# 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

## DEFINITIONS



## TITLE II

## SCOPE



## TITLE III

## MARKETING

### CHAPTER 1

### Marketing authorization

CHAPTER 2

Particular provisions applicable to homeopathic veterinary medicinal products



CHAPTER 3

Procedure for marketing authorization



CHAPTER 4

Mutual recognition procedure and decentralised procedure

## TITLE IV

## MANUFACTURE AND IMPORTS



## TITLE V

## LABELLING AND PACKAGE INSERT

## TITLE VI

## POSSESSION, DISTRIBUTION AND DISPENSING OF VETERINARY MEDICINAL PRODUCTS



## TITLE VII

## PHARMACOVIGILANCE



## TITLE VIII

## SUPERVISION AND SANCTIONS

TITLE IX

STANDING COMMITTEE



TITLE X

GENERAL PROVISIONS



TITLE XI

FINAL MEASURES



---

ANNEX I

CHEMICAL, PHARMACEUTICAL AND ANALYTICAL STANDARDS, SAFETY AND RESIDUE TESTS, PRE-CLINICAL AND CLINICAL TRIALS IN RESPECT OF TESTING OF VETERINARY MEDICINAL PRODUCTS

CHAPTER I:

PERFORMANCE OF TESTS

1. Introduction
2. Metabolism and residue kinetics
   - 2.1. Pharmacokinetics (absorption, distribution, metabolism, excretion)
   - 2.2. Depletion of residues
3. Residue analytical method

CHAPTER II:

PRESENTATION OF PARTICULARS AND DOCUMENTS

1. Identification of the product

PART 4:

PRE-CLINICAL AND CLINICAL TRIAL

CHAPTER I:

PRE-CLINICAL REQUIREMENTS

A. Pharmacology
   - A.1. Pharmacodynamics
   - A.2. Development of resistance
   - A.3. Pharmacokinetics

B. Tolerance in the target animal species

CHAPTER II:

CLINICAL REQUIREMENTS

1. General principles

2. Conduct of clinical trials

CHAPTER III:

PARTICULARS AND DOCUMENTS

1. Results of pre-clinical trials

2. Results of clinical trials

TITLE II

REQUIREMENTS FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

PART 1:

SUMMARY OF THE DOSSIER

A. ADMINISTRATIVE INFORMATION

B. SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET

C. DETAILED AND CRITICAL SUMMARIES

PART 2:

CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL/ MICROBIOLOGICAL INFORMATION (QUALITY)

A. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS
- 1. Qualitative particulars
- 2. ‘Usual terminology’
- 3. Quantitative particulars
- 4. Product development

B. DESCRIPTION OF MANUFACTURING METHOD

C. PRODUCTION AND CONTROL OF STARTING MATERIALS
- 1. Starting materials listed in pharmacopoeias
- 2. Starting materials not listed in a pharmacopoeia
  - 2.1. Starting materials of biological origin
  - 2.2. Starting materials of non-biological origin

D. CONTROL TESTS DURING THE MANUFACTURING PROCESS
- 1. The dossier shall include particulars relating to the control tests,...
- 2. For inactivated or detoxified vaccines, inactivation or detoxification shall be...

E. CONTROL TESTS ON THE FINISHED PRODUCT
- 1. General characteristics of the finished product
- 2. Identification of active substance(s)
- 3. Batch titre or potency
- 4. Identification and assay of adjuvants
- 5. Identification and assay of excipient components
- 6. Safety tests
- 7. Sterility and purity test
- 8. Residual humidity
- 9. Inactivation

F. BATCH-TO-BATCH CONSISTENCY

G. STABILITY TESTS

H. OTHER INFORMATION

PART 3:

SAFETY TESTS

A. INTRODUCTION AND GENERAL REQUIREMENTS

B. LABORATORY TESTS
- 1. Safety of the administration of one dose
- 2. Safety of one administration of an overdose
- 3. Safety of the repeated administration of one dose
- 4. Examination of reproductive performance
- 5. Examination of immunological functions
- 6. Special requirements for live vaccines
  - 6.1. Spread of the vaccine strain
  - 6.2. Dissemination in the vaccinated animal
  - 6.3. Reversion to virulence of attenuated vaccines
  - 6.4. Biological properties of the vaccine strain
  - 6.5. Recombination or genomic reassortment of strains
- 7. User safety
- 8. Study of residues
- 9. Interactions

C. FIELD STUDIES

D. ENVIRONMENTAL RISK ASSESSMENT

E. ASSESSMENT REQUIRED FOR VETERINARY MEDICINAL PRODUCTS CONTAINING OR CONSISTING OF...

PART 4:

EFFICACY TESTS

CHAPTER I

1. General principles The purpose of the trials described in...

1. General principles

2. Performance of trials

CHAPTER II

A. General requirements 1. The choice of antigens or vaccine...

A. General requirements
- 1. The choice of antigens or vaccine strains shall be justified...
- 2. Efficacy trials carried out in the laboratory shall be controlled...
- 3. The efficacy of an immunological veterinary medicinal product shall be...
- 4. The efficacy of each of the components of multivalent and...
- 5. Whenever a product forms part of a vaccination scheme recommended...
- 6. The dose to be used shall be the quantity of...
- 7. If there is a compatibility statement with other immunological products...

Part 2

The provisions of Part 2 shall apply to the documents...

(a) Terminology
(b) Control of starting materials
(c) Control tests on the finished medicinal product
(d) Stability tests

Part 3

The provisions of Part 3 shall apply to the simplified...

ANNEX II

PART A

Repealed Directives and their successive amendments

PART B

Time-limits for transposition into national law

ANNEX III

CORRELATION TABLE

(**1**) OJ C 75, 15.3.2000, p. 11.

(**2**) Opinion of the European Parliament of 3 July 2001 (not yet published in the Official Journal) and Council Decision of 27 September 2001.

(**3**) OJ L 317, 6.11.1981, p. 1. Directive as last amended by Commission Directive 2000/37/EC (OJ L 139, 10.6.2000, p. 25).

(**4**) OJ L 317, 6.11.1981, p. 16. Directive as last amended by Commission Directive 1999/104/EC (OJ L 3, 6.1.2000, p. 18).

(**5**) OJ L 373, 31.12.1990, p. 26.

(**6**) OJ L 297, 13.10.1992, p. 12.

(**7**) OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

(**8**) OJ L 184, 17.7.1999, p. 23.

(**9**) OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1274/2001 (OJ L 175, 28.6.2001, p. 14).