THE IRISH
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JANUARY – MARCH 2010

PATIENT CONSULTATION AREA

THALIDOMIDE UPDATE

RESPONSIBILITIES TO PATIENTS IN RESIDENTIAL CARE SETTINGS

THE OFFICIAL JOURNAL OF THE PHARMACEUTICAL SOCIETY OF IRELAND

Prescribing Information – Blopress® (candesartan cilexetil) (Refer to Summary of Product Characteristics before prescribing)

Blopress® (candesartan cilexetil) Abbreviated Prescribing Information
Presentation: Tablets containing 4mg, 8mg, 16mg or 32mg candesartan cilexetil. For specific patient populations 2mg. **Indication:** Essential Hypertension; Treatment of patients with heart failure and left ventricle systolic dysfunction (LVEF ≤40%) as add-on therapy to ACE-inhibitors or when ACE-inhibitors are not tolerated. **Dosage:** ***In hypertension:*** Starting and usual maintenance dose is 8mg od with or without food. If necessary, the dose can be increased to 16mg od. If after 4 weeks blood pressure is not sufficiently controlled, the dose may be increased further to 32mg od. No dose adjustment is necessary in the elderly. A starting dose of 4mg is recommended for patients with renal impairment (including haemodialysis) and those at risk of hypotension due to intravascular volume depletion. For patients with mild to moderate hepatic impairment, the recommended starting dose is 2mg. ***In heart failure:*** Usual starting dose is 4mg od with or without food. Uptitration to the target dose of 32mg od or the highest tolerated dose is done by doubling the dose at intervals of at least 2 weeks. No dose adjustment is necessary for elderly patients or in patients with intravascular volume depletion, renal impairment or mild to moderate hepatic impairment. Blopress can be administered with other heart failure treatment including ACE-inhibitors, beta-blockers, diuretics and digitalis or a combination of these. Safety and efficacy of Blopress not established in children. **Contra-indications:** Hypersensitivity to any component of Blopress. Pregnancy and lactation. Severe hepatic impairment and/or cholestasis. **Warnings and Precautions:** Monitoring of serum potassium and creatinine levels is recommended during dose titration of Blopress in patients with heart failure and regularly in patients taking concomitant ACE-inhibitors and potassium sparing diuretics such as spironolactone. Periodic assessments of renal function is also recommended especially in elderly heart failure patients ≥75 years and in heart failure patients with impaired renal function. Hypotension may occur during treatment with Blopress in heart failure patients. Risk of increased blood urea and serum creatinine in patients with renal artery stenosis. Periodic monitoring of serum potassium and creatinine levels is recommended in patients with renal impairment. Blopress should be carefully titrated with thorough monitoring of blood pressure in patients on haemodialysis. Caution should be observed when initiating therapy and correction of hypovolemia should be attempted. Possible hypotension during anaesthesia and surgery. Not recommended in patients with primary hyperaldosteronism. As with other vasodilators, use with caution in patients with aortic and/or mitral valve stenosis or obstructive hypertrophic cardiomyopathy. **Drug Interactions:** No clinically significant interactions identified. Possible interaction with NSAIDs. Antihypertensive effect of Blopress may be enhanced by other antihypertensives. Careful monitoring of serum lithium levels recommended during concomitant use. Increase in serum potassium may occur with potassium supplements and potassium sparing diuretics. **Side-effects:** ***In hypertension*** clinical trials, adverse events were mild and transient with the overall incidence comparable to placebo. Overall incidence showed no association with dose or age. Adverse events in clinical trials include: headache, respiratory infection, back pain and dizziness/vertigo. In ***heart failure*** clinical trials (e.g. CHARM), the adverse event profile of Blopress was consistent with the pharmacology of the drug and health status of the patients. In the CHARM clinical programme, 21% of the Blopress group and 16.1% of the placebo group discontinued treatment due to adverse events. Adverse reactions commonly seen were: hypotension, hyperkalaemia, renal impairment and increases in creatinine, urea and potassium. Postmarketing there have been very rare reports of: nausea, increased liver enzymes, abnormal hepatic function or hepatitis, arthralgia, myalgia, back pain, angioedema, rash, urticaria, pruritus, dizziness, headache, leucopenia, neutropenia, agranulocytosis, hyperkalaemia, hyponatraemia, decreased haemoglobin, increased creatinine and urea, and renal impairment/failure. **Legal Category:** SIB. **Packs and Authorisation numbers:** Blister packs. Blopress 2mg, 7 tablets and 28 tablets (PA1547/1/1); Blopress 4mg, 7 tablets and 28 tablets (PA1547/1/2); Blopress 8mg, 28 tablets (PA1547/1/3); Blopress 16mg, 28 tablets (PA1547/1/4); Blopress 32mg, 28 tablets (PA1547/1/5). **PI Date Code:** 08/2009 **Marketing Authorisation Holder:** Takeda UK Ltd., Takeda House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, BUCKS HP10 0HH. **For further information contact the Marketing Authorisation Holder:** Telephone: +44 1628 537900, Fax: +44 1628 526615. ® Registered trademark owned by Takeda Pharmaceutical Company Ltd.

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References:
1. Lacourcière Y *et al. Am J Hypertens* 1999; **12**: 1181-1187.
2. Bakris G *et al. J Clin Hypertens* 2001; **3**: 16-21.
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Date of Preparation: October 2009
BP090909c

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Baily Publications Limited
2 Lower Glenageary Road, Dún Laoghaire, Co. Dublin
Tel: 01 – 284 6161 Fax: 01 – 284 6192
ADVERTISING ENQUIRIES
Baily Publications ~ Tel: 01 – 284 6161; email: ipj@afloat.ie
Business Development Manager:
David O'Brien ~ Tel: 01 – 202 0370 (DDI); email: david@afloat.ie

EDITORIAL

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

EDITORS NOTE

PSI News

Registration Updates

Certificates of Continued Registration

For the vast majority of registered pharmacists, pharmaceutical assistants and retail pharmacy businesses on the Registers held by the PSI, their current certificate of continued registration expires on 31 December 2010. By now all those who applied for continued registration within the appropriate timeframe have received their certificate by post. (Any registrant who completed their application for continued registration within the appropriate timeframe and who has not received their certificate is asked to immediately contact the PSI).

The certificate of the supervising pharmacist, as well as that of the retail pharmacy business, must both be conspicuously displayed at the registered premises. It should be borne in mind that by virtue of Regulations 5(3) and 15(a) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), it is an offence for a supervising pharmacist not to have his or her certificate of registration on conspicuous display at the premises concerned, in accordance with the requirements of the Act.

Cards and Photographs

Pharmacists will also have received a 'European Health Professional Card for Pharmacists' which bears their photograph. Pharmacists are encouraged to use or wear this card as a pharmacist identification card, so that they are readily identifiable to patients and the public as a registered pharmacist. Pharmaceutical assistants have also been issued with registration cards bearing their photographs.

Pharmacists and pharmaceutical assistants should note that the photograph supplied as part of their application for continued registration for 2010 is valid for a maximum of 10 years and will be displayed on certificates and cards every year from now on. However, a pharmacist or pharmaceutical assistant may update their photograph within the 10-year validity period if they wish.

Timeframe for Applications for Continued Registration

Under the statutory rules governing registration, an application for continued registration should be made at least 30 days before the expiry date of the current certificate. Registrants whose certificate expires at the end of a particular month should therefore ensure that they apply before the beginning of that month. For registrants who use the online facility, once they log on there is a reminder regarding how long until the next application for continued registration needs to made. Registrants who fail to apply within the appropriate timeframe may be subject to payment of a late fee or a cancellation of registration (and removal from the Register) process.

Online Registrant Facility

In 2009, all registrants were issued with PINs and passwords to enable them to avail of the online registrant facility and a significant number of registrants have used this facility to apply for continued registration and pay their fees. Registrants are reminded that they are obliged to notify the PSI in writing of any change in their details held as part of the Register(s). The online facility may also be used for registrants wishing to update certain personal details, including contact details.

