

**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**

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 and Article 152(4)(b) thereof,

Having regard to the proposal of the Commission <sup>(1)</sup>,

Having regard to the Opinion of the European Economic and Social Committee <sup>(2)</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the procedure referred to in Article 251 of the Treaty <sup>(3)</sup>,

Whereas:

- (1) Directive 2001/82/EC of the European Parliament and of the Council of 23 October 2001 on the Community code relating to veterinary medicinal products <sup>(4)</sup> codified and consolidated previous Community legislation on veterinary medicinal products in a single text in the interests of clarity and rationalisation.
- (2) The Community legislation so far adopted has made a major contribution to the achievement of the objective of free and safe movement of veterinary medicinal products and the elimination of obstacles to trade in such products. However, in the light of the experience gained, it has become clear that new measures are necessary to eliminate the remaining obstacles to free movement.
- (3) It is therefore necessary to align national laws, regulations and administrative provisions that contain

differences with regard to the basic principles in order to promote the operation of the internal market without adversely affecting public health.

- (4) The main purpose of any regulation on the manufacture and distribution of veterinary medicinal products should be to safeguard animal health and welfare as well as public health. The legislation on marketing authorisations for veterinary medicinal products, and the criteria governing the granting of authorisations, are such as to strengthen the protection of public health. That aim should, however, be achieved by means that do not hinder the development of the pharmaceutical industry or trade in veterinary medicinal products within the Community.
- (5) Article 71 of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products <sup>(5)</sup> provided that, within six years of its entry into force, the Commission was required to publish a general report on the experience acquired as a result of the operation of the marketing authorisation procedures laid down in that Regulation and in other Community legal provisions.
- (6) In the light of the Commission's report on the experience acquired, it has proved necessary to improve the operation of the marketing authorisation procedures for veterinary medicinal products in the Community.
- (7) Particularly as a result of scientific and technical progress in the field of animal health, the definitions and scope of Directive 2001/82/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of veterinary medicinal products. In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, the definition of 'medicinal product' should be modified so as to avoid any doubt as to the applicable legislation when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products. Also, in view of the characteristics of pharmaceutical legislation, provision should be made for such legislation to apply. With the same objective of clarifying situations, where a given product comes under the defi-

<sup>(1)</sup> OJ C 75 E, 26.3.2002, p. 234.

<sup>(2)</sup> OJ C 61, 14.3.2003, p. 1.

<sup>(3)</sup> Opinion of the European Parliament of 23 October 2002 (OJ C 300 E, 11.12.2003, p. 390), Council Common Position of 29 September 2003 (OJ C 297 E, 9.12.2003, p. 72), Position of the European Parliament of 17 December 2003 (not yet published in the Official Journal) and Council Decision of 11 March 2004.

<sup>(4)</sup> OJ L 311, 28.11.2001, p. 1.

<sup>(5)</sup> OJ L 214, 24.8.1993, p. 1. Regulation repealed by Regulation (EC) No 726/2004 (see p. 1 of this Official Journal).

- inition of a veterinary medicinal product, but could also fall within the definition of other regulated products, it is necessary, in cases of doubt and in order to ensure legal certainty, to state explicitly which provisions have to be complied with. Where a product comes clearly under the definition of other product categories, in particular food, feed, feed additives or biocides, this Directive should not apply. It is also appropriate to improve the consistency of the terminology of pharmaceutical legislation.
- (8) The veterinary medicinal products sector has a number of very specific features. Veterinary medicinal products for food-producing animals may be authorised only on conditions that guarantee that the foodstuffs produced will be harmless to consumers as regards any residues of such medicinal products.
- (9) The costs of research and development to meet increased requirements as regards the quality, safety and efficacy of veterinary medicinal products are leading to a gradual reduction in the range of products authorised for the species and indications representing smaller market sectors.
- (10) The provisions of Directive 2001/82/EC also need, therefore, to be adapted to the specific features of the sector, particularly to meet the health and welfare needs of food-producing animals on terms that guarantee a high level of consumer protection, and in a context that provides adequate economic interest for the veterinary medicinal products industry.
- (11) In certain circumstances, particularly where certain types of pets are concerned, the need to obtain a marketing authorisation for a veterinary medicinal product in accordance with Community provisions is clearly disproportionate. Moreover, the absence of authorisation to market an immunological product in the Community should not be an obstacle to international movements of certain live animals for the purpose of which binding health measures have to be taken. The provisions on the authorisation or use of such medicinal products to take account of measures to combat certain infectious animal diseases at Community level also need to be adapted.
- (12) Evaluation of the operation of market authorisation procedures has revealed the need to revise, in particular, the mutual-recognition procedure in order to improve the opportunities for cooperation between Member States. This cooperation process should be formalised by setting up a coordination group for this procedure and by defining its operation so as to settle disagreements within the framework of a revised decentralised procedure.
- (13) With regard to referrals, the experience acquired reveals the need for an appropriate procedure, particularly in the case of referrals relating to an entire therapeutic class or to all veterinary medicinal products containing the same active substance.
- (14) Marketing authorisation for veterinary medicinal products should be limited initially to five years. After this first renewal, the marketing authorisation should normally be valid for an unlimited period. Furthermore, any authorisation not used for three consecutive years, that is to say, one which has not led to the placing on the market of a veterinary medicinal product in the Member States concerned during that period, should be considered invalid, in order, in particular, to avoid the administrative burden of maintaining such authorisations. However, exemptions from this rule should be granted when these are justified on public or animal health grounds.
- (15) Biological medicinal products similar to a reference medicinal product do not usually meet all the conditions to be considered as a generic medicinal product mainly due to manufacturing process characteristics, raw materials used, molecular characteristics and therapeutic modes of action. When a biological product does not meet all the conditions to be considered as a generic medicinal product, the results of appropriate tests should be provided in order to fulfil the requirements related to safety (pre-clinical tests) or to efficacy (clinical tests) or to both.
- (16) The criteria of quality, safety and efficacy should enable the risk-benefit balance of all veterinary medicinal products to be assessed both when they are placed on the market and at any other time the competent authority deems this appropriate. In this connection, it is necessary to harmonise and adapt the criteria for refusal, suspension and revocation of marketing authorisations.
- (17) In the veterinary sector, if no medicinal product has been authorised for a given species or a given disorder, the possibility of using other existing products should be made a straightforward matter, but without prejudicing consumer health in the case of medicinal products intended for administration to food-producing animals. In particular, medicinal products should be used only under conditions that guarantee that the foodstuffs produced will be harmless to consumers as regards any residues of medicinal products.

