THE IRISH PHARMACY JOURNAL

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PSI LAUNCHES NEW WEBSITE
IRELAND TO HOST FIP CONGRESS IN 2013
LAUNCH OF PEARs AND CPD REVIEW REPORTS

THE OFFICIAL JOURNAL OF THE PHARMACEUTICAL SOCIETY OF IRELAND

PSI
THE PHARMACEUTICAL SOCIETY OF IRELAND
Cumann Cógaiseoirí na hÉireann
THE PHARMACY REGULATOR

PHARMACISTS WITH AN INTEREST IN DISEASE MANAGEMENT PROGRAMMES REQUIRED FOR COMMITTEES

The Pharmaceutical Society of Ireland (PSI), the pharmacy regulator, has established a National Pharmacy Reference Group to progress the development of pharmacy practice in Ireland, in line with international evidence and best practice, in order to deliver improved patient care.
As part of that initiative, and in partnership with the HSE Quality and Clinical Care Directorate, the PSI is seeking expressions of interest from pharmacists with an interest and/or expertise in acute and chronic disease management. Selected pharmacists will work with the Directorate and the National Pharmacy Reference Group in supporting initiatives for the development of evidence-based and integrated care in acute and chronic disease management and contributing to the implementation of the pharmacy elements of these initiatives.

The initial focus of this work will be in the following disease areas:

Heart Failure
Stroke
Diabetes
Chronic Cardiovascular Disease
Chronic Obstructive Pulmonary Disease (COPD)/Asthma
Care of the Elderly
Mental Health
Acute Medicine Services

It is intended to form a panel of pharmacists for each of the disease areas listed above to participate in the work programme of the Directorate's committees in these areas. In the future, pharmacists will be invited to contribute to other clinical areas and programmes.

The Successful Candidates

The successful candidates will be registered pharmacists, preferably with a minimum of three years' post-registration experience. A postgraduate qualification will be desirable but not essential. Practice experience in one or more of the disease areas listed above, a willingness to work constructively in multidisciplinary teams and a passionate interest in the pursuit of excellence in patient care and pharmacy practice are essential.

Successful candidates will also be: team players, innovative, influential, self-starting and goal-orientated, with a strategic focus. Excellent IT skills and familiarity with pharmacy software systems are also essential.

Expressions of Interest

Please forward a CV, together with a short letter outlining your expertise, track record and vision for the future in the relevant disease area(s) to: opd@iol.ie by 21 January 2011.
Any queries can only be dealt with by email to opd@iol.ie

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2020 Vision Can Become a Reality

The new regulatory system brought about through the implementation of the Pharmacy Act 2007 was foreseen as having many significant benefits for patients, the public and the pharmacy profession. Among these was the opportunity to develop pharmacy practice in Ireland in line with the international evidence base and experience, as envisaged in the PSI's *Pharmacy Ireland 2020* initiative. This development would allow patients and the health service to gain the maximum benefits from the expansion of the professional and clinical competencies of the pharmacy profession in Ireland.

That robust regulatory framework envisaged by the Act is now in place. This includes the educational reform programme as well as the accountability provisions in the inspection and fitness to practise systems. The central role of the pharmacist in the safe and rational use of medicines is now underpinned by the legal and professional requirements laid out in the Regulation of Retail Pharmacy Businesses Regulations 2008 and the Code of Conduct. Pharmacists must now ensure that the supply of all medicinal products, prescription and non-prescription, is safe and appropriate for the individual patient's needs. Coupled with this is the requirement that patients receive the information and advice necessary to use their medicines safely and properly, and the introduction of private patient consultation areas in all pharmacies will facilitate and promote this important role of the pharmacist.

The establishment in 2011 of the Institute of Pharmacy will provide a further framework for the rapid development and improvement in practice. The new system of mandatory CPD, with patient safety at its core, will underpin the development of pharmacy practice and services, and the acquisition of specialisation by pharmacists. Improved integration of pharmacists with their colleagues in other professions in the provision of evidence-based clinical and therapeutic care, with a focus on optimising patient outcomes and meeting key safety, quality and cost-effectiveness objectives, will bring benefits for patients across the health system.

In its 2008 Interim Report, the *Pharmacy Ireland 2020* sub-group looked at aspects of pharmacy practice internationally which could bring added value to patient care and outcomes in Ireland. These included vaccination by pharmacists to help improve uptake in important national immunisation programmes, improving patient access to a greater range of medicines directly from pharmacists and a greater role for pharmacists in the management of chronic disease patients and their medicines. Some of these developments may have seemed aspirational two years ago, but many are now starting to become a reality.

It is now the responsibility of all involved to ensure that the vision of *Pharmacy Ireland 2020* is realised in line with the PSI's stated vision: *to ensure that pharmacy services are delivered in a competent, professional and ethical manner and in an appropriate environment, to the highest standards of quality care and best practice.*

The *Irish Pharmacy Journal* is the Official Journal of the Pharmaceutical Society of Ireland – the Pharmacy Regulator

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Editor's Note

The introduction of the role of the superintendent pharmacist was a critical aspect of the new regulatory structures provided for in the Pharmacy Act 2007. Engagement with pharmacists holding this role on their responsibilities and accountabilities is a priority for the PSI and through its joint taskforce with ICCPE, a number of initial meetings were organised at the end of 2010. It is intended to hold further meetings in early 2011.

The presentation given by the PSI at the first meetings is reproduced in this issue in article format. One of the feedbacks from those initial meetings was a request from superintendent pharmacists for clarification on what they should expect during a routine inspection by the PSI.

The PSI has developed a short guide to the inspection process and a checklist to assist superintendents and other pharmacists in preparing for an inspection. These documents were emailed to superintendent pharmacists and are available on the PSI website www.thePSI.ie and are also published in this issue (ps. 214-217).

The implementation of the pharmacy education reform programme is also now underway and the Institute of Pharmacy is expected to be up and running later this year. As part of the implementation planning, a study trip was organised to observe the CPD system pertaining in Ontario, as the new Irish system will be based on their model. Noel Stenson, a community pharmacist with a special interest in education and CPD, was part of the study trip and writes about his observations of the Ontario system with a view to helping his fellow practitioners here understand how the new model might work.

The PSI recently issued a call for expressions of interest from pharmacists with an interest/expertise in disease management, as part of its initiative to progress the development of pharmacy practice in Ireland and in partnership with the HSE Quality and Clinical Care Directorate. Fuller details are available in this issue and any pharmacists interested in participating in this initiative are encouraged to send a brief CV to opd@iol.ie as soon as possible.

Finally, the PSI has launched its new website www.thePSI.ie and this publication will now be re-developed in line with the review of PSI communications, so we hope to launch a new format of our official publication early in 2011.

PSI News

PSI Launches New Website

The PSI has launched a new, revamped website www.thePSI.ie, which replaces the old domain at pharmaceuticalsociety.ie.

All email addresses at the PSI are now also @thepsi.ie (replacing @pharmaceuticalsociety.ie) should readers wish to update any contact details they may have. The PSI's main public email contact point is now info@thepsi.ie. Other contact details are available on the website in the relevant sections. Feedback or comments on the new website are welcome to info@thepsi.ie.

The PSI Registrar and CEO, Dr Ambrose McLoughlin, said the new, revamped site would enhance the PSI's role as an effective and efficient regulator of pharmacy. "In keeping with a modern and progressive pharmacy sector and its new regulatory framework, we have overhauled the PSI website to make it a more user-friendly and functional information resource for the general public, the pharmacy profession and all our stakeholders. The new format facilitates easier access to key reports, documents and general material relevant to developments in the sector and the ongoing work of the PSI."

The PSI 's official publication will now be further reviewed and updated in line with the new website in 2011.

l-r: Mr Jon Billings, Director of Healthcare Quality, HIQA; Dr Tracey Cooper, Chief Executive, HIQA; Ms Kate O'Flaherty, Head of Communications and Public Affairs, PSI; Dr Ambrose McLoughlin, Registrar/CEO, PSI

PSI Registrar and CEO, Dr Ambrose McLoughlin and Dr Tracey Cooper, Chief Executive of HIQA signing the Memorandum of Understanding.

PSI signs MOU with HIQA

The PSI and the Health Information and Quality Authority (HIQA) have formally signed a Memorandum of Understanding (MoU) between the two regulators, which will increase mutual co-operation.

The MoU is intended to provide a framework to assist the joint working of the two organisations to ensure maximum effectiveness and efficiency when carrying out their statutory functions, in the interests of patient safety and public protection. The two bodies intend to collaborate closely in the discharge of their respective regulatory functions, particularly with regard to people residing in designated centres for older people (residential centres or nursing homes). The MoU sets out the principles underlying this collaboration and provides guidance on the exchange of information between the two bodies.

Dr Ambrose McLoughlin, Registrar and Chief Executive of the PSI, welcomed the agreement and said, "There already exists a strong co-operation between the PSI and HIQA, so we are pleased to formalise this arrangement towards ensuring more effective regulation in common areas of activity. This memorandum of understanding is designed to structure this relationship and meet each organisation's aims and objectives, particularly when there are similar interests and responsibilities. It is vital for patients and public health generally that there is cohesion between our two statutory agencies and this agreement will help to ensure that."

Dr Tracey Cooper, Chief Executive of HIQA, said, "This memorandum of understanding provides HIQA and the PSI with an excellent opportunity to demonstrate our commitment to driving high quality and safe care for people using our health and social care services."

Ireland to host FIP Congress in 2013

The PSI and the Convention Centre Dublin (The CCD) recently announced that Ireland has successfully bid for a major international pharmaceutical congress for Ireland in 2013.

Speaking about the event win, which is set to bring 3,000 delegates to Dublin and could be worth as much as €10 million in revenue to Ireland, Dr Ambrose McLoughlin, Registrar and CEO of the PSI said, "The PSI, with the support of the pharmacy profession and sector, is delighted to bring this prestigious event to Ireland. It presents a huge opportunity for Ireland and will be a boost to the national economy in 2013."

"The PSI appreciates the support it has gained from the pharmacy representative bodies, the schools of pharmacy, the pharmaceutical industry and the Government, in particular the Minister for Health and Children, Ms Harney, and her Department, in securing this important event. We are looking forward to working with FIP, our stakeholders here and The Convention Centre Dublin on making this world congress in 2013 a success."

"We are honoured to host such a prestigious event at The CCD," said Catherine Newhall Caiger, Sales Director, The Convention Centre Dublin. "With eight out of the top 10 pharmaceutical companies in the world based here, this international event will help to solidify Ireland's strong commitment to this industry."

The annual FIP Congress attracts pharmacists, pharmaceutical scientists and academics from around the globe to a week-long event to discuss a wide range of global healthcare and pharmacy topics, current trends in pharmacy practice and pharmaceutical sciences and issues facing the profession.

The FIP Congress was previously held in Ireland in 1975.

Mr Ton Hoek, Secretary General and CEO, FIP; Ms Noeleen Harvey, President, PSI; Mr Paul Fahey, Vice President, PSI.