Email Contact Details

The vast majority of registrants have provided email and other contact details (such as mobile phone numbers and fax numbers) to the PSI. It is important for the PSI to have such contact details as it facilitates the timely and efficient dissemination of important and often urgent information to registrants. Many other bodies, including the IMB, frequently request the PSI to disseminate important professional or patient safety information on their behalf, to ensure that pharmacists are updated and informed on matters that may impact on patient care and safety.

Registrants are therefore encouraged to ensure that their correct and up-to-date contact details, particularly their email addresses, are on the PSI database so as to ensure they receive information and updates from the PSI.

Registrants should note that these contact details are not published as part of the publicly available register.

Voluntary Cancellation of Registration

Pharmacists who no longer wish to practise as a registered pharmacist, for example after retirement, may voluntarily cancel their registration. Pharmacists who wish to cancel their registration must request to do so in writing and a form is available from the PSI for this purpose. This form can be downloaded from the PSI website (currently available in the 'Forms for Download' section under the Registration tab) or a form can be requested from the PSI Registration Unit.

Since the introduction in November 2008 of the new pharmaceutical registration systems under Part 4 of the Pharmacy Act 2007, the register of pharmacist is intended to be a 'live' register of practising pharmacists. The PSI recognises that a number of retired pharmacists have chosen, after many years of service to their respective communities and patients, to voluntarily cancel their registration as a pharmacist and so their names are no longer on the public register.

Retail Pharmacy Business Notifications

Pharmacy owners and superintendent pharmacists in particular are required to be aware of Sections 17(4)-(6) of the Pharmacy Act 2007, which provide that a change of ownership of a retail pharmacy business cancels its registration and the PSI must be notified of any such changes immediately. Changes in supervising and superintendent pharmacists are also required to be notified to the PSI as the holding of these positions, within the professional management of a retail pharmacy business, by appropriate people is a condition of the registration of the pharmacy. Pharmacy owners and superintendent pharmacists should also notify the PSI of other significant changes to the information provided as part of the registration process, such as changes in opening hours, changes in the range of professional services offered to the public or changes in regular staff employed in the retail pharmacy business.

Council Meeting Report: 26 January 2010

The 16th meeting of the PSI was held on 26 January 2010 in the Gresham Hotel, O'Connell St, Dublin 1. The main items on the agenda were the draft PSI Corporate Strategy 2010-2012 and draft Service Plan 2010; a Memorandum of Understanding with the Crisis Pregnancy Agency; a formal motion in respect of the amendment to PSI (Fees) Rules 2008 in relation to the temporary relocation of a retail pharmacy business for the purposes of renovation or refurbishment.

Following discussion of the draft three-year Corporate Strategy and the suggestion of some minor amendments, the document will go forward to the March meeting of Council for final approval. The draft Service Plan 2010 was approved by Council, with the acknowledgement that it is contingent on staffing issues which have been raised with the Departments of Health and Finance.

The Memorandum of Understanding with the HSE Crisis Pregnancy Programme (formerly the Crisis Pregnancy Agency), which will facilitate collaboration on matters and policies of common interest, was unanimously approved by Council.

The matter in relation to the amendment to the Fees Rules, had been considered at the December 2009 meeting of Council and a formal motion was approved at the January 2010 meeting. This amendment relates to the fee payable in respect of the continued registration of a retail pharmacy business that is being relocated for a maximum period of one year, in circumstances involving the renovation and/or refurbishment of the retail pharmacy business, and setting this fee at €1000.

The next scheduled meeting of the PSI Council is on Thursday 25 March 2010 and will be held in the RCSI, Dublin.

Public Consultation Document: Patient Consultation Area

Draft guidelines on patient consultation areas in pharmacies have been issued for public consultation by the PSI. From 01 November 2010, all retail pharmacy businesses will be required to provide a designated area for patients to discuss medication-related issues in private with a pharmacist, and receive advice and counselling from a pharmacist in an appropriately professional and private manner. Such a facility has been recognised internationally as an important element of good pharmacy practice and a beneficial resource for patients.

This requirement was introduced in Ireland by the Regulation of Retail Pharmacy Businesses Regulations 2008, which came into force on 29 November 2008, but which granted a two-year transition period for pharmacies in existence at the time until 01 November 2010.

These draft guidelines are being issued by the PSI Standard and Practice Committee to assist pharmacists and pharmacy owners in complying with the requirement and the draft guidelines are published in this issue, and are also available on the PSI website.

Calling on members of the public and the wider health sector to make comments and submissions on the issue of consultation areas in pharmacies, PSI Registrar and CEO, Dr Ambrose McLoughlin said communicating the correct information in a confidential manner to patients is as important as providing the medicine itself. "The World Health Organization (WHO) states patients should be entitled to request to use such a facility if they wish to speak in private to a pharmacist. The requirement to have a consultation area within a pharmacy already exists in many countries, including Scotland, The Netherlands and Australia, and it is widely recognised that patient consultation areas are a beneficial resource for patients in a pharmacy setting. It makes it much easier for patients to get the information and advice they need and it will also enhance and support the professional role of pharmacists."

Comments are welcome in writing to consultation@pharmaceuticalsociety.ie or to Public Consultation, Pharmaceutical Society of Ireland, 18 Shrewsbury Road, Ballsbridge, Dublin 4.

The closing date for the public consultation on the draft guidelines is Tuesday, 06 April, 2010.

Public Consultation on Safe Supply of Codeine

During December 2009 and January 2010, the PSI held a public consultation process on draft guidance for pharmacists on the safe supply to patients of non-prescription medicinal product containing codeine. The PSI would like to thank all those who made a submission to that process for their time and contribution. Following the consultation phase, the draft guidance has been reviewed and will be considered by the PSI Council at its meeting of 25 March 2010. The finalised guidance and other relevant information, including a 'start date' from which the guidance comes into force, will be publicised by the PSI to all stakeholders, including pharmacists and the public, once the process has been concluded. The various submissions to the consultation process and the PSI response to the comments made will also be published.

Regulators Forum publish Framework for Public Involvement in Regulation

The Health and Social Care Regulatory Forum of Chief Executives, of which the PSI is a member, recently launched a 'Framework for Public and Service User Involvement in Health and Social Care Regulation in Ireland'.

This Forum of Chief Executives of Health Regulatory Bodies was established in 2008 to provide a mechanism for exploring opportunities to harmonise certain business processes, share best practice and facilitate co-ordination where appropriate between member organisations. It also aims to share knowledge and expertise on matters of common interest with a view to enhancing the overall practice of health and personal social services regulation in Ireland for the benefit of public health.

In response to the recently published recommendations of the Commission for Patient Safety and Quality Assurance that "robust and validated patient and public involvement should be a requirement for all health care oversight, scrutiny, quality control and other accountability mechanisms", the Forum has published this report to encourage greater service user involvement among agencies involved in ensuring patient safety and quality assurance in the Irish health services.

Service users and members of the public should be involved in the work of regulatory bodies:

- to promote openness and transparency by enabling the public to review service quality and be directly involved in the development of rules and standards;
- to act as a safety solution so that health and social services can learn from the experiences of service users, carers and others, particularly as it relates to adverse events;
- to improve the quality of regulated services by ensuring that services are sensitive to the needs and preferences of service users and the public; and
- to focus the work of regulatory bodies on service users and encourage public accountability.

The framework points out that the countries with the best public services and indeed healthcare systems have very high levels of citizen empowerment, where public services strive to be truly personalised and power to shape those services is put as close to the individual citizen as possible. This is something which Ireland has made some progress on in the recent past but as highlighted by the OECD Ireland needs to extend the customer focus 'beyond narrowly defined customer service initiatives to all aspects of the work of the public service'.

The report refers to five levels of public and service user involvement: to Inform and Educate; to Gather Information; to Discuss; to Engage; and to Partner. Examples of best practice are provided for each activity. The report has been considered by the Board/Councils of the various regulatory agencies involved in the Forum and a commitment and a high intent has been expressed to ensure public and service user involvement in future regulatory activities.

