Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State (Text with EEA relevance)

COMMISSION IMPLEMENTING DIRECTIVE 2012/52/EU

of 20 December 2012

laying down measures to facilitate the recognition of medical prescriptions issued in another Member State

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[(1)], and in particular points (a), (c) and (d) of Article 11(2) thereof,

Whereas:

(1) Pursuant to Article 11(2) of Directive 2011/24/EU, the Commission has an obligation to adopt measures to facilitate the recognition of medical prescriptions issued in a Member State other than the Member State where the prescriptions are dispensed.

(2) Pursuant to point (a) of Article 11(2) of Directive 2011/24/EU, the Commission is to adopt a non-exhaustive list of elements to be included in those prescriptions. That list should enable the dispensing health professional to verify the authenticity of the prescription and whether it was issued by a member of a regulated health profession who is legally entitled to do so.

(3) The elements to be included in the prescriptions should facilitate the correct identification of medicinal products or medical devices as referred to in point (c) of Article 11 (2) of Directive 2011/24/EU.

(4) Medicinal products should therefore be indicated using the common name in order to facilitate the correct identification of products which are marketed under different brand names across the Union and of products that are not marketed in all Member States. That common name to be used should be either the International Non-proprietary name recommended by the World Health Organisation or, if such name does not exist, the usual common name. In contrast, the brand name of a medicinal product should only be used to ensure clear identification of biological medicinal products as defined in point 3.2.1.1.(b) of Annex I to 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[(2)], because of the special characteristics of those products, or of other medicinal products in cases where the prescribing professional considers it medically necessary.

(5) Medical devices do not have common names as medicinal products. Therefore the prescription should also include direct contact details of the prescriber which enable the dispensing professional, where necessary, to enquire about the prescribed medical device and correctly identify it.

(6) The non-exhaustive list of elements to appear on the prescriptions should facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, as referred to in point (d) of Article 11(2) of Directive 2011/24/EU. The Commission will regularly review the situation in order to assess whether additional measures are necessary to help patients understand the instructions concerning the use of the product.

(7) To enable patients to request appropriate prescriptions, it is important that national contact points referred to in Article 6 of Directive 2011/24/EU provide patients with adequate information on the content and purpose of the non-exhaustive list of elements that should appear in those prescriptions.

(8) As the overall impact of cross-border healthcare is limited, the non-exhaustive list of elements should apply only to prescriptions intended to be used in another Member State.

(9) As the principle of mutual recognition of prescriptions derives from Article 56 of the Treaty on the Functioning of the European Union, this Directive does not preclude the Member States from applying the principle of mutual recognition to prescriptions that do not contain the elements set out in the non-exhaustive list. At the same time, nothing in this Directive prevents the Member States from providing that prescriptions drafted on their territory, with a view to be used in another Member State, contain additional elements that are provided for under the rules applicable on their territory, as long as these rules are compatible with Union law.

(10) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Article 16(1) of Directive 2011/24/EU

HAS ADOPTED THIS DIRECTIVE:

Article 1 *U.K.*

Subject matter

This Directive lays down measures for the uniform implementation of Article 11(1) of Directive 2011/24/EU concerning the recognition of medical prescriptions issued in another Member State.

Article 2 U.K.

Scope

This Directive shall apply to prescriptions, as defined in point (k) of Article 3 of Directive 2011/24/EU, which are issued further to a request of a patient who intends to use them in another Member State.

Article 3 U.K.

Content of prescriptions

Member States shall ensure that prescriptions contain at least the elements set out in the Annex.

Article 4 U.K.

Information requirements

Member States shall ensure that the national contact points referred to in Article 6 of Directive 2011/24/EU inform patients about the elements to be included, pursuant to this Directive, in prescriptions issued in a Member State other than the Member State where they are dispensed.

Article 5 U.K.

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 25 October 2013 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 6 U.K.

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 7 *U.K.*

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 20 December 2012.

For the Commission

The President

José Manuel BARROSO

ANNEX U.K.

Non-exhaustive list of elements to be included in medical prescriptions

Headings appearing in bold in this Annex are not required to feature in prescriptions

Identification of the patient

Surname(s)

First name(s) (written out in full, i.e. no initials)

Date of Birth

Authentication of the prescription

Issue date

Identification of the prescribing health professional

Surname(s)

First name(s) (written out in full, i.e. no initials)

Professional qualification

Details for direct contact (email and telephone or fax, the latter both with international prefix)

Work address (including the name of the relevant Member State)

Signature (written or digital, depending on the medium chosen for issuing the prescription)

Identification of the prescribed product, where applicable

'Common name' as defined by Article 1 of 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

The brand name if:

(a) the prescribed product is a biological medicinal product, as defined in point 3.2.1.1. (b) of Annex I (Part I) to Directive 2001/83; or

(b) the prescribing health professional deems it medically necessary; in that case the prescription shall shortly state the reasons justifying the use of the brand name

Pharmaceutical formulation (tablet, solution, etc.)

Quantity

Strength, as defined in Article 1 of Directive 2001/83/EC

Dosage regimen

(**1**) OJ L 88, 4.4.2011, p. 45–65

(**2**) OJ L 311, 28.11.2001, p. 67.