

| Basic information  |                     |
|--|---------------------|
| <p><b>1999/0180(COD)</b></p> <p>COD - Ordinary legislative procedure (ex-codecision procedure)<br/>Directive</p>   | Procedure completed |
| <p>Veterinary medicinal products: Community code. Codification</p> <p>Repealed by <a href="#">2014/0257(COD)</a><br/>Amended by <a href="#">2001/0254(COD)</a><br/>Amended by <a href="#">2007/0064(COD)</a><br/>Amended by <a href="#">2008/0045(COD)</a></p> <p><b>Subject</b></p> <p>3.10.08 Animal health requirements, veterinary legislation and pharmacy<br/>3.10.08.01 Feedingstuffs, animal nutrition</p> |                     |

| Key players   |                               |   |   |                  |
|---|-------------------------------|---|---|------------------|
| European Parliament   | <b>Committee responsible</b>  |   | <b>Rapporteur</b>                             | <b>Appointed</b> |
|   | <b>JURI</b>                   | Legal Affairs and Internal Market           | BEYSEN Ward (ELDR)                            | 21/03/2001       |
|   | <b>Committee for opinion</b>  |   | <b>Rapporteur for opinion</b>                 | <b>Appointed</b> |
|   | <b>ENVI</b>                   | Environment, Public Health, Consumer Policy | The committee decided not to give an opinion. |                  |
|   | <b>AGRI</b>                   | Agriculture and Rural Development           | The committee decided not to give an opinion. |                  |
|   | Council of the European Union | <b>Council configuration</b>                |   | <b>Meetings</b>  |
| Competitiveness (Internal Market, Industry, Research and Space) |                               | 2371  | 2001-09-27                                    |                  |
| European Commission   | <b>Commission DG</b>          |   | <b>Commissioner</b>                           |                  |
|   | Legal Service                 |   |   |                  |

| Key events |   |  |                         |
|------------|---|--|-------------------------|
| Date       | Event   | Reference  | Summary                 |
| 08/09/1999 | Initial legislative proposal published                  | COM(1999)0213<br> | <a href="#">Summary</a> |
| 17/09/1999 | Committee referral announced in Parliament, 1st reading |  |                         |

|            |   |  |                         |
|------------|---|--|-------------------------|
| 23/10/2000 | Legislative proposal published                        | COM(2000)0657<br> | <a href="#">Summary</a> |
| 26/06/2001 | Vote in committee, 1st reading                        |  |                         |
| 03/07/2001 | Decision by Parliament, 1st reading                   | T5-0365/2001   | <a href="#">Summary</a> |
| 27/09/2001 | Act adopted by Council after Parliament's 1st reading |  |                         |
| 06/11/2001 | Final act signed                                      |  |                         |
| 06/11/2001 | End of procedure in Parliament                        |  |                         |
| 28/11/2001 | Final act published in Official Journal               |  |                         |

| Technical information             |   |
|-----------------------------------|---|
| <b>Procedure reference</b>        | 1999/0180(COD)  |
| <b>Procedure type</b>             | COD - Ordinary legislative procedure (ex-codecision procedure)  |
| <b>Procedure subtype</b>          | Codification  |
| <b>Legislative instrument</b>     | Directive   |
| <b>Amendments and repeals</b>     | Repealed by <a href="#">2014/0257(COD)</a><br>Amended by <a href="#">2001/0254(COD)</a><br>Amended by <a href="#">2007/0064(COD)</a><br>Amended by <a href="#">2008/0045(COD)</a> |
| <b>Legal basis</b>                | EC Treaty (after Amsterdam) EC 095<br>Rules of Procedure EP 52-p1   |
| <b>Stage reached in procedure</b> | Procedure completed   |

| Documentation gateway                                  |  |   |                         |                         |
|--|--|---|-------------------------|-------------------------|
| <b>European Parliament</b>                             |  |   |                         |                         |
| Document type  | Committee  | Reference   | Date                    | Summary                 |
| Text adopted by Parliament, 1st reading/single reading |  | <a href="#">T5-0365/2001</a><br>OJ C 065 14.03.2002, p. 0021-0033 E | 03/07/2001              | <a href="#">Summary</a> |
| <b>European Commission</b>                             |  |   |                         |                         |
| Document type  | Reference  | Date  | Summary                 |                         |
| Initial legislative proposal                           | COM(1999)0213<br> | 08/09/1999  | <a href="#">Summary</a> |                         |
| Legislative proposal                                   | COM(2000)0657<br> | 23/10/2000  | <a href="#">Summary</a> |                         |
| <b>Other institutions and bodies</b>                   |  |   |                         |                         |
| Institution/body                                       | Document type  | Reference   | Date                    | Summary                 |
| EESC   | Economic and Social Committee: opinion, report   | <a href="#">CES0081/2000</a><br>OJ C 075 15.03.2000, p. 0011        | 26/01/2000              |                         |

|    |                              |   |            |                         |
|----|------------------------------|---|------------|-------------------------|
| EU | Implementing legislative act | <a href="#">32006L0130</a><br>OJ L 349 12.12.2006, p. 0003-0014 | 11/12/2006 | <a href="#">Summary</a> |
| EU | Implementing legislative act | <a href="#">32006R1950</a><br>OJ L 367 22.12.2006, p. 0033-0045 | 13/12/2006 | <a href="#">Summary</a> |

| Additional information |          |      |
|------------------------|----------|------|
| Source                 | Document | Date |
| European Commission    | EUR-Lex  |      |

| Final act  |
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| <a href="#">Directive 2001/0082</a><br><a href="#">OJ L 311 28.11.2001, p. 0001</a> <span style="float: right;"><a href="#">Summary</a></span> |

## Veterinary medicinal products: Community code. Codification

1999/0180(COD) - 13/12/2006 - Implementing legislative act

ACT: Commission Regulation 1950/2006/EC establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae.

