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

Article 69

1 In addition to the clear mention of the words ‘homeopathic medicinal product’, the labelling and, where appropriate, the package insert for the medicinal products referred to in Article 14(1) shall bear the following, and no other, information:

— **[**[F1]the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 1(5); if the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name,**]**

— name and address of the registration holder and, where appropriate, of the manufacturer,

— method of administration and, if necessary, route,

— expiry date, in clear terms (month, year),

— pharmaceutical form,

— contents of the sales presentation,

— special storage precautions, if any,

— a special warning if necessary for the medicinal product,

— manufacturer's batch number,

— registration number,

— ‘homeopathic medicinal product without approved therapeutic indications’,

— **[**[F1]a warning advising the user to consult a doctor if the symptoms persist.**]**

2 Notwithstanding paragraph 1, Member States may require the use of certain types of labelling in order to show:

— the price of the medicinal product,

— the conditions for refunds by social security bodies.

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.