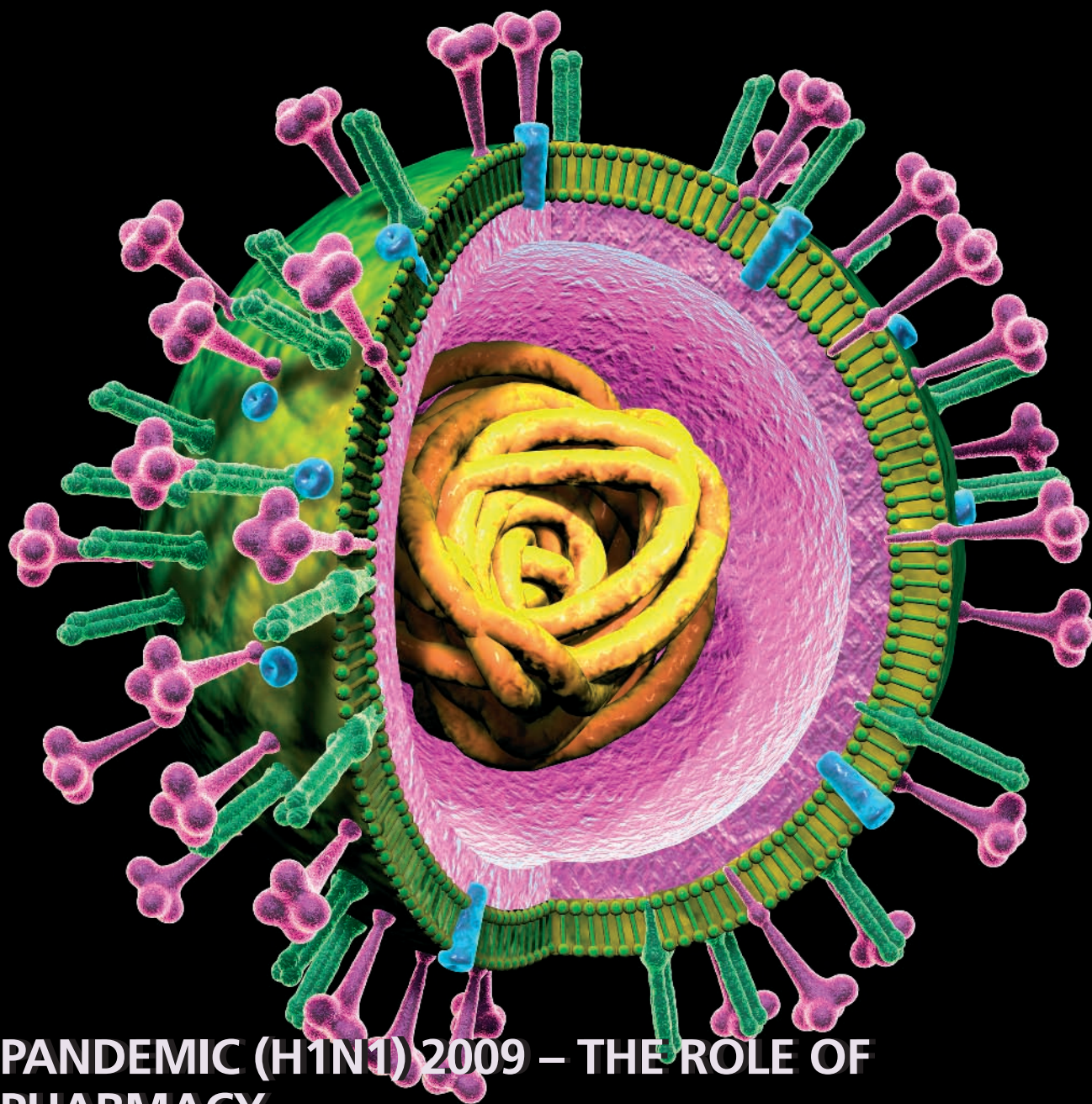


THE IRISH PHARMACY JOURNAL

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MAY-JULY 2009



**PANDEMIC (H1N1) 2009 – THE ROLE OF
PHARMACY**

PHARMACY ACT 2007 – PART 6

THE OFFICIAL JOURNAL OF THE PHARMACEUTICAL SOCIETY OF IRELAND

Professor John Feely



Professor John Feely, a former member of the PSI Council from May 2007 until his recent resignation due to ill health, died on 10 June 2009. Professor Feely was Head of the Department of Pharmacology and Therapeutics, Trinity College Dublin and consultant physician at St. James's Hospital Dublin.

Professor Feely was involved in many important and influential initiatives around medication and patient safety in Ireland, was widely published internationally and received many honours and awards during his impressive career. His compassionate intelligence and kind, generous nature left an impression on all those who had the pleasure to know him.

PSI President Noeleen Harvey extended the sympathies of the organisation to his family. "John's untimely death comes as a great shock to us all," she said. "He had given

wonderful service to the PSI at a critical time, following the passage of the new pharmacy legislation in 2007, the first major change in pharmacy legislation in a century and a modernisation of the law governing the regulation of pharmacists and pharmacy practice. John demonstrated his absolute commitment to ensuring that professions like pharmacy are well regulated, in the interests of patient safety and best practice, and public protection. He was part of the history made in 2007 when for the first time the Council of the PSI included a non-pharmacist majority."

Professor John Feely – An Appreciation

Pharmacy and the wider healthcare professions and, indeed, Ireland itself have all lost a great man in Professor John Feely. Although Prof Feely was not a pharmacist himself, time will show the enormous contribution he has made in progressing pharmacy as a profession in Ireland and I'm just sorry that my words are not enough to cover it.

I worked very closely with Professor Feely and he was single-handedly responsible for establishing and developing pharmaceutical services that were previously unheard of and hardly even imagined before his interventions. His support for the St. James's Hospital Pharmacy Department in establishing clinical pharmacy services that are now taken for granted there and elsewhere; the establishment of the National Medicines Information Centre; the National Centre for Pharmacoeconomics, and the first and second M.Sc. Degree courses in Clinical Pharmacy represent just some of the legacy of this great man.

