COMMISSION IMPLEMENTING REGULATION (EU) No 160/2013

of 21 February 2013

amending Regulations (EC) No 162/2003, (EC) No 971/2008, (EU) No 1118/2010 and (EU) No 169/2011 and Implementing Regulation (EU) No 888/2011 as regards the name of the holder of the authorisation of diclazuril in animal feed

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 13(3) thereof,

Whereas:

(1) Janssen Pharmaceutica NV has submitted an application under Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation as regards Commission Regulations (EC) No 162/2003 of 30 January 2003 concerning the authorisation of an additive in feedingstuffs [2], (EC) No 971/2008 of 3 October 2008 concerning a new use of a coccidiostat as additive in feedingstuffs [3], (EU) No 1118/2010 of 2 December 2010 concerning the authorisation of diclazuril as a feed additive for chickens for fattening (holder of authorisation Janssen Pharmaceutica NV) and amending Regulation (EC) No 2430/1999 [4] and (EU) No 169/2011 of 23 February 2011 concerning the authorisation of diclazuril as a feed additive for guinea fowls (holder of authorisation Janssen Pharmaceutica N.V.) [5] and Commission Implementing Regulation (EU) No 888/2011 of 5 September 2011 concerning the authorisation of diclazuril as a feed additive for turkeys for fattening (holder of authorisation Janssen Pharmaceutica N.V.) and amending Regulation (EC) No 2430/1999 [6].

(2) The applicant claims that, with effect from 7 July 2011, Janssen Animal Health, a division of Janssen Pharmaceutica NV, was acquired by Eli Lilly and Company Ltd, which now owns the marketing rights for the additive diclazuril. The applicant has submitted relevant data supporting its request.

(3) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The European Food Safety Authority was informed of the application.

(4) To allow Eli Lilly and Company Ltd to exploit its marketing rights it is necessary to change the terms of the authorisations.

(5) Regulations (EC) No 162/2003, (EC) No 971/2008, (EU) No 1118/2010 and (EU) No 169/2011 and Implementing Regulation (EU) No 888/2011 should therefore be amended accordingly.

(6) Since safety reasons do not require the immediate application of the amendments made by this Regulation to Regulations (EC) No 162/2003, (EC) No 971/2008, (EU) No 1118/2010 and (EU) No 169/2011 and Implementing Regulation (EU) No 888/2011, it is appropriate to provide for a transitional period during which existing stocks may be used up.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 162/2003

In column 2 of the Annex to Regulation (EC) No 162/2003 the words 'Janssen Pharmaceutica NV' are replaced by 'Eli Lilly and Company Ltd'.

Article 2

Amendment to Regulation (EC) No 971/2008

In column 2 of the Annex to Regulation (EC) No 971/2008 the words 'Janssen Pharmaceutica nv' are replaced by 'Eli Lilly and Company Ltd'.

Article 3

Amendment to Regulation (EU) No 1118/2010

In column 2 of the Annex to Regulation (EU) No 1118/2010 the words 'Janssen Pharmaceutica NV' are replaced by 'Eli Lilly and Company Ltd'.

Article 4

Amendment to Regulation (EU) No 169/2011

In column 2 of the Annex to Regulation (EU) No 169/2011 the words 'Janssen Pharmaceutica N.V.' are replaced by 'Eli Lilly and Company Ltd'.

Article 5

Amendment to Implementing Regulation (EU) No 888/2011

In column 2 of the Annex to Implementing Regulation (EU) No 888/2011 the words 'Janssen Pharmaceutica N.V.' are replaced by 'Eli Lilly and Company Ltd'.

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 26, 31.1.2003, p. 3.
[3] OJ L 265, 4.10.2008, p. 3.
[4] OJ L 317, 3.12.2010, p. 5.
[5] OJ L 49, 24.2.2011, p. 6.
[6] OJ L 229, 6.9.2011, p. 9.

Article 6

Transitional measure

Existing stocks of this additive which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until they are exhausted.

Article 7

Entry into force

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

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

Done at Brussels, 21 February 2013.

For the Commission

The President

José Manuel BARROSO