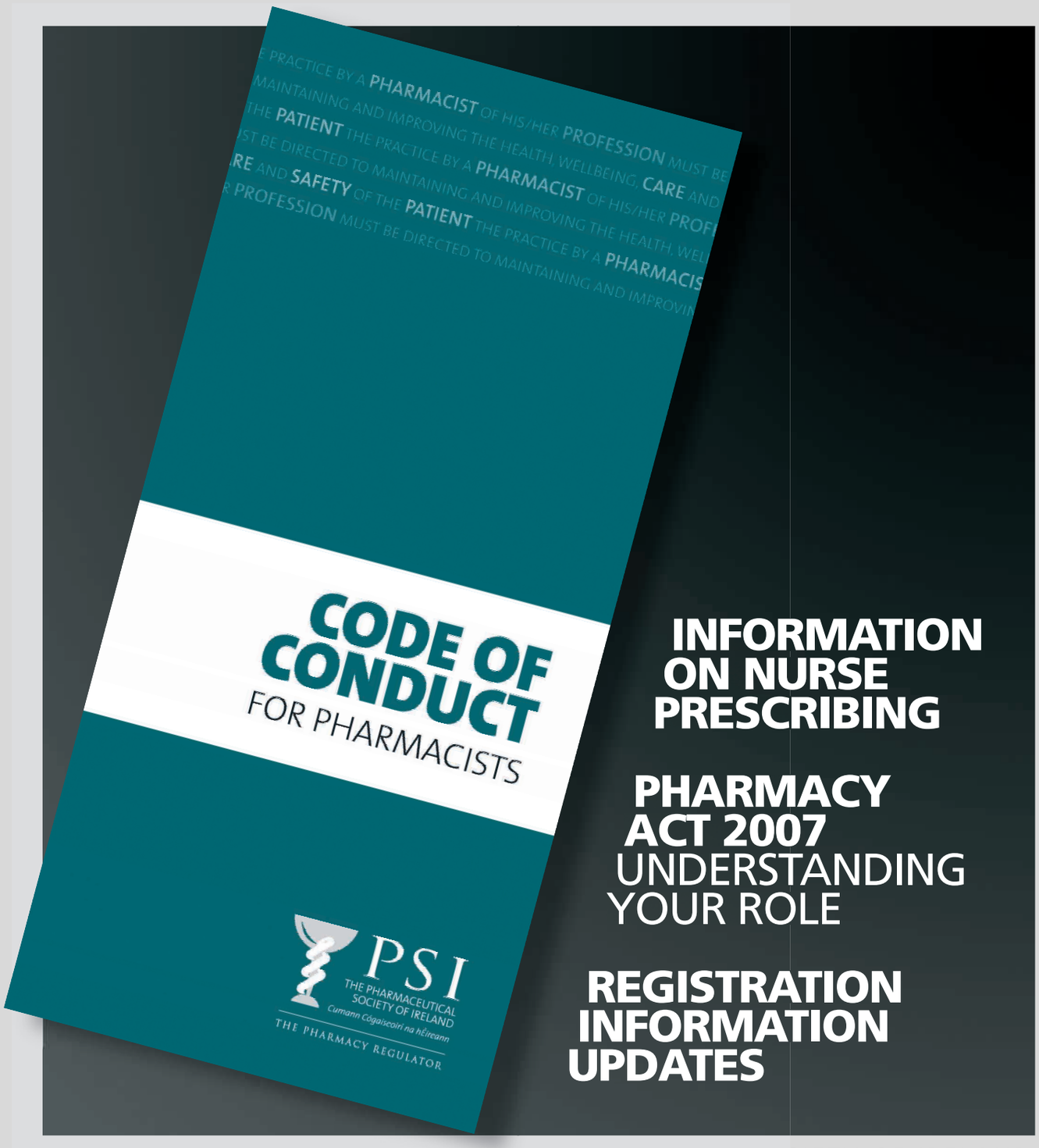
THE IRISH PHARMACY JOURNAL

VOL.88 NO.'S 3 AND 4

MARCH/APRIL 2009



THE OFFICIAL JOURNAL OF THE PHARMACEUTICAL SOCIETY OF IRELAND

THE IRISH
PHARMACY
JOURNAL

MARCH/APRIL 2009

VOLUME 88 NO.'S 3 AND 4

Contents

Produced by:
MP Publications Limited
2 Lower Glenageary Road, Dún Laoghaire, Co. Dublin
Tel: 01 – 284 6161 Fax: 01 – 284 6192

ADVERTISING ENQUIRIES
Production Editor:
Angela Bolton ~ Tel: 01 – 202 0374 (DDI); email: angela@afloat.ie
Business Development Manager:
David O'Brien ~ Tel: 01 – 202 0370 (DDI); email: david@afloat.ie

Redefining the pharmacist-patient relationship

Enclosed in this issue is a copy of the statutory Code of Conduct for pharmacists, which was formally laid before the Houses of the Oireachtas in February of this year. Along with the other major provisions of the Pharmacy Act 2007 such as the establishment of a non-pharmacist majority Council, the registration and regulation of retail pharmacy businesses, and fitness to practise and fitness to operate systems, this Code signals a profound departure for the profession of pharmacy in Ireland.

The legislation long sought by the profession clearly recognises the role of the pharmacist in the supply of medicines. The requirement that all medicines should be supplied by or under the personal supervision of a pharmacist acknowledges the fact that pharmacists are the most appropriate people to supply medicines to the public, including the supply of the information and advice necessary for the safe and appropriate use of those medicines.

However, the recognition of this role brings with it serious professional responsibilities for pharmacists, and particularly for pharmacists who hold the positions of superintendent and supervising pharmacists.

Under the new structures, these are the accountable people for the policies applied and operations conducted in every pharmacy in the country.

Pharmacists will recognise that the regulations made under Section 18 of the Act place good professional pharmacy practice on a legal footing. These requirements now form the basis on which every pharmacy in the State is registered and must be operated. These also provide a legislative basis for the pharmaceutical care that patients are entitled to expect from pharmacists and pharmacies.

The Code of Conduct for pharmacists is a document that every pharmacist in the country should regularly consult to ensure their professional practice, in whatever area of pharmacy they practise, is guided and supported by the six-principle Code.

As well as putting patients at the centre of pharmacy practice, the Code also supports the professional practice of pharmacy. Every pharmacist has a personal responsibility to ensure that everything they do, or that is done under their supervision, conforms with these principles.

In addition, superintendent pharmacists have a responsibility to ensure that the policies put in place in the retail pharmacy business(es) under their control facilitate the pharmacists employed in those pharmacies to comply with their Code of Conduct.

The last two years have seen massive changes in the pharmacy sector and profession in Ireland, and no doubt the next two years will be equally transformative as the final Sections of the Pharmacy Act 2007 are implemented.

Adaptation to change is not without its challenges, but the provisions of the Act are there not only for the protection of public health and well-being, but also to support the professional practice of pharmacy and form the basis of a new relationship between the pharmacy profession and they patients we all serve.

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

Editor: Kate O'Flaherty, BSc (Pharm), MSc, MA, MPSI

Administrator: Carol Keogh, Dip FA (DIT)

Editorial Address: 18 Shrewsbury Road
Ballsbridge
Dublin 4
Tel: 01 – 218 4000
Fax: 01 – 283 7678

Email: journal@pharmaceuticalsociety.ie

Editor's Note

The ICCPE provides a valuable educational resource for pharmacy and as part of its Spring programme, a joint educational session on the Pharmacy Act 2007 was provided, in conjunction with the PSI and the HSE. The PSI presentation given at those sessions is published in this issue in article form, in order to bring the content to a wider audience and especially pharmacists who were not able to make the ICCPE sessions.

PSI Practice Notices in relation to 'Section 18' regulations, supply of paracetamol and control of the supply of prescription-only medicines are also published, as is the PSI's recent notice in relation to orlistat 60mg (alli).

These documents are all also available to view and download from the PSI website under the 'Publication's' tab.

In this issue also, the PSI is pleased to publish another joint initiative, this time with the Office of the Nursing Service Director of the HSE, an information article for pharmacists about nurse/midwife prescribing in Ireland. I would like to especially thank Maureen Flynn from that Office for her assistance with this article. At the time of writing, the threat of an influenza pandemic is very much the major public health concern facing the country and indeed the world, and pharmacists have a key role to play in the many public health measures that may be required, including providing advice and information to the public.

In that context, the note to registrants included in the Registration Information Updates to ensure that the PSI has accurate contact details for every pharmacy (through superintendent and supervising pharmacists) is very relevant.

Over the coming months the PSI hopes to improve and revamp its website and this Journal and we welcome feedback as part of that process.

Kate O'Flaherty

PSI News

Results of 2009 election of pharmacists for appointment to PSI Council

The selection of pharmacists for appointment to the PSI Council has been carried out in accordance with PSI (Council) Rules 2008, and the counting of votes and declaration of results took place on 16 April 2009.

The returning officer Dr Ambrose McLoughlin, PSI Registrar, has declared the following five pharmacists as elected for the purposes of Section 10(3)(f) of the Pharmacy Act 2007, for appointment by the Minister for Health and Children to the PSI Council: Paul Fahey, Margaret Ann Doherty, John Collins, Eoghan Hanly and Georgina Ann Frankish.

The returning officer has, in accordance with the Rules, informed the Minister of these names, for these pharmacists to be appointed to Council for four year terms of office.

In accordance with Rule 13(2) of the Rules, the full election results, including details of the number of ballot papers issued (total electorate), the total valid poll and the votes and transfers at each count, are published on the PSI website.

In accordance with Rule 14, the list of persons to be included in a panel for the filling of certain vacancies on Council, consisting of the pharmacists deemed not to be elected, in decreasing order of the total number of votes cast for each candidate, is as follows:

Leonie Maria Clarke; Adrian Dunne; Margaret Mary Bernadette Grennan; William Boles; Mary Rose Burke; Peter Weedle; Orlaith Brennan.

The counting of votes in the 2009 election of pharmacists for appointment to the PSI Council took place on Thursday 16 April 2009 at the D4 Hotel, Ballsbridge, Dublin 4. The election count was carried out in the presence of scrutineers Vincent Cronin, Claire Kerr and John Lynch, of Jack Crowley, from the PSI internal auditors, and the PSI legal advisor Dominic Dowling. The PSI would like to thank the scrutineers and those who assisted with the count for their time and contribution to the smooth running of the event. The PSI would also like to thank Dublin County returning officer John Fitzpatrick and his colleague Ciaran Manning for their assistance and advice with the count process and the publication of results.

Counting the votes for the selection of pharmacists for appointment to the Council

Further information on appointments to Council

Five pharmacist members of Council, appointed by the Minister for Health and Children on 22 May 2007 under Section 10(3)(f) of the Pharmacy Act 2007, were appointed for a two-year term (ending 21 May 2009). They are Cormac Deasy, Dr William Boles, Brendan Hayes, Professor Peter Weedle and Paul Fahey. The election process for 2009, as detailed above, was carried out to select five pharmacists to fill these vacancies for appointment to the Council.

The Minister will also be making six further appointments to Council for the purposes of Section 10(3)(a)-(e), i.e. non-pharmacist members of Council, to vacancies arising from terms of office ending on 21 May 2009. The Council members whose terms end on that date are: Deirdre Larkin, Colm Fagan, Michelle Ni Longain, Asst. Comm. Noirin O'Sullivan, Ita Kelleher and Rita Purcell (IMB nominee).

The terms of office of the other Council members appointed on 22 May 2007 were for four years. In 2011 an election process will therefore be held for the four pharmacist vacancies arising from the ending of their terms of office.

The Minister for Health and Children Mary Harney TD is presented with samples of the new certificates of registration and EU professional cards for pharmacists by PSI President Dr Bernard Leddy and Prof Peter Weedle, Chair of the Registration and Qualification Committee

PSI Council meets in Dungarvan, Co. Waterford

The 10th meeting of the PSI was held in the Council Chamber of Waterford County Council, Civic Offices, Dungarvan, Co. Waterford, on 3 March 2009. Upon opening the meeting, PSI President Dr Bernard Leddy welcomed the two new Council members who had recently been appointed by the Minister, Ms Kate Mulvenna and Dr John Hillery. As the two new members appointed to Council are also members of the PSI Audit Committee, membership of that Committee was discussed. Dr Hillery indicated that he would resign immediately as Chair of the Audit Committee, and Kate Mulvenna indicated that she would continue as the pharmacist representative on the Committee until a replacement pharmacist was approved by Council. The Registrar indicated that both Mr John Gloster, former CEO of the Board of Postgraduate Medical and Dental Board, currently Postgraduate Training Officer, The College of Psychiatry, and Mr. Noel Conroy, former Garda Commissioner, were persons disposed to accepting invitations to join the Committee.

Annual Report/Financial Update

The Council approved the Annual Report and Financial Statements 2008, following a detailed briefing and discussion on key elements of expenditure by Mr Colm Fagan, Chair of the Administration, Finance and Corporate Governance Committee. Mr Fagan and the Registrar briefly outlined the approach to cost containment in 2009, and the Registrar also indicated that the proposed Service Plan for 2009 may require review/revision in light of the current difficult economic environment and any Government decisions that may be taken this year to address this.

Update on establishment of new pharmaceutical registration systems

Professor Peter Weedle, Chair of the Registration and Qualification Recognition Committee, reported to Council that the new pharmaceutical registration systems for retail pharmacy businesses, pharmacists, pharmaceutical assistants and druggists had been successfully established. The new Register of Retail Pharmacy Businesses was established on 1 January 2009, and the first phase of the online publication of this Register has been available to the public on the PSI website since 23 January 2009.

Prof Weedle reported the new personal registers were live and operative, and all persons appearing on the old Registers had been automatically and individually migrated to the new Registers. Consequently, all persons named on the previous Register of Pharmaceutical Chemists and Register of Pharmaceutical Assistants (and including those persons listed in Council Resolution No. 1 of Meeting No. 6 held on 27 May 2008), were transferred to the new registers with effect from 29 November 2008. New applicants (national and EU) were added to the new Register of Pharmacists during December 2008. The system of continued registration for pharmacists and pharmaceutical assistants commenced on 29 November 2008. Notification of the requirement to apply for continued registration and to pay the required registration fee was issued to all registrants who migrated to the new Registers, with the request to complete the process by 22 December 2008. A reminder of the requirement to apply for continued registration and/or payment of fee was sent to all persons who had failed to do so by letter on 30 January 2009.

Prof Weedle commended the PSI staff for processing approx. 6000 applications. He also thanked the profession for their co-operation and considerable effort put into complying with requirements.

Committee Reports

Inspection and Enforcement

Inspection and Enforcement Committee Chair, Asst Commissioner Noirin O'Sullivan, reported on the appointment of authorised officers and on inspection statistics to date.

At the December meeting the Council, pursuant to section 11(8) of the Pharmacy Act 2007, formally delegated to the Inspection and Enforcement Committee the authority to appoint an employee of the PSI as an authorised officer in accordance with and for all the purposes of Sections 67, Section 7(2)(b)(ix) and Section 7(2)(b)(x) of the Pharmacy Act 2007.

In line with the processes and procedures of the I&E Unit and the delegation to the I&E Committee, the following named individuals were appointed as authorised officers for the purposes of the Pharmacy Act 2007 and furnished with a warrant of appointment in this regard: John Bryan, Damhnait Gaughan, Joan Warren, Cora Nestor, Liz Kielty, Sinead O'Keeffe, Rory Kennedy, Cheryl Stokes

The following named individuals were also appointed as authorised officers for the purposes of the Irish Medicines Board Act 1995, pursuant to Section 32B(1)(a) of the Act and furnished with a warrant of appointment in this regard: Joan Warren; Cora Nestor.

Professional Learning and Development

The Chair of the Professional Learning and development Committee, Dr Paul Gallagher, reported on the establishment of a sub-committee to develop the PSI submission to the Higher Education Strategy Group (HESG) set up by the Minister for Education and Science, which is pertinent to the development of a revised pre-registration programme. The issue of placements for the upcoming training year (2009/10) was also discussed by the Committee and the need to be innovative was noted in light of a possible reduction in the supply of available placements while complying with the provisions of the statutory education and training rules.

The interim report of the PEARS review on the pre-registration training year is due in March 2009. Regarding the work package dealing with the undergraduate component of the five-year programme, the researchers are due to interview key staff in the schools of pharmacy over the coming weeks and the researchers are in the process of compiling the documentation that has been requested of the schools. The work package dealing with the accreditation models and criteria has also commenced. The PSI is now in the final stage of agreeing the contract terms and conditions with the selected bid, following the tender process for the review of Continuing Professional Development (CPD) models.

