

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

Article 1 For the purposes of this Directive, the following terms shall...

TITLE II  
SCOPE

Article 2 (1) This Directive shall apply to veterinary medicinal products, including...

Article 3 (1) This Directive shall not apply to:

Article 4 (1) Member States may provide that this Directive shall not...

TITLE III  
MARKETING

CHAPTER 1

Marketing authorization

Article 5 (1) No veterinary medicinal product may be placed on the...

Article 6 (1) A veterinary medicinal product may not be the subject...

Article 7 Where the health situation so requires, a Member State may...

Article 8 In the event of serious epizootic diseases, Member States may...

Article 9 No veterinary medicinal product may be administered to animals unless...

Article 10 (1) Member States shall take the necessary measures to ensure...

Article 11 (1) Member States shall take the necessary measures to ensure...

Article 12 (1) For the purposes of obtaining a marketing authorisation in...

Article 13 (1) By way of derogation from point (j) of the...

Article 13a (1) By way of derogation from point (j) of the...

Article 13b In the case of veterinary medicinal products containing active substances...

Article 13c After the marketing authorisation has been granted, the marketing authorisation...

Article 13d By way of derogation from point (j) of the first...

Article 14 The summary of the product characteristics shall contain, in the...

Article 15 (1) Applicants shall ensure that the detailed and critical summaries...

## CHAPTER 2

### Particular provisions applicable to homeopathic veterinary medicinal products

- Article 16 (1) Member States shall ensure that homeopathic veterinary medicinal products...
- Article 17 (1) Without prejudice to the provisions of Regulation (EEC) No...
- Article 18 A special, simplified application for registration may cover a series...
- Article 19 (1) Homeopathic veterinary medicinal products other than those referred to...
- Article 20 This Chapter shall not apply to immunological homeopathic veterinary medicinal...

## CHAPTER 3

### Procedure for marketing authorization

- Article 21 (1) Member States shall take all appropriate measures to ensure...
- Article 22 Where a Member State is informed, in accordance with point...
- Article 23 In order to examine the application submitted pursuant to Articles...
- Article 24 Member States shall take all appropriate measures to ensure that:...
- Article 25 (1) When granting a marketing authorisation, the competent authority shall...
- Article 26 (1) The marketing authorisation may require the holder to indicate...
- Article 27 (1) After a marketing authorization has been issued, the holder...
- Article 27a After a marketing authorisation has been granted, the holder of...
- Article 27b The Commission shall adopt appropriate arrangements for the examination of...
- Article 28 (1) Without prejudice to paragraphs 4 and 5, a marketing...
- Article 29 The granting of authorization shall not diminish the general legal...
- Article 30 The marketing authorisation shall be refused if the file submitted...

## CHAPTER 4

### Mutual recognition procedure and decentralised procedure

- Article 31 (1) A coordination group shall be set up for the...
- Article 32 (1) With a view to the granting of a marketing...
- Article 33 (1) If a Member State cannot, within the period allowed...
- Article 34 (1) If two or more applications submitted in accordance with...
- Article 35 (1) Member States or the Commission or the applicant or...
- Article 36 (1) When reference is made to the procedure laid down...
- Article 37 Within 15 days after receipt of the opinion, the Commission...
- Article 38 (1) The Commission shall take a final decision in accordance...
- Article 39 (1) Any application by the marketing authorization holder to vary...
- Article 40 (1) Where a Member State considers that the variation of...

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- Article 41 Articles 39 and 40 shall apply by analogy to veterinary...  
Article 42 (1) The Agency shall publish an annual report on the...  
Article 43 Articles 33(4), (5) and (6) and 34 to 38 shall...

#### TITLE IV

##### MANUFACTURE AND IMPORTS

- Article 44 (1) Member States shall take all appropriate measures to ensure...  
Article 45 In order to obtain the manufacturing authorization, the applicant shall...  
Article 46 (1) The competent authority of the Member State shall not...  
Article 47 The Member States shall take all appropriate measures to ensure...  
Article 48 If the holder of the manufacturing authorization requests a change...  
Article 49 The competent authority of the Member States may require from...  
Article 50 The holder of a manufacturing authorization shall at least be...  
Article 50a (1) For the purposes of this Directive, manufacturing active substances...  
Article 51 The principles and guidelines of good manufacturing practice for veterinary...  
Article 52 (1) Member States shall take all appropriate measures to ensure...  
Article 53 (1) Member States shall ensure that the qualified person referred...  
Article 54 (1) A person engaging, in a Member State, in the...  
Article 55 (1) Member States shall take all appropriate measures to ensure...  
Article 56 Member States shall ensure that the obligations of qualified persons...  
Article 57 The provisions of this Title shall apply to homeopathic veterinary...

