



Report from the CMD(h) meeting held on 24th and 25th July 2006

Sub-group meeting on Harmonisation of SPCs

There was a meeting of the Sub-Group on harmonisation of SPCs, to discuss the rationale for inclusion of the medicinal products proposed in the list for SPC harmonisation.

The Sub-Group on harmonisation of SPCs agreed to have further discussions in September 2006, with a view to finalising the list of medicinal products for which a harmonised SPC should be drawn up, in accordance with Article 30(2) of Directive 2001/83/EC, as amended.

Guidance on contacts with Representative Organisations

The CMD(h), having in regard the Rules of Procedure, Article 14, has agreed a Guidance document, which defines the scope and conditions of contacts with Representative Organisations.

Interactions with the following CMD(h) Stakeholders: Patients Organisations, Health Care Professionals and Pharmaceutical Industry Organisations are addressed in the Guidance document.

The Guidance on contacts with Representative Organisations will be published on the website.

Question and Answer on Combination packages

The CMD(h) has agreed a Q&A on combination packages, addressing the possibility to apply for a combination package via the MRP or DCP.

In principle, many MS can accept a combination package if there are strong arguments for the provision of a combination package with respect to benefit to public health or where the use of a combination package is more user friendly for the patient or healthcare professional. However, Applicants are advised to consult with the RMS well in advance of any MRP or DCP to clarify the acceptance of the combination package in the relevant MSs.

Harmonisation of the Package leaflet and labelling in the MRP

Applicants are reminded that the harmonisation of the labelling and package leaflet of a medicinal product in the MRP should, in principle, not imply any changes to the content of the Summary of Product Characteristics (SPC).

In case any changes to the SPC are requested with the harmonisation of the package leaflet and labelling, this should be submitted as a type II variation.

Best Practice Guide for the Reference Member State in the Mutual Recognition and Decentralised Procedures

The CMD(h) has agreed an updated BPG for the RMS in the MRP and DCP, mainly to consider the Decentralised procedure and the CMD(h) referral procedure.

Informed consent applications in Mutual Recognition and Decentralised Procedures - Recommendations

The CMD(h) has updated the document 'Informed consent applications in MRP and DCP – Recommendations', mainly to include the new legal references and to consider the possibility to follow the decentralised procedure for informed consent applications.

For information on the dossier requirements for informed consent applications, Applicants are advised to contact the National Competent Authorities.

Applicants are reminded that the CTD format has to be used for the submission of the Module 3 for informed consent applications (when requested).

Extension applications in Mutual Recognition and Decentralised Procedures – Member States Recommendations

The CMD(h) has agreed an updated document 'Extension applications in MRP and DCP – MSs Recommendations', to include the new legal references for the legal basis of the applications and to consider the decentralised procedure and the harmonisation of the labelling and package leaflet.

Best Practice Guide on Break-out sessions for Mutual Recognition and Decentralised Procedures

Further to the publication of the BPG on Break-out Sessions for a one month public consultation with the March 06 CMD(h) press release, the CMD(h) has considered the comments received from Interested Parties and agreed a final updated Best Practice Guide.

In the updated Best Practice Guide it has been clarified that Applicants are allowed to participate in the break-out session to ensure an efficient dialogue with Member States on the outstanding issues.

The CMD(h) would like to thank Interested Parties for the contribution on the revision of the Best Practice Guide on Break-out sessions.

Update of Guideline on dossier requirements for Type IA and IB notifications – Practical information on notifications 7, 8, 14 and 15

Applicants are informed that the Guideline on dossier requirements for Type IA and IB notifications has been updated and is published in Notice to Applicants, Volume 2C – Regulatory Guidelines http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/var_type_1a1b_guideline_06-2006.pdf

Notifications submitted as of 1 October 2006 have to comply with the Guideline on dossier requirements for Type IA and IB notifications.

Information on MR procedures for new active substances

A mutual recognition procedure for a medicinal product containing human normal immunoglobulin has been finalised on 08.06.2006. Please find below information on the Invented name, INN, MAH, Indication, Procedure number and Day 90.

Invented Name (RMS)	Gamunex 10%
INN	Human normal immunoglobulin
Marketing Authorisation Holder	Bayer Vital GmbH
Indication	<p><u>Replacement therapy in:</u> <i>Primary immunodeficiency syndromes such as:</i></p> <ul style="list-style-type: none"> - Congenital agammaglobulinaemia and hypogammaglobulinaemia - common variable immunodeficiency - severe combined immunodeficiency - Wiskott-Aldrich syndrome <p><i>Multiple myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections,</i></p> <p><i>Children with congenital AIDS and recurrent severe bacterial infections.</i></p> <p><u>Immunomodulation in:</u> <i>Idiopathic thrombocytopenic purpura (ITP) in adults and children at high risk of bleeding or to correct the platelet count prior to surgery,</i></p> <p><i>Guillain-Barré syndrome,</i></p> <p><i>Kawasaki disease (in conjunction with acetylsalicylic acid therapy).</i></p> <p><u>Allogeneic bone marrow transplantation.</u></p>
Procedure number	DE/H/0473/001/MR
Day 90	08.06.2006

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 6 and 10 July 2006.

