# 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)

## 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)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(1)], and in particular Article 10(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1950/2006[(2)] established a list of substances essential for the treatment of equidae which, by way of derogation from Article 11 of Directive 2001/82/EC, may be administered to equidae intended for slaughter for human consumption subject to a withdrawal period of not less than six months.

(2) 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[(3)] amended Article 10(3) of Directive 2001/82/EC in order to include in the list of substances referred to in that Article substances which bring added clinical benefit compared to other treatment options available for equidae, hereinafter 'substances bringing added clinical benefit', in addition to essential substances.

(3) A substance should only be included in the list as a 'substance bringing added clinical benefit' where it provides a clinically relevant advantage based on improved efficacy or safety or a major contribution to treatment. This may be the result, inter alia, of different modes of actions, different pharmacokinetic or pharmacodynamic profiles, different lengths of treatment or different routes of administration.

(4) Substances listed in the Annex to 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[(4)] should not appear on the list of essential substances and substances bringing added clinical benefit. Therefore,

it is necessary to amend the list in the Annex to Regulation (EC) No 1950/2006 to remove from that list any substances listed in Regulation (EU) No 37/2010.

(5) It is also appropriate to remove from the list in the Annex to Regulation (EC) No 1950/2006 several substances identified as alternatives to the substances listed, which are not available for the treatment of horses because they are not listed as 'essential substances' or 'substances bringing added clinical benefit' under Regulation (EC) No 1950/2006 nor listed in the Annex to Regulation (EU) No 37/2010.

(6) Due to changes in Union legislation since the adoption of Regulation (EC) No 1950/2006, the references in that Regulation to the relevant legislation on control mechanisms for equidae and on maximum residue limits should be updated.

(7) The amended list set out in the Annex to this Regulation has been subject to a scientific evaluation carried out by the Committee for Veterinary Medicinal Products of the European Medicines Agency established by Regulation (EC) No 726/2004 of the European Parliament and of the Council[(5)].

(8) Regulation (EC) No 1950/2006 should be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

(**1**) OJ L 311, 28.11.2001, p. 1.

(**2**) OJ L 367, 22.12.2006, p. 33.

(**3**) OJ L 152, 16.6.2009, p. 11.

(**4**) OJ L 15, 20.1.2010, p. 1.

(**5**) OJ L 136, 30.4.2004, p. 1.

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