Anybody who browses through Professor Feely's extensive list of publications will soon realise that most of his researchers were pharmacists and, in fact, at one time his own Department of Clinical Pharmacology and Therapeutics was the largest employer of pharmacists in the land.

I for one, and very many other pharmacists who have been fortunate to have come across Prof Feely, owe him a huge debt of gratitude, but with his untimely passing must regret not to have had the time to express to him what we feel about him - although I'm sure he would never have wanted or expected anything in return. His friendship and courtesy will always live with all of us who were privileged to have known him.

Ar dheis Dé go raibh a anam uasal dílis.

Professor Kamal Sabra

Benevolent Fund Draw

June 2009

PRIZE	NAME	REG. NO	AMOUNT	TICKET
1st	Leonie Clarke, Blackrock, Co. Dublin	5180	€4,000	77
2nd	Elizabeth O'Connor, Longwood, Co. Meath	4827	€3,000	33
3rd	Gerard Falvey, Bridge Street, Cork City	4662	€1,000	78
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Practice Notices

Advertising and Promotion of Medicinal Products on the basis of price or quantity discounts

The statutory mandatory Code of Conduct for pharmacists supports the rational and proper use of medicinal products in the interest of the health, wellbeing, care and safety of the patient. The Code requires that pharmacists provide honest, relevant, accurate, current and appropriate information to patients regarding the nature, cost, value and benefit of medicinal products, health-related products and services that they provide. The provision of information focusing on cost impacts on the essential impartial understanding of the medicinal needs of the patient (including safety in use) particularly in the mind of the patient or his/her carer(s).

Medicinal products are not ordinary market commodities; they are, with certain limited exceptions, regulated products that may not be supplied without the benefit of the expert advice of a pharmacist in respect of their safe, appropriate and responsible use. This position is supported by the various regulatory requirements, including those specified in the Regulation of Retail Pharmacy Businesses Regulations, 2008 (S.I. No. 488

of 2008), where certain obligations are laid down in respect of the circumstances in which the sale or supply of non-prescription medicinal products to the public by or under the personal supervision of a pharmacist is carried on in retail pharmacy businesses.

Pharmacists must discharge their professional obligations to patients seeking advice, guidance and assistance in respect of their pharmaceutical care and treatment. Self-selection of medicinal products without the provision of appropriate supervision, professional support, advice and information by the pharmacist is not appropriate. Supervising and superintendent pharmacists are reminded of their particular responsibilities to ensure that policies and procedures in place comply with these requirements.

In summary, therefore, the position is that neither the regulatory provisions, nor the professional codes in place, permit or support the advertising or promotion of medicinal products to the public on the basis of price or quantity discounts.

Good Dispensing Practice – High Tech Scheme

The management of the supply of medicinal products under the High Tech Scheme by a pharmacist from a retail pharmacy business requires specific and particular care. The pharmacist plays a critical role in partnership with the patient in the management of health status and the use of medicinal products. The following is an update on the guidance on Good Dispensing Practice as it applies to medicines provided via the High Tech Scheme.

When dispensing any medicine, patient care is the primary responsibility of the pharmacist. The dispensed medicine should be assembled, checked and recorded in a diligent and careful manner and supplied to the patient or their carer while ensuring they have sufficient and correct information regarding the proper use and storage of the medicine. Patients receiving care and treatment under the High Tech Scheme have complex medical and health needs, and management frequently involves vital treatment regimes with novel and/or toxic medicines.

- The operation of the scheme is under the auspices of the HSE and any pharmacist participating and delivering care to any patient under this service must ensure that they adhere fully to the operational requirements published by the HSE.
- Medicinal products, where possible, should be dispensed in the manufacturer's original pack. As such products are not routinely dispensed, or stocked, in a retail pharmacy business, care must be taken to ensure patients understand the necessity to allow adequate notice for ordering their own patient specific product.
- A prescription issued for a high tech medicinal product is subject to the same legal controls as any other prescription. The maximum validity period for any prescription issued is six months from the date of issue, when so indicated. Some prescriptions may only authorise a single supply, and care must be taken to ensure the prescriber's instructions are correctly interpreted. Irrespective of whether the product is indicated for lifelong use, the pharmacist must ensure that the prescription authorising supply is valid for each and every dispensing. The supervising pharmacist must ensure that he/she continues to meet his/her personal and professional obligations in respect of the patient, and particularly on the occasion of each visit by or on behalf of the patient.
- Where necessary, a General Practitioner may also issue a repeat prescription in respect of a high tech medicine provided that the product is for use within the date of review of therapy specified by the consultant on the health prescription form.
- A registered Nurse Prescriber may also issue a repeat prescription for a specific high tech medicinal product. As with all prescriptions, the pharmacist must be satisfied that this is within the provisions of the

legislation and that the nurse is operating and prescribing within his/her scope of practice having due regard to his/her place of practice. A Nurse Prescriber is not authorised to initiate high tech drug therapies under the scheme.

- This scheme operates as a patient-specific pharmaceutical care and treatment programme with a nominated pharmacy responsible for a specific patient and their complete and complex medication and health needs. Patient-specific dispensing occurs with a particular product obtained for a particular individual patient. Patient-specific monitoring is required on an ongoing basis and the pharmacist monitors overall medicines therapy notwithstanding that a high tech medicinal product may not be required at a particular patient visit. The supervising pharmacist has a primary responsibility in respect of the pharmaceutical care and treatment programme.
- Comprehensive patient counselling on the correct use, adverse effects, and warnings on precautions and the delivery of appropriate information and storage of the medicines is required to ensure a patient is aware of the appropriate use of the medication.
- Vigilance around adverse drug reactions, drug interactions and other adverse events must be constant, and procedures and policies must be in place for the documentation of any adverse events or errors and their management, including notification and /or referral of any important information to other healthcare professionals involved in the care of the patient.
- The requirement that these products be obtained, stored and dispensed in a manner which ensures a complete audit trail and accountability in their management is essential. This is the responsibility of the supervising pharmacist.
- The supervising pharmacist in a pharmacy practice delivering such a programme of care must ensure that all practitioners involved in the service are thoroughly familiar with the specific medicinal products and the conditions which they are used to treat, and that all pharmacists keep their professional knowledge of these products up to date. This knowledge must be sufficient for the provision of appropriate care to these patients who have complex medical and health needs, and whose health management frequently involves complex treatment regimes with novel and/or toxic medicinal products.

