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)

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Article 158 Review of measures regarding animals of the equine species
Article 159 Transitional provisions regarding certain certificates of good manufacturing practice
Article 160 Entry into force and application
Signature

ANNEX I

INFORMATION REFERRED TO IN POINT (A) OF ARTICLE 8(1)

1. Legal basis for the application for the marketing authorisation

2. Applicant

2.1. Name or company name and permanent address or registered place...

2.2. Name or company name and permanent address or registered place...

2.3. Name and address of the sites involved in the different...

3. Identification of the veterinary medicinal product

3.1. Name of the veterinary medicinal product and Anatomical Therapeutic Chemical...

3.2. Active substance(s) and, if applicable, diluent(s)

3.3. Strength or, in case of immunological veterinary medicinal product, biological...

3.4. Pharmaceutical form

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

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

2. Performance of trials

Chapter II

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

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).

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/6 of the European Parliament and of the Council.