The Framework document is available to view and download from the PSI website www.pharmaceuticalsociety.ie

Cancellations from the Registers: Public Notice

In accordance with the procedures prescribed under the Pharmacy Act 2007, the names of a number of persons were, on 02 March 2010, cancelled and removed from the Register of Pharmacists, for failure to make application for continued registration as a pharmacist in compliance with the legislation and for failure to pay the prescribed fee. Similarly, a number of cancellations and removals from the Registers of pharmaceutical assistants and retail pharmacy businesses, also for failure to apply for continued registration in compliance with the legislation and pay the prescribed fee, were also made on 02 March 2010. The full listing of relevant names is available on the PSI website in the Registration section. An information note on cancellation of registration as a pharmacist is on p.156

PSI Registrar speaks at International Conference on regulation

The PSI Registrar and CEO, Dr Ambrose McLoughlin was among the speakers at the second World Health Professions Conference on Regulation, which was held in February in Geneva. The conference was attended by a range of health professional regulatory bodies and professional associations from across the globe, and the aim of the conference was to discuss the future shape of health professional regulation within the context of global health systems' redesign and evolving roles.

Dr McLoughlin's presentation, entitled 'Patient Safety and Public Protection – is global regulatory collaboration the solution?' argued that a formalised structure that provides for collaboration between patient safety authorities and regulators at federal and global level is required to ensure patient safety and public protection.

"The EU, for example, has established effective regulatory regimes for civil aviation, for food safety," said Dr McLoughlin. "However, patient safety has yet to be properly addressed. Emphasis is shifting towards provision of irreversible care and treatment by increasing numbers of health professionals, as the roles of different professions evolve and governments and funders are seeking more care and treatment for less resources, with consequent changes in skills mix and professional practice. When we look at solutions and what we desire for the future, a formalised structure that provides for collaboration of patient safety authorities at global and federal level is required. The creation of a patient safety authority is necessary to promote a culture of safety, develop standards and guidelines and thereby reduce risks, develop a consensus on how to tackle patient safety issues and develop methodologies for the quality assurance of proper and safe movement of healthcare professionals."

"Individual professions cannot and should not be relied upon to ensure optimum patient safety," said Dr McLoughlin. "The political system has responsibility to ensure that legislative and regulatory reform takes place so that all countries meet minimum standards in practice. The healthcare sector must learn from the mistakes of the financial sector and ensure that accountable governance structures are in place, so that the obligations we have to patients, taxpayers and funders are met. Failure to effectively regulate healthcare and healthcare professionals would have massive consequences for patients and a formalised structure that provides for collaboration at global and federal level would assist in meeting regulatory challenges. Such a system must put patients first."

Dr McLoughlin thanked the President and Secretary General of the International Pharmaceutical Federation (FIP), who had extended the invitation to speak at the Geneva event.


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PSI publishes Service Plan 2010

The PSI Council has approved its Service Plan for 2010. The Plan is the first arising from the Corporate Strategy 2010-2012 (due to be published shortly, following Council approval) and is in line with the Code of Practice for the Governance of State Bodies published by the Department of Finance in 2009. The Plan was approved by Council with the acknowledgement that it is contingent on staffing issues which have been raised with the Departments of Health and Finance; in other words on the PSI having the necessary staffing resources to implement the Plan in full.

The Service Plan outlines how the PSI is using a Balanced Scorecard to measure its operational performance in 2010, which sets out our key objectives, targets and timescales over four quadrants, representing the main areas of the PSI's operational focus – its main business processes; its plans for learning and growth within the organisation; its relationship with its customers and stakeholders; and its arrangements for resource management and governance. Use of the scorecard – which mirrors that used at a strategic level and set out in the Corporate Strategy – provides both the PSI and its external stakeholders with a clear and straightforward mechanism for measuring performance in the areas of greatest importance.

Introduction from Service Plan 2010

Notwithstanding the present challenging and difficult times, all parts of the Pharmacy Act 2007 have been commenced and the PSI must meet its obligations. This Service Plan was developed in consultation with the Functional Units of the PSI, external advisors, and with the PSI Council and its Advisory Committees. The implementation of this Service Plan will be monitored by Council and its Advisory Committees, in conjunction with the Registrar, to ensure that targets are met.

This Service Plan has been developed in the context of the current economic environment. It is imperative the PSI ensures that patient safety and public protection are at the core of its work, whilst being mindful of making the best use of limited resources. In so doing, we will focus our resources on driving improvements that provide maximum impact and benefit for patients and members of the public. The PSI will organise itself to maximise current use of resources and provide best value for money. We will also work with other statutory bodies to reduce duplication, where possible.

This Service Plan will also be used as a vehicle to give effect to the recommendations outlined in the report of the Commission on Patient Safety and Quality Assurance, 'Building a Culture of Patient Safety'.

Overview

Substantial work will be required across the PSI in 2010 to ensure that the organisation continues its progress on a range of strategic developments, whilst at the same time delivering its operational functions, many of which are only now increasing in scale as a result of the full implementation of the 2007 Act.

Strategic Objectives Which Set Our Operational Direction

The strategic objectives being followed by the PSI in 2010 (and subsequently to 2012) are set out in detail in the Corporate Strategy, and it is important to note that the work required to meet these objectives will occupy significant amounts of senior staff time in 2010, and will also shape the operational functions undertaken by the PSI in 2010 and beyond. At a strategic level, our key challenges are:

- to ensure that all aspects of the Pharmacy Act 2007 are fully implemented, and are working effectively, in the interests of patients, the public and the profession;
- to apply the robust regulatory functions provided for within the 2007 Act, and to ensure that they are seen by the public and by the profession to be effective, for the protection of the public;
- to put in place a system of education, training and ongoing professional development for pharmacists in Ireland, which conforms with international best practice and supports improvements in professional practice and patient care;
- to develop evidence-based standards of good pharmacy practice in all settings, in line with evolving changes in the delivery of healthcare services;
- to encourage, facilitate and support the greater involvement of pharmacists in the delivery of integrated, patient-centred, cost-effective health services (this cannot be done by the PSI alone, but must take place in partnership with other key stakeholders within pharmacy and within the wider healthcare system);
- to grow the organisation in a structured manner, maintaining the confidence of patients and the public – organisational development will play a critical part in meeting the PSI's objectives;
- for the PSI – its Council, its Committees and its executive staff – to operate, and be seen to operate, in an independent and objective manner, in the interests of the safety of patients and the public;
- to develop a clear series of messages regarding its roles and responsibilities, and to continue to strengthen relationships with all stakeholders.

Operational Challenges for 2010

Aligned with the strategic objectives set out above, our key operational challenges for 2010 are:

- Ensure implementation of the Service Plan 2010 and Corporate Strategy 2010-2012 in an efficient and cost-effective manner;
- Continue to evaluate the implementation of the Pharmacy Act 2007, identifying any issues and advising the Council and Minister for Health and Children as appropriate;
- Build solid and efficient working relationships with other authorities and stakeholders and secure the presence of the PSI as a significant voice both at national and international level;
- Ensure implementation of the Corporate Governance framework of the PSI to ensure compliance with the Code of Practice for the Governance of State Bodies published by the Department of Finance in 2009;
- Embed risk management into all objectives of the PSI;
- Ensure preparation of the Annual Report in line with Schedule 1, Paragraph 17 of the Pharmacy Act 2007, and the Service Plan on an annual basis in line with Schedule 1, Paragraph 22 of the Act;
- Ensure necessary business processes, systems, procedures, protocols and staff to support the implementation of the legislation;
- Review the organisational structure in line with the Corporate Strategy of the PSI 2010-2012, to ensure that it is fit for purpose and fit for function;
- Ensure sufficient structures are in place to enable Council and its Advisory Committees to work effectively;
- Ensure that the PSI has staff with the appropriate qualifications, skills and experience to meet the objectives outlined in the Service Plan, including the continuing development and training of existing staff.

Realising Opportunities for Transformation

Pharmacy in Ireland has, for the first time, the basis for significant transformation into a modern, high-performing profession which will make an enhanced contribution to the health and wellbeing of the patients we serve and the wider public. The PSI will remain focussed in 2010 on playing its part to help maximise the contribution which pharmacists can make to the health and wellbeing of the population, as a vital component within the wider health and social care system in Ireland.