Dr Gallagher also outlined to Council the concerns of students in relation to securing placements in the 2009/2010 pre-registration year and the application fee approved by the Minister for Health and Children. Following consideration of both matters, it was agreed that the Registrar and Dr Gallagher will continue their discussions with Heads of Schools, class representatives and other stakeholders as appropriate.

contd. next page

Standards and Practice

The Chair of the Standards and Practice Committee, Noeleen Harvey, reported that the Committee was examining a number of pharmacy practice and patient safety issues with a view to generating and adopting a position on these, including the advertising of pharmacy services and medicinal products and delivery services. Discussions are also ongoing regarding the parameters of the proposed baseline study of pharmacy practice in Ireland. The committee has also considered the prioritisation requirements in respect of the development of Guidelines and the identification of important non-compliance issues.

Chairperson's Committee

The Chair of the Chairperson's Committee, Cathriona Hallahan, recommended that a working group be established on the role of the Vice President of the PSI. The members of this group are: Ms N. Harvey, Mr D. O'Loughlin, Prof P. Weedle, and Ms C. Hallahan, supported by the Registrar.

Other Council business

The Registrar referred to Section 17(3) of S.I. 492 of 2008 Pharmaceutical Society of Ireland (Council) Rules 2008, which states the requirement for the appointment of Presiding Officers, in advance of the Presidential/Vice-Presidential election to be held at the May Council meeting. Mr Tom McGuinn, Presiding Officer, and Mr John Bryan, alternate Presiding Officer were nominated.

Asst Comm Noirin O'Sullivan proposed to Council that Mr Martin Higgins, the CEO of Safefood, be co-opted to the Inspection and Enforcement Committee, which Council approved.

Mr Paul Turpin from the Institute of Public Administration (IPA) facilitated an initial discussion on some of the key issues in the draft PSI Corporate Governance Framework document. Council considered it essential that there be a further opportunity in the coming months to review the document, and it is likely that a similar discussion will be arranged for Council at a later date. The Council was also addressed by the PSI legal advisor, Mr Dominic Dowling, on the implications of Part 6 of the Pharmacy Act 2007, which is expected to be commenced this year.

The Registrar briefed Council on dialogue between the PSI and Pharmaceutical Society of Northern Ireland (PSNI), on the area of mutual co-operation, including the nomination of PSNI personnel to PSI Council's advisory Committees, and the nomination of PSI observers to some PSNI Committees.

Mr Colm Fagan said that he would be resigning from Council on the expiration of his term on 21 May 2009, due to other commitments. He praised the work of Council, the Registrar and staff, the commitment of members and staff, and thanked the President and Registrar for the courtesy shown to him.

The President read a letter from Ms Marita Kinsella, Chief Pharmacist at the Department of Health and Children, thanking Council for their gift which was presented to her on leaving the PSI.

A number of documents were circulated in relation to protected disclosures, which was introduced by Part 14 of the Health Act 2007. The Council was informed that Dr Cora Nestor has been nominated as the PSI officer to receive protected disclosures. This part of the Health Act was enacted on 1 March 2009 and the PSI is in a position to receive information under this legislation since its enactment.

The next Council meeting will be held on Tuesday, 26 May 2009 at the offices of An Bord Altranais, Carysfort Avenue, Blackrock, Co. Dublin.

PSI hosts HPCB Spring 2009 meeting

The PSI hosted the Spring 2009 meeting of the Healthcare Professionals Crossing Borders (HPCB) initiative in Dublin on 6 March 2009 at the Royal College of Physicians in Ireland's conference venue. The meeting, which was attended by more than 90 delegates from healthcare professional regulatory bodies across Europe, discussed patients' rights and effective healthcare regulation in Europe.

Dr John Hillery, PSI President Dr Bernard Leddy, Minister Mary Harney and HPCB meeting Chair, Dr Jos van den Heuvel at the Spring 2009 HPCB meeting hosted by the PSI in Dublin

(back l-r) Ginny Hanrahan, CEO Health & Social Care Professionals Council; Eugene Donoghue, CEO An Bord Altranais. (front l-r) John Lamont, CEO Medical Council; Dr Bernard Leddy, PSI President; Minister Mary Harney; Dr Ambrose McLoughlin, PSI Registrar/CEO

The meeting was addressed by Minister for Health and Children, Ms Mary Harney, TD, who stated that she welcomed the opportunity which the draft Directive on Patients' Rights in Cross-border Healthcare gives for consideration of a draft legal framework which will clarify the rights and obligations of both patients and Member States in relation to cross-border healthcare. She said, "It is important however that the proposed Directive not only provides legal clarity, but also achieves a balance between the rights of the individual patient and the obligation on Member States to provide healthcare for all their citizens."

PSI President, Dr Bernard Leddy, told the meeting that it was important for healthcare professional regulators to get the fundamentals right because the confidence of the public in their healthcare professionals, as well as in their regulators, depends on it. "The citizens and patients of Europe deserve that their rights as well as their safety and well-being are protected and effective healthcare regulation is an important part of that protection," said Dr Leddy. "It is essential that we have proper registration of healthcare professionals and service providers and that we have on our registers only those who are fit to practise or provide services. Also, greater collaboration and improved information exchange systems at European level are essential in the interests of patient safety."

Speakers at the meeting included John Lamont, Chief Executive of the Medical Council of Ireland, Dr John Jenkins of the UK General Medical Council and Ralph Hughes of the European Public Health Alliance, who all discussed the proposed EU directive on the application of patients' rights in cross-border healthcare. The meeting was also addressed by Professor Charles Normand of Trinity College Dublin, and the guest speaker was Dr John Hillery, Chair of the International Association of Medical Regulatory Authorities (IAMRA), who addressed the international dimensions and challenges of topic of ensuring regulation in the public interest.

Delegates also discussed the Portugal Agreement, an informal framework for European regulator collaboration agreed by HPCB members in 2007 and which comprises three specific strands of activity: identifying shared principles of regulation; transparent and accessible healthcare regulation; competence assurance of European healthcare professionals.

Copies of the presentations given at the meeting area are available to download from the HPCB website, at the following link: http://www.hpcb.eu/hpcb/ news/events.asp

new

a turning point for weight loss

real evidence – **alli** contains 60 mg orlistat, a clinically proven weight loss aid available without prescription.

real help – **alli** combines a capsule and a support programme to help users lose 50% more weight than by diet alone!

real benefits – **alli** brings positive change to customers and the opportunity for you to recommend with confidence.

find out more at www.alli.ie
product information, resources, pharmacy support

start the conversation

Product Information. For full prescribing information refer to the Summary of Product Characteristics. **alli** 60 mg hard capsules (orlistat). **Indication:** Weight loss in adults BMI ≥ 28. **Dosage** *Adults (18 or over)* One capsule within an hour of each of three main meals. Max 3 caps/day for up to 6 months. Use with lower fat mildly hypocaloric diet. If no weight loss within 12 weeks refer to GP. Diet and exercise should start prior to treatment. **Contraindications:** hypersensitivity to ingredients, concurrent treatment with oral anticoagulants or cyclosporin, chronic malabsorption syndrome, cholestasis, pregnancy, breastfeeding. **Special warnings and precautions:** See SPC re: amiodarone or medication for hypertension, hypercholesterolaemia or diabetes as control of these conditions may improve necessary alteration of therapy. Risk of GI symptoms increases with fat consumption. Take multivitamin at bedtime. See GP if rectal bleeding. Oral contraceptive efficacy may be reduced if severe diarrhoea; use additional contraception. **Drug interactions:** Ciclosporin, oral anticoagulants, fat soluble vitamins, acarbose, amiodarone. **Pregnancy and lactation:** Contraindicated during pregnancy or lactation. **Side effects:** See SPC for full details. Predominantly gastrointestinal e.g. oily stools, urgency, usually mild and transient, risk reduced by low fat consumption. Hepatitis, cholelithiasis, abnormal liver enzymes, anxiety, hypersensitivity reactions including anaphylaxis, bronchospasm, angioedema, pruritus, rash and urticaria, bullous eruption. **Legal category:** Pharmacy Only. **Marketing Authorisation Holder:** GlaxoGroup Limited, Greenford, Middlesex, UB6 0NN, U.K. **MA Number:** PA0040/007/001 & 009. **Last revised:** November 2008. **Further information is available on request from:** GlaxoSmithKline Consumer Healthcare, Stonemasons Way, Rathfarnham, Dublin 16, Ireland. **References:** **alli** Summary of Product Characteristics GlaxoSmithKline Consumer Healthcare.

alli is a registered trademark of the GlaxoSmithKline group of companies.

Registration Information Updates

New registration systems successfully established

The new pharmaceutical systems provided for in the Pharmacy Act 2007 have been successfully established, with the new Registers of Retail Pharmacy Businesses, Pharmacists, Pharmaceutical Assistants and Druggists established. These Registers are publicly available online on the PSI website as per the statutory requirement.

The establishment of all Registers on that date was necessary in order to synchronise the registration of retail pharmacy businesses with the continued registration of pharmacists, and especially the key roles of supervising and superintendent pharmacists, in order to assure the public and the profession of the probity and integrity of the registration system.

The registration files are now being subjected to audit, at the direction of the Registration and Qualification Recognition Committee, and the PSI will seek speedy resolutions to any matters or difficulties arising with the relevant parties.

The PSI would like to thank all pharmacy owners, pharmacists and pharmaceutical assistants for their co-operation with the implementation of the new legislation.

Pharmacy Contact details

The PSI would like to strongly encourage all superintendent and supervising pharmacists who have not already supplied an email address to the PSI to do so. This is to facilitate the speedy dissemination, to every registered retail pharmacy business, of urgent patient/medication safety alerts or practice updates/information from the PSI. In the near future, an online system will be available for all registrants that will allow for online updating of personal details, such as contact details, including email addresses and telephone numbers.

Certificates of Registration

The Certificates of Registration for 2009 for registered retail pharmacy businesses, pharmacists and pharmaceutical assistants have been issued in accordance with Section 20 of the Pharmacy Act 2007.

The certificate of registration of a retail pharmacy business is required to be conspicuously displayed at the premises, as is the certificate of registration of the supervising pharmacist.

Any registrant who has not received their certificate of registration for 2009 should contact the PSI urgently so that this can be dealt with.

Registrants are advised that should they, or the retail pharmacy business, cease to be registered before the date of expiry of the certificate, the certificate should be returned within 14 days of the cessation of registration to the Registrar of the PSI. It should also be noted that it is an offence, under Section 20(5) of the Pharmacy Act 2007, to give the certificate to another person with the intention that it be used to give the impression it is theirs or to allow another person to use this certificate in that way.

Updating/correcting information held on Registers

While the PSI takes every care to ensure the accuracy of these registers, Section 22(4) of the Pharmacy Act 2007 provides that: "A person to whom an entry in a register relates shall notify the Council in writing of – (a) any error that the person knows of in that entry, or (b) any change of circumstances that is likely to have a bearing on the accuracy of the entry, as soon as may be after the person becomes aware of that error or change in circumstances."

Therefore any registrant who finds an error in their details as published on the online public register (available on the PSI website www.pharmaceuticalsociety.ie) or on their certificate should inform the PSI of that error.

In the near future, an online system will be available for all registrants that will allow for online updating of personal details, such as addresses (the PSI (Registration) Rules 2008 require a practice address for publication in the public register and a residential address which is not made publicly available) and contact details, including email addresses and telephone numbers. Registrants will be informed of the new system in due course.

Professional Cards

Registered pharmacists have also been issued with 'European Professional Cards', which are plastic wallet cards and similar cards have also been issued to pharmaceutical assistants, which can be used by professional staff to identify themselves. It is envisaged that in future the cards will be further developed as 'smart' cards, holding a pharmacist's registration data and photograph.

Photograph required for applications for Continued Registration 2010

The Pharmaceutical Society of Ireland (Registration) Rules 2008 provide that applicants for registration or continued registration as a pharmacist or as a pharmaceutical assistant will be required, from this year onwards, to provide a recent photograph as part of their application.

This requirement will apply for the process of continued registration for 2010 which will be initiated in October 2009. Therefore all currently registered pharmacists who will be applying for continued registration for 2010 later this year will be required to provide the PSI with a recent photograph in advance of the process.

Registrants will shortly be notified of the details on how this requirement is to be implemented.

Retail Pharmacy Business Duty Register

The PSI formatted Retail Pharmacy Business Duty Register, which was developed to facilitate compliance with the requirement under paragraph 5(1)(c) of the Regulation of Retail Pharmacy Businesses Regulations 2008 ('Section 18' regulations), has been distributed to all registered retail pharmacy businesses. This requirement is that "an ongoing, contemporaneous and retrievable record of any other pharmacist, responsible for the retail pharmacy business or for the personal supervision of the sale and supply of medicinal products, including veterinary medicinal products, at the premises, is maintained". The PSI takes 'ongoing, contemporaneous and retrievable' to mean that this record is a continuous record, generated at the time of the individual pharmacist's attendance, and that this record is present, current and accessible at all times that the retail pharmacy business is in operation. The maintenance of the register is a legal requirement and is the responsibility of the superintendent pharmacist. The register distributed by the PSI has been designed as a day diary format, where the pharmacist(s) and pharmaceutical assistant(s) present record their name, registration number, time in/out of the pharmacy and signature. The PSI also recommends that the register is checked and signed regularly by the supervising pharmacist.

Retail Pharmacy Businesses – Change in Ownership

A change in ownership of a retail pharmacy business cancels its registration. A process of cancellation of the existing registration must be carried out by the previous pharmacy owner who must also return the certificate of registration to the Registrar. The new owner(s) must then apply to register the retail pharmacy business under the new ownership. This application for a new registration will incur the statutory application fee.

Retail Pharmacy Businesses – New Openings

From 1st January 2009, a pharmacy must be registered as a Retail Pharmacy Business with the PSI in order to operate and to comply with the Pharmacy Act 2007.

All applications to register a retail pharmacy business (new openings of pharmacies, or permanent relocations of existing pharmacies), must be carried out in accordance with the current legislation and, in particular, with the provisions of the Pharmacy Act 2007, the PSI (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495 of 2008) and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) made by the Minister for Health and Children under Section 18 of the Pharmacy Act 2007.

The PSI (Retail Pharmacy Businesses) (Registration) Rules 2008 set out the requirements that applicants must comply with and the procedures and timelines which will be followed by the PSI in carrying out its functions in relation to the registration of Retail Pharmacy Businesses.

Any person now wishing to open a new retail pharmacy business must make a valid application to register that pharmacy at least 60 days before it is due to open. This timeframe is to ensure that the application will be examined and the necessary inspection carried out in a timely manner so that the pharmacy concerned is appropriately registered as a retail pharmacy business under the Act. It is an offence under the Act for an owner to open or operate a pharmacy unless and until it is so registered and the other

requirements of Part 5 of the Act are also fully complied with.

It should also be noted that the provisions of the PSI (Fees) Rules 2008 provide for the urgent processing of a first application for registration of a retail pharmacy business where an additional fee of €1,000 is paid. This additional fee for the 'fast-track' service is in addition to the fee of €3,500 for the application to register a new retail pharmacy business. This additional fee will ensure that the processing of the application is undertaken by the PSI in a period that is less than 60 days. Pharmacy owners should note that the minimum required processing time for new applications to register is 21 calendar days.

As part of the process it is necessary for the pharmacy premises to be inspected. An inspection cannot be scheduled until a complete and valid application has been submitted to the PSI. The inspection must generally be carried out approximately eight (8) working days before the pharmacy is due to be registered/open. An Information Sheet which will assist with the preparation for such inspection is available from the PSI and will be sent to all applicants. This checklist outlines the equipment and procedures that must be in place before an inspection for the registration of a new retail pharmacy business can be carried out.

In the event that the proposed retail pharmacy business is located in a premises or part of a premises that is less than five years old, issues may arise under the Local Government Planning and Development Acts. In those circumstances, applicants will be required to provide a copy of the grant of final planning permission under which the premises was built or any renovations thereof which may have required planning permission; and/or evidence in the form of a certificate from an architect or engineer confirming that the premises (or the renovations thereof) were carried out in compliance with planning permission and that they comply with building regulations.

Applicants will also be requested to set out the nature of any economic or other relationships in relation to the proposed retail pharmacy business which may be affected by the provisions of Sections 63 to 65 of the Pharmacy Act 2007, if such circumstances are applicable.

Retail Pharmacy Businesses – Cancelling Registration and Closing

An application to cancel the registration of a retail pharmacy business where the pharmacy owner wishes to close the pharmacy must be made in writing to the PSI and on the form made available by the PSI for this purpose. This application should set out the arrangements made, or to be made, in respect of (a) the disposal of any medicinal products held at that pharmacy, and (b) the records of the dispensing or supply of medicinal products conducted at that pharmacy, having regard to the reasonable needs of patients to have access to such records. The cancellation of the registration of a retail pharmacy business, in the event of a closure, cannot be completed until such time as these requirements have been fully complied with.

