EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 March 2018
EMA/CVMP/103565/2018
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/003647/EXTN/0002

Name of the substance: Isoflurane (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Baxter Deutschland GmbH submitted to the European Medicines Agency on 19 April 2017 an application for the extension of maximum residue limits for isoflurane to porcine species.

On 7 September 2017 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 13 December 2017.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the extension of maximum residue limits for isoflurane in porcine species.

Therefore, the amendment of the entry for isoflurane in table 1 of the Annex to Regulation (EU) No 37/2010 of 22 December 2009, is recommended as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Isoflurane	NOT APPLICABLE	*Equidae*	No MRL required	NOT APPLICABLE	For use by inhalation	General anaesthetics
		Porcine	No MRL required	NOT APPLICABLE	For use by inhalation in piglets up to 7 days of age.	

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The Norwegian CVMP member agrees 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.

Annex I

European public MRL assessment report (EPMAR)