

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

TITLE VII

PHARMACOVIGILANCE

Article 72

1 Member States shall take all appropriate measures to encourage the reporting to the competent authorities of suspected adverse reactions to veterinary medicinal products.

[^{F12} Member States may impose specific requirements on veterinary practitioners and other health-care professionals in respect of the reporting of suspected serious or unexpected adverse reactions and human adverse reactions.]

Textual Amendments

F1 Substituted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)

Article 73

[^{F1}In order to ensure the adoption of appropriate and harmonised regulatory decisions concerning the veterinary medicinal products authorised within the Community, having regard to information obtained about suspected adverse reactions to veterinary medicinal products under normal conditions of use, Member States shall administer a veterinary pharmacovigilance system. This system shall be used to collect information useful in the surveillance of veterinary medicinal products, with particular reference to adverse reactions in animals and in human beings relating to the use of veterinary medicinal products, and to evaluate such information scientifically.]

Such information shall be collated with available data on the sale and prescription of veterinary medicinal products.

[^{F2}Member States shall ensure that suitable information collected within this system is communicated to other Member States and the Agency. This information shall be recorded in the database referred to in point (k) of the second subparagraph of Article 57(1) of Regulation (EC) No 726/2004 and shall be permanently accessible to all Member States and without delay to the public.]

This system also takes into account any available information related to the lack of expected efficacy, off-label use, investigations of the validity of the withdrawal period and on potential environmental problems, arising from the use of the product, interpreted in accordance with the Commission guidelines referred to in Article 77(1), which may have an impact on the evaluation of their benefits and risks.

Textual Amendments

F1 Substituted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)

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F2 Inserted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)

[^{F2}Article 73a

The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities in order to guarantee their independence.]

Textual Amendments

F2 Inserted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)

Article 74

The marketing authorization holder shall have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance.

[^{F1}That qualified person shall reside in the Community and shall be responsible for the following:]

- (a) the establishment and maintenance of a system which ensures that information about all suspected adverse reactions which are reported to the personnel of the company, including its representatives, is collected and collated in order to be accessible at least at one point within the Community;
- (b) the preparation for the competent authorities of the reports referred to in Article 75, in such form as may be laid down by those authorities, in accordance with the guidance referred to in Article 77(1);
- (c) ensuring that any request from the competent authorities for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a veterinary medicinal product is answered fully and promptly, including the provision of information about the volume of sales or prescriptions of the veterinary medicinal product concerned;
- (d) the provision to the competent authorities, of any other information relevant to the evaluation of the benefits and risks afforded by a veterinary medicinal product, including appropriate information on post-marketing surveillance studies.

Textual Amendments

F1 Substituted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)

[^{F1}Article 75

1 The marketing authorisation holder shall maintain detailed records of all suspected adverse reactions occurring within the Community or in a third country.

Save in exceptional circumstances, these reactions shall be communicated electronically in the form of a report in accordance with the guidelines referred to in Article 77(1).

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2 The marketing authorisation holder shall record all suspected serious adverse reactions and human adverse reactions relating to the use of veterinary medicinal products that are brought to his attention, and report them promptly to the competent authority of the Member State on whose territory the incident occurred, and no later than 15 days following receipt of the information.

The marketing authorisation holder shall also record all suspected serious adverse reactions and human adverse reactions related to the use of veterinary medicinal products of which he can reasonably be expected to have knowledge, and report them promptly to the competent authority of Member State on whose territory the incident occurred, and no later than 15 days following receipt of the information.

3 The marketing authorisation holder shall ensure that all suspected serious unexpected adverse reactions, human adverse reactions and any suspected transmission via a veterinary medicinal product of any infectious agent occurring on the territory of a third country are reported promptly in accordance with the guidelines referred to in Article 77(1), so that they are available to the Agency and the competent authorities of the Member States in which the veterinary medicinal product is authorised, and no later than 15 days following the receipt of the information.

4 By way of derogation from paragraphs 2 and 3, in the case of veterinary medicinal products which are covered by Directive 87/22/EEC, have benefited from the authorisation procedures under Articles 31 and 32 of this Directive or have been the subject of the procedures provided for in Articles 36, 37 and 38 of this Directive, the marketing authorisation holder shall additionally ensure that all suspected serious adverse reactions and human adverse reactions occurring in the Community are reported in such a way so as to be accessible to the reference Member State or a competent authority designated as reference Member State. The reference Member State shall assume responsibility for the analysis and follow-up of any such adverse reactions.

