Submission to the Public Consultation on what actions will enable the EU to improve the recognition of medical prescriptions issued in another Member State.

Additional Comments

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007. It is charged with, and is accountable for, the effective regulation of pharmacy services in Ireland, including responsibility for supervising compliance with the Act. It works for the public interest to protect the health and safety of the public by regulating the pharmacy profession and pharmacies.

The PSI is committed to sustaining, assuring and improving professional standards and, therefore, maintaining the health, care, safety and wellbeing of patients, and is committed to working with other organisations which have a particular focus on the protection and enhancement of public health. The PSI appreciates this opportunity to contribute to the Public Consultation on what actions will enable the EU to improve the recognition of medical prescriptions issued in another Member State and is supportive of initiatives which contribute to improving public health and facilitate effective prescribing and dispensing.

Current PSI guidance to pharmacists on the recognition of prescriptions issued in another Member State

The PSI currently provides the following guidance to pharmacists on the recognition of prescriptions issued in another Member State:

According to Ireland's Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) "prescription" means a prescription issued by a registered medical practitioner, or registered dentist or by a practitioner of equivalent status practising in another Member State with the address of the practitioner in that Member State, as the person issuing the prescription, shown on the prescription. The practitioner concerned can't be connected with any practice of medicine or dentistry in the State (Ireland) and the prescription can't have been issued with a view to enabling supply of a medicinal product by mail order.

Provided the above conditions are met and the prescription is not for a medicinal product containing a drug specified in Schedules 1, 2 or 3 of the Misuse of Drugs Regulations 1988 (as amended) and the prescribed medicinal product has a Marketing Authorisation (PA number) in this State, then it permissible for a prescription issued by a practitioner in another Member State to be dispensed by a pharmacist in Ireland. While this legislation therefore allows a prescription issued by a practitioner in another Member State to be dispensed by a pharmacist, a pharmacist can only dispense a medicinal

product that is prescription-only on foot of a valid prescription and it is the pharmacist's responsibility to establish the authenticity of any prescription presented to be dispensed.

If a pharmacist receives a prescription issued in another Member State, he/she must satisfy himself/herself that it satisfies the requirements for a prescription as set down in the regulations and given above. The pharmacist must be satisfied that the prescription is written by a practitioner of equivalent status to a registered medical practitioner or dentist in this country. They may currently do this by contacting the prescribing practitioner's official registration authority in the Member State concerned and confirming that he/ she is a registered medical practitioner or dentist in that Member State and that his qualification is equivalent to that of a registered medical practitioner or dentist in this country.

In addition, it should be noted that all pharmacists in Ireland are obliged, under regulation 9 of the Regulation of Retail Pharmacy Business Regulations 2008, to undertake an initial review of the prescription regarding the medicinal products therapeutic appropriateness for a patient. The pharmacist must also ensure each patient has sufficient information and advice on the proper use and storage of the product, and must offer to discuss all matters they in their professional judgement deem significant.

Restrictions on the recognition of prescriptions issued in another Member State

It is important that Member States are enabled to restrict the recognition of prescriptions when necessary and proportionate to safeguard public health. In Ireland, prescriptions from practitioners not registered in Ireland are not accepted for controlled drugs and unauthorised medicinal products due to the additional risks to patients if such products are not appropriately prescribed.[1] This also ensures that the prescribers of these products are subject to Ireland's regulatory and fitness to practice functions. It is, therefore, necessary that products containing drugs or substances defined as narcotic or psychotropic by the international United Nations conventions of 1961 (on narcotic drugs) and 1971 (on psychotropic substances) are excluded from the scope of this initiative. This will also enable Member States to exercise appropriate controls over the prescription, possession and use of narcotic or psychotropic products in their efforts to combat drug abuse and drug related crime.

Improving the recognition of prescriptions issued in another Member State

The PSI supports measures which:

- enable health professionals verify the authenticity of a prescription, by increasing their ability to identify whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so
- facilitate contact between the prescribing party and dispensing party in order to facilitate a discussion of all product and patient care related issues and to determine if substitution with a corresponding product is permissible
- facilitate the correct identification of medicinal products and medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns
- facilitate the comprehensibility of the information to patients concerning the prescription
- enable the establishment of electronic prescriber registers at both Member Sate and EU level.

[1] Misuse of Drugs Regulations 1988 (as amended) and Medicinal Products (Control of Placing on the Market) Regulations 2007 and 2009

The PSI supports all measures which improve the information on prescriptions issued in another Member State, which ensure sufficient information is on prescriptions to protect patients wellbeing and safety and which enable the pharmacist to identify all necessary issues prior to dispensing a medicine or medical device.

The establishment of a central database of all registered practitioners (at EU level), which contains all relevant information in all relevant languages and which all pharmacists can access, would be the preferred option for establishing the authenticity of a prescriber.

In addition, it is noted that central databases of all authorised human medicinal products and medical devices are currently being developed by the European Commission, via the EUDAMED and Eudrapharm/ European Medicines Webportal initiatives. It is important that these databases include all relevant information on the products, including the medicinal products' Summaries of Product Characteristics and Patient Information Leaflets, in all relevant languages and that all pharmacists can access these databases.

The PSI has provided responses to each of the questions posed in this public consultation survey. In these responses the options provided have been ranked from most important to least important in each relevant question. However, it should be noted that the PSI considers all presented options, including those which have been classified in our submission as the least important/ relevant aspect for a particular question, necessary for the correct identification of the prescriber, patient, medicine or medical device and/or for establishing the validly of a prescription, its appropriateness for a patient or for providing instructions and advice on a product's use. Therefore, the PSI submits that all of these elements should be included in the prescription or, where relevant, accessible to the pharmacist by another appropriate means.