EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2023
EMA/CVMP/206677/2023-Corr.1[1]
Committee for Veterinary Medicinal Products

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

Procedure no: EMEA/V/MRL/003652/EXTN/0004

Name of the substance: Ketoprofen (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Huvepharma NV submitted to the European Medicines Agency on 14 December 2020 an application for the extension of maximum residue limits for Ketoprofen to chicken.

On 12 May 2021 the Committee for Veterinary Medicinal Products adopted a list of questions to be addressed by the applicant. The response to the list of questions was submitted on 17 November 2021.

On 12 May 2022, the Committee for Veterinary Medicinal Products adopted an opinion recommending the extension of maximum residue limits for ketoprofen to chicken. Furthermore, with reference to Article 5 of Regulation (EC) No 470/2009 and in line with the criteria laid down in Commission Regulation (EU) 2017/880, the Committee agreed to extrapolate the conclusions to poultry. Four CVMP members did not support the recommendation for a "No MRL required" classification and signed a divergent position.

On 1 March 2023 the European Commission requested the Committee to reconsider its opinion of 12 May 2022 with a view to further examining the issues identified in the divergent opinion and indicated that if the proposed "No MRL required" status for poultry could not be further substantiated, then the CVMP was requested to recommend numerical MRLs for ketoprofen in chicken tissues.

Recommendation

The Committee, having considered the application, having evaluated the response to the list of

[1] The proposed entry for ketoprofen in table 1 of the Annex to Commission Regulation (EU) No 37/2010 is amended to indicate 'NOT APPLICABLE' in the 'marker residue' column for bovine, porcine and *Equidae*, for which a 'No MRL required' status is already established; 'Ketoprofen' is the marker residue for poultry, for which numerical MRLs are proposed.

questions and having considered the letter from the Commission, recommends the extension of maximum residue limits for ketoprofen to chicken in accordance with the table below. Furthermore, with reference to Article 5 of Regulation (EC) No. 470/2009 and in line with the criteria laid down in Commission Regulation (EU) 2017/880, the Committee agreed to extrapolate the conclusions to poultry. Therefore, the amendment of the entry for ketoprofen 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**
Ketoprofen	NOT APPLICABLE	Bovine, porcine, *Equidae*	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY
	Ketoprofen	Poultry	10 µg/kg 30 µg/kg 10 µg/kg 10 µg/kg	Muscle Skin and fat in natural proportion Liver Kidney	Not for use in animals from which eggs are produced for human consumption	NO ENTRY

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)