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 45

In order to obtain the manufacturing authorization, the applicant shall meet at least the following requirements:

(a) he shall specify the veterinary medicinal products and pharmaceutical forms which are to be manufactured or imported and also the place where they are to be manufactured and/or controlled;

(b) he shall have at his disposal, for the manufacture or import of the above, suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements which the Member State concerned lays down as regards both manufacture and control and the storage of products, in accordance with Article 24;

(c) he shall have at his disposal the services of at least one qualified person within the meaning of Article 52.

The applicant shall provide particulars in his application to establish his compliance with the above requirements.