

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 IV

MANUFACTURE AND IMPORTS

*Article 44*

1 Member States shall take all appropriate measures to ensure that the manufacture of veterinary medicinal products in their territory is subject to the holding of an authorization. This manufacturing authorization shall likewise be required for veterinary medicinal products intended for export.

2 The authorization referred to in paragraph 1 shall be required both for total and partial manufacture and for the various processes of dividing up, packaging or presentation.

However, such authorization shall not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out solely for retail supply by pharmacists in dispensing pharmacies or by persons legally authorized in the Member States to carry out such processes.

3 The authorization referred to in paragraph 1 shall also be required for imports from third countries into a Member State; this Title and Article 83 shall apply to such imports in the same way as to manufacture.

Member States shall take all appropriate measures to ensure that veterinary medicinal products brought into their territory from a third country and destined for another Member State are accompanied by a copy of the authorization referred to in paragraph 1.

[<sup>F1</sup>4 The Member State shall forward to the Agency a copy of the manufacturing authorisations referred to in paragraph 1. The Agency shall enter that information in the Community database referred to in Article 80(6).]

**Textual Amendments**

- F1** Inserted 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.](#)

*Article 45*

In order to obtain the manufacturing authorization, the applicant shall meet at least the following requirements:

- (a) he shall specify the veterinary medicinal products and pharmaceutical forms which are to be manufactured or imported and also the place where they are to be manufactured and/or controlled;
- (b) he shall have at his disposal, for the manufacture or import of the above, suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements which the Member State concerned lays down as regards both manufacture and control and the storage of products, in accordance with Article 24;

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- (c) he shall have at his disposal the services of at least one qualified person within the meaning of Article 52.

The applicant shall provide particulars in his application to establish his compliance with the above requirements.

#### *Article 46*

1 The competent authority of the Member State shall not issue the manufacturing authorization until it has established the accuracy of the particulars supplied pursuant to Article 45 by means of an inquiry carried out by its representatives.

2 In order to ensure that the requirements referred to in Article 45 are complied with, authorization may be made conditional on the fulfilment of certain obligations imposed either when authorization is granted or at a later date.

3 The authorization shall apply only to the premises specified in the application and to the veterinary medicinal products and pharmaceutical forms specified in that application.

#### *Article 47*

The Member States shall take all appropriate measures to ensure that the time taken for the procedure for granting the manufacturing authorization does not exceed 90 days from the day on which the competent authority receives the application.

#### *Article 48*

If the holder of the manufacturing authorization requests a change in any of the particulars referred to in Article 45, first paragraph, (a) and (b), the time taken for the procedure relating to this request shall not exceed 30 days. In exceptional cases, this period of time may be extended to 90 days.

#### *Article 49*

The competent authority of the Member States may require from the applicant further information concerning both the particulars supplied pursuant to Article 45 and the qualified person referred to in Article 52; where the competent authority concerned exercises this right, application of the time-limits referred to in Articles 47 and 48 shall be suspended until the additional data required have been supplied.

#### *Article 50*

The holder of a manufacturing authorization shall at least be obliged to:

- (a) have at his disposal the services of staff complying with the legal requirements existing in the Member State concerned as regards both manufacture and controls;
- (b) dispose of the authorized veterinary medicinal products only in accordance with the legislation of the Member States concerned;
- (c) give prior notice to the competent authority of any changes which he may wish to make to any of the particulars supplied pursuant to Article 45; the competent authority shall, in any event, be immediately informed if the qualified person referred to in Article 52 is replaced unexpectedly;
- (d) allow the representatives of the competent authority of the Member State concerned access to his premises at any time;

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- (e) enable the qualified person referred to in Article 52 to carry out his duties, particularly by placing at his disposal all the necessary facilities;
- (f) [<sup>F2</sup>comply with the principles and the guidelines on good manufacturing practice for medicinal products and use as starting materials only active substances which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials;]
- (g) keep detailed records of all veterinary medicinal products supplied by him, including samples, in accordance with the laws of the countries of destination. The following information at least shall be recorded in respect of each transaction, whether or not it is made for payment:
  - date,
  - name of the veterinary medicinal product,
  - quantity supplied,
  - name and address of the recipient,
  - batch number.

These records shall be available for inspection by the competent authorities for a period of at least three years.

#### Textual Amendments

- F2** 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.](#)

#### *[<sup>F1</sup>Article 50a*

1 For the purposes of this Directive, manufacturing active substances for use as starting materials shall include the complete or partial manufacture or the import of an active substance used as a starting material, as defined in Part 2, Section C of Annex I, and the various processes of dividing up, packaging or presentation prior to its incorporation in a veterinary medicinal product, including repackaging or re-labelling, such as carried out by a starting material distributor.

[<sup>F32</sup> The Commission shall adopt any amendments which may be necessary in order to adapt the provisions of paragraph 1 to take account of scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).]]

#### Textual Amendments

- F1** Inserted 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.](#)
- F3** Substituted by [Regulation \(EC\) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.](#)

### Article 51

[<sup>F3</sup>The principles and guidelines of good manufacturing practice for veterinary medicinal products referred to in Article 50(f) shall be adopted by the Commission in the form of a Directive addressed to the Member States. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).]

Detailed guidelines shall be published by the Commission and revised as appropriate to take account of scientific and technical progress.