In the clinical management of the dispensary, the supervising and superintendent pharmacists must ensure that clear, structured management procedures and policies are in place, with adequate and proper records maintained in respect of adherence to the requirements. These policies and procedures should include quality-assured safety checking systems for before,



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Use in children: Should not be used in children under 12 years. Use in the elderly: No dosage adjustment. Use in renal impairment: No dosage adjustment. Hepatic impairment: Imodium Plus should be used with caution in such patients because of reduced first pass metabolism. Imodium Instant: Adults and children over 12 years only: The usual dose is 2 tablets initially, followed by 1 tablet after each further episode of diarrhoea up to a maximum of 5 in 24 hours. **Efficacy:** No dose adjustment. **Method of administration:** Oral. **Contraindications:** Imodium should not be used in: Children less than 12 years of age. Patients with a known hypersensitivity (allergy) to any component of the product. Acute dysentery, which is characterised by blood in stool and high fever. Acute ulcerative colitis. Pseudomembranous colitis associated with broad spectrum antibiotics. Patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella and Campylobacter. In general, Imodium should not be used when inhibition of peristalsis is to be avoided due to the possible risk of significant sequelae including ileus, megacolon and toxic megacolon. It must be discontinued promptly if constipation, subileus and/or abdominal distension develop. The stated dose should not be exceeded. In addition to taking Imodium, patients should be advised to drink plenty of fluids such as water, clear soup and squash. Patients should be advised to consult their doctor if diarrhoea persists for more than 24 hours. In addition Imodium Plus Chewable should also not be used in: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency, because the product contains sorbitol and sucrose. **Special warnings and precautions for use:** In patients with (severe) diarrhoea, fluid and electrolyte depletion may occur. It is important that attention is paid to appropriate fluid and electrolyte replacement. If clinical improvement is not observed within 48 hours, the administration of Imodium must be discontinued. Patients should be advised to consult their physician. Patients with AIDS treated with Imodium Plus for diarrhoea should have therapy stopped at the earliest signs of abdominal distension. There have been very rare reports of toxic megacolon in AIDS patients with infectious colitis from both viral and bacterial pathogens treated with loperamide hydrochloride. Although no pharmacokinetic data are available in patients with hepatic insufficiency, Imodium should be used with caution in such patients because of reduced first pass metabolism. Patients with hepatic dysfunction should be monitored closely for signs of CNS toxicity. Imodium Plus should be used under medical supervision in patients with severe hepatic dysfunction. Since treatment of diarrhoea with loperamide and simeticone is symptomatic, diarrhoea should be treated causally whenever such treatment is available. **Interaction with other medicinal products and other forms of interaction:** Non-clinical data have shown that loperamide is a P-glycoprotein substrate. Concomitant administration of loperamide (16 mg single dose) with quinidine, or ritonavir, which are both P-glycoprotein inhibitors, resulted in a 2 to 3-fold increase in loperamide plasma levels. The clinical relevance of this pharmacokinetic interaction with P-glycoprotein inhibitors, when loperamide is given at recommended dosages (2 mg, up to 8 mg maximum daily dose), is unknown. **Adverse Effects:** Imodium Plus: Clinical trial data (common events only, reported for loperamide with simeticone). Gastrointestinal system disorders: Nausea. Special senses: Taste perversion. Post-marketing experience (reported with loperamide with simeticone, or loperamide alone). Skin and appendages: Very rare: skin rashes, pruritus and urticaria. Very rare (for loperamide): angioedema. Body as a whole, general: Very rare (for loperamide): allergic reactions and in some cases severe hypersensitivity reactions including anaphylactic shock and anaphylactoid reactions. Gastrointestinal system disorders: Very rare: abdominal pain, nausea, constipation, flatulence, vomiting, and dyspepsia. Very rare (for loperamide): abdominal distension, ileus and megacolon including toxic megacolon (See warnings and special precautions for use). Genitourinary: Very rare (for loperamide): urinary retention. Central and Peripheral Nervous System: Very rare (for loperamide): dizziness. Special senses: Very rare: taste perversion. Psychiatric: Very rare: drowsiness. Imodium Instant: In clinical trials, constipation and dizziness have been reported with greater frequency in loperamide hydrochloride treated patients than placebo treated patients. The following adverse events have also been reported with use of loperamide hydrochloride: **Skin and Appendages:** Very rare: rash, urticaria and pruritus. Isolated occurrences of angioedema, and bullous eruptions including Stevens-Johnson Syndrome, erythema multiforme, and toxic epidermal necrolysis. **Body as a whole, general:** Very rare: isolated occurrences of allergic reactions and in some cases severe hypersensitivity reactions including anaphylactic shock and anaphylactoid reactions. **Gastrointestinal System Disorders:** Very rare: abdominal pain, ileus, abdominal distension, nausea, constipation, vomiting, megacolon including toxic megacolon, flatulence, and dyspepsia. **Skin and Appendages:** Very rare: rash, urticaria and pruritus. Isolated occurrences of drowsiness. **Central and Peripheral Nervous System:** Very rare: dizziness. A number of the adverse events reported during the clinical investigations and post-marketing experience with loperamide are frequent symptoms of the underlying diarrhoeal syndrome (abdominal pain/discomfort, nausea, vomiting, dry mouth, tiredness, drowsiness, dizziness, constipation, and flatulence). These symptoms are often difficult to distinguish from undesirable drug effects. **MA Holder:** Imodium Plus: McNeil Ltd, Sanderton, High Wycombe, Buckinghamshire, HP14 4HJ. Imodium Instant: MA Holder: Janssen-Cilag Limited, Sanderton, High Wycombe, Buckinghamshire, HP14 4HJ UK. **MA Number:** Imodium tablets: PA755/3/2. Imodium Plus Chewable Tablets: PA755/3/1. Imodium Instant: PA 755/43/3. Not subject to medical prescription. Further information available upon request from Johnson & Johnson (Ireland) Ltd. Tel: 01-4665200. M11X220G

pharmacy practice

during and after the dispensing of prescribed medication. Ongoing evaluation of policies and procedures, with review and amendment if necessary, must be undertaken and basic requirements such as the expiration of the validity period of a prescription must be clearly addressed therein.

