



Submission to the Department of Health in preparation of a Statement of Strategy 2016-2019

Pharmaceutical Society of Ireland (PSI), the pharmacy regulator

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Introduction

As an agency of the Department of Health, the Pharmaceutical Society of Ireland (PSI), the pharmacy regulator, welcomes the opportunity to provide its input during the Department's development of its Statement of Strategy for the period 2016-2019.

The PSI, under the aegis of the Department of Health, has responsibility for pharmacy services in Ireland and works to protect and promote the health, safety and wellbeing of patients and the public. The overarching tenet of a next phase of the health strategy should be to ensure that service providers and regulatory systems work effectively, and cohesively, in the interest of patients and the public. Within a period that is focussed on planning reform of the health system– with the Oireachtas working towards a 10-year plan for a new model of healthcare in Ireland– the PSI believes it is vital that the Department gives due consideration to how the contribution of all healthcare professionals can be maximised and how scarce resources can be most effectively utilised. The Department's strategic leadership and implementation of proposed reforms should be such as to ensure that regulatory functions under its remit continue to be seen to be effective in protecting the public, and should also have a focus on how the various health and social care regulatory frameworks can be coordinated and streamlined to support and facilitate change and the achievement of quality outcomes within the broad health and social care domain.

Evolving the health service – policy and planning

The current *Programme for a Partnership Government* prioritises patient care that can be provided as close to a person's home as possible, thus seeking to enhance primary care and the integration of care between the primary and secondary care settings. The Government's intention to expand the role of the community pharmacist, as well as facilitate the growth of the GP role, is a welcome inclusion outlined in the Programme.

The PSI has recently undertaken extensive research, culminating in a soon to be published report, *Future of Pharmacy Practice –Meeting Patients' Needs*¹, that examines the role that pharmacists could be playing in furthering benefit to patients and to the health service. The PSI's research was undertaken in the context of changing healthcare demands, an ageing and more diverse population, the complexity of medicines and treatments and, in particular, with knowledge of the extensive regulatory, educational and training frameworks now in place to support the professional practice of Irish pharmacists. The report provides evidence as to how pharmacists, who already have extensive and frequent patient contact, can further support and enhance national public health initiatives, and be part of multidisciplinary approaches to care in, for example, the areas of chronic disease management or disease prevention.

As Government, together with the Department and the Health Service Executive, seeks to develop and ultimately implement a changed future healthcare model, this report's consideration of pharmacist care in a variety of settings is highly relevant. It points to the greater utilisation of pharmacists within the patient care journey, where medicines are the most common healthcare intervention and where both the use and

¹ In 2015, the PSI Council commissioned the Future of Pharmacy Practice –Meeting Patients' Needs report. It has included paper-based and face-to-face meetings and focus groups in its research and development, with the work overseen by a Steering Group, chaired by Dr Norman Morrow, former Chief Pharmaceutical Officer at the Department of Health, Social Services and Public Safety in Northern Ireland, and made up of representatives of the Department of Health, HSE, academic and practicing pharmacists and other relevant stakeholders. The report will be published by the PSI in November 2016

complexity of medicines is increasing. Central to the pharmacists' role is their contribution to obtaining optimal outcomes from medicines and providing a sustainable approach to clinical care and cost-effectiveness while reducing avoidable adverse events and waste.

Based on successful services involving pharmacists in other jurisdictions and trialled, or in operation on a smaller scale in Ireland, the report and its recommendations give real examples of the potential for optimal use of pharmacists' education and training. Examples include opportunities for pharmacists to be part of health screening and vaccination programmes, and how they can work with GPs or other healthcare professionals within agreed protocols to implement National Clinical Effectiveness initiatives, such as asthma care, diabetes and cardiovascular care. Many of those recommendations support and integrate with the work programmes targeted for achievement in the *Programme for a Partnership Government* and the ongoing national health strategy. Acknowledging that an integrated and multi-disciplinary approach to care of the population will yield improved outcomes, it follows that there is a clear opportunity to offer greater inclusion of pharmacists in many of the key public health and wellness interventions, including: public health screening, creating a national obesity action plan, implementing the national sexual health strategy, in working towards a tobacco-free Ireland by 2025, and ensuring that appropriately trained staff are available to support mental health and wellness programmes in primary care. Pharmacists should be included as a stakeholder in making decisions about, and in the development of, clinical care programmes, in commencing a cohesive National Drugs Strategy, in improving hospice and end of life services and outcomes in long-term residential care services, and in implementing the National Dementia Strategy, for example.

