

Report from the CMD(h) meeting held on 22nd, 23rd and 24th September 2008

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

The CMD(h)/EMA Sub-Group has agreed to start with the first-wave of the work-sharing for the assessment of paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation. Marketing Authorisation Holders will be requested to submit the paediatric studies to the appointed Rapporteur within one month of the request (i.e. by beginning of November 2008).

Further to the CMD(h) recommendation to Applicants to consider requesting the Paediatric Committee to assess compliance of the application for marketing authorisation with the agreed paediatric investigation plan, prior to the submission of the application, please note the publication on the EMA website <http://www.emea.europa.eu/pdfs/human/paediatrics/55363107en.pdf> of the 'Procedural advice for validation of new marketing authorisation application/extension/variation application and compliance check with an agreed PIP.' The procedural advice includes a template for compliance check request to be submitted by the Applicant.

The CMD(h) has finalised the Best Practice Guide on the EU Work Sharing procedure for paediatric studies submitted according to Article 45 of the Paediatric Regulation, further to the comments received during the consultation procedure. The final BPG will be published on the CMD(h) website.

The CMD(h) has agreed two additional questions and answers to address when is a medicinal product considered not authorised in the Community and the concept of global marketing authorisation, in the context of Articles 7 and 8 of the Regulation (EC) No 1901/2006, as amended.

The Q&As will be published on the CMD(h) website.

EU Work sharing Project – Assessment of paediatric data

The Paediatric public assessment reports for Zofran (ondansetron), Ciloxan (ciprofloxacin) and Glucovance (metformin/glibenclamide) will be made available on the CMD(h) website, under Paediatric data assessment, Assessment reports on paediatric data.

Ibuprofen and low dose aspirin interaction – Plan for implementation of agreed SPC changes (sections 4.5 and 5.1)

Further to the PhVWP report to CMD(h) on ibuprofen and low dose aspirin interaction, agreed by the PhVWP in June 2008, the following timetable has been agreed by the CMD(h) and PhVWP for implementation of agreed SPC changes (sections 4.5 and 5.1):

30 September 2008	Variation applications requested through CMD(h)
30 November 2008	Variation applications submitted by MA holders
30 January 2009	Variation applications approved by NCAs
30 April 2009	Updated PLs into new production batches

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

Sub-group meeting on Harmonisation of SPCs

There was a meeting of the Sub-Group on harmonisation of SPCs, to discuss the rationales for selection of the products to be included in the 2008 CMD(h) list for SPC harmonisation.

The CMD(h) will agree on a draft list of medicinal products for SPC harmonisation, that will be published for public consultation, at the October meeting.

Working Group on Validation issues/National requirements

Further to the work carried out by the Working Group on Validation issues/National requirements, the CMD(h) has agreed on a document on common grounds seen for invalidation/delaying day 0 for variations that will be published on the CMD(h) website.

Please note that an updated table with additional data requested for new applications in the mutual recognition and decentralised procedures has been published on the CMD(h) website under, Procedural guidance, Application for MA.

Informal CMD(h) meeting – Paris, France

An informal meeting will be held in Paris on 6-7 October 2008. The meeting will include a joint session with CHMP to discuss, amongst other topics, Article 29(4) referrals and legal tools on class reviews. The CMD(h) will discuss the Paediatric Regulation, proposals to reduce CMD(h) referrals, validation issues, resources in MRP/DCP and proposals for improvement of the functioning of the CMD(h).

Timetables for MRP/DCP applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended

The CMD(h) has adopted an updated guidance document with the timetables for MRP/DCP applications referred to the CMD(h) for the 60-days referral procedure for 2009. The updated guidance document will be published on the CMD(h) website under CMD(h) referrals.

Submission of Variations before a marketing authorisation has been granted

The CMD(h) has agreed a Q&A to reflect the CMD(h) agreement that in the situation where not all MSs involved in a mutual recognition or decentralised procedure have granted a marketing authorisation within 30 days after finalisation of the procedure, Marketing Authorisation Holders can submit variations after this date, provided that high quality translations of the agreed SPC, PL and labelling have been submitted to all involved MSs.

