

Report from the CMD(h) meeting held on 21st and 22nd January 2008

Summary of CMD(h) Activities in 2007

The CMD(h) has agreed to publish on the website, for transparency reasons, a summary of the main activities carried out by the CMD(h) and its sub-groups/working groups in the areas identified as priorities for 2007 in the CMD(h) work plan. A list of new and revised CMD(h) documents and questions & answers developed by the CMD(h) in 2007 is included as an Annex to the document.

MRP/DCP statistics in 2007

Statistics regarding new applications in the MRP and DCP in 2007 according to the 5-level classification will be published on the website.

The statistics will also include information on the referrals to the CMD(h), addressing the referrals to the CMD(h) per type of procedure (MRP vs DCP), per type of product, per therapeutic area, per legal basis, per grounds and per outcome.

CMD(h) Work plan for 2008

The CMD(h) has agreed a work plan for 2008. The work plan will be published on the website, for transparency reasons.

The CMD(h) identified as new priorities for 2008, the evaluation of the functioning of the CMD(h), to contribute to a successful implementation of the Paediatric Regulation, to increase transparency on outcome of referral discussions, to contribute to a truly mutual recognition with a focus on a targeted approach and elimination of full parallel assessment by CMSs, etc.

The CMD(h) maintained as priorities for 2008, an active participation of all CMD(h) Members, improvement of existing MR and DC procedures, to achieve a harmonised approach with regard to user consultation requirements and acceptance of bridging data, etc.

List of medicinal products for SPC harmonisation – Outcome of consultation with Interested Parties

The CMD(h) has considered, at the meeting of the sub-group on harmonisation of SPCs, the comments received from Interested Parties on the list of medicinal products for SPC harmonisation, published on the website for an eight week period for public consultation.

The CMD(h) concluded that, in principle, no change to the initial list was required. However, the CMD(h) agreed to further evaluate the need for the initiation of Article 30 referral procedures for Lescol (fluvastatin) and Seroquel (quetiapine) in 2008.

The final list of products for SPC harmonisation will be sent to the EC, as foreseen in Article 30(2) of Directive 2001/83/EC, as amended.

The EC or a Member State, in agreement with the EMEA and taking into account the views of Interested Parties, may refer these products to the CHMP in accordance with Article 30(1) of Directive 2001/83/EC, as amended.

It is envisaged that prior to the start of the Article 30 referral procedures, the respective Marketing Authorisation Holders will be invited for pre-referral meetings.

Requirements on electronic submissions for new applications in the MRP, DCP or national procedures

Further to the work carried out by the Working Group on Validation issues/National requirements, the CMD(h) has agreed to publish on the website a table listing the number of electronic copies requested by each National Competent Authority for new applications for marketing authorisation.

CMD(h) meeting with representatives of Interested Parties

The report from the CMD(h) meeting on 12 November 2007 with representatives of AESGP, EFPIA was agreed and will be published on the website, for transparency reasons.

User consultation with target patient groups – two years on from the introduction of the new legal requirement

On 22 November 2007, the EMEA and CMD(h) organised the 2nd workshop on user consultation in the context of readability testing of package leaflet for medicines. The workshop “User testing and how to review the data” was a follow up from the first one held on 23 October 2006 and was aimed at reviewing and bringing together experience and expertise of European regulators with readability testing of the package leaflet by target patient groups.

The press release from the workshop is available on the EMEA website

<http://www.emea.europa.eu/meetings/conference2007.htm#>

EU Work sharing Project – Assessment of paediatric data

The Paediatric public assessment report for Losec, omeprazole will be made available on the CMD(h) website, under Paediatric data assessment, Assessment reports on paediatric data.

Implementation of warnings on suicidal thoughts and behaviour for antidepressants

Further to the meeting of the CMD(h) and the PhVWP with representatives of Interested Parties on 12 December 2007, to discuss co-ordinated Europe wide implementation of core safety information for antidepressants, the following timetable has been agreed by the CMD(h) and PhVWP for implementation of warnings on suicidal thoughts and behaviour for antidepressants:

4 February 2008	Variation applications requested by NCAs
3 March 2008	Variation applications submitted by MA holders
3 June 2008	Variation applications approved by NCAs
3 October 2008	Updated PLs into new production batches

The agreed SPC and package leaflet wording and a PhVWP public assessment report will be published on the CMD(h) website, under Product information.

