

Report from the CMD(h) meeting held on 20th, 21st and 22nd October 2008

List of medicinal products for SPC harmonisation – Consultation with Interested Parties

The CMD(h) has agreed a new 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.

The list of medicinal products for SPC harmonisation will be published on the website for an eight week period for public consultation.

Any comments on the list of medicinal products for SPC harmonisation should be sent to the CMD(h) secretariat (H-CMDhSecretariat@emea.europa.eu) by **Friday, 19 December 2008**, coordinated where possible by trade associations.

With the aim of increasing transparency on the CHMP referrals for medicinal products included in the CMD(h) lists for SPC harmonisation, in accordance with Article 30(2) of Directive 2001/83/EC, as amended, the CMD(h) has agreed to publish a table with information on the status of the CHMP referral and, for the finalised referrals, to include the date of the CHMP opinion, a link to the respective Commission Decision and the Reference Member State.

CMD(h)/EMA Sub-Group on Paediatric Regulation

Further to the CMD(h) agreement to start with the work-sharing for the assessment of paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation, the CMD(h) has agreed to publish, for transparency reasons, a list of the active substances included in the first wave of the work-sharing procedure. This information will be published under Paediatric data assessment, Responsibilities from paediatric regulation.

Marketing Authorisation Holders are reminded to use the contact addresses for submission of paediatric information in Member States, available on the CMD(h) website, under 'Contact points', when submitting the paediatric studies for assessment to the attention of the Rapporteurs.

EU Work sharing Project – Assessment of paediatric data

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

Informal CMD(h) meeting – Paris, France

The CMD(h) convened for an Informal meeting on 6th and 7th October 2008 in Paris, France, held as part of a programme of events organised under the French Presidency of the Council of the EU.

The main topics discussed at the meeting included a joint session with the CHMP, to discuss Article 29(4) referrals and acceptance of new data during referral procedures, legal tools on class reviews, eligibility to therapeutic innovation, etc.

The CMD(h) discussed proposals to reduce the number of referral procedures, validation issues, Article 29 of the Paediatric Regulation and resources in MRP/DCP, including proposals for elimination of full parallel assessment in MRP/DCP.

The CMD(h) discussed also a proposed action plan to address the outcome of the questionnaire to CMD(h) Members and Interested Parties on the functioning of the CMD(h), including proposals for improvement of the CMD(h) website.

Name of generics of reference medicinal products authorised by the Community

The CMD(h) has agreed a Q&A to clarify that the name of a generic of a centrally authorised medicinal product should be the same in all Member States where it is authorised regardless of the procedure followed for authorisation, i.e. centralised, mutual recognition or decentralised procedure.

The CMD(h) has also agreed another Q&A to address the possibility to change the name of a generic of a centrally authorised medicinal product, following the transfer of the marketing authorisation to a new Marketing Authorisation Holder in one or several MS.

The new Q&As will be published on the CMD(h) website under FAQ, generics.

Recommendations for Mutual Recognition Procedure after finalisation of an arbitration procedure with a positive decision by the European Commission

The CMD(h) has agreed a revised version of the recommendation for mutual recognition procedure after finalisation of an arbitration procedure with a positive decision by the European Commission.

Any comments on the revised recommendation should be sent to the CMD(h) Secretariat (HCMDhSecretariat@emea.europa.eu) by **5th January 2009**, coordinated where possible by trade associations.

Use of QRD Templates in MRP/DCP

Applicants/MAHs are reminded to use QRD templates for submission of the product information in the framework of applications for marketing authorisation, variations and renewals.

