REPORT FOR RELEASE: November and December 2011

November 2011 product discussions

X products reached day 90 of the mutual recognition procedure (MRP) and X products reached day 210 of the decentralised procedure (DCP).

<table>
<thead>
<tr>
<th>Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)</th>
<th>MRP</th>
<th>DCP</th>
<th>Referrals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products*:</td>
<td>6</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Immunological</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* 1 product includes all strengths and pharmaceutical forms submitted but does not include duplicate applications, which are counted separately

CMDv referral procedures [article 33(1) of Directive 2001/82/EC]

Three MRPs (three strengths of the same product) with Day 90 in late October were referred to the CMDv since the Reference and Concerned Member States could not reach agreement. Potential serious risk to animal health was raised by one CMS. This ongoing referral procedure, due to conclude after the January CMDv meeting, involves a generic application under article 13(1) of Directive 2001/82/EC for an ACE inhibitor indicated in a companion animal species.

With regard to the referral procedure for Selenate Long acting 50 mg/ml suspension for injection for cattle that was finalised in September with non-agreement by the CMDv at Day 60, the procedure was referred to the CVMP under article 33(4) of Directive 2001/82/EC. At their November meeting, the CVMP considered the referral notification and subsequently informed the RMS that it could not be accepted, in line with clarifications received by the EMA in 2007 from the Commission on the conduct of article 33(4) referral procedures for generic veterinary medicinal products where disagreement relates to efficacy or safety of the product.

December 2011 product discussions

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<th>Referrals</th>
</tr>
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<tbody>
<tr>
<td>Products*:</td>
<td>9</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>Immunological</td>
<td>7</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
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CMDv referral procedures [article 33(1) of Directive 2001/82/EC]

Two ongoing CMDv referral procedures were concluded following the December CMDv meeting. In each case the applicant attended the CMDv meeting to present an oral explanation. One referral, involving an application under article 13(b) for a ‘fixed combination’ antiparasitic product indicated for a food-producing species, ended positively since the applicant withdrew the disputed claim from the SPC in the RMS and all CMS. The other referral, involving a hybrid application under article 13(3) of Directive 2001/82/EC for a systemic antibacterial product indicated for a food-producing species, was finalised with no agreement by the CMDv at Day 60 and the procedure was referred to the CVMP under article 33(4) of Directive 2001/82/EC.
A DCP with Day 210 in late December was referred to the CMDv since the Reference and Concerned Member States could not reach agreement. Potential serious risk to animal health has been raised by two CMS. This ongoing referral procedure, due to conclude after the February CMDv meeting, involves an application under article 13a of Directive 2001/82/EC (well-established use) for an opioid indicated in companion animal species.

**CMDv updates and advice to applicants**

1. **Election of the CMDv Chair**
   
   On 10 November, Dr. Esther Werner of the Paul-Ehrlich-Institut in Germany was unanimously re-elected as the Chair of the CMDv for a further three-year term.

2. **Variation worksharing applications**

   2.1. **November**
   
   Five informal worksharing procedures involving purely-national marketing authorisations (MAs) were discussed. The variations consisted of quality changes (manufacturing sites; specifications), safety (change to the withdrawal period) and efficacy (addition of vaccine strains). For one of the proposed worksharing procedures, further information was requested from the applicant on the list of purely-national MAs involved.

   Applicants are reminded that the CMDv has published a template letter of intent for worksharing variation applications to the CMDv. The template is applicable for both informal and formal worksharing procedures (please refer to the June/July and Sept/Oct CMDv reports for release for more information).

   2.2. **December**
   
   One informal worksharing procedure involving purely-national MAs was accepted – the variation involved quality testing for a vaccine. Another informal worksharing procedure was discussed and it was concluded that it was not eligible for worksharing since only a Type IA variation was involved and at least one of the variations should be a Type IB in order to qualify for worksharing.

3. **Presidency meeting in Poland**

   3.1. **CMDv and CVMP meetings**
   
   On 22 November, the Polish Presidency hosted an additional CMDv meeting with individual and joint sessions for the CMDv and CVMP. Agenda points for discussion during the CMDv session were:

   - Review of the ‘sunset clause’ – practical examples from two Member States.
   - Overview of the experience gained from the CMDv’s pilot SPC harmonisation procedure and feedback from Member States on their views for the future of this initiative.
Current review of the veterinary legislation – background information from the reports published on the Commission’s website and identification of the areas of main interest for the CMDv

- Discussion on the future of authorisation procedures.
- Discussion on options for changes to data protection periods to address availability issues.
- Discussion on pharmacovigilance at the time of MA renewal.

Simplification of current packaging and labelling requirements.

Experience from a Member State of current issues associated with the assessment of the detailed description of the pharmacovigilance system and periodic safety update reports

3.2. Warsaw packaging and labelling workshop

On 23 November, the Polish Presidency, in association with IFAH-Europe, hosted a workshop to discuss the possibilities for changes to packaging and labelling requirements in the context of the Commission's review of the legal framework for veterinary medicinal products. Building on their extensive previous work on packaging and labelling, the CMDv has been working on achieving a harmonised position between MS on the proposals for minimum requirements presented by IFAH-Europe at the CMDv interested parties meeting in September. Over the next two months, the CMDv will continue to discuss this topic extensively, given the tight timeline of the Commission’s review.

4. Handling change of company logo

A questionnaire was circulated amongst the CMDv members to establish how a change to the logo on the packaging is handled. The majority view was that if only the logo is changed then normally it will not be handled as a variation. The size of the logo should be appropriate and should not hamper the readability of the label. In a few Member States, problems arise when the logo and the name of the MAH not the 'same' (e.g. where the logo of the parent company is also included). In this case a change of the MAH (transfer or change of name) may also be required.

5. CTD format acceptance

The CMDv questionnaire on acceptance of CTD-format for both the quality part of the dossier (Part II) and the active substance master file was re-published on the CMDv website, having been updated in November.

6. Electronic submissions

During 2011, Sweden has led the CMDv in compiling Member States’ national requirements for electronic submissions (and any required paper documentation) for new applications and post-authorisation procedures. The information is presented in tables published under guidance on applications on the CMDv website.

7. CMDv documents

- At the December meeting it was agreed that the CMDv/SOP/006 on the standard operational procedure for production and publication of public assessment reports would be reviewed and updated in early 2012.
- The CMDv Best Practice Guide on variation worksharing (BPG 018-001) was updated and adopted at the November meeting. The main changes relate to:
  - Reference to the new template letter of intent to submit for formal/informal worksharing and procedural details to be included in the letter of intent.
  - Advice on prior contact with the reference authority before a worksharing request is sent to the CMDv.
8. Borderline product working group

Following on from the last meeting of this working group in October, a new Q&A on the inclusion of non-VMP devices in the packaging of a VMP was adopted in November and published on the CMDv website. The working group planned to have a virtual meeting in early January 2012 to discuss three product-specific cases, as well as to finalise a document for publication with details of the borderline network (contact points for classification) and a document giving an overview of the regulatory framework for borderline products.

Information

CMDv documents are available on www.hma.eu/cmdv.html
For further information, please contact the Secretariat at the European Medicines Agency, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK cmdv@ema.europa.eu