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

[F1TITLE VIIA

SALE AT A DISTANCE TO THE PUBLIC

Article 85c

1 Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of information society services as defined in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services[(1)] under the following conditions:

a the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established;

b the person referred to in point (a) has notified the Member State in which that person is established of at least the following information:

(i) name or corporate name and permanent address of the place of activity from where those medicinal products are supplied;

(ii) the starting date of the activity of offering medicinal products for sale at a distance to the public by means of information society services;

(iii) the address of the website used for that purpose and all relevant information necessary to identify that website;

(iv) if applicable, the classification in accordance with Title VI of the medicinal products offered for sale at a distance to the public by means of information society services.

Where appropriate, that information shall be updated;

c the medicinal products comply with the national legislation of the Member State of destination in accordance with Article 6(1);

d without prejudice to the information requirements set out in Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce)[(2)], the website offering the medicinal products contains at least:

(i) the contact details of the competent authority or the authority notified pursuant to point (b);

(ii) a hyperlink to the website referred to in paragraph 4 of the Member State of establishment;

(iii) the common logo referred to in paragraph 3 clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of

medicinal products. The common logo shall contain a hyperlink to the entry of the person in the list referred to in point (c) of paragraph 4.

2 Member States may impose conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services.

3 A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering medicinal products for sale at a distance to the public is established. That logo shall be clearly displayed on websites offering medicinal products for sale at a distance to the public in accordance with point (d) of paragraph 1.

In order to harmonise the functioning of the common logo, the Commission shall adopt implementing acts regarding:

a the technical, electronic and cryptographic requirements for verification of the authenticity of the common logo;

b the design of the common logo.

Those implementing acts shall, where necessary, be amended to take account of technical and scientific progress. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 121(2).

4 Each Member State shall set up a website providing at least the following:

a information on the national legislation applicable to the offering of medicinal products for sale at a distance to the public by means of information society services, including information on the fact that there may be differences between Member States regarding classification of medicinal products and the conditions for their supply;

b information on the purpose of the common logo;

c the list of persons offering the medicinal products for sale at a distance to the public by means of information society services in accordance with paragraph 1 as well as their website addresses;

d background information on the risks related to medicinal products supplied illegally to the public by means of information society services.

This website shall contain a hyperlink to the website referred to in paragraph 5.

5 The Agency shall set up a website providing the information referred to in points (b) and (d) of paragraph 4, information on the Union legislation applicable to falsified medicinal products as well as hyperlinks to the Member States' websites referred to in paragraph 4. The Agency's website shall explicitly mention that the Member States' websites contain information on persons authorised or entitled to supply medicinal products at a distance to the public by means of information society services in the Member State concerned.

6 Without prejudice to Directive 2000/31/EC and the requirements set out in this Title, Member States shall take the necessary measures to ensure that other persons than those referred to in paragraph 1 that offer medicinal products for sale at a distance to the public by means of information society services and that operate on their territory are subject to effective, proportionate and dissuasive penalties.

Article 85d

Without prejudice to the competences of the Member States, the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal

products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally at a distance to the public by means of information society services and of the functioning of the common logo, the Member States' websites and the Agency's website.**]**

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).

(1) **[**[F1]OJ L 204, 21.7.1998, p. 37.**]**

(2) **[**[F1]OJ L 178, 17.7.2000, p. 1.**]**

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