15 September 2011
EMA/CVMP/293093/2011 – Rev.1
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 EU/10/172/ELY

Name of the substance: Pegylated bovine granulocyte colony stimulating factor

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 4 March 2010 an application for the establishment of maximum residue limits for pegylated bovine granulocyte colony stimulating factor in bovine species.

On 14 July 2010 the Committee for Medicinal Products for Veterinary Use adopted a list of questions to be addressed by the applicant. The response to the list of questions was submitted on 4 February 2011.

On 5 May 2011 the Committee adopted an opinion recommending the establishment of maximum residue limits for pegylated bovine granulocyte colony stimulating factor in bovine species.

On 12 September 2011 the European Commission requested the Committee to review its previous opinion in order to motivate why the derogation provided for under Article 1 (2)(a) of Regulation (EC) No 470/2009 for active principles of biological origin intended to produce active or passive immunity or to diagnose a state of immunity, used in immunological veterinary medicinal products, does not apply to pegylated bovine granulocyte colony stimulating factor.

Recommendation

The Committee, having considered the application, evaluated the response to the list of questions and reviewed the request from the Commission, recommends by consensus the inclusion of pegylated bovine granulocyte colony stimulating factor in table 1 of the Annex to Commission Regulation (EU) No. 37/2010 of 22 December 2009 in accordance with the following table:

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Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Pegylated bovine granulocyte colony stimulating factor	Not applicable	Bovine	No MRL Required	Not applicable	NO ENTRY	Biological/ Immunomodulator

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 and to the applicant together with its appendices.

London, 15 September 2011

Signature on file

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

Annex I

European public MRL assessment report (EPMAR)