The Pharmaceutical Society of Ireland

Formal Submission of the Pharmaceutical Society of Ireland in respect of Consultation Regarding EU Community Action on Health Services

Introduction

The Pharmaceutical Society of Ireland (PSI) is the statutory regulator/competent authority of pharmacists and pharmacies in the Republic of Ireland. The PSI has a responsibility as a statutory body to ensure that its views are taken into account and welcomes the opportunity to present its formal views on these important matters. The decision of the EU Parliament and EU Council to exclude health services from the Services Directive, a decision which reflects the fact that health services require special consideration presents the health sector and policy and political decision makers with an opportunity to reflect on how best to meet the challenges of protecting the public and patients within the European Union Member States.

The PSI welcomes the opportunity to respond to this consultation given the role of Pharmacists not only in health systems generally, but in cross border provision of health services particularly. 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 more accessible than doctors and other health professionals. Frequently pharmacists provide health care services to travelers, tourists, short and long term residents or cross border care users. The pharmacist is a key player in counseling and referring patients to other professionals or to the hospital. Pharmacists are also responsible for the follow up of pharmaceutical treatment and are an important asset for ensuring continuity of care.

Key issues relevant to patients and members of the public and matters worthy of consideration include:

1) Quality and Standards of Prescriptions in the European Union.

2) Adverse reactions to medicines or other complex therapeutic regimes which emerge on return home.

3) Complications arising from the use of either prescription or non-prescription treatment which are either non-compatible or contraindicated. The key from the public patient safety and protection perspective is that the European Union must have safe systems in place to ensure high levels of safety and probity of services to patients who have the right to obtain cross-border care.

EU Questionnaire

The following is our reply to the EU questionnaire to which it was requested we respond:

Question 1:
What is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

The PSI, the statutory regulator/competent authority of pharmacists and pharmacies in the Republic of Ireland, agrees with the preliminary analysis and findings made by the study mentioned in the consultation "patient mobility in the EU", however, in order to provide an accurate and comprehensive assessment of the accessibility, quality and financial sustainability of healthcare systems a comprehensive review of the concepts of care treatment and practice must be part of any consideration of this question. The PSI's view is this should not be limited to hospital treatments and some specialized medical treatments such as obstetric care, cardiovascular services, respiratory services, etc. Pharmacy care treatment and practice are essential components of modern healthcare systems across the EU. The treatment of patients is often continuous and involves close collaboration with other health professionals. Patients falling ill may require incidental treatment or episodic care with the continuing treatment process resting with health professionals in the home state. Alternatively patients may go abroad for a complex care and treatment process or procedures which give rise to a long term need for continuing supervision of the process. Normally patients will move between Member States for such complex care and treatment while receiving their routine care in their home state.

Question 2:
What specific legal clarification and what practical information is required by whom (e.g. authorities, purchasers, providers, patients) to enable safe, high quality and efficient cross-border healthcare?

Professional Competencies

The PSI believe that it is important to protect the quality safety and welfare of patients and a number of issues are worthy of consideration to solve the difficulties and the risk that may arise. The professional competencies of the health professionals providing care and treatment must be assured through effective regulatory systems across the EU. The EU should maximize opportunities for consultation and convergence in respect of clinical, educational and continuing professional development standards within and between Member States.

Standardised Prescription

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.

Public Registers

All frontline health professionals, particularly those involved in irreversible care and treatment, should be on public registers which are easily accessible and available online to EU citizens. It should be possible to easily identify prescribers, professionals and other treatment providers and if necessary to verify and validate the professional standing of both the prescriber and the dispenser.

The establishment of common standards for prescriptions would greatly facilitate the evaluation and assessment of systems protecting both patients and the public. There are minimum international standards approved by WHO that would greatly assist the Commission. It is essential that the relevant authorities are in a position to validate both the people and the quality of the documentation on which EU citizens rely for their health and wellbeing.

European Medicines Database and Traceability of Medicines

The Commission should give high priority to the establishment of a comprehensive database of medicines as envisaged by recent EU legislation. It is essential from the perspective of regulators/competent authorities that such information should cover the legal status of medicines including details of whether the medicine is subject to license and/or prescription in the member states.

The traceability of medicines is critical to patient safety and welfare and to the growing challenge of counterfeit medicines. The evaluation of internet sales presents real problems for citizens of the EU. Therefore it is imperative that medicines in the European Union are supported by an EU mechanism of traceability which is endorsed by all member states.

Question 3:
Which issues (e.g. clinical oversight, financial responsibility) should be the responsibility of the authorities of which country?

It is the view of the PSI that notwithstanding the primary role of member states in matters relating to the regulation of profession and service delivery that the Commission must exercise some oversight in respect of clinical and regulatory matters. The EU has a duty of care, welfare and safety to its citizens. Failure to exercise such oversight may very well result in litigation against Member States and the EU in the future.

Question 4:
Who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

Quite clearly in most cases the responsibility will be on the member state where harm arises, or the country to which the patient moves to for treatment, and not the patients member state. There should not be a separate substantive rule on criminal negligence for cross-border patients as this will lead to confusion and complex litigation. The EU should ensure that all frontline health professionals are registered in their member state and that they are covered by adequate professional indemnity insurance. This is the case for

all health professionals and service providers in the Republic of Ireland. However, failure to monitor trends and patterns in relation to adverse incidents or systems failures in respect of cross-border care would be a most serious omission on the part of the Commission. The development of an EU Patient Safety Authority along the lines of similar bodies in aviation and the financial sector is to be commended and should be considered by the Commission.

