COMMISSION IMPLEMENTING REGULATION (EU) 2017/1126

of 23 June 2017

amending Regulation (EC) No 903/2009 and Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 as regards the name of the EU representative of the holder of the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789)

(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) Miyarisan Pharmaceutical Co. Ltd has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of its EU representative of the holder of the authorisation stated in Commission Regulation (EC) No 903/2009 ([2]) and Commission Implementing Regulations (EU) No 373/2011 ([3]), (EU) No 374/2013 ([4]) and (EU) No 1108/2014 ([5]).

(2) The applicant claims that Huvepharma NV Belgium has become the new representative for Miyarisan Pharmaceutical Co. Ltd for the feed additive 4b1830 preparation of *Clostridium butyricum* FERM-BP 2789 with effect from 12 January 2017. The applicant has submitted relevant data supporting its request.

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

(4) In order to allow Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium to exploit its marketing rights, it is necessary to change the conditions of the respective authorisations. Regulation (EC) No 903/2009, Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 should therefore be amended accordingly.

(5) Since safety reasons do not require the immediate application of the amendments provided for by this Regulation to Regulation (EC) No 903/2009, Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014, it is appropriate to provide for a transitional period during which existing stocks may be used up.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plant, Animals, Food and Feed,

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([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Regulation (EC) No 903/2009 of 28 September 2009 concerning the authorisation of the preparation of *Clostridium butyricum* (FERM-BP 2789) as a feed additive for chickens for fattening (holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U), (OJ L 256, 29.9.2009, p. 26).

([3]) Commission Implementing Regulation (EU) No 373/2011 of 15 April 2011 concerning the authorisation of the preparation of *Clostridium butyricum* (FERM-BP 2789) as a feed additive for minor avian species except laying birds, weaned piglets and minor porcine species (weaned) and amending Regulation (EC) No 903/2009 (holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U.) (OJ L 102, 16.4.2011, p. 10).

([4]) Commission Implementing Regulation (EU) No 374/2013 of 23 April 2013 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM BP-2789) as a feed additive for chickens reared for laying (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.) (OJ L 112, 24.4.2013, p. 13).

([5]) Commission Implementing Regulation (EU) No 1108/2014 of 20 October 2014 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM BP-2789) as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.) (OJ L 301, 21.10.2014, p. 16).

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 903/2009

Regulation (EC) No 903/2009 is amended as follows:

(1) In the Title, the words 'holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U' are replaced by the words 'holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium'.

(2) In the Annex to Regulation (EC) No 903/2009, in the second column 'Name of the holder of authorisation', the words 'Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.' are replaced by the words 'Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium'.

Article 2

Amendment to Implementing Regulation (EU) No 373/2011

Implementing Regulation (EU) No 373/2011 is amended as follows:

(1) In the Title, the words 'holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U' are replaced by the words 'holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium'.

(2) In the Annex to Implementing Regulation (EU) No 373/2011, in the second column, the words 'Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.' are replaced by the words 'Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium'.

Article 3

Amendment to Implementing Regulation (EU) No 374/2013

Implementing Regulation (EU) No 374/2013 is amended as follows:

(1) In the Title, the words 'holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U' are replaced by the words 'holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium'.

(2) In the Annex to Implementing Regulation (EU) No 374/2013, in the second column, the words 'Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.' are replaced by 'Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium'.

Article 4

Amendment to Implementing Regulation (EU) No 1108/2014

Implementing Regulation (EU) No 1108/2014 is amended as follows:

(1) In the Title, the words 'holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U' are replaced by the words 'holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium'.

(2) In the Annex to Implementing Regulation (EU) No 1108/2014, in the second column, the words 'Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.' are replaced by 'Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium'.

Article 5

Transitional measures

Existing stocks of the additive, premixtures and compound feed containing the 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 6

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, 23 June 2017.

For the Commission
The President
Jean-Claude JUNCKER