Patient safety considerations warrant that the supervising pharmacist personally audits all dispensing under their jurisdiction. Superintendent pharmacists must satisfy themselves that protocols and procedures are in place and that they are followed in each pharmacy for which they are responsible. It is essential that the requirements of Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (SI 488 of 2008) (see Appendix below) relating to the "review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription" are fully complied with and that appropriate policies are in place to ensure that the necessary review and counselling requirements are met. Due diligence must be exercised to ensure any patient availing of the High Tech Scheme presents, or obtains his or her supplies on foot of, a valid prescription and that such prescriptions are also reviewed within the appropriate time frame as may be provided for under the scheme.

APPENDIX

Extract from the Regulation of Retail Pharmacy Businesses Regulations 2008 (SI 488 of 2008)

Review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription:

- 9 (1) A person carrying on a retail pharmacy business, the superintendent pharmacist and the supervising pharmacist shall ensure that, prior to the dispensing of each prescription and prior to the supply of the medicinal product concerned, a registered pharmacist reviews the prescription having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for the patient.
- (2) The review provided for in paragraph (1) shall include screening for any potential therapy problems which may arise out of the use of any medicinal product that may have been prescribed. The potential

problems to be screened for shall include those which may be due to therapeutic duplication, interactions with other medicinal products (including serious interactions with non-prescription medicinal products or foods), incorrect dosage or duration of treatment, allergic reactions, and clinical abuse and/or misuse.

(3) Following completion of the review provided for in paragraph (1) the registered pharmacist shall ensure that each patient has sufficient information and advice for the proper use and storage of the prescribed medicinal product and shall offer to discuss with the patient, or with the carer of such a patient, all such matters as the pharmacist, in the exercise of his or her professional judgement, deems significant, and which may include one or more of the following as may be appropriate:

- (a) the identity of the medicinal product, its dosage form, the method and route of administration and the duration of therapy;
- (b) the therapeutic benefit which may be expected from the use of the medicinal product;
- (c) any special directions and precautions for the correct preparation, administration and use of the medicinal product;
- (d) the importance of the need for compliance with the directions for use including techniques for self-monitoring during therapy;
- (e) any common severe side-effects and adverse reactions or interactions and therapeutic contraindications which may be encountered, including their avoidance and the action to be taken should they occur;
- (f) the action to be taken in the event of a missed dose;
- (g) the methods for the safe disposal of the medicinal product in the event of the course of treatment not being completed, and;
- (h) any other matters which may be included or referred to in the summary of product characteristics for the medicinal product concerned.

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Pharmacy Act 2007: Code of Conduct for Pharmacists

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

PSI/ICCPE taskforce

The joint PSI/ICCPE taskforce established to support pharmacists during the implementation of key sections of the Pharmacy Act 2007 held a further series of educational meetings in June 2009. These sessions covered two topics – the role of pharmacy in an influenza pandemic and the Code of Conduct for pharmacists. As part of the session on the Code of Conduct, ICCPE tutors facilitated workshops/discussions on a number

of case study scenarios to explore and further understanding of the impact and implications on their practice of the profession of pharmacy. The PSI presentation given at part of that session is published here in a reader-friendly format. The PSI would like to thank the ICCPE tutors and HSE pharmacists who participated in the organisation and delivery of the joint programme over the past few months.

Introduction

The Pharmacy Act 2007 has brought significant changes to the way the profession of pharmacy is regulated in Ireland and to the roles and responsibilities of pharmacists. In particular, it provides for the adoption of a statutory code of Conduct for pharmacists and for the first time in Ireland, a 'fitness to practise' system for pharmacists.

Codes of Conduct or Ethics and Professionals

Codes of conduct or ethics exist in many professions, including pharmacy, and these codes frame the culture in which professionals practise and bring an 'internal accountability' to their practice. These codes generally express and outline the values, attitudes and behaviours required by members of a profession. They are the agreed standards relating to relationships within a profession, to ensure the 'good name' and status of the profession as a whole and ensure confidence in it, as well as relationships with other professions and with patients and the public.

The term 'profession', which at one time related to the three 'learned professions' of medicine, law and the clergy, is now broadly used to include any kind of work or occupation requiring special intellectual training, knowledge or skill. However, Dale and Applebe in Pharmacy Law and Ethics, say that "an organised profession requires more than the mere existence of an intellectual discipline . . . the essence of professionalism is the relationship of trust which exists between the practitioner and the person who receives advice or service". Professionalism has also been defined as the "autonomous application of capability in a professional environment which meets expectations of peers, patient, the public and society", with capability defined as an "all round human quality, an integration of knowledge, skills, attitudes and values used appropriately and effectively".

In modern practice of the professions, the old notions of 'paternalism' are being replaced by a 'partnership' approach with patients and other healthcare professionals. There is a promotion of the autonomy of patients, their rights, entitlement and expectations, and an emphasis on the protection of vulnerable patients. This brings additional accountability for all professions and an emphasis on the need to avoid conflicts of interest; patients must be able to trust the impartiality of professional advice. In the past, codes have primarily been a guide (only) to what is required or desired, more 'morally binding' rather than strictly legally binding. However, for pharmacists in Ireland, with the Pharmacy Act 2007, this moves to a statutory basis, setting a standard for registration and fitness to practise.

The Code of Conduct for pharmacists

Section 7 of the Pharmacy Act 2007 lays down the duties of PSI, which include "to draw up codes of conduct for pharmacists". Section 12 of the Act outlines the procedure for submitting this Code to the Competition Authority for its opinion on whether the provisions of the draft code might

be likely to result in competition being prevented, restricted or distorted, for obtaining consent of the Minister, publication of the Code and for laying before the Houses of the Oireachtas. The draft code went through an extensive consultation process during 2008 with the profession and the wider sector, and a positive opinion on the provisions of the draft code was received from the Competition Authority in October 2008. The Code was approved by the Minister for Health and Children on 14 November 2008 and formally laid before the Houses of the Oireachtas in February 2009.