Name of the product in the RMS	Uvadex
Active substance	methoxasalen
Pharmaceutical form	Solution for haemofiltration
Procedure number	UK/H/397/01/E/01
CMS	AT, DE (wave 1) BE, CZ, DK, EL, ES, FI, FR, HU, IT, NL, NO, PL, PT, SE (wave 2)
Legal basis	Article 8.3, Directive 2001/83/EC – Full dossier
Grounds for referral to CMD(h)	One CMS was concerned at the evidence supporting dose and irradiation conditions for photoactivation and characterisation of photoactivated cells in relation to clinical efficacy. CMS were reassured by clarification from the company along with a commitment to completion of further characterisation studies.
Day 60	06.07.06
Outcome	Agreement reached

Name of the product in the RMS	Ciprofloxacin Hikma
Active substance	ciprofloxacin
Pharmaceutical form	Solution for infusion
Procedure number	NL/H/679/01/MR
CMS	AT, DE, IE, IT, UK
Legal basis	Art 10.1, Directive 2001/83/EC - Generic
Grounds for referral to CMD(h)	The procedure highlighted differences in approved indications, posology and contra-indications between national ‘brand leader’ SPCs. Specifically, the referring CMSs objected to the RMS approved posology for complicated urinary tract infections, UTI (200-400 mg twice daily) and considered that the maximum recommended daily dose (1200mg) should be decreased to 800mg daily. In the absence of data in favour or against the different options under discussion a consensus could not be reached on the posology. Consensus was reached on the other grounds of referral, which means that the indications treatment of osteomyelitis and complicated skin infections was accepted by all Member States, like as the contraindication for the concomitant use with tizanidine, and the inclusion of a special warning for use in patients with pre-existent significant renal disorders. All CMD members were of the opinion that the organisms listed in the breakpoints and susceptibility table should be relevant to the indications exclusively. It was decided to add this point to the request for an article 29(4) referral as a remark.
Day 60	06.07.06
Outcome	Referred to CHMP for arbitration

Name of the product in the RMS	Alendronat Hexal
Active substance	alendronic acid
Pharmaceutical form	Tablet
Procedure number	SE/H/517/01/E01
CMS	DE, PL (wave 1) BE, DK, EL (wave 2)
Legal basis	Article 10.1, Directive 2001/83/EC – Generic
Grounds for referral to CMD(h)	The indication "Prophylaxis of glucocorticoid-induced osteoporosis" was initially not accepted by one member state, but was accepted during the CMD(h) referral. The indication "Treatment of osteoporosis in men" is not acceptable to two CMS.
Day 60	10.07.06
Outcome	Referred to CHMP for arbitration

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **60** new Mutual Recognition Procedures were finalised during the month of June 2006. **6** Mutual Recognition Procedures for new applications were referred to CMD(h) in this period. **1** Mutual Recognition Procedure for a new application was referred to CHMP in this period.

The status as of 30th June 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	253	258	43 N.A.	23	15

44 Mutual Recognition Procedures (regarding **94** products) started in June 2006. The categories of these procedures are as follows:

1 new active substance (classified as a multiple application).

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

35 abridged applications, including **13** multiple applications and **1** repeat use.

1 line extension application, which is a repeat use.

The new procedures started in June related to **3** full dossiers, **29** generics, **6** hybrid applications and **6** bibliographic applications.

The procedures consisted of **43** chemical substances and **1** biological blood product.

All of these procedures were prescription-only medicinal products in the reference Member State¹.

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.

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

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
CZ (1)	6
DE (3)	1
DE (3)	26
DE (3)	1
DE (1)	1
DE (2)	6
DE (2)	9
DE (7)	10
DE (1)	10
FI (1)	22
FI (1)	16
FI (1)	1
FI (1)	23
FI (1)	4
FI (3)	8
FI (9)	13
FI (3)	2
FI (3)	3
FI (3)	10
FI (1)	11
NL (2)	2
NL (2)	6
NL (2)	4
NL (2)	1
NL (2)	2
NL (2)	1
NL (2)	4
NL (2)	3
NL (2)	2
NL (2)	1
NL (2)	9
NL (2)	1
NL (1)	1
NL (3)	6
NL (2)	1
SE (1)	1
SE (1)	5
SE (2)	22
UK (1)	10
UK (2)	17
UK (1)	1
UK (2)	3
UK (2)	16
UK (2)	1

Decentralised Procedure

The status as of 30th June 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	--	202	--	--	--

44 Decentralised Procedures (regarding **75** products) started in June 2006. The categories of these procedures are as follows:

1 new active substance application (first application in the European Community).

43 abridged applications, including 24 multiple applications.

The new Decentralised procedures started related to 1 full dossier and 43 generic applications.

All of these procedures consisted of chemical substances.

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

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.

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

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
CZ (2)	2
DE (2)	1
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	1
DK (5)	11
DK (3)	17
DK (3)	3
DK (5)	1
FI (3)	9
NL (3)	22
NL (1)	23
NL (3)	3
NL (3)	3
NL (2)	6
NL (2)	14
NL (2)	6
NL (2)	1
NL (1)	21
NL (1)	16
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	19
NL (1)	4
NL (1)	10
NL (1)	9
NL (1)	14
NL (1)	5
NL (1)	5
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	1
NL (4)	11
UK (1)	17
UK (2)	20
UK (2)	20
UK (1)	1
UK (1)	1

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **284** type IA variations, **150** type IB variations and **154** type II variations were finalised during the month of June 2006. **26** renewals were finalised in this period.

The status as of 30th June 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	2119	1102	831	148	--

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/>