

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

[^{F1}CHAPTER 2a

Specific provisions applicable to traditional herbal medicinal products

[^{F1}Article 16e

1 Traditional-use registration shall be refused if the application does not comply with Articles 16a, 16b or 16c or if at least one of the following conditions is fulfilled:

- a the qualitative and/or quantitative composition is not as declared;
- b the indications do not comply with the conditions laid down in Article 16a;
- c the product could be harmful under normal conditions of use;
- d the data on traditional use are insufficient, especially if pharmacological effects or efficacy are not plausible on the basis of long-standing use and experience;
- e the pharmaceutical quality is not satisfactorily demonstrated.

2 The competent authorities of the Member States shall notify the applicant, the Commission and any competent authority that requests it, of any decision they take to refuse traditional-use registration and the reasons for the refusal.]

Textual Amendments

- F1** Inserted by [Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.](#)