ICCPE resource on hypertension

The Irish Centre for Continuing Pharmaceutical Education (ICCPE) has published a resource on the management of people with hypertension. Developed by Dr Briegeen Girvin MPSI on behalf of the ICCPE, the document looks at the evidence-based management of people with hypertension, including the use of antihypertensive agents and the treatment of the condition in special populations. The resource is available from ICCPE www.iccpe.ie or 01 2196000.

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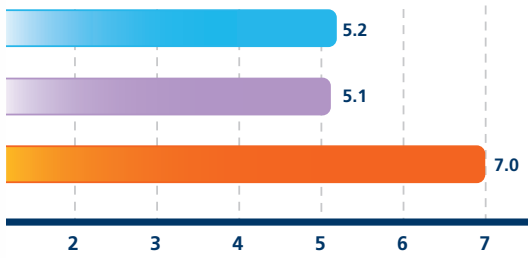

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Fresenius Kabi,
3B Fingal Bay Business Park, Balbriggan, Co Dublin.
Tel: +353 (0)1 841 3030 Fax: +353 (0)1 849 6949
Email: enquiries.ireland@fresenius-kabi.com
www.fresenius-kabi.ie

Date of preparation February 2009

Information Note: Cancellation of Registration as a Pharmacist

Introduction

Cancellation of registration as a pharmacist may be either:

- voluntary - at the request of the registrant in accordance with Section 59 of the Pharmacy Act 2007, or
- involuntary - removal from the Register for failure to apply for continued registration in compliance with Section 14 of the Act, and pay the prescribed fee (the procedures for this process are laid down in Rules 16 and 17 of the PSI (Registration) Rules 2008).

(It should be noted that similar procedures exist in relation to the registration of pharmaceutical assistants and retail pharmacy businesses also).

On 29 November 2008, the new pharmaceutical registration systems provided for in Part 4 of the Pharmacy Act 2007 were commenced. The establishment of these new Registers and the new system of continued registration, along with the provision for the Registers to be made publicly available online, now means that the public, the profession, policy-makers and others can rely on the accuracy and integrity of the Register. In addition, the requirement that all registrants notify the PSI of any errors in the Register, and notify and update relevant changes to their details, means the integrity of the Registers also depends on registrants meeting these obligations.

The requirement from 01 January 2010 for certificates and cards of registered pharmacists to bear photographic identification will also improve the transparency of and confidence in the registration system.

The pharmaceutical registration system under the Act provides for a 'live' practising Register (the Act does not provide for a 'non-practising register') and it is important for the public to be assured of the accuracy of the Register.

Voluntary Cancellations

Registered pharmacists may voluntarily cancel their registration, on request, in accordance with Section 59 of the Act (although the section does refer to the fact that the registrant is not, at the time of applying, the subject of a complaint under Part 6). A request for voluntary cancellation must be made in writing and the PSI has made a form available for this purpose.

The form contains the following text:

"I wish to voluntarily cancel my registration in the Register of Pharmacists in accordance with S59 of the Pharmacy Act 2007.

I understand that should I wish to practise as a pharmacist again in Ireland at a later stage I will be required to apply for and undertake a restoration process to be restored to the Register of Pharmacists.

I understand that by cancelling my registration as a pharmacist I will no longer be entitled to practise as a pharmacist in Ireland and my name will not appear in the Register of Pharmacists as of the confirmed date of cancellation of my registration. I understand and authorise the Council of the PSI to cancel my registration as a pharmacist in accordance with S59 of the Pharmacy Act 2007."

Registrants apply for voluntary cancellation for a variety of reasons, often personal, and these would include, but are not limited to, retirement or returning to another country.

Involuntary Cancellations and Removal from the Register

'Involuntary' cancellations of registration and removal from the Register are carried out, in accordance with Rules 16 and 17 of the PSI (Registration) Rules 208, where a registrant fails to make application for continued registration as a pharmacist in compliance with section 14 of the Act and for failure to pay the prescribed fee. The Rules outline the procedure which the PSI follows for this removal process. This includes a number of formal communications and demands to the registrant, within prescribed timeframes, to give them the opportunity to comply, and after which, if they do not, the PSI can be satisfied that their removal is in accordance with the legislation.

On average, there would be in the order of eight to ten (8-10) communications with a pharmacist, over a period of about three months, by letter, email and telephone, between the initial sending of the application form for continued registration (which includes reference to the option of applying for voluntary cancellation should a person not wish to apply for continued registration) and ultimate removal from the Register.

The PSI office is happy to assist and advise pharmacists and other registrants with any queries relating to their registration or the registration system generally.

MHC Consultation on Code of Practice

The Mental Health Commission (MHC) is developing a Code of Practice on the Mental Health Act 2001. The Commission carried out a review of the operation of Part 2 of the Mental Health Act 2001 in 2008 and one of the recommendations from this review was to develop a code of practice on the 2001 Act to guide people working in mental health services. A code of practice on the Act will give guidance on the exercise of functions under the 2001 Act; in other words, it would explain how certain parts of the legislation are best put into practice.

The Commission is interested to hear views on what parts of the Act, if any, further guidance should be provided on. The Commission has already produced some guidance on parts of the Mental Health Act. These include:

- rules on ECT under Sections 59 and rules on seclusion and mechanical restraint under Section 69;
- codes of practice under Section 33 on death notification and incident reporting; ECT; child admissions; physical restraint; admission, transfer and discharge to and from approved centres; and guidance for persons working in mental health services with people with intellectual disabilities; and
- procedural guidance and administrative protocols to Mental Health Tribunals.

The Commission also published a Quality Framework for Mental Health Services in 2007, which included minimum standards under the Mental Health Act 2001 (Approved Centres) Regulations 2006 as well as higher standards for approved centres and other mental health services.

Further details on the consultation are available on the MHC website www.mhcirl.ie in the 'Consultation Section' or by contacting MHC Policy Officer, Lisa O'Farrell on 01 6362400 or lisa.ofarrell@mhcirl.ie.

The closing date for receipt of feedback is Wednesday 28 April 2010.

BMJ editorial on tamoxifen/ paroxetine interaction

A recent British Medical journal (BMJ) editorial has highlighted the need for prescribers and pharmacists to be aware of the potential significance of the interaction between tamoxifen and paroxetine, following Canadian research that suggests that other anti-depressants should be considered for patients on tamoxifen. The research carried out by Dr Catherine Kelly and colleagues at the Institute for Clinical Evaluative Science (ICES) in Toronto concluded as follows:

"In conclusion, our findings indicate that the choice of antidepressant can significantly affect survival in women receiving tamoxifen for breast cancer. This observation is consistent with the critical role of CYP2D6 in the metabolic activation of tamoxifen, and highlights a drug interaction that is extremely common, widely underappreciated and uniformly avoidable. Tamoxifen is a crucial element of treatment for patients with hormone receptor positive breast cancer regardless of age or breast cancer stage. When co-prescription of tamoxifen with an antidepressant is necessary, preference should be given to antidepressants that show little or no inhibition of CYP2D6."

In an accompanying editorial, Frank Andersohn and Stefan Willich from Charite University Medical Center in Berlin state that clinicians should avoid co-prescribing paroxetine and tamoxifen in women with breast cancer but they also warn against any abrupt withdrawal of SSRI treatment in patients.

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Draft Guidelines on Patient Consultation Area

to facilitate compliance with Regulation 4(3) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

Note

From 01 November 2010, all retail pharmacy businesses will be required to provide a designated area for patients to discuss medication-related issues in private with a pharmacist, and receive advice and counselling from a pharmacist in an appropriately professional and private manner. These draft guidelines are being issued by the PSI for public consultation. The closing date for the public consultation on the draft guidelines is Tuesday, 06 April, 2010.

