

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 1014/2013

of 22 October 2013

amending Regulations (EC) No 2380/2001, (EC) No 1289/2004, (EC) No 1455/2004, (EC) No 1800/2004, (EC) No 600/2005, (EU) No 874/2010, Implementing Regulations (EU) No 388/2011, (EU) No 532/2011 and (EU) No 900/2011 as regards the name of the holder of the authorisation of certain additives in animal feed

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

(EC) No 600/2005 ⁽⁶⁾, (EU) No 874/2010 ⁽⁷⁾, Commission Implementing Regulations (EU) No 388/2011 ⁽⁸⁾, (EU) No 532/2011 ⁽⁹⁾ and (EU) No 900/2011 ⁽¹⁰⁾.

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) Pfizer Ltd has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisations as regards Commission Regulations (EC) No 2380/2001 ⁽²⁾, (EC) No 1289/2004 ⁽³⁾, (EC) No 1455/2004 ⁽⁴⁾, (EC) No 1800/2004 ⁽⁵⁾,

- (2) The applicant claims that, as a result of Pfizer Ltd's decision to make its Animal Health Division a stand-alone company under the name of Zoetis Belgium SA and transfer all the marketing authorisations for coccidiostats from Pfizer Ltd to Zoetis Belgium SA, the latter owns the marketing rights for the additives decoquinate, lasalocid A sodium, maduramicin ammonium alpha, robenidine hydrochloride and salinomycin.
- (3) The proposed change of the terms of the authorisations is purely administrative in nature and does not entail a new assessment of the additives concerned. The European Food Safety Authority was informed of the application.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 2380/2001 of 5 December 2001 concerning the 10 year authorisation of an additive in feedingstuffs (OJ L 321, 6.12.2001, p. 18).

⁽³⁾ Commission Regulation (EC) No 1289/2004 of 14 July 2004 concerning the authorisation for 10 years of the additive DeccoX® in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 243, 15.7.2004, p. 15).

⁽⁴⁾ Commission Regulation (EC) No 1455/2004 of 16 August 2004 concerning the authorisation for 10 years of the additive 'Avatec 15 %' in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 269, 17.8.2004, p. 14).

⁽⁵⁾ Commission Regulation (EC) No 1800/2004 of 15 October 2004 concerning the authorisation for 10 years of the additive Cycostat 66G in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 317, 16.10.2004, p. 37).

⁽⁶⁾ Commission Regulation (EC) No 600/2005 of 18 April 2005 concerning a new authorisation for 10 years of a coccidiostat as an additive in feedingstuffs, the provisional authorisation of an additive and the permanent authorisation of certain additives in feedingstuffs (OJ L 99, 19.4.2005, p. 5).

⁽⁷⁾ Commission Regulation (EU) No 874/2010 of 5 October 2010 concerning the authorisation of lasalocid A sodium as a feed additive for turkeys up to 16 weeks (holder of authorisation Alpharma (Belgium) BVBA) and amending Regulation (EC) No 2430/1999 (OJ L 263, 6.10.2010, p. 1).

⁽⁸⁾ Commission Implementing Regulation (EU) No 388/2011 of 19 April 2011 concerning the authorisation of maduramicin ammonium alpha as a feed additive for chickens for fattening (holder of authorisation Alpharma (Belgium) BVBA) and amending Regulation (EC) No 2430/1999 (OJ L 104, 20.4.2011, p. 3).

⁽⁹⁾ Commission Implementing Regulation (EU) No 532/2011 of 31 May 2011 concerning the authorisation of robenidine hydrochloride as a feed additive for rabbits for breeding and rabbits for fattening (holder of authorisation Alpharma Belgium BVBA) and amending Regulations (EC) No 2430/1999 and (EC) No 1800/2004 (OJ L 146, 1.6.2011, p. 7).

⁽¹⁰⁾ Commission Implementing Regulation (EU) No 900/2011 of 7 September 2011 concerning the authorisation of lasalocid A sodium as a feed additive for pheasants, guinea fowl, quails and partridges other than laying birds (holder of authorisation Alpharma (Belgium) BVBA) (OJ L 231, 8.9.2011, p. 15).

- (4) To allow the applicant to exploit its marketing rights under the name of Zoetis Belgium SA it is necessary to change the terms of the respective authorisations.
- (5) Regulations (EC) No 2380/2001, (EC) No 1289/2004, (EC) No 1455/2004, (EC) No 1800/2004, (EC) No 600/2005, (EU) No 874/2010, and Implementing Regulations (EU) No 388/2011, (EU) No 532/2011 and (EU) No 900/2011 should therefore be amended accordingly.
- (6) Since the modifications to the terms of the authorisations are not related to safety reasons, 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 2380/2001

In the second column of the Annex, the words 'Pfizer Ltd' are replaced by 'Zoetis Belgium SA'.

Article 2

Amendment to Regulation (EC) No 1289/2004

In the second column of the Annex, the words 'Pfizer Ltd' are replaced by 'Zoetis Belgium SA'.

Article 3

Amendment to Regulation (EC) No 1455/2004

In the second column of the Annex, the words 'Pfizer Ltd' are replaced by 'Zoetis Belgium SA'.

Article 4

Amendment to Regulation (EC) No 1800/2004

In the second column of the Annex, the words 'Pfizer Ltd' are replaced by 'Zoetis Belgium SA'.

Article 5

Amendment to Regulation (EC) No 600/2005

In the second column of Annex I, the words 'Pfizer Ltd' are replaced by 'Zoetis Belgium SA'.

Article 6

Amendment to Regulation (EU) No 874/2010

Regulation (EU) No 874/2010 is amended as follows:

- (a) in the title, the words 'Alpharma (Belgium) BVBA' are replaced by 'Zoetis Belgium SA';

- (b) in the second column of the Annex, the words 'Pfizer Ltd' are replaced by 'Zoetis Belgium SA'.

Article 7

Amendment to Implementing Regulation (EU) No 388/2011

Implementing Regulation (EU) No 388/2011 is amended as follows:

- (a) in the title, the words 'Alpharma (Belgium) BVBA' are replaced by 'Zoetis Belgium SA';

- (b) in the second column of the Annex, the words 'Pfizer Ltd' are replaced by 'Zoetis Belgium SA'.

Article 8

Amendment to Implementing Regulation (EU) No 532/2011

Implementing Regulation (EU) No 532/2011 is amended as follows:

- (a) in the title, the words 'Alpharma Belgium BVBA' are replaced by 'Zoetis Belgium SA';

- (b) in the second column of Annex I, the words 'Pfizer Ltd' are replaced by 'Zoetis Belgium SA';

Article 9

Amendment to Implementing Regulation (EU) No 900/2011

Implementing Regulation (EU) No 900/2011 is amended as follows:

- (a) in the title, the words 'Alpharma (Belgium) BVBA' are replaced by 'Zoetis Belgium SA';

- (b) in the second column of the Annex to Regulation (EU) No 900/2011, the words 'Pfizer Ltd' are replaced by 'Zoetis Belgium SA'.

Article 10

Transitional measures

The existing stocks which have been produced and labelled before 12 November 2013 in accordance with the rules applicable before 12 November 2013 may continue to be placed on the market and used until they are exhausted.

Article 11

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 is binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 October 2013.

For the Commission
The President
José Manuel BARROSO
