



## PGEU Response

---

*Consultation on measures for improving the recognition of medical prescriptions issued in another Member State*

## **PGEU**

---

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 31 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

### **Preliminary Remarks**

---

PGEU welcomes Commission's consultation on the recognition of prescriptions issued in other Member States. Bearing in mind different prescribing practices and differences in national prescription templates, we suggest 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.

An effective Europe wide system of authentication of prescriber, prescription template, patient, etc may be complex and costly. Therefore we very much welcome this opportunity to contribute to developing 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.

Prior to responding to this consultation we have carried out consultation with some of the stakeholders on bilateral basis. Our position is very much in line with the views of research based pharmaceutical industry (EFPIA) save with one difference of emphasis in connection with the point on the prescriber's recommendation regarding generic substitution. We recognize that prescribers need the ability to prescribe by brand in certain circumstances. Therefore we propose to provide a blank field in the prescription where prescriber can write a note to a pharmacist making a recommendation to dispense a specific brand. This would of course be subject to national dispensing rules, in accordance with the Directive.

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.

The role of the pharmacists in relation to the prescription goes beyond what is usually perceived by the patient or authorities. 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. In addition, 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). Also, it is important to ensure that contact between the prescribing party and a dispensing pharmacist is possible, allowing identifying and preventing potential medication errors and clarifying any other issues that may arise.

Finally we believe that recognition of cross-border prescriptions should be reserved for specific situations and not promote or encourage irrational medicines use as this may undermine national health systems and put patients at risk. In the last years, there have been some cases where "internet doctors" from the Netherlands or the UK have offered their services to German patients, aiming directly at "lifestyle medicines" such as medication that treats erectile dysfunction etc. These patients were asked to fill in an online questionnaire and received their prescription by mail and were not required to visit the doctor personally. We believe that pharmacists from other Member States where such "internet prescriptions" are illegal should not be obliged to accept them. We believe that such practice is unethical and poses a great risk of medicines misuse and improper treatment. In its measures based on Article 11 of Directive 2011/24/EU, the Commission should clarify that doubts about "internet prescriptions" can fall under Article 11 para 1 letter a) ("restriction that is limited to what is necessary and proportionate to safeguard public health"). In addition the same paragraph establishes that national practices governing prescription and dispensing must be respected. Therefore

when writing a prescription requires face to face contact with the prescriber “internet prescriptions” should not be recognised.

## B. Issues in the recognition of cross-border prescriptions

### B.1 Problems in the Recognition of cross-border prescriptions for dispensers

	1	2	3	4	5	6	7	8	9
Authenticating the legitimacy of the prescription									<input checked="" type="checkbox"/>
Authenticating the entitlement of the prescriber									<input checked="" type="checkbox"/>
Understanding the language the prescription was written									<input checked="" type="checkbox"/>
Understanding prescriptions that are hand-written									<input checked="" type="checkbox"/>
Dispensers having insufficient information on the prescription for the national (legal) requirements									<input checked="" type="checkbox"/>
The prescribed drug and/or device not being available on the local (national) market					<input checked="" type="checkbox"/>				
In case substitution is possible: no suitable alternative drug or device being available on the local (national) market	<input checked="" type="checkbox"/>								

### B.2 Which other elements could cause problems in the dispensing of cross-border prescriptions?

In relation to the last two potential problems identified (product not available on the market neither the alternative) in the consultation we believe that if the medicine is prescribed by INN and supported by comprehensive database of medicinal products marketed in the EU such a problem would be minimized. In addition we believe that list of medicines that will be outside of the scope of recognition should take into consideration and exclude those products that are solely marketed in a few member states.

Other prescription elements vary greatly in national templates of Member 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.

In addition, 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.

## C Identifying the prescribed product

### C.1 Which elements in prescription forms contribute to the identification of medicinal products?

	1	2	3	4	5	6	7	8	9
International Non-proprietary Name (INN) / generic name									<input checked="" type="checkbox"/>
Brand name									<input checked="" type="checkbox"/>
Form of administration									<input checked="" type="checkbox"/>
Quantity									<input checked="" type="checkbox"/>
Strength									<input checked="" type="checkbox"/>
Dosage regimen or direction for use									<input checked="" type="checkbox"/>
Intended duration of use									<input checked="" type="checkbox"/>

### C.2 Which other elements could contribute to a better identifying the medicinal product?

Indication is an important element of prescription in particular in cross-border context for identification of medicinal product. Medicinal products are often indicated for different conditions at different doses and dosage regimens. Therefore it is important that pharmacists when dispensing cross border prescriptions are aware of indication that medicinal product is prescribed for in order to prevent prescribing errors to occur and maximize patient safety. At the national context this is often covered by personal ad hoc contact between prescriber and pharmacist when problem arises, which is difficult to imagine in cross border context.

### C.3 Which elements in prescription forms contribute to the identification of medical devices?

	1	2	3	4	5	6	7	8	9
Generic name									<input checked="" type="checkbox"/>
Brand name									<input checked="" type="checkbox"/>
Product type									<input checked="" type="checkbox"/>
Directions for use									<input checked="" type="checkbox"/>
Quantity									<input checked="" type="checkbox"/>

### C.4 Which other elements could contribute to better identifying a prescribed medical device?

N.A.