ACE inhibitors and Angiotensin II Receptor Antagonists (AIIRAs) - Recommendations on the use during the 1st trimester of pregnancy

The CMD(h) has endorsed the recommendations from the PhVWP in October 2007 regarding the use of ACE inhibitors and Angiotensin II Receptor Antagonists (AIIRAs) during the 1st trimester of pregnancy. The agreed SPC wording for ACE inhibitors and AIIRAs will be published on the CMD(h) website, under Product information.

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 product in the RMS, active substance, pharmaceutical forms, procedure number, CMS, legal basis, grounds for referral to CMD(h), Day 60 and outcome of the procedure, for the referral to the CMD(h) finalised on 20.12.2007.

Name of the product in the RMS	Ribavirin "iQur"
Active substance	ribavirin
Pharmaceutical form	Hard capsule (DK/H/1081/001/DC) Film-coated tablet (DK/H/1081/002-004/DC)
Procedure number	DK/H/1081/001-004/DC
CMS	DE, EL, FR, IE, IT, PL
Legal basis	Art 10a Dir 2001/83/EC – Bibliographic
Grounds for referral to CMD(h)	The procedure was referred to the CMD(h) on the grounds that published references only are insufficient to support efficacy and safety of the product.
Day 60	20 December 2007
Outcome	An oral hearing took place at the December 2007 CMD(h) meeting. It was though not possible to reach agreement and the product is referred to the CHMP for arbitration.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **54** Mutual Recognition Procedures were finalised during the month of December 2007. **5** Mutual Recognition Procedures were referred to CMD(h) in this period. **No** Mutual Recognition Procedure was referred to CHMP in this period.

The status as of 31st December 2007 of procedures under Mutual Recognition is as follows:

Year	New applications finalised	New applications in process	Referred to CMD(h)	Agreement reached in the CMD(h) For procedures referred in		Withdrawn during CMD(h) referral	Applications referred to CHMP For procedures referred to CMD(h) in	
				2006	2007		2006	2007
2007	441 ¹	159	44	25	26	1	9	6

33 Mutual Recognition Procedures (regarding **81** products) started in December 2007. The categories of these procedures are as follows:

9 known active substance (already authorised in at least one member state) applications;

22 abridged applications, including **11** multiple and **3** repeat use applications.

2 New Active Substance applications, which are repeat-use applications.

The new procedures started in December 2007 related to **5** full dossier, **22** generics, **1** informed consent, **1** bibliographic and **4** fixed combination applications.

31 of these procedures consisted of chemical substances, **1** biological blood product and **1** biological vaccine product.

31 of these procedures related to prescription-only medicinal products and **2** to non-prescription medicinal products in the reference Member State².

Number of countries involved in the new applications in Mutual Recognition procedure started in December 2007.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
BE (3)	11
CZ (2)	8
DE (3)	6
DE (1)	12
DE (1)	11
DE (2)	2
DE (2)	24
DE (2)	28
DE (2)	2
DK (1)	2
DK (3)	4
DK (3)	3
DK (3)	4
DK (3)	7
DK (3)	3
DK (2)	4
DK (3)	2
DK (3)	6

¹ The total number of finalised procedures has been updated following the calculation of the annual statistics.

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.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (3)	6
DK (3)	4
DK (3)	6
DK (3)	2
FI (1)	11
IE (1)	1
NL (1)	25
NL (1)	5
NO (2)	3
NO (6)	25
PT (2)	1
PT (4)	13
SE (4)	2
SE (4)	3
UK (1)	14

Decentralised Procedure

The CMD(h) noted that there were **67** Decentralised Procedures finalised during the month of December 2007 with a positive outcome. There were **2** Decentralised procedures withdrawn after Day 120. **4** Decentralised Procedures were referred to the CMD(h) in this period. **1** Decentralised Procedure was referred to the CHMP in this period.

