



**Submission to the Joint Committee on Health and
Children
01 December 2009**

Submission to the Joint Oireachtas Committee on Health and Children
The Pharmaceutical Society of Ireland (PSI), the pharmacy regulator
Tuesday 01 December 2009

Introduction

2008 was the first full year of the PSI established under the Act, and over the past two years it has undertaken a significant work programme in relation to the implementation of the new legislation.

Since the 22 May 2007, the PSI has engaged in a substantial body of work relating to the implementation of the Act. The most significant developments relate to reforms of the education and training of pharmacists in Ireland (including the development of a new Masters-level Internship programme), the successful introduction of the new registration systems, the development of an enhanced registration database system which provides for online publication of the registers and online facilities for registrants, the promulgation of the Code of Conduct for pharmacists and the modernisation of the governance structures of the PSI.

The new registration systems provided for in the Act, with the associated regulations governing the operation of retail pharmacy businesses and the new professional management structures, are now in place. The Code of Conduct for pharmacists further underpins the 're-professionalisation' of pharmacy by ensuring that patients are the primary concern of pharmacists and their professional practice. The robust regulatory system provided for in the Act, including the sections dealing with complaints, inquiries and discipline, provide protection for the public in respect of patient safety, and also facilitate the development and expansion of the role of pharmacists and pharmacy services in line with the *Pharmacy Ireland 2020* initiative. The ongoing work in relation to the governance structures and processes of the PSI, including the further development of ICT supports, will enhance the performance of the regulator in the coming years.

In 2008/2009, the PSI successfully led an Irish bid for a future annual Congress of the International Pharmaceutical Federation (FIP) which typically attracts over 3,000 pharmacy delegates from across the world. The agreements for the hosting of FIP in Dublin will be signed in the coming days with the PSI and the Convention Centre Dublin. FIP in Dublin will provide a further focus for the profession and sector in terms of the development of education and practice in Ireland and engaging with international colleagues.

During 2008 and 2009 the PSI has also worked and engaged more closely with other statutory regulators in Ireland and Europe, primarily through the Health and Social Care Regulators Forum established by the healthcare regulators. The PSI signed a Memorandum of Understanding with the Pharmaceutical Society of Northern Ireland in

2007, the Irish Medicines Board in January 2009 and will continue to develop closer working relationships with other regulators in the healthcare sector in the interests of patients.

For 2010 the priority areas will include the development and introduction of Continuing Professional Development (CPD) for pharmacists and the development of pharmacy practice in line with international evidence and best practice experience. The significant reforms in the education and training of pharmacists, both those already achieved in 2009 and those planned for 2010 and beyond, will further enhance the development of the profession of pharmacy and the contribution it makes to the care and safety of patients within the Irish healthcare system.

The implementation of the report of the Commission on Patient Safety and Quality Assurance will also be a significant factor in the development of pharmacy practice and CPD for pharmacists into the future.

Corporate Governance and Modernisation

With the introduction of the Act, the PSI's role has changed significantly to that of an independent regulatory body with substantially enhanced responsibilities and powers. In light of these changes, the PSI has sought to establish a robust delivery infrastructure underpinned by a comprehensive set of policies and procedures and the necessary information communications and technology (ICT) systems to enable implementation of new processes and procedures. A detailed process mapping exercise and ICT review was carried out for a number of key functional areas. The PSI is also reviewing and redeveloping its communication channels, and in particular its website.

In 2008 the PSI engaged in the development of a Corporate Governance Framework which was approved by the Council in 2009. The Framework aims to strengthen the governance and accountability arrangements within the PSI and incorporates models of best practice including the Department of Finance "Code of Practice for the Governance of State Bodies" 2009 and other relevant legislation and best practice standards and codes. During 2009, the PSI also reviewed and developed its risk management structures which involved carrying out a comprehensive risk assessment with its internal auditors and the development of a risk register.

The PSI is currently engaged in the development of its Service Plan for 2010 and its corporate strategy for 2010-2012.