- (18) There is also a need to stimulate the interest of the veterinary pharmaceuticals industry in certain market segments in order to encourage the development of new veterinary medicinal products. The period of administrative data-protection vis-a-vis generics should be harmonised.
- (19) There is also a need to clarify the obligations of, and division of responsibilities between, the applicant for a marketing authorisation, the holder of a marketing authorisation and the competent authorities in charge of monitoring the quality of foodstuffs, particularly through compliance with the provisions on the use of veterinary medicinal products. In addition, in order to facilitate the testing of new medicinal products while guaranteeing a high level of protection for consumers, sufficiently long withdrawal periods should be laid down for foodstuffs that animals involved in tests might produce.
- (20) Without prejudice to the provisions aimed at guaranteeing consumer protection, the specific characteristics of homeopathic veterinary medicinal products, and particularly their use in organic farming, should be taken into account by establishing a simplified procedure for registration on terms defined in advance.
- (21) In order to increase the information available to users and to improve consumer protection in the case of food-producing animals, the provisions on the labelling of veterinary medicinal products and the accompanying package leaflet should be strengthened. The requirement that a veterinary medicinal product may only be dispensed after a veterinary prescription has been made out should, as a general principle, be extended to all medicinal products for food-producing animals. However, it should be possible to grant exemptions, where appropriate. The administrative procedures for supplying medicinal products for pets, on the other hand, should be simplified.
- (22) The quality of veterinary medicinal products manufactured or available in the Community should be guaranteed by requiring that the active substances used in their composition comply with the principles of good manufacturing practice. It has proved necessary to reinforce the Community provisions on inspections and to compile a Community register of the results of those inspections. The provisions for the official release of batches of immunological medicinal products should be reviewed in order to take account of the improvement of the general system for monitoring the quality of medicinal products and to reflect technical and scientific progress, and also in order to make mutual recognition fully effective.
- (23) The environmental impact should be studied and consideration should be given on a case-by-case basis to specific provisions seeking to limit it.
- (24) Pharmacovigilance and, more generally, market surveillance and sanctions in the event of failure to comply with the provisions should be stepped up. In the field of pharmacovigilance, account should be taken of the facilities offered by new information technologies to improve exchanges between Member States.
- (25) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(1)</sup>.
- (26) Directive 2001/82/EC should be amended accordingly,
- HAVE ADOPTED THIS DIRECTIVE:
- Article 1*
- Directive 2001/82/EC shall be amended as follows:
- 1) Article 1 shall be amended as follows:
- (a) point 1 shall be deleted;
- (b) point 2 shall be replaced by the following:
- ‘2. *Veterinary medicinal product:*
- (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or
- (b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.’;
- (c) point 3 shall be deleted;

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

(d) points 8, 9 and 10 shall be replaced by the following:

'8. *Homeopathic veterinary medicinal product:*

Any veterinary medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in Member States. A homeopathic veterinary medicinal product may contain a number of principles.

9. *Withdrawal period:*

The period necessary between the last administration of the veterinary medicinal product to animals, under normal conditions of use and in accordance with the provisions of this Directive, and the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits for active substances laid down pursuant to Regulation (EEC) No 2377/90.

10. *Adverse reaction:*

A reaction to a veterinary medicinal product which is harmful and unintended and which occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or to restore, correct or modify a physiological function.;

(e) the following point shall be inserted:

'17a. *Representative of the marketing authorisation holder:*

The person, commonly known as local representative, designated by the marketing authorisation holder to represent him in the Member State concerned.;

(f) point 18 shall be replaced by the following:

'18. *Agency:*

The European Medicines Agency established by Regulation (EC) No 726/2004 (\*);

(\* OJ L 136, 30.4.2004, p. 1.;

(g) point 19 shall be replaced by the following:

'19. *Risks relating to use of the product:*

— any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health;

— any risk of undesirable effects on the environment.;

(h) the following points shall be added:

'20. *Risk/benefit balance:*

An evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to the risks as defined above.

21. *Veterinary prescription:*

Any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law.

22. *Name of veterinary medicinal product:*

The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder.

23. *Common name:*

The international non-proprietary name recommended by the World Health Organisation, or, if one does not exist, the usual common name.

24. *Strength:*

The content of active substances, expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.

25. *Immediate packaging:*

The container or any other form of packaging that is in direct contact with the medicinal product.

26. *Outer packaging:*

The packaging into which is placed the immediate packaging.

27. *Labelling:*

Information on the immediate or outer packaging.

28. *Package leaflet:*

The leaflet containing information for the user that accompanies the medicinal product.;

2) Articles 2 and 3 shall be replaced by the following:

*‘Article 2*

1. This Directive shall apply to veterinary medicinal products, including pre-mixes for medicated feedingstuffs, intended to be placed on the market in Member States and prepared industrially or by a method involving an industrial process.

2. In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a “veterinary medicinal product” and within the definition of a product covered by other Community legislation, the provisions of this Directive shall apply.

3. Notwithstanding paragraph 1, this Directive shall also apply to active substances used as starting materials to the extent set out in Articles 50, 50a, 51 and 80 and additionally to certain substances that may be used as veterinary medicinal products that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties to the extent set out in Article 68.

*Article 3*

1. This Directive shall not apply to:

- (a) medicated feedingstuffs as defined in Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (\*);
- (b) inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality;
- (c) veterinary medicinal products based on radio-active isotopes;
- (d) any additives covered by Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (\*\*) where they are incorporated in animal feedingstuffs and supplementary animal feedingstuffs in accordance with that Directive; and
- (e) without prejudice to Article 95, medicinal products for veterinary use intended for research and development trials.

However, medicated feedingstuffs referred to in subparagraph (a) may be prepared only from pre-mixes that have been authorised under this Directive.

2. Except for the provisions on the possession, prescription, dispensing and administration of veterinary medicinal products, this Directive shall not apply to:

- (a) any medicinal product prepared in a pharmacy in accordance with a veterinary prescription for an individual animal or a small group of animals, commonly known as the magistral formula; and
- (b) any medicinal product prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the end-user, commonly known as the officinal formula.

(\*) OJ L 92, 7.4.1990, p. 42.

(\*\*) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).;

3) Article 4(2) shall be replaced by the following:

‘2. In the case of veterinary medicinal products intended solely for aquarium fish, cage birds, homing pigeons, terrarium animals, small rodents, and ferrets and rabbits kept exclusively as pets, Member States may permit exemptions, in their territory, from the provisions in Articles 5 to 8, provided that such products do not contain substances the use of which requires veterinary control and that all possible measures are taken to prevent unauthorised use of the products for other animals.’;

4) Articles 5 and 6 shall be replaced by the following:

*‘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.

## 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 been declared, in accordance with Commission Decision 93/623/EEC of 20 October 1993 establishing the identification document (passport) accompanying registered equidae (\*) 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 (\*\*), 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.

(\*) 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).

(\*\*) OJ L 23, 28.1.2000, p. 72.;

5) Article 8 shall be replaced by the following:

### '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.;

6) Articles 10 to 13 shall be replaced by the following:

### '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.

#### 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:
  - (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).

#### 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) 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.

- (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.



### 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 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 phar-

maceutical 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.

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.;

7) the following Articles shall be inserted:

*'Article 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.

*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.

*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.

*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.;

8) Articles 14 to 16 shall be replaced by the following:

*'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,
  - 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.

#### 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.

#### Article 16

1. Member States shall ensure that homeopathic veterinary medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 17, 18 and 19, except where such veterinary medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. In the case of homeopathic medicinal products registered in accordance with Article 17, Article 32 and Article 33(1) to (3) shall apply.
  2. Member States shall establish a simplified registration procedure for the homeopathic veterinary medicinal products referred to in Article 17.
  3. By way of derogation from Article 10, homeopathic veterinary medicinal products may be administered to non-food producing animals under the responsibility of a veterinarian.
  4. By way of derogation from Article 11(1) and (2), Member States shall permit the administration of homeopathic veterinary medicinal products intended for food-producing species the active constituents of which appear in Annex II to Regulation (EEC) No 2377/90 under the responsibility of a veterinarian. Member States shall take appropriate measures to control the use of veterinary homeopathic medicinal products registered or authorised in another Member State in accordance with this Directive for use in the same species.;
- 9) Article 17 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. Without prejudice to the provisions of Regulation (EEC) No 2377/90 on the establishment of maximum residue limits of pharmacologically active substances intended for food-producing animals, only homeopathic veterinary medicinal products which satisfy all of the following conditions may be subject to a special, simplified registration procedure:

- (a) they are administered by a route described in the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in Member States;
- (b) no specific therapeutic indication appears on the labelling of the veterinary medicinal product or in any information relating thereto;
- (c) there is a sufficient degree of dilution to guarantee the safety of the medicinal product. In particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture.

