

Report from the CMD(h) meeting held on 20th and 21st April 2009

Sub-group meeting on Harmonisation of SPCs

There was a meeting of the Sub-group on harmonisation of SPCs.

The Sub-group started to work on a new list of medicinal products for which a harmonised SPC should be drawn up and will consider additional proposals from Member States at the next meeting of the Sub-group, scheduled to take place in May 2009.

CMD(h)/EMA Subgroup on Paediatric Regulation

The CMD(h) has published a Best Practice Guide, in order to facilitate the assessment of information about nationally authorised medicinal products (including MRP and DCP) in a harmonised way according to Article 46 of the Paediatric Regulation. The Best Practice Guide includes sections on the organisation of the work-sharing, public paediatric assessment report, appointment of Rapporteurs, content of applications and a flow-chart on the assessment procedure.

The CMD(h)/EMA Sub-group has agreed to ask Marketing Authorisation Holders to confirm receipt of the EMA request for submission of paediatric studies in advance of the start of future waves of the work-sharing in accordance with Article 45 or 46 of the Paediatric Regulation.

Marketing Authorisation Holders are also requested to inform the EMA in case the Contact person for submission of paediatric studies or the details of the Marketing Authorisation Holder changes.

Marketing Authorisation Holders are reminded that they should have the paediatric studies ready for submission to the appointed Rapporteur within one month of the request.

Updated tables with requirements on electronic submission for New Applications & for Renewals and Variations within MRP, DCP or national procedures

The CMD(h) has agreed updated tables with requirements on electronic submission for new applications and for renewals and variations within MRP, DCP or national procedures, which will be published on the CMD(h) website, under Procedural guidance, Application for MA, eSubmissions.

Recommendation on implementation of Article 30 decisions for generics/hybrid/biosimilar medicinal products

The CMD(h) has agreed an updated recommendation, to address implementation of Article 30 decisions also for hybrids and biosimilar medicinal products.

The CMD(h) has also agreed that a proposal for harmonised package leaflet and labelling can be submitted within the Type IB variation – 46, provided that the proposed package leaflet and labelling are identical for the concerned sections to that annexed to the Commission decision and the submission takes place within 90 days of the publication of the Commission Decision.

Implementation of Commission Decisions after Article 30 referral procedures

A link to the Commission decisions, including the SPC, package leaflet and labelling of the finalised Article 30 referral procedures for **ramipril**, **ramipril/hydrochlorothiazide**, **valsartan** and **venlafaxine** has been published on the CMD(h) website.

Generic Companies are encouraged to contact the Reference Member State to harmonise the product information of the medicinal products authorised via MRP/DCP to conform to the Commission Decision, through submission of a Type IB variation – 46, provided the conditions set up in the Commission Regulation (EC) No 1084/2003 are met.

The CMD(h) has updated the tracking table on referrals in accordance with Article 30 of Directive 2001/83/EC, as amended, to include the respective procedure number following the referral procedure. The updated tracking table will be published on the CMD(h) website.

Question and Answer – Article 18 of Directive 2001/83/EC, as amended

The CMD(h) has agreed a revised Q&A on Article 18 of Directive 2001/83/EC, as amended, to address the situation of different dossiers for a medicinal product with the same qualitative and quantitative composition in active substances, the same pharmaceutical form and the same MAH.

The revised Q&A will be published on the CMD(h) website, under Questions & Answers, Applications for Marketing Authorisation.

Question and Answer - Legal basis for applications for marketing authorisation for products for local use

The CMD(h) has agreed a Q&A to address Member States views on the appropriate legal basis for applications for marketing authorisation where bioequivalence cannot be demonstrated through bioavailability studies, such as for products for local use intended to act without systemic absorption after e.g. oral, nasal, inhalation, ocular administration.

The CMD(h) recommends the submission of such applications according to Article 10(3) of Directive 2001/83/EC, as amended.

The submission of the results of the appropriate pre-clinical tests or clinical trials OR justification for its absence depends on the need for bridging vis-à-vis the reference medicinal product and will be assessed during the evaluation of the application.

The Q&A will be published on the CMD(h) website, under Questions & Answers, Generics & Usage patents.

Date of authorisation of a medicinal product in accordance with the Acquis Communautaire

The CMD(h) would like to inform Applicants that the EU harmonised birthdates published on the Heads of Medicines Agencies website should only be used for the purpose of PSUR Work-sharing.

