

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 52b

1 Notwithstanding Article 2(1), and without prejudice to Title VII, Member States shall take the necessary measures in order to prevent medicinal products that are introduced into the Union, but are not intended to be placed on the market of the Union, from entering into circulation if there are sufficient grounds to suspect that those products are falsified.

2 In order to establish what the necessary measures referred to in paragraph 1 of this Article are, the Commission may 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 paragraph 1 of this Article as regards the criteria to be considered and the verifications to be made when assessing the potential falsified character of medicinal products introduced into the Union but not intended to be placed on the market.]

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 \(Text with EEA relevance\)](#).