If it appears justified in the light of new scientific evidence, points (b) and (c) of the first subparagraph may be adapted in accordance with the procedure referred to in Article 89(2).

At the time of registration, Member States shall determine the classification for the dispensing of the medicinal product.;

(b) paragraph 3 shall be deleted;

10) Article 18 shall be amended as follows:

(a) the third indent shall be replaced by the following:

‘— manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation.;

(b) the sixth indent shall be replaced by the following:

‘— one or more mock-ups of the outer packaging and immediate packaging of the medicinal products to be registered.;

(c) the following eighth indent shall be added:

‘— proposed withdrawal period together with all requisite justification.;

11) Article 19 shall be replaced by the following:

‘Article 19

1. Homeopathic veterinary medicinal products other than those referred to in Article 17(1) shall be authorised in accordance with Articles 12, 13a, 13b, 13c, 13d and 14.

2. A Member State may introduce or retain on its territory specific rules for the safety tests and pre-clinical and clinical trials of homeopathic veterinary medicinal products intended for pet species and non-food-producing exotic species other than those referred to in Article 17(1), in accordance with the principles and characteristics of homeopathy as practised in that Member State. In this case, the Member State concerned shall notify the Commission of the specific rules in force.;

12) Articles 21, 22 and 23 shall be replaced by the following:

‘Article 21

1. Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for a veterinary medicinal product is completed within a maximum of 210 days after the submission of a valid application.

Applications for marketing authorisations for the same veterinary medicinal product in two or more Member States, shall be submitted in accordance with Articles 31 to 43.

2. Where a Member State notes that another marketing authorisation application for the same medicinal product is being examined in another Member State, the Member State concerned shall decline to assess the application and shall advise the applicant that Articles 31 to 43 apply.

Article 22

Where a Member State is informed, in accordance with point (n) of Article 12(3), that another Member State has authorised a veterinary medicinal product which is the subject of an application for authorisation in the Member State concerned, that Member State shall reject the application unless it was submitted in compliance with Articles 31 to 43.

Article 23

In order to examine the application submitted pursuant to Articles 12 to 13d, Member States' competent authorities:

- 1) shall check that the documentation submitted in support of the application complies with Articles 12 to 13d and ascertain whether the conditions for the issue of the marketing authorisation have been fulfilled;
- 2) may submit the medicinal product, its starting materials and if necessary intermediate products or other constituent materials for testing by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose, in order to ensure that the testing methods employed by the manufacturer and described in the application documents, in accordance with point (i) of the first subparagraph of Article 12(3), are satisfactory;
- 3) may similarly check, in particular through consultation of a national or Community reference laboratory, that the analytical method used for detecting residues presented by the applicant for the purposes of Article 12(3)(j), second indent is satisfactory;
- 4) may, where appropriate, require the applicant to provide further information as regards the items listed in Articles 12, 13a, 13b, 13c and 13d. Where the competent authorities take this course of action, the time-limits specified in Article 21 shall be suspended until the further data required have been provided. Similarly, these time-limits shall be suspended for any period which the applicant may be given to provide oral or written explanations.;

13) Article 25 shall be replaced by the following:

‘Article 25

1. When granting a marketing authorisation, the competent authority shall inform the holder of the summary of product characteristics that it has approved.

2. The competent authority shall take all necessary measures to ensure that information concerning the veterinary medicinal product, and in particular the labelling and package leaflet, is in conformity with the summary of product characteristics approved when the marketing authorisation was granted or subsequently.

3. The competent authority shall make the marketing authorisation publicly available without delay, together with the summary of product characteristics for each veterinary medicinal product that it has authorised.

4. The competent authority shall draw up an assessment report and comments on the file as regards the results of the pharmaceutical, safety and residue tests and the pre-clinical and clinical trials of the veterinary medicinal product concerned. The assessment report shall be updated whenever new information becomes available which is of importance for the evaluation of the quality, safety or efficacy of the veterinary medicinal product concerned.

The competent authority shall make the assessment report and its reasons for the opinion publicly available without delay, after deleting any information of a commercially confidential nature.;

14) Article 26 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. The marketing authorisation may require the holder to indicate on the immediate packaging and/or the outer wrapping and the package leaflet, where the latter is required, other particulars essential for safety or health protection, including any special precautions relating to use and any other warnings resulting from the clinical and pharmacological trials prescribed in Article 12(3)(j) and in Articles 13 to 13d or from experience gained during the use of the veterinary medicinal product once it has been marketed.;

(b) paragraph 2 shall be deleted;

(c) paragraph 3 shall be replaced by the following:

'3. In exceptional circumstances, and following consultation with the applicant, the authorisation may be granted subject to a requirement for the applicant to introduce specific procedures, in particular concerning the safety of the veterinary medicinal product, notification to the competent authorities of any incident relating to its use, and action to be taken. Such authorisations may be granted only for objective, verifiable reasons. Continuation of the authorisation shall be linked to the annual reassessment of these conditions.;

15) Article 27 shall be amended as follows:

(a) paragraphs 2 and 3 shall be replaced by the following:

'2. The competent authority may require the applicant or the marketing authorisation holder to provide sufficient quantities of the substances to enable controls to be made on the identification of the presence of residues of the veterinary medicinal products in question.

At the competent authority's request, the marketing authorisation holder shall provide his technical expertise to facilitate the implementation of the analytical method for detecting residues of the veterinary medicinal products in the national reference laboratory designated under Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (\*).

3. The authorisation holder shall immediately supply the competent authority with any new information that might entail the amendment of the particulars or documents referred to in Articles 12(3), 13, 13a, 13b and 14 or Annex I.

In particular, he shall immediately inform the competent authority of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is placed on the market and of any other new information which might influence the assessment of the benefits and risks of the veterinary medicinal product concerned.

In order to permit continuous assessment of the risk-benefit balance, the competent authority may at any time ask the marketing authorisation holder to forward data demonstrating that the risk-benefit balance remains favourable.

(\*) OJ L 125, 23.5.1996, p. 10. Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).;

(b) paragraph 4 shall be deleted;

(c) paragraph 5 shall be replaced by the following:

'5. The marketing authorisation holder shall immediately inform the competent authorities, with a view to authorisation, of any alteration which he proposes to make to the particulars or documents referred to in Articles 12 to 13d.;

16) the following Article shall be inserted:

*'Article 27a*

After a marketing authorisation has been granted, the holder of the authorisation shall inform the competent authority of the authorising Member State of the date of the actual placing on the market of the veterinary medicinal product in that Member State, taking into account the various presentations authorised.

The holder shall also notify the competent authority if the product ceases to be placed on the market of the Member State, either temporarily or permanently. Such notification shall, otherwise than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product.

Upon request by the competent authority, particularly in the context of pharmacovigilance, the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the veterinary medicinal product, and any data in his possession relating to the volume of prescriptions.'

17) Article 28 shall be replaced by the following:

*'Article 28*

1. Without prejudice to paragraphs 4 and 5, a marketing authorisation shall be valid for five years.

2. The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance.

To this end, the marketing authorisation holder shall submit a consolidated list of all documents submitted in respect of quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, at least six months before the marketing authorisation ceases to be valid in accordance with paragraph 1. The competent authority may require the applicant to submit the listed documents at any time.

3. Once renewed, the marketing authorisation shall be valid for an unlimited period, unless the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal in accordance with paragraph 2.

4. Any authorisation that is not followed within three years of its granting by the actual placing on the market of the authorised veterinary medicinal product in the authorising Member State shall cease to be valid.

5. When an authorised veterinary medicinal product previously placed on the market in the authorising Member State is no longer actually present on the market in that Member State for a period of three consecutive years, the authorisation granted for that veterinary medicinal product shall cease to be valid.

