

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 III

MARKETING

CHAPTER 1

Marketing authorization

F1 Article 5

1 No veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been granted by the competent authorities of that Member State in accordance with this Directive or a marketing authorisation has been granted in accordance with Regulation (EC) No 726/2004.

When a veterinary medicinal product has been granted an initial authorisation in accordance with the first subparagraph, any additional species, strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions, shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 13(1).

2 The marketing authorisation holder shall be responsible for the marketing of the medicinal product. The designation of a representative shall not relieve the marketing authorisation holder of his legal responsibility.

Textual Amendments

F1 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 6

1 A veterinary medicinal product may not be the subject of a marketing authorisation for the purpose of administering it to one or more food-producing species unless the pharmacologically active substances which it contains appear in Annexes I, II or III to Regulation (EEC) No 2377/90.

2 If an amendment to the Annexes to Regulation (EEC) No 2377/90 so warrants, the marketing authorisation holder or, where appropriate, the competent authorities shall take all necessary measures to amend or revoke the marketing authorisation within 60 days of the date on which the amendment to the Annexes to that Regulation was published in the *Official Journal of the European Union*.

3 By way of derogation from paragraph 1, a veterinary medicinal product containing pharmacologically active substances not included in Annexes I, II or III to Regulation (EEC) No 2377/90 may be authorised for particular animals of the equidae family that have

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been declared, in accordance with Commission Decision 93/623/EEC of 20 October 1993 establishing the identification document (passport) accompanying registered equidae⁽¹⁾ and Commission Decision 2000/68/EC of 22 December 1999 amending Decision 93/623/EEC and establishing the identification of equidae for breeding and production⁽²⁾, as not being intended for slaughter for human consumption. Such veterinary medicinal products shall neither include active substances that appear in Annex IV to Regulation (EEC) No 2377/90 nor be intended for use in the treatment of conditions, as detailed in the authorised Summary of Product Characteristics, for which a veterinary medicinal product is authorised for animals of the equidae family.]

Textual Amendments

- F1** 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 7

Where the health situation so requires, a Member State may authorise the marketing or administration to animals of veterinary medicinal products which have been authorized by another Member State in accordance with this Directive.

[^{F1} Article 8

In the event of serious epizootic diseases, Member States may provisionally allow the use of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use.

The Commission may avail itself of the option set out in the first paragraph when explicit provision is made for that option under Community rules concerning certain serious epizootic diseases.

If an animal is being imported from, or exported to, a third country and is thereby subject to specific binding health rules, a Member State may permit the use, for the animal in question, of an immunological veterinary medicinal product that is not covered by a marketing authorisation in the Member State in question but is authorised under the legislation of the third country. Member States shall take all appropriate measures concerning the supervision of the importation and the use of such immunological products.]

Textual Amendments

- F1** 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 9

No veterinary medicinal product may be administered to animals unless the marketing authorization has been issued, except for the tests of veterinary medicinal products referred to in Article 12(3)(j) which have been accepted by the competent national authorities, following notification or authorization, in accordance with the national rules in force.

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[^{F1}Article 10

1 Member States shall take the necessary measures to ensure that, if there is no authorised veterinary medicinal product in a Member State for a condition affecting a non food-producing species, by way of exception, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animal concerned with:

- a a veterinary medicinal product authorised in the Member State concerned under this Directive or under Regulation (EC) No 726/2004 for use with another animal species, or for another condition in the same species; or
- b if there is no product as referred to in point (a), either:
 - (i) a medicinal product authorised for human use in the Member State concerned in accordance with Directive 2001/83/EC of the European Parliament and of the Council or under Regulation (EC) No 726/2004, or
 - (ii) in accordance with specific national measures, a veterinary medicinal product authorised in another Member State in accordance with this Directive for use in the same species or in another species for the condition in question or for another condition; or
- c if there is no product as referred to in subparagraph (b), and within the limits of the law of the Member State concerned, a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with the terms of a veterinary prescription.

The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.

