COMMISSION IMPLEMENTING REGULATION (EU) No 201/2014

of 3 March 2014

amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance tildipirosin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council [1], and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) The maximum residue limit ('MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is to be established in accordance with Regulation (EC) No 470/2009.

(2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 [2].

(3) Table 1 of the Annex to Commission Regulation (EU) No 759/2010 [3] provisionally lists tildipirosin as an allowed substance for bovine, caprine and porcine species, applicable to muscle, fat (skin and fat for porcine species), liver, and kidney, excluding animals from which milk is produced for human consumption, until 1 January 2012. In accordance with that Annex, the MRLs for muscle did not apply to the injection site for which higher levels are provided for.

(4) Additional data were provided and assessed leading the Committee for Medicinal Products for Veterinary Use to recommend the establishment of final MRLs for tildipirosin for bovine, caprine and porcine species, applicable to muscle, fat (skin and fat in natural proportions for porcine species), liver and kidney, excluding animals from which milk is produced for human consumption. Taking into account that the Commission and residue control authorities consider that, in order to ensure the feasibility of residue controls, a single MRL for muscle must be established, the Committee for Medicinal Products for Veterinary Use, in a revised opinion, did not recommend to provide for a separate MRL for injection site muscle as this was the case in its previous opinions.

(5) In accordance with Article 5 of Regulation (EC) No 470/2009 the European Medicines Agency is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.

(6) The Committee for Medicinal Products for Veterinary Use recommended the extrapolation of the MRLs for tildipirosin in bovine species to caprine species. It also concluded that the extrapolation to other food producing species cannot be supported for this substance.

(7) The entry for tildipirosin in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include final MRLs for the pharmaceutical substance tildipirosin for bovine, caprine and porcine species, applicable to muscle, fat (skin and fat in natural proportions for porcine species), liver and kidney. The provisions on the MRLs for the injection site as regards muscle and on provisional MRLs should be removed.

(8) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take measures that may be required to comply with the newly set MRLs.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

[1] OJ L 152, 16.6.2009, p. 11.

[2] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

[3] Commission Regulation (EU) No 759/2010 of 24 August 2010 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance tildipirosin (OJ L 223, 25.8.2010, p. 39).

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 3 May 2014.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 March 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance tildipirosin is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic classification
'Tildipirosin	Tildipirosin	Bovine, caprine	400 µg/kg	Muscle	Not for use in animals from which milk is produced for human consumption.	Anti-infectious agents/Antibiotics'
			200 µg/kg	Fat		
			2 000 µg/kg	Liver		
			3 000 µg/kg	Kidney		
		Porcine	1 200 µg/kg	Muscle		
			800 µg/kg	Skin and fat in natural proportions		
			5 000 µg/kg	Liver		
			10 000 µg/kg	Kidney		