6. The competent authority may, in exceptional circumstances, and on human or animal health grounds, grant exemptions from paragraphs 4 and 5. Such exemptions shall be duly justified.'

18) Article 30 shall be replaced by the following:

*'Article 30*

The marketing authorisation shall be refused if the file submitted to the competent authorities does not comply with Articles 12 to 13d and Article 15.

The authorisation shall also be refused if, after examination of the documents and particulars listed in Articles 12 and 13(1), it is clear that:

- (a) the risk-benefit balance of the veterinary medicinal product is, under the authorised conditions of use, unfavourable; when the application concerns a veterinary medicinal product for zootechnical use, particular regard shall be had to the benefits for animal health and welfare and to consumer safety; or
- (b) the product has no therapeutic effect or the applicant has not provided sufficient proof of such effect as regards the species of animal which is to be treated; or
- (c) its qualitative or quantitative composition is not as stated; or
- (d) the withdrawal period recommended by the applicant is not long enough to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer, or is insufficiently substantiated; or
- (e) the labelling or the package leaflet proposed by the applicant does not comply with this Directive; or
- (f) the veterinary medicinal product is offered for sale for a use prohibited under other Community provisions.

However, when a Community legislative framework is in the course of being adopted, the competent authority may refuse authorisation for a veterinary medicinal product where such action is necessary for the protection of public health, consumer or animal health.

The applicant or marketing authorisation holder shall be responsible for the accuracy of documents and data submitted.;

19) the title of Chapter 4 shall be replaced by the following:

*'CHAPTER 4*

**Mutual recognition procedure and decentralised procedure';**

20) Articles 31 to 37 shall be replaced by the following:

*'Article 31*

1. A coordination group shall be set up for the examination of any question relating to marketing authorisation of a veterinary medicinal product in two or more Member States in accordance with the procedures laid down in this Chapter. The Agency shall provide the secretariat of this coordination group.

2. The coordination group shall be composed of one representative per Member State appointed for a renewable period of three years. Members of the group may arrange to be accompanied by experts.

3. The coordination group shall draw up its own rules of procedure, which shall enter into force after a favourable opinion has been given by the Commission. These rules of procedure shall be made public.

*Article 32*

1. With a view to the granting of a marketing authorisation for a veterinary medicinal product in more than one Member State, the applicant shall submit an application based on an identical dossier in those Member States. The dossier shall contain all the administrative information and scientific and technical documentation described in Articles 12 to 14. The documents submitted shall include a list of Member States concerned by the application.

The applicant shall request one Member State to act as reference Member State and to prepare an assessment report in respect of the veterinary medicinal product in accordance with paragraphs 2 or 3.

Where appropriate, the assessment report shall contain an evaluation for the purposes of Article 13(5) or Article 13a(3).

2. If the veterinary medicinal product has already received a marketing authorisation at the time of application, the concerned Member States shall recognise the marketing authorisation granted by the reference

Member State. To this end, the marketing authorisation holder shall request the reference Member State either to prepare an assessment report in respect of the veterinary medicinal product or, if necessary, to update any existing assessment report. The reference Member State shall prepare or update the assessment report within 90 days of receipt of a valid application. The assessment report together with the approved summary of product characteristics, labelling and package leaflet shall be forwarded to the concerned Member States and the applicant.

3. If the veterinary medicinal product has not received authorisation by the time of application, the applicant shall request the reference Member State to prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet. The reference Member State shall prepare these drafts within 120 days of the receipt of a valid application and shall send them to the concerned Member States and the applicant.

4. Within 90 days after receipt of the documents referred to in paragraphs 2 and 3, the Member States concerned shall approve the assessment report, the summary of product characteristics, the labelling and the package leaflet and inform the reference Member State accordingly. The reference Member State shall record the agreement of all parties, close the procedure and inform the applicant accordingly.

5. Each Member State in which an application following paragraph 1 has been submitted shall adopt a decision in conformity with the approved assessment report, summary of product characteristics, labelling and package leaflet within 30 days after acknowledgement of the agreement.

*Article 33*

1. If a Member State cannot, within the period allowed in Article 32(4), agree with the assessment report, summary of product characteristics, labelling and package leaflet on grounds of a potential serious risk to human or animal health or to the environment, a detailed statement of the reasons shall be provided to the reference Member State, the other Member States concerned and the applicant. The points of disagreement shall be referred without delay to the coordination group.

If a Member State to which an application has been submitted invokes the reasons referred to in Article 71(1), it shall no longer be regarded as a Member State concerned by this Chapter.

2. The Commission shall adopt guidelines defining a potential serious risk for human or animal health or for the environment.

3. Within the coordination group, all Member States referred to in paragraph 1 shall use their best endeavours to reach agreement on the action to be taken. They shall provide the applicant with the opportunity to make his point of view known orally or in writing. If, within 60 days of the communication of the reasons for disagreement to the coordination group the Member States reach an agreement, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. Article 32(5) shall apply.

4. If within the period of 60 days the Member States fail to reach an agreement, the Agency shall be immediately informed with a view to application of the procedure laid down in Articles 36, 37 and 38. The Agency shall be provided with a detailed description of the matters on which agreement could not be reached and the reasons for the disagreement. The applicant shall be provided with a copy of this information.

5. As soon as the applicant has been informed that the matter has been referred to the Agency, he shall forthwith forward to the Agency a copy of the information and documents referred to in the first subparagraph of Article 32(1).

6. In the case referred to in paragraph 4, the Member States that have approved the assessment report, summary of product characteristics, labelling and package leaflet of the reference Member State may, on request by the applicant, grant a marketing authorisation for the veterinary medicinal product without waiting for the outcome of the procedure laid down in Article 36. In that case, the authorisation granted shall be without prejudice to the outcome of that procedure.

#### Article 34

1. If two or more applications submitted in accordance with Articles 12 to 14 have been made for marketing authorisation for a particular veterinary medicinal product and Member States have adopted divergent decisions concerning the authorisation of that veterinary medicinal product, or suspension or revocation of authorisation, a Member State, or the Commission, or the marketing-authorisation holder may refer the matter to the Committee for Medicinal Products for Veterinary Use, hereinafter referred to as "the Committee", for the application of the procedure laid down in Articles 36, 37 and 38.

2. With a view to promoting the harmonisation of veterinary medicinal products authorised in the Community, and to strengthening the efficiency of the provisions of Articles 10 and 11, Member States shall send to the coordination group, no later than 30 April 2005, a list of veterinary medicinal products for which a harmonised summary of product characteristics should be prepared.

The coordination group shall agree on a list of medicinal products, on the basis of proposals sent by Member States, and shall forward the list to the Commission.

The medicinal products on the list shall be subject to the provisions in paragraph 1 in accordance with a timetable established in cooperation with the Agency.

The Commission, acting in collaboration with the Agency, and taking into consideration the views of the interested parties, shall agree the final list and timetable.

#### Article 35

1. Member States or the Commission or the applicant or marketing authorisation holder shall, in specific cases where the interests of the Community are involved, refer the matter to the Committee for the application of the procedure laid down in Articles 36, 37 and 38 before a decision is reached on a request for a marketing authorisation or on the suspension or withdrawal of an authorisation, or on any other variations to the terms of a marketing authorisation which appear necessary, so as to take account in particular of the information collected in accordance with Title VII.

The Member State concerned or the Commission shall clearly identify the question which is referred to the Committee for consideration and shall inform the applicant or the marketing authorisation holder.

The Member State and the applicant or the marketing authorisation holder shall forward to the Committee all available information relating to the matter in question.

2. Where the referral to the Committee concerns a range of medicinal products or a therapeutic class, the Agency may limit the procedure to specific parts of the authorisation.