PSI Registrar and CEO, Dr Ambrose McLoughlin and Mr Ton Hoek, Secretary General and CEO, FIP, sign the formal agreement between FIP and the PSI for hosting the 2013 Congress

Call for Pharmacists with Interest in Disease Management

The PSI has called for expressions of interest from pharmacists with an interest or expertise in chronic disease management to participate in initiatives to improve patient care and work with a National Pharmacy Reference Group, which has been established to progress the development of pharmacy practice in Ireland in line with international best practice. (See notice in this issue). The closing date for applications is Friday 21 January 2011.

Background

The *Pharmacy Ireland 2020* initiative of the PSI Council has, since the publication of its Interim Report in 2008, continued to explore the avenues through which pharmacy services and pharmacist roles can be developed, in line with international evidence and best practice, in order to deliver better outcomes for patients.

Following meetings in recent months with the Minister for Health and Children, and subsequently with Dr Barry White, HSE Quality and Clinical Care Directorate (QCCD), it is now possible to move ahead on the Pharmacy Ireland 2020 agenda in the context of the work of the QCCD.

National Pharmacy Reference Group

To that end, the PSI has established a National Pharmacy Reference Group (NPRG) of practitioners, of required expertise and calibre, to participate at a strategic level to ensure active involvement of pharmacists at the appropriate decision and policy-making level. A main role of the NPRG in the framework for implementation of the various programmes of the Directorate will be to advise on the implementation of the programmes in pharmacy, including the most appropriate inputs required from pharmacists to gain maximum benefits for patients. The members of the NPRG are as follows:

Professor Peter Weedle (chair), Professor Paul Gallagher, Dr Aisling O'Leary, Dr Tamasine Grimes, Dr Stephen Byrne, Dr Mark Ledwidge, Dr. Caitriona Bradley, Ms Mary Rose Burke, Ms Cicely Roche, Mr Ciaran Meegan, Ms Leonora O'Brien (PSI rapporteur).

Pharmacists with an Interest in Disease Management Programmes Required for Committees

As part of that initiative, and in partnership with the HSE Quality and Clinical Care Directorate, the PSI is seeking expressions of interest from pharmacists with an interest and/or expertise in acute and chronic disease management.

Successful applicants will work through the Reference Group with the HSE Quality and Clinical Care Directorate to support initiatives around the development of evidence-based and integrated care in chronic and acute disease management as well as contributing to the implementation of the pharmacy elements of these initiatives.

The PSI Registrar and CEO, Dr Ambrose McLoughlin, said the initial focus of this work will be on heart failure, stroke, diabetes, chronic cardiovascular disease, chronic obstructive pulmonary disease (COPD)/ asthma, care of the elderly and mental health.

"The aim is to form a panel of pharmacists for each specific chronic disease area to participate in the work programme of the Directorate's committees in these areas. In the future, pharmacists will be required to contribute to other clinical areas and programmes. The overall objective is to continue to progress the development of pharmacy practice in Ireland, in line with international evidence and best practice, to deliver improved patient care in keeping with the *Pharmacy Ireland 2020* vision. In Ireland we now have a robust regulatory framework to ensure patient safety and, in particular with the ongoing developments in pharmacy education and training, this means that pharmacists in Ireland can now begin to make a more significant contribution to the care of patients, in line with international evidence, to improve the quality and safety of care, particularly when it comes to the use of medicines, as well as improvements in the accessibility and cost-effectiveness of care and treatment. With the establishment of the new Reference Group and the soon-to-be established Institute of Pharmacy, and working in partnership with the HSE and other healthcare professionals, patients and the health service generally could gain real benefits in the very near future."

Expressions of interest should be in the form of a CV with a short letter outlining expertise, track record and vision for the future in the relevant disease area(s). Applications should be sent to opd@iol.ie by Friday, 21 January 2011. Any queries should also be sent to opd@iol.ie.

IMB advice in relation to traceability when ordering exempt medicinal products from parties outside Ireland

Subject to certain exemptions, medicinal products which are placed on the Irish market are required to have a Product Authorisation issued by the IMB (PA number or PPA number) or, in the case of centrally authorised products, an authorisation issued by the European Commission (EU number) (Regulation 6 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 as amended). Schedule 1 to these regulations includes an exemption for the supply of unauthorised medicinal product in response to a bona fide unsolicited order from a practitioner for individual patients under his/her direct responsibility, in order to fulfil the special needs of those patients. Such products are defined as "exempt medicinal products..."

The Medicinal Products Regulations (SI 538/2007 and SI 539/2007 as amended) require wholesalers and manufacturers in Ireland which receive or import, respectively, exempt medicinal products to notify the IMB of their receipt. Since February 2008, an electronic notification system has been in place which allows the IMB to receive and store the notifications on a database. The main purpose of this database is to allow for the identification of exempt medicinal products on the Irish market place that may be the subject of a recall or safety issue the IMB has been made aware of.

Two recent recalls of exempt medicinal products from the Irish market included the presence of glass particles in a solution for injection and a microbial contamination issue with an infusion solution. In both cases, data from the IMB notification system was used to identify that these products were on the Irish market, enabling contact to be made with customers in order to execute the recalls in a timely fashion. This is not possible where the wholesaler placing the exempt product on the Irish market has not notified the product details and quantities to the IMB as outlined above.

Notification is not a statutory requirement for wholesalers and manufacturers that are not located in Ireland. However, it would be of considerable benefit to patient safety for the IMB to receive from these wholesalers and manufacturers details of exempt medicinal products which are sent directly to pharmacists and practitioners in Ireland. It is important that pharmacists ordering exempt medicinal products are aware of whether or not their supplier is submitting these notifications to the IMB. The IMB recommends that pharmacists request this confirmation from wholesalers and manufacturers, especially those located outside Ireland, prior to placing orders for exempt medicinal products.

Dr Ambrose McLoughlin, Registrar/CEO, PSI; Ms Mary Harney, Minister for Health and Children; Ms Deanna Williams, Registrar, Ontario College of Pharmacists; Mr Paul Fahey, Vice President, PSI at the unveiling of RCSI's new TTAP programme presentation

Minister launches pharmacy education and training reform programme

The Minister for Health and Children, Ms Mary Harney TD, formally launched the two major pharmacy education review reports on 15 October 2010. These are the Pharmacy Education and Accreditation Reviews (PEARs) project, which was a root-and-branch review of the five-year education and training programme, and the Review of International CPD Models, which recommended a model for mandatory CPD for pharmacists in Ireland and the establishment of an Institute of Pharmacy.

These reports were both approved by the PSI Council at its meeting of 01 June 2010. The new framework for the undergraduate and pre-registration education and training will mean a five-year, Masters-level, fully integrated programme of education, training and assessment as the basis for application for registration as a pharmacist in place of the existing '4 + 1' model. The system of mandatory CPD of pharmacists, which will be managed and delivered through an Institute of Pharmacy, will be fully operational, including peer assessment and practice review, and support and remediation where needed, by 2014.

The PSI Registrar and CEO, Dr Ambrose McLoughlin, said the aim of the reform agenda is to bring pharmacy education and training in Ireland in line with international best practice. "Following the passing of the Pharmacy Act in 2007, the Council of the PSI prioritised a programme of reform in pharmacy education and training. These two new reports commissioned by the PSI constitute major reviews of the programmes that currently exist both domestically and internationally. The aim of the reform agenda is to support improvements in professional practice and patient care, leading to enhanced patient safety and public protection. Today marks the commencement of the implementation of these major changes in Ireland."

Dr McLoughlin continued, "For the vast majority of pharmacists, pharmacy has changed from an absolute focus upon the preparation, formulation and supply of medicines to a clinical role involving advice and the provision of an increasing range of clinical services to patients. There was general agreement amongst those contributing to the PEARs project, supported by international trends in pharmacy education, that a fully integrated period of education and practice-based learning is the optimum way of ensuring the achievement of a clearly defined set of common educational outcomes at registration."

Professor Paul Gallagher, Chair of the Professional Development and Learning Committee of the PSI Council, said that the new CPD framework should become an integral part of a healthcare professional's practice experience. "The new system has been determined by the Council of the PSI," said Professor Gallagher, "on the basis of best international practice and experience and following a thorough consultation with pharmacists and other key stakeholders. There is no doubt that there is solid support for this new CPD system. Pharmacists are anxious to expand on the services they provide and to provide the best possible care to their patients and to the public."

Deanna Williams, Registrar of the Ontario College of Pharmacists, was also present at the announcement and outlined the merits of the new CPD model, which is based on a template that has existed in Ontario since 1997, for Irish pharmacists. Ms Williams highlighted that the effectiveness of the Ontario CPD model for pharmacists is reflected in its roll out across other healthcare professions in that region.

Paul Fahey, Vice-President of the PSI, said, "In essence, the overall aim of what we are formally setting in train today is to embed a culture of patient safety into the core of pharmacy education and training at all levels, from the entry level graduate all the way through a pharmacist's professional career. And on behalf of the PSI Council I wish to assure all of our ongoing commitment to deliver on this aim, in the interests of the patients we all serve."

The new Tutor Training and Accreditation Programme (TTAP) was also formally unveiled at the launch. This is an innovative programme which has been developed by the Royal College of Surgeons in Ireland (RCSI), on behalf of the PSI, to train and accredit tutor pharmacists who oversee the workplace training of pharmacy interns. (A clip from the TTAP is available to view on the PSI website at www.thepsi.ie/gns/education/becoming-a-pharmacist/tutors.aspx)

MPharm graduation news: Prof. Eilis McGovern, President, RCSI; Prof. Paul Gallagher, Head of School of Pharmacy, RCSI; Prof. Hannah McGee, Dean of the Faculty of Medicine and Health Sciences, RCSI; Dr Maurice Manning, Chancellor, NUI; Prof. Cathal Kelly, CEO/Registrar, RCSI

l-r: Una Rice, Fermoy, Co Cork ; Deirdre O'Mahony, Blarney, Co Cork, graduates

l-r: Shane McGlynn , Letterkenny, Co Donegal ; Michael McDermott , Sligo Town; Diarmuid Semple, Derry, graduates

First MPharms Graduate

The first cohort of MPharm graduates were among those conferred at ceremonies which took place at the Royal College of Surgeons in Ireland (RCSI) on Thursday, 18 November 2010. The National Pharmacy Internship Programme, which is delivered by the RCSI on behalf of the PSI and introduced a Masters in Pharmacy in Ireland for the first time, was launched in 2009 and the first cohort of 139 MPharm graduates were conferred at the ceremonies.

Professor Eilis McGovern, President of RCSI said, "The variety and number of awards being presented here today reinforces RCSI's key role as a leading provider in healthcare education in Ireland. Today's conferring is particularly special for the College with Ireland's first Masters in Pharmacy class being conferred by RCSI. RCSI has extended its expertise in post-graduate healthcare education to the profession of pharmacy as a significant contributor to the delivery of healthcare in the state. I would like to congratulate all the students here today and wish them every success in the future."

Dr Ambrose McLoughlin, Registrar/ CEO of the PSI said, "Today is a significant event for the profession of pharmacy in Ireland, bringing it into line with international best practice, as the new MPharm is now the basis of qualification to join the profession. This will support further developments in pharmacy practice in Ireland to deliver high quality, safe and cost-effective care to patients, in partnership with the other professions. I congratulate all the graduates here today who will have opportunities in the future to make significant contributions to patients, the public and the wider society."

