

## REPORT FOR RELEASE: May 2011

### May 2011 product discussions

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

	MRP	DCP	Referrals to CMDv
Procedures	6	8	0
Products*	6	6	0
Immunological	0	2	0
Pharmaceutical	6	4	0

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

### CMDv referral procedures

There are no ongoing CMDv referral procedures.

## Update and Advice to Applicants

### CMDv working groups

The start-up meeting of the working group on borderline products took place in May, chaired by Belgium. The results of a questionnaire show that only approximately a quarter of national competent authorities (NCAs) have a specialised department/committee to deal with borderline product issues. The rest of the NCAs rely on a case-by-case basis, using a decision tree/precedent list and/or taking into account decisions of the European Court of Justice. The first tasks of the working group will be to create:

- A document showing the contact points for borderline product issues in all Member States (this will be called the European Borderline Assessment Network or 'EUBAN');
- A document giving an overview of the full regulatory framework for borderline products.








It was agreed that there would be cooperation between this CMDv working group and the new CVMP ad-hoc working group on biologicals, which will also discuss borderline cases.

### Access to documents

CMDv took note of the human-led guidance document produced by the EMA/HMA transparency working group on identification of commercially confidential information and protection of personal data within the structure of the marketing authorisation dossier, which was released on 1 June for a three-month consultation period to stakeholders – [click here for link](#). CMDv will start discussions on how to adapt this 'human' document, which relates to dossiers in CTD-format, for veterinary dossiers in Notice to Applicants format.

### Presidency meeting in Budapest, Hungary 30-31 May

Agenda points for discussion during the CMDv session are as follows:

-  Review of the veterinary legislation
-  Experienced gained from the pilot CMDv SPC harmonisation procedure, so far
-  Follow-up on the identification of the European Borderline Assessment Network
-  Report from human-led ad-hoc group on Active Substance Master File assessment
-  Transparency initiatives
-  Availability problems
-  Honeybee health

There will also be a joint CVMP-CMDv session.

### Variation worksharing applications

Five informal worksharing applications were accepted (involving a mix of MRP and purely-national marketing authorisations).

### Monitoring of products originating from Japan

The EMA secretariat provided a summary of the situation to date and CMDv discussed the role of the Reference Member State (RMS) in coordinating activities in the case where potential risk is identified for a particular product (N.B. The EMA published a related [news item](#) on its website on 3 May 2011)

### Products containing altrenogest

The withdrawal periods for altrenogest-containing veterinary medicinal products (VMPs) were discussed. In some Member States, such products are authorised with a withdrawal period longer than 15 days after the end of treatment whereas Directive 96/22/EC provides that hormonal medicinal products with a withdrawal period of more than 15 days may not be authorised. The European Commission clarified to the CMDv that altrenogest-containing VMPs currently authorised with a withdrawal period greater than 15 days do not comply with the provisions of Directive 96/22/EC. CMDv noted the importance of these products and that they

should continue to be available, if at all possible. The consequential impact on these products was considered and it was agreed that Member States needed to proceed in a harmonised and coordinated way.

**Post-meeting note:** Further to discussion by the Heads of Medicines Agencies (HMA) about the overall situation, it was thought that a scientific approach might be possible to resolve the conflict between these products and the requirements of Directive 96/22/EC. Subsequently, the UK submitted a request under Article 11 of Regulation (EC) 470/2009 and, at their June meeting, the CVMP started a procedure for the review of the maximum residue limits (MRLs) for altrenogest considering that, since the establishment of MRLs for altrenogest, new information has become available relevant for the re-consideration of the MRLs.

### **Communication and Tracking System (CTS)**

The Chair of the joint CMDh-v working group on CTS gave a presentation to CMDv demonstrating a possible upgrade with new functionalities. This upgrade could make available in the public domain the product details, approved product information and public assessment reports for medicinal products authorised via MRP/DCP. The resource implications for this upgrade would be further considered during 2011.

### **New declaration by the Qualified Person for GMP of active substance manufacture**

The [new QP declaration template and associated Q&A document](#) was released for consultation in December with a deadline for comments of 30 April 2011. The EMA has extended the deadline for comments until **30 September 2011** whilst the new anti-falsification legislation in the field of the manufacture of APIs and of finished products is finalised.

### **CMDv documents and guidance**

The Best Practice Guide for the repeat-use procedure (RUP) was discussed (BPG-003). Outstanding points were resolved and the document would be adopted in June.

The outcome of the external consultation for the harmonised MRP/DCP/QRD product information templates was noted by CMDv and some outstanding points discussed, mainly on how to keep the mention of possible additional national requirements within the annotated version of the template.

### **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, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK [cmdv@ema.europa.eu](mailto:cmdv@ema.europa.eu)