#### TITLE V

##### LABELLING AND PACKAGE INSERT

- Article 58 (1) Except in the case of the medicinal products referred...  
Article 59 (1) As regards ampoules, the particulars listed in the first...  
Article 60 Where there is no outer package, all the particulars which...  
Article 61 (1) The inclusion of a package leaflet in the packaging...  
Article 62 Where the provisions of this Title are not observed and...  
Article 63 The requirements of Member States concerning conditions of supply to...  
Article 64 (1) Without prejudice to paragraph 2, homeopathic veterinary medicinal products...

## TITLE VI

POSSESSION, DISTRIBUTION AND DISPENSING  
OF VETERINARY MEDICINAL PRODUCTS

- Article 65 (1) Member States shall take all appropriate measures to ensure...
- Article 66 (1) Member States shall take all appropriate measures to ensure...
- Article 67 Without prejudice to stricter Community or national rules relating to...
- Article 68 (1) Member States shall take all measures necessary to ensure...
- Article 69 Member States shall ensure that the owners or keepers of...
- Article 70 By way of derogation from Article 9 and without prejudice...
- Article 71 (1) In the absence of specific Community legislation concerning the...

## TITLE VII

## PHARMACOVIGILANCE

- Article 72 (1) Member States shall take all appropriate measures to encourage...
- Article 73 In order to ensure the adoption of appropriate and harmonised...
- Article 73a The management of funds intended for activities connected with pharmacovigilance,...
- Article 74 The marketing authorization holder shall have permanently and continuously at...
- Article 75 (1) The marketing authorisation holder shall maintain detailed records of...
- Article 76 (1) The Agency, in collaboration with Member States and the...
- Article 77 (1) In order to facilitate the exchange of information about...
- Article 78 (1) Where, as a result of the evaluation of veterinary...
- Article 79 The Commission shall adopt any amendments which may be necessary...

## TITLE VIII

## SUPERVISION AND SANCTIONS

- Article 80 (1) The competent authority of the Member State concerned shall...
- Article 81 (1) Member States shall take all appropriate measures to ensure...
- Article 82 (1) Where it considers it necessary for reasons of human...
- Article 83 (1) Member States' competent authorities shall suspend, revoke, withdraw or...
- Article 84 (1) Without prejudice to Article 83, Member States shall take...
- Article 85 (1) The competent authority of a Member State shall suspend...
- Article 86 The provisions of this Title shall apply to homeopathic veterinary...
- Article 87 Member States shall take appropriate measures to encourage veterinarians and...

## TITLE IX STANDING COMMITTEE

- Article 88 The Commission shall adopt any changes which are necessary in...
- Article 89 (1) The Commission shall be assisted by a Standing Committee...

## TITLE X GENERAL PROVISIONS

- Article 90 Member States shall take all necessary measures to ensure that...
- Article 91 (1) Each Member State shall take all appropriate measures to...
- Article 92 Member States shall communicate to each other all the information...
- Article 93 (1) At the request of the manufacturer or exporter of...
- Article 94 Any decision referred to in this Directive, taken by the...
- Article 95 Member States shall not permit foodstuffs for human consumption to...
- Article 95a Member States shall ensure that appropriate collection systems are in...
- Article 95b When a veterinary medicinal product is to be authorised in...

## TITLE XI FINAL MEASURES

- Article 96 Directives 81/851/EEC, 81/852/EEC, 90/677/EEC and 92/74/EEC referred to in Annex...
- Article 97 This Directive enters into force on the 20th day following...
- Article 98 This Directive is addressed to the Member States.

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## ANNEX I

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

#### INTRODUCTION AND GENERAL PRINCIPLES

1. The particulars and documents accompanying an application for marketing authorisation...
2. In assembling the dossier for application for marketing authorisation, applicants...
3. For veterinary medicinal products other than immunological veterinary medicinal products,...
4. The manufacturing process shall comply with the requirements of Commission...
5. All information which is relevant to the evaluation of the...
6. Pharmacological, toxicological, residue and safety tests shall be carried out...

7. Member States shall ensure that all experiments on animals are...
8. In order to monitor the risk/benefit assessment, any new information...
9. The environmental risk assessment connected with the release of veterinary...
10. In cases of applications for marketing authorisations for veterinary medicinal...