Applicants should confirm with National Competent Authorities the date of the first authorisation of a medicinal product in accordance with the Acquis Communautaire, if they want to refer to this product in an application for marketing authorisation in accordance with Articles 10(1), 10(3) or 10(4) of Directive 2001/83/EC, as amended.

Alendronic acid and the risk of stress fractures of the proximal femoral shaft

The CMD(h) has endorsed the PhVWP report on alendronic acid and risk of stress fractures of the proximal femoral shaft and recommends the implementation of the PhVWP wording for the SPC and PL for all alendronic acid containing products.

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

Consultation with Target Patient Groups – meeting the requirements of Article 59(3) without the need for a full test – Recommendations for Bridging

The CMD(h) has agreed an updated version of the above mentioned recommendation. The recommendation clarifies the term 'bridging', which is used to describe the situation where because the leaflets are sufficiently similar in both content and layout, a successful user consultation on one leaflet can be used to demonstrate that another leaflet meets the requirements of Article 59(3) of Directive 2001/83/EC, as amended.

The updated recommendation provides also additional clarifications and examples on 'bridging'.

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 26.03.2009 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 **30** Mutual Recognition Procedures were finalised during the month of March 2009. **1** Mutual Recognition Procedures was referred to CMD(h) in this period. There was **1** Mutual Recognition Procedure referred to CHMP in this period.

The status as of 31st March 2009 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	
				2008	2009		2008	2009
2009	96	77	5	2	1	0	0	1

28 Mutual Recognition Procedures (regarding **71** products) started in March 2009. The categories of these procedures are as follows:

21 abridged applications, including **1** multiple and **5** repeat use applications.

5 known active substance applications, including **3** repeat use applications.

2 Line Extension applications, including **1** repeat use application.

The new procedures started in March 2009 related to **3** full dossier, **16** generic, **6** hybrid and **3** bibliographic applications.

27 of these procedures consisted of chemical substance products and **1** procedure consisted of a biological other product.

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.'

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

New applications in Mutual Recognition procedure started in March 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	2	9
Belgium		8
Bulgaria		10
Cyprus		5
Czech Republic	1	8
Denmark	8	14
Estonia		4
Finland	1	3
France	2	8
Germany	10	17
Greece		8
Hungary		7
Iceland		3
Ireland		3
Italy		9
Latvia		9
Lithuania		5
Luxembourg		4
Malta		3
Netherlands	4	9
Norway		5
Poland		10
Portugal		3
Romania		8
Slovak Republic		6
Slovenia		6
Spain		5
Sweden		7
United Kingdom		7

Decentralised Procedure

The CMD(h) noted that there were **44** Decentralised Procedures finalised with a positive outcome and **2** procedures finalised with a negative outcome. **2** Decentralised procedures were withdrawn after day 120 during the month of March 2009. **1** Decentralised Procedure was referred to the CMD(h) in this period. There were **no** Decentralised Procedures referred to the CHMP in this period.

The status as of 31st March 2009 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 2008	2009		For procedures referred to CMD(h) in 2008	2009
2009	182	13	1806	6	8	0	0	1	0

120 Decentralised Procedures (regarding **243** products) started in March 2009. The categories of these procedures are as follows:

106 abridged applications, including **22** multiple applications.

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.

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

7 line extension applications.

1 new active substance application.

The new Decentralised procedures started in December related to **6** full dossiers, **101** generic, **3** bibliographic, **1** informed consent and **9** hybrid.

119 of these procedures consisted of chemical substance applications and **1** procedure consisted of a herbal substance application.

113 of these procedures related to prescription-only medicinal products and **7** procedures related to non-prescription medicinal products in the reference Member State⁴.

New applications in Decentralised procedure started in March 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	4	35
Belgium		35
Bulgaria		37
Cyprus		12
Czech Republic	3	43
Denmark	8	37
Estonia		22
Finland		28
France	6	38
Germany	23	72
Greece		27
Hungary	2	41
Iceland	3	5
Ireland	2	31
Italy	3	48
Latvia		23
Lithuania		29
Luxembourg		21
Malta	1	5
Netherlands	9	40
Norway	9	33
Poland		55
Portugal	1	36
Romania		37
Slovak Republic	1	46
Slovenia		16
Spain		42
Sweden	6	36
United Kingdom	39	65

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **651** type IA variations, **250** type IB variations and **336** type II variations were finalised during the month of March 2009. **47** renewals were finalised in this period. There was **1** procedure referred to the CHMP in this period.

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.

The status as of 31st March 2009 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
2009	1603	795	707	120	1

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