Commission Regulation (EU) No 122/2013 of 12 February 2013 amending Regulation (EC) No 1950/2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae (Text with EEA relevance)

Article 1

Regulation (EC) No 1950/2006 is amended as follows:

(1) the title of Regulation (EC) No 1950/2006 is replaced by the following:
Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae and of substances bringing added clinical benefit;

(2) Article 1 is replaced by the following:

Article 1

The list of substances essential for the treatment of equidae, hereinafter "essential substances", as well as of substances which bring added clinical benefit compared to other treatment options available for equidae, hereinafter "substances bringing added clinical benefit", applicable by way of derogation from Article 11 of Directive 2001/82/EC, is set out in the Annex to this Regulation.;

(3) in Article 2, the second subparagraph is replaced by the following:

Substances bringing added clinical benefit may be used, for the specific disease conditions, treatment needs or zootechnical purposes specified in the Annex, where they provide a clinically relevant advantage based on improved efficacy or safety or a major contribution to treatment compared to medicinal products authorised for equidae or referred to in Article 11 of Directive 2001/82/EC.

For the purposes of the first and second subparagraphs, the alternatives listed in the Annex shall be considered.;

(4) Articles 3 and 4 are replaced by the following:

Article 3

1 Essential substances and substances bringing added clinical benefit shall be used only in accordance with Article 10(1) of Directive 2001/82/EC.

2 The details of a treatment with essential substances shall be recorded in accordance with the instructions laid down in Section IX of the identification document for equidae set out in Commission Regulation (EC) No 504/2008[(1)].

Article 4

Any substance that is entered in one of the lists in the Annex to Commission Regulation (EU) No 37/2010[(2)], or the use of which for equidae is prohibited by Union legislation, shall no longer be used for the purposes of this Regulation.;

(5) in Article 5, paragraph 2 is replaced by the following:

2. Where Member States or veterinary professional associations request the Commission to amend the list set out in the Annex, they shall duly substantiate their request and include any relevant scientific data available.;

(6) the Annex to Regulation (EC) No 1950/2006 is replaced by the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third 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, 12 February 2013.

For the Commission

The President

José Manuel BARROSO

(**1**) OJ L 149, 7.6.2008, p. 3.

(**2**) OJ L 15, 20.1.2010, p. 1.';

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 122/2013.