In that case, Article 39 shall apply to those medicinal products only if they are covered by the marketing authorisation procedure referred to in this Chapter.

#### Article 36

1. When reference is made to the procedure laid down in this Article, the Committee shall consider the matter concerned and shall issue a reasoned opinion within 60 days of the date on which the matter was referred to it.

However, in cases submitted to the Committee in accordance with Articles 34 and 35, this period may be extended by the Committee for a further period of up to 90 days, taking into account the views of the marketing authorisation holders concerned.



In an emergency, and on a proposal from its Chairman, the Committee may agree to a shorter deadline.

2. In order to consider the matter, the Committee shall appoint one of its members to act as rapporteur. The Committee may also appoint independent experts to advise it on specific questions. When appointing such experts, the Committee shall define their tasks and specify the time limit for the completion of these tasks.

3. Before issuing its opinion, the Committee shall provide the applicant or the marketing authorisation holder with an opportunity to present written or oral explanations within a time limit that it will specify.

The opinion of the Committee shall include the draft summary of product characteristics and the drafts of the labelling and package leaflet.

If it considers appropriate, the Committee may invite any other person to provide information relating to the matter before it.

The Committee may suspend the time limit referred to in paragraph 1 to allow the applicant or the marketing authorisation holder to prepare the explanations.

4. The Agency shall forthwith inform the applicant or the marketing authorisation holder when the opinion of the Committee is that:

- the application does not satisfy the criteria for authorisation, or
- the summary of product characteristics proposed by the applicant or the marketing authorisation holder in accordance with Article 14 should be amended, or
- the authorisation should be granted subject to conditions, with regard to conditions considered essential for the safe and effective use of the veterinary medicinal product including pharmacovigilance, or
- a marketing authorisation should be suspended, varied or revoked.

Within 15 days after receipt of the opinion, the applicant or the marketing authorisation holder may notify the Agency in writing of his intention to request a re-examination of the opinion. In that case, he shall forward to the Agency the detailed grounds for the request within 60 days after receipt of the opinion.

Within 60 days following receipt of the grounds for the request, the Committee shall re-examine its opinion in accordance with the fourth subparagraph of Article 62(1) of Regulation (EC) No 726/2004. The reasons for the conclusion reached shall be annexed to the assessment report referred to in paragraph 5 of this Article.

5. Within 15 days after its adoption, the Agency shall forward the final opinion of the Committee to Member States, the Commission and the applicant or the marketing authorisation holder, together with a report describing the assessment of the veterinary medicinal product and the reasons for its conclusions.

In the event of an opinion in favour of granting or maintaining a marketing authorisation, the following documents shall be annexed to the opinion:

- (a) a draft summary of the product characteristics, as referred to in Article 14; where necessary this will reflect the differences in the veterinary conditions in Member States;
- (b) any conditions affecting the authorisation within the meaning of paragraph 4;
- (c) details of any recommended conditions or restrictions with regard to the safe and effective use of the veterinary medicinal product; and
- (d) drafts of the labelling and package leaflet.

#### Article 37

Within 15 days after receipt of the opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account Community law.

In the event of a draft decision that envisages the granting of a marketing authorisation, the documents referred to in the second subparagraph of Article 36(5) shall be annexed.

If, exceptionally, the draft decision is not in accordance with the opinion of the Agency, the Commission shall also annex a detailed explanation of the reasons for the differences.

The draft decision shall be forwarded to Member States and the applicant or marketing authorisation holder.;

21) Article 38 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. The Commission shall take a final decision in accordance with, and within 15 days after the end of, the procedure referred to in Article 89(3).';

(b) In paragraph 2, the second and third indents shall be replaced by the following:

— Member States shall have 22 days to forward their written observations on the draft decision to the Commission. However, if a decision has to be taken urgently, a shorter time-limit may be set by the Chairman according to the degree of urgency involved. This time-limit shall not, otherwise than in exceptional circumstances, be shorter than 5 days,

— Member States shall have the option of submitting a written request that the draft decision be discussed in a plenary meeting of the Standing Committee.;

(c) paragraph 3 shall be replaced by the following:

'3. A decision as referred to in paragraph 1 shall be addressed to all Member States and communicated to the marketing authorisation holder or the applicant for information. The concerned Member States and the reference Member State shall either grant or withdraw marketing authorisation, or vary the terms of a marketing authorisation as necessary to comply with the decision within 30 days of its notification and shall refer to it. They shall inform the Commission and the Agency accordingly.;

22) in Article 39, the third subparagraph of paragraph 1 shall be deleted;

23) in Article 42, paragraph 2 shall be replaced by the following:

'2. At least every ten years the Commission shall publish a report on experience gained on the basis of the procedures provided for in this chapter and shall propose any amendments necessary to improve the procedures. The Commission shall submit this report to the European Parliament and the Council.;

24) Article 43 shall be replaced by the following:

'Article 43

Articles 33(4), (5) and (6) and 34 to 38 shall not apply to the homeopathic veterinary medicinal products referred to in Article 17.

Articles 32 to 38 shall not apply to the homeopathic veterinary medicinal products referred to in Article 19(2).;

25) in Article 44, the following paragraph shall be added:

'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).;

26) in Article 50, point (f) shall be replaced by the following:

'(f) 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.;

27) the following Article shall be inserted:

'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.

2. Any amendments which may be necessary to adapt the provisions of this Article to scientific and technical progress shall be adopted in accordance with the procedure referred to in Article 89(2).;

28) in Article 51, the following paragraphs shall be added:

'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).;

29) in Article 53, paragraph 1 shall be replaced by the following:

'1. 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.;

30) in Article 54, paragraph 1 shall be replaced by the following:

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

31) in Article 55, paragraph 1(b) shall be replaced by the following:

'(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.';

32) Article 58 shall be amended as follows:

(a) paragraph 1 shall be amended as follows:

(i) The introductory wording shall be replaced by the following:

'Except in the case of the medicinal products referred to in Article 17(1), the competent authority shall approve the immediate packaging and outer packaging of veterinary medicinal products. Packaging shall bear the following information, which shall conform with the particulars and documents provided pursuant to Articles 12 to 13d and the summary of product characteristics, and shall appear in legible characters:';

(ii) Points (a) and (b) shall be replaced by the following:

'(a) the name of the medicinal product, followed by its strength and pharmaceutical form. The common name shall appear if the medicinal product contains only one active substance and its name is an invented name;

(b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using the common names:';

(iii) Point (e) shall be replaced by the following:

'(e) name or corporate name and permanent address or registered place of business of the marketing authorisation holder and, where appropriate, of the representative designated by the marketing authorisation holder:';

(iv) Point (f) shall be replaced by the following:

'(f) the species of animal for which the veterinary medicinal product is intended; the method and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated:';

(v) Point (g) shall be replaced by the following:

'(g) the withdrawal period for veterinary medicinal products to be administered to food-producing species, for all the species concerned and for the various foodstuffs concerned (meat and offal, eggs, milk, honey), including those for which the withdrawal period is zero:';

(vi) Point (j) shall be replaced by the following:

'(j) specific precautions relating to the disposal of unused medicinal products or waste derived from veterinary medicinal products, where appropriate, as well as a reference to any appropriate collection system in place:';

(vii) Point (l) shall be replaced by the following:

'(l) the words "For animal treatment only" or, in the case of the medicinal products referred to in Article 67, the words "For animal treatment only — to be supplied only on veterinary prescription".';

(b) the following paragraph shall be added:

'5. In the case of medicinal products that have been granted a marketing authorisation under Regulation (EC) No 726/2004, Member States may permit or require that the outer packaging bear additional information concerning distribution, possession, sale or any necessary precautions, provided that such information is not in infringement of Community law or the terms of the marketing authorisation, and is not promotional.

