

Report from the CMD(h) meeting held on 19th, 20th and 21st October 2009

CMD(h) Best Practice Guide for the submission and processing of variations in the Mutual Recognition Procedure

The CMD(h) has updated the Best Practice Guide for submission and processing of variations in Mutual Recognition Procedure to reflect changes introduced by Commission Regulation (EC) No 1234/2008. The updated BPG will be published on the CMD(h) website under “Procedural guidance, Variation”.

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

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

The CMD(h) has adopted the list that was published for consultation with no changes and will send the final list of products for SmPC harmonisation 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.

CMD(h)/EMEA Sub-group on Paediatric Regulation

The CMD(h) has updated the Best Practice Guides and the Q&A document on Articles 45 and 46 of Regulation (EC) No 1901/2006 to introduce an accelerated timetable for type II variations submitted following an Article 45 or 46 worksharing procedure for MRP/DCP products.

The updated BPG will be published on the CMD(h) website under “Paediatric Regulation”.

Adverse events to be included in the Product Information of HMG CoA Reductase Inhibitors

The CMD(h) has endorsed the PhVWP report on HMG CoA Reductase Inhibitors and adverse events and recommends the implementation of the PhVWP agreed wording for the SmPC and PL for all HMG CoA reductase inhibitor containing products.

The agreed changes in the SmPC and PL should be implemented rapidly commencing from the end of October 2009 according to timescales notified by the RMS and national competent authorities.

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

Apomorphine containing products and risk of QT interval prolongation

The CMD(h) has endorsed the PhVWP report on apomorphine and the risk of QT interval prolongation and recommends the implementation of the PhVWP wording for the SmPC and PL for all apomorphine containing products.

The following timetable has been agreed by the CMD(h) and PhVWP for implementation of agreed SmPC and PL changes:

Report from the CMD(h) meeting held in October 2009

| | |
|-------------------------|---|
| 15 November 2009 | Variation applications requested through CMD(h) |
| 15 December 2009 | Variation applications submitted by MA holders |
| 15 February 2010 | Variation applications approved by RMS |

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

Short-acting beta agonists and risk of myocardial ischemia

The CMD(h) has endorsed the PhVWP report on short-acting beta agonist and the risk of myocardial ischemia and recommends the implementation of the PhVWP wording for the SmPC and PL for all short-acting beta agonist containing products.

The agreed changes in the SmPC and PL can be implemented at the next regulatory opportunity.

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

Vigabatrin and MRI abnormalities and movement disorders

The CMD(h) has endorsed the PhVWP report on vigabatrin and the risk of MRI abnormalities and movement disorders and recommends the implementation of the PhVWP wording for the SmPC and PL of the concerned vigabatrin containing product.

The agreed changes in the SmPC and PL can be implemented at the next regulatory opportunity.

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

Antipsychotics and increased mortality

The CMD(h) has endorsed the PhVWP report on antipsychotics and the risk of increased mortality and recommends the implementation of the PhVWP wording for the SmPC and PL for all products containing conventional antipsychotics.

The following timetable has been agreed by the CMD(h) and PhVWP for implementation of agreed SmPC and PL changes:

| | |
|------------------------|---|
| 1 December 2009 | Variation applications requested through CMD(h) |
| 5 January 2010 | Variation applications submitted by MA holders |
| 1 March 2010 | Variation applications approved by RMS |

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

Antipsychotics and VTE

The CMD(h) has endorsed the PhVWP report on antipsychotics and the risk of VTE and recommends the implementation of the PhVWP wording for the SmPC and PL for all products containing antipsychotics.

The following timetable has been agreed by the CMD(h) and PhVWP for implementation of agreed SmPC and PL changes:

| | |
|------------------------|---|
| 1 December 2009 | Variation applications requested through CMD(h) |
| 5 January 2010 | Variation applications submitted by MA holders |
| 1 March 2010 | Variation applications approved by RMS |

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

Electronic submissions

The CMD(h) encourages the applicants to submit their applications in e-CTD. The CMD(h) “Best Practice Guide on the use of e-CTD in the MRP/DCP” is being updated in order to simplify the use of e-CTD format. Further comments from users are still welcome. Any comments on the BPG should be sent to the CMD(h) secretariat (H-CMDhSecretariat@emea.europa.eu).

Informal CMD(h) meeting – Uppsala, Sweden

The CMD(h) convened for an informal meeting on 5th and 6th October 2009 in Uppsala, Sweden, held as part of a programme of events organised under the Swedish Presidency of the Council of the EU.

There was a joint session with the CMD(v) on topics of common interest including some proposals to avoid parallel assessment, the implementation of the variation Regulation, the increasing need for transparency and proposals to improve the MRI-Product Index. The rules of procedures of both coordination groups are being updated in parallel to reflect the changes in the legislation.

The CMD(h) discussed also the future of CMD(h). New tasks for the CMD(h) are foreseen in the variation Regulation 1234/2008/(EC) and in EC proposal to amend the pharmacovigilance legislation. Some areas for improvement in the processing of MRP/DCP have been identified.