INTRODUCTION AND BACKGROUND

It has been accepted that communicating the correct information and advice to patients is as important as providing the medicine itself, and the World Health Organization (WHO) states that patients should feel able to express a need and be assured of confidentiality about their illness and treatment when receiving pharmacy services (Wiedenmayer, T. et al, 2006; Wuliji, T. et al, 2005). Facilities for confidential conversation between a pharmacist and a patient about their medicines and general health matters, that cannot be overheard by others, are also recognised as an essential element of 'Good Pharmacy Practice' by the International Pharmaceutical Federation (FIP, Good Pharmacy Practice Guidelines, 1997). Therefore the requirement to have a consultation area within a pharmacy already exists in many countries, including Scotland, The Netherlands and Australia, and it is widely recognised that patient consultation areas are a beneficial resource for patients in a pharmacy setting, aiming to improve patient confidentiality and patient outcomes.

A patient consultation area that is correctly designed and utilised allows the patient and the pharmacist to interact in a setting that respects the privacy of the patient and enhances the professional interaction and relationship between the patient and the pharmacist, on medication and other health issues. It also facilitates and supports patients in requesting and availing of the professional input and counselling they require from the pharmacist. In addition, a designated area within a pharmacy specifically for patient consultation will enable the pharmacist to become a more integral part of the multidisciplinary team involved in a patient's care. The confidential and personal nature of a consultation within a consultation area has huge potential to improve patients' health, by increasing patient education and medication compliance and thus reducing medication-related problems.

Previously in Ireland, there have been contractual requirements for pharmacists to have a consultation area in place. However, since the introduction of the Regulation of Retail Pharmacy Businesses Regulations in November 2008, all retail pharmacy businesses are now required to provide a designated area for patient consultation within the premises. A transition period was granted for retail pharmacy businesses already in existence at the coming into force of the regulations, until 1st November 2010.

LEGISLATIVE BASIS

The operation of a retail pharmacy business is governed by the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. 488 of 2008).

These regulations have been made by the Minister for Health and Children under Section 18 of the Pharmacy Act 2007, for the purposes of the health, safety and convenience of the public. Retail pharmacy business owners and superintendent pharmacists are required to conduct the retail pharmacy business in compliance with these regulations.

These draft guidelines have been written in accordance with Regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008, which allows the PSI Council, with the prior approval of the Minister, publish detailed guidelines to facilitate compliance with the Regulations. These particular draft guidelines seek to facilitate compliance with Regulation 4(3).

Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. 488 of 2008) Regulation 4 (3): "The pharmacy owner shall provide a separate and designated area conveniently located within the pharmacy premises so that a pharmacist may review and discuss in private with the person for whom a prescription has been issued, or with the carer of such a person, such matters relating to the medicine therapy as either of the said persons may request or as the pharmacist, in the exercise of his or her professional judgement, may deem necessary."

GUIDANCE ON REQUIREMENTS

1. PRIVACY

The area must be constructed so as to ensure a reasonable level of privacy for the patient, at all times, i.e. any discussion between the pharmacist and the patient, when speaking at a normal volume, should not be overheard by others. In addition, the visual privacy of the patient should be considered and the pharmacist should be in a position to demonstrate medicinal products and/or medical devices to the patient without being overseen.

Visual and sound barriers can be used to ensure the above criteria are met. However, it is not always necessary to create an enclosed room to achieve an appropriate level of privacy.

2. SEPARATE AND DESIGNATED

The patient consultation area should be a designated area and therefore used solely by the pharmacist for the purpose of patient consultation and counselling. The area should not be used for other purposes, e.g. the storage of medicines or excess stock. The area should not be an access route to other areas of the pharmacy, e.g. a store-room, bathroom or the dispensary. There should be a sign in place which informs patients that the facility exists and is available for their use, should they wish to request the professional input of the pharmacist. Each retail pharmacy business should also have written policy and procedures, which encourage and train staff to direct patients to the consultation area and inform them of their entitlement to such a facility.

3. CONVENIENTLY LOCATED

The area should be conveniently located and easily accessible to the patient and the pharmacist and therefore should be close/adjacent to the dispensary and non-prescription medicines area. There should be direct access for the patient from the public area of the pharmacy. A convenient location will help to ensure that the consultation area is availed of more frequently and will allow patient-pharmacist interactions to take place in an environment that respects a patient's dignity and privacy and enhances the professional role of the pharmacist.

4. SIZE

The area must have sufficient space and facilities to allow the pharmacist, the patient and/or their carer or guardian to be seated. The area must be accessible to all patient profiles and therefore must be wheelchair accessible.

5. FIXTURES AND FITTINGS

The area should be fit for purpose. It should be professionally finished and furnished to a high standard to reflect the professional nature of the area. The equipment available should allow for counselling and demonstration on the correct

and safe use of specific medicinal products and medical devices, as required, i.e. there should be a table or worktop in the room to facilitate such demonstrations, the writing of notes by patients or their carers, etc.

6. SUPERVISION

The pharmacy layout must be appropriate, and adequate pharmacist personnel must be in place to allow for the required supervision of any preparation, dispensing, compounding, sale or supply of medicinal products. This should be considered when planning and constructing the area. The superintendent and supervising pharmacists should consider the availability of other pharmacists to fulfil these and other requirements as envisaged under the legislation.

7. SECURITY

The security and safety of the patient and the pharmacist is paramount. The consultation area should not be used when, by entering the area, there is deemed to be a potential risk to the personal safety of a patient, pharmacist or another staff member. The use of security features such as CCTV cameras or panic buttons can be considered in the area. Patients must be informed of the presence of these devices in the consultation area.

8. ADDITIONAL OR EXTENDED PHARMACY SERVICES

Consultation area use, and therefore requirements, will vary depending on the services provided by the pharmacy. The regulatory requirement is that, at a minimum, the area allows for private discussions between the pharmacist and the patient on medication and health issues. If a pharmacy currently provides additional services such as health screening and monitoring services, or may consider providing such services in the future, there will be additional requirements for an area that can facilitate these services. This includes the degree of privacy required, the size of the area and the equipment requirements.

For further guidance on the requirements for premises providing such services please consult 'Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care'. Please note if a pharmacy is engaged in point of care testing on a large scale or volume it is necessary that a separate area be provided for this, so that the patient consultation area is always available for its intended purpose.

GENERAL REFERENCES

- Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008). http://www.pharmaceuticalsociety.ie/Publications/Publications/Legislation.html or http://www.irishstatutebook.ie/home.html
- Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care, 2009. http://www.pharmaceuticalsociety.ie/Publications/Publications/Navigation.html
- Wiedenmayer, K., Summers, R.S., Mackie, C.A., Gous, A.G.S., Everard, M. & Tromp, T.F.J. (2006). Developing pharmacy practice – A focus on patient care. Geneva: World Health Organization. http://whqlibdoc.who.int/hq/2006/WHO_PSM_PAR_2006.5_eng.pdf Accessed 06.11.07
- Wuliji, T., Airaksinen, M. (eds.) (2005). Counselling, concordance, and communication: innovative education for pharmacists. The Hague, The Netherlands: International Pharmaceutical Federation Pharmacy Information Section and International Pharmaceutical Students' Federation
- Standards for Quality of Pharmacy Services. Good Pharmacy Practice. International Pharmaceutical Federation (FIP), 1997. http://www.fip.org/?page=menu_goodpharmacypractice

Re: Responsibilities to patients living in residential care settings for older people

The following is a letter outlining the responsibilities of pharmacists in respect of patients of the retail pharmacy business(es) for which they are responsible, who are living in residential care settings for older people. It was recently sent by The Registrar/CEO, Dr. Ambrose McLoughlin to all superintendent pharmacists.

Dear Superintendent Pharmacist,

I am writing to you in your capacity as a superintendent pharmacist with specific reference to your responsibilities in respect of the services being provided to patients who are living in residential care settings.

The provision of pharmacy services to these patients must ensure that they receive the same level of care as those patients who attend personally at the pharmacy practice. The legal and professional requirements relating to the sale and supply of medicinal products apply in all circumstances, irrespective of whether the patient is living in his/her own home or in a residential care setting.