The PSI will be happy to assist and advise pharmacy owners in complying with these requirements, to ensure that the needs' of patients are appropriately met.

Third Country Qualification Recognition Process Open

The 'Recognition of Third Country Pharmacist Qualification as a Qualification Appropriate for Practice in Ireland' process for non-EU/EEA applicants is now operational. Application forms and an explanatory information booklet are available for download from the PSI website. Potential applicants who had contacted the PSI about this process have been emailed to inform them that the process is open.

Pharmacy successfully prosecuted for lack of professional cover

The PSI successfully prosecuted a Dublin city pharmacy, Temple Bar Pharmacy Limited, for the supply of medicinal products without such supply being by or under the personal supervision of an authorised person/registered pharmacist as required by legislation.

The managing director of Temple Bar Pharmacy Ltd, Mr Kieran Maguire, pleaded guilty to the offences at Court 49 Dolphin House, Dublin 2 on 6 April 2009. Judge Tom O'Donnell fined Temple Bar Pharmacy €500 in respect of one summons and took three others into account on account of the defendant's ultimate guilty plea.

Judge O'Donnell expressed the view that this was a serious matter and advised Mr Maguire in his own interest not to let a matter of this nature occur again. The PSI was awarded costs in the sum of €1760.38.

Confidential support programme for pharmacists

The Combined Professional Health Support Programme is a confidential service which provides support, early intervention and referral to treatment for health professionals who have substance misuse/addiction problems. The programme is operated by trained health professionals who have both clinical and personal experience of such problems. The programme co-ordinator Joe Mee and this confidential service can be accessed through a dedicated helpline number: 01 2837409. Family members, colleagues or employers who are concerned about a pharmacist or other health professional and their use of alcohol or other drugs can contact the programme at the helpline number.

'Whistleblower's' legislation introduced

The Minister for Health and Children, Mary Harney TD, commenced the protected disclosures provisions of the Health Act 2007 on 01 March 2009. These disclosures provisions provide a 'whistleblower's' provision in relation to risks to the health, safety of welfare of the public, and provide for statutory protection in respect of disclosures made in good faith, including disclosures made by a person to a professional regulatory body. Dr Cora Nestor has been appointed as the officer to accept protected disclosures by the PSI.

Practice Notices

Supply of Paracetamol

A Practice Notice was disseminated regarding the supply of medicinal products containing paracetamol, highlighting in particular the responsibilities of the supervisory pharmacists in ensuring that supply of all medicinal products, including those containing paracetamol, complies with the relevant articles under 'Section 18' regulations, as well as the regulations governing paracetamol specifically

A report recently published in the *Irish Journal of Medical Science*, (DOI 10.1007/s11845-008-0270-8) entitled "Paracetamol availability in pharmacy and non-pharmacy outlets in Dublin, Ireland", reported concerns about the compliance with statutory regulations governing the sale of paracetamol. The study, carried out by Professor Patricia Casey and colleagues in the Department of Adult Psychiatry in UCD and the Mater Misericordiae University Hospital, found that amounts of paracetamol in excess of statutory limits for a single transaction were purchased in 50% of pharmacies. The study also noted deficits in the patient counselling/interview carried out in some of the pharmacies surveyed. (The Practice Notice is published on page 49).

Supply of certain prescription-only medicines

A Practice Notice was disseminated in response to a National Advisory Committee on Drugs (NACD) bulletin looking at the prevalence of sedative, tranquilliser and anti-depressant use in Ireland and Northern Ireland. One of the findings reported in the data was that 2% of respondents in Ireland who used sedatives or tranquillisers had bought them without a prescription at a pharmacy. This practice notice outlined the importance of having robust policies and procedures in place to ensure compliance with the legislation governing the supply of medicinal products, as well as the Code of Conduct for pharmacists.The NACD bulletin is available from the National Advisory Committee on Drugs website http://www.nacd.ie/ (the Practice Notice is published on page 50).

Pharmacy Act 2007: Understanding your role

(ICCPE / PSI / HSE joint educational session Spring 2009)

PSI / ICCPE taskforce

A joint PSI/ICCPE taskforce has been set up to advise the ICCPE and the PSI Registrar/CEO on how best to effectively collaborate with and support pharmacists during the implementation of key sections of the Pharmacy Act 2007. This taskforce, in conjunction with HSE pharmacists, held 12 meetings around the country as part of the ICCPE Spring programme, at which the PSI gave a presentation on the roles and responsibilities of the superintendent and supervising pharmacists, and the implications of 'Section 18' regulations. Along with ICCPE tutors and HSE pharmacists, workshops/discussions on a number of case study scenarios were facilitated to further understanding of these requirements through a practical exploration of the responsibilities and requirements of the new legislative framework. The first session was followed in all locations by a second workshop, facilitated by ICCPE tutors, on self-audit processes using the PSI Pharmacy Practice Guidance Manual as a tool for this process.

The PSI presentation given as part of the ICCPE Spring programme 2009 is published here in a reader-friendly format.

Introduction

The Pharmacy Act 2007 has brought significant changes to the way the profession is regulated in Ireland and to the roles and responsibilities of pharmacists. It has introduced a professional management structure through the roles and responsibilities of the superintendent pharmacist and the supervising pharmacist and provides for the adoption of a statutory Code of Conduct for pharmacists.

Pharmacy Act 2007 – three phase commencement process

The Pharmacy Act 2007 is being commenced in three phases. The first phase was commenced on 22 May 2007 and provided for the establishment of the PSI with a broad range of functions and duties (and the dissolution of the old body of the same name). It also provided for the establishment of a new Council with a non-pharmacist majority.

In preparation for the second phase of commencement, the PSI developed a number of statutory rules and a draft Code of Conduct for pharmacists, which were subject to public consultation during 2008. The five statutory rules related to Registration, Retail Pharmacy Business Registration, Council, Education and Training and Fees, and are intended to set out in greater detail the procedures and requirements which will be operated by the PSI in carrying out its various functions under the provisions of the Act.

In addition, the PSI developed a Pharmacy Practice Guidance Manual (PPGM), which was disseminated to all pharmacies in the country via the Roadshow meetings held during the summer of 2008, to inform pharmacy owners and supervising pharmacists of the new regulatory environment which would pertain once the registration of pharmacies was introduced. The PPGM was a self-audit tool to allow individual owners and pharmacists audit and evaluate their own practices, and feedback was welcomed.

In preparation for the second phase, the Department of Health and Children developed draft regulations under Section 18 of the Pharmacy Act 2007 to govern the operation of retail pharmacy businesses.

Second phase of commencement process

The second phase of the Pharmacy Act 2007 was commenced on 29 November 2008, and included Parts 4, 5, 7 and 8 of the Act. Part 4 pertains to the new pharmaceutical registration systems– the registration of retail pharmacy businesses, and continued registration for pharmacists and pharmaceutical assistants. Part 5 relates to Offences, primarily relating to the operation of retail pharmacy businesses, Part 7 provides for new powers of investigation and enforcement of the PSI and Part 8 relates to miscellaneous provisions, primarily the revocation of old legislation, including the old Pharmacy Acts.

Final phase of commencement process

The remaining Part of the Act, Part 6 which relates to complaints, inquiries and discipline, is expected to be commenced in 2009, and this Part provides for 'fitness to practise' and 'fitness to operate' systems. This Part also includes Sections 63 and 64, which concerns economic relationships with doctors, etc.

A further provision of the Act to be implemented is the requirement for Continuing Professional Development (CPD) for pharmacists. The PSI has commissioned a review of international CPD models and it is envisaged that the report of this review will be presented to Council before the end of 2009, with a view to initiating pilot rollout during 2010. It should be noted that in applying for the registration of a retail pharmacy business, the pharmacy owner/superintendent pharmacist undertakes to make appropriate arrangement for CE and CPD for the pharmacists they employ.

Registration of Retail Pharmacy Businesses

Part 4 of the Pharmacy Act 2007 outlines a number of conditions that pertain to the registration of a retail pharmacy business. Some conditions are comparable to the system pertaining under the old legislation, while some are new.

- Ownership: pharmacist, a partnership of pharmacists, a corporate body or a representative of a deceased pharmacist;
- The retail pharmacy business must be under the personal control of a superintendent pharmacist (new) – the role of superintendent pharmacist is a new requirement under the Act;
- At each premises, there must be a supervising pharmacist in whole-time charge of carrying on the business;
- The sale and supply of medicinal products in the retail pharmacy business must be by or under the personal supervision of a pharmacist (new) – this requirement involves a subtle updating of Irish medicinal product legislation to the EU norm, whereby the 'default' position in relation to the supply of medicinal products is now 'by or under the personal supervision of a pharmacist in a pharmacy', as opposed to the previous situation where supply was controlled by virtue of a medicinal product being listed on a schedule attached to regulations;
- The name and certificate of registration of the supervising pharmacist must be conspicuously displayed at the premises;
- The certificate of registration of the retail pharmacy business must be conspicuously displayed at the premises (new) – certificates of registration relating to the pharmacy premises were not previously issued under the old legislation.

There is a further condition on a corporate body in that in order to conduct a retail pharmacy business, a corporate body must have submitted a statement to the Registrar specifying:

- the name of the superintendent pharmacist and
- declaring whether or not he or she is a Director in the corporate body.

This statement must be signed by the superintendent pharmacist and on behalf of the corporate body.

There are also further conditions on the pharmacists who may fill the roles of superintendent and supervising pharmacist in that they must have a minimum of 3 years' post registration experience practising whole-time as a registered pharmacist in a retail pharmacy business (or the equivalent under the old legislation or corresponding experience in another country).

When applying for registration of a retail pharmacy business, the pharmacy owner must:

- Nominate superintendent and supervising pharmacists, detailing their relevant three years' post-registration experience;
- Declare that the retail pharmacy business shall be conducted in accordance with 'Section 18' regulations;
- Declare that sale and supply of medicinal products shall be by or under the personal supervision of a registered pharmacist at all times. This latter requirement gives rise to the question where a pharmaceutical assistant (PA) is acting on behalf of a registered pharmacist in their temporary absence, and there is no change in the current provision for a PA to so act. However, it should be noted that the PA is acting on behalf of the registered pharmacist, and so therefore it will be the registered pharmacist and the supervising pharmacist who will be held accountable for the actions of the PA acting on behalf of a registered pharmacist. The supervising pharmacist is at all times responsible for the operation of the pharmacy.

Superintendent pharmacist

The requirement for a superintendent pharmacist comes from Part 5, Sections 26 to 29 from Act. The term 'superintendent' is not used as such in the Act, but the requirement comes from these sections that a condition of registration of a retail pharmacy business is: "that the part of the business that consists of the **management and administration** of the **sale and supply of medicinal products** is **under the personal control** of a registered pharmacist who has three years' minimum post-registration experience". There are further conditions in relation to retail pharmacy businesses owned by corporate bodies (as outlined above) and this is outlined in Section 28. The requirement for a superintendent pharmacist essentially hands the professional management of pharmacy practice back to the profession, back to the pharmacist.

Supervising pharmacist

The requirement for a supervising pharmacist comes from the same Part of the Act, where the condition is "that, at the premises where the business is carried on or, if there are two or more of those premises, at each of them, there is a registered pharmacist who has three years' minimum post-registration experience, in **wholetime charge** of the **carrying on of the business** there."

The requirement for a supervising pharmacist is not a completely new concept; it is comparable to the principal authorised person under the old system – but the requirement is now firmly enshrined in legislation. There must be one supervising for each retail pharmacy business, and while the superintendent can act in respect of more than one retail pharmacy business, the supervising can not. In addition, both roles can rest in the one person.

'Section 18' regulations

The Regulation of Retail Pharmacy Businesses Regulations 2008 (SI No 488 of 2008) have been made under Section 18 of the Pharmacy Act 2007 by the Minister for Health and Children. These regulations, made for the 'purposes of the health, safety and convenience of the public', govern the operation of retail pharmacy businesses, and essentially are the framework within which the superintendent and supervising pharmacists carry out their roles. The rationale behind these regulations was to ensure that proper regulation and control of the 'supply chain' of medicinal products, from manufacturer to patient, is now in place. The manufacture and distribution of medicinal products is highly regulated, whereas prior to the Pharmacy Act 2007 and the registration and regulation of retail pharmacy businesses, it can be argued that the final, and indeed most important link in that supply chain, was not subject to robust, modern regulation.

The PSI has issued a Practice Notice outlining the implications and requirements of 'Section 18' regulations – this Practice Notice is re-printed in this issue and is also available to download from the PSI website, under the 'Publications' tab and selecting 'Practice Notices'.

Much of the content of these regulations is not new, and will be recognised by pharmacists as putting 'good pharmacy practice' or 'good dispensing practice' on a legislative basis, so that these are now the requirements that all retail pharmacy businesses must operate to. In addition, from the patient's point of view, these regulations also give a legislative basis to the pharmaceutical care that patients are entitled to receive, and in particular in the provisions of articles 9 and 10 which relate, respectively, to the review and counselling of prescribed medicinal therapy and non-prescription controlled medicines. These articles also recognise the role of the pharmacist, not only in the supply of medicinal products, but also of the information and advice necessary for the correct and safe use of medicines.

Among the new requirements contained in these regulations are:

- that the pharmacy layout must enable the supervision by a pharmacist of the sale/supply of medicinal products (this is a reason why pharmacy owners must include a plan of the retail pharmacy business when applying for registration, to demonstrate that the physical layout of the pharmacy facilitates the pharmacist meeting their obligations in this regard);
- a retail pharmacy business must include a separate designated area to allow for review/discussion with patients in private (this provision pertains to all existing pharmacies from 01 November 2010);
- the requirement for supervising and superintendent pharmacists is re-iterated;
- a 'duty register' (an ongoing, contemporaneous, retrievable record of the registered pharmacists at the premises) must be maintained. To facilitate compliance with this requirement the PSI has distributed a duty register in a day-diary format to all registered retail pharmacy businesses.
- the pharmacy owner and superintendent pharmacist must be satisfied as to the competency of pharmacists and other staff employed, and also to the identity and registration status of pharmacists;
- in relation to record-keeping, there is a provision which will allow for the validation and certification of pharmacy computer software in future.

The regulations also state that the PSI Council may publish guidelines to facilitate compliance with the regulations, and such guidelines will be issued over the coming months. In addition, the regulations designates a number of relevant provisions for the purpose of offences, but it should be borne in mind that if a requirement is not denoted as an offence in these regulations, it may well be covered elsewhere in the legislation or indeed have implications in terms of 'fitness to practise' or continued registration.

Roles and Responsibilities of Superintendent and Supervising Pharmacists

Superintendent pharmacist

The responsibilities of the superintendent pharmacist are broadly the same as that of the pharmacy owner. The superintendent pharmacist has overall control of the legal, professional and clinical policies pursued in the retail pharmacy business. They have overall control over the whole operation of either a single pharmacy or of all pharmacies within the entity/chain for which they act, and also for the monitoring and evaluation of the policies applied.

These policies should reflect good pharmacy practice, comply with legislation, standards and the Code of Conduct for pharmacists, and should also facilitate compliance with Code of Conduct for all pharmacists employed. These policies should ensure compliance with the requirements of 'Section 18' regulations and superintendent pharmacists are also encouraged to use the Pharmacy Practice Guidance Manual (PPGM) as a tool to audit practice and inform the development of policies. (The second session of this ICCPE module involved using the PPGM as a tool for self-audit processes.)

The superintendent pharmacist must be satisfied as to the competence of pharmacists employed, including the supervising pharmacist(s), and other staff; they must have an ongoing satisfaction that the supervisory role of pharmacist is facilitated in each retail pharmacy business; and they are responsible for the maintenance of the duty register.

Supervising pharmacist

The supervising pharmacist is in 'whole-time charge' of the operation of the retail pharmacy business, and is responsible for operations even when absent. There is no specific definition in terms of minimum hours in the Act but requirement is that they must be practising in the pharmacy on a consistent and continuous basis, and for a significant proportion of the hours of business of the pharmacy in order to be able to fully exercise their responsibilities, and they must also be able to demonstrate how they exercise control when not there.

The supervising pharmacist is responsible for the management and control of the operation of the retail pharmacy business on a day-to-day basis; they are responsible for ensuring that appropriate procedures are in place to comply with legislation, standards, etc, and the policies of the pharmacy. In many instances, the supervising pharmacist may have a reporting relationship to the superintendent pharmacist.

The supervising pharmacist must ensure that staff are competent for the tasks assigned to them; they therefore have an important role in staff training, for example, training non-professional staff with regard to patient counselling and when patients should be referred to the pharmacist. The certificate of registration of the pharmacist acting as supervising pharmacist should be on conspicuous display in the retail pharmacy business.

