

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 VII

**[<sup>F1</sup>WHOLESALE DISTRIBUTION AND  
BROKERING OF MEDICINAL PRODUCTS]**

*Article 76*

[<sup>F21</sup>] Without prejudice to Article 6, Member States shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorization has been granted in accordance with Community law are distributed on their territory.

[<sup>F22</sup> In the case of wholesale distribution and storage, medicinal products shall be covered by a marketing authorisation granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this Directive.]

[<sup>F13</sup> Any distributor, not being the marketing authorisation holder, who imports a medicinal product from another Member State shall notify the marketing authorisation holder and the competent authority in the Member State to which the medicinal product will be imported of his intention to import that product. In the case of medicinal products which have not been granted an authorisation pursuant to Regulation (EC) No 726/2004, the notification to the competent authority shall be without prejudice to additional procedures provided for in the legislation of that Member State and to fees payable to the competent authority for examining the notification.

4 In the case of medicinal products which have been granted an authorisation pursuant to Regulation (EC) No 726/2004, the distributor shall submit the notification in accordance with paragraph 3 of this Article to the marketing authorisation holder and the Agency. A fee shall be payable to the Agency for checking that the conditions laid down in Union legislation on medicinal products and in the marketing authorisations are observed.]

**Textual Amendments**

**F2** Inserted 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.](#)

*Article 77*

[<sup>F11</sup> Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorisation to engage in activity as a wholesaler in medicinal products, stating the premises located on their territory for which it is valid.]

2 Where persons authorized or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the authorization provided for in paragraph 1.

3 Possession of a manufacturing authorization shall include authorization to distribute by wholesale the medicinal products covered by that authorization. Possession of an authorization to engage in activity as a wholesaler in medicinal products shall not give dispensation from the obligation to possess a manufacturing authorization and to comply with

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the conditions set out in that respect, even where the manufacturing or import business is secondary.

[<sup>F14</sup> Member States shall enter the information relating to the authorisations referred to in paragraph 1 of this Article in the Union database referred to in Article 111(6). At the request of the Commission or any Member State, Member States shall provide all appropriate information concerning the individual authorisations which they have granted under paragraph 1 of this Article.

5 Checks on the persons authorised to engage in activity as a wholesaler in medicinal products, and the inspection of their premises, shall be carried out under the responsibility of the Member State which granted the authorisation for premises located on its territory.]

6 The Member State which granted the authorization referred to in paragraph 1 shall suspend or revoke that authorization if the conditions of authorization cease to be met. It shall forthwith inform the other Member States and the Commission thereof.

7 Should a Member State consider that, in respect of a person holding an authorization granted by another Member State under the terms of paragraph 1, the conditions of authorization are not, or are no longer met, it shall forthwith inform the Commission and the other Member State involved. The latter shall take the measures necessary and shall inform the Commission and the first Member State of the decisions taken and the reasons for those decisions.

#### *Article 78*

Member States shall ensure that the time taken for the procedure for examining the application for the distribution authorization does not exceed 90 days from the day on which the competent authority of the Member State concerned receives the application.

The competent authority may, if need be, require the applicant to supply all necessary information concerning the conditions of authorization. Where the authority exercises this option, the period laid down in the first paragraph shall be suspended until the requisite additional data have been supplied.

#### *Article 79*

In order to obtain the distribution authorization, applicants must fulfil the following minimum requirements:

- (a) they must have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products;
- (b) they must have staff, and in particular, a qualified person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned;
- (c) they must undertake to fulfil the obligations incumbent on them under the terms of Article 80.

#### *Article 80*

Holders of the distribution authorization must fulfil the following minimum requirements:

- (a) they must make the premises, installations and equipment referred to in Article 79(a) accessible at all times to the persons responsible for inspecting them;

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- (b) they must obtain their supplies of medicinal products only from persons who are themselves in possession of the distribution authorization or who are exempt from obtaining such authorization under the terms of Article 77(3);
- (c) they must supply medicinal products only to persons who are themselves in possession of the distribution authorization or who are authorized or entitled to supply medicinal products to the public in the Member State concerned;
- (ca) [<sup>F3</sup>they must verify that the medicinal products received are not falsified by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts referred to in Article 54a(2);]
- (d) they must have an emergency plan which ensures effective implementation of any recall from the market ordered by the competent authorities or carried out in cooperation with the manufacturer or marketing authorization holder for the medicinal product concerned;
- (e) [<sup>F1</sup>they must keep records either in the form of purchase/sales invoices or on computer, or in any other form, giving for any transaction in medicinal products received, dispatched or brokered at least the following information:
  - date,
  - name of the medicinal product,
  - quantity received, supplied or brokered,
  - name and address of the supplier or consignee, as appropriate,
  - batch number of the medicinal products at least for products bearing the safety features referred to in point (o) of Article 54;]
- (f) they must keep the records referred to under (e) available to the competent authorities, for inspection purposes, for a period of five years;
- (g) they must comply with the principles and guidelines of good distribution practice for medicinal products as laid down in Article 84[<sup>F1</sup>;]
- (h) [<sup>F3</sup>they must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities;
- (i) they must immediately inform the competent authority and, where applicable, the marketing authorisation holder, of medicinal products they receive or are offered which they identify as falsified or suspect to be falsified.]