As superintendent pharmacist, it is your responsibility to ensure that patients in a residential care setting are provided with a comprehensive pharmacy service which facilitates the safe and timely supply of medicines, information and care to ensure the best possible outcome for each patient living there. A structured set of policies and procedures must be in place to govern the effective management of all services offered and provided to patients living in residential care settings.

A partnership model should be established with the management and staff of the residential unit to ensure that procedures are comprehensive, appropriate and robust.

In order to fully meet professional obligations to patients and to ensure compliance with legal and professional requirements, including the Code of Conduct for pharmacists, you must consider the following aspects in the discharge of your responsibilities to these patients:

(a) Prescription-only medicines may only be supplied on the authority of a valid original prescription from a prescriber for an individual patient. The use of faxes or medication administration charts or equivalent does not constitute a valid authority to supply.

(b) In exceptional circumstances prescription-only medicines may be supplied on the personal order of a registered medical practitioner who has accepted full responsibility, in writing, for the medicines supplied and for their subsequent use.

(c) The supply of controlled drugs must be carried out in accordance with the requirements of the Misuse of Drugs Acts 1977 to 2006, and their associated regulations. The requirements for the management of these medicines, including record-keeping and accountability are critical. Where any such drugs are to be supplied other than on foot of a prescription of a registered medical practitioner in the name of an individual patient, the pharmacist must be satisfied that the institution concerned has the authority to be in lawful possession of these medicines.

(d) In every supply, the pharmacist is obliged to comply with Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) in respect of the "review of medicine therapy and counselling of patients". All patients are fully entitled to the professional input of their pharmacist and pharmacists are obliged to provide appropriate pharmaceutical care. Support services must be provided to patients and/or staff at the residential care home, as appropriate, in respect of medication review, patient counselling, interactions, adverse effects, drug information and health promotion. Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations (S.I. No. 488 of 2008) also imposes certain obligations on pharmacists in respect of the supply of non-prescription medicines and the counselling of patients in regard of these products.

(e) The supply of medicines and the provision of pharmaceutical care to patients living in a residential care setting should also take into account the Health Information and Quality Authority (HIQA) 'National Quality Standards for Residential Care Settings for Older People in Ireland', and in particular Standards 14 and 15 which relate to medication management. This publication may be downloaded from www.hiqa.ie.

(f) Compliance with the Code of Conduct for Pharmacists must also be considered, in particular the primary principle which states that "the practice by a pharmacist of his/her profession must be directed to maintaining and improving the health, wellbeing, care and safety of the patient". Pharmacists must be alert to medicines management and other patient care issues within a residential care setting that may compromise the health or safety of the patients living there.

(g) It is essential that documented policies and procedures are in place to address the ordering, storage, preparation, compounding, dispensing, delivery and supply of medicines and services to patients in residential care settings. Operating systems must be continuously evaluated and reviewed objectively to ensure that the care provided meets patient needs and expectations and that practice is continuously improved.

The pharmacist providing a 'best-practice' service to a residential care setting actively participates in the development of medicines management policies within the care setting and acts as a positive influence there to assure patient care and public safety. It is your responsibility to actively and critically review existing practices as they relate to medicinal products, to assure yourself that a proper standard of practice and care is being provided to your patients in the residential care setting and that the rights of each patient are being respected, including their dignity, autonomy and entitlements.

The Pharmacy Act 2007 has brought significant and important changes to the regulation and practice of pharmacy and pharmacists in Ireland. Superintendent pharmacists play a vital role in assuring the wellbeing, care and safety of all of the patients of the retail pharmacy businesses for which they are responsible.

In your role as a superintendent pharmacist you play a key role in protecting vulnerable individuals and it is expected that cases of mistreatment, abuse or poor professional performance by other healthcare professionals will be referred, as necessary, to the appropriate authority.

Yours sincerely,
Dr Ambrose McLoughlin
Registrar & CEO
PSI – the pharmacy regulator

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Thalidomide:

Information for Pharmacists including Guidance from Irish Medicines Board

Introduction

Thalidomide is a powerful human teratogen, inducing a high frequency of severe and life-threatening birth defects, even after a single dose. Consequently, thalidomide must never be used by women who are pregnant or could become pregnant. In the 1950s and 1960s, approximately 12,000 children were born with severe birth defects caused by thalidomide after their mothers were prescribed the drug for symptoms such as nausea and insomnia while pregnant. Approximately 5,000 of these people are alive today, including at least 32 survivors in Ireland. The ongoing health and other difficulties experienced by thalidomide survivors have been highlighted recently in the media here and in the UK.

Thalidomide belongs to a group of medicines known as 'immunomodulatory' medicines, and Thalidomide Celgene (formerly Thalidomide Pharmion), in combination with melphalan and prednisone, is currently approved across Europe for the first-line treatment of multiple myeloma. Because of the risks involved with the drug, it must be prescribed and dispensed according to a pregnancy prevention programme (PPP). Since thalidomide may be present in the semen of male patients, both male and female patients must follow pregnancy prevention measures. There are other potential side effects that patients need to be aware of and full information on potential side effects and recommended precautions are available in the SPC.

Healthcare professionals have specific obligations that must be followed when prescribing or dispensing Thalidomide Celgene. Pharmacists have an important role to play in ensuring that this drug is used safely and correctly. Pharmacists must ensure that:

- The pharmacy registers with the Thalidomide Celgene PPP by completing the appropriate registration form. This registration is valid for two years and must be renewed if the pharmacy wishes to continue dispensing the drug.
- The 'Prescription Authorisation Form' is checked for completeness and countersigned prior to dispensing. This form must contain confirmation that the patient has received counselling on the safe use of Thalidomide Celgene, the patient category (i.e. male, women of childbearing potential or women of non-childbearing potential), and for women of childbearing potential, the medically-supervised pregnancy test date and result.
- Ideally for women of childbearing potential, the pregnancy testing, issuing of prescription and dispensing should all occur on same day. However, dispensing must occur within a maximum of seven days of prescription date and 10 days of negative pregnancy test date.
- When dispensing Thalidomide Celgene, the pharmacist must ensure that they dispense the blisters intact; capsules should not be removed from blisters and packaged into bottles.
- For each prescription, a maximum of four weeks supply can be dispensed.
- All pharmacists within the pharmacy must be educated about the dispensing procedures for Thalidomide Celgene.
- Patients are instructed to return any unused Thalidomide Celgene to the pharmacy. Pharmacies must accept any unused drug returned by patients for destruction and follow Good Pharmacy Guidelines for destruction of dangerous medicines.
- At each supply, patients must be reminded of key education messages for safe use of Thalidomide Celgene.
- Thalidomide Celgene must be dispensed in accordance with the measures described in the PPP information booklet and the SPC.

Irish Medicines Board Guidance on Thalidomide

Thalidomide Celgene 50mg Hard Capsules is the subject of an EU-wide Marketing Authorisation granted by the European Commission. The product was formerly known as Thalidomide Pharmion 50mg Hard Capsules and has been available as an authorised product in Ireland since 08 September 2008. Due to the known teratogenic effects of thalidomide and its important clinical risks, a risk management plan for authorised thalidomide was implemented in agreement with the European Medicines Agency and the Irish Medicines Board. This plan includes a controlled distribution system and a pregnancy prevention programme.

The IMB is concerned that pharmacists continued to order unauthorised thalidomide from September 2008 to mid-2009, despite the availability of Thalidomide Pharmion (now known as Thalidomide Celgene). This Practice Guidance Note is intended to emphasise to pharmacists that:

- where a prescription for Thalidomide Celgene (or Pharmion) is presented, Thalidomide Celgene (formerly Pharmion) must be dispensed;
- where a prescription for thalidomide (no brand specified) is presented, Thalidomide Celgene (formerly Pharmion) must be dispensed;
- where a prescription for an unauthorised brand of thalidomide is presented, please consult the prescriber to advise that the IMB does not permit such products to be sourced.

