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

[F1 Article 54a

1 Medicinal products subject to prescription shall bear the safety features referred to in point (o) of Article 54, unless they have been listed in accordance with the procedure pursuant to point (b) of paragraph 2 of this Article.

Medicinal products not subject to prescription shall not bear the safety features referred to in point (o) of Article 54, unless, by way of exception, they have been listed in accordance with the procedure pursuant to point (b) of paragraph 2 of this Article, after having been assessed to be at risk of falsification.

2 The Commission shall adopt, by means of delegated acts in accordance with Article 121a and subject to the conditions laid down in Articles 121b and 121c, measures supplementing point (o) of Article 54 with the objective of establishing the detailed rules for the safety features referred to in point (o) of Article 54.

Those delegated acts shall set out:

a the characteristics and technical specifications of the unique identifier of the safety features referred to in point (o) of Article 54 that enables the authenticity of medicinal products to be verified and individual packs to be identified. When establishing the safety features due consideration shall be given to their cost-effectiveness;

b the lists containing the medicinal products or product categories which, in the case of medicinal products subject to prescription shall not bear the safety features, and in the case of medicinal products not subject to prescription shall bear the safety features referred to in point (o) of Article 54. Those lists shall be established considering the risk of and the risk arising from falsification relating to medicinal products or categories of medicinal products. To this end, at least the following criteria shall be applied:

   (i) the price and sales volume of the medicinal product;

   (ii) the number and frequency of previous cases of falsified medicinal products being reported within the Union and in third countries and the evolution of the number and frequency of such cases to date;

   (iii) the specific characteristics of the medicinal products concerned;

   (iv) the severity of the conditions intended to be treated;

   (v) other potential risks to public health;

c the procedures for the notification to the Commission provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b);

d the modalities for the verification of the safety features referred to in point (o) of Article 54 by the manufacturers, wholesalers, pharmacists and persons authorised or entitled to supply medicinal products to the public and by the competent authorities. Those modalities shall allow the verification of the authenticity of each supplied pack of the

medicinal products bearing the safety features referred to in point (o) of Article 54 and determine the extent of such verification. When establishing those modalities, the particular characteristics of the supply chains in Member States, and the need to ensure that the impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account;

e provisions on the establishment, management and accessibility of the repositories system in which information on the safety features, enabling the verification of the authenticity and identification of medicinal products, as provided for in point (o) of Article 54, shall be contained. The costs of the repositories system shall be borne by the manufacturing authorisation holders of medicinal products bearing the safety features.

3 When adopting the measures referred to in paragraph 2, the Commission shall take due account of at least the following:

a the protection of personal data as provided for in Union law;

b the legitimate interests to protect information of a commercially confidential nature;

c the ownership and confidentiality of the data generated by the use of the safety features; and

d the cost-effectiveness of the measures.

4 The national competent authorities shall notify the Commission of non-prescription medicinal products which they judge to be at risk of falsification and may inform the Commission of medicinal products which they deem not to be at risk according to the criteria set out in point (b) of paragraph 2 of this Article.

5 Member States may, for the purposes of reimbursement or pharmacovigilance, extend the scope of application of the unique identifier referred to in point (o) of Article 54 to any medicinal product subject to prescription or subject to reimbursement.

Member States may, for the purposes of reimbursement, pharmacovigilance or pharmacoepidemiology, use the information contained in the repositories system referred to in point (e) of paragraph 2 of this Article.

Member States may, for the purposes of patient safety, extend the scope of application of the anti-tampering device referred to in point (o) of Article 54 to any medicinal product.**]**

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).