EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 June 2012
EMA/CVMP/382060/2012
Committee for Medicinal Products for Veterinary Use

Final opinion of the Committee for Medicinal Products for Veterinary Use on the establishment of maximum residue limits

Procedure nos: EU/11/196/CYG
EU/11/197/LEV

Name of the substance: Prednisolone (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Cygnus BV submitted to the European Medicines Agency on 28 September 2011 an application for the extension of maximum residue limits for prednisolone to *Equidae*.

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Le Vet BV submitted to the European Medicines Agency on 29 September 2011 an application for the extension of maximum residue limits for prednisolone to *Equidae*.

On 8 March 2012 the Committee adopted an opinion recommending the establishment of maximum residue limits for prednisolone in *Equidae*.

On 23 March 2012 Le Vet submitted a request for the re-examination of the CVMP opinion.

The grounds for re-examination were submitted on 19 April 2012.

Recommendation

The Committee, having considered the detailed grounds for the re-examination request in accordance with Article 8(3) of Regulation (EC) No 470/2009 of 6 May 2009 recommends by consensus the establishment of maximum residue limits for prednisolone in horses and the amendment of table 1 of the Annex to Regulation (EU) No 37/2010 as follows:

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Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Prednisolone	Prednisolone	*Equidae*	4 µg/kg 8 µg/kg 6 µg/kg 15 µg/kg	Muscle Fat Liver Kidney	NO ENTRY	Corticoids/ Glucocorticoids

The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the Committee.

The scientific conclusions of the Committee are presented in the European public MRL assessment report (EPMAR), provided in Annex I of this opinion.

The analytical method for monitoring of residues is appended to this opinion.

The present opinion is forwarded to the European Commission and to each applicant together with its appendices.

London, 14 June 2012

Signature on file

Dr. A. Holm

Chair, on behalf of the CVMP

Annex I

European Public MRL Assessment Report (EPMAR)