Professional Development and Learning

▪ **Pharmacy Education and Accreditation Reviews (PEARs) Project**

The Council of the PSI has embarked on a 'root-and-branch' review of the five-year programme of education and training for the pharmacist qualification in Ireland and a review of the accreditation models and standards. The Pharmacy Education and Accreditation Reviews (PEARs) project is being carried out by the Pharmacy Practice Research Group, based within the School of Pharmacy, at Aston University, UK.

The final report from the Project is due in January 2010 and will include a proposal for the most appropriate form of pharmacy education and training in Ireland which will require the approval of the Council of the PSI. Based on the interim findings of the research to date, it appears that the likely outcome is pointing to a preference for a five-year Masters level qualification incorporating a vocational training component of six months' duration. (The minimum training requirements for pharmacists as laid down at EU level require the completion of a five-year programme of study that must include a six-month clinical placement in either community or hospital pharmacy.) Ireland is one of the last remaining EU Member States that does not award a Masters level pharmacist qualification and is one of a small minority of Member States in which an integrated five-year training programme is not delivered.

▪ **National Pharmacy Internship Programme (NPIP)**

Following from the above, there was a need to develop a transitional programme as an interim measure for the in-service practical training year, pending the outcome and recommendations from the PEARs project.

During 2009, the PSI worked closely with the key stakeholders and in particular with the schools of pharmacy, the Department of Health and Children, the HSE, the Department of Education and Science and the Higher Education Authority to develop an appropriate solution.

Following an independently assessed selection process, the development, delivery and management of the interim programme was awarded to the Royal College of Surgeons in Ireland (RCSI) for a 3-year period starting with the 2009-2010 training year.

The National Pharmacy Internship Programme (NPIP) will be provided for the next three academic years by RCSI, with the assistance of the University of Dublin (Trinity College) and University College Cork (both universities have Schools of Pharmacy).

The NPIP will lead to the higher degree of M Pharm which will be awarded by the National University of Ireland and accredited by the PSI. The PSI is currently developing internationally benchmarked accreditation standards for the delivery of experiential learning programmes, with the assistance of a number of national and international experts. In addition, the M Pharm programme will also go through the RCSI's quality assurance processes and a parallel accreditation regime is in train with the NUI.

The M Pharm is a 12-month, full-time, distance-learning programme which will be principally delivered online. Successful completion of a number of taught modules (including tutor-assessed competency standards), a research dissertation module and a Professional Registration Examination will be required. Each intern will also undertake a placement which will include the mandatory six-month clinical requirement under the supervision of a tutor pharmacist in either a hospital or community pharmacy.

The basis for the curriculum is the identification and definition of competence standards that describe the knowledge, skills and behaviours required of a newly-registered pharmacist. These competence standards are consistent with international norms for pharmacy professional education. The development of the NPIP brings pharmacy education and training in Ireland in line with international norms and further enhances the career options of these new graduates in the many areas of professional practice, including the pharmaceutical industry.

- **Continuing Professional Development (CPD)**

The Act provides for the introduction of a Continuing Professional Development (CPD) system for pharmacists. A review of international models of CPD has been commenced, with a view to developing a system of mandatory CPD for pharmacists from 2010. The introduction of CPD, in line with the requirements in the Act, is a priority area for the PSI in 2010.

Registration and Qualification Recognition

The Registration and Qualification Committee oversaw major policy and procedure development in 2008 in preparation for the commencement of Part 4 of the Act (the new pharmaceutical registration systems) and the transposition into Irish law of Directive 2005/36/EC on the Recognition of Professional Qualifications.

- **Pharmacists**

The system of continued registration for pharmacists and pharmaceutical assistants (i.e. the requirement for the re-registration on an annual basis of all registrants) was also commenced on 29 November 2008 by the Minister. The PSI, with the support of registrants, was successful in implementing this new statutory system of continued registration by the due date of 31 December 2008.

Continued registration for 2010 for registrants whose certificates expire on 31 December 2009 (the vast majority on all registers) is currently underway.

In 2009 investment in ICT development and in particular the new database system for registration enabled the publication on the registers online on the PSI website, in accordance with the requirements of the Act, making the registers available and accessible to the public. In addition, the PSI introduced online facilities for registrants

which allow them to apply for continued registration, and pay the prescribed fee, online for the first time.