PSI/ICCPE taskforce in initiative on Superintendents

The PSI and the Irish Centre for Continuing Pharmaceutical Education (ICCPE) joint taskforce has held a series of educational meetings for pharmacists around the country over the last two years, focussing on key professional issues arising from the implementation of the Pharmacy Act 2007.

In November 2010, the PSI/ICCPE taskforce organised an initial series of meetings for superintendent pharmacists. The aim of these meetings was to provide an understanding of the legal requirement for a superintendent pharmacist and the responsibilities of superintendent pharmacists, as well as the leadership, governance and accountability aspects of the role. Some of the main aspects of the PSI presentation given at the meetings are summarised here.

The aim was also to provide an opportunity for superintendent pharmacists to give feedback, with a view to informing the development of future resources for the CPD of pharmacists holding this important role.

Meetings were held in Cork and Dublin in late November which were well attended, with many superintendent pharmacists travelling considerable distances to make the meeting and contribute to the valuable discussion and feedback that took place. Unfortunately, due to the recent bad weather and in particular the treacherous road conditions, the meetings in Galway and Dublin North, which were planned for early December, had to be cancelled. It is envisaged that these meetings will be re-scheduled in early 2011.

The feedback received and points raised at the meetings are being incorporated into the development of a structured information system in 2011, specifically for superintendent pharmacists. This 'toolkit' will serve as a point of reference and guidance for superintendents to facilitate professional development and support compliance with legislation and best practice.

One of the main points of feedback raised at the meetings was a request for further information and guidance in relation to the inspection process of the PSI. The PSI has developed a short guide on what to expect during a PSI inspection and a checklist to assist pharmacists in preparing for any future inspection. These documents are available on the PSI website www.thePSI.ie and are also printed in this issue (pages 214 - 217).

The checklist is intended for use as a self-assessment tool, to facilitate a structured approach to preparing for inspection. It is not an exhaustive list of what may possibly be reviewed by an Authorised Officer of the PSI during an inspection of a retail pharmacy business, however, as it may be necessary for an Authorised Officer to focus on some aspects in particular, or other areas of concern, depending on their findings within a particular pharmacy practice on any given day.

The PSI welcomes queries from superintendents in relation to guidance issued by the PSI or any matters of concern relating to their role and responsibilities. Such queries should be sent in writing, preferably by email, to info@thepsi.ie.

PSI Signatory to *Patient Safety First* Inititiative

The PSI is a signatory and partner organisation to the *Patient Safety First* initiative which was formally launched by the Minister for Health and Children in September 2010.

This wide-ranging initiative is a programme of change to deliver services of consistently higher quality that are safer for patients, with errors reduced to as low a level as possible. Its current focus is on implementing the recommendations of the Commission on Patient Safety and Quality Assurance, Building a Culture of Patient Safety, primarily through a number of key projects under the stewardship of an Implementation Steering Group. These projects include the Medication Safety Forum which is chaired by the Chief Pharmacist at the Department of Health and Children, Marita Kinsella, and in which the PSI participates. The PSI's guidance on the safe supply of non-prescription codeine medicines was endorsed under the Medication Safety Forum's work programme in 2010 and further initiatives in relation to patient and medication safety will be progressed in 2011.

Patient Consultation Areas

From 01 November 2010, all retail pharmacy businesses are required to provide a patient consultation area in compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008 and the guidelines issued by the PSI to facilitate compliance with these regulations.

As laid out in the guidelines, there must be a sign in place which informs patients that the facility exists and is available for their use, should they wish to request the professional input of the pharmacist. Each retail pharmacy business should also have a written policy and procedure which encourages and trains staff to direct patients to the consultation area and inform them of their entitlement to a private consultation with a pharmacist.

Requests from a small number of retail pharmacy businesses for an exemption from the size requirement of the area have been deemed appropriate by the PSI in the particular circumstances pertaining to those individual premises. However, all pharmacy owners and superintendent pharmacists are reminded that it is likely in the future that the availability of a patient consultation area that meets all requirements of the guidelines may be necessary in order for the retail pharmacy business to provide certain new services or carry out certain activities. Patients and other members of the public are also likely to expect patient consultation facilities of a high standard, in line with best practice.

The Council of the PSI would prefer that all pharmacy premises and patient consultation areas are easily accessible to all patients requiring pharmacy services, and reach the highest possible standards of patient care, as pharmacies are an essential part of the health service infrastructure readily available to the public. The provision of a facility for private consultation between a pharmacist and a patient will enhance the professional interaction and relationship between pharmacists and their patients, and will enable pharmacists to further develop their role in the multidisciplinary team involved in patient care.

Baseline study of Pharmacy Practice

In 2009, the PSI commissioned a baseline study of pharmacy practice in Ireland, to generate a reference understanding of the nature and type of pharmacy services currently being delivered in Ireland, and to provide an analysis of the key issues influencing the practice of pharmacy.

Following a public tender process, the consultancy group Horwath Bastow Charleton (HBC) were commissioned to undertake this work.

During the summer of 2010, HBC carried out a confidential quantitative survey of all community pharmacies and, in a second phase of the survey, a sample of supervising pharmacists participated in a more detailed, qualitative follow-up interview to ascertain their views on the current and future developments in pharmacy practice and service delivery in Ireland, and the factors impacting on that future. Following anonymisation and analysis of the data collected, HBC are currently preparing a report on the survey findings for the PSI Council.

The PSI would like to thank the supervising and other pharmacists who participated in this important survey for their time, engagement and contribution.

CONTINUED REGISTRATION 2011 UPDATES

Certificates of Continued Registration

All registrants (pharmacists, pharmaceutical assistants and retail pharmacy business owners) who have recently completed their applications for continued registration for 2011 in the appropriate timeframe (whose certificates of registration expire on 31 December 2011), should receive their certificate of registration in the post before the end of January. (Any registrant who completed their application for continued registration within the appropriate timeframe and who has not received their certificate is asked to immediately contact the PSI.)

The certificate of registration of the retail pharmacy business should be conspicuously displayed in the pharmacy, along with the certificate of the supervising pharmacist.

Pharmacists will also have received their 'European Health Professional Card for Pharmacists', which bears their photograph, and pharmacists are encouraged to wear this card so they are readily identifiable to patients and the public as a registered pharmacist.

Retail Pharmacy Business Duty Register

For the past two years, the PSI has sent a specially-formatted 'retail pharmacy business duty register' free-of-charge to every registered retail pharmacy business, to facilitate compliance with the requirement of Regulation 5(1)(c) of the Regulation of Retail Pharmacy Businesses Regulations 2008, i.e. "an ongoing, contemporaneous and retrievable record of any other registered pharmacist, responsible for the retail pharmacy business or for the personal supervision of the sale and supply of medicinal products..."

As the feedback from pharmacy owners and superintendent pharmacists suggests that this register is being widely used and meets the needs of most pharmacies, the PSI has again issued a register to every retail pharmacy business for 2011, to facilitate compliance with the above requirement.

Online Registrant Facility

Many pharmacists and other registrants have availed of the online registrant facility to apply for continued registration and pay the appropriate fee, and the PSI wishes to thank those who have given useful feedback to help make the facility as user-friendly as possible. The online facility may also be used to update certain personal details, such as contact details, and registrants are reminded that they are obliged to notify the PSI in writing of any change in their details held as part of a Register.

Email Contact Details

It is important for the PSI to have contact details of all registrants, including email addresses, to facilitate the timely and efficient dissemination of important and often urgent information. Many other bodies, including the Irish Medicines Board and the HSE, frequently request the PSI to disseminate important professional or patient safety information on their behalf, to ensure that pharmacists are informed and updated on matters that may impact on patient care and safety, and email will continue to be an important channel of communicating with pharmacists.

Registrants are therefore encouraged to ensure that their correct and up-to-date contact details, particularly their email addresses, are on the PSI database. Personal contact details are not published as part of the publicly available registers.

Core Competency Framework

The PSI's programme of pharmacy education and practice development, including CPD for pharmacists, will require the definition of a competency framework for pharmacists practising in Ireland.

To that end, the PSI is participating in an initiative of the international Pharmacy Education Taskforce (PET) to develop a competency framework that meets the needs of pharmacists around the world and across all practice settings, both clinical and non-clinical. The PET is a co-ordinating taskforce set up under the auspices of the International Pharmaceutical Federation (FIP), the World Health Organisation (WHO) and the United Nations Educational, Scientific and Cultural Organisation (UNESCO).

In October 2010, pharmacists in Ireland were invited to participate in an international survey on the draft Global Competency Framework and the PSI would like to thank all those who participated in this survey. In early 2011, the PSI will be engaging in a public consultation on this global framework to ensure its applicability in Ireland and offer an opportunity for practitioners to input further.

The competency framework will be instrumental in assisting pharmacists to pursue the CPD activities that meet their practice context needs with a clear focus on the need to promote patient safety.

PSI Guidelines on Retail Pharmacy Business Regulations

The PSI is currently developing guidelines with a view to facilitating compliance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008. These guidelines will cover the major sections of the regulations which include the following requirements:

- Sourcing, Storage and Disposal of Medicines
- Premises and Equipment
- Supply/Patient Counselling for prescription medicines (Regulation 9)
- Supply/Patient Counselling for non-prescription medicines (Regulation 10)
- Record-keeping
- Management and Supervision

In 2010, formal guidelines were published in respect of the safe supply of non-prescription codeine medicines and patient consultation areas. All pharmacists and pharmacies are expected to comply in full with the guidelines issued by the PSI.

In 2010, draft guidelines were also issued for public consultation in respect of the Sourcing, Storage and Disposal of medicinal products. These draft guidelines are currently being reviewed following the consultation process and finalised guidelines will be brought to the PSI Council early in 2011 for formal approval and publication. The PSI would like to thank all the pharmacists and other stakeholders who have contributed to its consultation process on the guidelines so far.

In 2011 and into 2012, the PSI will issue guidelines to facilitate compliance with the other main requirements of the regulations.

Council Meeting Report: 30 September 2010

The Public session of the 20th meeting of the PSI was held on Thursday 30 September 2010 at the offices of An Bord Altranais, Blackrock, Co Dublin.

The Council was addressed by Dr Deirdre Mulholland, Head of Standards and Methodology, Healthcare Quality and Safety Directorate at HIQA, on HIQA's draft national standards for safer, better healthcare standards. The Council also formally approved a Memorandum of Understanding between the two bodies at this meeting.

Council also formally approved a number of education-related matters; specifically the tutor training and accreditation programme; a proposed appeals process under Rule 18 of the PSI (Education and Training) Rules 2008; an appeals process for Third Country Qualification Recognition applicants who wish to review the decision of the Professional Development and Learning Committee arising from the Equivalence Examination; the examination and appeals procedure for the Professional Registration Examination and the Examiners for the November 2010 sitting of this exam; the programme document for the National Pharmacy Internship Programme; the Marks and Standards 2009-2010 document for the MPharm; and the accreditation standards and accreditation process in relation to the MPharm.

