

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 54

The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:

- (a) [^{F1}the name of the medicinal product followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name;]
- (b) a statement of the active substances expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;
- (c) the pharmaceutical form and the contents by weight, by volume or by number of doses of the product;
- (d) a list of those excipients known to have a recognized action or effect and included in the [^{F1}detailed guidance] published pursuant to Article 65. However, if the product is injectable, or a topical or eye preparation, all excipients must be stated;
- (e) [^{F1}the method of administration and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;]
- (f) [^{F1}a special warning that the medicinal product must be stored out of the reach and sight of children;]
- (g) a special warning, if this is necessary for the medicinal product;
- (h) the expiry date in clear terms (month/year);
- (i) special storage precautions, if any;
- (j) [^{F1}specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place;]
- (k) [^{F1}the name and address of the marketing authorisation holder and, where applicable, the name of the representative appointed by the holder to represent him;]
- (l) the number of the authorization for placing the medicinal product on the market;
- (m) the manufacturer's batch number;
- (n) [^{F1}in the case of non-prescription medicinal products, instructions for use;]
- (o) [^{F2}for medicinal products other than radiopharmaceuticals referred to in Article 54a(1), safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:

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- verify the authenticity of the medicinal product, and
- identify individual packs,

as well as a device allowing verification of whether the outer packaging has been tampered with.]

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.](#)
- F2** Inserted by [Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products \(Text with EEA relevance\).](#)