Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

London, 27 April 2011

REPORT FOR RELEASE: March 2011

March 2011 product discussions

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

	MRP	DCP	Referrals to CMDv
Procedures	4	14	4
Products*:	4	13	4
Immunological	1	0	0
Pharmaceutical	3	13	4

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

CMDv referral procedures

The four referral procedures which reached day 60 in March were discussed and the outstanding concerns were resolved due to agreement from the applicant to amend the disputed claims in the SPC; therefore the referral procedures concluded positively.

Among the products which reached day 210 of the DCP this month, one pharmaceutical has been referred to CMDv under article 33(1) due to environmental concerns and the 60-day referral procedure started in March.

Update and Advice to Applicants

CMDv working groups

There has been a change in terminology: CMDv subgroups will be replaced by the term CMDv working groups.

The mandate for the new working group on borderline products was discussed and will be adopted, with the first meeting planned for May.

Membership of the working groups is being updated and will be published on the CMDv website after the May meeting. The mandates of the existing working groups have been recently published on the website.

Presidency meeting

Previously termed as 'informal' meetings, it has been agreed within the CMDv to change the terminology for the additional meeting traditionally hosted by the Member State holding the 6-monthly EU Presidency to the 'Presidency meeting'.

Under the Hungarian Presidency, a joint CVMP/CMDv meeting will be held in Budapest on 30-31 May.

Variation worksharing requests

The first pre-submission notification was discussed for a worksharing variation involving a centrally authorised product (CAP) and national marketing authorisations (MAs) authorised via MRP. The EMA would act as the reference authority, as is the case by default when a CAP is involved.

In addition, the CMDv discussed and accepted two informal variation worksharing requests where purely national MAs were included; France and Germany (Paul-Ehrlich-Institut) accepted to act as reference authorities. Regarding a formal variation worksharing request involving only MRP/DCP MAs, the UK accepted to act as the reference authority.

Transparency initiatives within CMDv

The CMDv endorsed an initiative to increase transparency between Member States regarding suspended products, the rationale being that products suspended nationally can have implications in other Member States under the prescribing cascade. A table of suspended products will be populated by MS and updated on a quarterly basis (for internal use only by CMDv).

Also, a proposal was discussed for CMDv to initiate informal worksharing of safety variations to avoid differing national assessments based on the same data set for purely-national MAs (e.g. different withdrawal periods being set from the same residue data).

On the subject of transparency, the Chair provided feedback from the February meeting of the HMA/EMA group on transparency. The CMDv will review the documents being worked on by the HMA/EMA group, which have so far been human-led, in order to provide veterinary input.

Generics

The following issues were discussed regarding generic marketing authorisation applications:

- What recourse is open to a Concerned Member State should they identify potential serious risk relating to an application for a generic when the reference product itself is already expired. The specific situation in question appears to be the first time this situation has arisen on either the human or veterinary side and legal interpretation is being sought.
- How is the global marketing authorisation affected if a product is transferred to a new Marketing Authorisation Holder (MAH)? There is preliminary agreement within CMDv that the period of data protection is not amended as a function of a product being transferred away from the original MAH.

Post-authorisation commitments

There was a first discussion on how to deal with the situation where assessment of a post-authorisation commitment results in a negative benefit-risk balance for the product. In April, the CMDv will receive a presentation from the EMA secretariat on the latest advice from the Commission regarding the equivalent 'follow-up measure' for centrally authorised products.

Electronic submission

At the TIGes Vet subgroup meeting on 16 February 2011, a revised guideline on the e-submission for veterinary dossiers was adopted. The guideline is published on the TIGes Vet web page publically available and will come into effect in September 2011. However, applicants can already submit their dossiers in line with the revised guideline. The actual requirements of the guideline have not been changed, but more explanations have been included, making the existing requirements a bit clearer.

In addition, a new table with 'validation criteria' has been finalised and published. This includes only the 'hard' validation criteria, i.e. those an applicant MUST fulfil to be validated.

CMDv Q&As

A proposal is being discussed for a new Q&A on how to handle changes to the invented product name during a new marketing authorisation application. The issue is where changes to the product name are not discussed by the Member States affected during the procedure and this causes difficulties after the close of the procedure during the national phase.

CMDv documents and guidance

The following CMDv guidance documents are being updated due to changes in the membership of CMDv; the revised documents will be published in May:

- GUI-001 Contact points for public assess/general enquiries
- GUI-007 List of CMDv members & qualifications

In March the CMDv continued the discussion on the new Best Practice Guide on informed consent (BPG-012). The outstanding points are the collection of information on the specific national dossier requirements of Member States; how to deal with applications where the originator product being referred to has no environmental risk assessment and the life-cycle of the informed consent Marketing Authorisation in relation to its reference product.