Council Meeting Report: 04 November 2010

The public session of the 21st meeting of the PSI was held on Thursday 4th November 2010 in the Gresham Hotel, Dublin 1.

Among the items brought to Council's attention was a memorandum of advice from the Registrar, for their consideration and discussion at a future meeting, relating to concerns arising out of certain commercial practices in the establishment and development of retail pharmacy businesses.

A report from the Fitness to Practice Taskforce was introduced by the Vice-President Paul Fahey and Council was updated on the taskforce's deliberations on the issues arising. Council was also apprised of the series of meetings being held by the joint PSI/ICCPE taskforce on the responsibilities and accountabilities of superintendent pharmacists.

The Registrar also briefed Council on progress in relation to the *Pharmacy Ireland 2020* initiative, following meetings in recent months with the Minister for Health and Children, and subsequently with Dr Barry White, HSE Quality and Clinical Care Directorate and his team.

Through its *Pharmacy Ireland 2020* initiative, the PSI is committed to assisting in the effective implementation of the programmes of the Directorate and, in particular, in supporting pharmacy engagement with the programmes. This engagement will facilitate and support the implementation of evidence-based, protocol-driven, integrated clinical and therapeutic care, with a focus on optimising patient outcomes and meeting key safety, quality and cost-effectiveness objectives.

To that end, the PSI had received an invitation to nominate a reference group of practitioners, of required expertise and calibre, to participate at a strategic level in ensuring active involvement of pharmacists at the appropriate decision and policy-making level. Other healthcare professions are also engaging with the implementation of the Directorate's programme, chiefly through their respective professional Colleges and Institutes, and once the 'Institute of Pharmacy', as recommended in the context of the introduction of CPD, is established, it will be possible to base the reference group in this structure.

A main role of the reference group in the framework for implementation of the various programmes of the Directorate will be to advise on the implementation of the programmes in pharmacy, including the most appropriate inputs required from pharmacists to gain maximum benefits for patients. This framework will also provide a 'ready-made' structure to enable the piloting or road-testing of protocols or initiatives in the pharmacy context, within the network of 'teaching pharmacies' and tutor pharmacists.

The practitioners nominated for the reference group are: Professor Peter Weedle (chair); Professor Paul Gallagher; Dr Aisling O'Leary; Dr Tamasine Grimes; Dr Stephen Byrne; Dr Mark Ledwidge; Dr Caitriona Bradley/Ms Mary Rose Burke; Ms Cicely Roche; Mr Ciaran Meegan; Ms Leonora O'Brien (PSI rapporteur).

The Pharmaceutical Society of Ireland

Short Guide on what to expect during the Inspection Process

PSI Authorised Officers (the formal title of the inspectors) will identify themselves at the start of an inspection. All Authorised Officers carry a PSI identity card and their warrant as Authorised Officer, which is their authority to enter pharmacies and other premises. You can ask to see the warrant to assure yourself the person is an Authorised Officer of the PSI.

On arrival at a pharmacy for inspection, the inspector will first ask to see the pharmacist or pharmacists who are present.

Most pharmacists will choose to keep the pharmacy open during an inspection, which means that patients and members of the public will need to be attended to during the inspection.The PSI and its Authorised Officers make it clear that patient needs are everyone's priority. During the inspection, the pharmacist will be asked to source particular records or documents for the inspector, but this will be done while ensuring that patients are being dealt with as the priority, and where necessary, the inspector will wait while the pharmacist attends to patients.

So what will the inspectors look for during an inspection?

- The PSI has produced a checklist to assist pharmacy owners and pharmacists in preparing for a future inspection and to inform them on what to expect during an inspection.

The following areas should be covered in any self-assessment:

- Premises: security arrangements, 'keyholding' policy (including policy around the pharmacy not opening when no pharmacist is present), layout to allow for supervision of professional activities and to restrict access to dispensary and medicinal products, patient consultation area; also storage areas, staff areas, bathroom; housekeeping/cleaning records; clean, uncluttered dispensary and professional areas, including proper paper record-filing arrangements.
- Registration certificates (retail pharmacy business and supervising pharmacist) on conspicuous display.
- Documented policies and procedures/SOPs recommended by PSI, including those listed in the checklist, as well as any recommended in PSI guidelines or practice notices.
- Compliance with codeine guidance, including location of non-prescription codeine medicines in the dispensary.
- Properly maintained duty register; evidence that supervising pharmacist practises at the pharmacy for a significant proportion of the opening hours; superintendent and supervising pharmacists properly notified to the PSI.
- Prescription records/daily dispensing report (signed and dated) – you may be asked to produce original prescriptions and records of emergency supply dispensing.
- Controlled Drugs (CD) register – balances will be checked and you may be asked to produce original CD prescriptions.
- CD safe – 'keyholding' policy, Garda certification, segregation of out-of-date/returned CD stock for destruction.
- Pharmacy fridge – cleanliness, temperature monitoring, condition of stock, expiry dates of stock.
- Dispensary stock – expiry dates of stock, documented policies and procedures for sourcing, storage and disposal of medicines.
- Extemporaneous dispensing – SOPs, records, equipment.
- Veterinary medicines – storage/location, expiry dates, records.
- Supply to nursing homes/residential care settings – documented policies and procedures, in line with PSI Practice Notice, record-keeping, e.g. patient visits.
- Clinical waste bins/disposal policy.
- Shredder for confidential paper waste.
- Reference material – current reference books, e.g. BNF, or easy access to online versions, copies of or access to PSI guidance documents and legislation.
- Error/Incident log and management policy.
- Locum induction/communication policy.

Regular pharmacy inspections may typically take up to about two to three hours.

After an inspection has been carried out, an inspection report will be generated and sent to the pharmacy, with a response sought to any issues highlighted in the report.

The following is a non-exhaustive list of what may be reviewed by an Authorised Officer of the PSI during an inspection of a retail pharmacy business (RPB). This checklist is intended as a self-assessment tool to assist you in preparing for an inspection.

1.0	Registration Certificates	Yes	No
1.1	Has the retail pharmacy business (RPB) the correct certificate of registration and is it prominently displayed to the public?		
1.2	Has the supervising pharmacist the correct certificate of registration and is it prominently displayed to the public?		

2.0	Codeine Containing Products	Yes	No
2.1	Are codeine-containing products stored in the dispensary, out of sight of the public?		

3.0	Policies and Procedures	Yes	No
3.1	Has the RPB a full suite of documented policies and procedures/SOPs? The following are recommended:		
	a) Dispensing, including therapeutic review and patient counselling; high-risk/High Tech medicines		
	b) Storage of medicines		
	c) Sourcing of medicines		
	d) Expiry date checking		
	e) Sale and supply of medicinal products		
	f) Storage and record-keeping for controlled drugs		
	g) Disposal and/or destruction of medicines (including controlled drugs)		
	h) Management of additional services provided (including supply to residential care homes)		
	i) Error and incident management (including error logs)		
	j) Locum induction/communication policy		
	k) Housekeeping and cleanliness of dispensary and shop floor (inc. cleaning records)		
	l) Use of patient consultation area		
	m) Policy on use of child resistant containers		
	n) Keyholding policy (to premises and CD Safe)		
3.2	Is there an implementation date on all SOPs?		
3.3	Is there a review date on all SOPs?		
3.4	Is there evidence that staff have been trained on SOPs?		

4.0	Duty Register	Yes	No
4.1	Has the RPB a duty register/log for the current year?		
4.2	Is the duty register being correctly maintained?		
4.3	Is there professional cover available for all hours of opening?		
4.4	Does the supervising pharmacist provide adequate cover?		

5.0	Prescription Register/Daily Dispensing Report	Yes	No
5.1	Is the daily dispensing report printed on a daily basis (within 24 hours)?		
5.2	Is the dispensing report certified by the Pharmacist?		
5.3	Is the dispensing report completed in the correct format in accordance with Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended)? Are the dispensing reports/prescriptions for the previous two years available for review on the premises? *(Note: Any area of the premises where pharmacy records or medicinal products are stored must be included on the floor plan submitted as part of the registration file)*		
	Note: You may be asked to produce prescriptions.		

6.0	Controlled Drug Register	Yes	No
6.1	Has the RPB a CD register?		
6.2	Is the CD register completed in accordance with instructions and regulations?		
6.3	Is there evidence of routine review and stock balance checks?		
	Note: You may be asked to produce controlled drug prescriptions.		

7.0	Controlled Drug Inventory	Yes	No
7.1	The actual balance of CDs will be checked against the balance recorded in the CD register.		

8.0	Controlled Drug Safe	Yes	No
8.1	Has the RPB a CD safe?		
8.2	Is there a written 'keyholding' policy for the CD safe?		
8.3	Is the safe secured in accordance with regulations?		
8.4	Has the CD safe been certified by the Gardai? (*Note: This certificate is valid for two years from date of issue*)		
8.5	Does the safe have sufficient capacity?		

9.0	Storage of Medicinal Products	Yes	No
9.1	Has the RPB a pharmaceutical grade fridge?		
9.2	Is the fridge temperature monitored and recorded on a daily basis?		
9.3	Is the temperature in the dispensary and any additonal storage areas monitored and recorded on a daily basis?		
	Note: Cleanliness of fridge, condition of stock and expiry dates in the fridge and dispensary will be checked.		

10.0	Extemporaneous Compounding/Locally Prepared Medicinal Products	Yes	No
10.1	The following will be checked in relation to extemporaneous compounding, etc.:		
	a) Standard operating procedures		
	b) Record-keeping		
	c) Labelling procedures		
	d) Equipment (i.e. is there proper equipment in place, cleanliness, calibration)		

11.0	Veterinary Medicinal Products	Yes	No
11.1	The following will be checked in relation to veterinary medicinal products:		
	a) Location of prescription-only medicines, companion animal remedies and fridge items		
	b) Expiry Dates		
	c) Veterinary records (veterinary register, prescriptions, etc.) *(Note: Records for the previous five years must be available for review on the premises)*		

12.0	Supply to Patients in Nursing Homes/Other Residential Care Homes/Community Care	Yes	No
12.1	The following will be checked in relation to supply to nursing homes, etc.:		
	a) Documented policies and procedures/SOPs (to include receipt of prescription, delivery, management of CDs, patient visits/counselling, etc.)		
	b) Record-keeping		

13.0	Premises	Yes	No
13.1	Are there adequate security arrangements in place? Has the PSI/Garda Security Assessment been completed? Is there a written keyholding policy for the pharmacy?		
13.2	**Dispensary** - Does the location of the dispensary allow the pharmacist to supervise the sale of medicinal products at the medicines counter? Is access to the dispensary restricted?		
13.3	**Medicines Counter** - Does the location of the medicines counter restrict access to medicinal products which should not be available to the public for self-selection?		
13.4	**Consultation Area** - Does the consultation area meet the requirements set out in the PSI Guidelines on Patient Consultation Areas?		
13.5	Is housekeeping in the pharmacy at an acceptable standard?		
	Note: The location of staff areas/bathrooms and any storage areas will also be checked.		

