# 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 I U.K.

## DEFINITIONS

### *Article 1* *U.K.*

For the purposes of this Directive, the following terms shall bear the following meanings:

| | | |
|---|---|---|
| | : | |
| **[**F2 2.Veterinary medicinal product | : | (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or<br>(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.**]** |
| | : | |
| 4. Substance | : | Any matter irrespective of origin which may be:<br>— human, e.g.<br>human blood and human blood products;<br>— animal, e.g.<br>micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;<br>— vegetable, e.g.<br>micro-organisms, plants, parts of plants, vegetable secretions, extracts;<br>— chemical, e.g.<br>elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis. |
| 5. Pre-mix for medicated feedingstuffs | : | Any veterinary medicinal product prepared in advance with a view to the subsequent manufacture of medicated feedingstuffs. |
| 6. Medicated feedingstuffs | : | Any mixture of a veterinary medicinal product or products and feed or feeds which is ready prepared for marketing and intended to be fed to animals without further processing, because of its curative or preventive properties or other properties as a medicinal product covered by point 2. |
| 7. Immunological veterinary medicinal product | : | A veterinary medicinal product administered to animals in order to produce active or passive immunity or to diagnose the state of immunity. |
| **[**F2 8.Homeopathic veterinary medicinal product | : | Any veterinary medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in Member |

States. A homeopathic veterinary medicinal product may contain a number of principles.

9.Withdrawal period : The period necessary between the last administration of the veterinary medicinal product to animals, under normal conditions of use and in accordance with the provisions of this Directive, and the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits for active substances laid down pursuant to Regulation (EEC) No 2377/90.

10.Adverse reaction : A reaction to a veterinary medicinal product which is harmful and unintended and which occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or to restore, correct or modify a physiological function.**]**

11. Human adverse reaction : A reaction which is noxious and unintended and which occurs in a human being following exposure to a veterinary medicine.

12. Serious adverse reaction : An adverse reaction which results in death, is life-threatening, results in significant disability or incapacity, is a congenital anomaly/birth defect, or which results in permanent or prolonged signs in the animals treated.

13. Unexpected adverse reaction : An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of the product characteristics.

14. Periodic safety update reports : The periodical reports containing the records referred to in Article 75.

15. Post-marketing surveillance studies : Pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorization, conducted with the aim of identifying and investigating a safety hazard relating to an authorized veterinary medicinal product.

16. Off-label use : The use of a veterinary medicinal product that is not in accordance with the summary of the product characteristics, including the misuse and serious abuse of the product.

17. Wholesale dealing in veterinary medicinal products : Any activity which includes the purchase, sale, import, export, or any other commercial transaction in veterinary medicinal products, whether or not for profit, except for:

— the supply by a manufacturer of veterinary medicinal products manufactured by himself,

— retail supplies of veterinary medicinal products by persons entitled to carry out such supplies in accordance with Article 66.

**[**F3 17a.Representative of the marketing authorisation holder : The person, commonly known as local representative, designated by the marketing authorisation holder to represent him in the Member State concerned.**]**

**[**F2 18.Agency : The European Medicines Agency established by Regulation (EC) No 726/2004(1).**]**

**[**F2 19.Risks relating to use of the product : — any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health;

— any risk of undesirable effects on the environment.**]**

**[**F3 20.Risk/benefit balance : An evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to the risks as defined above.

21.Veterinary prescription : Any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law.

| | | |
|---|---|---|
| 22.Name of veterinary medicinal product | : | The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder. |
| 23.Common name | : | The international non-proprietary name recommended by the World Health Organisation, or, if one does not exist, the usual common name. |
| 24.Strength | : | The content of active substances, expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form. |
| 25.Immediate packaging | : | The container or any other form of packaging that is in direct contact with the medicinal product. |
| 26.Outer packaging | : | The packaging into which is placed the immediate packaging. |
| 27.Labelling | : | Information on the immediate or outer packaging. |
| 28.Package leaflet | : | The leaflet containing information for the user that accompanies the medicinal product.**]** |

**Textual Amendments**

**F1** Deleted 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** 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** 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.

**(1)** **[**[F2]OJ L 136, 30.4.2004, p. 1.**]**

**Textual Amendments**

**F2** 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.