EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 July 2013
EMA/CVMP/383203/2013
Committee for Medicinal Products for Veterinary Use

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

Procedure no: EMEA/V/MRL/003721/FULL/0001

Name of the substance: Triptorelin acetate (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Eli Lilly and Company Limited submitted to the European Medicines Agency on 29 January 2013 an application for the establishment of maximum residue limits for triptorelin acetate in porcine species.

Recommendation

The Committee, having considered the application, concluded that the establishment of maximum residue limits for triptorelin acetate in porcine species is not necessary for the protection of human health.

Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the conclusions to all food producing species, and therefore recommends by consensus the inclusion of triptorelin acetate in table 1 of the Annex to Regulation (EU) No 37/2010 in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Triptorelin acetate	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	Agents acting on the reproductive system

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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 present opinion is forwarded to the European Commission.

London, 18 July 2013

Signature on file

Dr. A. Holm
Chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)