



PGEU Policy Statement

Recognition of Cross-Border Prescriptions

INTRODUCTION

The scope of cross-border health services and their coverage by national healthcare systems is highly complex across EU Member States. The greatest concern to citizens is the conditions under which they have the right to receive healthcare in another EU Member State. Following the legislative proposal by the European Commission in 2008, and after much negotiation, the European Parliament on 19 January, 2011 adopted a Directive on cross-border healthcare that permits patients to seek treatment in another EU country and be reimbursed at home provided certain conditions are fulfilled. It also made recognition of prescriptions from another EU Member State mandatory. The Directive puts in place a set of measures and guidelines to facilitate this recognition, including a proposal for development of a non-exhaustive list of elements to be included in the cross-border prescription.

PGEU carried out a study in 2008/2009 investigating the feasibility of an EU template, or non-exhaustive list of requirements, that could facilitate recognition of cross border prescriptions. The system of prescriptions in different Member States was investigated. For every country five aspects were considered: the legal basis of the prescription, templates of prescription, general requirements and elements of the prescription, electronic prescription, and recognition of European prescription and the role of the pharmacists in relation to the prescription.

Before presenting our findings and conclusions, we would like to highlight that the role of the pharmacists in relation to the prescription goes beyond what is usually perceived by the patient or authorities. This was clearly appreciated in every country profile. From a public health perspective, pharmacists need to assess, authenticate and validate the prescription. They also need to provide advice to the patient on the medicines' use and follow the rules of substitution in the countries where substitution is in force. In some countries they need to consider different alternatives to the prescribed medicine in cases of urgent need. Moreover there is a significant burden of bureaucracy related to the management and authentication of the

prescriptions. Pharmacists need to record prescriptions for reimbursement purposes, keep records or register the dispensing of medicines under special provision (narcotics, etc). Additionally, it is important to ensure that contact between the prescribing party and a dispensing pharmacist is possible, allowing to identify and prevent potential medication errors and clarify any other issues that may arise.

PGEU EXPERIENCE WITH NATIONAL PRESCRIPTION TEMPLATES

Some major challenges that need to be taken in consideration when developing mechanism of recognition of cross-border prescriptions:

- (I) National templates of prescriptions vary greatly across Member States, from strict form of prescriptions depending on the status of the medicine, to some Member States accepting a simple paper sheet as long as it bears all necessary elements and the prescriber can be identified.
- (II) More than one alphabet exists in the EU territory; we suggest that cross-border prescriptions should be issued in Latin alphabet which is the most common used and widely accepted. Additionally, to ensure readability of the prescription it should be printed opposed to handwritten.
- (III) The name by which the medicine is prescribed varies from State to State. For example, a medicine must be prescribed by INN¹(generic name) in Lithuania and is common practice in the Netherlands, which facilitates identification of the medicine to be dispensed and allows generic substitutions when appropriate. The most complex case for recognition of foreign prescriptions is when a medicine is prescribed by the brand name, which is a case in Greece, Austria, Hungary, Ireland, Turkey, Finland, Switzerland, Slovakia, Slovenia, Sweden, Luxembourg,

¹ International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name (WHO)

etc. The same generic medicines are often branded differently for different markets, or some manufacturers supply only certain regions or countries. As a result a practitioner may be not familiar with the brand name of the medicine prescribed and therefore would not be able to dispense it. However, prescribers need the ability to prescribe by brand in certain circumstances. For example, the therapeutic index of certain brands of anti-epilepsy drugs is very narrow therefore it is recommended that patients should always be maintained on the same brand, moreover some patients become attached to a particular brand, and will become distressed or refuse to comply if offered another brand. An EU prescription has to be supported by a comprehensive database containing information on all medicines authorized in EU27 under national or centralized procedures and available in all Community languages.

- (IV) In some Member States, for purposes of authentication, validation and reimbursement, prescriptions bear a unique bar code or serial number. We therefore need to consider how prescriptions which bear an incompatible code, or no code at all, can be integrated into the system.
- (V) When authenticating a prescription, it is essential not only to identify a patient, but also be able to verify a prescriber. Identification of the prescribing party and the possibility to contact the individual prescriber is essential to maximize patient safety and prevent medication errors occurring. In most EU countries the ability to identify the prescriber is a legal requirement that pharmacist needs to meet before dispensing a medicine. Additionally, it is important to ensure that a pharmacist can contact a prescriber if there are any concerns in relation to prescription. Community pharmacists are used to work closely with their local GPs or specialist doctors, often discussing issues related to prescriptions that come into the pharmacy. Therefore, we strongly believe that this contact has

to be facilitated and encouraged in the framework of cross-border health care.