This additional information shall appear in a box with a blue border to separate it clearly from the information referred to in paragraph 1.';

33) Article 59 shall be amended as follows:

(a) the introductory wording of paragraph 1 shall be replaced by the following:

'1. As regards ampoules, the particulars listed in the first paragraph of Article 58(1) shall be given on the outer package. On the immediate packaging, however, only the following particulars shall be necessary:';

(b) paragraphs 2 and 3 shall be replaced by the following:

'2. As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the particulars mentioned in paragraph 1, the requirements of Article 58(1), (2) and (3) shall apply only to the outer package.

3. The particulars mentioned in the third and sixth indents of paragraph 1 shall appear on the outer package and on the immediate packaging of the medicinal products in the language or languages of the country in which they are placed on the market.';

34) Article 60 shall be replaced by the following:

*'Article 60*

Where there is no outer package, all the particulars which should feature on such a package pursuant to Articles 58 and 59 shall be shown on the immediate packaging.;

form. The common name shall appear if the product contains only one active substance and its name is an invented name. Where the medicinal product is authorised according to the procedure provided for in Articles 31 to 43 under different names in the Member States concerned, a list of the names authorised in each Member State.;

35) Article 61 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the immediate packaging and the outer packaging. Member States shall take all appropriate measures to ensure that the package leaflet relates solely to the veterinary medicinal product with which it is included. The package leaflet shall be written in terms that are comprehensible to the general public and in the official language or languages of the Member State in which the medicinal product is marketed.

The first subparagraph shall not prevent the package leaflet from being written in several languages, provided that the information given is identical in all the languages.

Competent authorities may exempt labels and package leaflets for specific veterinary medicinal products from the obligation for certain particulars to appear and for the leaflet to be in the official language or languages of the Member State in which the product is placed on the market, when the product is intended to be administered only by a veterinarian.;

(b) paragraph 2 shall be amended as follows:

(i) The introductory wording shall be replaced by the following:

'2. The competent authorities shall approve package leaflets. Leaflets shall contain at least the following information, in the order indicated, which shall conform to the particulars and documents provided pursuant to Articles 12 to 13d and the approved summary of product characteristics.;

(ii) Points (a) and (b) shall be replaced by the following:

'(a) name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where appropriate, of the representative of the marketing authorisation holder;

(b) name of the veterinary medicinal product followed by its strength and pharmaceutical

(c) paragraph 3 shall be deleted;

36) Article 62 shall be replaced by the following:

*'Article 62*

Where the provisions of this Title are not observed and a formal notice addressed to the person concerned has been ineffectual, Member States' competent authorities may suspend or revoke the marketing authorisation.;

37) Article 64(2) shall be amended as follows:

(a) the introductory wording shall be replaced by the following:

'2. In addition to the clear mention of the words "homeopathic veterinary medicinal product without approved therapeutic indications", the labelling and, where appropriate, package leaflet for the homeopathic veterinary medicinal products referred to in Article 17(1) shall bear the following information and no other information.;

(b) the first indent shall be replaced by the following:

'— the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used in accordance with point (8) of Article 1. If the homeopathic veterinary medicinal product is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks.;

38) the title of Title VI shall be replaced by the following:

**TITLE VI**

**POSSESSION, DISTRIBUTION AND DISPENSING OF VETERINARY MEDICINAL PRODUCTS;**

39) Article 65 shall be amended as follows:

(a) the following paragraph shall be inserted:

'3a. The holder of a distribution authorisation shall have an emergency plan guaranteeing the effective implementation of any recall operation ordered by the competent authorities or undertaken in cooperation with the manufacturer of the medicinal product in question or the holder of the marketing authorisation.;

(b) the following paragraph shall be inserted:

'5. Any distributor, not being the marketing authorisation holder, who imports a product from another Member State shall notify the marketing authorisation holder and the competent authority in the Member State to which the product will be imported of his intention to import it. In the case of products which have not been granted an authorisation pursuant to Regulation (EC) No 726/2004, the notification to the competent authority shall be without prejudice to additional procedures provided for in the legislation of that Member State.';

40) Article 66 shall be amended as follows:

(a) paragraph 2 shall be amended as follows:

(i) The introductory wording shall be replaced by the following:

'Any person permitted under paragraph 1 to supply veterinary medicinal products shall be required to keep detailed records for veterinary medicinal products that may be supplied only on prescription, the following information being recorded in respect of each incoming or outgoing transaction:';

(ii) The third subparagraph shall be replaced by the following:

'These records shall be available for inspection by the competent authorities for a period of five years.';

(b) paragraph 3 shall be replaced by the following:

'3. Member States may permit the supply on their territory of veterinary medicinal products for food-producing animals for which a veterinary prescription is required by or under the supervision of a person registered for this purpose who provides guarantees with respect to qualifications, record-keeping and reporting in accordance with national law. Member States shall notify the Commission of relevant provisions of national law. This provision shall not apply to the supply of veterinary medicinal products for the oral or parenteral treatment of bacterial infections.';

(c) paragraph 4 shall be deleted;

41) Article 67 shall be amended as follows:

(a) the first paragraph shall be amended as follows:

(i) The introductory wording shall be replaced by the following:

'Without prejudice to stricter Community or national rules relating to dispensing veterinary medicinal products and serving to protect human and animal health, a veterinary prescription shall be required for dispensing to the public the following veterinary medicinal products:';

(ii) The following point shall be inserted:

'(aa) veterinary medicinal products for food-producing animals.

However, Member States may grant exemptions from this requirement according to criteria established in accordance with the procedure referred to in Article 89(2).

Member States may continue to apply national provisions until either:

(i) the date of application of the decision adopted in accordance with the first subparagraph; or

(ii) 1 January 2007, if no such decision has been adopted by 31 December 2006;';

(iii) The third indent of point (b) shall be deleted;

(iv) Point (d) shall be replaced by the following:

'(d) official formula, within the meaning of Article 3(2)(b), intended for food-producing animals.';

(b) the second paragraph shall be replaced by the following:

'Member States shall take all necessary measures to ensure that, in the case of medicinal products supplied only on prescription, the quantity prescribed and supplied shall be restricted to the minimum amount required for the treatment or therapy concerned.

In addition, a prescription shall be required for new veterinary medicinal products containing an active substance that has been authorised for use in a veterinary medicinal product for fewer than five years.';

42) the first paragraph of Article 69 shall be replaced by the following:

'Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products to such animals for five years after their administration, including when the animal is slaughtered during the five-year period.';

- 43) the introductory wording of Article 70 shall be replaced by the following:

'By way of derogation from Article 9 and without prejudice to Article 67, Member States shall ensure that veterinarians providing services in another Member State can take with them and administer to animals small quantities of veterinary medicinal products not exceeding daily requirements other than immunological veterinary medicinal products which are not authorised for use in the Member State in which the services are provided (hereinafter: "host Member State"), provided that the following conditions are satisfied:;

- 44) the following subparagraph shall be added to Article 71(1):

'The Member State may also invoke the provisions of the first subparagraph in order to withhold marketing authorisation in accordance with a decentralised procedure as provided for in Articles 31 to 43.;

- 45) in Article 72, paragraph 2 shall be replaced by the following:

'2. Member States may impose specific requirements on veterinary practitioners and other health-care professionals in respect of the reporting of suspected serious or unexpected adverse reactions and human adverse reactions.;

- 46) Article 73 shall be amended as follows:

- (a) the first paragraph shall be replaced by the following:

'In order to ensure the adoption of appropriate and harmonised regulatory decisions concerning the veterinary medicinal products authorised within the Community, having regard to information obtained about suspected adverse reactions to veterinary medicinal products under normal conditions of use, Member States shall administer a veterinary pharmacovigilance system. This system shall be used to collect information useful in the surveillance of veterinary medicinal products, with particular reference to adverse reactions in animals and in human beings relating to the use of veterinary medicinal products, and to evaluate such information scientifically.;

- (b) after the second paragraph, the following paragraph shall be inserted:

'Member States shall ensure that suitable information collected within this system is communicated to other Member States and the Agency. This information shall be recorded in the database referred to in point (k) of the second subparagraph of Article 57(1) of Regulation (EC) No 726/2004 and shall be permanently accessible to all Member States and without delay to the public.;

- 47) The following article shall be inserted:

*'Article 73a*

The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities in order to guarantee their independence.'

