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

London, 12 May 2011

REPORT FOR RELEASE: April 2011

April 2011 product discussions

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

	MRP	DCP	Referrals to CMDv
Procedures	5	7	2
Products*:	2	3	1
Immunological	0	0	0
Pharmaceutical	2	3	1

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

CMDv referral procedures

Two referral procedures reached day 60 in April. As no agreement was reached, the procedures were referred to the CVMP pursuant to Article 33(4) of Directive 2001/82/EC - see table below for details.

Proc. no.	Product	Active subs.	Legal basis	CMS	D60	Grounds for ref.	Outcome
IE/V/0260/001/DC	Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	doramectin	Art 13 generic	AT, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HU, IS, LT, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	18 April 2011	Potential serious risk to human health (withdrawal period not accepted) and to the environment	Not resolved, referred to CVMP under article 33(4)
IE/V/0260/002/DC	Prontax 5 mg/ml pour-on solution for cattle			AT, BG, DK, ES, FI, FR, HU, IS, NL, NO, PL, PT, RO, SE, SI		Potential serious risk to the environment	

Also, a referral procedure due to end in May was concluded early in April since the issues for discussion could be resolved and the procedure was therefore able to conclude positively.

Update and Advice to Applicants

CMDv working groups

The mandate for the new working group on borderline products was discussed and would be adopted after endorsement by the Heads of Medicines Agencies (HMA). The first task would be to establish the relevant contact points for borderline products in each Member State in order to create a network for sharing of information and discussion.

CMDv meetings during the 2012 Olympic period in London

Planning started for the location of the CMDv meetings scheduled in June and July 2012 since it will not be possible to hold these two meetings in London.

Generics

There was a discussion on the current issues faced by Member States in applying the concept of the European Reference Product.

Electronic submission

A member of the TIGes Vet group gave a presentation and requested CMDv members to complete a questionnaire on their current national requirements regarding electronic submissions for new applications as well as post-authorisation procedures i.e. electronic only submissions, electronic + paper or paper only. The information would be collected and discussed again at the June meeting of CMDv.

Communication and Tracking System (CTS)

The future of the existing veterinary mutual recognition product index (VMRI) was discussed, as there is a proposal for a joint human/vet product index using CTS, which is a database already used by all Member States to track ongoing mutual recognition and decentralised authorisation procedures. The need is recognised to find a solution to the current, out of date VMRI but the issue is complicated due to, ideally, the compatibility of the new product index with existing national databases to avoid duplication of work in uploading SPCs.

CVMP /CMDv Task Force on referrals

The CMDv supported an initial proposal for consideration regarding a strategy for SPC harmonisation and prioritisation of referrals, which would be sent to HMA for endorsement (N.B. this is an internal document).

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 April the CMDv continued the discussion on the new Best Practice Guide on informed consent (BPG-012). The outstanding points are how to deal with applications where the originator product being referred to has no environmental risk assessment and also the subsequent life-cycle of the informed consent Marketing Authorisation in relation to its reference product.

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