14.0	Miscellaneous	Yes	No
14.1	Does the pharmacy have appropriate reference books/easy access to online versions?		
	Martindale (current or most recent edition)		
	Current BNF		
	Current BNF for Children		
	Current Drug Interaction reference		
14.2	Does the pharmacy have clinical waste bins?		
14.3	Does the pharmacy have a shredder for confidential paper waste?		
14.4	Is the pharmacy registered with the Data Protection Commissioner?		
14.5	Does the pharmacy have a confidentiality policy in place for all staff?		

Superintendent Pharmacists – Responsibilities and Accountabilities

Leonora O'Brien M.P.S.I.
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PSI/ICCPE taskforce on initiative on Superintendents

In November 2010, the PSI/ICCPE taskforce organised an initial series of meetings for superintendent pharmacists. The aim of these meetings was to provide an understanding of the legal requirement for a superintendent pharmacist and the responsibilities of superintendent pharmacists, as well as the leadership, governance and accountability aspects of the role. Some of the main aspects of the PSI presentation given at the meetings are summarised here.

The introduction of the role of the superintendent pharmacist is a significant driver for the implementation of the Pharmacy Act 2007 (the Act) and the development of pharmacy in Ireland, establishing a framework for achievement of a high quality, safe and consistent service for the benefit of patients and public as well as facilitating the development of the professional role of the pharmacist.

The Legal Requirement for a Superintendent Pharmacist

The role of the superintendent pharmacist, established by the Act, ensures that the management and administration of the sale and supply of medicinal products in retail pharmacy businesses (pharmacies) in Ireland, is firmly under the control of a senior pharmacist with a defined minimum level of experience. The superintendent pharmacist position is one of management and leadership and in company terms is equivalent to a 'Chief Officer' role, carrying full-time responsibility and accountability within a company.

Prior to the Act, pharmacy in Ireland was largely unregulated in terms of openings and practice. It was possible for non-healthcare professionals to form a company and operate a pharmacy without having a robust or defined relationship between that pharmacy owner and the responsible pharmacist(s). The responsibilities and accountabilities for that pharmacy practice and most importantly, for the patient, were not clearly defined.

Now the role of the pharmacist and owner are inextricably linked. Since the Act, engaging a superintendent pharmacist is a legal pre-requisite for a company to open or operate a registered pharmacy. Companies must formally enter into agreement with a named superintendent by signing the 'Statement By Pharmacist And On Behalf Of A Corporate Body' provided for in section 28(a) of the Act. By signing this statement, the corporate body officially recognises that all decisions and processes pertaining to medicinal products must be under the personal control of the superintendent, that the pharmacist is accountable and that both accept this responsibility.

Pharmacy owners now have a legal duty to understand and facilitate the management and professional obligations of the superintendent. They must consider and act on the advice of the superintendent pharmacist when dealing with the management of medicinal products within the business and provide the superintendent pharmacist with the necessary support and resources to fulfil their legal and professional obligations and in turn, those of all registered pharmacists engaged within that business.

Succession Planning

An element of reflection and effective planning is required in all businesses and pharmacy is no exception, particularly as it involves ensuring the continuity of patient care. A company for example, cannot lawfully trade in medicinal products or conduct a pharmacy without a superintendent, therefore it follows that due consideration must be given to succession planning within the business.

For superintendents in control of two or more pharmacies, drafting a succession plan normally involves identifying a supervising pharmacist within the organisation with the right knowledge, skills and attitudes required to discharge the duties of superintendent; a pharmacist who would be committed to driving the professional performance and legal compliance of the pharmacy and who, on assuming the role, would accept the accompanying responsibilities and accountability. The name of this appropriate successor is then agreed internally and documented in a contingency plan.

If the supervising pharmacist nominated in this succession plan subsequently leaves the organisation or changes their mind for whatever reason, another potential successor is identified and the contingency plan is updated accordingly. Succession planning is not an officially binding process necessitating communication to the Regulator; it is, however, an example of good organisational practice which demonstrates a superintendent's attention to risk-assessment, continuity of patient care and legislative compliance.

It is advisable for a superintendent to arrange for their successor to shadow them for a period of time before the date they are to be solely and officially in personal control.

In situations where a pharmacist is acting in the capacity as both the superintendent and supervising pharmacist, for example a Sole Trader, identifying a successor to include in a succession plan may prove more difficult. In these cases, the superintendent pharmacist should simply communicate to those who may be tasked with carrying on the business in unforeseen circumstances (such as sudden death of a superintendent), that the appointment of a new superintendent, with a minimum of three years' post-registration experience, is a condition of the operation of and maintenance of the registration of that pharmacy. The name of the nominated superintendent must be submitted to the Registrar. Those who may be tasked with carrying on the business should be informed that in such unforeseen circumstances they may contact the PSI for support and advice as necessary.

In cases where a particular superintendent is appointed only for an interim period until a long-term superintendent has been recruited, they must nonetheless undertake to be fully responsible and officially accountable for that pharmacy business during this time.

Key Legal and Professional Responsibilities of a Superintendent

All superintendent pharmacists declare in law that they are aware of their legal responsibilities under the Act and that they undertake to use the best of their endeavours "to ensure compliance therewith and with any Regulations, Code of Conduct, Statutory Rules and professional guidelines as may be in force". Superintendents have overall responsibility for ensuring that ethical and appropriate policies and procedures are in place and implemented within their organisation in order to achieve full compliance with such legislation and to govern every aspect of the sale and supply of medicinal products. They must promote the rational and safe use of medicines in the interests of patients and the public and ensure that the appropriate assessment, information and advice are made available for each individual patient.

Policies and Procedures – why are they required?

The requirement for a superintendent to have policies and procedures in place should not

be viewed as a redundant administrative burden but as a responsible and demonstrable approach to risk management within a pharmacy. Robust policies and procedures are now required across most sectors and businesses, e.g. Aviation, Manufacturing, Service Industry, Retail, Telecommunications, Energy, Hospitality, etc. It's now common practice for many hotels for example, to have SOPs in place for simple tasks such as answering the reception telephone, in order to guarantee a standardised level of service. Within healthcare facilities such as a pharmacy, it is understandable that documented procedures are essential, given the potential that exists for irreversible harm to patients.

Policies and procedures are simply a mechanism used by superintendents to ensure that their pharmacy's processes and services are performed in a consistent way according to pre-defined standards. Superintendents must maintain a reporting relationship with their supervising pharmacists and ensure that all registered pharmacists engaged within that pharmacy are free to raise professional or ethical concerns or queries they may have about any policy or procedure, without fear of reprisal.

Having policies and procedures in place promotes safe practice regardless of whether the superintendent is physically present or not, enabling the superintendent to demonstrate full-time control and governance over all pharmacy operations. By clearly defining exactly what is to be carried out, how and by whom, documented procedures also help the superintendent communicate and underpin the responsibilities and accountability of all their staff. All persons engaged within the pharmacy, including all supervising and registered pharmacists, must be compliant with the superintendent's policies and procedures. If an incident occurs, the superintendent is able to track and demonstrate that they have communicated the correct procedure and facilitated appropriate training for staff and that a procedural violation has occurred for which that staff member may subsequently be held responsible. It is the superintendent's responsibility to analyse the cause of the violation or error and endeavour to prevent recurrence.

All organisational policies must be in line with the *Code of Conduct for Pharmacists* and must not impair or compromise the ability of any registered pharmacist to adhere to this, their statutory professional code. This has particular relevance in larger organisations where certain tasks may be delegated to functional departments, for example HR, Marketing, or Finance. It remains the superintendent's responsibility, and not that of other staff employed in such departments, to ensure the legal compliance of all policies that impact on the operations of the individual pharmacies. The law is clear about where this accountability lies.

In relation to HR for example, it is the superintendent pharmacist in co-operation with the pharmacy owner that must, inter alia, ensure that they are satisfied that all staff "have the requisite knowledge, skills, including language skills, and fitness to perform the work for which they are, or are to be, responsible". For example, if an error occurs due to a language competency issue, the superintendent can be held accountable if they do not have a robust policy or mechanism in place to govern the process of recruitment and selection, including provision for a thorough screening process and reference checks to facilitate appropriate and safe engagement within that pharmacy. For locums, measures taken by a superintendent may include development of a Service Level Agreement with their locum agency; or a policy of using known locums only or those which have passed a standard vetting procedure which has been pre-defined by the superintendent.

In relation to a marketing or advertising function, again it is the superintendent who is legally responsible for the pharmacy's compliance with all legislation pertaining to the advertising and promotion of medicinal products. A superintendent must have robust policies and procedures in place to govern fundamental aspects such as the rational and safe use of medicines and accessibility of medicines (for POMs, non-prescription medicines, CD5s, products with abuse potential, etc.), including a process for effective vetting of all promotional material. All personnel within that pharmacy, both in the pharmacy itself as well as relevant office personnel, must have read, understood and signed off on such policy.

All persons holding positions of responsibility, including pharmacy owners and members of the board of a corporate body, as well as all departments and centralised management functions, must be aware of the superintendent's formal training in pharmacy law and ethics, understand their responsibility for legal compliance within that pharmacy and must not thwart the superintendent's professional judgement or decisions.

'Full-time Accountability'

To err is human; to analyse, learn and prevent is superintendent policy

Is a superintendent directly and solely responsible for every human error made by others within a pharmacy? And if not, how can they assume full-time accountability for that pharmacy?

As autonomous professionals, registered pharmacists are responsible and professionally accountable in their day-to-day practice. They are required to possess, maintain, update and display competence in respect of the management of the health of a patient and the delivery of an appropriate standard of pharmaceutical care.

However, it is the superintendent who has overall responsibility and accountability for the maintenance and adherence to a sound system of controls in order to manage risk and promote patient safety within the pharmacy. This is assured by, for example, having appropriate policies and procedures in place within that pharmacy. This is a mandatory practice requirement which is the responsibility of the superintendent. If mandatory requirements are not met by the superintendent, they fail in this responsibility and may be held accountable for any negative repercussions. Accountability is simply the acknowledgment and assumption of a set of responsibilities. It is not unique to pharmacy; it is the backbone of any effective healthcare system. Having an effective system of accountability, simply means someone is answerable for deficiencies found within our professional practice or for any resulting consequences for our patients.

In the words of Alexander Pope, "to err is human" – a fact which necessitates this structure of defined responsibility and accountability within a pharmacy. Without a system of accountability, no one is tasked with taking responsibility for analysing errors and experiences and incorporating any learnings into our systems and processes in order to facilitate continuous improvement and development.

Error Management Within a Pharmacy

To further understand the nature of the responsibility and accountability structure within a pharmacy, it is important to consider the many types of error which can occur in practice. Reason's Swiss Cheese Model, (see fig.1) is a particular method of illustrating Risk-Cause analysis and is useful for superintendents to reflect on error management within their individual healthcare facilities. Simply put, the holes in the Swiss Cheese represent weaknesses within our systems or standards of practice and they vary in size and position. When these individual weaknesses align, an error can occur resulting in patient harm. The holes, or weaknesses within our practice, can be caused by 'active failures', i.e. unsafe acts directly linked to the error such as staff carelessness or aberrant mental processes; or 'latent failures', i.e. contributory factors within the system which may have lain dormant for a long time but have finally contributed to an error.