Question 5:
What action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital service accessible to all? (for example by means of financial compensation for their treatment in 'receiving' countries)

This is essentially a matter for financial authorities and those in service delivery, however, from the point of view of patients and members of the public any balanced medical and hospital services accessibility must provide for professional follow-up in such areas as pharmacy, in the interest of patient care and the best therapeutic benefit. Primary care practitioners and clinical health professionals such as pharmacists must not be excluded from any balanced hospital or medical service accessibility.

Question 6:
Are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by community legislation?

The view of the PSI is that the Professional Recognition Directive be implemented effectively across the EU. This directive needs considerable enhancement to ensure all registered health professionals can be held accountable. In addition the Commission should mandate that all health service providers and health service delivery entities are registered and licensed to ensure accountability in every member state in which they provide the service.

Question 7:
Are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States – such as healthcare providers and social security institutions – suggest in order to facilitate cross-border healthcare?

The PSI is committed to working with the Commission in relation to the Internal Market Information System. This system will facilitate the effective transmission of information relating to migrant professionals who move to other Member States. The Commission will gain significant benefits and added value from monitoring the outputs of this information system. Consideration should be given to any EU-wide manpower planning process to ensure the needs of EU citizens can be met in addition to any international obligations that arise for support for the developing world.

The public health and wellbeing of citizens of the Member States is vital for a sustainable economic and social system across the EU. In the area of pharmacy a number of legal certainties have already been referred to, including the capacity to trace both medicines and personnel, a standard for EU prescriptions and to have an oversight on the competency of the health professionals.

Question 8:
In what ways should European action help support the health systems of the Member States and the different actors within them? Are there areas not identified above?

Patient safety, public protection and the health and well-being of the citizens of the EU are vital to all of the Member States, in order to sustain its economic and social viability. The EU Commission should give consideration to the performance measurement of key fundamentals of health and well-being including lessons to be learned from adverse incidents and system failures. Health protection and social protection in the EU should be underpinned by new structures which will facilitate the promulgation of guidelines on best practice, minimum standards and also enable the member state to work jointly to achieve best patient value and best outcomes. The Member States of the EU have a vested interest in ensuring there are adequate numbers of health professionals competent and capable of meeting the needs of its citizens. The EU must fund health services research, support cutting edge clinical research, and ensure that the standards of undergraduate and postgraduate education across the EU are capable of supporting the next generations of EU citizens in respect of their health and ongoing welfare needs.

The threat of an influenza pandemic or other serious public health threat must be capable of being managed on a federal level as well as within the Member States. Resources and personnel must be capable of being moved within the EU to contain and deal effectively with such threats where the risk of high levels of mortality and morbidity would threaten the viability of the EU.

Question 9:
What tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through community legislation and what through non-legislative means?

While recognizing the primacy of the responsibility of Member States the EU should concentrate on facilitating the highest possible level of co-ordination and consultation between EU Member States to solve the problems that emerge in the health sector. The issue of equal access to high quality cost effective care cannot be ignored. The EU should also give consideration to consultation and co-ordination of efforts by the regulators and the various frontline health professions to ensure the maximum level of convergence on codes of conduct, professional standards, professional education and accountability. The PSI perceives this to be complementary to the role of Member States.

The EU Commission should strengthen its legislative frameworks and management capacity to deal effectively with public health emergencies and natural and other disasters which have the potential to impact on the health and wellbeing of citizens across the EU.

Conclusions

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 patients and citizens of the European Union deserve a framework for the regulation of health services at EU level that supports and quality assures the delivery of the best care and treatment services and one that supports a high level of public protection and patient safety.

Recommendations to the EU Commission

- The establishment of an EU-wide Pharmacy Forum by the EU Commission is required to ensure appropriate advice is made available at the highest levels on all matters relating to pharmacy care, treatment and practice. This includes the development of strategies to facilitate the consultation and co-ordination of health policies.

- An EU Regulatory Framework for Pharmacy be established to ensure that

  1) undergraduate, continuing professional development and post-graduate training provisions meet the required standard across the EU, and

  2) that the application of systems of registration, fitness to practice pharmacy and fitness to operate pharmacies are monitored effectively at EU level and that information on practitioners and service providers is shared between the statutory regulators/competent authorities within the Member States.

- An EU "Patient Safety and Quality Authority" be put in place to ensure that the information on safety is easily accessible to patients, health professionals, regulators and EU Member States.

- A comprehensive database and a system to guarantee the traceability of medicines be put in place including details of the status of the medicines with a standardised system to be put in place across the European Union

- The establishment of a standardised prescription within the EU which will facilitate accountability and traceability of both the health professionals involved and the medication.

- In respect of balanced health and medical service provisions. This must include all frontline service providers including pharmacy care, treatment and practice.

- The strengthening of the role of the EMA, working towards the phasing out of national medicines licensing agencies in favour of a centralised EMA.