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

[F1 Article 26

1 The marketing authorisation shall be refused if, after verification of the particulars and documents listed in Articles 8, 10, 10a, 10b and 10c, it is clear that:

a the risk-benefit balance is not considered to be favourable; or

b its therapeutic efficacy is insufficiently substantiated by the applicant; or

c its qualitative and quantitative composition is not as declared.

2 Authorisation shall likewise be refused if any particulars or documents submitted in support of the application do not comply with Articles 8, 10, 10a, 10b and 10c.

3 The applicant or the holder of a marketing authorisation shall be responsible for the accuracy of the documents and the data submitted.**]**

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.