The Q&A will be published on the CMD(h) website under FAQ, variations.

Joint DIA-EMEA-CMD(h) Workshop on User Testing, 5 December 2008, London, UK

A joint DIA-EMEA-CMD(h) Workshop on User Testing, aimed at discussing EMEA and MSs experience in the assessment of user tests and give recommendations how the test can contribute to improve the quality of a package leaflet will be held in London on 5 December 2008.

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 03.07.2008 and 31.07.2008 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 **69** Mutual Recognition Procedures were finalised during the months of July and August 2008. **8** Mutual Recognition Procedures were referred to CMD(h) in this period. There were **2** Mutual Recognition Procedures referred to CHMP in this period.

The status as of 31st August 2008 of procedures under Mutual Recognition is as follows:

Year	New applications finalised¹	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
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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.’

				2007	2008		2007	2008
2008	279	139	35	7	12	1	2	3

94 Mutual Recognition Procedures (regarding **198** products) started in July and August 2008. The categories of these procedures are as follows:

73 abridged applications, including **33** multiple and **7** repeat use applications.

7 line extension applications.

11 known active substance applications, including **4** repeat use applications.

3 new active substance applications, which are **all** repeat use applications.

The new procedures started in July and August 2008 related to **11** full dossier, **63** generic, **7** bibliographic, **1** fixed combination, **1** informed consent and **11** hybrid applications.

92 of these procedures consisted of chemical substance products and **2** biological other products.

92 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 July and August 2008.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (1)	2
AT (1)	1
BE (1)	4
CZ (3)	3
CZ (4)	1
CZ (4)	1
CZ (4)	3
CZ (4)	1
CZ (4)	4
DE (1)	4
DE (1)	4
DE (1)	3
DE (1)	11
DE (2)	2
DE (1)	1
DE (1)	3
DE (2)	12
DK (1)	1
DK (2)	1
DK (4)	1
DK (1)	3
DK (1)	5
DK (2)	3
FI (2)	12
FR (1)	14
FR (1)	3
FR (1)	14
HU (2)	2
HU (2)	4
HU (2)	2
HU (2)	13
HU (1)	2
HU (2)	6
HU (2)	1
HU (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.

withdrawn after day 120. **7** Decentralised Procedures were referred to the CMD(h) in this period. There was **1** Decentralised Procedures referred to the CHMP in this period.

The status as of 31st August 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	482	5	1382	26	2	12	1	2	1

253 Decentralised Procedures (regarding **519** products) started in July and August 2008. The categories of these procedures are as follows:

226 abridged applications, including **72** multiple applications.

19 known active substance applications, including **2** multiple applications.

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

1 new active substance application.

The new Decentralised procedures started in July and August related to **194** generic, **5** fixed combination, **8** bibliographic, **32** hybrid and **14** full dossiers.

249 of these procedures consisted of chemical substance applications, **2** biological vaccines and **2** herbal products.

245 of these procedures related to prescription-only medicinal products and **8** to non-prescription medicinal products in the reference Member State⁴.

Number of countries involved in the new applications in Decentralised procedures started in July and August 2008.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (1)	2
AT (1)	2
AT (1)	6
AT (3)	8
AT (3)	10
AT (3)	1
AT (3)	1
AT (3)	1
AT (3)	1
AT (3)	4
AT (3)	1
AT (3)	1
AT (3)	1
AT (2)	5
AT (1)	14
AT (1)	14
AT (1)	9
AT (1)	7
AT (1)	6
AT (1)	7
AT (1)	4

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.

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.

