

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 V

LABELLING AND PACKAGE LEAFLET

[^{F1}Article 65

In consultation with the Member States and the parties concerned, the Commission shall draw up and publish detailed guidance concerning in particular:

- (a) the wording of certain special warnings for certain categories of medicinal products;
- (b) the particular information needs relating to non-prescription medicinal products;
- (c) the legibility of particulars on the labelling and package leaflet;
- (d) the methods for the identification and authentication of medicinal products;
- (e) the list of excipients which must feature on the labelling of medicinal products and the way in which these excipients must be indicated;
- (f) harmonised provisions for the implementation of Article 57.]

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.](#)