



## **Report from the CMD(h) meeting held on 18<sup>th</sup> and 19<sup>th</sup> September 2006**

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

The CMD(h) has agreed a 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 and has forwarded the list to the European Commission.

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 ([sonia.ribeiro@emea.europa.eu](mailto:sonia.ribeiro@emea.europa.eu)) by 30 November 2006, coordinated where possible by trade associations.

### Usage Patents – Implementation within the framework of the Mutual Recognition and Decentralised Procedures

The CMD(h) has agreed a Q&A document to address the implementation of usage patents within the framework of MRP and DCP, in accordance with Article 11(12), second paragraph of Directive 2001/83/EC, as amended.

### Change in the product information of a generic medicinal product following an Article 30 referral procedure for the originator – Use of Variation No. 46, Type IB

The CMD(h) has agreed that Applicants can use variation No. 46, type IB to change the SPC, package leaflet and labelling following a Commission Decision for a referral for an original medicinal product in accordance with Article 30 of Directive 2001/83/EC, as amended.

The proposed SPC, package leaflet and labelling should be identical for the concerned sections to that annexed to the Commission Decision on the referral procedure for the original product.

### CMD(h) Standard Operating Procedure – Disagreement in Procedures – Referral to CMD(h) & Guidance on oral explanations to CMD(h)

In order to make optimal use of the 60 days timeline in case of disagreement between Member States in a particular mutual recognition or decentralised procedure, the CMD(h) agreed, at the February CMD(h) meeting, to change the timelines for the procedure and to work with the new timelines for a pilot period of 6 months.

The CMD(h) has revised at the September CMD(h) meeting the CMD(h) SOP – Disagreement in Procedures – Referral to CMD(h) & Guidance on oral explanations to CMD(h), to reflect the currently agreed timetable for the 60 days procedure in the CMD(h).

### New Question and Answer on CMD(h) SOP –Disagreement in Procedures – Referral to CMD(h)

The CMD(h) has agreed a new Q&A to clarify that if on Day 210 of a DCP there is consensus among the RMS and the CMS(s) that the application is not approvable, this will not be referred to the CMD(h) for the 60 days referral procedure. An application can only be referred to the CMD(h) if the MSs involved in the procedure cannot reach consensus.

### Manufacturing authorisation in the Decentralised procedure

With a view to avoiding delays in the start of the procedure, the CMD(h) has agreed that in exceptional cases it should be possible to validate a decentralised procedure application, where an inspection of sites outside the EU has not yet been carried out. The manufacturing authorisation has to be available for the restart of the procedure on Day 106.

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 4 August 2006 and on 17 August 2006.

<b>Name of the product in the RMS</b>	Protaminsulfat Leo Pharma
<b>Active substance</b>	Protamine sulfate
<b>Pharmaceutical form</b>	Solution for injection
<b>Procedure number</b>	SE/H/562/01/MR
<b>CMS</b>	AT, BE, DE, DK, EE, EL, ES, FI, FR, IE, IS, LT, LU, NL, NO, PT, SI, UK
<b>Legal basis</b>	Article 10.1(a)(ii), Directive 2001/83/EC - Bibliographic
<b>Grounds for referral to CMD(h)</b>	Potential serious risk to public health concerns were raised by one CMS, especially relating to the posology and the declaration of the strength.
<b>Day 60</b>	04.08.06
<b>Outcome</b>	Agreement reached

<b>Name of the product in the RMS</b>	Matrifen
<b>Active substance</b>	Fentanyl
<b>Pharmaceutical form</b>	Transdermal patch
<b>Procedure number</b>	SE/H/568/01-05/MR
<b>CMS</b>	BE, CZ, DK, EE, EL, ES, FI, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, SI, SK, UK
<b>Legal basis</b>	Article 10.1, Directive 2001/83/EC – Generic
<b>Grounds for referral to CMD(h)</b>	Potential serious risk to public health concerns were raised by one CMS regarding the wording of the indication.
<b>Day 60</b>	04.08.06
<b>Outcome</b>	Agreement reached