[<sup>F1</sup>The principles of good manufacturing practice as regards the manufacturing of active substances for use as starting materials as referred to in Article 50(f) shall be adopted in the form of detailed guidelines.

The Commission shall also publish guidelines on the form and content of the authorisation referred to in Article 44(1), the reports referred to in Article 80(3) and the form and content of the certificate of good manufacturing practice referred to in Article 80(5).]

#### Textual Amendments

- F1** Inserted 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.](#)
- F3** Substituted by [Regulation \(EC\) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.](#)

### Article 52

1 Member States shall take all appropriate measures to ensure that the holder of the manufacturing authorization has permanently and continuously at his disposal the services of at least one qualified person who fulfils the conditions laid down in Article 53 and is responsible, in particular, for carrying out the duties specified in Article 55.

2 If he personally fulfils the conditions laid down in Article 53, the holder of the authorization may himself assume the responsibility referred to in paragraph 1.

### Article 53

[<sup>F21</sup> Member States shall ensure that the qualified person referred to in Article 52(1) fulfils the conditions of qualification referred to in paragraphs 2 and 3.]

2 The qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary science, chemistry, pharmaceutical chemistry and technology, biology.

However, the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of at least one year and includes a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level.

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Where two university or recognized equivalent courses coexist in a Member State and where one of these extends over four years and the other over three years, the diploma, certificate or other evidence of formal qualifications awarded on completion of the three-year university course or its recognized equivalent shall be considered to fulfil the condition of duration referred to in the first subparagraph in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognized as equivalent by the State in question.

The course shall include theoretical and practical tuition bearing upon at least the following basic subjects:

- experimental physics,
- general and inorganic chemistry,
- organic chemistry,
- analytical chemistry,
- pharmaceutical chemistry, including analysis of medicinal products,
- general and applied biochemistry (medical),
- physiology,
- microbiology,
- pharmacology,
- pharmaceutical technology,
- toxicology,
- pharmacognosy (study of the composition and effects of the active principles of natural substances of plant and animal origin).

Tuition in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in Article 55.

In so far as certain diplomas, certificates or other evidence of formal qualifications mentioned in this paragraph do not fulfil the criteria laid down above, the competent authority of the Member State shall ensure that the person concerned provides evidence that he has, in the subjects involved, the knowledge required for the manufacture and control of veterinary medicinal products.

3 The qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorized manufacturers, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of veterinary medicinal products.

The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years.

#### Textual Amendments

**F2** 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.](#)

#### Article 54

[<sup>F2</sup>1 A person engaging, in a Member State, in the activities of the person referred to in Article 52(1) on the date on which Directive 81/851/EEC became applicable, without complying

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with the provisions of Article 53, shall be eligible to continue to engage in those activities within the Community.]

2 The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course — or a course recognized as equivalent by the Member State concerned — in a scientific discipline allowing him to engage in the activities of the person referred to in Article 52 in accordance with the laws of that State may — if he began his course prior to 9 October 1981 — be considered as qualified to carry out in that State the duties of the person referred to in Article 52, provided that he has previously engaged in the following activities for at least two years before 9 October 1991 in one or more undertakings with a manufacturing authorization; production supervision and/or qualitative and quantitative analysis of active substances, and the necessary testing and checking under the direct authority of a person as referred to in Article 52 to ensure the quality of veterinary medicinal products.

If the person concerned has acquired the practical experience referred to in the first subparagraph before 9 October 1971, a further one year's practical experience in accordance with the conditions referred to in the first subparagraph shall be completed by him immediately before he engages in such activities.

#### Textual Amendments

**F2** 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](#).

#### Article 55

1 Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 52 is, without prejudice to his relationship with the holder of the manufacturing authorization, responsible, in the context of the procedures referred to in Article 56, for ensuring that:

- a in the case of veterinary medicinal products manufactured within the Member State concerned, each batch of veterinary medicinal products has been manufactured and checked in compliance with the laws in force in that Member State and in accordance with the requirements of the marketing authorization;
- [<sup>F2</sup>b in the case of veterinary medicinal products coming from third countries, even if manufactured in the Community, each production batch imported has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances, and all the other tests or controls necessary to ensure the quality of veterinary medicinal products in accordance with the requirements of the marketing authorisation.]

Batches of veterinary medicinal products which have undergone such controls in a Member State shall be exempt from the above controls if they are placed on the market in another Member State, accompanied by the control reports signed by the qualified person.

2 In the case of veterinary medicinal products imported from a third country, where appropriate arrangements have been made by the Community with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down by the Community and to ensure that the controls referred to under point (b) of the first subparagraph of paragraph 1 have been carried out in the exporting country, the qualified person may be relieved of responsibility for carrying out those controls.

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3 In all cases, and particularly where the veterinary medicinal products are released for sale, the qualified person shall certify, in a register or equivalent document provided for the purpose, that each production batch satisfies the provisions of this Article; the said register or equivalent document shall be kept up to date as operations are carried out and shall remain at the disposal of the representatives of the competent authority for the period specified in the provisions of the Member State concerned and, in any event, for at least five years.

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**Textual Amendments**

**F2** 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](#).

*Article 56*

Member States shall ensure that the obligations of qualified persons referred to in Article 52 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct.

Member States may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary proceedings against him for failure to fulfil his obligations.

*Article 57*

The provisions of this Title shall apply to homeopathic veterinary medicinal products.