CZ, HU, IE, LT, LU, LV, PL, SK (Wave 1) EE, EL, ES, PT (Wave 2)	AT, BE, CZ, HU, LU, LV, PL, SK (Wave 1) EE, EL, ES, PT (Wave 2)
Legal basis	Article 10.1, Directive 2001/83/EC – Generic		
Grounds for referral to CMD(h)	One CMS could not accept the indication ‘Uncomplicated gonorrhoea: urethritis and cervicitis’ and two CMS could not accept the indication ‘Treatment of early stage Lyme disease (stadium 1) and subsequent prevention of late complications in adults and children above 12 years of age’.		
Day 60	25.09.06		
Outcome	<p>Referred to CHMP for arbitration for the indication ‘Uncomplicated gonorrhoea: urethritis and cervicitis’.</p> <p>The CMD(h) was able to reach agreement on the approval of the indication ‘Treatment of early stage Lyme disease (stadium 1) and subsequent prevention of late complications in adults and children above 12 years of age’.</p>		

Name of the product in the RMS	Fexofenadin Teva
Active substance	fexofenadine hydrochloride
Pharmaceutical form	Film-coated tablet
Procedure number	DK/H/0911/01-02/MR
CMS	AT, CZ, DE, ES, FR, HU, IE, IT, LT, NL, NO, PL, PT, SE, SK, UK
Legal basis	Article 10.1, Directive 2001/83/EC – Generic
Grounds for referral to CMD(h)	Referring CMSs considered that bioequivalence of the test and reference formulations has not been demonstrated given that the bioequivalence study does not meet the conventional 90% confidence interval acceptance limits of 80-125% for Cmax.
Day 60	25.09.06
Outcome	Referred to CHMP for arbitration

Name of the product in the RMS	Grazax
Active substance	Standardised allergen extract of grass pollen from Timothy (<i>Phleum pratense</i>)
Pharmaceutical form	Tablet
Procedure number	SE/H/612/01/MR
CMS	AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IS, IT, LT, LU, LV, MT, NO, NL, PL, PT, SI, SK, UK
Legal basis	Article 8.3, Directive 2001/83/EC - Full Dossier
Grounds for referral to CMD(h)	Potential serious risk to public health concerns were raised by one CMS which questioned the immunomodulatory effect of the product since efficacy was shown only over one season.
Day 60	25.09.06
Outcome	At the CMD(h) meeting the RMS presented their view and the company was invited for an oral hearing. The general opinion of CMD(h) was that the outstanding issue could be solved by appropriate changes to the SPC and a post-approval commitment to provide yearly results from the already ongoing GT-08 extension study which will be concluded after the pollen season 2009. Agreement was reached based on the revised SPC and the commitment given by the applicant.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **41** new Mutual Recognition Procedures were finalised during the month of September 2006. **6** Mutual Recognition Procedures for new applications were referred to CMD(h) in this period. **2** Mutual Recognition Procedures for a new application were referred to CHMP in this period.

The status as of 30th September 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	408	203	63 N.A.	31	19

75 Mutual Recognition Procedures (regarding **158** products) started in September 2006. The categories of these procedures are as follows:

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

60 abridged applications, including **24** multiple and **2** repeat use applications.

6 line extension applications, including **1** repeat use application.

The new procedures started in September related to **7** full dossiers, **61** generics, **1** hybrid, **1** fixed combination application and **5** bibliographic applications.

All of these procedures consisted of chemical substance applications.

73 of these procedures related prescription-only medicinal products and 2 procedures related to non-prescription medicinal products in the reference Member State¹.

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

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
BE (1)	4
CZ (3)	6
CZ (2)	21
DE (2)	2
DE (4)	1
DE (4)	4
DE (5)	20
DK (1)	3
DK (4)	5
DK (3)	2
DK (3)	3
DK (3)	2
DK (2)	12
FI (3)	3
FI (3)	3
FI (2)	8
FI (1)	5
FI (1)	4
FI (1)	1
FR (1)	7
IE (3)	1
IE (3)	1
IE (3)	1
IE (3)	1
IS (2)	9
IS (2)	6
IS (3)	7
IS (3)	2
IS (3)	2
NL (1)	3
NL (2)	22
NL (1)	1
NL (2)	1
NL (2)	2
NL (2)	8
NL (2)	1
NL (1)	6
NL (2)	2
NL (2)	1
NL (2)	18
NL (2)	1
NL (2)	1
NL (1)	1
NL (1)	7
NL (1)	10
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	3
NL (1)	1
NL (1)	13
NL (1)	7
NL (7)	4
NL (8)	8
NL (1)	1

¹ 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.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
NL (1)	5
NL (1)	8
NO (1)	3
PT (1)	3
PT (1)	3
SE (1)	10
SE (1)	6
SE (1)	13
SE (1)	3
SE (1)	2
SE (1)	3
SE (5)	6
SE (5)	1
SE (5)	1
UK (4)	7
UK (1)	3
UK (1)	1
UK (1)	2
UK (1)	2

Decentralised Procedure

The CMD(h) noted that **4** new Decentralised Procedures were finalised during the month of September 2006.

The status as of 30th September 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	14	303	--	--	--

35 Decentralised Procedures (regarding **74** products) started in September 2006. The categories of these procedures are as follows:

26 abridged applications, including **4** multiple applications.

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

4 line extension applications, including **3** multiple applications.

The new Decentralised procedures started related to **8** full dossier, **24** generic, **2** hybrid and **1** bibliographical applications.

All of these procedures consisted of chemical substance applications.

These procedures related to **34** prescription-only and **1** non-prescription medicinal products in the reference Member State².

Number of countries involved in the new applications in Decentralised procedures started in September 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
BE (1)	17
DE (2)	1
DE (2)	1
DE (3)	14
DE (3)	14

² 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.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	1
DK (2)	13
DK (2)	9
DK (2)	5
DK (1)	5
DK (1)	7
DK (2)	5
NL (1)	24
NL (1)	1
NL (1)	2
NL (1)	2
NL (1)	1
NL (1)	5
SE (7)	24
SE (4)	1
SE (4)	1
SE (4)	6
SE (4)	1
SE (4)	2
UK (1)	26
UK (1)	21
UK (1)	21
UK (4)	22
UK (1)	4
UK (2)	1
UK (3)	24
UK (4)	11
UK (3)	1
UK (1)	1
UK (1)	24

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **391** type IA variations, **198** type IB variations and **138** type II variations were finalised during the month of September 2006. **32** renewals were finalised in this period.

The status as of 30th September 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	3324	1629	1351	264	--

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/>