Notifications to the PSI

Changes in the name of the superintendent and/or supervising pharmacists in a retail pharmacy business must be notified to the PSI. Given that the nomination of these two positions are conditions of registration of a retail pharmacy business, the pharmacy owner and the pharmacist(s) holding these positions must be mindful of the need for an orderly transition. It follows therefore that the replacement of these pharmacists is quite a formal process and that there could be legal or fitness to practise consequences if not done properly.

A change of ownership of a retail pharmacy business cancels its registration – the pharmacy owner/superintendent pharmacist are obliged to inform the PSI, and the new owner must apply to register the retail pharmacy business.

Where a retail pharmacy business cancels its registration due to closing, the PSI must be informed in writing, and details given of the arrangements in place for the disposal of medicines held in the pharmacy and for patient access to records held.

The PSI/ICCPE taskforce intend to deliver further educational sessions later this year. During June it is planned to deliver a number of sessions on the Code of Conduct for pharmacists, including an outline of Part 6 of the Pharmacy Act 2007 which relates to complaints, inquiries and discipline.

Further details of this initiative will be posted on the PSI and ICCPE websites and pharmacists will be notified by email of the details of dates, locations, etc., when these are finalised.

The PSI would like to thank the ICCPE for the opportunity to co-operate on this educational programme and the HSE pharmacists for their co-operation on this important educational activity. The PSI would also like to thank all the participants at the educational sessions for their engagement and feedback. A copy of this article and related legislation and Practice Notices are available to view and download from the PSI website www.pharmaceuticalsociety.ie under the 'Publications' tab.

Practice Notice

Control of the supply of non prescription medicinal products containing orlistat 60mg (alli®)

The European Medicines Agency (EMEA) has reclassified the centrally authorised medicine containing orlistat 60mg (alli®) from prescription-only to non-prescription in the EU.

Alli® (60mg) is used, in conjunction with dieting and exercise, with a view to weight loss in the case of overweight patients who have a body mass index (BMI) of 28 or above.

This medicine is now available in Ireland through retail pharmacy businesses without a prescription.

Article 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 require that when supplying any non-prescription medicinal product a pharmacist must be satisfied that:

(a) the purchaser is aware of the appropriate use of the medicine

(b) the medicine is being sought for that use, and

(c) as far as the pharmacist is aware, the product is not intended for misuse and/or abuse.

In the supply of alli® to a patient, it is important that the pharmacist must also ensure compliance with the conditions of the Marketing Authorisation which includes the following:

Treatment programme: Diet and exercise are important parts of a weight loss programme. It is recommended that a diet and exercise programme is started before beginning treatment with orlistat and pharmacists should ensure this programme is started before considering the supply of orlistat.

Indication; weight loss in adults who are overweight (body mass index (BMI) ≥ **28** kg/m2) and should be taken in conjunction with a mildly hypocaloric, lower-fat diet.

Age: should not be used in children and adolescents below 18 years of age.

Dosage: one 60mg capsule to be taken three times daily. This dosage should not be exceeded.

Treatment duration: If patients have been unable to lose weight after 12 weeks of treatment with orlistat, they should consult their doctor or a pharmacist. It may be necessary to discontinue treatment. Treatment should not exceed 6 months.

Special warnings and precautions: Special care should be taken with patients already on medication for high blood pressure, high cholesterol or diabetes. In addition, orlistat may reduce the effectiveness of oral contraceptives particularly in cases of severe diarrhoea. Because of the potential reduction in the absorption of fat-soluble vitamins, patients should be advised to use a multivitamin supplement.

For full information on this product, including information on special warnings, precautions, contraindications, drug interactions and side-effects, you are referred to the Summary of Product Characteristics (SPC). This SPC is available from the European Medicines Agency website: <http://www.emea.europa.eu/humandocs/PDFs/EPAR/alli%20/H-854-PI-en.pdf>

Each superintendent and supervising pharmacist must ensure that any retail pharmacy business for which he or she is responsible has appropriate policies and procedures in place to ensure compliance with all of the above. In addition, these policies and procedures must be in conformity with the provisions of the statutory PSI Code of Conduct for Pharmacists which encourages the rational and proper use of medicines in the interest of the patient. In general, this Code requires that pharmacists provide honest, relevant, accurate, current and appropriate information to patients regarding the nature, cost, value and benefit of any medicine, health related product or service that he or she may provide.

Watch customers burst into your pharmacy

with our €15 cashback promotion

Don't miss out on one of the year's best promotions – the Pharmaton® Capsules' **Burst into Spring for less €15 cashback offer.** This tempting offer is sure to give your customers a bargain and help boost your sales.

A Big Incentive

- Customers who purchase Pharmaton® 100's will receive €10 back when they send their completed claim form, together with their receipt and product barcode from outer packaging. It's that easy.
- To get the full €15 back, customers must supply their email address. They'll then be emailed a second claim form entitling them to a further €5 off their next purchase.

A Big Attraction

To create awareness and attract as much attention as possible we've designed some eye catching Point of Sale (POS) materials for your pharmacy including:

- A2 window display – to attract potential customers
- Dummy packs – to support your window display
- Shelf barkers – Sure to grab the attention of customers already in store
- In-store leaflets – ensuring everyone's aware of the promotion

What's more, this promotion is supported by a Pharmaton radio campaign to help drive customers to your pharmacy.

Demand is bound to be high so make sure you've got enough stock to keep up. Not only will your customers have a spring in their step, your sales will too.

To find out more contact your Pharmaton Rep or call 01 630 5260

Always read the label. Ask your pharmacist. If symptoms persist please consult your doctor.

PHARMATON CAPSULES: Product Information. Active ingredients: [illegible] **Uses** [illegible] **Children:** [illegible] **Contraindications** [illegible] **Precautions:** [illegible] **Dosage: Adults** [illegible] **Pregnancy:** [illegible] **Side effects** [illegible] **Pack size:** [illegible] **Marketing Authorisation Holder:** [illegible] **Marketing Authorisation Number:** [illegible] **Legal status:** [illegible] **Further information available from:** [illegible]

Nursing Homes Standards launched

Standards 14 and 15 relate to medication management, monitoring and review.

Standard 14 states: **Each resident is protected by the residential care setting's policies and procedures for medication management and, where appropriate, is responsible for his/her own medication**.

It states that there should be a medication management policy and procedures dealing with the safe administration of medication, for the prescription, supply, receipt, self-administration by residents, recording, storage, handling and disposal of medicines. In addition, all medication errors, suspected adverse reactions and incidents are recorded, reported and analysed within an open culture of reporting, and that learning is fed back to improve patient safety and prevent reoccurrence. It also states that records be kept to account for all medicines, including all medicines received, administered to residents, given to residents on leaving the RCS and returned to the pharmacy. The resident may self-administer medications, where the risks have been assessed and his/her competence is confirmed, and there should also be mechanisms in place to ensure the use of non-prescribed medicinal products is brought to the attention of the medical officer and/or GP. In the case of a post-mortem following the death of a resident, all medication (including non-prescription items) is retained until the results of the post-mortem are known.

Standard 15 states: **Each resident benefits from his/her medication to increase the quality or duration of his/her life. He/she does not suffer unnecessarily from illness caused by the excessive, inappropriate or inadequate consumption of medicines**.

It states that staff have comprehensive, up-to-date information on all aspects of medication management, and that the RCS has policies and procedures in place relating to working arrangements with the pharmacist. Residents should be reviewed at three-monthly intervals, or more frequently, where there is a significant change in their care or condition. In the event of a resident being treated as an in-patient in an acute general hospital, any change to his/her medication must be directly communicated, both verbally and evidenced in writing to the pharmacist, the GP and the RCS within six hours of discharge.

Each resident on long-term medication is reviewed by his/her medical practitioner on a three-monthly basis, in conjunction with nursing staff and the pharmacist. Special consideration is given to the use of: antipsychotic medication; sleeping tablets and other sedating medication; anticonvulsant medication; medication for the management of depression; analgesic medication (pain management); medication for the management of constipation; antiplatelet and anticoagulant medication (prevention of stroke); influenza and pneumococcal vaccines; non-steroidal anti-inflammatory drugs.

Speaking at the launch, Dr Tracey Cooper, CEO of HIQA said: "These standards are an important and significant milestone for the protection of the rights of our older people in residential care settings across the country. They will also guide and assist service providers in the provision of the highest quality of care to their residents.

Dr Marion Witton, Chief Inspector of Social Services at HIQA, said: "These standards put great emphasis on what it should be like for older people living in residential care settings. They are about promoting not only the best possible care for older people in these settings, but also ensuring that they can enjoy the best possible quality of life. Under these standards, each resident must now receive a contract setting out what they can expect regarding accommodation, food, care and services. As we have stressed previously, the emphasis will be on evidence that residents are being looked after properly and that individual needs are being met."

IMB statement re: topical salicylate products for oral use in children

The Irish Medicines Board (IMB) is aware of the Medicines and Healthcare Products Regulatory Agency (MHRA) decision to restrict the use of salicylate containing products for oral use in children under 16. This decision has been taken following a risk/benefit review which was conducted following publication of a case report in June 2008, of a suspected but unconfirmed case of Reye's syndrome associated with the use of an oral gel containing choline salicylate in a 20 month old child. The review concluded that the symptoms reported in the case report were not consistent with Reye's syndrome and were more likely to reflect salicylate toxicity due to incorrect use of the gel.

The IMB states that following its own review, it is satisfied that the risk-benefit for the use of salicylate containing products in children is positive when used according to their approved conditions of use. The IMB will continue to monitor these products closely on the Irish market.

The IMB's advice to parents and carers is that oral gels containing choline salicylate should be applied very sparingly and only at the frequency indicated in the product information. These products should only be used when clearly necessary and are intended for short-term use only.

The IMB states that at present there are two relevant products containing this active ingredient licensed in Ireland, Bonjela Oromucosal Gel and Teejel Gel. These products are licensed for use in children since 1983 for the treatment of infant teething. The IMB states that the risk associated with their short term use is extremely low and to date has received no reports of adverse reactions in children with these products. The risk of toxicity is associated with incorrect use or over-dosing.

The IMB wishes to emphasise that before any medicine is administered to a child, parents are advised to read the product information (labelling/patient information leaflet) carefully and consult with their doctor or pharmacist as appropriate. The IMB suggests that any parent or child minder, who has concerns or who requires further guidance on the correct use of these products, should contact their doctor or pharmacist.

FIP 2009 Congress in Istanbul

The International Pharmaceutical Federation (FIP) is holding its 2009 World Congress of Pharmacy and Pharmaceutical Sciences in Istanbul, Turkey. The theme for this year's Congress, which runs from 3rd to 8th September, is 'Responsibility for Patient Outcomes – are you ready?'

The Congress, which typically attracts more than 3,000 delegates from all over the world, offers a range of educational sessions and workshops which look at global changes and trends within the pharmacy profession and pharmaceutical sciences. The preliminary programme, registration details and further information are available at http://www.fip.org/ istanbul2009.

RCSI offers Healthcare Management course for Pharmacists

The RCSI Institute of Leadership and Healthcare Management is offering a MSc/postgraduate diploma course in healthcare management tailored for pharmacists, aimed at those in supervisory/management roles. Among the modules covered are leadership and strategic management; managing organisations and people; operations and quality management; evaluation, measurement and research; quality and risk management and specialist skills for pharmacists. Further information is available on www.rcsileadership.org. The closing date for applications is 05 June 2009.

'news' continues on page 47

PSI/RSA leaflet Medicines and Driving

The PSI/RSA leaflet Medicines and Driving is being distributed nationwide. This leaflet highlights for the public the fact that many commonly prescribed and recommended medicines can impair the ability to drive safely. It also advises that patients check with their prescriber or pharmacist if their particular medicines risk affecting the ability to drive safely. The leaflet is available to download from the PSI website www.pharmaceuticalsociety.ie or the RSA website www.RSA. Please contact either organisation if you would like to order copies of the leaflet.

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

Feidhmeannacht na Seirbhíse Sláinte Health Service Executive

Office of the Nursing Services Director

Information for Pharmacists about Nurse and Midwife Medicinal Product Prescribing in Ireland

April 2009

Introduction

2007 saw the introduction of legislation giving prescriptive authority to nurses and midwives in Ireland. In summary, this legislation allows a registered nurse or midwife, who has:

(a) completed an approved education programme,

(b) the appropriate clinical experience,

(c) registered with An Bord Altranais as a Registered Nurse Prescriber (RNP), and

(d) authority from the health service provider who employs them,

to prescribe a range of medications within their scope of practice.

The first nurse and midwife prescribers were registered with An Bord Altranais (ABA) at the end of January 2008. As of March 2009, there are currently 74 RNPs registered with ABA (12 practising in PCCC and 62 in the acute hospital sector). Recently a number of policy directions in relation to nurse and midwife prescribing of medicinal products under the various drug schemes have been agreed and these are outlined in this article.

Background

In 2005, a report entitled 'Review of Nurses and Midwives in the Prescribing and Administration of Medicinal Products' was published, which recommended that prescriptive authority be extended to nurses and midwives, subject to regulations.

The following year, the Irish Medicines Board (IMB) (Miscellaneous Provisions) Act 2006 provided for amendments to medicines regulations to allow prescribing by nurses and midwives. In addition, the Department of Health and Children established a national steering Resource and Implementation Group (RIG) on nurse and midwife prescribing, whose membership came from a wide variety of stakeholders, including the PSI, and one of its main terms of reference was to advise on issues relating to the drafting of regulations.

These regulations – the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 and the Misuse of Drugs (Amendment) Regulations – were subsequently signed into law on 1 May 2007, and they specify the legislative conditions and requirements for prescribing by nurses and midwives.

The main conditions that must be satisfied for a nurse to have prescriptive authority are:

- The nurse/midwife must be employed by a health service provider in a hospital, nursing home, clinic or other health service setting (including any case where the health service is provided in a private home).
- The medicinal product is one that would be given in the usual course of service provided in the health service setting in which the nurse/midwife is employed.
- The prescription is issued in the usual course of the provision of that health service.
- The An Bord Altranais registration number, also known as the personal identification number (PIN), must be stated on the prescription written by the Registered Nurse Prescriber (RNP).

The 2007 regulations also allow a health service provider to determine further conditions for the prescriptive authority of the nurse or midwife. In addition, the Nurses Rules 2007 established the registration and professional regulation aspects of nurse prescribing.

The amendment to Misuse of Drugs legislation creates a new Schedule 8, which confines the prescribing of specified Schedule 2 and 3 drugs by nurses within one of four particular areas of practice (See Table 1).

Table 1

Schedule 8 drugs which practitioners who are registered nurse prescribers may prescribe within MDA Schedules 2 and 3

Part I
DRUGS FOR PAIN RELIEF IN HOSPITAL

I For the pain relief of a person in hospital in respect of a possible myocardial infarction;

II For the relief of the acute or severe pain of a person in a hospital after trauma; or for the post-operative pain relief of a person in a hospital who has had either condition described in I or II.

DRUG	ROUTE OF ADMINISTRATION
Morphine sulphate	oral, intravenous, intramuscular
Codeine phosphate	oral

Part II
DRUGS FOR PALLIATIVE CARE

DRUG	ROUTE OF ADMINISTRATION
Morphine sulphate	oral, subcutaneous
Hydromorphone	oral, subcutaneous
Oxycodone	oral, subcutaneous
Buprenorphine	transdermal
Fentanyl	transmucosal, transdermal
Methylphenidate	oral
Codeine phosphate	oral

Part III
DRUGS FOR THE PURPOSES OF MIDWIFERY

DRUG	ROUTE OF ADMINISTRATION
Pethidine	intramuscular

Part IV
DRUGS FOR NEONATAL CARE IN HOSPITAL

DRUG	ROUTE OF ADMINISTRATION
Morphine sulphate	oral, intravenous
Fentanyl	intravenous

Note: as morphine sulphate is not currently authorised in Ireland for neonatal use, this drug is not being prescribed to neonates by RNPs, notwithstanding the fact that it is listed in Schedule 8, as RNPs cannot prescribe unlicensed medicines.

Regulatory Framework for Prescriptive Authority

The regulatory framework for the prescriptive authority provided for in the legislation covers four main parameters: education, registration, clinical competence and clinical governance.

Education

Currently the certificate of nursing education programme for RNPs is delivered at the Catherine McAuley School of Nursing and Midwifery, UCC and the School of Nursing, RCSI and entails a six-month course, combining theoretical modules taught through the Schools, with a practical element which is provided by a named mentor (medical practitioner) at the nurse's place of employment.

Before admission to the programme of education and training to be a RNP, there are a number of minimum entry requirements that a nurse/midwife must fulfil. The nurse/midwife must already be registered in one of the divisions of the ABA Register (general, psychiatric, children's, intellectual disability, midwife, public health nurse); they must have at least three years' post-registration clinical experience; and the equivalent of one year full-time experience in their specific area of practice. There should also be demonstrable evidence of further education and a competent level of IT literacy.