CONTENT: no veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with Directive 2001/82/EC or in accordance with Regulation 726/2004/EC of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Veterinary medicinal products for food-producing animals including equidae 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, in accordance with Council Regulation 2377/90/EEC laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

According to the Commission, the available range of authorised veterinary medicinal products, particularly for food-producing animals, is gradually decreasing.

By means of the derogation provided for in Directive 2001/82/EC, equidae intended for slaughter for human consumption may be administered substances essential for their treatment, hereinafter 'essential substances', subject to a withdrawal period of at least six months. For the purpose of that derogation, the list of essential substances is established in the Annex to this Regulation.

Essential substances may be used, for the specific disease conditions, treatment needs or zootechnical purposes specified in the Annex, where no medicinal product authorised for equidae would yield equally satisfactory results in terms of successfully treating the animal, avoiding unnecessary suffering for the animal, or ensuring the safety of those treating the animal.

The European Medicines Agency shall, at the request of the Commission, ensure that the Committee for Medicinal Products for Veterinary Use carries out a scientific evaluation of any draft amendment to the list set out in the Annex. Within 210 days of receiving such a request, the European Medicines Agency shall deliver an opinion to the Commission on the scientific suitability of the amendment. Where appropriate, the European Food Safety Authority shall also be consulted.

When Member States or veterinary professional associations ask the Commission to amend the list set out in the Annex they shall duly substantiate their request and include any relevant scientific data available.

ENTRY INTO FORCE: 18.12.2006.

## Veterinary medicinal products: Community code. Codification

1999/0180(COD) - 06/11/2001 - Final act

**PURPOSE** : to codify and rationalise the rules on the marketing of veterinary medicinal products. **COMMUNITY MEASURE** : Directive 2001/82/EC of the European Parliament and the Council on the Community code relating to veterinary medicinal products. **CONTENT** : this Directive codifies and assembles in one text the following directives, which have been frequently and substantially amended: Directives 81/851/EEC, 81/852/EEC, 90/677/EEC, and 92/74/EEC. It also rationalises the marketing of veterinary medicinal products. No such product may be placed on the market of a Member State unless a marketing authorization has been issued in accordance with this directive or been granted in accordance with Regulation 2309/93/EEC. The particulars and documents required to obtain such authorization are set out. There are special provisions relating to homeopathic veterinary medicinal products. Provisions are also made for mutual recognition. A Committee for Veterinary Medicinal Products is set up, which is part of the European Agency for the Evaluation of Medicinal Products. The Committee will make a scientific evaluation where there is disagreement between Member States about the quality or the safety or the efficacy of a medicinal product. The Directive lays down the circumstances under which marketing authorization must be refused. One such circumstance is where the withdrawal period indicated is not long enough to eliminate health hazards arising from residues. The competent authorities are empowered to prohibit the use of an immunological veterinary medicinal product when the immunological responses of the treated animal will interfere with a national or Community programme for the diagnosis, eradication or control of animal diseases. This Directive does not apply to medicated feedingstuffs. **ENTRY INTO FORCE** : 18 December 2001.

## **Veterinary medicinal products: Community code. Codification**

1999/0180(COD) - 11/12/2006 - Implementing legislative act

**ACT**: Commission Directive 2006/130/EC implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription.

**CONTENT**: Pursuant to Article 67 of Directive 2001/82/EC, veterinary medicinal products may be dispensed to the public only against prescription. However, as certain substances, contained in veterinary medicinal products for food-producing animals, do not present a risk to human or animal health or to the environment, exemptions from that general requirement may be granted in accordance with Article 67.

This Directive establishes the criteria on the basis of which Member States may grant exemptions from the requirement to dispense veterinary medicinal products intended for food-producing animals to the public only against prescription.

**ENTRY INTO FORCE**: 01.01.2007.

## **Veterinary medicinal products: Community code. Codification**

1999/0180(COD) - 23/10/2000 - Legislative proposal

In light of the opinion of 21 February of the Consultative Group of Legal Services provided for in the Agreement of 20.12.1994 (official codification of legislative texts), the Commission presented a modified proposal which also takes into account the results of work already done in the Council.

## **Veterinary medicinal products: Community code. Codification**

1999/0180(COD) - 08/09/1999 - Initial legislative proposal

**PURPOSE**: The purpose of this proposal is for the legislative codification of Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products; 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicology and clinical standards and protocols in respect of the testing of veterinary medicinal products; 90/677/EEC extending the scope of Directive 81/851/EEC on the approximation of the laws of Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products; and 92/74/EEC widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products. **CONTENT**: The new directive would supercede the various directives incorporated in it; their content is fully preserved, and they are brought together with only such formal amendments as are required by the codification exercise itself.

## **Veterinary medicinal products: Community code. Codification**

1999/0180(COD) - 03/07/2001 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted the proposal without debate.