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
_	and, where appropriate, the package insert for the medicinal products referred to in
Article 1	4(1) shall bear the following, and no other, information:
	[FI 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 labelling	Notwithstanding paragraph 1, Member States may require the use of certain types of in order to show:
_	the price of the medicinal product.

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.

the conditions for refunds by social security bodies.