

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 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.](#)
- 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.](#)