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

[F1TITLE VIIIa

INFORMATION AND ADVERTISING]

Article 96

1 Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

a the number of samples for each medicinal product each year on prescription shall be limited;

b any supply of samples shall be in response to a written request, signed and dated, from the prescribing agent;

c those supplying samples shall maintain an adequate system of control and accountability;

[F1d each sample shall be no larger than the smallest presentation on the market;**]**

e each sample shall be marked ‘free medical sample — not for sale’ or shall show some other wording having the same meaning;

f each sample shall be accompanied by a copy of the summary of product characteristics;

g no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, such as the United Nations Conventions of 1961 and 1971, may be supplied.

2 Member States may also place further restrictions on the distribution of samples of certain medicinal products.

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.