The Code of Conduct for pharmacists sets out the key principles or professional ethical standards in accordance with which pharmacists should practise their profession. It is a public declaration of these principles and ethical standards, which the public, patients and other healthcare professionals require and expect of pharmacists. The Code also provides support and guidance to pharmacists and empowers them in the practice of their profession. Breaches of the Code may be considered 'professional misconduct' under Part 6 of the Pharmacy Act 2007, which defines 'professional misconduct' as including "a breach of the Code of Conduct for registered pharmacists" (Section 33), with potential implications for a pharmacist's fitness to practise:

Section 33: professional misconduct" is defined in relation to a registered pharmacist as being any act, omission or pattern of conduct that –

- (a) *is a breach of the code of conduct for registered pharmacists,*
- (b) *is infamous or disgraceful in a professional respect (notwithstanding that, if the same or like act, omission or pattern of conduct were committed by a member of another profession, it would not be professional misconduct in respect of that profession),*
- (c) *Involves moral turpitude, fraud or dishonesty of a nature or degree which bears on the carrying on of the profession of a pharmacist, or*
- (d) *(application to persons registered, etc., outside the State)*

but does not include an act, omission or pattern of conduct that consists of a wrongly but honestly formed professional judgement.

Every pharmacist is personally responsible under the Code of Conduct for his/her own acts or omissions. Pharmacists may also be responsible under the Code for the acts or omissions of persons operating in the area of pharmacy under their direction, control or supervision, and this may be particularly relevant to supervising and superintendent pharmacists who have important roles in ensuring and supporting compliance with the Code.

The Code applies to all pharmacists whether they practise in community, hospital, industry, regulatory or administrative environments or in any other form of professional practice.

Principles of the Code

The Code contains a broad definition of **the patient**, to include a "person or persons who stand in such a degree of relationship to a pharmacist that the pharmacist ought to reasonably apprehend that such

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MOB/008/01

a person or person's health, wellbeing and care are likely to be affected by the acts or omissions of that pharmacist". The Code contains six principles and under each principle is a number of guidance notes which set out some of the main practical considerations which pharmacists should take into account when applying the principles of the Code. These lists of guidance notes are neither exhaustive nor exclusive and decisions must be made by pharmacists on a case-by-case basis.

Every pharmacist should regularly consult the Code and familiarise themselves with its contents, and reflect on how principles of Code and various guidance notes impact on their own practice and guide their professional development. Application of and adherence to the Code ensures that the important relationship of trust with patients is protected. It also empowers pharmacists in relation to professional practice, thereby enhancing the reputation of the pharmacy profession as a whole.

The Code of Conduct for pharmacists is available to view and download from the PSI website at <http://www.pharmaceuticalsociety.ie>

Principles of the Code of Conduct

- 1 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. This is the primary principle and the following principles must be read in light of this principle.
- 2 A pharmacist must employ his/her professional competence, skills and standing in a manner that brings health gain and value to the community and the society in which he/she lives and works.
- 3 A pharmacist must never abuse the position of trust which they hold in relation to a patient and, in particular, they must respect a patient's rights including their dignity, autonomy, and entitlements to confidentiality and information.
- 4 A pharmacist must conduct himself/herself in a manner which enhances the service which their profession as a whole provides to society and should not act in a way which might damage the good name of their profession.
- 5 A pharmacist must maintain a level of competence sufficient to provide his/her professional services effectively and efficiently.
- 6 A pharmacist must be aware of his/her obligations under this Code and should not do anything in the course of practising as a pharmacist, or permit another person to do anything on his/her behalf, which constitutes a breach of this Code or impairs or compromises his/her ability to observe this Code.

Part 6 of the Pharmacy Act 2007

Complaints, Inquiries and Discipline

Introduction

Part 6 of the Pharmacy Act 2007 relates to Complaints, Inquiries and Discipline and essentially establishes a 'fitness to practise' system for pharmacists and a 'fitness to operate' system in relation to retail pharmacy businesses. Section 34 states that the Council shall establish the following disciplinary committees:

- Preliminary Proceedings Committee (PPC)
- Professional Conduct Committee (PCC)
- Health Committee (HC)

And this section also outlines the parameters of membership of the Committees, i.e. these should have a non-pharmacist majority, with at least one-third of the members being pharmacists and at least two members pharmacists who are pharmacy owners. Members of disciplinary committees have the same rights and immunities as a judge of the High Court.

Preliminary Proceedings Committee

The PPC is responsible for considering complaints against pharmacists and retail pharmacy businesses in the first instance. Section 35 outlines the grounds upon which a complaint against a pharmacist may be made. These are:

- professional misconduct
- poor professional performance
- impairment of the pharmacist's ability to practice because of a physical or mental disability
- failure to comply with one or more condition(s) attached to the pharmacist's registration
- failure to comply with an undertaking given by the pharmacist to the PSI or to take any action specified in a consent given by the pharmacist in response to a request from a Committee of Inquiry under Section 46 of the Pharmacy Act 2007
- contravention of a provision of the Pharmacy Act 2007 or Rules made by the Council of the PSI under the Act
- conviction in the State for an offence triable on indictment (or if convicted outside the State for an offence which would constitute an offence triable on indictment in this jurisdiction).

The PPC also considers complaints relating to retail pharmacy businesses under one or more of the following grounds (Section 36):

- the pharmacy owner or an employee or a partner of the pharmacy owner,

or representative or person engaged by the representative, has been convicted of a relevant offence referred to in Section 36(1) of the Pharmacy Act 2007

- the pharmacy owner or an employee or a partner of the pharmacy owner, or representative or person engaged by the representative, has been convicted of any other offence or committed misconduct and the nature of such offence or misconduct is such that, if that person were applying to the Council for registration as a pharmacist, the Council would be likely to refuse the person.

When the PPC is satisfied that it has sufficient information from both the complainant and the pharmacist/pharmacy complained against, it will then decide what course of action should be taken:

- No further action should be taken; or
- The complaint is one that could be resolved by mediation or other informal processes (requires consent of the complainant and the pharmacist); or
- The complaint should be referred to the Professional Conduct Committee or Health Committee for inquiry.

