EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 May 2010
EMA/CVMP/261782/2010
Veterinary Medicine and Product Data Management

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

Procedure no EU/09/168/PFZ

Name of the substance: Derquantel (INN)

Basis for the opinion

Pursuant to Article 6 of Council Regulation (EC) No 2377/90 of 26 June 1990, Pfizer Limited submitted to the European Medicines Agency on 5 June 2009 an application for the establishment of maximum residue limits for derquantel in ovine species.

On 16 September 2009 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 20 April 2010.

Recommendation

The Committee, having considered the application and having evaluated the response to the List of Questions, recommends by consensus the establishment of maximum residue limits for derquantel in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Derquantel	Derquantel	Ovine	2 µg/kg 40 µg/kg 20 µg/kg 5 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	Antiparasitic agents/Agents against endoparasites

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

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

London, 19 May 2010

Signature on file

Dr. G. Moulin
Chairman, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)