- 48) The introductory wording of the second paragraph of Article 74 shall be replaced by the following:

'That qualified person shall reside in the Community and shall be responsible for the following:;

- 49) Article 75 shall be replaced by the following:

*'Article 75*

1. The marketing authorisation holder shall maintain detailed records of all suspected adverse reactions occurring within the Community or in a third country.

Save in exceptional circumstances, these reactions shall be communicated electronically in the form of a report in accordance with the guidelines referred to in Article 77(1).

2. The marketing authorisation holder shall record all suspected serious adverse reactions and human adverse reactions relating to the use of veterinary medicinal products that are brought to his attention, and report them promptly to the competent authority of the Member State on whose territory the incident occurred, and no later than 15 days following receipt of the information.

The marketing authorisation holder shall also record all suspected serious adverse reactions and human adverse reactions related to the use of veterinary medicinal products of which he can reasonably be expected to have knowledge, and report them promptly to the competent authority of Member State on whose territory the incident occurred, and no later than 15 days following receipt of the information.

3. The marketing authorisation holder shall ensure that all suspected serious unexpected adverse reactions, human adverse reactions and any suspected transmission via a veterinary medicinal product of any infectious agent occurring on the territory of a third country are reported promptly in accordance with the guidelines referred to in Article 77(1), so that they are available to the Agency and the competent authorities of the Member States in which the veterinary medicinal product is authorised, and no later than 15 days following the receipt of the information.

4. By way of derogation from paragraphs 2 and 3, in the case of veterinary medicinal products which are covered by Directive 87/22/EEC, have benefited from the authorisation procedures under Articles 31 and 32 of this Directive or have been the subject of the procedures provided for in Articles 36, 37 and 38 of this Directive, the marketing authorisation holder shall additionally ensure that all suspected serious adverse reactions and human adverse reactions occurring in the Community are reported in such a way so as to be accessible to the reference Member State or a competent authority designated as reference Member State. The reference Member State shall assume responsibility for the analysis and follow-up of any such adverse reactions.

5. Unless other requirements have been laid down as a condition for the granting of the marketing authorisation or subsequently as indicated in the guidelines referred to in Article 77(1), reports of all adverse reactions shall be submitted to the competent authorities in the form of a periodic safety update report, immediately upon request or at least every six months after authorisation until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the market and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

The periodic safety update reports shall include a scientific evaluation of the risk-benefit balance of the veterinary medicinal product.

6. Amendments to paragraph 5 may be adopted in accordance with the procedure referred to in Article 89(2) in the light of the experience gained from its operation.

7. Following the granting of a marketing authorisation, the holder of such authorisation may request the amendment of the periods referred to in paragraph 5 of this Article in accordance with the procedure laid down by Commission Regulation (EC) No 1084/2003 (\*).

8. The holder of a marketing authorisation may not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorised veterinary medicinal product without giving prior or simultaneous notification to the competent authority.

In any case, the marketing authorisation holder shall ensure that such information is presented objectively and is not misleading.

Member States shall take the necessary measures to ensure that a marketing authorisation holder who fails to discharge these obligations is subject to effective, proportionate and dissuasive penalties.

(\*) OJ L 159, 27.6.2003, p. 1.;

50) Article 76(1) shall be replaced by the following:

'1. The Agency, in collaboration with Member States and the Commission, shall set up a data-processing network to facilitate the exchange of pharmacovigilance information regarding veterinary medicinal products marketed in the Community in order to allow the competent authorities to share the information at the same time.;

51) in Article 77(1), the second subparagraph shall be replaced by the following:

'In accordance with those guidelines, the marketing authorisation holder shall use internationally agreed veterinary medical terminology for the transmission of reports on adverse reactions.

The Commission shall publish the guidelines, which shall take account of international harmonisation work achieved in the field of pharmacovigilance.;

52) Article 78 shall be amended as follows:

(a) paragraph 2 shall be replaced by the following:

'2. If urgent action is necessary for protecting human or animal health, the Member State concerned may suspend the marketing authorisation of a veterinary medicinal product, provided that the Agency, the Commission and the other Member States are informed on the following working day at the latest.;

(b) the following paragraph shall be added:

'3. When the Agency is informed in accordance with paragraphs 1 or 2, it shall give its opinion as soon as possible, according to the urgency of the matter.

On the basis of this opinion, the Commission may request all Member States in which the veterinary medicinal is marketed to take temporary measures immediately.

Final measures shall be adopted in accordance with the procedure referred to in Article 89(3).;

53) Article 80 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. The competent authority of the Member State concerned shall ensure, by means of repeated inspections and, if necessary, unannounced inspections, and where appropriate, by asking an Official Medicines Control Laboratory or a laboratory designated for that purpose to conduct tests on samples, that the legal requirements relating to veterinary medicinal products are complied with.

The competent authority may also carry out unannounced inspections at the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and of the premises of the marketing authorisation holder whenever it considers that there are grounds for suspecting non-compliance with the provisions of Article 51. Such inspections may also be carried out at the request of another Member State, the Commission or the Agency.

In order to verify whether the data submitted in order to obtain a conformity certificate comply with the monographs of the European Pharmacopoeia, the standardisation body for nomenclatures and quality norms within the meaning of the Convention relating to the elaboration of a European Pharmacopoeia (\*) (European Directorate for the Quality of Medicines) may ask the Commission or the Agency to request such an inspection when the starting material concerned is the subject of a European Pharmacopoeia monograph.

The competent authority of the Member State concerned may carry out inspections of starting material manufacturers at the manufacturer's own request.

Such inspections shall be carried out by authorised representatives of the competent authority who shall be empowered to:

- (a) inspect manufacturing or trading establishments and any laboratories entrusted by the holder of the manufacturing authorisation with the task of carrying out control tests pursuant to Article 24;
- (b) take samples including with a view to an independent analysis by an Official Medicines Control Laboratory or by a laboratory designated for that purpose by a Member State;
- (c) examine any documents relating to the object of the inspection, subject to the provisions in force in the Member States on 9 October 1981 placing restrictions on these powers with regard to the description of the manufacturing method;
- (d) inspect the premises, records and documents of marketing authorisation holders or any firms

performing the activities described in Title VII, and in particular Articles 74 and 75 thereof, on behalf of a marketing authorisation holder.

(\*) OJ L 158, 25.6.1994, p. 19.;

(b) paragraph 3 shall be replaced by the following:

'3. The authorised representatives of the competent authority shall report after each of the inspections mentioned in paragraph 1 on whether the principles and guidelines on good manufacturing practice referred to in Article 51 or, where appropriate, the requirements set out in Title VII, are being complied with. The inspected manufacturer or market authorisation holder shall be informed of the content of such reports.'

(c) the following paragraphs shall be added:

'4. Without prejudice to any arrangements which may have been concluded between the Community and a third country, a Member State, the Commission or the Agency may require a manufacturer established in a third country to undergo an inspection as referred to in paragraph 1.

