

## REPORT FOR RELEASE

### Meeting of 15 – 16 January 2009

#### **National validation requirements**

CMDv finalised its review of the current validation requirements following initial input last year by IFAH Europe, a European veterinary pharmaceutical industry representative organisation. CMDv is pleased to confirm that the majority of the national requirements as previously indicated are no longer applicable as they do not conform with the actual situation. Moreover, the requirements head more towards a harmonised approach among the MS although some discrepancies still exist due to current national legislation.

Industry is advised to consult the Notice to Applicants ([http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol6\\_en.htm](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol6_en.htm)) to avoid unnecessary invalidation. Also, CMDv recommends the use of the newly adopted CMDv cover letter template as published on the CMDv website for each new application for Mutual Recognition or Decentralised procedures ([http://www.hma.eu/uploads/media/Template\\_for\\_submission\\_of\\_application\\_dossier.doc](http://www.hma.eu/uploads/media/Template_for_submission_of_application_dossier.doc)).

CMDv trusts companies will accurately fill in all fields of this cover letter and of the NtA application form which will facilitate each Member State to carry out the validation process. At the time of submission of an application dossier, the company would also be required to certify the authenticity and identity of each document submitted in parallel to different authorities, as applicable.

#### **Product information templates**

CMDv agreed to align the product information templates with the EMEA QRD templates for the centralised procedures. The updated CMDv templates will be published as soon as available on the CMDv website to replace current versions (<http://www.hma.eu/166.html>).

#### **Clinical supplies**

The use of veterinary medicinal products without marketing authorisation in clinical trials is not covered by European Community legislation. Consequently national rules apply. The Association of Veterinary Consultants (AVC) raised their concerns over different approaches between the Member States and the problems these may cause.

CMDv took note of the matter and would start a review of the current existing national legislation for veterinary clinical supplies, the competent authorities, restrictions and additional requirements on import and use of clinical trial supplies and the requirements for Reference Products not licensed in the Member State where a trial is conducted.

#### **Product discussion**

In January 2009, 3 products reached day 78 of the mutual recognition procedure and a further 2 reached day 198 of the decentralised procedure. Out of these, 2 were discussed.

|                   | MRP | DCP | Referrals |
|-------------------|-----|-----|-----------|
| <i>Procedures</i> | 3   | 2   | 4         |
| Products          | 3   | 2   | 2         |
| Immunological     | 0   | 1   | 0         |
| Pharmaceutical    | 3   | 1   | 2         |
| Discussed         | 0   | 2   | 2         |

It was noted that agreement was reached on all procedures at day 90 in December 2008.

### **2009 Survey**

CMDv agreed with IFAH Europe to continue the survey exercise in order to monitor and control the successful handling of the mutual recognition and decentralised procedures.

### **The Presidency of the European Council**

As of 1 January 2009 Czech Republic holds Presidency until 30 June 2009. The Czech member, Iveta Obrovská, will be the vice chair of CMDv during this period.

The next CMDv informal meeting will take place in Brno on 27-28 April, 2009.

### **New Members**

Mr Paul McNeill has been appointed as new CMDv member on behalf of Ireland and Dr Laimis Jodkonis on behalf of Lithuania.

### **Information**

CMDv documents are available on [www.hma.eu/cmdv.html](http://www.hma.eu/cmdv.html)

For further information, please contact the secretariat at the European Medicines Agency, for the attention of Wim Riepma, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK [wim.riepma@emea.europa.eu](mailto:wim.riepma@emea.europa.eu)