At a time of proposed developments in the health service, the PSI also believes that the appointment of a Chief Pharmacist in the Department of Health would deliver real benefits in relation to professional leadership, and legislative, policy and strategic guidance which would help deliver optimal pharmacist contribution within a multidisciplinary model of healthcare. Leadership and guidance on pharmacy at the strategic level within the Department, alongside professional counterparts in medicine, nursing and other fields, would allow for the appropriate realisation of pharmacy potential, and would help foster a truly integrated future model of healthcare focused on the interest of patients. In addition, the role of a Chief Pharmacist could ensure that the requisite medicines and pharmacist expertise is available to support Government and to oversee legislative and policy development for the safeguarding of access to and use of medicines, medical devices and pharmacy services.

Multi-disciplinary education and training

Encouraging and facilitating integrated and collaborative care requires commencement of shared education and learning opportunities amongst trainee health and social care professionals from undergraduate years through to practice, and providing for the channels that allow for consultation and communication among all relevant parties in looking after patients, including through the integrated clinical care programmes. As already outlined, consideration should be given to enhancing the role that pharmacists can play in public health awareness and intervention programmes. A collaborative, multidisciplinary approach to healthcare provision, where each health and social care professionals' knowledge and experience is put to most effective use, will in the longer term deliver the greatest public benefit in keeping with the level of public resources invested in the professional education system.

Enabling Change – legislation, funding, people and technology

The Department's role in the strategic development of the health system in the next number of years also warrants examining current legislation and payment structures, which may not always allow for, facilitate or encourage the immediate delivery of a changed care model.

In the area of technology and e-health, there have been extensive advances since the Pharmacy Act 2007 and other related legislation was implemented. With the intention to facilitate these advances in pharmacy, the PSI has submitted proposals to the Department seeking the amendment and/or inclusion of various legislative provisions that are necessary to allow for improved efficiencies, modernisation of systems, and ultimately support patient safety. Among these is a need to address the legislative requirements governing pharmacy record-keeping and the potential, through validation of pharmacy computer software systems, to maintain statutory pharmacy records electronically rather than by hard-copy means². Current requirements mean that a number of records must be readily available in hardcopy in the pharmacy, when the records are existing in tandem in computer records. The regulations pertaining to pharmacy records require that a computer software system used in the retention of records in electronic form be independently validated and certified by a person approved by the Minister for Health, and to date this provision has not yet been implemented. Consideration should be given to this item as an enabler to other changes as part of the healthcare reform agenda.

Government continues to give priority to the financing and roll-out of a 21st century IT health infrastructure, and working towards universal use of data across primary and secondary care to improve overall integrated care delivery and the achievement of relevant outcomes. Ultimately, there is the potential to provide greater patient access to their own data and greater access to data for health professionals that will enable work efficiencies and safer transitions of care. Careful consideration should be given to appropriate electronic data sharing and assuring patients and practitioners of the safe storage and appropriate use of that data. Including all relevant stakeholders in the development and piloting of these programmes is vital, as is clarity of message around the intention and use of advanced technological resources. Again, in the area of e-health, certain legislative change will be needed to allow for the implementation of particular proposals, and these changes should be considered at the earliest possible opportunity if roll-out of these important initiatives is to be timely and efficient.

Pharmacy resourcing, both in hospitals and community pharmacies, and reimbursement for services, are substantial enablers to the advancement of clinical pharmacy activities. Due consideration to effective deployment of the pharmacy workforce and adequate resourcing of a new model of healthcare will prove beneficial in the longer term. Current models of care, payment systems and structures of access may need to be examined to ensure that exchequer funds are being spent most effectively.

Role of Regulation

Across the health and social care professions, regulatory frameworks have been established, under a variety of pieces of legislation, that facilitate and support good professional standards, which recognise the weight

² Pharmacies are required to maintain a number of records under legislation, and in many circumstances there is an obligation to hold hardcopies of those records. The prescription register, for example, must be printed daily, and certified and dated within 24 hours by the pharmacist. Paper records must be preserved and kept readily available for inspection at the pharmacy for two years from the date to which they relate.

of responsibility on those professions in providing, often, irreversible care, and which create robust systems of professional accountability. The PSI oversees the regulatory framework in regard to the provision of pharmacy services – both by the individual pharmacists involved and by the registered pharmacy business within which many work. The effective operation of this system, coupled with well-developed education, training, continuous professional development and guidance for pharmacists, serves to ensure safety and to facilitate expanded care by pharmacists so as to meet patient need and health sector demands.

