Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

TITLE VIII

SUPERVISION AND SANCTIONS

Article 80

[[F1]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[(1)] (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.**]**

2 Member States shall take all appropriate measures to ensure that the manufacturing processess used in the manufacture of immunological veterinary medicinal products are completely validated and batch-to-batch consistency is ensured.

[[F1]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.**]**

[F2 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.**]**

Textual Amendments

F1 Substituted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

F2 Inserted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

Article 81

1 Member States shall take all appropriate measures to ensure that the marketing authorization holder and, where appropriate, the holder of the manufacturing authorization furnish proof of the control tests carried out on the veterinary medical product and/or on the constituents and intermediate products of the manufacturing process, in accordance with the methods laid down for the purposes of marketing authorization.

2 For the purposes of implementing paragraph 1, Member States may require the marketing authorization holder for immunological veterinary medicinal products to submit to the competent authorities copies of all the control reports signed by the qualified person in accordance with Article 55.

The marketing authorization holder for immunological veterinary medicinal products shall ensure that an adequate number of representative samples of each batch of veterinary medical products is held in stock at least up to the expiry date, and provide samples promptly to the competent authorities on request.

[F1 *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.**]**

Textual Amendments

F1 Substituted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

Article 83

1 **[**[F1]Member States' competent authorities shall suspend, revoke, withdraw or vary marketing authorisations when it is clear that:**]**

[[F1]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;**]**

b the veterinary medicinal product does not have any therapeutic effect on the species of animal for which the treatment is intended;

c its qualitative and quantitative composition is not as stated;

d the recommended withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer;

e the veterinary medicinal product is offered for sale for a use which is prohibited by other community provisions[F1;]

[F3However, pending Community rules, the competent authorities may refuse to grant authorization for a veterinary medicinal product where such action is necessary for the protection of public, consumer or animal health;]

[F1f information given in the application documents pursuant to Articles 12 to 13d and 27 is incorrect;]

g the control tests referred to in Article 81(1) have not been carried out[F1.]

[F3h the obligation referred to in Article 26(2) has not been fulfilled.]

[F2However, 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.]

2 [F1Marketing authorisations may be suspended, revoked, withdrawn or varied when it is established that:]

[F1a 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);]

b any new information as referred to in Article 27(3) has not been communicated to the competent authorities.

Textual Amendments

F1 Substituted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

F2 Inserted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

F3 Deleted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

Article 84

1 Without prejudice to Article 83, Member States shall take all necessary measures to ensure that supply of a veterinary medicinal product is prohibited and that the medicinal product concerned is withdrawn form the market where:

[F1a 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;]

b the veterinary medicinal product has no therapeutic effect on the species of animal for which the treatment was intended;

c the qualitative and quantitative composition of the veterinary medicinal product is not as stated;

d the recommended withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer;

e the control tests referred to in Article 81(1) have not been carried out, or any other requirement or obligation relating to the grant of the manufacturing authorization referred to in Article 44(1) has not been complied with.

2 The competent authority may confine the prohibition on supply and withdrawal from the market solely to the contested production batches.

Textual Amendments

F1 Substituted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

Article 85

1 The competent authority of a Member State shall suspend or withdraw the manufacturing authorization for a category of preparations or for all preparations if any of the requirements laid down in Article 45 are no longer met.

2 The competent authority of a Member State may, in addition to the measures provided for in Article 84, either suspend manufacture or imports of veterinary medicinal products from third countries or suspend or withdraw the manufacturing authorization for a category of preparations or for all preparations in the event of non-compliance with the provisions regarding manufacture or imports from third countries.

[[F2]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.**]**

Textual Amendments

F2 Inserted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

Article 86

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

Article 87

Member States shall take appropriate measures to encourage veterinarians and other professionals concerned to report to the competent authorities any adverse reaction of veterinary medicinal products.

(1) **[**[F1]OJ L 158, 25.6.1994, p. 19.**]**

Textual Amendments

F1 Substituted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.