[<sup>F3</sup>For the purposes of point (b), where the medicinal product is obtained from another wholesale distributor, wholesale distribution authorisation holders must verify compliance with the principles and guidelines of good distribution practices by the supplying wholesale distributor. This includes verifying whether the supplying wholesale distributor holds a wholesale distribution authorisation.

Where the medicinal product is obtained from the manufacturer or importer, wholesale distribution authorisation holders must verify that the manufacturer or importer holds a manufacturing authorisation.

Where the medicinal product is obtained through brokering, the wholesale distribution authorisation holders must verify that the broker involved fulfils the requirements set out in this Directive.]

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#### Textual Amendments

- F3** 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 \(Text with EEA relevance\)](#).

#### *[<sup>F4</sup> Article 81*

With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the holder of a distribution authorisation which has been granted by another Member State any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.

The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.]

#### Textual Amendments

- F4** 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](#).

#### *Article 82*

For all supplies of medicinal products to a person authorized or entitled to supply medicinal products to the public in the Member State concerned, the authorized wholesaler must enclose a document that makes it possible to ascertain:

- the date,
- [<sup>F4</sup>the name and pharmaceutical form of the medicinal product,]
- the quantity supplied,
- the name and address of the supplier and consignor[<sup>F1</sup>,]
- [<sup>F3</sup>batch number of the medicinal products at least for products bearing the safety features referred to in point (o) of Article 54.]

Member States shall take all appropriate measures to ensure that persons authorized or entitled to supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product.

#### Textual Amendments

- F3** 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](#),

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as regards the prevention of the entry into the legal supply chain of falsified medicinal products (Text with EEA relevance).

- F4** 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.](#)

#### *Article 83*

The provisions of this Title shall not prevent the application of more stringent requirements laid down by Member States in respect of the wholesale distribution of:

- narcotic or psychotropic substances within their territory,
- medicinal products derived from blood,
- immunological medicinal products,
- radiopharmaceuticals.

#### *[<sup>F4</sup>Article 84*

The Commission shall publish guidelines on good distribution practice. To this end, it shall consult the Committee for Medicinal Products for Human Use and the Pharmaceutical Committee established by Council Decision 75/320/EEC<sup>(1)</sup>.]

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#### **Textual Amendments**

- F4** 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.](#)

#### *[<sup>F4</sup>Article 85*

This Title shall apply to homeopathic medicinal products.]

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#### **Textual Amendments**

- F4** 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.](#)

#### *[<sup>F3</sup>Article 85a*

In the case of wholesale distribution of medicinal products to third countries, Article 76 and point (c) of Article 80 shall not apply. Moreover, points (b) and (ca) of Article 80 shall not apply where a product is directly received from a third country but not imported. The requirements set out in Article 82 shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.

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#### **Textual Amendments**

- F3** 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 \(Text with EEA relevance\).](#)

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### Article 85b

1 Persons brokering medicinal products shall ensure that the brokered medicinal products are covered by a marketing authorisation granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this Directive.

Persons brokering medicinal products shall have a permanent address and contact details in the Union, so as to ensure accurate identification, location, communication and supervision of their activities by competent authorities.

The requirements set out in points (d) to (i) of Article 80 shall apply *mutatis mutandis* to the brokering of medicinal products.

2 Persons may only broker medicinal products if they are registered with the competent authority of the Member State of their permanent address referred to in paragraph 1. Those persons shall submit, at least, their name, corporate name and permanent address in order to register. They shall notify the competent authority of any changes thereof without unnecessary delay.

Persons brokering medicinal products who had commenced their activity before 2 January 2013 shall register with the competent authority by 2 March 2013.

The competent authority shall enter the information referred to in the first subparagraph in a register that shall be publicly accessible.

3 The guidelines referred to in Article 84 shall include specific provisions for brokering.

4 This Article shall be without prejudice to Article 111. Inspections referred to in Article 111 shall be carried out under the responsibility of the Member State where the person brokering medicinal products is registered.

If a person brokering medicinal products does not comply with the requirements set out in this Article, the competent authority may decide to remove that person from the register referred to in paragraph 2. The competent authority shall notify that person thereof.]

#### Textual Amendments

- F3** 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 \(Text with EEA relevance\)](#).

#### Textual Amendments

- F1** Substituted 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 \(Text with EEA relevance\)](#).

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(1) [<sup>F4</sup>OJ L 147, 9.6.1975, p. 23.]

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**Textual Amendments**

**F4** 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.](#)