<b>Name of the product in the RMS</b>	Fentanyl ratiopharm 25, 50, 75, 100 mcg/h Matrixpflaster Fentanyl CT 25, 50, 75, 100 mcg/h Matrixpflaster Ribofentanyl 25, 50, 75, 100 mcg/h Matrixpflaster
<b>Active substance</b>	Fentanyl
<b>Pharmaceutical form</b>	Transdermal patch
<b>Procedure number</b>	DE/H/634/01-04/MR DE/H/635/01-04/MR DE/H/636/01-03/MR
<b>CMS</b>	CZ, DK, FI, HU, IT, NO, PL, SE, SK
<b>Legal basis</b>	Article 10.1, Directive 2001/83/EC – Generic
<b>Grounds for referral to CMD(h)</b>	Potential serious risk to public health concerns were raised by one CMS regarding the wording of the indication.
<b>Day 60</b>	25.09.06
<b>Outcome</b>	Agreement reached

## NEW APPLICATIONS

### Mutual Recognition Procedure

The CMD(h) noted that **114** new Mutual Recognition Procedures were finalised during the months of July and August 2006. **14** Mutual Recognition Procedures for new applications were referred to CMD(h) in this period. **2** Mutual Recognition Procedure for a new application were referred to CHMP in this period.

The status as of 31<sup>st</sup> August 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	367	167	57 N.A.	29	17

**132** Mutual Recognition Procedures (regarding **334** products) started in July and August 2006. The categories of these procedures are as follows:

**2** new active substances (classified as a multiple application), including **1** repeat use.

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

**105** abridged applications, including **42** multiple and **6** repeat use applications.

**10** line extension applications, including **3** repeat use applications.

The new procedures started in July and August related to **9** full dossiers, **110** generics, **3** hybrid applications, **2** fixed combination applications and **8** bibliographic applications.

These procedures consisted of **129** chemical substance applications and **2** biological blood product and **1** biological other products.

**All** of these procedures were prescription-only medicinal products in the reference Member State<sup>1</sup>.

Number of countries involved in the new applications in Mutual Recognition procedure started in July and August 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	12
DE (1)	8
DE (1)	11
DE (8)	1
DE (2)	13
DE (2)	9
DE (3)	1
DE (2)	10
DE (1)	4
DE (1)	13
DE (1)	3
DE (1)	1
DE (1)	13
DE (1)	2
DE (6)	16
DE (4)	5
DE (4)	5

<sup>1</sup> 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 (1)	2
DK (1)	3
DK (4)	3
DK (2)	3
DK (3)	1
DK (2)	11
DK (4)	2
DK (3)	11
DK (3)	1
DK (3)	1
DK (4)	16
DK (3)	1
DK (3)	1
DK (3)	1
DK (4)	1
DK (4)	1
DK (3)	9
DK (2)	1
DK (3)	1
DK (3)	4
DK (3)	19
DK (5)	2
DK (4)	18
DK (4)	1
DK (4)	1
DK (4)	20
DK (4)	1
DK (4)	1
DK (1)	5
DK (3)	1
DK (3)	1
DK (3)	2
DK (4)	1
DK (1)	1
DK (3)	1
DK (3)	1
DK (3)	1
ES (1)	8
FI (4)	1
FI (5)	1
FI (3)	7
FI (4)	5
FI (2)	9
FI (2)	2
FI (2)	1
FI (2)	1
FR (1)	10
FR (1)	18
HU(1)	6
HU(1)	2
HU(1)	3
HU(1)	5
HU(1)	2
IT (1)	6
IT (1)	7
IT (1)	4
IT (1)	3
IT (1)	6
NL (4)	14
NL (4)	2
NL (4)	3
NL (4)	1
NL (1)	2
NL (2)	3
NL (1)	11