As well as receiving certificates of registration (as provided for in the Act) pharmacists also receive a 'European Health Professional Card for pharmacists', which is a wallet-sized card. From 2010 photographic identification is required on certificates of registration for pharmacists and they are being encouraged to use or wear these as a pharmacist identification card, so that they are readily identifiable to patients and the public as a registered pharmacist.

The certificates of registration of the supervising pharmacist (as well as the registration certificate of the retail pharmacy business itself) must be conspicuously displayed in the particular retail pharmacy business.

The PSI also processes applications for registration as a pharmacist under EU free movement directives for EU/EEA citizens who have obtained their qualifications in the EU/EEA.

In March 2009, following on from the commencement of Part 4, a new process for the 'Recognition of Third Country Pharmacist Qualification as a Qualification Appropriate for Practice in Ireland' became operational and processes applications from 'third countries', i.e. those outside the EU/EEA.

Pharmacist Registration Stats:

Number of pharmacists registered as at 23 November 2009: **4444**

Number registered from 01 January 2009 to 23 November 2009: 106 (91 via the EU route of registration and 15 via the national route)

Number voluntary cancellations of registration from 01 January to 23 November 2009: 233

Pharmaceutical Assistants:

Number of pharmaceutical assistants registered as at 23 November 2009: 537

▪ **Retail Pharmacy Businesses**

In line with the commencement of Part 4 on 29 November 2008, the PSI managed the registration of retail pharmacy businesses (pharmacies) in Ireland for the first time. In conjunction with the full support of the sector, the PSI succeeded in establishing compliance with the new system by the due date of 31 December 2008, with the registration of 1680 retail pharmacy businesses upon the establishment of the Register on 01 January 2009. A major organisational effort by the PSI through a period of intensive activity ensured the successful fulfilment of this statutory requirement. The PSI provided a dedicated telephone helpline and email service to deal with queries and assist pharmacy owners with making their applications. The helpline dealt with more than 650 telephone calls, and a further 350 queries by email and telephone were dealt with by PSI staff.

With the commencement of Part 4 of the Act and the establishment of the Register of retail pharmacy businesses, any person now wishing to open a retail pharmacy business must apply to register that pharmacy and have the application processed (including an inspection by the PSI) and be registered in accordance with the relevant statutory rules before it may operate.

Retail Pharmacy Business Registration Stats:

Number of retail pharmacy businesses registered as at 23 November 2009: **1703**

Number of new registrations from 01 January to 23 November 2009: 58

Of these 41 were new openings, 35 of which were still operating on 23 November 2009; 10 were as a result of permanent relocations of existing pharmacies to new addresses; 7 were as a result of transfers of ownership (under the Act, a change in ownership of a retail pharmacy business cancels its registration and the new owner must apply to register the new retail pharmacy business).

Number of cancellations of registration (closures) from 01 January to 23 November 2009: 27

Note: There were 66 new openings of pharmacies in 2008, mainly in the urban centres of Dublin and Cork, continuing the trend in recent years of decreasing numbers of new openings. The new openings notified to the PSI in the preceding years were as follows - 2007 : 68; 2006: 95; 2005: 137.

Inspection and Enforcement

During 2008, the inspection and enforcement functions of the PSI provided for in the Act were developed, including the development of the processes and procedures for inspection, investigation and enforcement. Prior to the commencement of Part 6 of the Act, which deals with complaints, inquiries and discipline, the Inspection and Enforcement function handled complaints received by the PSI.

In 2008 the PSI received and investigated 49 complaints, compared to 35 in 2007. This upward trend is likely to continue as public awareness of the regulator and its functions increases. The main categories of complaint were alleged dispensing errors, refusal to supply and alleged breaches of law, primarily pharmacy and medicines law.

In 2009, prior to the commencement of Part 6 processes on 01 August, the PSI received 52 complaints under the interim complaints system, 32 of which relate to one particular issue.

During 2009 the new inspection and investigation functions became fully operational.

To date in 2009, there are 10 investigations open or underway.

