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Formal Submission of the Pharmaceutical Society of Ireland on the European Commission's Proposed Directive on Cross-Border Healthcare

Introduction

The Pharmaceutical Society of Ireland (PSI) is the statutory regulator of pharmacists and pharmacies in the Republic of Ireland. The PSI carries out this function in the interests of public health and patient safety. As a statutory regulatory body, the PSI welcomes the opportunity to present its formal views on these important matters.

The PSI considers that the proposal to bring forward a directive dealing with patients' right to cross border healthcare is important, timely and in the interests of patients throughout the European Union (EU). As outlined in the *Communication from the Commission*, the PSI agrees that there are very significant issues that arise in this proposal for the health, welfare and safety of patients that require serious consideration. As in all aspects of healthcare service provision, guaranteeing the quality and safety of healthcare is and has to be the paramount consideration.

Pharmacists play an important role in cross border provision of health services. Pharmacists through the wide network of pharmacies in the Member States, are the health professionals who European citizens see most often, and are deeply involved with the treatment of individuals moving between Member States. Pharmacists and pharmacies are generally more accessible than general practice surgeries and many other health professionals. Frequently pharmacists provide health care services to travellers, tourists, short and long term residents or cross border care users. The pharmacist is a key player in counselling and referring patients to other professionals or to the hospital. Pharmacists are also responsible for the follow up of pharmaceutical treatment and frequently play a central role for patients in coordinating healthcare received from a number of healthcare professionals and providers. The PSI welcomes the opportunity to respond to the consultation given the role pharmacists play not only in health systems generally, but in cross border provision of health services.

According to the Commission the draft directive seeks to provide that:

1. Patients have the right to seek healthcare abroad and be reimbursed up to what they would have received at home

1.1 Guaranteeing the quality and safety of cross-border healthcare

The PSI as the regulator of pharmacists and pharmacies in Ireland hold patient safety of paramount importance. The PSI agrees that patients have the right to seek healthcare abroad and be reimbursed accordingly, however, it would be necessary for high standards of healthcare across all Member States to be in place.

The Proposal for a Directive and Communication from the Commission Documents, quite rightly, identify guaranteeing the quality and safety of cross-border healthcare as a key issue with regard to this proposed directive. It is the PSI's view that this is the most critical issue associated with this proposed directive and has to be the fundamental basis for the Directive.

Patients deserve the same level of care no matter where they receive it in the EU. Consequently, there have to be real and meaningful uniform standards for what is accepted as proper, safe, effective, appropriate care throughout the Community.

While recognising the primacy of the responsibility of Member States in the area of healthcare services, there must be proper oversight of the delivery of safe and high-quality healthcare amongst the Member States. The EU should concentrate on facilitating the highest possible level of co-ordination and consultation between EU Member States to coordinate standards in the provision of health services. It is the PSI's view that an EU authority with responsibility for overseeing the quality and safety of health services should be put in place to so that the quality and safety of cross-border healthcare can be properly guaranteed in the interests of EU patients.

1.2 Regulation of healthcare providers and healthcare professionals

A core aspect of guaranteeing the quality and safety of cross-border healthcare is the system of regulation of healthcare providers and healthcare professionals in each of the Member States. With regard to healthcare providers, it is essential that providers such as hospitals, clinics, and other care providers in all Member States are properly licensed, audited, regulated and that proper systems of accountability exist.

In addition, it is essential that proper systems of regulation of health professionals exist also. The professional competencies of the health professionals providing care and treatment must be assured through effective regulatory systems across the EU. The EU should maximise opportunities for consultation and convergence in respect of clinical, educational and continuing professional development standards within and between Member States. The Professional Qualifications Directive establishes systems to allow for the movement of health professionals between Member States and minimum training requirements but it does not establish systems to raise professional competence throughout the EU or systems of accountability. Moreover, the proposed Directive makes no reference to requirements for healthcare professionals to demonstrate on an ongoing basis their continuing competence.

2. Member States are responsible for healthcare provided on their territory

The proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare outlines that the aim of the directive is to ensure that "the requirements to ensure that healthcare is provided according to common principles and clear quality and safety standards are applicable to all healthcare services in order to ensure the freedom to provide and obtain cross border healthcare." However the proposed framework also states that "it remains up to Member States to decide on the standards for healthcare in their country." The proposal does not then require each Member State to make public what such standards of competence should be for all healthcare professionals and as defined by the national healthcare regulatory bodies. For cross-border healthcare to operate in line with the framework's stated objectives, then shared principles on the regulation of health professionals would be required among all Member States.