In addition, there are 'site requirements' for the nurse's place of employment and practice, which must support the nurse's education and practice as a RNP. A site declaration form must be submitted by the nurse's employer, confirming an organisational policy for nurse prescribing, appropriate risk management systems, access to a Drugs and Therapeutics Committee (DTC), a named mentor for each nurse, a prescribing site co-ordinator, and a commitment to continuing education for nurse prescribers.

The CPA

One of the key documents relating to nurse prescribing is the Collaborative Practice Agreement (CPA). This is a written agreement drawn up between the RNP, a medical practitioner (approved by the health service provider/employer) and the health service provider, outlining the parameters of the RNP's prescriptive authority, i.e. their scope of practice.

It contains a general description of the practice setting to include population and conditions for which the RNP has responsibility, as well as a list of specific medications (by generic name) and/or categories of medications that the RNP is competent to prescribe.

The CPA is underpinned by the principles of professional accountability, responsibility, competence and clinical governance. It also provides a template for the development, audit and evaluation of the RNP's prescribing practices within the healthcare setting.

CPAs must be reviewed and renewed annually, and are considered null and void on the termination/movement of employment for which they were originally intended. The CPA also states a commencement date for prescriptive authority.

Registration

The professional regulatory framework for nurse/midwife prescribing is established through the Nurses Rules 2007, which allows for the creation of a division of the Register for Nurse Prescribers. This Register is publicly accessible on the ABA website, www.nursingboard.ie, where it can be easily checked if a nurse is a RNP.

Click on the 'Check the Register' tab, and enter either the name or PIN (which must be written on all prescriptions) of the nurse. Under the individual nurse's details, the Division(s) of the Register that apply to the individual are listed, and this list will include the term 'nurse prescriber'. The register will also indicate if a CPA is on file (A CPA must be in place in order for the RNP to prescribe).

Practice Standards

The professional responsibilities of a RNP are addressed in the Practice Standards, which outline the requirements of An Bord Altranais and augment the clinical governance structures at local and national level. There are nine individual standards described and these are:

1 Prescription writing: Prescriptions must be written accurately and correctly, as required by relevant legislation and site policy.

2 Prescribing for self, family and significant others: This is not acceptable professional practice.

3 Repeat prescribing: This outlines need for regular review and assessment of patient for the repeat/continuation of previously prescribed medication and the requirement for the RNP to have a valid therapeutic relationship with the patient.

4 Prescribing of unlicensed medicines: RNPs are not authorised under current medicines legislation to prescribe unlicenced or exempt medicinal products.

5 Prescribing by means of verbal/telephone, email or fax: This is not acceptable practice under any circumstances.

6 Separation of responsibilities in the medication management cycle: This outlines best practice in the separation of prescribing and supplying/administering, and prescribing and dispensing, and states that, in the interests of patient safety, there should be a clear separation of these activities. It notes that "the pharmacist has a particular role and expertise for dispensing, as does the nurse/midwife involved with supply and/or administration of medications, particularly in acute care settings". However, it is acknowledged that the local site specific CPA may outline situations where the RNP may be involved in a crossover and merging of these activities as part of the provision of patient care, and states that the CPA should provide for the auditing of such practices.

7 Influence of outside interests (relationships with pharmaceutical representation or similar organisations): This states the RNP should only prescribe based on the best interests of the patient, and should not be influenced by factors such as financial support by pharmaceutical and/or other healthcare interests.

8 Communication and documentation: This states that RNPs have a responsibility to communicate effectively and efficiently to the patient, as well as to the other healthcare professionals involved in the patient's care.

9 Continuing professional development and continued competency: This states that the RNP has a professional and personal responsibility to maintain their individual competency for prescribing practice, and obliges them to commit to, and engage in, continuing professional development relating to assurance of competency for prescribing practices. It also states that health service providers/employers have a responsibility to provide support and access to continuing professional development and assessment of competence.

Evaluation

An independent external evaluation of nurse and midwife prescribing is currently underway. This two-year review is being undertaken by a research team in UCD. The review comprises four distinct phases: an audit of nurse/midwife prescribing; an evaluation of the educational programme, patient satisfaction survey; evaluation of health professionals, including stakeholder bodies and members of the nursing profession itself.

Since the introduction of prescribing by RNPs, each individual nurse/midwife records information for every prescription they write in a central web-based database. The information recorded includes the clinical indication (prophylaxis, diagnosis or treatment), the name, dose, frequency and route of the medicinal product prescribed, as well as details of the prescribing site and the RNP. Analysis of this data will be part of the audit of prescribing in the evaluation.

Recent Developments in Nurse/Midwife Prescribing

RNPs prescribing in PCCC

As of April 2009, there are 12 RNPs working within the PCCC sector and more than 30 nurses from PCCC currently in training to become RNPs. A high level group composed of representatives from the Department of Health and Children and the HSE was established last year to discuss the implementation of nurse prescribing under the various drug schemes.

The policy directions for each of the main schemes have now been agreed and will be implemented in the near future. The introduction of nurse/midwife prescribing does not alter in any way the current arrangements for reimbursement under the various schemes. Circulars from the HSE will communicate the alignment to the various schemes to community pharmacists upon implementation, and the policy directions for each scheme are outlined below:

- GMS: The community RNP will be issued with a prescription pad with their own allocated GMS number. This number will be allocated once the PCRS has been notified that the RNP is authorised by the HSE to commence prescribing. This number is different to the RNPs PIN which also must be written on all prescriptions. *Note: From 01 July 2009 all prescribers, including medical practitioners, will have to put their professional registration number on each prescription that they write – this is to ensure that the person who actually writes a prescription is identifiable*. The RNP prescriptions will be the standard GMS monthly prescription only. These will most likely be in a different colour to those used by GPs, to facilitate audit. These prescriptions will be in quadruplicate – one copy for the RNP, one for the patient's GP and a copy and the original for the community pharmacist.

- Hospital emergency for GMS patient: Emergency discharge prescriptions written by hospital RNPs for GMS patients will be similar to those written by other prescribers within the hospitals, i.e. a pharmacist may give up to seven day's emergency supply (or an OP where appropriate), and process for reimbursement in the normal way. The prescription will show that the prescriber was an RNP and the RNP's PIN will be written on the prescription.

- DPS: The commencement order for Section 26 of the IMB Act was signed by the Minister for Health and Children on 25 February 2009, with effect from 27 February 2009, and this allows for prescriptions written by RNPs to be included on the Drugs Payment Scheme (DPS). The HSE will also be monitoring the impact of the introduction of nurse prescribing to the DPS and other schemes on prescribing levels.

- LTI: Prescriptions for LTI patients by RNPs are allowable under the scheme, provided that the medicinal product prescribed is listed in the RNP's CPA and is also approved at local level for the particular patient's condition.

- High Tech: Maintenance (repeat) prescriptions can be written by the RNP once the High Tech drug has been initiated by the collaborating medical practitioner (typically the consultant leading a particular multidisciplinary team). RNPs cannot initiate High Tech drug therapies.

However, in issuing a maintenance prescription, they are permitted to make dose changes for therapies already initiated. Under the practice standards for RNPs, they can write repeat prescriptions if they have a valid therapeutic relationship with the patient and there has been appropriate review/assessment of the patient's needs.

- HAA: The current arrangements for the Health Amendment Act (HAA) scheme are being extended to include a prescription written by a RNP.
- Public Mental Health Clinics (Dublin): It has been agreed that prescriptions written by RNPs are not to be included in this scheme at this time.

Guiding Framework and National Policy documents

In November 2008, the Office of the Nursing services Director in the HSE, which oversees the implementation of nurse/midwife prescribing, published its Guiding Framework. This comprehensive document outlines the various elements of the implementation programme.

The CPA (collaborative practice agreement) is a key document for RNPs as it outlines the general description of the practice setting to include population and conditions for which the RNP has responsibility, as well as a list of specific medications (by generic name) and/or categories of medications that the RNP is competent to prescribe. In the hospital setting, the medicinal product listing in the CPA must be approved by the Drugs and Therapeutic Committee (DTC), and copies of the CPA are disseminated to relevant healthcare professionals within the wider team, such as the pharmacy department in a hospital setting.

The Guiding Framework also states that copies of the CPA should be disseminated to "individuals and groups outside the healthcare setting, for example, community pharmacists", and that discussions and decisions should be undertaken locally on making the CPA medicinal product listing available to other key professionals, such as community pharmacists.

It is envisaged that within PCCC this exchange of information would take place in a manner similar to any other new prescriber arriving in a particular area – the community pharmacist and RNP would introduce themselves to each other and set about establishing a professional relationship, which would include the RNP sharing the medicinal product listing in the CPA with any community pharmacists with whom they share or are likely to share the care of patients.

The HSE is also developing a number of national policy documents for nurse medicinal product prescribing – one has been developed for the intellectual disability (ID) sector and one relating to PCCC is currently in development. These policy documents have been developed to support a standardised approach to the implementation of nurse/midwife prescribing and are intended as a guide towards best practice. Section 6.9 of the policy for the ID sector outlines the roles and responsibilities of the pharmacist/pharmacy department in relation to nurse prescribing. These are:

6.9.1 The pharmacist/pharmacy department will provide support and guidance to the nurse or midwife prescribers and advise on the development of the nurse or midwife prescriber's medicinal product listing

6.9.2 Provide medicines information on request to registered nurse prescribers.

6.9.3 Support the risk-management processes in relation to nurse prescribing and collaborate in audit where appropriate.

6.9.4 Inform registered nurse prescribers of alert notices and bulletins received.

Frequently asked questions

- ***How will I know if a prescription has been written by a RNP?***
- All prescriptions must include the RNP's PIN. Many hospitals which employ RNPs will also include a tick-box or other feature on the prescription to show the qualification of the prescriber. In addition, GMS prescriptions written by RNPs may be a different colour to those written by GPs. To check if a nurse is appropriately registered with An Bord Altranais, check on www.nursingboard.ie by clicking on the 'Check the Register' tab and use either the nurse's name or PIN to verify their registration status. Alternatively An Bord Altranais can be contacted by phone at 1890 200 116.

- ***Do I treat a prescription written by a RNP in any way differently to that written by a medical practitioner?***
- No. The requirements for prescription writing under the relevant regulations equally apply to all prescribers and the requirements in relation to the review of therapy and counselling of patients, as per Article 9 of the Regulation of Retail Pharmacy Businesses regulations ('Section 18' regulations), equally apply to all prescriptions. In addition, as with all other prescribers, RNPs should be contacted by a pharmacist to query or discuss a prescription when necessary. The Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 outline the conditions and requirements for nurse prescribing and Schedule 8 outlines the specifics in relation to certain drugs in Schedules 2 and 3 of Misuse of Drugs regulations. All prescriptions written by a RNP must include the RNP's PIN (this will apply to all prescribers after 1 July 2009). The alignments to the main drug schemes, to include prescriptions written by RNPs and as outlined above, will be communicated by the HSE on implementation.

- ***Can a pharmacist have access to the medicinal product listing in the CPA of a RNP?***
- Copies of the CPA of RNPs within the hospital sector are typically disseminated to the pharmacy department, which also has an input into the development through the Drugs and Therapeutics Committee (DTC). The Guiding Framework for nurse/midwife medicinal product prescribing states that copies of the CPA should be disseminated to 'individuals and groups outside the healthcare setting, for example, community pharmacists', and that discussions and decisions should be undertaken locally on making the CPA medicinal product listing available to other key professionals such as community pharmacists. Within PCCC, it is envisaged that as part of the building of new professional relationships, the CPA of a RNP would be disseminated to community pharmacists with whom they share patient care. The CPA is not available to view via the register on the ABA website. However, it should be noted that a pharmacist does not have to cross-reference the medicinal product prescribed against the CPA listing. The assumption must be made that if an RNP prescribes a medicinal product, then they are entitled to do so under their CPA. The sharing of the CPA is primarily to ensure good professional relationships and ensure patient care and safety are optimised.

- ***Can RNPs prescribe unlicensed or 'off-label' medicines?***
- RNPs are not authorised under current medicines legislation to prescribe unlicensed or unauthorised medicines. This is currently understood to include all 'unlicensed' factors, including 'off-label' use for an unlicensed indication, formulation, population, etc. However, it is likely that there will be further clarification of the legislative situation in this regard in the future.

- ***Where can I get further information about nurse/midwife prescribing?***
- Further details of the information outlined here can be accessed on the An Bord Altranais website www.nursingboard.ie, or on the HSE website www.hse.ie, by clicking on the button for 'About the HSE', selecting 'Nursing Services' and then 'Prescribing of medicinal products'. The HSE website also provides contact details for the staff of the Office of the Nursing Services Director, who will welcome any queries about nurse and midwife prescribing.

IMB information on Medicines for the Management of ADHD

(I) Atomoxetine (Strattera)

Atomoxetine is authorised for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of six years and older, and in adolescents, as part of a comprehensive treatment programme. Treatment with atomoxetine must be initiated by, or under the supervision of, a physician with appropriate knowledge and experience in treating ADHD. A comprehensive treatment programme typically includes psychological, educational and social measures and is aimed at stabilising children with a behavioural syndrome characterised by symptoms which may include chronic history of short attention span, distractability, emotional liability, impulsivity, moderate to severe hyperactivity, minor neurological signs and abnormal EEG. Learning may or may not be impaired. Pharmacological treatment is not indicated in all children with this syndrome and the decision to use the drug must be based on a very thorough assessment of the severity of the child's symptoms in relation to the child's age and the persistence of symptoms.

In light of concern about the increased risk of suicidal thoughts and behaviour associated with its use, a European review of available data on the risks and benefits of atomoxetine was undertaken. This review concluded that the overall balance of risks and benefits of atomoxetine remains positive in the treatment of ADHD in children of six years and older and in adolescents. However, in order to optimise the safe use of atomoxetine, the IMB wishes to highlight the following safety information to healthcare professionals:

Due to concerns about an increased risk of suicidal thoughts and behaviour, patients should be monitored for signs of depression, suicidal thoughts or suicidal behaviour and referred for appropriate treatment if necessary.

Seizures are a potential risk with atomoxetine and it should therefore be introduced with caution in patients with a history of seizure. Discontinuation of atomoxetine should be considered in any patient developing seizure or if there is an increase in seizure frequency. Caution is advised with concomitant use of medicines which are known to lower the seizure threshold (such as antidepressants, neuroleptics, mefloquine, buproprion or tramadol).

Reports of QT interval prolongation have been received in association with atomoxetine. Therefore, it should be used with caution in those with congenital or acquired long QT or a family history of QT prolongation. This risk may be increased if atomoxetine is used concomitantly with other drugs that produce QT prolongation (such as neuroleptics, class IA and III anti arrhythmics, moxifloxacin, erythromycin, methadone, mefloquine, tricyclic antidepressants or lithium), drugs that can cause electrolyte disturbances (such as thiazide diuretics) and those that inhibit cytochrome P450 2D6.

There is a risk of rare, but sometimes severe, hepatic disorders. Atomoxetine should be discontinued in patients with jaundice or laboratory evidence of liver injury, and should not be restarted.

Healthcare professionals are reminded to adhere to the approved recommendations for use of atomoxetine and to closely monitor patients during use, advising them to report any symptoms associated with treatment to their doctor. To date, adverse reactions reported in Ireland have been consistent with the known safety profile of the product and healthcare professionals are encouraged to continue reporting suspected cases to the IMB in the usual way. Online reporting is available by following the links at www.imb.ie.

(II) – Methylphenidate

The European Medicines Agency (EMEA) in conjunction with the IMB has completed a review of the benefits and risks of methylphenidate after recent concerns about its cardiovascular, cerebrovascular, and psychiatric safety and its long-term effects. Following this review of the currently available data, the EMEA's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of methylphenidate continue to outweigh the risks when used in its licensed indication. Methylphenidate is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged six years or older and adolescents, who are diagnosed according to DSM-IV criteria or guidelines in ICD-10.