The 'clean' QRD template for use in MRP, DCP or referral procedure is published in all languages on the website of the EMEA, under Human Medicines – Quality Review of Documents (QRD) <http://www.emea.europa.eu/htms/human/qrd/qrdtemplate.htm>

Biphosphonates and Atrial fibrillation

Further to the PhVWP report to CMD(h) on biphosphonates and atrial fibrillation, agreed by the PhVWP in September 2008, the following timetable has been agreed by the CMD(h) and PhVWP for implementation of agreed SPC and PL changes for medicinal products containing pamidronic acid

30 November 2008	Variation applications requested through CMD(h)
31 December 2008	Variation applications submitted by MA holders
28 February 2009	Variation applications approved by NCAs

The PhVWP recommended SPC and package leaflet wording will be published on the CMD(h) website, under 'Pharmacovigilance, PhVWP recommendations'.

EU GMP Guide Part II Basic Requirements for Active Substances used as Starting Material – GMP compliance for Active Substances

The CMD(h) would like to refer Applicants/MAHs to the Q&A published on the EMEA website, under Inspections – Good Manufacturing Practices <http://www.emea.europa.eu/Inspections/gmp/q27.htm> addressing the submission of declarations by the Qualified Persons that the active substances used are manufactured in accordance with GMP for active substances not normally used as pharmaceutical active substances.

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

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 referrals to the CMD(h) finalised on 02.10.2008 will be available on the table with information on all applications referred to the CMD(h), published under 'CMD(h)-Referrals'.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **43** Mutual Recognition Procedures were finalised during the month of September 2008. **1** Mutual Recognition Procedures was referred to CMD(h) in this period. There were **no** Mutual Recognition Procedures referred to CHMP in this period.

The status as of 30th September 2008 of procedures under Mutual Recognition is as follows:

Year	New applications finalised ¹	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	
				2007	2008		2007	2008
2008	332	94	36	7	12	1	2	3

34 Mutual Recognition Procedures (regarding **67** products) started in September 2008. The categories of these procedures are as follows:

26 abridged applications, including **6** multiple and **3** repeat use applications.

7 known active substance applications, including **2** repeat use applications.

1 new active substance application, which is a repeat use application.

The new procedures started in September 2008 related to **5** full dossier, **25** generic, **3** bibliographic and **1** hybrid application.

32 of these procedures consisted of chemical substance products and **2** biological blood products.

¹ Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised.'

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

Number of countries involved in the new applications in Mutual Recognition procedure started in September 2008.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
CZ (2)	1
DE (1)	22
DE (2)	11
DE (1)	1
DK (3)	8
DK (2)	16
DK (2)	8
DK (1)	28
FI (3)	10
FR (2)	10
IE (4)	1
NL (3)	22
NL (1)	4
NL (2)	7
NL (1)	6
NL (3)	1
NL (3)	1
NL (3)	1
NL (3)	1
NL (2)	1
NL (4)	1
PT (1)	2
PT (1)	1
SE (1)	2
SE (2)	1
SE (1)	4
SE (2)	1
SE (1)	25
UK (1)	2
UK (1)	3
UK (2)	8
UK (2)	6
UK (2)	1
UK (2)	9

Decentralised Procedure

The CMD(h) noted that there were **74** Decentralised Procedures finalised with a positive outcome and **2** with negative outcome during the month of September 2008. **2** Decentralised Procedures were withdrawn after day 120. **4** Decentralised Procedures were referred to the CMD(h) in this period. There were **no** Decentralised Procedures referred to the CHMP in this period.

The status as of 30th September 2008 of procedures under Decentralised Procedure is as follows:

Year	New applications finalised ³	New applications withdrawn (After day 120)	New applications in process	Referred to CMD(h)	Agreement reached in the CMD(h)		Withdrawn during CMD(h) referral	Referred to CHMP	
					For procedures referred in 2007	2008		For procedures referred to CMD(h) in 2007	2008
2008	568	7	1494	30	2	12	1	2	1

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.

³ Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. This cumulative figure includes positive and negative procedures as well as those referred to CHMP.

166 Decentralised Procedures (regarding **298** products) started in September 2008. The categories of these procedures are as follows:

164 abridged applications, including **69** multiple applications.

2 known active substance applications.