## TITLE I

### REQUIREMENTS FOR VETERINARY MEDICINAL PRODUCTS OTHER THAN IMMUNOLOGICAL VETERINARY MEDICINAL...

#### 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:

##### PHARMACEUTICAL (PHYSICO-CHEMICAL, BIOLOGICAL OR MICROBIOLOGICAL INFORMATION (QUALITY))

- A. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS
  1. Qualitative particulars
  2. Usual terminology
  3. Quantitative particulars
    - 3.1. In order to give 'quantitative particulars' of all the active...
    - 3.2. Active substances present in the form of compounds or derivatives...
    - 3.3. For veterinary medicinal products containing an active substance which is...
  4. Development pharmaceuticals
- B. DESCRIPTION OF THE MANUFACTURING METHOD
- C. CONTROL OF STARTING MATERIALS
  1. General requirements
    - 1.1. Active substances
      - 1.1.1. Active substances listed in pharmacopoeias
      - 1.1.2. Active substances not in a pharmacopoeia
      - 1.1.3. Physico-chemical characteristics liable to affect bioavailability
    - 1.2. Excipients
    - 1.3. Container-closure systems
      - 1.3.1. Active substance
      - 1.3.2. Finished product
    - 1.4. Substances of biological origin
- D. CONTROL TESTS CARRIED OUT AT INTERMEDIATE STAGES OF THE MANUFACTURING...
- E. TESTS ON THE FINISHED PRODUCT
  1. General characteristics of the finished product

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2. Identification and assay of active substance(s)
3. Identification and assay of excipient components
4. Safety tests

F. STABILITY TEST

1. Active substances(s)
2. Finished product

G. OTHER INFORMATION

PART 3:

SAFETY AND RESIDUES TESTS

A. Safety tests

CHAPTER I:

PERFORMANCE OF TESTS

1. Precise identification of the product and of its active substance(s)...
2. Pharmacology
  - 2.1. Pharmacodynamics
  - 2.2. Pharmacokinetics
3. Toxicology
  - 3.1. Single-dose toxicity
  - 3.2. Repeat-dose toxicity
  - 3.3. Tolerance in the target species
  - 3.4. Reproductive toxicity including developmental toxicity
    - 3.4.1. Study of the effects on reproduction
    - 3.4.2. Study of developmental toxicity
  - 3.5. Genotoxicity
  - 3.6. Carcinogenicity
  - 3.7. Exceptions
4. Other requirements
  - 4.1. Special studies
  - 4.2. Microbiological properties of residues
    - 4.2.1. Potential effects on the human gut flora
    - 4.2.2. Potential effects on the microorganisms used for industrial food processing...
  - 4.3. Observations in humans
  - 4.4. Development of resistance
5. User safety
6. Environmental risk assessment
  - 6.1. Environmental risk assessment of veterinary medicinal products not containing or...
  - 6.2. Environmental risk assessment for veterinary medicinal products containing or consisting...

CHAPTER II:

PRESENTATION OF PARTICULARS AND DOCUMENTS

B. Residue tests

## 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...

8. For diagnostic immunological veterinary medicinal products administered to animals, the...
  9. For vaccines intended to allow a distinction between vaccinated and...
- B. Laboratory trials
1. In principle, demonstration of efficacy shall be undertaken under well-controlled...
  2. If possible, the immune mechanism (cell-mediated/humoral, local/general classes of immunoglobulin)...
- C. Field trials
1. Unless justified, results from laboratory trials shall be supplemented with...
  2. Where laboratory trials cannot be supportive of efficacy, the performance...

#### PART 5:

### PARTICULARS AND DOCUMENTS

- A. INTRODUCTION
- B. LABORATORY STUDIES
- C. FIELD STUDIES

#### PART 6:

### BIBLIOGRAPHICAL REFERENCES

#### TITLE III

### REQUIREMENTS FOR SPECIFIC MARKETING AUTHORISATION APPLICATIONS

1. Generic veterinary medicinal products
2. Similar biological veterinary medicinal products
3. Well-established veterinary use
4. Combination veterinary medicinal products
5. Informed consent applications
6. Documentation for applications in exceptional circumstances
7. Mixed marketing authorisation applications

#### TITLE IV

### REQUIREMENTS FOR MARKETING AUTHORISATION APPLICATIONS FOR PARTICULAR VETERINARY MEDICINAL PRODUCTS...

1. IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS
  - A. VACCINE ANTIGEN MASTER FILE
  - B. MULTI-STRAIN DOSSIER
2. HOMEOPATHIC VETERINARY MEDICINAL PRODUCTS

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## 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

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- (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](#)).