AT (1)	1
CZ (1)	5
CZ (1)	8
DE (1)	11
DE (3)	1
DE (1)	16
DE (1)	1
DE (1)	4
DE (1)	4
DE (3)	4
DE (3)	17
DE (3)	4
DE (1)	11
DE (1)	8
DE (1)	8
DE (1)	1
DE (1)	4
DE (1)	1
DE (1)	17
DE (1)	11
DE (2)	7
DE (1)	1
DE (4)	2
DE (4)	15
DE (1)	16
DE (4)	19
DE (1)	1
DE (1)	2
DE (1)	2
DE (4)	18
DE (4)	1
DE (1)	2
DE (4)	19
DE (4)	3
DE (4)	2
DE (4)	1
DE (3)	1
DE (3)	1
DE (1)	3
DE (1)	9
DE (3)	6
DE (4)	1
DE (4)	13
DE (2)	5
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	9
DE (1)	1
DE (1)	1
DE (1)	2
DE (1)	1
DE (1)	3
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	1
DE (1)	2
DE (1)	1
DK (1)	5
DK (4)	5
DK (4)	5
DK (4)	1
DK (4)	1
DK (4)	1
DK (4)	1
DK (4)	1
DK (2)	1

DK (2)	1
DK (3)	9
DK (3)	3
DK (2)	9
DK (1)	8
FR (1)	25
FR (1)	18
FR (3)	28
FR (2)	2
FR (1)	6
HU (3)	1
HU (3)	2
HU (3)	2
IE (1)	1
IE (1)	5
IE (1)	3
IE (1)	1
IE (1)	1
IE (1)	1
IE (1)	1
IT (1)	6
IT (2)	5
IT (2)	6
IT (2)	3
IT (2)	4
IT (2)	1
NL (1)	15
NL (2)	5
NL (3)	24
NL (3)	9
NL (3)	8
NL (3)	12
NL (3)	11
NL (1)	5
NL (1)	14
NL (1)	9
NL (4)	2
NL (4)	3
NL (4)	4
NL (2)	2
NL (2)	3
NL (2)	4
NL (1)	18
NL (1)	6
NL (1)	1
NL (1)	2
NL (1)	3
NL (1)	5
NL (1)	1
NL (1)	1
NL (4)	3
NL (10)	18
NL (10)	4
NL (4)	1
NL (4)	1
NL (4)	1
NL (4)	1
NL (4)	3
NL (1)	23
NL (1)	5
NL (1)	11
NL (1)	2
NL (2)	4
NL (2)	14
NL (4)	13
NL (4)	1
NL (4)	2

NL (4)	1
NL (4)	6
NL (4)	9
NL (4)	1
NL (4)	1
NL (4)	1
NL (4)	1
NL (4)	1
NL (1)	13
NL (1)	1
NL (1)	2
NL (1)	1
NL (1)	7
NL (1)	9
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	1
NL (2)	1
NL (2)	1
NL (2)	1
PT (2)	2
PT (2)	1
PT (2)	1
PT (2)	10
SE (2)	14
SE (2)	11
SE (2)	6
SE (2)	1
SE (1)	21
SE (1)	1
SE (2)	22
SE (3)	1
SE (2)	20
SE (4)	3
SE (4)	1
SE (4)	1
SE (2)	18
SE (2)	1
SE (2)	5
SE (6)	14
UK (1)	9
UK (1)	1
UK (1)	1
UK (4)	6
UK (1)	7
UK (1)	1
UK (1)	1
UK (1)	3
UK (1)	5
UK (4)	5
UK (1)	5
UK (2)	7
UK (1)	1
UK (1)	1
UK (1)	23
UK (1)	23
UK (2)	7
UK (1)	1
UK (1)	25
UK (2)	12
UK (1)	9
UK (2)	2
UK (1)	2
UK (3)	8
UK (1)	1
UK (1)	1

UK (1)	5
UK (1)	24
UK (1)	18
UK (1)	4
UK (1)	11
UK (3)	1
UK (2)	1
UK (1)	21
UK (1)	1
UK (1)	15
UK (4)	7
UK (1)	7
UK (1)	4
UK (1)	9
UK (1)	18
UK (1)	7
UK (1)	6
UK (1)	4
UK (3)	11
UK (1)	1
UK (1)	5
UK (1)	6
UK (1)	5
UK (4)	5
UK (4)	3
UK (4)	1
UK (3)	3
UK (1)	1
UK (2)	1
UK (2)	4
UK (2)	5

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **1254** type IA variations, **506** type IB variations and **519** type II variations were finalised during the months of July and August 2008. **95** renewals were finalised in this period. There were **no** procedures referred to the CHMP in this period.

The status as of 31st August 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	4515	1795	1895	298	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):

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