The PPC does not decide whether a complaint is proven; it advises the Council of the PSI as to what action, if any, should be taken in relation to your complaint. Before arriving at its advice the PPC will consider all information available and whether the complaint is trivial, vexatious or made in bad faith.

Where the PSI receives a complaint where there is a serious risk to the health and safety of the public, the Council may apply to the High court to make an order for interim suspension of registration, pending further procedures under Part 6.

Committees of Inquiry

There are two Committees of Inquiry – the Professional Conduct Committee (PCC) and Health Committee (HC). A registered medical practitioner with relevant expertise will be appointed by Council to advise the HC in relation to each complaint referred to it.

Hearings before the PCC will be held in public, unless the Committee believes it would be appropriate to be held in private. Hearings before the HC shall normally be held in private. Hearings will include the giving of testimony by witnesses with the right to cross-examine witnesses and call evidence in defence and reply. The Committee will issue a report on its findings to council at the conclusion of the inquiry.

Sanctions

The Committees of Inquiry reports will usually be considered by the Council of the PSI within eight weeks of the completion of the inquiry. If the Committee finds that allegations against the pharmacist or pharmacy owner have been proven, the Council of the PSI may consider imposing one or more of the following sanction(s) on the pharmacist or pharmacy owner:

- Admonish or censure the pharmacist or pharmacy owner in writing;
- Attach conditions to the registration of the pharmacist or retail pharmacy business;
- Suspend the registration for a specified period;

- Cancel the pharmacist's registration or that of the registered retail pharmacy business;
- Prohibit the pharmacist or pharmacy owner from applying to restore their name to the Register for a specified period.

Any sanctions applied will be notified to the pharmacist or pharmacy owner and the PSI must apply to the High Court to confirm disciplinary sanctions, at which stage the pharmacist or pharmacy owner to apply to the High Court to cancel the disciplinary sanction.

The PSI must inform the Minister of any disciplinary sanctions imposed and a public notification of sanctions imposed will also be published in the public interest.

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(Prisoner Population: approx. 1100) **Wheatfield Prison, Cloverhill Road, Clondalkin, Dublin 22**

Lot 2: Midlands **Midlands Prison, Dublin Road, Portlaoise, Co. Laois**
(Prisoner Population: approx. 865) **Portlaoise Prison, Dublin Road, Portlaoise, Co. Laois**

Applicants may tender for one or both lots.

Tender documents are available on www.etenders.gov.ie or by email from cputenders@irishprisons.ie. Completed tender documents must be returned in hard copy, by 12 noon on 30 October 2009 to the Irish Prison Service, Central Procurement Unit, IDA Industrial Estate, Ballinalee Road, Longford, Ph. 043 333 5187.

For further information, please contact Healthcare Directorate, IPS, on 043 333 5119.


 pandemic (h1n1)

Pandemic (H1N1) 2009: The Role of Pharmacy

M. Henman, BPharm, MA, PhD, MPSI

Dr Martin Henman is a Senior Lecturer and Co-ordinator of the Centre for the Practice of Pharmacy in the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin.

Background

This article is based on a presentation given by Dr Martin Henman at the joint PSI/CCPE educational sessions held earlier this summer. The sessions around pharmacy and the influenza pandemic were held under the auspices of the Expert Pharmacy Advisory Taskforce, which comprises representatives of the PSI, IPU, academic pharmacy, hospital pharmacy, HSE pharmacists and public health doctors. The taskforce was established to advise and inform Government and the Health Services of the relevant issues, and to support pharmacists in their role. The taskforce is fortunate in having Pamela Logan from the IPU as a member as Pamela has been nominated to represent European community pharmacists on the European Scientific Working group on Influenza (ESWI).

The email database of the PSI Register of Pharmacists is being used as a communication channel by the HSE, and clinical information and updates are disseminated to pharmacists via this database. The most recent letter to all clinicians dated 29 July was sent to pharmacists by email and is also available on the PSI website at www.pharmaceuticalsociety.ie. Pharmacists are kindly

requested to ensure that the email addresses on the PSI database are the correct and most convenient ones for them to continue to receive updates on the pandemic.

Pharmacists are also advised to regularly consult the websites of the HSE www.hse.ie, Department of Health and Children www.dohc.ie, and the Health Protection Surveillance Centre www.hpsc.ie. The HPSC site has a link for advice for health professionals on Pandemic (H1N1) 2009, as the virus is now termed, with a further link for pharmacists and pharmaceutical information.

The website of the Irish Medicines Board www.imb.ie is another useful resource, including the SPCs of the antivirals and information on the reporting of adverse events and the extension of the shelf-life of Tamiflu from 5 to 7 years.

The European Centre for Disease Prevention and Control www.ecdc.europa.eu and the European Medicines Agency www.emea.europa.eu are also useful resources.

Introduction

In Mexico in March of this year, and then in the US in April, health authorities began to report cases of influenza caused by a novel form of influenza virus. Influenza is an acute, easily transmitted infection of the upper respiratory tract that can cause extensive morbidity even in its mildest forms and considerable mortality when complications such as pneumonia also occur. Influenza viruses cause infections each autumn/winter, known as seasonal influenza, and each autumn a new vaccine is made available to protect those at risk of serious complications. This annual undertaking is necessary because influenza viruses are uniquely and rapidly able to change their genes.