Regulatory frameworks which establish systems of accountability and fitness to practise must be proportionate and used with specific intent to deliver clear outcomes relating back to public assurance and patient safety. As has been highlighted in recent times by the Ombudsman, there must be accessible, understandable routes of redress, offering solutions at the right levels depending on the nature of concern or complaint. The PSI, together with other health and social care regulators, has submitted a report to the Department on the potential to create a more unified approach to disciplinary measures across each of the professional regulatory bodies, and to streamline legislation, as appropriate. As part of the Department's consideration of strategy, these proposals should be considered as important enablers that can be used to sustain health reform and to improve public confidence in the health-related professions.

In addition, the PSI has previously highlighted to the Department its concerns in relation to the current pharmacy legislation and the lack of a comprehensive regulatory framework relating to hospital pharmacies and the services provided in them, particularly for inpatients. Under the Pharmacy Act 2007, hospitals (including clinics, nursing homes or similar services) must only register their pharmacy with the PSI where medicinal products are provided to outpatients, staff or patients on discharge. This situation raises a clear patient safety concern regarding the management of medicines for hospital inpatients. Currently, there are number of different oversight and management structures and different pharmacy staffing arrangements within these various settings and this degree of unregulated variation represents potential risk to all involved. The PSI welcomes proposals for the mandatory licencing of healthcare providers where this will ensure consistent standards in the delivery of patient care with demonstrably safe systems of governance. The current lack of standardisation of pharmacy care and services and the absence of regulatory oversight or licencing in all of these care settings is a matter requiring urgent attention by the Department and PSI would submit that it is an area requiring close attention as part of the reform proposals for hospital groups.

As a regulator which also registers and inspects individual retail pharmacy businesses (RPBs), PSI is concerned to ensure that appropriate regulatory tools and methods are available as part of the overall scheme for the regulation of RPBs. Currently, there are some gaps and weaknesses in the relevant legislation which PSI believes should be addressed. These include such matters as the introduction of a notifications regime to ensure that key risk events in RPBs are reported to the PSI and the introduction of a form of statutory warning notice whereby PSI could require that key safety-related improvements be made in an RPB and where failure to comply would be grounds for an application for an enforcement order in the District Court. As part of the current strategy considerations by the Department, the PSI would submit that an ongoing programme of regulatory reform and updating should be developed within the Department which would allow for these, and other necessary, improvements to be discussed, defined and implemented in partnership with the health-related regulatory bodies and other relevant stakeholders.

Governance

We welcome the updated Code of Practice for the Governance of State Bodies by the Department of Public Expenditure and Reform. It serves to strengthen the oversight, reporting and relationship measures to

ensure best practice in corporate governance. As part of the updated Code we also welcome the inclusion of performance evaluation for board members, and the introduction of performance delivery agreements and periodic critical reviews as useful mechanisms to ensure state bodies meet business and public needs. The PSI is very keen that high standards of transparency and accountability exist between parent department and agency, as well as within each state organisation. The updated Code demonstrates best practice in governance and will ensure that regulatory legislation will evolve towards ensuring that governance structures are of a standard that will allow an organisation to work most effectively and in line with best practice. The PSI would welcome the inclusion of governance reform as a key issue to be advanced within the term of the next Strategy Statement.

Conclusion

Patient demand for healthcare in Ireland is growing at a rapid rate in terms of volume, cost and complexity. It is apparent that the only affordable solution to meeting this demand is through a multi-disciplinary approach to healthcare in order to deliver the highest quality of care, as close to the patient's home as possible. This submission has pointed to ways in which pharmacists' expertise can be more extensively realised to offer solutions and supports in meeting health objectives and to serving patients in optimising their own health. Additional information is available in the pending PSI *Future of Pharmacy Practice – Meeting Patients' Needs* report.

Reforms in regulation and legislation will be necessary to address some of the proposals set out by the PSI, and in order to facilitate implementation of new models via the Department and the HSE which will deliver more efficient service provision and which will keep pace with changes in technology and other demands.

The PSI looks forward to continuing to work with the Department in delivering on its role to provide and assure patient and public health and safety by regulating pharmacists and pharmacies, and in supporting the Minister, Department and Government with advice and information as is relevant. The PSI is available to provide further information in relation to all aspects of its work, and pharmacy provided care and services, as is useful to the Departments in its current and ongoing strategy and policy developments.