2 By way of derogation from Article 11, the provisions of paragraph 1 of this Article shall also apply to the treatment by a veterinarian of an animal belonging to the equidae family provided that it has been declared, in accordance with Commission Decisions 93/623/EEC and 2000/68/EC, as not being intended for slaughter for human consumption.

3 By way of derogation from Article 11, and in accordance with the procedure referred to in Article 89(2), the Commission shall establish a list of substances essential for the treatment of equidae and for which the withdrawal period shall be not less than six months according to the control mechanisms laid down in Commission Decisions 93/623/EEC and 2000/68/EC.

Textual Amendments

- F1** 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 11

1 Member States shall take the necessary measures to ensure that, if there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing species, by way of exception, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned on a particular holding with:

- a a veterinary medicinal product authorised in the Member State concerned under this Directive or under Regulation (EC) No 726/2004 for use with another animal species, or for another condition in the same species; or
- b if there is no product as referred to in point (a), either:

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- (i) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004, or
- (ii) a veterinary medicinal product authorised in another Member State in accordance with this Directive for use in the same species or in another food-producing species for the condition in question or for another condition; or
- c if there is no product as referred to in subparagraph (b), and within the limits of the law of the Member State concerned, a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with the terms of a veterinary prescription.

The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.

2 Paragraph 1 shall apply provided that pharmacologically active substances included in the medicinal product are listed in Annex I, II or III to Regulation (EEC) No 2377/90, and that the veterinarian specifies an appropriate withdrawal period.

Unless the medicinal product used indicates a withdrawal period for the species concerned, the specified withdrawal period shall not be less than:

- 7 days for eggs,
- 7 days for milk,
- 28 days for meat from poultry and mammals including fat and offal,
- 500 degree-days for fish meat.

However, these specific withdrawal periods may be modified in accordance with the procedure referred to in Article 89(2).

3 With regard to homeopathic veterinary medicinal products in which active principles figure in Annex II to Regulation (EEC) No 2377/90, the withdrawal period referred to in the second subparagraph of paragraph 2 shall be reduced to zero.

4 When a veterinarian has recourse to the provisions of paragraphs 1 and 2 of this Article, he shall keep adequate records of the date of examination of the animals, details of the owner, the number of animals treated, the diagnosis, the medicinal products prescribed, the doses administered, the duration of treatment and the withdrawal periods recommended, and shall make these records available for inspection by the competent authorities for a period of at least five years.

5 Without prejudice to the other provisions of this Directive, Member States shall take all necessary measures concerning the import, distribution, dispensing of and information on the medicinal products which they permit for administration to food-producing animals in accordance with paragraph 1(b)(ii).

Textual Amendments

- F1** 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 12

1 For the purposes of obtaining a marketing authorisation in respect of a veterinary medicinal product, otherwise than under the procedure established by Regulation (EC)

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No 726/2004, an application shall be lodged with the competent authority of the Member State concerned.

In the case of veterinary medicinal products which are intended for one or more food-producing species but whose pharmacologically active substances have not yet been included, for the species in question, in Annexes I, II or III to Regulation (EEC) No 2377/90, a marketing authorisation may not be applied for until after a valid application has been made for the establishment of maximum residue limits in accordance with that Regulation. At least six months shall elapse between a valid application for the establishment of maximum residue limits and an application for a marketing authorisation.

However, in the case of veterinary medicinal products referred to in Article 6(3), a marketing authorisation may be applied for without a valid application in accordance with Regulation (EEC) No 2377/90. All the scientific documentation necessary for the demonstration of the quality, safety and efficacy of the veterinary medicinal product, as provided for in paragraph 3, shall be submitted.