5 Unless other requirements have been laid down as a condition for the granting of the marketing authorisation or subsequently as indicated in the guidelines referred to in Article 77(1), reports of all adverse reactions shall be submitted to the competent authorities in the form of a periodic safety update report, immediately upon request or at least every six months after authorisation until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the market and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

The periodic safety update reports shall include a scientific evaluation of the risk-benefit balance of the veterinary medicinal product.

[^{F36} The Commission may amend paragraph 5 in the light of the experience gained from its operation.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).]

7 Following the granting of a marketing authorisation, the holder of such authorisation may request the amendment of the periods referred to in paragraph 5 of this Article in accordance with the procedure laid down by Commission Regulation (EC) No 1084/2003⁽¹⁾.

8 The holder of a marketing authorisation may not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorised veterinary medicinal product without giving prior or simultaneous notification to the competent authority.

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In any case, the marketing authorisation holder shall ensure that such information is presented objectively and is not misleading.

Member States shall take the necessary measures to ensure that a marketing authorisation holder who fails to discharge these obligations is subject to effective, proportionate and dissuasive penalties.]

Textual Amendments

- F1** Substituted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)
- F3** Substituted by [Regulation \(EC\) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.](#)

Article 76

[^{F1} The Agency, in collaboration with Member States and the Commission, shall set up a data-processing network to facilitate the exchange of pharmacovigilance information regarding veterinary medicinal products marketed in the Community in order to allow the competent authorities to share the information at the same time.]

2 Making use of the network foreseen in the first paragraph, Member States shall ensure that reports of suspected serious adverse reactions and human adverse reactions, in accordance with the guidance referred to in Article 77(1), that have taken place on their territory are immediately made available to the Agency and the other Member States, and in any case within 15 calendar days of their notification, at the latest.

3 The Member States shall ensure that reports of suspected serious adverse reactions and human adverse reactions, that have taken place on their territory are immediately made available to the marketing authorisation holder, and in any case within 15 calendar days of their notification at the latest.

Textual Amendments

- F1** Substituted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)

Article 77

1 In order to facilitate the exchange of information about pharmacovigilance within the Community, the Commission, in consultation with the Agency, Member States and the interested parties, shall draw up guidance on the collection, verification and presentation of adverse reaction reports, including technical requirements for electronic exchange of veterinary pharmacovigilance information in accordance with internationally agreed terminology.

[^{F1}In accordance with those guidelines, the marketing authorisation holder shall use internationally agreed veterinary medical terminology for the transmission of reports on adverse reactions.

The Commission shall publish the guidelines, which shall take account of international harmonisation work achieved in the field of pharmacovigilance.]

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2 For the interpretation of the definitions referred to in Article 1 points 10 to 16 and principles outlined in this title, the marketing authorisation holder and the competent authorities shall refer to the detailed guidance referred to in paragraph 1.

Textual Amendments

- F1** Substituted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)

Article 78

1 Where, as a result of the evaluation of veterinary pharmacovigilance data, a Member State considers that a marketing authorization should be suspended, withdrawn or varied to restrict the indications or availability, amend the posology, add a contraindication or add a new precautionary measure, it shall forthwith inform the Agency, the other Member States and the marketing authorization holder.

[^{F12} If urgent action is necessary for protecting human or animal health, the Member State concerned may suspend the marketing authorisation of a veterinary medicinal product, provided that the Agency, the Commission and the other Member States are informed on the following working day at the latest.]

[^{F23} When the Agency is informed in accordance with paragraphs 1 or 2, it shall give its opinion as soon as possible, according to the urgency of the matter.

On the basis of this opinion, the Commission may request all Member States in which the veterinary medicinal is marketed to take temporary measures immediately.

Final measures shall be adopted in accordance with the procedure referred to in Article 89(3).]

Textual Amendments

- F1** Substituted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)
- F2** Inserted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)

[^{F3} Article 79

The Commission shall adopt any amendments which may be necessary to update Articles 72 to 78 to take account of scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).]

Textual Amendments

- F3** Substituted by [Regulation \(EC\) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.](#)

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(1) [^{F1}OJ L 159, 27.6.2003, p. 1.]

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Textual Amendments

F1 Substituted by [Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.](#)