# 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 III

## MARKETING

### CHAPTER 1

### Marketing authorization

*Article 14*[F1]

The summary of the product characteristics shall contain, in the order indicated below, the following information:

1) name of the veterinary medicinal product followed by the strength and the pharmaceutical form;

2) qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used;

3) pharmaceutical form;

4) clinical particulars:

   4.1. target species,

   4.2. indications for use, specifying the target species,

   4.3. contra-indications,

   4.4. special warnings for each target species,

   4.5. special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals,

   4.6. adverse reactions (frequency and seriousness),

   4.7. use during pregnancy, lactation or lay,

   4.8. interaction with other medicinal products and other forms of interaction,

   4.9. amounts to be administered and administration route,

   4.10. overdose (symptoms, emergency procedures, antidotes), if necessary,

   4.11. withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero;

5) pharmacological properties:

   5.1. pharmacodynamic properties,

5.2. pharmacokinetic particulars;

6) pharmaceutical particulars:

6.1. list of excipients,

6.2. major incompatibilities,

6.3. shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time,

6.4. special precautions for storage,

6.5. nature and composition of immediate packaging,

6.6. special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate;

7) marketing authorisation holder;

8) marketing authorisation number(s);

9) date of the first authorisation or date of renewal of the authorisation;

10) date of revision of the text.

For authorisation under Article 13, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.**]**

**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.