In 2009, the PSI has carried out 277 inspections of retail pharmacy businesses. These include inspections conducted in respect of an application for registration of a retail

pharmacy business and inspections to assess compliance with the legislative requirements of the Act and in particular the Regulation of Retail Pharmacy Businesses Regulations 2008.

Two prosecutions were taken in 2008, and to date in 2009 two prosecutions, the first under the Act, have been successfully taken.

Standards and Practice

In 2008, the main activities under this function related to the development of the draft Code of Conduct for pharmacists and the development and communication of guidance and information for pharmacists and pharmacy owners in respect of the implications of the Act. As part of this activity, the PSI developed an educational and self-audit tool to assist pharmacy owners and pharmacists in auditing their own practices. The Pharmacy Practice Guidance Manual was distributed to every pharmacy in the State and a series of regional meetings held during the summer of 2008, to which all pharmacy owners and supervising pharmacists were invited, to deliver information on the PPGM, the draft statutory rules being developed for the registration of pharmacies and the draft regulations under section 18 being developed by the Department.

During 2008 and 2009, the PSI has provided advice and support to pharmacists and the public with their queries in relation to pharmacy practice matters and the implications of the new legislation.

The PSI has just commenced a baseline analysis of pharmacy practice in Ireland which will provide information to assist the PSI to understand the nature and scope of pharmacy provision in Ireland and identify its strengths and opportunities. It will also inform the PSI in the development of policies to improve service provision, aid the development of professional standards and competencies assisted by a structured CPD system.

A number of guidance documents, including guidelines for the purpose of facilitating compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008, are currently being drafted.

The PSI has also done significant work during 2009, in conjunction with colleagues within the profession and in support of work coordinated by the Chief Pharmacist of the Department, on pharmacy-related matters in preparation for, and dealing with, the protection of public health during the influenza pandemic. This has included the preparation, and dissemination, of information for pharmacists and facilitating communication from the HSE, IMB and DoHC of pandemic-related and other patient safety information utilising the PSI database of pharmacist and pharmacy contact details.

Professional and Services Conduct

Part 6 of the Act, which deals with complaints, inquiries and discipline, was commenced by the Minister on 01 August 2009. Over the past few months, the PSI has been engaged in setting up the machinery of the new system required for dealing with these matters, including the establishment of the three statutory committees provided for in the Act. The first of these committees, the Preliminary Proceedings Committee (PPC) was formally established by the Council at its meeting of 29 September 2009 and, following recent induction and training, it will begin processing complaints received by the PSI since the commencement of Part 6. To date (23 November) 13 formal complaints have been received and referred to the PPC, while a further 40 'expressions of concern' which may result in receipt of formal complaints have been received.

The other two statutory committees of inquiry, the Professional Conduct Committee (PCC) and the Health Committee (HC) are expected to be formally established by Council at its meeting of 01 December 2009.

The PSI has published an initial 'Guide to Making a Complaint about a Pharmacist or a Retail Pharmacy Business' which is available on its website, and further publications and information will be disseminated to the profession and the public once the full details of the systems and processes are finalised early in 2010.

Pharmacy Ireland 2020

In 2008, the Council began an initiative, in line with its duties under the Act to advise the Minister and to 'improve the profession of pharmacy', called *Pharmacy Ireland 2020*, which aims to develop and expand the role of the pharmacist and the provision of pharmacy services in line with the international evidence and experience. In April 2008, an interim report "Advancing Clinical Pharmacy Practice to Deliver Better Patient Care and Added Value Services" was presented to the Minister which makes recommendations in relation to an enhanced role for pharmacy in the following areas:

- chronic disease management
- pharmaceutical care, medicines management and medication use reviews
- development of a national minor ailments scheme
- reclassification of medicines
- medication error reporting
- health screening in pharmacies
- prescribing competencies for pharmacists with prescribing authority
- pharmacy vaccination clinics
- further utilisation of clinical pharmacy in hospitals

The Report recommends that a national policy be developed for each of the elements listed above and cites examples of where cost savings could be achieved by advancing pharmacy services in line with international practice. During the summer of 2008 the PSI, through its Pharmacy Ireland 2020 working group, engaged in extensive public consultation on the Interim Report, including holding focus groups with 35 different organisations, from a wide range of stakeholder groups including patient and public support, advocacy and representative bodies, pharmacy and other healthcare professional representative bodies, academic institutions and other statutory and regulatory bodies.

