PSI
CUMANN CÓGAISEOIR NA hÉIREANN
The Pharmaceutical Society of Ireland
AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Chief Executive's Office
Health Products Regulatory Authority
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2,
Ireland.

25th March 2015

Re: Public consultation on the HPRA strategic plan 2016-2020

Dear Mr O'Mahony,

The Pharmaceutical Society of Ireland (PSI) as the independent statutory body, established by the Pharmacy Act 2007 charged with and accountable for, the effective regulation of pharmacists and pharmacies in their delivery of pharmacy services in Ireland, welcomes the opportunity to provide input into the HPRA strategic plan for the years 2016 to 2020. The PSI recognises the importance of the role and functions of the HPRA in the context of the wide health care services environment, and in the specific context of the delivery of medicinal products as part of pharmaceutical care and service delivered by pharmacists to patients.

The PSI carries out its role in the public interest to protect the health, safety and welfare of the public by regulating the pharmacy profession and pharmacies. Under the Pharmacy Act, the PSI is required to:

- Maintain registers of pharmacists, pharmaceutical assistants and pharmacies;
- Prescribe the qualifications required for practice as a pharmacist, accredit education and training programmes leading to qualification, and ensure that pharmacists undertake appropriate continuing professional development;
- ensure compliance with the pharmacy and medicines laws of the State;
- set professional standards and provide advice and guidance in relation to pharmacy practice;
- receive and act on complaints and information about the competence and conduct of pharmacists and pharmacy owners and conduct inquiries into complaints and impose sanctions as appropriate;
- report and be accountable to the Minister for Health, the Department of Health, and to the Oireachtas.

The primary role of the PSI Council is the protection of public health and the assurance of patient safety through the effective regulation of the profession and practice of pharmacy.

The supply chain for all classes of medicines, medical devices, cosmetics, and blood, tissue and organ products must be safe, protected and guarantee patient safety, and the PSI supports the mission of the HPRA in delivering on this. The role of the pharmacist in supplying regulated medicines to the patient end user is premised and supported by the confidence the individual practitioner has, as a healthcare professional in the regulatory systems delivered on by the HPRA. The role of the pharmacist, particularly in the context of the regulatory framework provided by the Pharmacy Act 2007, as amended, provides a framework which can support the decision making of the HPRA in terms of medicines classification, and appropriate supply routes.

The PSI, under section 7 of the Pharmacy Act 2007, has a statutory duty "to take suitable action to improve the profession of pharmacy". The PSI recognises that the operating model of pharmacy practice is evolving. In this context a decision was taken by the Council of the PSI in December 2014 to further explore a project to consider future pharmacy practice policy. Work has now begun on the production of a report entitled *'Future Pharmacy Practice in Ireland – Meeting Patients' Needs'*. This project is intended to

explore how pharmacy can most valuably contribute to the health and wellbeing of patients in our evolving healthcare system and environment, in the context of existing and emerging national health strategies, and transitioning pharmacy education and training structures. The wider health care system faces a number of challenges in the broader healthcare environment. Pharmacy and pharmacists, as accessible healthcare resources, are ideally placed to respond to these needs within the system. The PSI is committed to ensuring that throughout the delivery of this project, wide stakeholder engagement will occur. In this context, it is critical that the HPRA and the PSI continue to work collaboratively to ensure that developing models operate appropriately in the patient interest.

The area of medicines and health legislation is complex, necessarily dynamic and it is vitally important that it provides and ensures a framework of regulation that guarantees that patients are protected. Patients and the public must have confidence that the regulatory system holistically ensures that the safety, integrity and appropriateness of medicinal and health products are such, that the tenet of patient safety through appropriate regulation, is conserved through the processes of initial research and product development, and from manufacture with regulated raw material right through to the ultimate receipt of the product by the patient end user. This must also be delivered in a way that does not unnecessarily restrict access or limit the potential of the health system to allow care be delivered at the most accessible appropriate access point in the regulated framework. The co-operative engagement and communication of the HPRA with other healthcare regulatory bodies and agencies to deliver on this goal is beneficial to patient interest and the continuation of this strategic direction going forward is vital.

The role of the HPRA in influencing and contributing to the development of the regulatory system at a national and international level is supported. The obligations arising practically, from the operation of a global supply and operations environment is recognised, and the valuable role to be played in participating in the structuring and operation of the required frameworks is recognised. It is hoped that the HPRA will continue be in a position to recognise and address this in its strategic direction going forward.

PSI looks forward to the production of the HPRA strategic plan 2016-2020, and would welcome any further opportunities to participate and contribute to this process as you see fit.

Yours sincerely

Damhnait Gaughan
Acting Head of Communications