Background information:

The Marketing Authorisation for Thalidomide Celgene requires the implementation of the aforementioned risk management plan. This includes the provision of an Educational Kit to all prescribers and pharmacists involved in prescribing or dispensing the product. Prescribers and pharmacists must register with the Thalidomide Celgene Pregnancy Prevention Programme prior to prescribing the product. The PPP places considerable obligations on the prescriber and pharmacist prior to each supply of the medication. These include:

- counselling of the patient (male/female) to ensure that the risks of the treatment are understood;
- instigation of pregnancy prevention measures (as appropriate)

The pharmacist is required to limit dispensing of Thalidomide Celgene as follows:

- to within 7 days of the prescription date, and
- to within 10 days of a negative, medically-supervised pregnancy test.
- The dispensing volume is limited to a 4-week supply of Thalidomide Celgene.

The Educational Kit should be consulted for further details.

Accordingly, it is emphasised that, when a prescription for Thalidomide is presented in a pharmacy, only Thalidomide Celgene 50mg Hard Capsules may be dispensed. In circumstances where the prescription specifies an unauthorised branded thalidomide product, the prescriber must be consulted to advise that such products cannot be sourced. In circumstances where thalidomide 100mg tablets are prescribed, 2 x Thalidomide Celgene 50mg Hard Capsules must be dispensed. In the exceptional event that thalidomide 25mg is prescribed, it is advisable to contact the IMB Market Compliance Section (01- 6764971) to discuss the special need to source an unauthorised thalidomide.

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Children and the Law:
Dispensing prescriptions to minors

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

A friend's only daughter has just reached the age of 16. I asked how she would react if the family GP gave her daughter a prescription without her knowledge. Suffice to say that her initial reaction was one of 'indignity' that her GP would dare to do so and her presumption was that I was referring to oral contraceptives. This 'parental' reaction occurred despite decades of experience working in a pharmacy and a reputation for an entirely professional approach to dealing with teenagers when fulfilling her workplace responsibilities.

'Gillick Competency' is a term generally referenced when considering whether someone under 18 may be capable of making independent decisions about healthcare interventions. Its origins lie in a case brought by Mrs Victoria Gillick, who challenged health service guidance that would have allowed her daughters aged under 16 to receive contraceptive advice without her knowledge. It addresses whether doctors should be entitled to give advice or treatment to under 16-year-olds without parental consent, and its philosophy proposes that the right of a younger child to independently consent is considered to be proportionate to his/her competence, rather than just a matter of age. 'Gillick Competency' seeks to frame an objective assessment of an individual's competence to understand and evaluate the advantages and disadvantages of a proposed treatment, including the risks and potential alternative courses of action "so the consent, if given, can be properly and fairly described as true consent".

The associated 'Fraser guidelines', as proposed by Lord Fraser in his judgement of the Gillick case in the House of Lords (1985), relate specifically to contraception, the preference that parents be involved in related decisions and the risks of unprotected sex. However, these guidelines also tend to be more widely used to help assess whether a child has the maturity to make his/her own decisions and to understand the implications of consenting to or refusing treatment options.

"...a doctor could proceed to give advice and treatment provided he is satisfied in the following criteria:

1) that the girl (although under the age of 16 years of age) will understand his advice;

2) that he cannot persuade her to inform her parents or to allow him to inform the parents that she is seeking contraceptive advice;

3) that she is very likely to continue having sexual intercourse with or without contraceptive treatment;

4) that unless she receives contraceptive advice or treatment her physical or mental health or both are likely to suffer;

5) that her best interests require him to give her contraceptive advice, treatment or both without the parental consent."

Of particular relevance to my friend with the 16-year-old daughter, Lord Scarman's comments in his judgement of the Gillick case included specific reference to the passing of authority from parents to children, as maturity, rather than a specific age, is reached:

"Parental right yields to the child's right to make his own decisions when he reaches a sufficient understanding and intelligence to be capable of making up his own mind on the matter requiring decision."

Notwithstanding that the Courts appear to be moving towards a position whereby it may be accepted that some form of assessment of patient's capacity to consent is required,[1] it is important to clarify that 'Gillick Competence' does not apply in Ireland. The Non-Fatal Offences Against the Person Act (1997) allows children of 16 years of age to consent to medical treatment without permission from their parents, yet it does not provide any guidance on whether there is a right to refuse medical treatment. (Shannon 2007). (While the general issues related to refusal of healthcare interventions do merit review in the context of pharmacy practice, they are considered beyond the scope of this particular article.) However, the general view is that children under 16 do not have power to consent to medical treatment and in most such circumstances parental consent should, if at all possible, be obtained.[2]

The Law Reform Commission consultation paper, Children and the Law: medical treatment, "provisionally recommends that, in the context of healthcare provision, the law should respect the evolving capacity of individuals under the age of 17, with the aim of promoting access to necessary medical treatment", thereby seeking, effectively, to promote the adoption of an Irish version of Gillick. It also highlights deficiencies related to the treatment of minors in other pieces of legislation, e.g. the comparatively reduced protection of such minors under the Mental Health Act 2001. Given current national debate regarding the desirability of constitutional amendment of matters related to children's rights, the LRC consultation process is particularly timely and to be welcomed.

However, if capacity (to make decisions) is an evolving process, pharmacists dispensing medicines require to satisfy themselves as to the competency of minors in the context of the patient-pharmacist healthcare relationship and the corresponding responsibilities of a pharmacist to a patient in such a relationship. The LRC consultation paper places the focus on the decision that a medical practitioner will make in deciding to, for example, write a prescription. It does not appear to consider the related decision-making that occurs with a pharmacist when the patient seeks to have a prescription dispensed. Under the LRC proposals, the doctor should seek to obtain parental consent with the agreement of the child and record his or her attempts to obtain such consent. It is not clear how a pharmacist would be made aware of the basis on which the GP considers an under-18 competent and, where required, whether the parents have been notified. This could raise the spectre of a pharmacist being obliged to repeat the process of inquiry with the minor – in order to meet the pharmacist's independent responsibilities to the patient during the dispensing process. Such repetition of inquiry might not be in the patient's best interests.

Issues that may arise for pharmacists, especially those practising in primary care, include:

- Clarification of the nature of the pharmacist's professional responsibility to the 'child', including expectations of health promotion and health education during the process.
- Privacy, confidentiality and data protection rights of the child: once the healthcare practitioner/patient relationship has been engaged, the pharmacist is duty-bound to maintain the trusting relationship on which the professional relationship is founded, including those situations where professional resilience may be required to resist requests from parents, guardians, carers (e.g. the HSE) or other healthcare professionals to disclose information regarding the dispensing of prescriptions to minors.
- Issuance of MED-1 tax receipts, wherein the pharmacist facilitates authentication of financial governance on behalf of the Comptroller and Auditor General, by signing to validate annual receipts of expenditure on prescription medicines, but may inadvertently violate the privacy of a minor where records of the minor's prescription history are included on the family's MED-1 receipt, without specific authorisation to share such personal information.

Many scenarios may cause difficulty for pharmacists dispensing prescriptions. Oral contraceptives or the morning-after-pill are the examples commonly highlighted. However, depression, psychiatric illness and related treatments are also areas of sensitivity where young people may seek treatment on condition that privacy is respected, and STDs (sexually transmitted diseases) inevitably attract peer pressure to not disclose. Indeed the provision of a 'private area', to provide an environment in which sensitive matters can be discussed without fear of being overheard, will inevitably form part of pharmacy's professional management of such scenarios. For some young people, impetigo and similar contagious diseases cause acute distress, while lice, scabies and similar infestations would certainly be regarded as personal information and 'not for disclosure'. Treatment for addictions, including but not restricted to smoking cessation or methadone maintenance (where family addictions may discourage an individual from seeking maintenance therapy), also merit consideration in this context. It must not be forgotton, either, that many of the above scenarios have the potential to provide indicators of underlying social problems, thereby further increasing the need for ethical guidance to practitioners.

Legislative change is required in order to clarify the issues surrounding the consent by minors to medical treatment, and the LRC consultation process seeks to address this. However, the consultation paper as currently presented suggests that a pharmacist's responsibilities in the process by which a patient acquires medicines are not altogether apparent to organisations such as the LRC. To me, this simply further emphasises the importance of having a forum such as PLEA (Ireland) in which to consider the pharmacy perspective of such issues, and seeking to formulate considered contributions to discussion and debate on a wider scale.