The status as of 31st December 2007 of procedures under Decentralised Procedure is as follows:

Year	New applications finalised		New applications withdrawn ³	New applications in process	Referred to CMD(h)	Agreement reached in the CMD(h) For procedures referred in		Withdrawn during CMD(h) referral	Referred to CHMP For procedures referred to CMD(h) in	
	Positive outcome	Negative outcome				2006	2007		2006	2007
2007	386 ⁴	6	20	1038	25	1	11	3	--	7

76 Decentralised Procedures (regarding **192** products) started in December 2007. The categories of these procedures are as follows:

65 abridged applications, including **21** multiple applications.

2 known active substance applications.

1 New active substance.

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

The new Decentralised procedures started in December related to **62** generic, **3** fixed combination, **4** hybrid and **7** full dossiers.

All of these procedures consisted of chemical substance applications.

74 of these procedures related to prescription-only medicinal products and **2** to non-prescription medicinal products in the reference Member State⁵.

³ After day 120.

⁴ The total number of finalised procedures has been updated following the calculation of the annual statistics.

⁵ 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.

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Number of countries involved in the new applications in Decentralised procedures started in December 2007.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (5)	8
DE (4)	24
DE (3)	4
DE (3)	10
DE (2)	8
DE (1)	7
DE (3)	6
DE (3)	2
DE (2)	4
DE (5)	1
DE (5)	1
DE (5)	5
DK (1)	1
DK (2)	3
DK (1)	6
DK (1)	2
DK (1)	15
DK (1)	1
DK (1)	1
DK (2)	2
FR (3)	14
FR (1)	5
FR (1)	10
FR (2)	15
FR (2)	1
FR (1)	18
HU (3)	2
NL (2)	17
NL (2)	3
NL (2)	5
NL (1)	14
NL (1)	28
NL (1)	14
NL (1)	25
NL (2)	19
NL (6)	6
NL (6)	4
NL (6)	4
NL (1)	8
NL (1)	1
NL (6)	1
NL (3)	1
NL (6)	1
NL (5)	3
NL (2)	4
NL (2)	5
PL (2)	3
PL (3)	2
PL (3)	2
PL (3)	2
PL (3)	2
SE (1)	25
SE (1)	2
SE (1)	1
SE (1)	1
SE (9)	11
SE (2)	6
SE (2)	19
UK (4)	6
UK (4)	2
UK (4)	16
UK (1)	13
UK (1)	8

UK (2)	6
UK (1)	9
UK (2)	1
UK (3)	1
UK (4)	1
UK (3)	1
UK (3)	8
UK (2)	17
UK (3)	2
UK (1)	12
UK (1)	17
UK (1)	8
UK (2)	1

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **403** type IA variations, **173** type IB variations and **136** type II variations were finalised during the month of December 2007. **36** renewals were finalised in this period.

The status as of 31st December 2007 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	Applications referred to CHMP
2007	5640	2298	2167	395	8

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The global status since 1st January 1995 is as follows (further detailed statistics can be found at the CMD(h) website):

YEARS	MRP NEW APPLICATIONS FINALISED	DCP NEW APPLICATIONS FINALISED	TYPE I VARIATIONS FINALISED	TYPE IA VARIATIONS FINALISED	TYPE IB VARIATIONS FINALISED	TYPE II VARIATIONS FINALISED	MRP/DCP REFERRED TO CMD(H)	ARBITRATIONS REFERRED TO CHMP
1995	10		16			17		1 N.A.
1996	84		49			73		1 N.A. and 1 variation
1997	146		101			163		1 N.A. and 1 variation
1998	182		339			222		1 N.A. and 4 variations
1999	228		671			301		2 N.A. and 2 variations
2000	306		1007			320		3 N.A. and 2 variations
2001	443		1487			474		1 N.A. and 3 variations
2002	420		2104			527		2 N.A. and 7 variations
2003	529		2473	230	94	754		5 N.A. and 3 variations
2004	760		43	3240	1998	1083		9 N.A.
2005	954		N/A	4044	1944	1509	10 N.A.	2 N.A. and 7 variations
2006	535	57	N/A	4524	2209	1916	105 N.A.	22 N.A.
2007	441	392	N/A	5640	2298	2167	69 N.A.	22 N.A. and 8 variations
1995-2007	5038	449	N/A	17678	8543	9526	184 N.A.	72 N.A. and 38 variations

All documents mentioned in this press release can be found at the CMD(h) website 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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<http://www.hma.eu/cmdh.html>