Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

Section 5

Specific requirements for generic, hybrid and combination veterinary medicinal products and for applications based on informed consent and bibliographic data

Section 6

Marketing authorisations for limited market and in exceptional circumstances

Section 7

Examination of applications and basis for granting marketing authorisations

Section 8

Protection of technical documentation

CHAPTER VII

SUPPLY AND USE

Section 1

Wholesale distribution

Section 2

Retail

Section 3

Use

Section 4

Advertising

3.5. Route of administration

3.6. Target species

4. Manufacturing and pharmacovigilance information

4.1. Proof of a manufacturing authorisation or certificate of good manufacturing...

4.2. Reference number of pharmacovigilance system master file

5. Veterinary medicinal product information

5.1. Proposed summary of the product characteristics drawn up in accordance...

5.2. Description of the final presentation of the veterinary medicinal product,...

5.3. Proposed text of the information to be provided on the...

6. Other information

6.1. List of countries in which a marketing authorisation has been...

6.2. Copies of all the summaries of product characteristics as included...

6.3. List of countries in which an application has been submitted...

6.4. List of Member States in which the veterinary medicinal product...

6.5. Critical expert reports on quality, safety and efficacy of the...

ANNEX II

REQUIREMENTS REFERRED TO IN POINT (B) OF ARTICLE 8(1)

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 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

Pharmaceutical (physico-chemical, biological or microbiological information (quality))

Basic principles and requirements

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 pharmaceutics

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

PART 4

Efficacy tests

Chapter I

Chapter II

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 III

LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 136(1)

the obligation, as an applicant, to provide accurate information and...

ANNEX IV

(**1**) OJ C 242, 23.7.2015, p. 54.

(**2**) Position of the European Parliament of 25 October 2018 (not yet published in the Official Journal) and Decision of the Council of 26 November 2018.

(**3**) 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 (OJ L 311, 28.11.2001, p. 1).

(**4**) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

(**5**) Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (see page 1 of this Official Journal).

(**6**) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

(**7**) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

(**8**) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

(**9**) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

(**10**) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

(**11**) Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ L 376, 27.12.2006, p. 21).

(**12**) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

(**13**) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(**14**) Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (OJ L 44, 14.2.2009, p. 10).

(**15**) OJ L 123, 12.5.2016, p. 1.

(**16**) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(**17**) Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).

(**18**) Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ L 376, 27.12.2006, p. 36).