Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

TITLE III

PLACING ON THE MARKET

CHAPTER 3

Procedures relevant to the marketing authorization

Article 19

In order to examine the application submitted in accordance with **[**[F1]Articles 8, 10, 10a, 10b and 10c**]**, the competent authority of the Member State:

1. must verify whether the particulars submitted in support of the application comply with the said **[**[F1]Articles 8, 10, 10a, 10b and 10c**]** and examine whether the conditions for issuing an authorization to place medicinal products on the market (marketing authorization) are complied with.

2. may submit the medicinal product, its starting materials and, if need be, its intermediate products or other constituent materials, for testing by **[**[F1]an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose**]** in order to ensure that the control methods employed by the manufacturer and described in the particulars accompanying the application in accordance with Article 8(3)(h) are satisfactory.

3. may, where appropriate, require the applicant to supplement the particulars accompanying the application in respect of the items listed in the **[**[F1]Articles 8(3), 10, 10a, 10b and 10c**]**. Where the competent authority avails itself of this option, the time limits laid down in Article 17 shall be suspended until such time as the supplementary information required has been provided. Likewise, these time limits shall be suspended for the time allowed the applicant, where appropriate, for giving oral or written explanation.

Textual Amendments

F1 Substituted by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.