Viruses can only live by infecting the cells of a host organism and using that cell's genetic machinery to read the virus's genes and replicate new viral particles. Influenza viruses are made up of an outer coat which protects the viral genes and other proteins which are carried inside the spherically shaped particle. The outer coat contains a number of types of proteins; one of these, the M protein, enables influenza viruses to be identified, because its structure is highly stable. Influenzas are grouped into three types, A, B and C, and the A and B types infect humans. The infectivity of each influenza virus strain is largely determined by two other proteins found in the outer coat, the H and N proteins. The H protein - haemagglutinin, enables the virus to bind to the surface of the cell, and to trigger the process that brings the virus inside the cell and initiates viral replication. The new viral particles are attached to the outside of the host cell. The N protein - neuraminidase - is an enzyme that cuts the bond holding these new viral particles to the cell wall, allowing them to pass on in the fluids of the body to infect other cells. The haemagglutinin and neuraminidase proteins can be classed into particular variants (for influenza A there are 16 variants of the haemagglutinin and 9 of the neuraminidase) and within each variant changes in structure can, and do occur regularly; for example, not all H1 or N1 variants are the same, giving rise to different strains. Hence, when influenza viruses are named they are typed according to their group, A, B or C, and according to the variants of the haemagglutinin and neuraminidase - thus, influenza A/H1N1 is a general name, but more detailed analysis of the H1 and N1 proteins is used to identify the strain. Given the importance of the H and N proteins to the infectivity and transmission of the virus, analysing and recording the H and N protein sequences is crucial. When the immune system detects influenza viruses, it recognises these unusual proteins as antigens and it produces antibodies against them. Specific antibodies for the particular variants of the H and N proteins in the viral coat circulate in the blood. It also establishes 'memory cells' that enable a quicker immune response if the virus returns, but with so many possibilities for variation and such potential for rapid change, influenza viruses present a difficult target

for the immune system.

Minor variations in influenza occur when a small change in the sequence of a gene occurs. Every gene in the virus contains the code for a protein through its sequence of nucleic acid bases. The genes of the influenza virus are divided up into eight separate segments that work together to produce the virus. When the virus replicates, it produces a new set of genes, and during replication all genes can undergo small changes in their sequences - mutations, that in turn slightly alter the structure of the protein that is produced from the gene. This is one level at which changes in influenza viruses occur, leading to slightly different influenza viruses each autumn. This means that the new strain of influenza virus may be just different enough so that the immune system's response is only partially effective, even though antibodies to the previous virus may still be present in the blood. Small changes in the influenza viral genome are known as antigenic drift.

Another level at which change can occur is that of an entire gene and this can bring about major changes in the virus, known as antigenic shift, because the extent of change makes it unlikely that the viral antigens have been in circulation before. The segmentation of the influenza genes means that each segment, and therefore each gene in its entirety, can be swapped, without affecting the ability of the virus to operate. Since it is also possible for more than one virus to infect a cell at once, reassortment of the genome is not difficult. Exactly how this happens is not known but what is known is that influenza viruses are often made up of genes that originated in a different species to their present host. Birds and humans have different receptors on the surfaces of some of their respiratory tract cells that allow only avian or human influenza haemagglutinin protein to bind to them. Consequently viruses usually remain within the species in which they originated, infecting birds or humans, not both, which is why influenzas are usually referred to also by their host species. Rarely, they 'jump', as avian influenza H5N1 ('bird flu') did when its avian haemagglutinin had changed sufficiently to enable it to infect human cells.

However, the most likely way in which influenza is thought to move between species and swap segments of genetic material involves pigs. These animals have receptors that can accept swine, avian and human influenza haemagglutinin proteins on to the cells of their respiratory tracts, so they can become infected with viruses that originated in any of the three species. A pig cell that is simultaneously infected by two viruses from different species provides a place in which swapping of viral genes can occur, potentially leading to influenza viruses made up of mixtures of avian, human and pig genes - a reassortant virus. Influenza A/H1N1 (recently re-named by WHO as Pandemic (H1N1) 2009), the virus causing this pandemic, contains just such a mixture. It represents a 'new' virus, a major change. Analysis of the genes of this virus and comparison with isolates of

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Special Educational Feature: Pandemic (H1N1) 2009 and the Role of Pharmacy

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In this comprehensive educational article on Pandemic (H1N1) 2009, Dr Martin Henman, School of Pharmacy and Pharmaceutical Sciences in Trinity College Dublin, details information in relation to this novel influenza virus, the anti-viral drugs used to treat it, complications of influenza and the management of 'at risk' patients and issues around vaccination, as well as the specific roles played by pharmacists and pharmacies in the public health management of the pandemic.

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Ethics and Legal Issues: In this issue Cicely Roche looks at the ethical issues presented when a colleague is suspected or found to have a drug or substance dependence, and discusses the various factors that will have to be taken into account when dealing with such a scenario, where one should support a colleague but also ensure that patient safety is not compromised.

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Preserving the essence of Professional Pharmacy Practice

All remaining sections of the Pharmacy Act 2007 came into force on 01 August 2009, just over two years since its enactment in May 2007. This is a significant achievement for the PSI and the pharmacy sector and profession, and ensures that the modern robust regulatory framework provided for in the new legislation is now in place. This framework, and the various provisions of the Act, offers protection and benefits for the patients who use the professional services and skills of pharmacists, as well as for members of the pharmacy profession.

The Pharmacy Act 2007, and in particular the Code of Conduct for pharmacists, explicitly places the patient as the primary focus of a pharmacist. The role and responsibilities of pharmacists as the experts in the safe supply of medicines is recognised, with the aim of ensuring that the same standards of quality and safety apply to all patients in all pharmacies at all times. Equally the provisions of Part 6 of the Act put in place a robust process by which complaints against pharmacists and pharmacies can be processed.

The framework provided for by the Act also now means that the necessary safeguards are in place to facilitate the expansion of the role of pharmacists and pharmacies, in line with the international experience and evidence. In its submission to a recent consultation by the Department of Health and Children Expert Group on Resource Allocation and Financing in the Health Sector, the PSI re-iterated the case for the development of pharmacy services in this country in line with the international evidence. And the Minister has again expressed her intention to further discuss the future of, and developmental role for, pharmacy services in this country and this is to be welcomed by all in the profession.

Our wider economy and society face significant challenges at present; as well as the financial and social strains of the recession, the threat posed by Pandemic (H1N1) 2009 has the potential to stretch the health and other resources of this country to their limits. The role of the pharmacist in their community will be invaluable in providing information and reassurance for the public, as well as their professional expertise in the treatment and management of associated ill health. Pharmacists need to be cognisant of their responsibilities to the communities they serve, as the activities of pharmacists and retail pharmacy businesses form an essential part of the health service infrastructure readily available to the public.

The future development of the role of pharmacists will also require some 're-professionalisation' of pharmacy, as the responsibilities under the new legislation for pharmacists in all roles, but especially superintendent and supervising pharmacists, bring the profession into a new era of accountability. The essence of professionalism has been described as the "relationship of trust" between the practitioner and the patient, and all within the profession must strive to ensure that is preserved – that the patient is, and will always be, the primary concern of a pharmacist.