2 A marketing authorisation may only be granted to an applicant established in the Community.

3 The application for marketing authorisation shall include all the administrative information and scientific documentation necessary for demonstrating the quality, safety and efficacy of the veterinary medicinal product in question. The file shall be submitted in accordance with Annex I and shall contain, in particular, the following information:

- a name or business name and permanent address or registered place of business of the person responsible for placing the product on the market and, if different, of the manufacturer or manufacturers involved and of the sites of manufacture;
- b name of veterinary medicinal product;
- c qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its international non-proprietary name (INN) recommended by the WHO, where an INN exists, or its chemical name;
- d description of the method of manufacture;
- e therapeutic indications, contra-indications and adverse reactions;
- f dosage for the various species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;
- g reasons for any precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals and disposing of waste, together with an indication of potential risks that the veterinary medicinal product might pose to the environment, to human and animal health and to plants;
- h indication of the withdrawal period in the case of medicinal products intended for food-producing species;
- i description of the testing methods employed by the manufacturer;
- j results of:
 - pharmaceutical (physico-chemical, biological or microbiological) tests,
 - safety tests and residue tests,
 - pre-clinical and clinical trials;
 - tests assessing the potential risks posed by the medicinal product for the environment. This impact shall be studied and consideration shall be given on a case-by-case basis to specific provisions seeking to limit it.

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- k a detailed description of the pharmacovigilance system and, where appropriate, the risk management system that the applicant will put in place;
- l a summary in accordance with Article 14 of the product characteristics, a mock-up of the immediate packaging and the outer packaging of the veterinary medicinal product, together with the package leaflet, in accordance with Articles 58 to 61;
- m a document showing that the manufacturer is authorised in his own country to produce veterinary medicinal products;
- n copies of any marketing authorisation obtained in another Member State or in a third country for the relevant veterinary medicinal product, together with a list of those Member States in which an application for authorisation submitted in accordance with this Directive is under examination. Copies of the summary of the product characteristics proposed by the applicant in accordance with Article 14 or approved by the competent authority of the Member State in accordance with Article 25 and copies of the package insert proposed, details of any decision to refuse authorisation, whether in the Community or a third country and the reasons for that decision. All this information shall be updated on a regular basis;
- o proof that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country;
- p in the case of veterinary medicinal products intended for one or more food-producing species and containing one or more pharmacologically active substances not yet included, for the species in question, in Annexes I, II or III to Regulation (EEC) No 2377/90, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with the aforementioned Regulation.

The documents and particulars relating to the results of the tests referred to in point (j) of the first subparagraph shall be accompanied by detailed and critical summaries, drawn up as specified in Article 15.

Textual Amendments

- F1** 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 13

1 By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 5 for not less than eight years in a Member State or the Community.

A generic veterinary medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subparagraph shall also apply when the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is

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submitted, the competent authority of the other Member State shall transmit, within a period of one month, confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.

However, the ten-year period provided for in the second subparagraph shall be extended to 13 years in the case of veterinary medicinal products for fish or bees or other species designated in accordance with the procedure referred to in Article 89(2).

2 For the purposes of this Article:

- a 'reference medicinal product' shall mean a product authorised within the meaning of Article 5 in accordance with the provisions of Article 12;
- b 'generic medicinal product' shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information intended to provide proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

3 In cases where the veterinary medicinal product does not fall under the definition of a generic medicinal product set out in paragraph 2(b) or where bio-equivalence cannot be demonstrated through bioavailability studies or in the case of changes to the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration vis-à-vis the reference medicinal product, the results of the appropriate safety and residue tests and pre-clinical tests or clinical trials shall be provided.

4 Where a biological veterinary medicinal product which is similar to a reference biological veterinary medicinal product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

5 In the case of veterinary medicinal products intended for one or more food-producing species and containing a new active substance that has not been authorised in the Community by 30 April 2004 the ten-year period provided for in the second subparagraph of paragraph 1 shall be extended by one year for each extension of the marketing authorisation to another food-producing species, if it is authorised within the five years following the granting of the initial marketing authorisation.

This period shall not, however, exceed a total of 13 years, for a marketing authorisation for four or more food-producing species.

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The extension of the ten-year period to 11, 12, or 13 years for a veterinary medicinal product intended for food-producing species shall be granted only if the marketing authorisation holder also originally applied for determination of the maximum residue limits established for the species covered by the authorisation.

6 Conducting the necessary studies, tests and trials with a view to the application of paragraphs 1 to 5 and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products.]

