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 IV

MANUFACTURE AND IMPORTATION

[F1 Article 47a

1 The safety features referred to in point (o) of Article 54 shall not be removed or covered, either fully or partially, unless the following conditions are fulfilled:

a the manufacturing authorisation holder verifies, prior to partly or fully removing or covering those safety features, that the medicinal product concerned is authentic and that it has not been tampered with;

b the manufacturing authorisation holder complies with point (o) of Article 54 by replacing those safety features with safety features which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging as defined in point 23 of Article 1.

Safety features shall be considered equivalent if they:

(i) comply with the requirements set out in the delegated acts adopted pursuant to Article 54a(2); and

(ii) are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;

c the replacement of the safety features is conducted in accordance with applicable good manufacturing practice for medicinal products; and

d the replacement of the safety features is subject to supervision by the competent authority.

2 Manufacturing authorisation holders, including those performing the activities referred to in paragraph 1 of this Article, shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in Directive 85/374/EEC.**]**

Textual Amendments

F1 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).