- (VI) Other prescription elements vary greatly in national templates of Members States and even across various existing templates within one Member State. For example, prescriptions are valid for 5 days in Greece up to an unlimited period of time in Belgium. A prescriber can prescribe 1 medicine per prescription in Hungary, Slovenia, and Lithuania to unlimited number of medicines in Ireland, France and Denmark. We suggest that only one item per prescription should be allowed in the cross-border context in order to facilitate necessary flexibility for patients when obtaining their medicines in different countries or from different pharmacies and in addition, to avoid fraud when adding extra items on the form.
- (VII) For a prescription to be legal it is required to specify an indication for which medicine is prescribed to patients in Denmark. Therefore it is important to consider all the national elements when developing a list of required items for cross-border prescriptions. Such a list should not undermine national prescribing or dispensing practices.
- (VIII) Finally, in some Member States nurse and pharmacist can prescribe independently, when they have completed the requisite qualification; they have the same prescribing rights as a doctor. It is important to respect the rights to prescribe for non-physician prescribers in other countries. Consideration should be given to means of ascertaining whether the prescription is consistent with national restrictions on the categories of medicines which can be prescribed by certain prescribers.

RECOGNITION OF CROSS-BORDER PRESCRIPTION

We believe that, while pharmacy practice varies little across Member States, the legal framework and national prescribing practices and habits of individual prescribers may have direct influence on dispensing procedures. In order to facilitate a

smooth recognition of cross-border prescriptions and most importantly, ensure continuity of cross-border care and maximize patient safety (particularly when preventing medication errors) it is important to ensure that all the necessary authentication features of the prescription as well as essential elements are considered.

Considering the above mentioned differences in the templates of national prescriptions, and bearing in mind different prescribing practices, we argue that creating a mechanism for recognition of cross-border prescriptions is a very complex task and requires extensive consultation with all concerned parties including pharmacists and prescribers. Since many elements (the prescription document, prescriber, patient, etc) need to an effective Europe wise system of authentication may be highly complex and costly.

Considering the findings of our study we suggest that any selected mechanism to facilitate the recognition of cross-border prescriptions should bear these essential elements (Figure 1: Illustration of list of essential elements for cross-border prescriptions as suggested by PGEU):

- (I) **Identification of Patient:** name, date of birth, address, phone number, national ID, health card number and gender.
- (II) **Identification of Prescriber:** name, ID/License number, address, international phone number, e-mail and signature. Additionally we propose to provide a blank field where prescriber can write a note to a pharmacist.
- (III) **Identification of Treatment:**
 - a. Medication prescribed, to be filled in by a prescriber stating INN name (brand name when it is appropriate) of the medicine prescribed, pharmaceutical form, strength,

number of pharmaceutical forms, indication, and duration of treatment, dosage and space for repeats if applicable.

- b. Medication dispensed, to be filled in by a pharmacist stating brand name of the medicine dispensed, pharmaceutical form, number of pharmaceutical forms dispensed, dosage, description of how to take a medicine and additional remarks if applicable.

- (IV) **Authentication and Validity of Prescription:** Issue date and place of a prescription, validity of prescription in months and unique authentication feature.
- (V) **Identification of Dispenser:** name, ID/license number, name of the pharmacy and address, phone number of the pharmacy, signature and dispensing date of prescription.

CONCLUSIONS

As most treatment results in a medication being prescribed to the patient, recognition of cross-border prescriptions is an integral part of wider cross-border healthcare policy. We acknowledge and support patients' right to seek and receive treatment in other Member States, and to have their prescriptions recognised abroad.

However, we would argue that any harmonisation of prescriptions via a list of essential elements should be as comprehensive as possible so as to help guarantee patient safety and continuity of care in the cross-border health care context.

-END-

ANNEX I: ILLUSTRATION* OF A SUGGESTED LIST OF ELEMENTS FOR CROSS-BORDER PRESCRIPTIONS

(I) **Illustration of a PGEU suggested European prescription in the context of cross-border care**

(II) **Patient** Name: _____ Date of birth: DD/MM/YYYY Gender F M
 Address, telephone: _____
 ID/Health Card No.: _____

Prescriber Name: _____ ID/License No.: _____ If applicable: _____
 Address: _____
 Phone No.: (country code + number) Email: _____ *Digital Signature*

Remarks to other HCP: _____

(IIIa) **Medication Prescribed** INN: _____ Brand: _____ Strength: _____ No. of Items: _____
 Form: _____ Indication: _____
 Dosage: _____ Duration of treatment: _____
 How to take: _____
 Number of prescription repeats (if applicable): _____

(IIIb) **Medication Dispensed** Brand name: _____
 Form: _____ Strength: _____
 No. of Items: _____
 How to take: _____
 Additional remarks: _____

(IV) **Issuing Date** DD/MM/YYYY **Issuing Place** City, Country **Validity Period** In months **Authentication feature** 

(V) **Pharmacist** Name: _____ ID/License No.: _____ If applicable: _____
 Pharmacy name and address: _____
 Phone No.: (country code + number) Email: _____ *Digital Signature*

Dispensing Date DD/MM/YYYY

Figure 1: Illustration of list of essential elements for cross-border prescriptions as suggested by PGEU

* This list was drawn from the study conducted by PGEU in 2009 that examined national prescription forms and consulted practitioners on their views on essential elements that cross-border prescription should bear in order to ensure patient safety and continuity of care.