The EU review concluded that new recommendations on prescribing methylphenidate, on pre-treatment screening and ongoing monitoring of patients are needed in order to optimise the safe use of these medicines. The IMB wishes to alert healthcare professionals to the following recommendations for safe use of methylphenidate:

Key safety information and advice for healthcare professionals:

Contraindications—methylphenidate should not be used in patients with:

- Diagnosis or history of severe depression, anorexia nervosa or anorexic disorders, suicidal tendencies, psychotic symptoms, mania, schizophrenia, severe mood disorders, or psychopathic or borderline personality disorder
- Diagnosis or history of severe and episodic (type I) bipolar (affective) disorder that is not well-controlled
- Pre-existing cerebrovascular disorders e.g. cerebral aneurysm and vascular abnormalities, including vasculitis or stroke
- Unless specialist cardiac advice has been obtained: in pre-existing cardiovascular disorders, including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, and dysfunction of cardiac ion channels

Pre-treatment screening

- Before prescribing, the patient's baseline cardiovascular status, including blood pressure and heart rate, should be assessed
- A complete history should be taken, documenting: concomitant medicines; past and present medical and psychiatric disorders or symptoms; family history of sudden cardiac death, unexplained death, or malignant arrhythmia; and accurate pre-treatment height and weight on a growth chart. Patients who are being considered for treatment with methylphenidate should also have physical examination for the presence of heart disease
- Patients should receive further specialist cardiac evaluation if initial findings suggest such history or disease. Caution should be used when treating patients whose underlying medical conditions might be compromised by increased blood pressure or heart rate

Ongoing monitoring

- Blood pressure and pulse should be recorded on a centile chart at every dose adjustment and then at least every six months.
- Height, weight, and appetite should be recorded at least every 6 months on a growth chart.
- Methylphenidate could cause or worsen some psychiatric disorders such as depression, suicidal thoughts, hostility, anxiety, agitation, psychosis, and mania. Development of new or worsening of pre-existing, psychiatric symptoms should be monitored at every dose adjustment and then at least every 6 months, and at every visit.
- Prescribers should look out for signs of diversion (transfer of the medicine from the individual for whom it was prescribed to one for whom it is not prescribed), misuse, and abuse of methylphenidate.
- Patients who develop symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of heart disease during methylphenidate treatment should undergo prompt specialist cardiac evaluation.

There is a lack of data on the long-term effects of methylphenidate. When patients are prescribed methylphenidate for extended periods (i.e. >one year), physicians should periodically interrupt treatment at least once a year to assess whether continuation is necessary. The longer-term safety of methylphenidate remains under close review, and the results of ongoing studies to better characterise the known or potential risks of ADHD medicines will be evaluated when available.

As part of the on-going monitoring of the safety of methylphenidate, healthcare professionals are reminded to adhere to the approved recommendations for use of methylphenidate and to closely monitor patients during use, advising them to report any symptoms associated with treatment to their doctor. To date, adverse reactions reported in Ireland have been consistent with the known safety profile of the product and healthcare professionals are encouraged to continue reporting suspected cases to the IMB in the usual way. Online reporting is available by following the links at www.imb.ie

Practice Notices

Implications of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

The Pharmacy Act 2007 provides under Section 18 that the Minister may, for the purposes of the health, safety and convenience of the public, make regulations regarding the operation of retail pharmacy businesses. These regulations (which came into force on 29 November 2008), taken in tandem with the provisions of Section 27, 28 and 29 of the Act, provide a framework to ensure that certain criteria are met in the operation of each and every retail pharmacy business. It is intended that during the course of 2009, the Council, with the prior approval of the Minister, will publish detailed Guidelines for the purpose of facilitating compliance. This preliminary notice is intended to assist in identifying issues that practitioners may already be aware of as being provided for in these regulations, and act as a quick self-check mechanism to ensure that the minimum requirements are being met. This notice is not intended to be a legal interpretation and does not purport to capture all the requirements of the regulations. It is recommended that reference be made to the regulations themselves where specific queries or issues arise.

The Regulation of Retail Pharmacy Businesses Regulations 2008 set out certain requirements to be complied with by persons carrying on retail pharmacy businesses. These also lay down requirements in respect of the sourcing, sale, supply and keeping of records in respect of medicinal products (including veterinary medicinal products). Requirements in respect of staff, premises, equipment and procedures are also laid down, including certain responsibilities that must be discharged by the superintendent and supervising pharmacists. The following points should, therefore, be considered as a check-list in their application:

- A pharmacist must supervise all the professional activity within the practice
- There is a requirement for a separate and designated area for patient counselling
- There must be a safe compliant with the Misuse of Drugs (Safe Custody) Regulations, 1982 (as amended) for the storage of controlled drugs
- Obsolete medicinal products must be disposed of in a manner which will not present a danger to public health or to the environment
- There must be a named supervising pharmacist in whole-time control
- A contemporaneous 'duty register' must be maintained
- A written provision that the practice will not operate in the absence of a pharmacist should be present
- Public access should be prevented in the case of prescription-controlled medicinal products and CD5 controlled drugs
- Product withdrawal and recalls should be processed immediately on notification
- Performance assessments, adequate reference and competence evaluations should be carried out in respect of all personnel
- The identity and registration status of any pharmacist employed should be vouchsafed
- All medicinal products must be sourced from an authorised source and appropriate evidence of this retained
- All medicinal products supplied should be authorised appropriately for use
- Obsolete stock should be segregated and disposed of appropriately in a timely manner
- Storage provisions should be in place to manage returned controlled substances
- It should be ensured that a prescription review occurs as required by Article 9 of the regulations
- It should be ensured that the patient has sufficient information regarding storage of prescription-controlled medicinal products
- It should be ensured that the patient has sufficient information regarding proper use of the medicinal product
- It should be ensured that each patient presenting with a prescription is offered a counselling opportunity
- A written dispensing policy which encompasses the requirements of the Regulations should be in place
- A pharmacist must be aware of the supply of every prescription-exempt medicinal product
- All the required details must be recorded when a prescription, either for human or animal use, is dispensed
- Required records must be available for inspection as required

Staff, Premises, Equipment and Procedures

Articles 1 to 3 address the citation, commencement provision and interpretation provisions of these regulations. Of particular note are the definitions of the terms "superintendent pharmacist" and "supervising pharmacist" as they relate to the provisions of Sections 27, 28 and 29 of the Pharmacy Act 2007.

Article 4 of the regulations deals with staff, premises equipment and procedures, and the associated responsibilities as they apply to the pharmacy owner. This article addresses adequacy of the staff, premises, equipment and procedures and the requirement that pharmacy services be delivered from a registered premises. They refer to the layout of the practice and the requirement that it facilitate the supervision by a pharmacist of all the professional activity therein. They address the requirement for a separate and designated area for patient counselling (for existing practices this requirement comes into force on 1 November 2010) and refer to the provisions in place in respect of safe storage of controlled drugs. This Article also addresses the requirement to safely dispose of obsolete medicinal products.

Management and Supervision of Retail Pharmacy Businesses

Article 5 addresses the management and supervisory requirements pertaining to a retail pharmacy business, and delineates the particular responsibilities held by the pharmacy owner and the superintendent pharmacist. The article addresses the requirement that the part of the retail pharmacy business that consists of the management and administration of the sale and supply of medicinal products is carried out in accordance with all legal requirements and under the personal control of the superintendent. Each retail pharmacy business must be in the whole-time charge of a supervising pharmacist having a specified degree of experience, and a record of the pharmacists on duty must be maintained in a contemporaneous, ongoing retrieval form. The operation of the pharmacy must at all times be under the supervision of a registered pharmacist with prescription-controlled medicinal products, both human and veterinary, and prescription-exempt medicinal products which would be classified as CD5, not publicly accessible. Co-operation with product withdrawal and/or recalls must be provided for. All staff must be fit and competent to discharge the duties assigned to them and the identity and registration status of any pharmacist employed must be satisfactorily established. It is required that the certificate of registration of the supervising pharmacist be conspicuously displayed.

Medicinal Products: Sourcing, Storage, Sale and Supply

Article 6 addresses the sourcing of authorised medicinal products and requires that any medicinal product sourced by the RPB is obtained from an authorised manufacturer or wholesaler in accordance with the legislative provisions in place which regulate this activity. The article makes provision for the acceptance of returned obsolete stock on the

understanding that this would never be reused but disposed of appropriately. It also provides for the professional requirement when meeting the immediate need of an individual patient or of the occasional transfer of stock between Retail Pharmacy Businesses. Article 7 addresses the requirement for the appropriate storage of medicinal products, and provides that the quality of medicinal products being handled by that pharmacy should be assured by adherence to storage conditions as specified in the marketing authorisation or other applicable standards. Article 8 relates to what medicinal products may be sold or supplied and requires that any such product is licensed in accordance with the legislative provisions in place which regulate that activity.

Patient Counselling: Prescription and Non-prescription

Article 9 of the regulations addresses the review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription. It provides that a pharmacist, prior to the dispensing of a prescription and supply of a medicinal product, shall review the prescription having regard to its pharmaceutical and therapeutic appropriateness for the patient. The nature of the review is indicated in broad professional and patient safety terms and requires that, subsequent to the review, the pharmacist shall ensure that the patient has sufficient information and advice for the proper use and storage of the prescribed medicinal product. The pharmacist shall offer to discuss with the patient or his/her representative such professional matters as appropriate.

Counselling when supplying medicinal products, other than on foot of a prescription, is provided for in Article 10 of the Regulations, which require that in the course of such supply a pharmacist is satisfied of a number of criteria, encompassing that the purchaser is aware of the correct use of the product, the product is being sought for the correct use and, insofar as the pharmacist is aware, the product is not intended for abuse or misuse.

Other Requirements

Article 11 addresses the provisions in place in respect of veterinary medicinal products which may be sold or supplied in accordance with the applicable legislative provisions in place which regulate this activity, i.e. animal remedies regulations.

Article 12 addresses the record-keeping requirements applicable in the case of the supply of medicinal products and refers to those provided for in the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended, and the Misuse of Drugs Regulations 1988, as amended. It also makes provision for the validation and certification of computer software that may be in use.

The keeping of records, marking of prescriptions and other related matters as applicable to veterinary medicines are addressed in Article 13.

The publication of Guidelines by the Council to facilitate compliance and designated offences are specified in Articles 14 and 15 respectively.

Supply of products containing Paracetamol

The supply of medicinal products containing Paracetamol, in both pharmacy and non-pharmacy outlets, is governed by specific provisions detailed in the Medicinal Products (Prescription and Control of Supply) Regulations, 2003–2008. The supply of a product containing Paracetamol, from a pharmacy, must always occur by or under the personal supervision of a pharmacist, irrespective of the pack size or formulation provided.

The regulations provide that, except in accordance with a prescription, products containing paracetamol may only be supplied in the following specified circumstances (see Table).

The supply of a product containing Paracetamol by or under the personal supervision of a pharmacist in a pharmacy, or from a non-pharmacy outlet, is restricted to the quantities as specified in the table, in any one transaction.

In certain circumstances, however, and only in a pharmacy, a greater amount may be supplied. This supply is predicated on the requirement that the pharmacist personally interviews the patient requesting the product, and that he or she is satisfied that it is safe, in the circumstances, to supply the product.

For products where the dosage unit is in the form of a tablet or capsule, or other similar pharmaceutical form, the total quantity supplied may be up to fifty dosage units. For a product which is formulated in any other manner two packs only may be supplied.

It is also a requirement that over-the counter supply of medicinal products containing Paracetamol, which are formulated in a solid unit dosage form, must be supplied in blister packing, or an equivalent, as determined under its product authorisation.

The regulations also provide for particular statements that shall appear on the outer packaging of a medicinal product, or on its immediate packaging if there is no outer packaging, and also for statements that shall appear on the package leaflet.

Practitioners are reminded of these controls to ensure the safe and appropriate management of the supply of Paracetamol-containing products in the interest of the health, safety and welfare of patients.

The full text of the amendment Regulations may be accessed at:

http://www.dohc.ie/legislation/statutory_instruments/pdf/si20080512.pdf

CIRCUMSTANCES UNDER WHICH NON-PRESCRIPTION PARACETAMOL PRODUCTS MAY BE SUPPLIED

Dosage strength and form	Pharmacy only	Non-pharmacy outlet
Dosage unit containing more than 120mg but not more than 500mg of Paracetamol.	Pack size of 24 units or less	Pack size of 12 units or less
Dosage unit containing more than 500mg but not more than 600mg of Paracetamol.	Pack size of 20 units or less	Pack size of 10 units or less
Dosage unit containing more than 600mg but not more than 1000mg of Paracetamol.	Pack size of 12 units or less	Pack size of 6 units or less
Dosage unit containing not more than 120mg of Paracetamol intended for use in children under 6 years of age.	Pack size of 24 units or less	Pack size of 12 units or less
Liquid formulation containing not more than 120mg of Paracetamol per 5mls intended for use in children under 6 years of age.	Pack size of 140mls or less	Pack size of 60mls or less
Liquid formulation containing not more than 250mg of Paracetamol per 5mls intended for use in children over 6 years and under 12 years of age other than a product intended for use in children under 6 years of age.	Pack size of 140mls or less	N/A
Liquid formulation containing not more than 250mgs of Paracetamol per 5mls other than a product intended for use in children under 6 years of age.	Pack size of 60mls or less	
Liquid formulation containing not more than 250mgs of Paracetamol per 5mls, other than a product intended for use in children under 6 years of age or a product intended for use in children between the ages of 6 and 12 years.	Pack size of 240mls or less	N/A

Good Dispensing Practice – Control of the supply of 'prescription only' medicinal products

The Pharmacy Act 2007 provides that the sale or supply of medicinal products, other than medicinal products on a general sales list, must occur in a registered retail pharmacy business by or under the personal supervision of a pharmacist. Articles 9 and 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 detail the legal obligations associated with the supply of such products. Article 9 requires the review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription and article 10 provides for counselling in the supply of medicinal products other than those supplied on foot of a prescription.

The supply of any medicinal product designated as "prescription only" must only take place on the authority of a valid prescription requesting such supply. In the case of those products which are subject to prescription control under the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2008, each product dispensed to a patient must only be supplied on receipt of a valid prescription written in accordance with the requirements specified in Article 7 of these Regulations. In the case of those products, the supply of which is governed by the Misuse of Drugs Regulations 1988 (as amended), each product dispensed to a patient must only be supplied on receipt of a valid prescription written in accordance with the requirements specified in Article 13 of these Regulations.

There are provisions in the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2008 to provide for emergency supply situations at the request of a patient or practitioner. In no case, at the request either of a practitioner or a patient, may any medicine listed as a controlled drug specified in Schedule 1, 2, 3 or 4 of the Misuse of Drug Regulations 1988 (as amended) be supplied without prescription, except products containing methylphenobarbitone, phenobarbitone or phenobarbitone sodium for the treatment of epilepsy. Additionally, an emergency supply of any medicinal product containing any substance listed in the Fourth Schedule to the Medical Products (Prescription and Control of Supply) Regulations 2003 to 2008 may not be made at the request of a patient.

The Pharmacy Act 2007 provides for the critical and important role of both superintendent and supervising pharmacists, and sets out an appropriate arrangement for management and accountability in each retail pharmacy business, in respect of the pharmacy services provided. The supporting provisions detailed in other legislation, including the Regulation of Retail Pharmacy Businesses Regulations 2008, the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2008, the Medicinal Products (Control of Placing on the Market) Regulations 2007, the Misuse of Drugs Regulations 1988 (as amended) and the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998, provide the appropriate operational controls which ensure that the important patient safety, education and gatekeeper roles of the pharmacist are facilitated. This is all further underpinned by the provisions set out in the PSI Code of Conduct which govern pharmacists in the practice of their profession.

In all instances, a pharmacist should only supply a prescription-only medicinal product on foot of a valid prescription and only after he or she has established the authenticity of the prescription to be dispensed, or the appropriateness of any emergency supply situation. A supervising pharmacist should ensure that all procedures carried out in the retail pharmacy business are in compliance with the legislative requirements. In addition, the superintendent pharmacist must ensure that there are approved policies in place so as to ensure appropriate compliance with those requirements and the requirements of the PSI Code of Conduct for pharmacists.

TRINITY COLLEGE
The University of Dublin

School of Pharmacy and
Pharmaceutical Sciences

Postgraduate Diploma/M.Sc. in Community Pharmacy

Applications are invited for admission to the postgraduate Diploma/M. Sc. in Community Pharmacy in Trinity College Dublin. This course has been specifically designed to meet the needs of community pharmacists practising in Ireland and also complies fully with the recommendations for specialist community pharmacy courses issued by the EU Advisory Committee on Pharmaceutical Training. Because of its distance-learning format, participants can continue in full-time employment throughout the course.

The course is intended to help community pharmacists to:

- develop their clinical, managerial and research skills;
- fulfil continuing professional development obligations under the Pharmacy Act 2007;
- meet duties imposed by the HSE contract;
- undertake the role of a supervising pharmacist or superintendent pharmacist with confidence;
- extend their professional role;
- contribute to patient care as part of the primary health care team.

Course structure

The diploma and M.Sc. have core material in common. Participants initially enter at diploma level, and on successful completion of the common material they may choose either to graduate with a Diploma in Community Pharmacy or to apply for transfer to the M.Sc. in Community Pharmacy.