In 2009 the focus has been on the economic modelling of some of the recommendations of the Interim Report, including discussions with the ESRI and further discussions with the Minister with a view to integrating the implementation of some of the recommendations in line with clinical care and service reform within the HSE.

In June 2009, the PSI made a submission on these and related issues to the Department of Health and Children Expert Group on Resource Allocation and Financing in the Health Sector.

Background to the PSI and the Pharmacy Act 2007

The Pharmaceutical Society of Ireland (PSI), the pharmacy regulator, was established by the Pharmacy Act 2007 (the 'Act'), which dissolved the old body of the same name and revoked legislation dating back to 1875.

The Act gives the PSI a broad remit, principally to 'regulate the profession of pharmacy in the State having regard to the need to protect, maintain and promote the health and safety of the public'.

The functions and duties of the PSI include the promotion of high standards of education and training of pharmacists (from undergraduate level to Continuing Professional Development), keeping and maintaining the registers of pharmacists, pharmaceutical assistants and retail pharmacy businesses (pharmacies) and determining and applying criteria for registration, to act as the competent authority for mutual recognition of qualifications from other EU countries, to give the Minister information and advice about matters relating to its functions and to 'take suitable action to improve the profession of pharmacy'.

Among the powers of the PSI are inspection, investigation and enforcement powers, including conducting inquiries into the qualifications and fitness of person to practice and the imposition of sanctions on pharmacists or pharmacy owners where they are found to be unfit to practise or operate a retail pharmacy business.

Three-phase commencement of the Act

The Act has been commenced in three phases over the past two years.

The first phase, commenced 22 May 2007, established the PSI and its new Council which has a non-pharmacist (lay) majority.

The second phase was commenced on 29 November 2008 and included the parts of the Act relating to the new pharmaceutical registrations systems (including the registration of retail pharmacy businesses [pharmacies] for the first time) (Part 4), new powers of inspection and investigation of the PSI (Part 7) and a number of offences relating to the operation of retail pharmacy businesses (Part 5). A number of statutory rules, relating to registration, education and training of pharmacists, the functioning of the Council and fees, to facilitate the proper and effective governance of the PSI, were also introduced on that date. In November 2008, the Minister for Health and Children also approved the new statutory Code of Conduct for pharmacists, which was laid before the Houses of the Oireachtas in February 2009.

On 1 August 2009, the remaining sections of the Act (Part 6) which deal with complaints, inquiries and discipline and which introduce 'fitness to practise' for pharmacists and 'fitness to operate' for retail pharmacy businesses, were commenced.

The PSI Council

The Council of the PSI has 21 members appointed by the Minister.

The Council has a non-pharmacist majority and includes a nominee of the Irish Medicines Board, a nominee of the Health Services Executive and a person representative of the provision of CPD, as well as other non-pharmacists appointed for their particular qualifications, experience or expertise or in the public interest.

The 10 pharmacist members on Council include a pharmacist nominated by the Schools of Pharmacy and nine pharmacists selected by registered pharmacists.

The Council elects a President and Vice-President each year from among the pharmacist members. The current President is Ms Noeleen Harvey and the Vice-President is Mr Paul Fahey.

The Council has established six main Advisory committees – Professional Development and Learning, Registration and Qualification Recognition, Inspection and Enforcement, Standards and Practice, and Administration, Finance and Corporate Governance, as well as a Chairperson's Committee comprising of the President, Vice-President and the Chairs of

the Advisory Committees. There are a number of non-Council members co-opted to the various committees for their expertise, experience or perspective.