Textual Amendments

F1 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.](#)

f²Article 13a

1 By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law on the protection of industrial and commercial property, the applicant shall not be required to provide the results of safety and residue tests or of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the veterinary medicinal product have been in well-established veterinary use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I. In that event, the applicant shall provide appropriate scientific literature.

2 The assessment report published by the Agency following the evaluation of an application for the establishment of maximum residue limits in accordance with Regulation (EEC) No 2377/90 may be used in an appropriate manner as literature, particularly for the safety tests.

3 If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another food-producing species, new residue studies in accordance with Regulation (EEC) No 2377/90, together with further clinical trials, it shall not be permissible for a third party to use such studies or such trials pursuant to Article 13, for a period of three years from the grant of the authorisation for which they were carried out.

Textual Amendments

F2 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 13b

In the case of veterinary medicinal products containing active substances used in the composition of authorised veterinary medicinal products but not hitherto used in combination for therapeutic purposes, the results of safety and residue tests, if necessary, and new pre-clinical tests or new clinical trials relating to that combination shall be provided in accordance with point (j) of the first subparagraph of Article 12(3), but it shall not be necessary to provide scientific references relating to each individual active substance.

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Textual Amendments

- F2** 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 13c

After the marketing authorisation has been granted, the marketing authorisation holder may allow use to be made of the pharmaceutical, safety and residues, pre-clinical and clinical documentation contained in the file for the veterinary medicinal product with a view to examining a subsequent application for a veterinary medicinal product having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.

Textual Amendments

- F2** 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 13d

By way of derogation from point (j) of the first subparagraph of Article 12(3), and in exceptional circumstances with respect to immunological veterinary medicinal products, the applicant shall not be required to provide the results of certain field trials on the target species if these trials cannot be carried out for duly substantiated reasons, in particular on account of other Community provisions.]

Textual Amendments

- F2** 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.](#)

[^{F1}Article 14

The summary of the product characteristics shall contain, in the order indicated below, the following information:

- 1) name of the veterinary medicinal product followed by the strength and the pharmaceutical form;
- 2) qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used;
- 3) pharmaceutical form;
- 4) clinical particulars:
 - 4.1. target species,
 - 4.2. indications for use, specifying the target species,
 - 4.3. contra-indications,

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- 4.4. special warnings for each target species,
- 4.5. special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals,
- 4.6. adverse reactions (frequency and seriousness),
- 4.7. use during pregnancy, lactation or lay,
- 4.8. interaction with other medicinal products and other forms of interaction,
- 4.9. amounts to be administered and administration route,
- 4.10. overdose (symptoms, emergency procedures, antidotes), if necessary,
- 4.11. withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero;
- 5) pharmacological properties:
 - 5.1. pharmacodynamic properties,
 - 5.2. pharmacokinetic particulars;
- 6) pharmaceutical particulars:
 - 6.1. list of excipients,
 - 6.2. major incompatibilities,
 - 6.3. shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time,
 - 6.4. special precautions for storage,
 - 6.5. nature and composition of immediate packaging,
 - 6.6. special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate;
- 7) marketing authorisation holder;
- 8) marketing authorisation number(s);
- 9) date of the first authorisation or date of renewal of the authorisation;
- 10) date of revision of the text.

For authorisation under Article 13, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.

Textual Amendments

F1 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.](#)

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Article 15

1 Applicants shall ensure that the detailed and critical summaries referred to in the second subparagraph of Article 12(3) are drafted and signed by persons with the requisite technical or professional qualifications, set out in a brief curriculum vitae, before being submitted to the competent authorities.

2 Persons with the technical or professional qualifications referred to in paragraph 1 shall justify any use made of the scientific literature referred to in Article 13a(1) in accordance with the conditions set out in Annex I.

3 A brief curriculum vitae of the persons referred to in paragraph 1 shall be appended to the detailed critical summaries.]

Textual Amendments

F1 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.](#)

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- (1) [^{F1}OJ L 298, 3.12.1993, p. 45. Decision as amended by Commission Decision 2000/68/EC (OJ L 23, 28.1.2000, p. 72).]
- (2) [^{F1}OJ L 23, 28.1.2000, p. 72.]

Textual Amendments

- F1** 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.