3. European co-operation on healthcare

3.1 Access by patients to appropriate information regarding the cross-border health services

As outlined in the consultation documentation, under this scheme it will be essential that patients can access appropriate information so that they can make an informed choice about the treatment. It is essential that the information provided to patients by health service providers is fair and balanced; not only advertising the benefits of certain treatments / service providers but also outlining the risks associated, and information about a patient's course of redress in the event that they are dissatisfied with or are harmed in any way by the service. In the interests of patients availing of cross-border services, there is also a need for greater transparency of health professional and health service regulation. Public registers of health professionals and health service providers should be available in Member states so that patients can easily identify prescribers, professionals and other treatment providers and if necessary to verify and validate the professional standing of the health professionals providing care.

The international evidence illustrates that the most practical way for patients to have access to information on their current or prospective healthcare providers is via the publication of public registers of such practitioners. Such registers should now be available via the Internet and should allow the patient to access the relevant data by searching either via the name or via the registration number of the healthcare provider (or indeed by searching via geographical area). The relevant data that should be in the public domain should be, at a minimum, the name, registration number and practice address of the healthcare professional, the date of their first registration on that register, the expiry date of their current registration, and any conditions or restrictions on their practice or suspensions should this be the case. Healthcare professionals who are not registered, be it for voluntary reasons or if struck off for whatever reason, should not appear on such register.

It is outlined in the consultation documentation that it is the responsibility of each Member State to police the provision of information and advertising of services provided in that state. However, it will be necessary to clarify the responsibility and jurisdiction of Member States for the control of information provision, where the service is provided in one Member State but is advertised directly into another state. Policing of advertising to ensure that it is fair and balanced in the interests of patients will be a significant undertaking by Member State authorities. Issues of language also arise because patients will require access to information, counselling and professional advice in their native language.

The proposed directive points out the need for co-operation between providers, purchasers and regulators of different Member States. However, it does not mandate that healthcare regulatory bodies should define and share transparent and relevant information with regard to the free movement of health professionals, be it of a permanent or of a temporary or occasional nature, or indeed the information that patients should have access to in the event of patient mobility. Information that competent authorities should share should be defined as information that covers sanctions and undertakings arising from criminal behaviour, professional misconduct, professional incompetence, poor performance and also sanctions imposed as a result of impaired fitness to practise by reason of ill health. In addition to such information, the exchange of information between competent authorities should also extend to checks, if required relating to professional qualifications, identity checks if reasonable doubt exists and information relevant to certificates of current professional status (also known as certificates of good standing).

3.2 Provision of emergency or post-treatment care to cross-border patients

Another central patient safety issue that will require consideration as part of the development of this proposed directive is the provision of emergency treatment and post-treatment care to the cross-border patient when they return home. It will be necessary to clarify how post-treatment care is to be managed, and what the responsibilities of the service provider in the host Member State should be to that patient.

In addition, issues such as patient mobility immediately post-treatment will have to be considered. It is stated that EU patients should not be treated more favourably that nationals in the state in which the service is provided. It will therefore be necessary to consider how post-treatment care is to be provided to a cross-border patient, particularly where they may not be in a position to fly/travel home directly after

certain procedures and therefore will require longer convalescent care in the host state than a national of that state.

3.3 Mechanisms for redress by cross-border patients

It is outlined in the consultation documentation that medical errors and adverse incidents are of serious concern to citizens and that harm can arise in up to 10% of cases. Consequently, issues of liability and patient access to systems of redress are pertinent issues. Real and accessible systems of redress must be available to patients receiving cross-border care. This should include systems of redress for serious harm done to patients but also for less serious complaints that patients may have regarding the treatment or care provided. Jurisdictional issues such as differing laws relating to negligence, professional misconduct, levels of compensation etc. in different Member States will require clarification as part of this proposed Directive to ensure that patients can obtain appropriate redress. There is also a need to monitor trends and patterns in relation to adverse incidents or systems failures in respect of cross-border care and the development of an EU Patient Safety Authority should be considered by the Commission.

4. Health technology assessment

Health technology assessment is a multidisciplinary process that summarises information about the medical, social economic and ethical issues related to the use of health technology. This would help to reduce overlap and duplication of efforts and hence promote the effective and efficient use of resources. The PSI would be very supportive of such an initiative which would increase co-operation between national authorities or bodies and support provision of objective, reliable, timely, transparent and transferable information on the short and long term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies.