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
NL (2)	9
NL (4)	1
NL (2)	5
NL (2)	3
NL (4)	9
NL (3)	10
NL (1)	7
NL (2)	15
NL (2)	1
NL (3)	1
NL (3)	1
NL (3)	1
NL (3)	1
NL (3)	2
NL (2)	1
NL (2)	1
NL (2)	1
NL (1)	7
PT (3)	2
PT (1)	17
PT (1)	15
PT (1)	19
SE (2)	9
SE (3)	1
SE (4)	13
SE (1)	1
SE (1)	9
SE (1)	6
SE (1)	5
SE (1)	7
SE (1)	7
SE (1)	11
SE (4)	2
SE (3)	1
SE (3)	1
SE (4)	7
SE (4)	1
SE (4)	1
SE (4)	1
SE (4)	1
SE (4)	3
UK (2)	1
UK (4)	4
UK (4)	5
UK (1)	6
UK (4)	3
UK (1)	12
UK (2)	6
UK (4)	17
UK (1)	1

**Decentralised Procedure**

The CMD(h) noted that **10** new Decentralised Procedures were finalised during the months of July and August 2006.

The status as of 31<sup>st</sup> August 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	10	273	--	--	--
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**84** Decentralised Procedures (regarding **215** products) started in July and August 2006. The categories of these procedures are as follows:

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

**74** abridged applications, including **23** multiple applications.

**6** known active substance applications.

**3** line extension applications.

The new Decentralised procedures started related to **4** full dossier, **74** generic, **1** hybrid and **5** bibliographical applications.

These procedures consisted of **81** chemical substance and **3** biological vaccine applications.

These procedures related to **81** prescription-only and **3** non-prescription medicinal products in the reference Member State<sup>2</sup>.

Number of countries involved in the new applications in Decentralised procedures started in July and August 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
CZ (3)	5
CZ (3)	8
DE (1)	8
DE (3)	7
DE (2)	13
DE (1)	2
DE (4)	17
DE (1)	21
DE (1)	11
DE (4)	15
DE (4)	13
DE (3)	2
DE (1)	4
DE (1)	4
DE (1)	4
DE (4)	3
DE (6)	6
DE (1)	1
DE (1)	9
DE (3)	3
DE (2)	1
DE (3)	11
DE (3)	8
DE (1)	6
DE (1)	1
DE (1)	9
DE (2)	1
DK (2)	14
DK (4)	3
DK (1)	10
DK (1)	10
DK (1)	9
DK (1)	9
DK (5)	7

<sup>2</sup> 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.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (6)	13
DK (4)	2
DK (4)	1
DK (6)	8
DK (4)	2
DK (5)	13
DK (5)	3
DK (5)	2
DK (3)	5
DK (3)	15
DK (2)	6
DK (6)	2
FI (3)	6
FI (3)	1
FR (1)	18
NL (2)	19
NL (2)	21
NL (1)	2
NL (4)	1
NL (4)	2
NL (4)	4
NL (4)	1
NL (4)	3
SE (1)	1
SE (1)	1
SE (4)	4
SE (1)	23
UK (1)	1
UK (2)	13
UK (1)	22
UK (4)	11
UK (2)	1
UK (2)	1
UK (2)	1
UK (2)	2
UK (4)	11
UK (1)	22
UK (1)	22
UK (1)	20
UK (1)	1
UK (1)	5
UK (1)	5
UK (2)	21
UK (4)	15
UK (1)	1
UK (4)	1
UK (4)	1
UK (1)	3
UK (1)	1
UK (4)	1

## VARIATIONS AND RENEWALS

### **Mutual Recognition and Decentralised Procedures**

The CMD(h) noted that **814** type IA variations, **329** type IB variations and **382** type II variations were finalised during the months of July and August 2006. **84** renewals were finalised in this period.

The status as of 31<sup>st</sup> August 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	2933	1431	1213	232	--

**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/>