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,

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 122/2013. (See end of Document for details)*

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:

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[(6)].

Article 4

Any substance that is entered in one of the lists in the Annex to Commission Regulation (EU) No 37/2010[(7)], 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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 122/2013. (See end of Document for details)*

ANNEX

ANNEX

List of substances essential for the treatment of equidae and substances bringing added clinical benefit compared to other treatment options available for equidae

The withdrawal period for each of the substances on the following list shall be six months.

Indication	Active substance	Justification and explanation of use
Anaesthetics, analgesics and substances used in association with anaesthesia		
Sedation and premedication (and antagonism)	Acepromazine	Purpose: premedication prior to general anaesthesia, mild sedation. Identification of alternatives: detomidine, romifidine, xylazine, diazepam, midazolam. Discussion of the specific advantages: acepromazine has consistently been shown to reduce risk of anaesthetic death. Mode of action (on limbic system) and unique quality of sedation cannot be produced by the alpha-2 agonist sedatives (detomidine, romifidine and xylazine) or the benzodiazepines (diazepam, midazolam).
	Atipamezole	Purpose: α-2 adrenoceptor antagonist used for reversal of α-2 agonists. Identification of alternatives: none identified. Discussion of the specific advantages: only treatment for hypersensitive individual and overdose. Emergency medicine. Specifically used in cases of respiratory depression.
	Diazepam	Purpose: premedication and induction of anaesthesia. Mild (benzodiazepine) tranquilisation with minimal cardiovascular and respiratory side effects. Anti-

	convulsant, essential for treatment of seizures. Identification of alternatives: acepromazine, detomidine, romifidine, xylazine, midazolam, primidone, phenytoin. Discussion of the specific advantages: in modern medicinal standards an essential component of anaesthetic induction protocols with very considerable equine experience. Used with ketamine for induction of anaesthesia, producing essential relaxation that allows smooth induction and intubation. Mode of action (acts at GABA receptor) and unique tranquilisation without cardiorespiratory depression cannot be produced by the α-2 agonist sedatives (detomidine, romifidine and xylazine) or acepromazine.
Flumazenil	Purpose: intravenous reversal agent for benzodiazepines. Reversal of benzodiazepine effect during recovery from Total Intravenous Anaesthesia (TIVA) techniques. Identification of alternatives: sarmazenil. Discussion of the specific advantages: different mode of action from sarmazenil providing additional means of benzodiazepine reversal at the end of TIVA techniques. Sarmazenil is partial inverse agonist of benzodiazepine receptors whereas flumazenil is an antagonist competitively inhibiting the benzodiazepine binding site at the GABA receptor.
Midazolam	Purpose: premedication and induction of anaesthesia.