Both courses are available on a part-time basis, the diploma being conducted over two years with one additional year for students who progress to the M.Sc. In both courses participants undertake a series of modules covering clinical, social and business aspects of pharmacy practice, with opportunities for specialisation in particular fields. Pharmacists who advance to M.Sc. level undertake an additional module on research methods and perform a research project relevant to community pharmacy practice.

Entry requirements

Applicants must:

- be registered (or entitled to registration) as a pharmacist with the Pharmaceutical Society of Ireland;
- work on a regular basis (full/part-time) in community pharmacy.

Additional information from:

Address Diploma/M.Sc. in Community Pharmacy, School of Pharmacy and Pharmaceutical Sciences, Trinity College, Dublin 2.

Telephone 01 896 3736 (Monday and Wednesday 9am-5pm, Thursday 9am-12 45pm)

Fax 01 608 2524

E-mail community.pharmacy@tcd.ie

Online applications to: www.pac.ie

For the course commencing in October 2009, the closing date for applications is 26th June 2009.

ETHICAL AND LEGAL ISSUES IN HEALTHCARE

Research ethics and the ethics of research

Cicely Roche *has worked in community pharmacy in Canada and Ireland since graduating from Trinity College Dublin in 1983. She holds an MSc in Community Pharmacy from Queen's University Belfast (2001) and an MSc in Healthcare Ethics and Law from RCSI (2007).*

A 'long-standing' patient asks for your advice. She is a capable, middle-aged lady and a respected professional in the local community. Her regular three-item prescription successfully manages her previously high blood pressure. She tells you that her GP has asked her to join a group of patients taking a new medicine recently released for the control of blood pressure. It will involve replacing one of her existing medicines with this new one. He has given her explanatory paperwork and asked her to sign a consent form agreeing to be included in a 'double-blind, placebo-controlled trial'. She comments that her blood pressure is well controlled and doesn't think that she should risk being given a placebo in place of her 'proven' medicine. She asks you to advise her as to what would be in her best interests…

"Medical research involving human subjects differs substantially from medical treatment". (Kuhse and Singer). While medical treatment focuses on the healthcare needs of individual, identifiable patients, research generally seeks to improve the health and well-being of current or future *groups* of patients, or of society as a whole. The use of placebos in trials is considered to increase the reliability of such studies. Hence a patient's involvement in research does not necessarily focus on his or her individual 'best interests'. Indeed, the nature of such clinical research being to establish the safety profile of new medicines, there will inevitably be some risk of increased adverse reactions during a trial period. Protection of subjects enlisted in trials is therefore the priority.

In Ireland, The European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 govern most of the regulation of clinical trials. They define clinical trials as investigations on human subjects, other than non-interventional trials, intended to ascertain the safety or efficacy of medicinal products. Elements included in the regulations are ethics committees, the clinical trials authorisation process, good practice in clinical trials, pharmacovigilance and the manufacture, importation and labelling of investigational medicinal products. The Irish Medicines Board (IMB) is designated the competent authority for granting permission to run clinical trials. The process proposed must be deemed to meet the standards of good clinical practice as specified in the regulations and approval of a study design by an ethics committee is required prior to application to the IMB.

The operation of ethics committees in Ireland, regularly referred to in the literature as Research Ethics Boards (REBs), "are under the supervision of the Minister for Health, who may either recognise committees appointed by institutions or appoint her own committees with either national responsibility or responsibility for particular classes of clinical trials. Where the Minister recognises an ethics committee, she must indicate to them their terms of reference". (Mills). Research ethics boards may therefore be variable in their 'modus operandi'. However, they generally operate under the basic premise that if consent can be feasibly obtained it should be sought. This requirement does raise the concern that opportunities to access existing data in healthcare records are being further restricted and this matter is currently under much debate in the literature (Willison et al). While the specific mandate of ethics committees in non-interventional trials is not always clear, regulation does refer to how consent should be obtained from participants, and to the safeguarding of the rights of each subject to privacy and the protection of data concerning him or her in accordance with the Data Protection Act 1998 and 2003.

The desire to have societal control of the operation of clinical trials evolves largely from the 'Nuremberg' reaction to the atrocities carried out both in German concentration camps and in Japan during World War II. Prisoners were subjected to horrific 'interventions', ostensibly in the name of medical research. The dilemma for humanity was that, given the manner in which this scientifically valuable medical information was amassed, whether it could ever be morally justifiable to use that information for the betterment of human kind. Such justification was deemed to be dependent on an assurance that such atrocities could never recur. The 10-point Nuremberg code, and the subsequent declaration of Helsinki (World Medical Association, 1964), were determined attempts to prevent a re-occurrence by ensuring that the right of an individual to consent to or refuse a healthcare intervention was enshrined in law and, most specifically, in all aspects of medical research.

Despite the outcome of the Nuremberg trials, research ethics continue to have a chequered history; the most notable violation being the Tuskegee Syphilis Study USA (1932–1971). The objective in Tuskegee was to study the nature and course of syphilis on an island community by leaving the people untreated, even though they received free medical examinations on a regular basis. They were told they had 'bad blood', were intentionally not 'drafted' for the war and denied access to penicillin even after it became freely available in 1940. The Tuskegee report (1973) determined that "society can no longer afford to leave the balancing of individual rights against scientific progress to the scientific community". The subsequent Belmont report (1979) reaffirmed the requirement for consent, and added specific additional ethical principles which focussed on assurances that benefits and harm are balanced and that there is an equitable distribution between the burdens and benefits of research. Given the treatment of the residents of Tuskegee (amongst others), there is nothing I would think or write that would be intended to diminish attention to such injustice, or the desire to prevent a re-occurrence of same.

Notwithstanding the above, I do think that new approaches to practice-based research may be required. 'Much health research is heavily dependent on access to information from medical records' (Willison et al 2008). As privacy law and the protection of personal data have become more heavily regulated, access to medical records for research purposes has also become more tightly controlled. The debate has become somewhat focussed on whether there is a risk that even anonymised data might be potentially identifiable. Debate suggests that the use of outside researchers or research assistants to gather data, rather than engaging the primary healthcare professional themselves, increases the likelihood of such breach of privacy. Removal of unnecessarily specific identifiers such as date of birth, when 'year of birth' may be perfectly adequate and/or the utilisation of dispensing software to encode identifiers in such a manner that only the practitioner caring for the patient could subsequently re-identify the patient, are further approaches that could reduce those risks. Pharmacoeconomics research is currently facilitated by the provision of anonymised data from the PCRS – the weakness in that system being that the database, which excludes non-reimbursed medicines, is incomplete. It would appear that there is an undeveloped role that practitioners could legitimately play in making existing records of dispensing available for research and collation purposes, the skill-set required for which is not unrelated to data review for quality improvements.

There should be no intention of diminishing respect for autonomy, or the rights to privacy or confidentiality, but rather to seek more appropriate means by which to maximise opportunities to promote the 'greater good' while adhering to the core principle of 'do no harm'.

Going back to the patient who asked for advice as to whether I thought her involvement in this double-blind, placebo-controlled trial was in her best interest. I could not pretend that to be the case. I have to accept that encouraging a specific patient to involve herself in a double-blind, placebo-controlled trial is tantamount to telling her that a placebo is an acceptable element in her care. This type of scenario represents the classic conflict between patient-focussed care and a strategic approach to population health – a discussion topic particularly neglected in continuing education/professional development for community pharmacy practice. Notwithstanding the detail of the above scenario, and the presumption that the GP will be satisfied that a particular patient will be unlikely to come to harm by being involved in the trial, the principles of responsibility to 'the greater good' and the use of placebos in healthcare continue to be a source of unease for practitioners.

It seems that the adverse implications of such 'unease' could be

contd. next page

MORE & BETTER FOR LESS

TEVA brings **more** year on year to the Irish market. As the number 1 generic drug company in the world, its strategic manufacturing presence in Waterford employs over 800 people and contributes over €50 million to the Irish economy.

TEVA is rapidly evolving in Ireland. It is constantly expanding its range of products to **better** meet the needs of community pharmacists, doctors and hospital pharmacists.

TEVA is committed to delivering value for money to its customers through its philosophy of **less** is more, in terms of price versus off-patent branded medicines. A company that understands your business and works with you to create value.

FREEPHONE 1800 201700 | www.teva.ie

For further information, please contact:
Teva Pharmaceuticals Ireland,
Unit 1, The Business Centre, Blackthorn Business Park,
Coe's Rd., Dundalk, Co. Louth
Ph: 042 9395892
Fax: 042 9395898

Date of preparation: December 2008 Tevirl C02/12/08

TEVA PHARMACEUTICALS IRELAND

Doing more and better for less

ameliorated by exploring ways in which academia and practitioners could effectively collaborate; with practitioners, rather than attempting to become researchers, instead developing an ethically and academically acceptable system for extracting anonymised data from records held on file, and those in research having an opportunity to facilitate practitioners in maximising what contributions they can make to the 'greater good' of healthcare research.

cicelyroche@eircom.net

References ~

- Kuhse, H., and Singer, P. (2006) Experimentation with Human Subjects. In: Bioethics, an Anthology. Oxford. Blackwell Publishing. P499–503
- Mills, S. (2007) *Clinical Practice and the Law*. 2nd Ed. Ireland, Butterworths Ltd.
- Willison, D.J. (2007) Data Protection and the Promotion of Health Research: If the Laws are not the Problem, Then what is? *Healthcare Policy*. 2(3): 39–43
- Willison, D., Emerson, C., et al. (2008) Access to medical records for research purposes: varying perceptions across research ethics boards. *Journal of Medical Ethics*. 34:308–314

COMMUNITY SPIRIT

The Pros and Cons of 'Polypills'

***Colin Deeny** is a community pharmacist based in Donegal. He has an interest in the development of professional pharmacy practice. In addition he has particular interest in respiratory care and the causes and effects of hyperventilation.*

I noted with interest the publication of a study in India[1] on the use of a tablet that contains five drugs, in a single tablet, that have until now been used separately to reduce or prevent cardiovascular events. In other words a 5-in-1 tablet. The concept of a having more than one drug in a medication, or a 'polypill' as it has been dubbed, is not new. The accepted name for this is a Fixed Dose Combination (FDC). We already have several available that contain two drugs in one tablet, and the concept of having more than that was discussed at least as far back as the late 1980's. However the first time that a combination of several drugs for the treatment of multiple cardiovascular risk factors appears to have been seriously mooted was when Salim Yusef, of the Population Health Research Institute at McMaster University in Canada, did so in an editorial in the Lancet in 2002[2]. Then in 2003, two London physicians, Wald and Law, published a paper that attempted to determine what combination of drugs, and at what dose, such a 'polypill' should contain to be effective with minimal adverse effects[3]. They proposed a tablet containing a statin, three blood-pressure lowering drugs (for example, a thiazide, a beta-blocker, and an ACE inhibitor), each at half standard dose, 0.8mg folic acid and 75mg aspirin. They then called this a 'polypill' and the name has stuck for the concept. They estimated that such a combination tablet could reduce ischaemic heart events by 88%, and stroke by 80%, and that one third of people taking this pill from age 55 would benefit – with what they suggested are an acceptable incidence of adverse effects in about 8–15% of people.

Then the above-mentioned Dr Yusef and his colleagues took the concept one step further and put it to the test. Their fixed dose combination (branded as Polycap) consists of 12.5mg thiazide, 50mg atenolol, 5mg ramipril, 20mg simvastatin and 100mg aspirin. They compared this to eight other groups – aspirin alone, simvastatin alone, hydrochlorothiazide alone, three combinations of the two blood-pressure-lowering drugs, three blood-pressure-lowering drugs alone, or three blood-pressure-lowering drugs plus aspirin. For some reason they did not compare it to a group taking all five of the medications separately. They then examined the effects of Polycap, and each of the other groups, on blood pressure, lipids, heart rate, and urinary thromboxane B2. The results demonstrated that the Polycap combination reduced blood pressure, reduced LDL, reduced heart rate and reduced 11-dehydrothromboxane B2 broadly in line with what would be expected, and was found by the individual medications. But in reality this is hardly surprising, is it? Perhaps of more relevance, tolerability to Polycap was similar to that of other treatments, with no evidence of increasing intolerability with an increasing number of active components in one pill.

As pharmacists we are only too aware that compliance with any long-term or life-long therapy is difficult, not least so cardiovascular medication. While non-compliance may mean stopping taking the medication altogether, it may also mean failure to comply adequately with the treatment regimen sufficiently to obtain adequate dosing or dosage. As such, the patient is not receiving optimum treatment. Research shows that patients are less well motivated to comply long-term with preventative treatments or those targeting asymptomatic conditions with no immediately apparent benefits[4, 5]. It has been shown that compliance can drop to less than fifty per cent after two years[5]. In their interpretation of their results, as published in the *Lancet*[1], Yusef et al state that "this Polycap formulation could be conveniently used to reduce multiple risk factors and cardiovascular risk". This may or may not be the case. But I question how they can conclude this, as they did not actually measure convenience, adherence or compliance. Further research comparing compliance with the 'polypill' to all the five medicines taken together would surely be necessary to confirm this. That said, I would not be surprised if such research found that it is actually not only more convenient but also improves compliance. The beauty of the 'polypill' concept is the simplicity of a single daily tablet. One would expect this should be more convenient. It could also be easier to remember to take one tablet daily than five. That however may not necessarily be the case as, in the case of the five drugs in Polycap, they could take these all at the same time anyway. However, as the person would not have the opportunity to pick and choose which of the five medications they will take, this may improve compliance in certain patients. It is all or nothing. Then again, this is also a down side as if they do not adhere to take one medicine they will not be taking any – be that due to forgetfulness or deliberate non-adherence, with consequences for the health of many of these patients. In addition, compliance issues may also relate to a patient's own understanding, justifiable opinions and prejudices about certain or all of the medications. Therefore we must look not only at compliance but also concordance. As such, a 5-in-1 tablet would not be all things to all people.

The other matter that is obvious in the term FDC is that there is no room for dose adjustment, unless there are various dosages available for all the possible combinations. As pharmacists we are only too well aware of the hazards of poly-pharmacy and yet here we have a 'poly-pill'. So does this go against the grain? Would we be turning a blind eye to a basic principle of good pharmacy – minimal medication, maximum therapy? I suppose my concern here is whether there would be a tendency to over-use or over-prescribe a 'polypill' rather than consider the merits of each medicine individually for the individual patient. And how would we be able to identify which active ingredient may be causing an adverse effect? Safe medicine-taking is when the benefits outweigh the risks. I would therefore suggest that each patient should be prescribed these five medicines individually first, in whatever combination is appropriate, and the dosages adjusted as necessary. And only if and when the patient is actually on the same medications and at the same dosage should the combination tablet be considered. Otherwise we are sacrificing the principles of good pharmacy and good care. If this is the case, then it may be that there would be less use of a 'polypill'. Then there is the fact that there are other potential combinations. For example, the Clinical Trials Research Unit of the University of Auckland is currently undertaking a pilot study of another 'polypill' containing 10mg lisinopril, 12.5mg hydrochlorothiazide, 20mg simvastatin and 75mg aspirin. But what about other statins, other ACE inhibitors? There is also a combination available in the USA for cardiovascular risk factors containing amlodipine and atorvastatin (Caduet).

If there are to be numerous combinations available this raises another question. Would such combinations be commercially viable, or at least cheaper than what is available already? Well, perhaps if they are used by a large enough population they will be. The 'polypill' used in Yusef's trial was manufactured in India and the study took place there. Some proponents of the 'polypill' have suggested that they may be of particular

Target your customers with the No. 1 selling over the counter brand*

With a presence in all three categories; Adult analgesics, Paediatric analgesics, and Cold & Flu, Nurofen's range of targeted pain relievers continues to achieve double digit growth within pharmacy. More innovation, more of your needs met, more pain relieved. That's our ongoing target!

NUROFEN®

Date of Preparation: Jan 08
Rbecca Code: N-IE-18-08

Full prescribing information available from Reckitt Benckiser Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24. Nurofen products are available through pharmacies only.

*Source: IMS OTC IRL Qt 3 08

use in the developing world[6, 7]. That is, that a cheaper, combination tablet would make medicine more affordable for populations that would otherwise not have access to them. Chronic diseases are often associated with developed countries; however their prevalence is increasing in the developing world also. In fact only twenty per cent of chronic disease deaths occur in high-income countries — while eighty per cent occur in low- and middle-income countries[8]. An article accompanying the publication of the Polycap results in the *Lancet* states the 'polypill' concept has "obvious appeal and vast implications for global health", with the possibility of reducing heart disease by 80%'[7]. The World Health Organisation estimates that a cardiovascular 'polypill' could be produced at a cost of little more than US$1 per patient per month[9].