5. E-health

Information and communication technologies have enormous potential to improve the quality, safety and efficiency of healthcare. However, in order for it to be successful there is a need for shared formats and standards that can be used between different systems and different countries which are currently across the European Union. The directive will allow for such formats and standards to be put in place, enabling informal co-operation and individual projects to be continued and generalised on a more solid and sustainable basis. As there is currently a huge difference across Member States regarding the level of e-health provided, if any in some instances, the PSI supports that the proposal does not oblige any introduction of e-Health systems or services but aims at ensuring interoperability one the choice of introducing such systems is done by Member States. However, the EU need to be cognisant of standards regarding e-Health across Member States and a system should be put in place to ensure the same standard of high quality care is delivered across all Member States.

6. Comments specifically related to the pharmaceutical care of cross-border patients

It is the pharmacist's responsibility to confirm the authenticity of prescriptions, verify the content of the prescription and act as a second check to ensure that the prescribed medicines are appropriate for the patient, having regard to the patient's health, history, condition treated and other medication taken by the patient. In the performance of this function it is essential pharmacists have access to the necessary information regarding the patient's history and can contact the prescriber to clarify and verify the patient's treatment. In the context of pharmacy the authenticity and standard of the prescription should be validated through the adoption and the immediate introduction of an EU standard prescription format. The use of technology including security systems should greatly enhance the inter-operability of Member States in relation to such standardised prescriptions.

6.1 Recognition of EU prescriptions

With regard to facilitating the cross-border pharmaceutical care of patients, a central issue will be mechanisms for the recognition of EU prescriptions. It is essential that there is an EU-wide system which will allow pharmacists to confirm authenticity of prescriptions. It will also be essential for pharmacists to be able to verify the content of the prescription, particularly where there are different prescribing languages, prescribing practices, different products and formulations and to be able to clarify issues relating to the medicinal therapy with the prescriber in the Member State of treatment. Another problem regarding EU prescriptions is the differences in licensing of different drugs between countries for example a prescription from one Member State could be for a drug that is not licensed in another Member State.

6.2 Pharmacist counselling of patients including the provision of information and advice on medicines

An integral part of the role of the pharmacist is in the provision of information and counselling to patients regarding their medicinal therapy. It is essential that the pharmacist has access to the patient's full medicinal therapy history, including prescription and non-prescription therapies in order that they can counsel patients appropriately on the use of their medicines.

There if no mention in the proposed directive on the need to ensure the linguistic competence of the health professional. In the interest of patient safety it is fundamental that the health professional has adequate linguistic competence in a language that is understood fully by the patient.

6.3 Access to medical records and the maintenance of patients' medical files

A further patient safety issue which must addressed as part of the consideration of this proposed directive is the issue of ensuring that the cross-border patient's file is maintained and that health professionals requiring access to those records in the interest of the patient can gain access to the relevant information. The system of cross-border patient mobility could be detrimental to the patient's health if health professionals in both countries are not able to quickly and openly access the patient's medical records.

This is an issue of particular importance to pharmacists in the performance of their role, who will play a role in the care of the patient on their return home. It is essential that if matters arise regarding the medicine and pharmaceutical care of the patient, that the patient's pharmacist will be able to access the relevant health professionals to clarify issues in the patient's interest.

Conclusion

Pharmacy provides a very high level of care and treatment within the EU. Pharmacists work in the most comprehensive and easily accessible network of care, treatment and service across the EU. Pharmacists play very significant and important roles as both sources of information/advice and provision of care and treatment in the community, in hospitals and in specialist institutions.

- The proposed directive should define real and meaningful uniform standards for what is accepted as proper, safe, effective appropriate care throughout the EU.

- The proposed directive should make it mandatory for all competent authorities in each Member State to publish an electronic and searchable register for healthcare professionals and healthcare providers

so that patients may make informed and evidence-based decisions on the choice of their healthcare provider.

- The proposed directive should require Member States to make public their minimum standards of competence for each healthcare profession and also the means by which healthcare professionals are required to demonstrate their continuing competence.

- The proposed directive should require Member States to define and share transparent and relevant information with regard to the free movement of health professionals.

- As part of the proposed directive it will be necessary to clarify how post-treatment care is to be managed, and what the responsibilities of the service provider in the host Member State should be to the patient.

- Further clarity is necessary with respect to jurisdictional issues such as differing laws relating to negligence, professional misconduct, levels of compensation etc. in different Member States in order to ensure that patients can obtain appropriate redress.

- The proposed directive should require the health professional to be able to communicate to the patient in a language that is understood fully by the patient.

- There is a need for the sharing of patient's information being cognisant of data protection laws across Member States. The system of cross border patient mobility could be detrimental to the patient's health if health professionals in both countries are not able to quickly and openly access the patient's medical records.