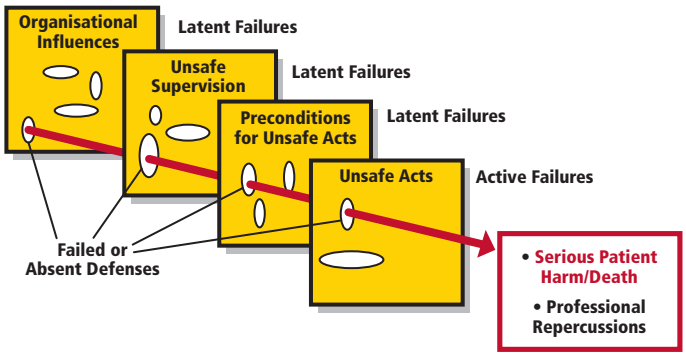

Fig 1: Reason's Swiss Cheese Model; paradigm for error analysis and prevention

Identifying Latent Failures and Active Failures

A common latent failure in pharmacy practice is the lack of regularly reviewed dispensing procedures. If, for example, a superintendent has not introduced a procedure for the systematic checking of expiry dates and removal of expired medicines from stock, this is one latent failure (or hole in the cheese). To compound the risk, if the superintendent has not introduced a dispensing procedure with a provision for date-checking of all medicines at the point of dispensing, another latent failure is permitted. If on top of this, you add an active failure such as pharmacist tiredness, an out-of-date medicine may be dispensed, resulting in an ineffective treatment and/or serious patient harm.

A second example of a latent failure would be lack of a policy reflecting the necessity for having a registered pharmacist present at all times and engaging in effective supervision of the pharmacy. If a staff member opens a pharmacy and medicinal products are subsequently sold or supplied, the superintendent can be held accountable. A superintendent must be able to demonstrate that they have an effective and robust policy in place to ensure full-time supervision and control of that pharmacy, and that all pharmacy staff are made aware of, trained in and are in compliance with this policy. All pharmacy staff should be formally made aware of the procedure to follow should, for example, a locum not present themselves to conduct the pharmacy. Such a procedure should outline what to do to (pharmacy not to open) and what not to do (e.g. no sale of non-prescription medicinal products), and who to contact (e.g. superintendent pharmacist, locum agency).

For the most part, latent failures are preventable. It is the duty of the superintendent pharmacist to reflect on their particular practice, to proactively identify the preconditions and endeavour to minimise, and where possible eliminate, risks and incident occurrence.

A third example of a preventable latent failure is the failure to incorporate guidance of the Regulator into the pharmacy's systems and procedures. An example with potentially serious repercussions is failure to action the points of guidance provided in the PSI's Methotrexate Practice Notice. If the superintendent has no policy or specific training in place for the safe dispensing of high-risk medicines, the risk is compounded and another weakness is introduced in the system. If a superintendent also fails to introduce a policy to reflect the requirement for therapeutic review and patient counselling by the registered pharmacist (to comply with Regulation 9 of S.I. No. 488 of 2008), an inappropriate label may be printed, the patient may not be adequately counselled and a daily dose of methotrexate taken by the patient, which could result in serious side effects, hospitalisation or even death.

Many active failures can also be predicted and prevented, for example introducing a minimum break period for a certain number of hours worked; or identifying busy periods within the practice and organising sufficient support and cover accordingly.

Error Review and Root-Cause Analysis

All errors that do occur must be systematically recorded in the pharmacy and be subjected to a regular review and root-cause analysis by the superintendent pharmacist. Learnings made from such a review must then be incorporated into the policies and procedures of the pharmacy in order to prevent recurrence.

Fig. 2: Superintendent pharmacist's error prevention cycle

When a superintendent reviews and analyses the errors for example, they may find that some medicinal products have a higher risk of being dispensed incorrectly, within one individual pharmacy or across numerous pharmacies. When the cause is examined it may be due to storage proximity to another product with a similar name, brand, ingredient or packaging - a Sound-Alike Look-Alike-Drug (SALAD) error. Such errors or near misses should be routinely reported to manufacturers and the Irish Medicines Board so that any necessary changes to the product can be examined.

If a superintendent is in control of one pharmacy, they should communicate both the cause of the error as well as their updated or new procedure to all staff engaged within that pharmacy and maintain a record of any re-training completed. If a superintendent is in control of numerous pharmacies, they must ensure that learnings made from incidents occurring in the originating pharmacy are communicated to all pharmacies and that the overarching policies for the organisation are updated.

The appropriate process to follow when an error is reported must be outlined, including, for example, how to deal with errors reported by patients over the telephone. Under no circumstances should a patient be left with incorrect medicine(s) at home, nor should the onus be on the patient to return the incorrect medicine to the pharmacy, or the error left for the next pharmacist to address. When an error is reported, the pharmacist on duty must act immediately to retrieve any incorrect medicine, assess any risks to the patient's health, give the appropriate advice and follow-up and furnish the patient with their correct treatment, as appropriate.

To take effective ownership of the situation does not necessarily mean accepting 'responsibility' for making the error. According to a defined procedure, the pharmacist on duty must communicate what has occurred to the supervising pharmacist and/or the superintendent pharmacist and the error is appropriately documented, along with any remedial actions taken.

For an error-reporting system to be truly effective, the superintendent should foster a no-blame culture and encourage transparency within the pharmacy. Such reflective practice and incorporation of learning into review of procedures are equally important both for superintendents that are in personal control of one pharmacy and those in control of many.

An Effective Complaints System

In parallel with an effective Error Review process, every pharmacy must have a robust complaints system in place in the interest of patients and the public. A patient or member of the public may be dissatisfied or concerned with the treatment they have received in a pharmacy, or with the behaviour, conduct, practice or health of a particular pharmacist. If there is no effective complaints process in place within that pharmacy, the person may feel it necessary to escalate their grievances to the PSI.

Although the possibility of such an escalation is a vital mechanism which must exist to enable patients to report serious concerns and complaints, or for the Regulator to detect real and immediate public risk, many complaints are escalated simply because the patient feels they have not been treated appropriately when they raised their concerns within the pharmacy.

Many complaints can be easily resolved within the pharmacy itself if a simple, standardised procedure is in place to facilitate local action. This documented procedure should have clearly outlined responsibilities and give explicit instructions on how complaints are to be dealt with, from the point of reporting by the patient until full resolution. The procedure must specify any person(s) to be notified of the complaint (i.e. supervising pharmacist and superintendent pharmacist) and give details of what procedures and timelines they themselves will adhere to and in what instances, for example, reporting to the prescriber where necessary.

Soft skills and communication training are vital elements here for pharmacy staff. A defensive tone or attitude, or failure to take ownership over the complaint, may lead to escalation of even the simplest of grievances. The complaints policy of a pharmacy should remind pharmacists to be mindful of their Code of Conduct which necessitates professionalism and accountability. Pharmacy staff must be trained to deal with concerns respectfully and with understanding and to ensure the patient's experience of

pharmacy is a professional and positive one. A patient will feel compelled to escalate their complaint if they feel that their concern is not being taken seriously or if they sense apathy or fear a recurrence.

Patients should be given appropriate reassurance, such as explaining how the pharmacies procedures have been updated as a result of the error and the nature of any re-training carried out. All complaints and errors must be followed up thoroughly until a satisfactory conclusion is reached.

Professional Guidance of the Regulator

All superintendents undertake to comply with professional guidelines of the Regulator. Official formal guidelines are being published by the PSI in order to facilitate compliance with the Act and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008). All pharmacists and pharmacies are expected to comply in full with these formal guidelines. In 2010, for example, guidelines were published in relation to Patient Consultation Areas and Safe Supply of non-prescription Codeine Medicines (accessible via PSI website). Guidelines for the safe and appropriate Sourcing, Storage and Disposal of medicinal products will be published early in 2011, with guidelines relating to Premises and Equipment, Record-keeping, Management and Supervision, and Supply and Counselling of Prescription and Non-prescription Medicines Regulation (Regulations 9 and 10) to be published later.

PSI Practice Notices and Guidance – example of implementation process

As various guidance documents are published and disseminated by the PSI, it is the superintendent's responsibility to reflect on how they apply to their pharmacy and ensure the recommendations are implemented. An example is the recent Practice Notice on Supply by Pharmacists of Medicines to Patients in Residential Care Settings/Nursing Homes. This should be reviewed along with HIQA's National Quality Standards for Residential Care Settings for Older People which set out what a quality, safe service for an older person living in a residential care setting should be.

When implementing the recommendations of the Practice Notice, superintendent pharmacists must review their current processes to ensure patients in such care settings receive the same level of professional care as those who attend the pharmacy in person.

How is this achieved?

Firstly, it is important to identify where pharmacist intervention is required (example see fig. 3) and then decide on the exact procedures to be implemented in order for the individual pharmacy to provide an appropriate, standardised system for pharmaceutical care to the residential setting – one which facilitates counselling by the pharmacist of each individual patient. It is essential that the pharmacist personally and physically attends to the patient in the home, on a frequency appropriate to the individual patient's needs. Records of these visits to patients by the pharmacist should be retained and be available for review in the pharmacy and in the care setting itself.

There must be regular, and frequently as required, contact with medical personnel responsible for the patients in the care setting, particularly in relation to new patients, to establish any needs or requirements specific to that patient. Such contact and all resulting actions should be systematically documented and maintained for reference and inspection.

The delivery process must incorporate provision for a registered pharmacist's supervision and intervention. No queries must be answered or advice given by a person who is not qualified to provide such information. All healthcare professionals involved in deliveries to the care setting, including all pharmacy employees, must be readily identifiable to receiving patients and their carers. A demonstrable mechanism must be in place whereby the patients are made aware that there is ready and ongoing access to a pharmacist.

All pharmacists involved in the care of a patient within a residential care setting must actively participate in the development of appropriate policies governing medicines safety and management, in co-operation with other named healthcare professionals involved in patient care within the organisation. Going forward, in line with the HIQA National Quality Standards for Residential Care Settings for Older People in Ireland, all pharmacists will be required to participate in an Interdisciplinary Medication Review of each patient on long-term medication, at least on a three-monthly basis. These reviews should give special consideration to the specific medicinal products referred to in the HIQA standards, including antipsychotic medication, sleeping tablets and other sedating medication and analgesics.

With all guidance documents issued by the PSI, the superintendent must decide whether any new procedures or amendments to current procedures are required. They must ensure that all pharmacy employees involved in provision of specific pharmaceutical services are appropriately trained to carry out the clearly defined role(s) for which they are responsible. Competency assessment sheets must be signed and a record of associated training maintained.

Fig. 3: Reflection on Practice Notice for Patients in Residential Care. Identification of pharmacist intervention requirements.

Other tools for improvement of standards and professional guidance have been provided by the PSI; for example, many superintendent pharmacists and owners have found the the Security Assessment Template, developed jointly by the PSI and An Garda Síochána, and the PSI's Pharmacy Practice Guidance Manual valuable mechanisms for the facilitation of self-audit.

