Dear Sir/Madam

Consultation on the European Commission’s proposals for a Directive on the application of patients’ rights in cross-border healthcare

The Practice Committee of the Pharmaceutical Society of Northern Ireland has recently reviewed the Department of Health in England’s consultation document on the European Commission’s proposals for a Directive on the application of patients’ rights in cross-border healthcare.

Having considered the proposals contained in the consultation we make the following principal comments:

Support for the Draft Directive’s Aim

As the regulator for pharmacy in the only part of the United Kingdom to share a land border with another EU state, we support the rationale for the proposed legislation: that EU citizens should be able to exercise a right to access treatment in other EU States under Article 49 of the Treaty establishing the European Community. It is recognised however that the legal frameworks as currently exist are unclear and it is therefore desirable for the UK Government to work with European member states to address known anomalies and areas of uncertainty through the application of a new Health Directive.

The stated aim of the Directive: “to establish a general framework for the provision of safe, high-quality and efficient cross-border healthcare in the EU and to ensure free movement of health services and a high level of health protection” is supported by the Pharmaceutical Society of Northern Ireland.

Standardised Prescription Scripts across Europe
The Pharmaceutical Society of Northern Ireland supports greater standardisation in prescription scripts across Europe to:

- aid cross-border access to healthcare services by reducing “legitimate and justified doubts about the authenticity or content of an individual prescription” that, under Article 14 of the proposed directive could lead to prescriptions not being recognised.
- assist pharmacists in combating any counterfeit prescription claims; and
- help prevent error.

We therefore firmly support the statement within Article 14 of the Draft Directive that the Commission will bring forward measures to facilitate recognition of prescriptions, including an EU-wide prescription template and interoperability of e-prescriptions.

**Standardisation across Europe of health professional registers**

In making dispensing decisions in relation to non-UK prescriptions, UK pharmacists would be greatly aided by a common system of health professional registration across borders and support calls for a legal requirement upon every member state to hold a publicly accessible database of registered Doctors, Pharmacists and Dentists, in common with current UK practice. This would serve to simplify matters should a pharmacist wish to check the bona fides of a prescriber mentioned on a prescription script or discuss the prescription details.

Such databases should be real-time, web-based and publicly searchable, preferably in accordance with character and health checks such as those required by UK health professional regulators.

**A legal duty upon health professional regulators to share Fitness to Practise information**

The Pharmaceutical Society of Northern Ireland firmly supports calls for a new legal requirement upon health professional regulators across Europe to share information with each other in relation to Fitness Practise issues. This should be supported with appropriate IT infrastructure. We remind the UK Government that such a legal requirement was supported by a vote in the European Parliament in May 2007.

The pharmacy regulator in Northern Ireland endorses the contention of the Alliance of UK Health Regulators on Europe, that, “*Placing a new legal duty on regulators across the EU to exchange registration and disciplinary information, and to act on it, will provide the tools to enable free-movement whilst at the same time ensuring the safety of patients and the public.*”

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2. Ibid.
We urge the UK Government to have awareness that although Directive 2005/36/EC requires a level of information exchange between regulators it is currently hampered in its effectiveness by over-rigid national interpretations of data protection legislation. A new and explicit legal duty upon health professional regulators to share Fitness to Practise information to a common standard could thus go a great way to resolving this difficulty and provide greater protections for patient safety and should therefore be pursued by the UK Government in ongoing negotiations on the Directive.

The new Health Directive should also empower regulators to check the language competency of healthcare practitioners who intend to provide healthcare services on their territory.

**The need to correct inconsistencies in Health Professional Regulation across the EU**

As the growth in health professionals working across the EU continues the UK public needs reassurance that standards of conduct and fitness to practise across the EU match those of the UK. We therefore urge the UK Government to pursue a negotiating position calling for a minimum standard of professional regulation across Europe. This is in line with the Commission’s stated belief that “patients should be able to rely on clear principles for quality and safety for healthcare so patients can access cross-border healthcare with confidence” (p11).

By way of example, some Member States maintain a strong distinction between professional and private conduct and would not consider imprisonment for a crime unrelated to professional practice as impinging on a practitioner’s right to practice. This becomes particularly pertinent for UK citizens in respect of Directive 2005/36/EC which gives EU health professionals the right to provide health services on a temporary and occasional nature in the UK based on that professional’s right to practice in their home Member State, rather than the Member State in which they practice.

The forthcoming Health Directive to clarify patient rights is therefore an ideal opportunity to correct some of the inconsistencies that currently exist in health professional regulation across the EU, and in particular, to amend Directive 2005/36/EC so that a professional’s right to practice in another EU state is based on the standards of the state in which they seek to practice.

**Recognising pharmacist and nurse prescriber prescriptions across borders**

Any new European legal framework for an EU citizen’s right to access health services across borders should make it possible for pharmacist and nurse prescriptions to be recognised across the 27 EU states. Without this clarity, patients receiving prescriptions from their local pharmacist in the UK may not be able to access vital health services in another EU country.
**Sharing Patient Data**

The pharmacy regulator in Northern Ireland supports the Draft Directive’s intentions to enable patients accessing treatment in another Member State to access their medical records subject to data protection provisions. This will be an important aid to patient safety but should obviously be supported by appropriate data protection protocols.

**Impact of the Directive**

The Department seeks views from stakeholders as to the likely impact of the Directive on UK health services. We urge the Department of Health in London to correspond with its counterparts in the Department of Health, Social Services in relation to likely impacts in Northern Ireland, the only part of the United Kingdom to share a land border with another EU state. The Pharmaceutical Society of Northern Ireland certainly envisages ongoing challenges in terms of professional regulation and is working closely with the Pharmaceutical Society of Ireland on these matters.

I hope this brief submission is informative as the UK Government finalises its negotiation position on the forthcoming Directive on Patient Rights.

Yours sincerely,

Mark Nelson
Chair of the Practice Committee
Pharmaceutical Society of Northern Ireland

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The Pharmaceutical Society of Northern Ireland is the regulatory and professional body for pharmacists in Northern Ireland. It exists to register, regulate and develop pharmacists and to promote the pharmacy profession within Northern Ireland, ensuring public safety and addressing public concerns. The Society currently maintains a register of over 2,000 pharmacists and over 500 premises registered within Northern Ireland.