5. Within 90 days after an inspection as referred to in paragraph 1, a certificate of good manufacturing practice shall be issued to the manufacturer if the inspection established that the manufacturer in question is complying with the principles and guidelines on good manufacturing practice as provided for by Community law.

In the event of an inspection carried out at the request of the European Pharmacopoeia, a certificate of compliance with the monograph shall be issued, if appropriate.

6. Member States shall enter the certificates of good manufacturing practice which they issue in a Community database managed by the Agency on behalf of the Community.

7. If the outcome of the inspection as referred to in paragraph 1 is that the manufacturer does not comply with the principles and guidelines of good manufacturing practice as provided for by Community legislation, the information shall be entered in the Community database as referred to in paragraph 6.'

54) Article 82 shall be replaced by the following:

'Article 82

1. Where it considers it necessary for reasons of human or animal health, a Member State may require the marketing authorisation holder for an immunological veterinary medicinal product to submit samples of batches of the bulk product and/or veterinary medicinal product for control by an Official Medicines Control Laboratory before the product is put into circulation.



2. On request by the competent authorities, the marketing authorisation holder shall promptly supply the samples referred to in paragraph 1, together with the reports of the control referred to in Article 81(2).

The competent authority shall inform all the other Member States in which the veterinary medicinal product is authorised as well as the European Directorate for the Quality of Medicines of its intention to control batches or the batch in question.

In such cases, the competent authorities of another Member State shall not apply the provisions of paragraph 1.

3. After studying the control reports referred to in Article 81(2), the laboratory responsible for the control shall repeat, on the samples provided, all the tests carried out by the manufacturer on the finished product, in accordance with the relevant provisions shown in the dossier for marketing authorisation.

The list of tests to be repeated by the laboratory responsible for the control shall be restricted to justified tests, provided that all Member States concerned, and if appropriate the European Directorate for the Quality of Medicines, agree to this.

For immunological veterinary medicinal products authorised under Regulation (EC) No 726/2004, the list of tests to be repeated by the control laboratory may be reduced only after agreement by the Agency.

4. All Member States concerned shall recognise the results of the tests.

5. Unless the Commission is informed that a longer period is necessary to conduct the tests, Member States shall ensure that this control is completed within 60 days of receipt of the samples.

The competent authority shall notify the other Member States concerned, the European Directorate for the Quality of Medicines, the marketing authorisation holder and, if appropriate, the manufacturer, of the results of the tests within the same period of time.

If a competent authority concludes that a batch of a veterinary medicinal product is not in conformity with the control report of the manufacturer or the specifications provided for in the marketing authorisation, it shall take all the necessary measures vis-a-vis the marketing authorisation holder and the manufacturer, where appropriate, and shall inform accordingly the other Member States in which the veterinary medicinal product is authorised.;

55) Article 83 shall be amended as follows:

(a) paragraph 1 shall be amended as follows:

(i) The introductory words shall be replaced by the following:

'Member States' competent authorities shall suspend, revoke, withdraw or vary marketing authorisations when it is clear that:;

(ii) Point (a) shall be replaced by the following:

'(a) the risk-benefit assessment of the veterinary medicinal product is, under the authorised conditions of use, unfavourable, particular regard being had to the benefits for animal health and welfare and to consumer safety, when the authorisation concerns a veterinary medicinal product for zootechnical use;';

(iii) The second subparagraph of point (e) shall be deleted;

(iv) Point (f) shall be replaced by the following:

'(f) information given in the application documents pursuant to Articles 12 to 13d and 27 is incorrect;';

(v) Point (h) shall be deleted;

(vi) The following second subparagraph shall be added:

'However, when a Community legislative framework is in the course of being adopted, the competent authority may refuse authorisation for a veterinary medicinal product where such action is necessary for the protection of public health, consumer and animal health.;

(b) paragraph 2 shall be amended as follows:

(i) The introductory words shall be replaced by the following:

'Marketing authorisations may be suspended, revoked, withdrawn or varied when it is established that:;

(ii) Point (a) shall be replaced by the following:

'(a) the particulars supporting the application, as provided for in Articles 12 to 13d, have not been amended in accordance with Article 27(1) and (5);';

56) in Article 84, point (a) of paragraph 1 shall be replaced by the following:

'(a) it is clear that the risk-benefit assessment of the veterinary medicinal product is, under the authorised conditions of use, unfavourable, particular regard being had to the benefits for animal health and welfare and to the safety and health benefits for the consumer, when the authorisation concerns a veterinary medicinal product for zootechnical use.;

57) in Article 85, the following paragraph shall be added:

'3. Member States shall prohibit the advertising to the general public of veterinary medicinal products that:

(a) in accordance with Article 67, are available on veterinary prescription only; or

(b) contain psychotropic drugs or narcotics, such as those covered by the United Nations Conventions of 1961 and 1971.;

58) in Article 89, paragraphs 2 and 3 shall be replaced by the following:

'2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

4. The Standing Committee shall adopt its rules of procedure. These rules of procedure shall be made public.;

59) Article 90 shall be replaced by the following:

'Article 90

Member States shall take all necessary measures to ensure that the competent authorities concerned communicate the appropriate information to each other, particularly regarding compliance with the requirements adopted for the authorisations referred to in Article 44, for the certificates referred to in Article 80(5) or for authorisation to place products on the market.

Upon reasoned request, Member States shall forthwith communicate the reports referred to in Article 80(3) to the competent authorities of another Member State.

The conclusions reached following an inspection as referred to in Article 80(1) carried out by the inspectors

of the Member State concerned shall be valid for the Community.

However, by way of exception, if a Member State has not been able, for serious reasons of human or animal health, to accept the conclusions of an inspection as referred to in Article 80(1), that Member State shall forthwith inform the Commission and the Agency. The Agency shall inform the Member States concerned.

When the Commission is informed of such serious reasons, it may, after consulting the Member States concerned, ask the inspector of the competent supervisory authority to carry out a new inspection; the inspector may be accompanied by two other inspectors from Member States that are not parties to the disagreement.;

60) in Article 94, the third subparagraph shall be replaced by the following:

'Decisions to grant or revoke a marketing authorisation shall be made publicly available.;

61) Article 95 shall be replaced by the following:

'Article 95

Member States shall not permit foodstuffs for human consumption to be taken from test animals unless the competent authorities have established an appropriate withdrawal period. The withdrawal period shall either:

(a) be at least as laid down in Article 11(2), including, where appropriate, a safety factor reflecting the nature of the substance being tested; or

(b) if maximum residue limits have been established by the Community in accordance with Regulation (EEC) No 2377/90, ensure that this maximum limit will not be exceeded in foodstuffs.;

62) the following articles shall be inserted:

'Article 95a

Member States shall ensure that appropriate collection systems are in place for veterinary medicinal products that are unused or expired.

Article 95b

When a veterinary medicinal product is to be authorised in accordance with Regulation (EC) No 726/2004 and the Scientific Committee in its opinion refers to recommended conditions or restrictions with regard to the safe and effective use of the veterinary medicinal product as provided for in Article 34(4)(d) of that Regulation, a decision addressed to Member States shall be adopted in accordance with the procedure laid down in Articles 37 and 38 of this Directive, for the implementation of those conditions or restrictions.'

*Article 2*

The periods of protection provided for in Article 1, point 6, which amends Article 13 of Directive 2001/82/EC, shall not apply to reference medicinal products for which an application for authorisation has been submitted before the date of transposition referred to in Article 3 first paragraph.

*Article 3*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 October 2005 at the latest. They shall immediately inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

*Article 4*

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

*Article 5*

This Directive is addressed to the Member States.

Done at Strasbourg, 31 March 2004.

*For the European Parliament*

*The President*

P. COX

*For the Council*

*The President*

D. ROCHE

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