

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 XI

SUPERVISION AND SANCTIONS

f¹ Article 117a

1 Member States shall have a system in place which aims at preventing medicinal products that are suspected to present a danger to health from reaching the patient.

2 The system referred to in paragraph 1 shall cover the receipt and handling of notifications of suspected falsified medicinal products as well as of suspected quality defects of medicinal products. The system shall also cover recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market ordered by national competent authorities from all relevant actors in the supply chain both during and outside normal working hours. The system shall also make it possible to recall, where necessary with the assistance of health professionals, medicinal products from patients who received such products.

3 If the medicinal product in question is suspected of presenting a serious risk to public health, the competent authority of the Member State in which that product was first identified shall, without any delay, transmit a rapid alert notification to all Member States and all actors in the supply chain in that Member State. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.

4 Member States shall by 22 July 2013 notify the Commission of the details of their respective national systems referred to in this Article.]

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