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 IV

MANUFACTURE AND IMPORTS

Article 44

1 Member States shall take all appropriate measures to ensure that the manufacture of veterinary medicinal products in their territory is subject to the holding of an authorization. This manufacturing authorization shall likewise be required for veterinary medicinal products intended for export.

2 The authorization referred to in paragraph 1 shall be required both for total and partial manufacture and for the various processes of dividing up, packaging or presentation.

However, such authorization shall not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out solely for retail supply by pharmacists in dispensing pharmacies or by persons legally authorized in the Member States to carry out such processes.

3 The authorization referred to in paragraph 1 shall also be required for imports from third countries into a Member State; this Title and Article 83 shall apply to such imports in the same way as to manufacture.

Member States shall take all appropriate measures to ensure that veterinary medicinal products brought into their territory from a third country and destined for another Member State are accompanied by a copy of the authorization referred to in paragraph 1.

[[F1]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).**]**

Textual Amendments

F1 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.