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Public consultation on measures for improving the recognition of prescriptions issued in another Member State

Background

Article 11 of the <u>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</u> (hereinafter "CBHC Directive") addresses the recognition of prescriptions issued in another Member State.

In Article 11 of the Directive is stated that the Commission shall adopt the following measures:

- "Article 11 para. 2 (a): measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing a non-exhaustive list of elements to be included in the prescriptions and which must be clearly identifiable in all prescription formats, including elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection;
- Article 11 para. 2 (c): measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, inter alia, using the International Non-proprietary Name and the dosage of medicinal products;
- Article 11 para. 2 (d): measures to facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, including an indication of active substance and dosage."

In Article 11 para 4 of the Directive it is stated that the Commission shall have regard to the proportionality of compliance costs as well a likely benefits from the above measures which the Commission plans to **adopt by 25 October 2012**. In keeping with this, the Commission is conducting an impact assessment to evaluate various policy options under consideration. The Commission seeks to understand stakeholder views in this respect.

Public Consultation

DG Health & Consumers is launching a stakeholder consultation: "Measures for Improving the recognition of prescriptions issued in another Member State".

Target groups

Patients, health professionals prescribing medicinal products and/or medical devices, health professionals dispensing prescriptions for medicinal products and/or medical devices, and the medical industry involved in manufacturing and wholesale dealing of medicinal products and/or medical devices are welcome to give their views.

Consultation period

28 October until 08 January 2012

Objective of the consultation

The Commission consults stakeholders to see how the recognition of cross-border prescriptions could be improved. Stakeholder input will feed into the impact assessment as announced on the <u>European Commission</u>'s impact assessment webpage.

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Consultation document

Impact assessment roadmap "Implementing measures for improving the recognition of prescriptions issued in another Member State under Article 11 para. 2 of the Directive on the Application of Patients' Rights in Cross-Border Healthcare (CBHC)" (43 KB)