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 III

PLACING ON THE MARKET

CHAPTER 2

Specific provisions applicable to homeopathic medicinal products

Article 16

1 Homeopathic medicinal products other than those referred to in Article 14(1) shall be authorized and labelled in accordance with **[**[F1]Articles 8, 10, 10a, 10b, 10c and 11**]**.

2 A Member State may introduce or retain in its territory specific rules for the **[**[F1]preclinical tests**]** and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practised in that Member State.

In this case, the Member State concerned shall notify the Commission of the specific rules in force.

3 Title IX shall apply to homeopathic medicinal products, with the exception of those referred to in Article 14(1).

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.