Whatever my opinion, it would appear that there is now some momentum behind the 'polypill' concept. However, I would personally caution any notion that a 'polypill' could be a cardiovascular panacea. There is nothing to suggest from the evidence currently available that it is really much better than what we already have available. Perhaps that is because we already have these drugs available individually anyway. However, the fact that the drugs being discussed are all off patent means that there may be room for a pharmaceutical company to make the concept commercially viable and permit these drugs to become more accessible for those on lower incomes. However I would personally be concerned about using a 'polypill' to treat vast populations indiscriminately. The evidence is not there for that. Furthermore, for pharmacists to accept the routine use of a 'polypill' would mean a paradigm shift in our practice away from individualising therapy.

colindeeny@iol.ie

References ~

1 The Indian Polycap Study. Effects of a Polypill (Polycap) on risk factors in middle-aged individuals without cardiovascular disease (TIPS): a phase II, double-blind, randomised trial. *Lancet* 2009; 373: 1341–1351.

2 Yusuf, S. Two decades of progress in preventing vascular disease. *Lancet* 2002; 360: 2–3.

3 Wald, N.J., Law, M.R. A strategy to reduce cardiovascular disease by more than 80%. *British Medical Journal* 2003; 326: 1419.

4 Furnham, A. Overcoming the obstacles – the outsider's view. *Atherosclerosis* 1999; 147 (Suppl 1): S53–S56.

5 Ockene, I.S., Hayman, L.L., Pasternak, R.C., Schron, E., Dunbar-Jacob, J. Task Force #4–adherence issues and behaviour changes: achieving a long-term solution. *Journal of the American College of Cardiology* 2002; 40 631–640.

6 Combination Pharmacotherapy and Public Health Research Working Group. *Combination Pharmacotherapy for Cardiovascular Disease Annals of Internal Medicine* 2005; 143: 593–599.

7 Cannon CP. Can the polypill save the world from heart disease? *Lancet* 2009; 373: 1312

8 WHO global report. Preventing chronic diseases: a vital investment. 2005. ISBN 92 4 156300 1.

9 Kaplan, W. Laing, R. WHO Report. Priority Medicines for Europe and the World. 2004.

So many symptoms...

Treat the core of depression with Lexapro®

Lexapro®
escitalopram

The No.1 prescribed anti-depressant in Ireland[1]

LX 1/1/09

Lundbeck

THE HISTORY OF PHARMACY
MARCH/APRIL 2009

Compiled by Carol Keogh, Dip FA (DIT), *Irish Pharmacy Journal* Administrator

MARCH/APRIL 1909

STUDENT ANTICS

At the Dublin Police Court in March 1909, a university student by the surname of Allison was prosecuted for the unlawful possession of a lifebuoy and for having assaulted pharmaceutical chemist, Mr John Isaac Bernard, proprietor of Price's Medical Hall, Clare Street. It was reported that the accused cut down the lifebuoy from its position along the quay, and when approached by Mr Bernard who had observed the act, "got into a scuffle with the latter" and assaulted him. Despite his solicitors apologies on his behalf, Mr Allison was fined £2 for the assault and £1 for the illegal possession of the lifebuoy.

HISTORICAL REPORTINGS

The C&D reported on an Irish newspaper article outlining the history of Messrs Fannin & Company, surgical instrument and medical appliance manufacturers. The firm was established in 1829, and remained in the family until the time of the report.

The C&D also reported on a history lecture delivered by Professor A L Meldrum before the National Literary Society, St Stephen's Green, Dublin. The subject of the lecture was "Two Irish Chemists", referring to Messrs Bryan and William Higgins, "who in the eighteenth century anticipated many of the developments which took place in science during the nineteenth century".

Bryan Higgins was born in 1737 and graduated as a medical doctor at Leyden in 1765, opening a school of chemistry in Greek Street, Soho, London. He carried on the school for twenty-three years, "probably the pioneer school of practical instruction in chemistry in Great Britain", and, moreover, "attempted to combine the teaching with research". Mr Higgins founded a club for the advancement of science, but this was short-lived owing to his departure for the West Indies. He discovered the "musical hydrogen flame" in 1777, while his most important research was on "Experiments and Observations on Acetous Acid", which was published in 1786. William Higgins was Bryan's nephew and acted as "demonstrator of chemistry" to his uncle. On the foundation of the Apothecaries' Hall in Ireland in 1791, William Higgins was appointed superintendent at a salary of £200 per annum and given apartments. Some time afterwards he became mineralogist and chemist to the Royal Dublin Society.

ROBBING BANKERS

Before the Dublin City Commission on April 2nd and 3rd 1909, Patrick Joseph Kelly and John MacDonnell, manager and accountant, and teller respectively, of the Great Brunswick Street branch of the National Bank, were charged with falsifying the accounts of the bank with intent to defraud. Mr Seymour Bushe, KC, prosecuting for the Crown, said that four years previously the bank had opened a new branch at 43 Great Brunswick Street, and the defendants had been transferred to that branch. "Here they manipulated accounts and made false entries in order to deceive the bank." On January 28 an inspector found that there was a deficit of £10,436 and no less than 500 individual falsifications. A number of overdrafts had been improperly made and concealed. In one particular case, overdrafts had been made to "Ozonia" and "Ozonia Ltd." against the orders of the bank. The company owner, Mr Moss Jay, and his wife who was the principal shareholder, were alleged to be friends of the defendants – the company's product "Ozonia" a purported cure for rheumatism.

Mr O'Toole, one of the bank's inspectors, admitted under cross-examination that the Ozonia advance had been for £8,000, while it was represented as £1,388. Mr T M Healy, for the defence, argued that the accused had not personally benefited from the fraudulent activity. They were "stuffed with the idea that to-morrow or the next day the Ozonia Co. would find a Klondyke in rheumatism, but these prospects would be ruined by stopping their cheques". Mr Lynch KC, representing MacDonnell, pleaded that the accused may have been "guilty of folly or weakness", but that it did not amount to fraud. The jury found the accused guilty on eight of the nine counts. Mr Justice Kenny sentenced them to eight months' imprisonment with hard labour.

1959

NEW POISONS LAWS DEBATE

At the March Council Meeting of the PSI, Mr P. O'Briain, the Society's Inspector, made a detailed report on site visits he had made to the counties Cavan, Mayo and Sligo, and Dun Laoghaire in Co Dublin. He urged that wider publicity should be given in the pharmaceutical press regarding regulations governing the sale of barbiturates, cortisone and similar preparations.

Mr Kennelly considered that directives in this matter should come from Council, while Mr K. Banks said the sale of antibiotics and tranquilisers had become a serious concern, and the Council should push for a new Poisons Bill as soon as possible. Mr G.C. O'Neill stressed that conditions in Ireland differed from those in England, "where people were given large quantities of tablets for a shilling" and the Council should not panic about such things.

Mr Miller agreed with Mr Kennelly that the onus should not be on pharmacists keeping open shop to determine whether or not they should sell a particular preparation. Mr Gleeson believed the Council should "go slow" on the matter. As a profession, he said, they had "a very clean record and they did not want any more regulations if they could avoid them". Mr Kissane concurred, saying that "a man of professional training and standing should accept responsibility in these matters".

The President affirmed that the Council would lobby for new poisons legislation. The matter was not pursued further at the April meeting.

POST-GRADUATE COURSE

A postal course of instruction in physiology and therapeutics was announced in the April issue of the Irish C&D. The course had been arranged by the Post-Graduate Study Group of the PSI, and was to consist of ten lectures by Dr O'Conor Ward, MD, MRCPI, DCH. Modules were to be posted to students at approximately fortnightly intervals, with emphasis to be laid on the pharmacology of drugs used in the treatment of a large number of pathogenic conditions.
The syllabus would cover the digestive system, metabolism and nutrition, blood and lymph, the cardiovascular system, the respiratory system, the endocrine system, the nervous system, the urinary system, infection and allergy, intestinal parasites and poisoning.

STUDENT CONGRESS

Notice was posted in the April 1959 issue of the forthcoming Congress of the International Pharmaceutical Students' Federation, from 5 to 15 September, in Noordwijk-on-Sea, near Leiden, Holland. The cost of attending from Dublin, including travel, accommodation and participation in all of the Leiden tours, would be £30. Accommodation was to be provided in student hostels. Amenities would include a bar and conversation room at the disposal of the students. The programme was to include full-day excursions, social evenings, meetings, films and a farewell dinner.

—COMPANY ANNOUNCEMENT—

Abbott Innovations in Gastroenterology Bursary 2008 Winner announced

Professors Michael Maher and Fergus Shanahan and Doctors Kevin O'Regan and Alan Desmond of Cork University Hospital have been awarded the 2008 Abbott Innovation in Gastroenterology Bursary for their submission entitled, 'Diagnostic Imaging of Patients with Inflammatory Bowel Disease (IBD): a collaborative project to reduce radiation exposure and optimise outcomes'. The bursary, which is valued at ?10,000, will be used to develop low-radiation imaging strategies for patients with IBD. The bursary is an initiative of Abbott to recognise and celebrate innovation and pioneering work that improves the practice of health care in Gastroenterology.

Medical imaging is a vital diagnostic tool in the optimal management of IBD. The bursary submission highlighted that in the last decade there has been a three-fold increase in the annual number of imaging studies performed for patients with IBD. Concerns exist regarding the possible harmful effects that cumulative exposure to diagnostic radiation may have on IBD patients as they often present in adolescence and may already carry an increased risk of developing small bowel lymphoma and other gastro-intestinal malignancies.

Commenting on the Abbott Innovation in Gastroenterology Bursary, Professor David Rampton, Professor of Clinical Gastroenterology, Royal London Hospital, said, "The applications for the 2008 Abbott Innovations in Gastroenterology Bursary were of a high standard, well presented, fulfilled all entry criteria and demonstrated that they would have a positive impact on the patient population making the final decision a difficult task. However, the winner, 'Diagnostic Imaging of Patients with Inflammatory Bowel

from left ~ Eoin Murphy (Abbott), Professor Michael Maher (Cork University Hospital), Dr. Kevin O'Regan (Cork University Hospital), Dr. Alan Desmond (Cork University Hospital), Brenda Egan (Abbott), Professor Fergus Shanahan (Alimentary Pharmabiotic Centre /Cork University Hospital)

Disease: a collaborative project to reduce radiation exposure and optimise outcomes', seemed to most closely address the requirement for innovation and pioneering work in Gastroenterology."

The judging panel, comprised Professor David Rampton, Professor of Clinical Gastroenterology, Royal London Hospital; Professor Sarah Rogers, Consultant Dermatologist, St. Vincent's University Hospital and Mr Kevin Keating, Sales & Editorial Director, Irish Medical News.

The Abbott Innovations in Gastroenterology Bursary was created in recognition of the fact that it is only with innovative healthcare delivery that the true potential of research can be realised. Therefore the bursary is awarded each year to an initiative that is already in place or could be implemented on receipt of funding which encourages innovative healthcare delivery in the field of Gastroenterology.

—COMPANY ANNOUNCEMENT—

Actavis announces launch of more cost effective generic treatments

Treatments for CHD and Alzheimer's disease could save in excess of €7.3 million

Actavis has announced the launch of two more generic drug products on the Irish market; Percarnil and Donecept will be available from the 1st of April. Percarnil, for the treatment of coronary heart disease, and Donecept, indicated for Alzheimer's disease, will provide substantial savings in health expenditure. These treatments for coronary heart disease and Alzheimer's disease could save in excess of €7.3 million.

Tony Hynds, CEO of Actavis Ireland said: "We are delighted to increase our portfolio of generic drugs available on the Irish market. It is vital that Irish patients are offered greater choice and better value in the treatments offered by their doctors. Generic prescribing is traditionally very low in Ireland and Actavis Ireland is committed to changing this and creating more competition within the pharmaceutical market".

Percarnil is indicated in the treatment for coronary heart disease. It was the first choice treatment for hypertension in 2008[1]. Actavis' generic version of Perindopril offers 54% savings compared to the innovator. Percarnil is available in 4mg and 8mg tablets. Cardiovascular disease (CVD) is a serious health issue in Ireland. Approximately 10,000 people die from CVD in Ireland every year making it the most common cause of death[2].

Donecept is indicated in the symptomatic treatment of mild to moderately severe Alzheimer's dementia. Actavis' version of Donepezil offers an annual saving to the Irish market of €2.7 million as Actavis offers a 33% saving compared to the innovator. Donecept is the first choice treatment for Alzheimer disease[3] and has a market growth of over 12%. It is available in 5mg and 10mg tablets and has identical tablet shape and colour as well as a convenient patient pack which aids patient compliance. There are 40,000 sufferers of dementia in Ireland, with over 50% of that figure suffering Alzheimer's disease.

Actavis is a leading generic pharmaceutical company with operations in over 40 countries. Globally the company has built a strong reputation for the production and efficient delivery of first class generic pharmaceuticals at affordable prices. There are currently over 830 Actavis products on the market worldwide and there are over 350 products under development and pending registration. These products are currently sold in markets all over the globe including the EU, US and Japan. It has had significant growth since it was established in 1999 when it employed just 146 people. Currently it employs 10,500 globally. Actavis Ireland is based in Cork. So far this year Actavis has launched gemcitabine, an oncology treatment which could potentially save €1.8 million in health expenditure.

References –

1 IPU list Feb 09 and IMS Feb 2009

2 Irish Heart Foundation website

3 IMS Data December 2009

PHARMACY BOOK CLUB

ESSENTIAL REFERENCE	No.	€		No.	€
1 Martindale (36th Edition) – 2 volume, hardback *NEW		450.00	7 Stockley's Pocket Companion 2009 *NEW		30.00
2 Martindale (36th Edition) CD ROM *NEW		450.00	8 Stockley's Drug Interactions (8th Edition) – hardback		175.00
3 Martindale (36th Edition) – hardback + CD ROM COMBI *NEW		640.00	9 Stockley's Drug Interactions (8th Edition) – CD ROM		175.00
4 BNF (57th Edition) March 2009 *NEW		38.00	10 Stockley's Drug Interactions (8th Edition) – hardback + CD ROM COMBI		250.00
5 BNF for Children (4th Edition)		41.00			
6 The Veterinary Formulary (6th Edition)		56.00	11 Irish Medicines Formulary (5th Edition) January 2009 *NEW		47.00

REGISTERS, BOOKLETS AND CARDS					
12 Controlled Drug Register		10.00	15 Steroid Cards (pack of 25)		10.00
13 Poisons Register		8.00	16 Warfarin Therapy Information Pack (pack of 10)		20.00
14 MAOI Cards (pack of 25)		6.00			

PLEASE FILL IN DELIVERY AND CONTACT DETAILS

PLEASE READ TERMS AND CONDITIONS BELOW

I, THE UNDERSIGNED, ATTACH A CHEQUE/POSTAL ORDER or AUTHORISE THE PHARMACEUTICAL SOCIETY OF IRELAND TO DEBIT MY CREDIT CARD FOR THE FOLLOWING AMOUNT: € . . . . . .

Name (please print): . . . . . Telephone: . . . . . .

Delivery Address: . . . . . Email: . . . . . .

. . . . . .

. . . . . .

. . . . . .

Credit Card No.: ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Expiry Date: ☐☐☐☐ Security Code: ☐☐☐ (last 3 digits on back of card)

Signature: . . . . . .

Terms and Conditions:

1 A practice delivery address MUST be specified as couriers will not deliver to residential addresses. Orders specifying a residential address will be returned to sender.
2 Cheques should be made payable to the PHARMACEUTICAL SOCIETY OF IRELAND.
3 If paying by credit card, fax the completed order form to (01) 283 7678.
4 If paying by cheque/postal order, post the completed form with your payment to: Book Club, 18 Shrewsbury Road, Ballsbridge, Dublin 4.
5 The PSI does not accept laser card payments.
6 The PSI does not accept cash.
7 Credit card payments cannot be processed without the cardholder's signed authorisation and three-digit security code.

Please note that the Book Club no longer supplies general reference titles.
Additional titles can be sourced from www.amazon.co.uk or www.clarendonmedical.com
Pharmaceutical Press titles can be ordered directly from their website: www.pharmpress.com
All titles can also be ordered from any major high street bookstore.

Prices quoted are valid until the end of April 2009


RoC
WE KEEP OUR PROMISES®
"Why take risks with the sun on my face?"
FIGHTS 90% OF CELLULAR DAMAGE*
RoC
MINESOL TRIPLE DEFENSE
50±
VERY HIGH PROTECTION
FLUID CREAM
Your customers deserve the best in sun protection.
MINESOL® TRIPLE DEFENCE
This exclusive formula offers 3 scientifically proven levels of defence:
1. Anti-UVB against sun burn.
2. Anti-UVA against premature skin aging.
3. Anti-OXIDANT against skin cell's alteration.**
Result: You've never felt so well protected with RoC® MINESOL® TRIPLE DEFENCE.
Available to order for your pharmacy today.
*Ex-vivo test on human skin explant (UV induced cellular damage) **In vitro test.