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 55

1 The particulars laid down **[**[F1]in Article 54**]** shall appear on immediate packagings other than those referred to in paragraphs 2 and 3.

2 The following particulars at least shall appear on immediate packagings which take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 54 and 62.

— **[**[F1]the name of the medicinal product as laid down in point (a) of Article 54,**]**

— the name of the holder of the authorization for placing the product on the market,

— the expiry date,

— the batch number.

3 The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 54 and 62 cannot be displayed:

— **[**[F1]the name of the medicinal product as laid down in point (a) of Article 54 and, if necessary, the route of administration,**]**

— the method of administration,

— the expiry date,

— the batch number,

— the contents by weight, by volume or by unit.

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.