As policies and procedures should be in place to govern all processes within a pharmacy that may impact on patients, the superintendent should determine their own practice-specific requirements in this regard. All guidance and support documentation are accessible on the PSI website, www.thePSI.ie, under the Pharmacy Practice section.

The PSI welcomes queries from superintendents in relation to guidance issued by the PSI or any matters of concern relating to their role and responsibilities. Such queries should be sent in writing, preferably by email, to info@thepsi.ie.

PSI Study Group visit to Ontario College of Pharmacy

Noel Stenson M.P.S.I.

Editor's Background Note:
The Pharmacy Act 2007 introduces the requirement for pharmacists in Ireland to undertake appropriate Continuing Professional Development (CPD), including the acquisition of specialisation.

In September 2009, the PSI commissioned PA Consulting to carry out educational research to review and critically assess Continuing Professional Development (CPD) models and the associated assessment and audit systems, in order to guide the Council in developing an appropriate and effective system of mandatory CPD for pharmacists in Ireland.

The final report from this review and its recommendations was approved by the PSI Council at its meeting on 01 June 2010 and the document was formally launched by the Minister for Health and Children, Mary Harney TD, on 15 October 2010. The PSI is currently engaged in progressing the implementation of the report, which includes a procurement process for the establishment of an Institute of Pharmacy to oversee the management and delivery of CPD for pharmacists and to progress the development of pharmacy practice in Ireland in line with international best practice and evolving healthcare needs, and intensive consultation and engagement with key stakeholders. A series of information meetings for pharmacists will be held in early 2011.

As the proposed model for CPD for pharmacists in Ireland borrows heavily from the model used by Ontario College of Pharmacists (OCP) in Canada, one important aspect of the consultation and planning was a PSI study group trip to Toronto in November 2010 to observe their 'Quality Assurance' programme in action, including the peer-reviewed practice review sessions that form part of its CPD system.

Noel Stenson, MPSI, is a pharmacist with a special interest in education and CPD, who was a member of the steering group for the CPD review project and is a member of the Management Committee of the ICCPE. Noel was part of the study group and has kindly agreed to write the article below describing his impressions and learning from an intensive weekend of work in Toronto.

Introduction

On the 15th of October last, the PSI policy document around CPD for pharmacists, as developed by PA Consulting, was formally launched by the Minister for Health and Children. The introduction of mandatory CPD, even for the more 'engaged' of us, truth be told, represents a brave new world facing us in the years to come.

During 2009 and the early part of 2010, I was involved in the steering group of stakeholders that had been brought together by the PSI to assist PA Consulting in developing the policy document. The process was challenging, as it brought together the numerous branches of the profession in this country, each with their own agenda and vision of what CPD should mean for the profession. The group was driven by a focus on improving patient safety and health outcomes for the Irish populations. We are all familiar to some extent with the UK model, which involved a portfolio and periodic review of same – unfortunately, the research carried out by PA Consulting revealed that this model, along with numerous other international models, would be difficult to audit in line with the PSI's vision for the CPD model, which is to be outcomes-focussed and reflecting improved performance that should ultimately contribute to improved patient safety and health outcomes.

However, there was one model based on a CPD Quality Assurance (QA) process which, with a little tweaking, could be made to fit the Irish cohort as well as tick the boxes in terms of the patient safety and improved health outcomes brief. That model is the current CPD-QA system in place for the Ontario College of Pharmacists (OCP) in Toronto Canada. One of the main lessons for the PSI and the Irish system to learn from OCP was around the QA Process which the College operates for the 12,000 pharmacists on the register in Ontario.

About mid-September last, I was asked if I would join a PSI study team, (as a non-member of the PSI Council with an interest in CPD) being put together to visit the OCP in Toronto and examine the processes around one of their peer review weekends, with a view to its implementation in the Irish pharmacy practice field. And before the predictable comments about 'junkets', can I assure you that the entire group were put to work within hours of arriving in Toronto for the three-day visit and it was an intensive schedule, as we had a lot to see within a short time-frame. By the way, these guys start early – 7.45am – and I don't do mornings that well in my own time zone, let alone a Canadian one.

So, what did we see and what did I learn? I guess a little background as to the Ontarian CPD-QA procedures is needed first.

CPD in Ontario

Pharmacists in Ontario are, like in the UK, required to maintain a Portfolio of their CPD activities throughout the year. CPD activities can range from the formal Continuing Education (CE) sessions we in Ireland

are all familiar with, to recording day-to-day learning experiences, and, even further, to post-graduate degree programmes.

There are some significant differences between the regulatory framework in Ontario and the one we have here under the Pharmacy Act 2007. Like the PSI, the OCP is responsible for the registration of pharmacists in Ontario and also for assuring the public of the competence of all pharmacists on its Register. However, the OCP only accredits certain programmes for Ontario– many national or self-study programmes are handled by other parties in the field, e.g. Ontario Pharmacists Association and universities. Unlike the legislative situation in Ireland, the OCP pharmacist register is divided into Part A – for pharmacists in patient-facing roles, and Part B – for pharmacists who have no direct patient contact. Pharmacists can move between the different parts of the register as required. However, entry into part A means that they must complete the Peer Review process before being allowed to practise. Competency standards for pharmacy practice in Canada are drawn up by the National Association of Pharmacy Regulatory Authorities (NAPRA) – a nationwide body in Canada. The PSI is currently engaged with the FIP regarding the development of a global competency framework which will be adapted for Ireland. With the standards laid down by NAPRA, each regional pharmacy regulator then must have a QA programme in place which ensures the standards are maintained and developed within the profession. A quality assurance process is also a legislative requirement in Ontario for all regulated health professions.The OCP's Quality Assurance Committee and its Continuing Competency Department are responsible for this role in Ontario.

CPD QA Programme

The focus of the CPD QA programme is not so much around the physical examination of portfolios but is focussed on the tools and processes that a pharmacist needs to ensure they maintain their levels of competency in the profession. The OCP centres the QA programme around the following areas:

1. Learning Portfolio – which all part A and part B pharmacists are required to keep and present on request. The OCP accepts hard copy or e-versions and also provides tools based on the 'Learning Cycle' approaches to help the pharmacist maintain the portfolio.

2. Self-Assessment (also referred to as Practice Review Phase 1) - 20% of part A pharmacists are required to complete a Self -Assessment Tool and submit it to OCP each year. This process builds on the Portfolio process by ensuring each pharmacist examines his/her current skills and identifies gaps which he/she needs to address to maintain competency, as laid out in the NAPRA standards. Again, the focus is on providing the pharmacist with the CPD tools they need – and not on trying to find fault with their practice. It also provides the OCP with a measure of the global competency and skills profile of the pharmacist register. So each pharmacist on part A is required to do this every five years. There is no mandatory requirement to submit your Portfolio as part of this process; the self-assessment process is confidential. (However, portfolios are submitted during the Peer Review process and brought to the Portfolio Workshop.) This self-assessment process is based to a large extent on an 'honour' system, which requires pharmacist to confirm that that they have completed the assessment – something I found refreshing from a regulatory body.

3. Peer Review (also referred to as Practice Review Phase 2) - This is the part on which there has been much comment and discussion among pharmacists over the past few months, as it is regarded as by far the 'scariest' part of the QA process for the practitioner. Approximately 240 (about 3% of the register) lucky souls are picked randomly each year. Other candidates also come from the process whereby they are moving onto part A of the register. There are some exemptions to this part of the process, e.g. newly qualified pharmacists up to five years in practice, pharmacists working as assessors involved in the Peer Review process (all of whom, it must be said, will previously have gone through the practice review process).

Peer Review Process

So what is involved in this Peer Review process? Having met three cohorts of 15 lucky souls (with a broad age range) on the weekend we were there (where the atmosphere in the room at the start of the day can be cut with a knife) you will be forgiven for imagining that it may feel like something akin to torture. But I have to reassure you at this point that the very strained laughter at the start of the day gave way to relaxed belly laughs by the end – and that included those going through the assessment.

The Peer Review process assesses the following components of practice:

- Clinical Knowledge – each of the candidates had to sit a Clinical Knowledge Assessment (CKA) – basically a two-hour, open-book exam with 20 case studies and three MCQ's per case study. Candidates have access to standard dispensary texts and software to complete the exam. The exam case studies are written and compiled by pharmacist peers and each case study goes through a three-committee review process before it can be added to the case study bank for inclusion in the CKA exam. This part can be regarded as both scary by practitioners (in that most of us haven't sat a test in standard exam conditions since University) and familiar at the same time.

For the record, all the pharmacists on the PSI study team volunteered to sit the exam that was run that weekend. And despite the fact that the drugs and texts were all 'alien' Canadian texts … not to mention the jetlag ... all passed comfortably and completed the exam well within the two-hour allocated time. And that was with zero 'preparation'.

- Gathering Information
- Patient Management and Follow up
- Communication skills

These three components are accessed using Standardised Patient Scenarios (SPS) – our latest crop of interns will be more familiar with a similar type of process called an OSCE (Observed Structured Clinical Examination). Basically, actors who specialise in acting as patients (in Ontario the local Toronto medical school has a separate Patient Actor programme in which students can participate) present themselves in a particular scenario to the candidate. The Assessors and Patient Actors have a standardisation process, before the candidates attend, to agree to behaviours and questions that may come up in the scenario. The candidate is assessed on the three latter components by a trained assessor – a peer assessor, i.e. a practising part A pharmacist who has been trained to assess the SPS. The scenarios are subjected to the same rigorous three-committee design process involving peer-practising pharmacists in order to qualify for inclusion as an SPS. The process again is open book and candidates have access to all normal dispensary texts. They have 12 minutes to 'analyse' the case as presented, formulate a course of action and deliver it as though it is a real-life clinical situation. I have to say there was a lot to get into 12 minutes but each one of the five standardised patient interviews completed is weighted differently in the marking scheme and failure in one SPS doesn't mean a global fail.

Portfolios are requested to be brought along by each candidate for the purposes of a Portfolio Review Workshop during the day. Again, an 'honour' system applies and the physical portfolios are not individually examined or critiqued. However, they do have to be submitted, and the pharmacist must confirm they have completed the annual self-assessment. In keeping with the core focus of the QA process, the workshop centres around individuals sharing experiences and advice around maintaining the portfolio. I understand that the OCP did in the early years insist on a physical examination of a sample of portfolios from the register but moved to the Practice Review Phase 1 and Phase 2 format after it became clear that the sampling process was not only labour-intensive but also served to contribute little to the ultimate aim of improving patient safety by enabling pharmacists to maintain their competency in practice.

The groups spend the day at OCP rotating through each of the three phases of the peer review process:

1. Clinical Knowledge Assessment
2. Simulated Patient Scenarios
3. Portfolio Workshop

And finally at the end of their day, the cohort are brought back in and encouraged to share feedback about the whole experiences. This gives the OCP a mechanism by which they continually audit and amend the peer-reviewed Practice Review process.

