

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 X

**GENERAL PROVISIONS**

*[<sup>F1</sup>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.]

**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 91*

1 Each Member State shall take all appropriate measures to ensure that the Agency is informed immediately of decisions granting marketing authorization and of all decisions refusing or withdrawing marketing authorization, cancelling a decision refusing or withdrawing marketing authorization, prohibiting supply or withdrawing a product from the market, together with the reasons on which such decisions are based.

2 The marketing authorization holder shall be obliged to notify the Member States forthwith of any action taken by him to suspend the marketing of a veterinary medicinal product or to withdraw a product from the market, together with the reasons for such action if it concerns the effectiveness of the veterinary medicinal product or the protection of public health. Member States shall ensure that this information is brought to the attention of the Agency.

3 Member States shall ensure that appropriate information about actions taken pursuant to paragraphs 1 and 2 which may affect the protection of health in third countries is forthwith brought to the attention of the relevant international organizations, with a copy to the Agency.

---

*Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

---

### Article 92

Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic veterinary medicinal products manufactured and marketed within the Community, and in particular the information referred to in Articles 90 and 91.

### Article 93

1 At the request of the manufacturer or exporter of veterinary medicinal products, or the authorities of an importing third country, Member States shall certify that such manufacturer is in possession of the manufacturing authorization. When issuing such certificates, Member States shall comply with the following conditions:

- a they shall have regard to the prevailing administrative arrangements of the World Health Organization;
- b for veterinary medicinal products intended for export which are already authorized in their territory, they shall supply the summary of the product characteristics as approved in accordance with Article 25 or, in the absence thereof, an equivalent document.

2 Where the manufacturer is not in possession of an authorization to place the product on the market, he shall provide the authorities responsible for establishing the certificate referred to in the first paragraph with a declaration explaining why such authorization is not available.

### Article 94

Any decision referred to in this Directive, taken by the competent authorities of the Member States, may only be taken on the grounds set out in this Directive and shall state in detail the reasons on which it is based.

Such a decision shall be notified to the party concerned who shall at the same time be informed of the remedies available to him under current legislation and the time allowed for seeking such remedies.

[<sup>F1</sup>Decisions to grant or revoke a marketing authorisation shall be made publicly available.]

#### 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.](#)

### [<sup>F1</sup>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.]

---

**Status:** EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

---

.....

**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.](#)

*[<sup>F2</sup>Article 95a*

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

.....

**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 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.]

.....

**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.](#)