On further conversation with the friend whose daughter had reached the age of 16 years, we agreed that the GP would likely deal with her daughter as an 'adult' should she require a prescription. Indeed, we probably reached a consensus that not only was he entitled to do so, but would be likely to assure her daughter that she was always free to consult the GP in absolute privacy!

cicelyroche@eircom.net

References:
1 • Fitzpatrick –v- K [2008] IEHC 104 per Laffoy J.
2 • North Western Health Board –v- W(H) [2001] 3 IR 622
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• Gillick v West Norfolk and Wisbech AHA (1985) 2 BMLR 11
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PLEA (Ireland), the Pharmacy Law and Ethics Association, was established during the meeting held on 03 March 2010, electing Cicely Roche MPSI as its chairperson and Jane De Barra BL MPSI as its secretary (plea.ireland@gmail.com). The next meeting will be in early June. New members all welcome.

An invisible profession:

Pharmacists and the population with intellectual disability

Bernadette Flood B.Sc. Pharm., M.Sc. Primary Health Care, Cert. Counselling Skills NUI, MPSI
Dr . Martin Henman Senior lecturer, School of Pharmacy & Pharmaceutical Sciences, TCD

Bernadette Flood has spent most of her professional career working in hospital pharmacy and has worked in a residential centre for people with intellectual disabilities for the past nine years. She completed an M.Sc. in Primary Health Care in 2007 and is currently undertaking a Ph.D. in Trinity College Dublin, under the supervision of Dr Martin Henman

The Chairman's Statement in the Annual Report of the National Intellectual Disability Database (NIDD) Committee 2008,[1] states that "the objective of the NIDD is to ensure that information is available to provide appropriate services to people with intellectual disability and their families in Ireland". The report (p 75) identifies, rightly, that there was substantial demand for new services and enhanced services relating to all therapeutic inputs in 2008.

Two of the services most commonly availed of by adults with intellectual disability were medical services (6,322 adults) and psychiatry (6,096 adults).[1] Both of these services are strongly associated with the prescription and use of medication. Speech and language therapy was one of the most commonly availed of multidisciplinary supports (7,839)[1] and the influence of medication on the swallowing process is an area of growing concern for the population ageing with intellectual disability. The Annual Report of the NIDD Committee 2008 and all previous reports of the committee, however, have been silent about the need for pharmaceutical care provided by pharmacists, for this vulnerable population.

Pharmaceutical care provided by a pharmacist is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve or maintain a patient's quality of life.[2] Medication use is the biggest therapeutic intervention in the population with intellectual disability. There is a high level of patient complexity in this population due to intellectual disability, neurological difficulties, sensory difficulties, medical conditions, behavioural problems, poly-pharmacy and the number of attendant drug therapy challenges, including dysphagia. The poorer health experienced by many people with intellectual disabilities has been described as a 'cascade of disparities.[3] To date, the need for specialised pharmaceutical care for the ageing population with intellectual disability has not been widely recognised. Comprehensive assessment of medication use in the population ageing with intellectual disability is the foundation for effective care planning.

Pharmacists have an important role to play in the healthcare of the population ageing with intellectual disability. Pharmaceutical care, rational medication use and effective medicines supply management are key components of an accessible, sustainable, affordable and equitable healthcare system, which ensures the efficacy, safety and quality of medicines. The Health Information and Quality Authority (HIQA) in its National Quality Standards for Residential Care Settings for Older people in Ireland states in Criteria 15.2 of Standard 15: Medication Monitoring and Review, "the condition of the resident on medication is monitored and subject to review at three monthly intervals or more frequently where there is a significant change in the resident's care or condition."[4] Criteria 15.6 also states that "each resident on long term medication is reviewed by his/her medical practitioner at least on a three monthly basis, in conjunction with nursing staff and the pharmacist". These criteria are the supporting statements that set out how a service can be judged as to whether the standard is being met or not. In contrast, the HIQA National Quality Standards: Residential Services for People with Disabilities,[4] in which there is no mention of the pharmacist, states in Standard 9: Health, Criteria 9.14 that "the individual's medication is monitored and subject to review at regular intervals, appropriate to the individual's needs".

Diagnostic overshadowing, which is a common clinician bias occurring during assessment of people with intellectual disability, is a factor in the healthcare of people with intellectual disability. Side effects of medication use may be a problem if unrecognised and can seriously affect the health and quality of life of an individual with intellectual disability. The range of side effects caused by medication use can be confused with symptoms of an underlying condition and an undiagnosed condition may be incorrectly diagnosed as a side effect of a medication and vice versa. These problems are often exacerbated by difficulties experienced by patients with intellectual disabilities in communicating with those providing healthcare.

Due to patient complexity in the intellectually disabled population, resources, time and effort will be required by pharmacists, in caring for the patient's medication-related needs. In an ageing intellectually disabled population particularly, the time required for documentation and follow up will be greater than for a non-intellectually disabled or younger population. Pharmaceutical care is designed to complement existing patient care practices to make medication therapy more effective and safe. Of those with intellectual disability in Ireland in receipt of multidisciplinary support services, the highest percentage increase over a 5-year period was in those accessing speech and language therapy (181%).[5] Review of medications has been listed as part of the clinical evaluation of eating, drinking and swallowing difficulties in the current Royal College of Speech and Language Therapists Clinical Guidelines.[6] This review, carried out by pharmacists, helps to ensure safe and quality medication use in the population with intellectual disability and dysphagia, and yet in the NIID 20081 report there is no mention of how such needs can be met in these vulnerable patients.

Pharmaceutical care, provided by qualified pharmacists with an interest in the healthcare of the population with intellectual disability, is a valuable resource in the multidisciplinary care of this vulnerable population group. The following statement recognises the positive impact of a pharmacist on a multidisciplinary team in the NHS: "the direct inclusion of a pharmacist in the multidisciplinary team has enabled us significantly to improve the quality of healthcare provided to people with learning difficulties, working in partnership with other professions

and agencies, including the local community pharmacists."[7]

It is to be hoped that in future reports, the NIDD will be in a position to provide recognition for the contribution currently made by pharmacists to the care of people with intellectual disability, and the need for pharmaceutical care in the future as this vulnerable population ages.

beflood@tcd.ie

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As with all SSRIs it is advisable to closely monitor patients for suicide and self-harm risk in the first few weeks of treatment and until significant remission occurs. Caution is advised in patients with coronary heart disease. The use of SSRIs/SNRIs has been associated with the development of akathisia, increasing the dose in these patients may be detrimental. Drug Interactions: MAO inhibitors (see Contraindications/ Precautions), advise caution in use with irreversible selective MAO-B inhibitors (selegiline). Caution in use with lithium, tryptophan, serotonergic medicinal products or with products capable of lowering the seizure threshold. Avoid concomitant use with St. John's Wort. In known poor metabolisers, with respect to CYP2C19, an initial 5 mg/day dose should be used, which can be increased to 10 mg after assessment. Caution is advised with co-administration of drugs metabolised by enzymes CYP2C19 and CYP2D6. 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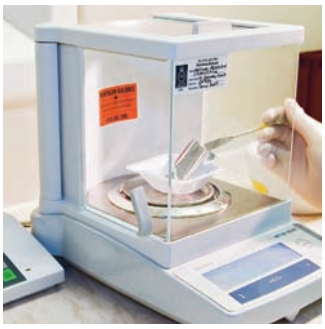


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Cahill May Roberts

Dublin
Cahill May Roberts

Tel: + 353 1 630 5432
Fax: + 353 1 626 8164
email: alchemy@cmrg.ie

Sligo
Cahill May Roberts

Tel: +353 71 9161801
Fax: +353 71 9161977
email: alchemy@cmrg.ie

Cork
Cahill May Roberts

Tel:+353 21 4965588
Fax: +353 21 4965669
email: alchemy@cmrg.ie