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 30.07.2009 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 **32** Mutual Recognition Procedures were finalised during the month of September 2009. **3** Mutual Recognition Procedures were 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 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) | | Withdrawn during CMD(h) referral | Applications referred to CHMP | |
|------|---|-----------------------------|--------------------|---------------------------------|------|----------------------------------|---|------|
| | | | | For procedures referred in 2008 | 2009 | | For procedures referred to CMD(h) in 2008 | 2009 |
| 2009 | 277 | 86 | 13 | 2 | 5 | 3 | 0 | 1 |

50 Mutual Recognition Procedures (regarding **84** products) started in September 2009. The categories of these procedures are as follows:

32 abridged applications, including **7** multiple and **6** repeat use applications.

15 known active substance applications, including **1** multiple and **7** repeat use applications.

2 Line Extension applications, which are all repeat use applications.

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.’

Report from the CMD(h) meeting held in October 2009

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

The new procedures started in September 2009 related to **13** full dossier, **30** generic, **4** bibliographic, **1** similar biological and **2** hybrid applications.

44 of these procedures consisted of chemical substance products, **1** procedure consisted of a biological vaccine product, **4** procedures consisted of a biological blood product and **1** procedure consisted of a biological other product.

47 of these procedures related to prescription-only medicinal products and **3** procedures related to non-prescription medicinal products in the reference Member State².

New applications in Mutual Recognition procedure started in September 2009.

| Member State | Number of times involved in a procedure as RMS | Number of times involved in a procedure as CMS |
|---------------------|---|---|
| Austria | 2 | 10 |
| Belgium | | 10 |
| Bulgaria | | 14 |
| Cyprus | | 8 |
| Czech Republic | 4 | 14 |
| Denmark | 6 | 12 |
| Estonia | | 11 |
| Finland | 2 | 17 |
| France | 2 | 10 |
| Germany | 6 | 17 |
| Greece | | 8 |
| Hungary | 3 | 12 |
| Iceland | 5 | 10 |
| Ireland | 1 | 9 |
| Italy | | 8 |
| Latvia | | 13 |
| Lithuania | | 12 |
| Luxembourg | | 5 |
| Malta | | 7 |
| Netherlands | 10 | 17 |
| Norway | | 12 |
| Poland | | 16 |
| Portugal | 1 | 11 |
| Romania | | 13 |
| Slovak Republic | | 15 |
| Slovenia | | 8 |
| Spain | | 10 |
| Sweden | 1 | 8 |
| United Kingdom | 7 | 12 |

Decentralised Procedure

The CMD(h) noted that there were **128** Decentralised procedures finalised with a positive outcome and **1** procedure finalised with a negative outcome. **1** Decentralised procedure was withdrawn after day 120. **2** Decentralised procedure was referred to the CMD(h) in this period. There were **no** Decentralised procedures referred to the CHMP in this period.

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.

Report from the CMD(h) meeting held in October 2009

The status as of 30th September 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 | 854 | 19 | 1679 | 17 | 8 | 3 | 0 | 1 | 4 |

58 Decentralised Procedures (regarding **92** products) started in September 2009. The categories of these procedures are as follows:

48 abridged applications, including **3** multiple applications.

4 known active substance applications.

4 line extension applications.

2 applications for a new active substance.

The new Decentralised procedures started in December related to **24** generic, **3** full dossier, **1** informed consent, **3** bibliographic, **1** fixed and **26** hybrid.

57 of these procedures consisted of chemical substance applications and **1** procedure consisted of a biological other product.

51 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 September 2009.

| Member State | Number of times involved in a procedure as RMS | Number of times involved in a procedure as CMS |
|----------------|--|--|
| Austria | | 16 |
| Belgium | | 19 |
| Bulgaria | | 9 |
| Cyprus | | 4 |
| Czech Republic | | 18 |
| Denmark | 4 | 15 |
| Estonia | | 11 |
| Finland | | 18 |
| France | | 20 |
| Germany | 5 | 32 |
| Greece | | 10 |
| Hungary | | 17 |
| Iceland | | 4 |
| Ireland | | 14 |
| Italy | 1 | 29 |
| Latvia | | 11 |
| Lithuania | | 12 |
| Luxembourg | | 11 |
| Malta | | 2 |
| Netherlands | 7 | 26 |
| Norway | | 12 |
| Poland | 6 | 17 |
| Portugal | 5 | 20 |
| Romania | | 9 |

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.

Report from the CMD(h) meeting held in October 2009

| | | |
|-----------------|----|----|
| Slovak Republic | | 15 |
| Slovenia | | 7 |
| Spain | | 28 |
| Sweden | 9 | 24 |
| United Kingdom | 21 | 33 |

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **610** type IA variations, **424** type IB variations and **255** type II variations were finalised during the month of September 2009. **31** renewals were finalised in this period. There were **no** procedures referred to the CHMP in this period.

The status as of 30th September 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 | 5342 | 2752 | 2261 | 398 | 5 |

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>