

London, 18 October 2010

## REPORT FOR RELEASE

**Period: July - September 2010**

### July 2010 product discussions

Three products reached day 78 of the mutual recognition procedure (MRP) and a further twelve products reached day 198 of the decentralised procedure (DCP).

	MRP	DCP	Referrals
Procedures	6	13	0
Products:	3	12	0
Immunological	0	1	0
Pharmaceutical	3	11	0

It was noted that, following the July 2010 meeting, agreement was reached on the granting of marketing authorisations (MAs) for all products discussed.

### September 2010 product discussions

Four products reached day 78 of the mutual recognition procedure (MRP) and a further four products reached day 198 of the decentralised procedure (DCP).

	MRP	DCP	Referrals
Procedures	6	5	0
Products:	4	4	0
Immunological	1	0	0
Pharmaceutical	3	4	0

It was noted that, following the September 2010 meeting, agreement was reached on the granting of marketing authorisations (MAs) for all products discussed.

## **Update and Advice to Applicants**

### **CMDv in the improvement of legislation**

A new CMDv subgroup has been set up with the aim of reviewing and providing comments on any amendments proposed by the European Commission to the veterinary legislation in the context of the recent public consultation on better regulation of veterinary medicines. CMDv's contribution to the Commission's consultation was sent in July. The first meeting of the legislation subgroup took place in September and the next meeting is foreseen after the publication of the Commission's report on the public consultation (foreseen late 2010/early 2011).

### **SPC harmonisation**

A pilot procedure was started with a company on 24<sup>th</sup> September.

### **CMDv classification of unforeseen variations (article 5 of variation regulation)**

Following the September meeting, CMDv published a recommended classification for replacement of a biological or immunological reference preparation as a Type II under B.II.d.2.e. See the following page on the CMDv website for full details of CMDv, as well as CMDh variation classifications: <http://www.hma.eu/163.html> Additionally, recommended submission dates have now been published for requests made to CMDv under article 5. It is proposed to introduce a validation period for such requests in order to ensure that the variation is truly considered unforeseen and not a Type IB by default, or that other bodies (CMDh, EMA) have not previously recommended a classification for the variation. The BPG will be updated accordingly.

### **Informal meeting in Antwerp**

In the framework of the presidency of the council of the European Union, an informal joint CMDv/CVMP meeting was held on 27-28 September in Antwerp.

During the CMDv session, presentations and discussion took place on the following:

- Borderline products (VMP/non-VMP) – national initiatives to formally classify such products and plans to increase awareness at EU level of the growing problem;
- CMDv product discussions – virtual versus face-to-face discussions;
- Prescription status of VMPs in MRP/DCP – possibility of a harmonised approach;
- Duplicate applications – summary of available guidance (CMDh, NTA, EMA, European Commission), discussion of acceptable differences between duplicate and original product;
- Parallel imports – current issues e.g. pharmacovigilance responsibilities, case-law;
- Policy development in relation to the use of antimicrobials in animal husbandry.

During the CMDv/CVMP session, there were presentations and the opportunity for discussion on topics of joint interest:

- Swine influenza
- How to deal with environmental risk assessment for older products e.g. at renewal;
- Generics – data exclusivity, SPC restrictions;
- Referrals

## **CMDv guidance**

Following the planned review of documents as part of the 2010 workplan, the following were adopted in July/September and published on the CMDv website:

BPG-001 on mutual recognition procedure

BPG-002 on decentralised procedure

BPG-007 on renewals

GUI0-002 on sunset clause

BPG-003 on the repeat use procedure (RUP) remains under discussion but should be adopted in October. The discussion relates to the classification and timing of a variation required to update an SPC in line with the outcome of the RUP.

## **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)