Of course you may be asking – what happens if I 'bomb' the whole process – am I disciplined and maybe even struck off? While around 10% typically require some type of peer-guided remediation, the Canadian experience of 13 years is that they have had serious difficulties with two – yes, you read it right – two pharmacists (out of an average register count of 12,000 pharmacists). And the outcome in both these cases was that the pharmacists in question were encouraged to move to part B of the register and remove themselves from patient-facing roles.

By now you can see how OCP's ethos is to engage and provide pharmacists with the tools and methodology to ensure that they maintain competency and access CPD programmes efficiently. Whilst only two pharmacists have been problematic for them, there is still a small percentage who will fail to reach the standards of the Practice Review process at the first attempt. OCP's approach to this cohort is to support the pharmacist's development and learning to reach the standard through a process of remediation. It should be noted that remediation is a process, i.e. it has no set timeline – it has a purpose. Any candidate who fails to reach the standard will see the results of the Practice Review process and can identify where they have issues. OCP operates specific remediation workshops for these candidates, which focus on the weaknesses and work with the candidate to address these in a future re-run of the Practice Review process. It may involve multiple issues, which the candidate can address individually or at the same time. The main emphasis is to grow the individual's confidence and ability to overcome the identified weaknesses. Those of you who have had students under the City and Guilds/IPU Pharmacy Technician course will be familiar with this approach to learning – there is no pass/fail mark, there is only the student's development.

Whilst the 'lucky' random picks for the Peer Review process can take some solace in the OCP's continuing competence and quality assurance ethos, it still doesn't mean that getting called is any less stressful. But I have to hand it to the OCP's Continuing Competence Department team - they go out of their way to keep the formal process, well, relatively informal for the candidates.

The Canadian model is very much the 'carrot' rather than 'stick' approach. The team at OCP did say that the early years were difficult in terms of pharmacists' expectations around the process. This mind-set changed over the years and now it is considered part and parcel of practice. What impressed me was that the process assumes that an 'honour' system is in place, whereby practitioners are treated as professionals from the outset and are not seen as a flawed cohort.

I can only hope that PSI and the proposed Institute of Pharmacy take this message on board as I think it will definitely engage pharmacists more quickly and with less confrontation.

In summary then, many pharmacists will have some key questions about potential adaptations from the Canadian Model into the Irish Model:

- Do I need to keep a Portfolio?
Yes, this is inescapable. The PSI will provide guidance as to how they should be structured and recorded.

- Will the Portfolio be 'called in'? The PSI and the new Institute have to make a decision around what assessment processes are put in place. The OCP found little value in taking in and critiquing Portfolios in terms of outcome returns of the CPD process and the additional man-power costs around sampling may also be a consideration.

- How often will I have to be "tested"?
First of all the OCP do not test – they facilitate and provide the tools to the pharmacist. They ask that each pharmacist record this assessment of CPD needs every five years. So that's a given. As for the peer-reviewed Practice Review model – the OCP hits about 3% of the register each year for this – so chances are a pharmacist could be called only once in their career – twice if they are really unlucky.

- Can I fail the Practice Review and be struck off?
The OCP model teaches us that in the event of failing to meet the standards in the Practice Review, a structured remediation process is key. The evidence to date in OCP is that only two pharmacists proved resistant to the remediation process in 13 years. So assuming the PSI embraces this model, the potential for removal from the register is remote.

- Will there be mock Practice Review sessions?
It is anticipated that as part of the roll out of mandatory CPD, the PSI would have presentations and information sessions around the CPD Quality Assurance process that will be put in place in Ireland.

Ethics and decision-making: 'Tools to Reason with'.

Cicely Roche M.Sc., MPSI is a Senior Lecturer (PT) at the school of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin and holds M.Sc.(s) in Healthcare Ethics and Law and in Community Pharmacy. She is currently undertaking a PhD by research in TCD.

The practice of pharmacy generally requires pharmacists to deal with people. Dealing with people can be a complex matter. The practice of pharmacy is guided by legislation, the Code of Conduct and various guidelines. However, the reality is that there are times when the existence of these alone is not sufficient to steer a pharmacist through 'dilemma' scenarios as are faced in everyday practice... scenarios where there may be two or more options by which appropriate patient care can be achieved but none of which options seem to the pharmacist to entirely meet the letter of the law or a literal interpretation of the Code of Conduct or guidelines.

An understanding of ethics and ethical frameworks will assist pharmacists with the generation of 'action' options in such cases, increasing the likelihood that the practitioner will choose options considered professional. Reasoning competencies can be developed – as is the case with any competency supportive of professional practice. The development of such reasoning competencies will increase the likelihood that pharmacists will make decisions consistent with the ethical principles in the professional statutory code, and be able to justify those decisions in a manner that behaviour (and the justifications for choosing one option over another) withstands external scrutiny of professional conduct.

Community Pharmacists Required to Participate in Educational Research

My aim is to 'validate' a profession-specific CPD module that aims to develop reasoning competencies in practising pharmacists[1]. In order to do that, I need colleagues to volunteer to partake in a module that incorporates review of a series of scenarios designed to reflect ethical concepts encountered by practitioners in contemporary practice[2]. Participants will review a series of scenarios, in a structured/facilitated manner, both individually and then in groups (online). The delivery of the module is designed to suit the working schedules of practitioners. Commitment by participants will involve one day on-site in the School of pharmacy in TCD[3] (April or August 2010), a 16-week online module, no more than a couple of hours contact per month (as most of the 'learning' involves reflection on dilemmas proposed) and then a half day on-site/ online to complete the final elements of the programme. Participants will be encouraged, and facilitated, to maintain a journal/diary of the process but this will not be obligatory. Supporting materials, including podcasts, will be available for download.

Lest the notion of the online environment should intimidate any would-be participants, please be assured that the full day's initiation in the school of pharmacy in TCD aims to ensure that everyone involved will be fully comfortable with the process, the technology involved and the theory behind 'reasoning through dilemmas'. In addition, I will be available to participants for the duration of the programme. Participants simply require internet access from their home or place of work.

Please also be assured that all participants will be 'anonymous' for the duration of the programme - an aim achieved by having one of the training managers in TCD assign email addresses that will, in fact, be pseudonyms. The use of pseudonyms will assure that I, or other participants in the module, will not be in a position to link contributions made to individual participants. This is a protection mechanism (should participants be concerned that by openly engaging in discussion surrounding dilemmas, they would expose less developed reasoning competencies) and, by reducing the barriers to active engagement in debate surrounding 'action options' potentially available to resolve a dilemma, it is considered to facilitate acceleration of the development of 'reasoning competencies'.

As this initial delivery of the module 'Ethics and decision-making: Tools to reason with' will be part of the validation process, it is preferred that I concentrate on one practice environment... that of community pharmacy. This does not rule out that pharmacists in other practice environments would not potentially benefit or would not partake in future deliveries. As the preference, for validation purposes, is that a relatively 'homogenous' group be engaged, the ideal would be that supervising pharmacists would apply to take part – as they may be defined as all practising 'whole time' in the community pharmacy environment and with a minimum of three years' post-registration experience. However, if registered pharmacists other than those holding supervising pharmacist positions wish to apply, please feel free to make contact.

Up to 80 pharmacists can be accommodated in the pilot programme – which will engage up to 40 pharmacists from April to August and the other 40 from August to early December 2011, all assigned by random allocation from those who apply to take part. As it is a validated study, each group will act as the 'control group' for the other – thereby allowing for impact of external variables such as significant events in the professional or commercial influences on practice. The measure of the impact of the educational initiative will be the Defining Issues Test (DIT2)[4], a pen and paper measure of reasoning that involves reasoning through 5 dilemmas of a general (rather than profession-specific) nature, and which generally takes 20 to 30 minutes to complete.

If you would be prepared to be a participant in the programme and/or if you would like further details, please contact me (Cicely Roche, MPSI - contact details below) at your earliest convenience.

It would be appreciated if pharmacists interested in participating would make contact, if possible, by January 31st 2011. Further information is available on request. Cicely Roche MPSI, Senior Lecturer, Practice of Pharmacy, School of Pharmacy, Panoz Building, Trinity College, Dublin 2. Phone: 086 8158121 or email: rocheci@tcd.ie

References:

1 The research to which this pilot is related has been registered for a Ph.D. by Research at the School of Pharmacy and Pharmaceutical Sciences in Trinity College Dublin, under the supervision of Prof. Marek Radomski, Head of the School, and co-supervised by Prof Joy Wingfield (Nottingham) and Prof Steve Thoma (Alabama). The title of the study is the 'Development of Moral Reasoning competencies in Irish Community Pharmacy Practitioners'.

2 The ethical concepts are developed to the formula of intermediate-Concept-Measures (ICMs : Bebeau & Thoma, 2009). The components of an ICM are a short Profession-specific 'dilemma' scenario, and series of action and justification choices. The profession-specific dilemma is prepared to include relevance to ethical concepts identified as relevant to contemporary practice by means of review of relevant literature. The case study, action choices and justification items are presented in sequence and options proposed include those with a focus on self interest, maintaining rules and norms, and societal interests.

3 These full day sessions are scheduled for Trinity College Dublin as computer facilities are available for up to 40 users in the School of Pharmacy. If a group of intending participants wishes to propose an alternate location, with equivalent facilities available to the group, then it could be possible to also make an induction day available in that alternate location.

4 The Defining Issues Test is a pen-and-paper measure of Moral reasoning that has been in use for almost 30 years across a number of professions. The database is held at the Centre for the study of ethical development in Alabama, under the directorship of Prof Steve Thoma who is a supervisor to the PhD being undertaken by Cicely Roche. Further details may be obtained from http://www.centerforthestudyofethicaldevelopment.net/

IRISH PHARMACY UNION

NI Centre for Pharmacy Learning & Development

Irish Centre for Continuing Pharmaceutical Education

hpai Hospital Pharmacists Association of Ireland

5th All Ireland Pharmacy Conference

CALL FOR DELEGATES

The conference aim is to share good practice in pharmaceutical care across the primary and secondary care sectors; pharmacists, technicians and qualified assistants will be encouraged to exchange ideas for pharmaceutical service development.

The conference venue is the Ballymascanlon House Hotel, which is located 2 miles north of Dundalk in Co Louth. A location map for the hotel can be accessed on the hotel's website at www.ballymascanlon.com

The cost of the conference dinner on Monday 7th February 2011 will be covered by sponsorship. The day delegate rate for the conference (Tuesday 8th February 2011) is €50 and the cost of overnight accommodation, if required, is €90 single and €75 sharing. The conference costs for the main presenter of each oral presentation will be covered by NICPLD/ICCPE. For those presenting posters, the day delegate fee only will be covered.

Payment by cheque must accompany the application below and should be made out to HSE-NE for delegates from the Republic of Ireland. Delegates should contact the Ballymascanlon Hotel directly to book and pay for their overnight accommodation, if required.

FIFTH ALL IRELAND PHARMACY CONFERENCE APPLICATION FORM

Name:

Address:

Daytime telephone email

I will attend:
Dinner on 7th February 2011 ☐ Main proceedings on 8th February 2011 ☐

Special dietary requirements

Applications should be returned to: ICCPE, 18 Shrewsbury Road, Dublin 4 along with a cheque for the delegate fee.