Code of Conduct for pharmacists

During 2008 the PSI drew up a Code of Conduct for pharmacists, in line with its duties under Section 7 of the Act and in line with the procedures under Section 12, which included submitting this Code to Competition Authority for its opinion on whether the provisions of the draft code might be likely to result in competition being prevented, restricted or distorted, for obtaining consent of Minister, publication of the Code and for laying before the Houses of Oireachtas. The draft code went through an extensive consultation process during 2008 with the profession and the wider sector, and the opinion of Competition Authority, received in October 2008, was that no provision of the draft Code would, if given effect, be likely to result in competition being prevented, restricted or distorted. The Code was approved by the Minister for Health and Children on 14 November 2008 and formally laid before the Houses of the Oireachtas in February 2009.

The Code of Conduct for pharmacists sets out the key principles or professional ethical standards in accordance with which pharmacists should practise their profession. It is a public declaration of these principles and ethical standards, which the public, patients and other healthcare professionals require and expect of pharmacists. The Code also provides support and guidance to pharmacists and empowers them in the practise of their profession. Breaches of the Code may be considered 'professional misconduct' under Part 6 of the Act, which defines 'professional misconduct' as including "a breach of the Code of Conduct for registered pharmacists" (Section 33), with potential implications for a pharmacist's fitness to practise.

The Code is a six-principle code and the first and primary principle is that:
"The practice by a pharmacist of his/her profession must be directed to maintaining and improving the health, wellbeing, care and safety of the patient".

During 2009, the PSI has engaged in extensive promulgation of the code, both within the profession and to the wider healthcare system and public, including a number of educational meetings for pharmacists around the country during the year and an inter-professional ethics symposium in conjunction with Trinity College Dublin in September.

Retail Pharmacy Businesses Regulations 2008 {SI No. 488 of 2008}

The Regulation of Retail Pharmacy Businesses Regulations 2008, made by the Minister under Section 18 of the Act 'for the purposes of the health, safety and convenience of the public', govern the operation of retail pharmacy businesses. The rationale behind these regulations was to ensure that proper regulation and control of the final link in the 'supply chain' of medicinal products, from manufacturer to patient, is now in place.

These regulations specify requirements in relation to the premises, staffing, equipment and procedures in a retail pharmacy business, the management and supervision of the pharmacy, the sourcing, storage and supply of medicinal products, including veterinary medicinal products, and record-keeping. A 'duty register' of each pharmacist at the premises is now a requirement, and to facilitate compliance with this, the PSI distributed a specially-formatted register to each retail pharmacy business in 2009 and will continue to provide these registers in 2010.

The regulations also include provisions which relate to the review and counselling a patient should receive in respect of the supply of both prescription and non-prescription medicines, including the provision of the information and advice required for the safe and proper use of medicines.

The regulations reiterate the broader requirements of the Act in relation to the supply of medicinal products and the operation of retail pharmacy businesses. These include the requirement that all medicinal products should be sold or supplied by or under the personal supervision of a pharmacist. In addition, the Act introduces a professional management structure in pharmacies through the roles and responsibilities of the superintendent and supervising pharmacists.

- **Superintendent Pharmacist**

The requirement for a superintendent pharmacist comes from Part 5, Sections 26 to 29 from Act, that a condition of registration of a retail pharmacy business is: "that the part of the business that consists of the management and administration of the sale and supply of medicinal products is under the personal control of a registered pharmacist who has three years' minimum post-registration experience". There are further conditions in relation to retail pharmacy businesses owned by corporate bodies (Section 28). The requirement for a superintendent pharmacist essentially hands the professional management of pharmacy practice back to the profession, back to the pharmacist. The superintendent pharmacist has overall control of the legal, professional and clinical policies pursued in the retail pharmacy business.

- **Supervising pharmacist**

The requirement for a supervising pharmacist comes from the same Part of the Act, where the condition is "that, at the premises where the business is carried on or, if there are two or more of those premises, at each them, there is a registered pharmacist who has three years' minimum post-registration experience, in wholetime charge of the carrying on of the business there." There must be one supervising for each retail pharmacy business, and while the superintendent can act in respect of more than one retail pharmacy business, the supervising can not. In addition, both roles can rest in the one person. The supervising pharmacist is in 'wholetime charge' of the operation of the retail pharmacy business and is responsible for the management and control of the operation of the retail pharmacy business on a day-to-day basis.