The new Decentralised procedures started in September related to **158** generic, **1** bibliographic, **6** hybrid and **1** full dossier.

All of these procedures consisted of chemical substance applications.

All of these procedures related to prescription-only medicinal products in the reference Member State⁴.

Number of countries involved in the new applications in Decentralised procedures started in September 2008.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (1)	1
AT (1)	1
AT (1)	2
AT (1)	1
CZ (2)	8
CZ (4)	11
DE (4)	7
DE (1)	1
DE (1)	27
DE (1)	1
DE (1)	2
DE (1)	2
DE (1)	2
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	22
DE (1)	2
DE (1)	3
DE (1)	9
DE (1)	4
DE (1)	3
DE (3)	16
DE (2)	8
DE (2)	9
DE (2)	9
DE (4)	11
DE (4)	13
DE (4)	8
DE (4)	1
DE (4)	1
DE (1)	5
DE (1)	11
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	16
DE (1)	1
DE (1)	1
DE (1)	5
DE (1)	9
DE (1)	1
DE (1)	1

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.

DE (1)	1
DK (5)	19
DK (5)	4
DK (5)	4
DK (1)	6
DK (1)	1
DK (1)	1
DK (1)	12
DK (1)	2
DK (1)	2
DK (1)	1
DK (1)	1
DK (1)	2
DK (1)	14
DK (1)	15
DK (1)	1
DK (1)	1
DK (1)	1
DK (1)	14
DK (1)	3
DK (1)	1
DK (1)	2
FR (3)	1
FR (3)	1
FR (3)	1
FR (3)	7
FR (3)	1
FR (3)	1
HU (1)	5
HU (1)	7
HU (1)	11
HU (1)	7
IT (3)	8
NL (1)	5
NL (3)	27
NL (1)	2
NL (1)	1
NL (1)	5
NL (3)	7
NL (3)	3
NL (3)	1
NL (3)	1
NL (3)	1
NL (3)	1
NL (3)	1
NL (3)	1
NL (4)	6
NL (4)	1
NL (4)	3
NL (4)	1
PT (3)	6
PT (1)	8
SE (1)	15
SE (2)	2
SE (2)	20
SE (1)	1
SE (1)	1
SE (1)	1
SE (1)	1
SE (1)	3
SE (1)	1
SE (1)	6
SE (1)	6
SE (1)	6
SE (1)	6
SE (2)	2

SE (2)	2
UK (3)	4
UK (4)	8
UK (2)	4
UK (1)	4
UK (2)	6
UK (1)	5
UK (2)	3
UK (1)	2
UK (2)	5
UK (1)	13
UK (1)	1
UK (1)	10
UK (2)	1
UK (2)	1
UK (1)	1
UK (1)	1
UK (4)	12
UK (2)	4
UK (2)	10
UK (2)	16
UK (1)	6
UK (1)	4
UK (2)	5
UK (2)	1
UK (1)	6
UK (2)	6
UK (2)	4
UK (1)	22
UK (1)	5
UK (1)	4
UK (5)	18
UK (5)	1
UK (1)	11
UK (5)	1
UK (2)	7
UK (2)	2
UK (2)	3
UK (2)	8
UK (2)	7
UK (2)	1
UK (1)	1
UK (1)	1
UK (1)	17
UK (1)	4
UK (1)	1
UK (1)	1
UK (1)	1
UK (1)	2
UK (1)	1
UK (1)	2
UK (1)	1
UK (4)	2
UK (2)	2
UK (1)	1

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **538** type IA variations, **236** type IB variations and **205** type II variations were finalised during the month of September 2008. **46** renewals were finalised in this period. There were **no** procedures referred to the CHMP in this period.

The status as of 30th September 2008 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
2008	5053	2031	2100	344	2

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) or from the CMD(h) Secretariat:

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*Or you could visit the **CMD(h) web site** at:*

<http://www.hma.eu/cmdh.html>