## D. Identifying the patient

---

### D.1 Which elements in prescriptions contribute to the identification of the Patient?

	1	2	3	4	5	6	7	8	9
Surname									<input checked="" type="checkbox"/>
First name(s) or initials									<input checked="" type="checkbox"/>
Gender									<input checked="" type="checkbox"/>
Date of birth									<input checked="" type="checkbox"/>
Home address									<input checked="" type="checkbox"/>

### D.2 Which other elements could contribute to a better identification of the patient?

National ID number and/or health insurance number would be useful in the cross-border context for reimbursement purposes. In addition to home address we suggest adding e-mail address and a phone number as an additional communication channels.

## E. Improving patient understanding of prescriptions

---

### E.1 Which elements in prescription forms contribute to a better patient understanding of what is prescribed?

	1	2	3	4	5	6	7	8	9
Wording of dosage (written out in full, use of non-Latin terms, etc.)	<input checked="" type="checkbox"/>								
Use of icons (representing what time to take the medicine)	<input checked="" type="checkbox"/>								
Length of treatment									<input checked="" type="checkbox"/>
Instructions for proper use (e.g. "take with food", etc.)	<input checked="" type="checkbox"/>								
Print prescriptions (instead of handwriting)									<input checked="" type="checkbox"/>

### E.2 Which other elements could contribute to a better patient understanding of what is prescribed?

Prescription is usually an order for medication, therapy, or therapeutic device given by a properly authorised person, which ultimately goes to a person properly authorized to dispense or perform the order. In many cases it is retained in

the dispensing pharmacy. Therefore we would argue that it is not the most suitable tool to provide information on prescribed treatment to patients. In the national circumstances doctor would reach an agreement with the patient on the use of any proposed medication, and the management of the condition by exchanging information and clarifying any concerns. The amount of information one gives to the patient varies according to factors such as the nature of the patient's condition, risks and side effects of the medicine and the patient's wishes. This information is reinforced when pharmacist dispenses prescribed medication and can be supported with printed information that is available in majority of EU pharmacy databases. It would be of great help to pharmacy profession if patient information leaflets and SmPCs of all medicines authorised in the EU would be available for download from EMA's website in 23 community languages. Considering that information on prescribed treatment is complex and needs to be tailored to individual patient needs and that prescription is intended to instruct a dispensing party, we argue that initial purpose of prescription should be kept in mind and information provision to patients should be tackled using other means.

## F. Identifying the prescriber

### F.1 What are the main reasons to have clear prescriber identification in prescription forms (minimum of one choice)?

- To verify the legal entitlement of an individual to prescribe in his/her Member State ("prescriber authentication"),
- To enable contact between dispenser (pharmacist, etc.) and prescriber (physician, etc.) to allow for a better understanding of the prescriptions (e.g. to understand unclear handwriting).

### F.2 How can prescriber authentication best be guaranteed?

	1	2	3	4	5	6	7	8	9
"Paper" solutions using elements in prescriptions to identify the prescriber such as name, address, qualification, prescriber code, etc.					<input checked="" type="checkbox"/>				
"Paper" solutions using elements in prescriptions to 1) identify prescriber such as name, address, qualification, prescriber code, etc. A 2) enable contact with the prescriber such as phone/fax number, email etc.							<input checked="" type="checkbox"/>		
<b>National</b> prescriber databases accessible to dispensers(e.g. accessed internet) using information on the prescription as a starting point.					<input checked="" type="checkbox"/>				
An <b>EU-level</b> prescriber database accessible to dispensers (eg via internet) using information on the prescription as a starting point.							<input checked="" type="checkbox"/>		
A "paperless" e-prescription solution, eg allowing dispensers verify information in a central repository on prescriber, prescription and patient.			<input checked="" type="checkbox"/>						

### F.3 Which other solutions could improve prescriber authentication?

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 many 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 working 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.

### F.4 Which elements in prescription forms contribute to the identification of the Prescriber?

	1	2	3	4	5	6	7	8	9
Surname									<input checked="" type="checkbox"/>
First name(s) or initials									<input checked="" type="checkbox"/>
Professional qualification									<input checked="" type="checkbox"/>

Work address									<input checked="" type="checkbox"/>
Details for direct contact with prescriber (either telephone, fax or email)									<input checked="" type="checkbox"/>
Signature (written or digital)									<input checked="" type="checkbox"/>

**F.5 Which other elements could contribute to a better identification of the prescriber (optional)?**

In addition we believe that it is essential to have a unique national ID number of the prescriber or his license number. This may help identify a prescriber in the national health professional register.

**G. Other Information**

---

**G.1 Which other information is necessary in prescriptions?**

	1	2	3	4	5	6	7	8	9
Indication for prescribing									<input checked="" type="checkbox"/>
Date of prescription									<input checked="" type="checkbox"/>
Period that prescription is valid									<input checked="" type="checkbox"/>
Generic substitution possible (yes/no)?	<input checked="" type="checkbox"/>								

**G.2 Which other elements would you add?**

We believe that the proposal above among other items to allow prescriber to disable generic substitution maybe harmful as in case the specific brand of the medicinal product is not available in the dispensing country. This provision will prevent a pharmacist to dispense an alternative medicinal product to the patient. This may leave patients without necessary and sometimes time sensitive medication. Moreover, the Directive in Article 11 (1) explicitly says that recognition of prescriptions ‘shall not affect national rules governing prescribing and dispensing, <...>, including generic or other substitution’. ‘Locking a prescription’ in those countries where generic substitution is allowed will infringe national rules of dispensing.

However, we recognize that 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. Therefore we propose to provide a blank field in the prescription were prescriber can write a note to a pharmacist making a recommendation to dispense specific brand.

**H. Comments**

---

**Please find attached PGEU Policy Statement on recognition of cross-border prescriptions.**

**END**