E U R O P E A N E C O N O M I C A R E A

STANDING COMMITTEE
OF THE EFTA STATES

Ref: 1111287 9 February 2012

SUBCOMMITTEE IV ON FLANKING AND HORIZONTAL POLICIES

EEA EFTA Comment on the Public Consultation of the European Commission on measures for improving the recognition of prescriptions issued in another Member State:

1. EXCEUTIVE SUMMARY:

The EEA EFTA States (Iceland, Liechtenstein and Norway) welcome this opportunity to submit their comments to the Public Consultation of the European Commission concerning measures for improving the recognition of prescriptions issued in another Member State.

Article 11 of the 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 addresses the recognition of prescriptions issued in another Member State and states that the Commission shall adopt measures to facilitate the implementation of cross-border recognition of prescriptions.

As input into the Impact Assessment of the Commission and the evaluation of various policy options under consideration, the EEA EFTA States would hereby like to take the opportunity to submit their comments on how the recognition of cross-border prescriptions could be improved.

2. ARTICLE 11 PARAGRAPH 2 (A):

In Article 11 paragraph 2 (a) of the Directive, it is stated that the Commission shall adopt the following measures:

'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;'

EEA EFTA Comment to Article 11 paragraph 2 (a) of the Directive:

The EEA EFTA States propose that a web portal providing easy access to all national registers of health professionals with the right to prescribe medicinal products be established. As a first step, we suggest limiting the scope of national registers to doctors and dentists. In the future, it could, however, be desirable to establish a common European register (or merge national registers) of prescribers.

We consider that the use of national prescription forms should be limited, as this is not in accordance with the intention of the Directive.

3. ARTICLE 11 PARAGRAPH 2 (C) :

In Article 11 paragraph 2 (c) of the Directive, it is stated that the Commission shall adopt the following measures:

'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;'

EEA EFTA Comment to Article 11 paragraph 2 (c) of the Directive:

We support the use of the International Non-proprietary Name (INN) and the dosage of medicinal products on all prescriptions. In addition, the EEA EFTA States propose to introduce a mandatory information requirement regarding the dosage form on all prescriptions (e.g. differentiate between tablets with normal or controlled release).

The EEA EFTA States consider that harmonised short forms concerning dosage should be introduced throughout the European Economic Area (e.g. '1x2' for one tablet twice a day, '1x3 (VII) for one tablet three times a day for seven day period). Furthermore, we consider that an expiration date for the dispensing of the medicinal product should be included on all prescriptions, as the expiry date for prescriptions varies across different Member States.

In order to protect patient safety and for valid medical reasons, we believe that the prescriber should have the possibility to prohibit generic substitution. Reservations concerning generic substitution should be marked in a uniform way throughout the EEA.

We propose that the following information should be included in the minimum requirement for prescriptions:

i) The full name and occupation of the prescriber, the address and telephone number of the prescribers business premises and the national health professional ID-number of the prescriber.
ii) The patients' full name and home address, sex, date of birth, and national identity number.
iii) Information about the medicinal product: e.g. the INN, ATC code, dosage, strength and amount of the product to be dispensed (and/or duration of treatment).

4. ARTICLE 11 PARAGRAPH 2 (D):

In Article 11 paragraph 2 (d) of the Directive, it is stated that the Commission shall adopt the following measures:

'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.'

EEA EFTA Comment to Article 11 paragraph 2 (d) of the Directive:

We consider the display of the Non-proprietary Name on all prescriptions to be of key importance in facilitating comprehensibility of information. The Non-proprietary Name will allow healthcare professionals and patients to uniformly identify the active substances in medicinal products. Furthermore, using the Non-proprietary Name when surveying literature, the Internet and national SCP databases, will ensure access to relevant information. In this respect, we emphasize that some countries have national databases where SPC and PIL are accessible to the public when conducting searches based on the Non-proprietary Name. We therefore propose the establishment of a central web portal that provides easy access to national sites or search engines where SPC and/or packaging leaflets in national languages are accessible. Member States should be responsible for updating their respective databases.

In addition, the EEA EFTA States suggest that all pharmacies should ensure that patients receive a link to the central web address or a copy of the relevant SPC/PIL in the patient's native language.

We invite the Commission to note the results of a Norwegian study demonstrating that a new standardised design of drug packaging, where the active ingredient is prominently displayed in the upper right-hand corner of the package, substantially increases patient recognition of products containing the same active substance (cf. '*Bakke L W et al. Improved patient safety with new drug packaging design*'. Currently under review for publication: 2011). This effect is especially pronounced in elderly patients. The findings of the study suggest that a standardised design of medicinal products with increased visibility of the Non-proprietary Name may increase patient compliance and decrease the occurrence of patients unknowingly taking two medicines containing the same active ingredient associated with generic substitution. The EEA EFTA States thus invite the Commission to consider mandatory requirements for the standardised and clearly visible display of the Non-proprietary Name on the outer packaging of medicinal products. An abstract of the study can be made available to the Commission by the Norwegian Medicines Agency.

5. ARTICLE 11 PARAGRAPH 4:

In Article 11 paragraph 4 of the Directive, it is stated that the Commission shall have regard to:

'the proportionality of any costs of compliance with, as well as the likely benefits of, the measures or guidelines.'

EEA EFTA Comment to Article 11 paragraph 4 of the Directive:

The EEA EFTA States consider that ensuring the high visibility of the Non-proprietary Name on all prescriptions and external packaging of medicinal products is the key to facilitate the safe filling of prescriptions across national boarders. In a study by Håkonsen ['*Håkonsen H. Generic substitution: additional challenge for adherence in hypertensive patients?'* Current Medical Research and Opinion. 2009; 25(10): 2515- 2521]**,** 5% of patients subjected to generic substitution unknowingly used two generic products at the same time. Based on this study and the pronounced effects on patient recognition of generic products as a result of the high visibility of the Non-proprietary Name, the proposed measure of mandatory and clear display of the Non-proprietary Name on all prescriptions and external packaging of medicinal products seems proportional to the positive and beneficial effect on patient safety.

_____