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Editor's Note



Pandemic (H1N1) 2009 is expected to present a significant challenge to the health services of many countries, including this one over the coming months. The role of pharmacists and pharmacy, as essential frontline health professionals and services in their communities, will have a valuable role to play, not just in the provision of those services but in the provision of information and re-assurance to the public. In recent months pharmacists have already been involved in these roles, and to support

them in this work the Expert Pharmacy Advisory Taskforce, in conjunction with the PSI and ICCPE, was pleased to have Dr Martin Henman, TCD prepare a comprehensive presentation on the pandemic and the role of pharmacy.

This presentation was originally delivered at PSI/ICCPE meetings in June and to further disseminate this important information, it is being published here in article form and will also be available via the PSI website. It is essential reading for all pharmacists. The PSI is extremely grateful to Dr Henman for the effort and commitment he has given to this work in recent weeks.

The final sections of the Pharmacy Act 2007, ie Part 6 which relates to complaints, inquiries and discipline, have been commenced by the Minister and an initial information article on Part 6 and the Code of Conduct for pharmacists is also included in this issue. Further information and details of the new systems and procedures will be disseminated in the coming months. An initial 'Guide to Making a Complaint against a Pharmacist or Retail Pharmacy Business' is available on the PSI website.

Following the appointment of new, and re-appointment of some, PSI Council members by the Minister in May, we publish a brief profile of all current Council members and we also remember former Council member Professor John Feely, who sadly passed away earlier this summer. Prof Feely made many significant contributions to pharmacy and the development of the role of pharmacists in his distinguished career and he will be missed by many.

Kate O'Flaherty

PSI News

Part 6 of Pharmacy Act 2007 commenced

The outstanding sections of the Pharmacy Act 2007, Part 6 of the Act, came into force on the 1st of August 2009. These sections provide for a Complaints, Inquiries and Discipline regime for pharmacy – a 'fitness to practise' system for pharmacists and a 'fitness to operate' system for retail pharmacy businesses. Part 6 of the Act also includes sections 63 and 64, which relate to the prohibition of certain economic relationships between pharmacists or pharmacies, and medical practitioners or medical practices.

Announcing the commencement of these sections on the 28 July, the Department of Health and Children stated that the Pharmacy Act 2007 is an essential piece of legislation that provides for the health, safety and welfare of patients and the public. "The Act enables pharmacists to practise in a regulated, controlled and safe environment and in a manner which will ensure the provision of high-quality service, in the context of increasingly complex and evolving care and therapeutic regimens for patients. It also requires pharmacy owners to demonstrate responsible and accountable practices, whilst providing the highest level of patient care and service. The Act, now fully enacted, puts in place a modern fitness to practice structure aimed at safeguarding the public, and members of the profession in respect of their professional conduct."

The commencement of Part 6 of the Pharmacy Act 2007 completes the third and final stage of implementation of the Act. Two separate commencement orders were signed by the Minister, one concerning Part 6 and a second concerning the application of Sections 63 and 64 to registered retail pharmacy businesses, or medical practices, which were in existence immediately before the passing of the Act. The Minister has specified in this Order that the date from which the Section 64(9) of the Act will come into effect is 1st May 2010.

Welcoming the commencement, Dr Ambrose McLoughlin, Registrar and CEO of the PSI said: "This commencement is in line with the 3-phase process agreed in 2007. The commencement process for the Act is now complete, and this is a significant achievement for the PSI and the pharmacy sector, providing a modern, robust regulatory framework for the protection and benefit of patients and the profession. The Act provides for a non-pharmacist majority council, new registration systems for pharmacy and pharmacists and the

commencement of Part 6 brings pharmacy into line with the other healthcare professions. The PSI has worked and engaged with the profession and sector - which is heavily supportive of the process - in the preparation for the new system. The PSI will now continue with the full implementation of the Act in the interests of the health, safety and welfare of patients and the public."

An outline of the provisions of Part 6 of the Pharmacy Act 2007 is on page 76 of this issue.

Council Meeting 26 May 2009

The PSI Council held its 11th meeting on 26 May 2009 at the offices of An Bord Altranais, Blackrock, Dublin. This was the first meeting of the new Council following the appointment of a number of new members by the Minister, including a number of pharmacists selected by an election process, and the re-appointment of other members whose original term of office had expired.

Election of President and Vice-President

The first item on the agenda was the election of President and Vice-President. The Presiding Officer for the election was the PSI's Pharmacy Policy Advisor Tom McGuinn, and the PSI's internal auditor, Jack Crowley, acted as independent scrutineer for the election process. There were two candidates for President – outgoing President Dr Bernard Leddy and Noeleen Harvey, Chair of the Standards and Practice Committee, while there was just one candidate nominated for the Vice-President, Paul Fahey. Following a brief statement from each candidate outlining their credentials for the vacant posts, Paul Fahey was questioned as to whether he considered that his connection with the IPU would conflict with his role as Vice-President of the PSI, and if so had he considered severing this connection, as there may be an issue of public perception, and the public trust in and perception of the PSI as an independent regulator was of paramount importance. Paul Fahey responded that he was not an officer of the IPU and informed Council that he provides a consultancy service on IT and economic issues to a number of clients, including the IPU. He added that he was very conscious of keeping the various areas of his professional life separate and that he would be guided in the role of Vice President by the provisions of the Pharmacy Act 2007 and the relevant codes of conduct.

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- ✓ Nettle rash
- ✓ Heat rash
- ✓ Sunburn
- ✓ Chickenpox
- ✓ Personal itching



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Date of last review: April 2008
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Novartis Consumer Health, Horsham, R112 5AB.
*IMS OTC Quarterly Pharmacy Sales 52 Wk 12/2008

The Council then proceeded to hold the election and Noeleen Harvey was elected President, while Paul Fahey was elected Vice-President. The Registrar, on behalf of all the staff, congratulated both on their respective elections and wished them success. He thanked their predecessors Bernard Leddy and Brendan Hayes for their service and commitment. Council agreed that the membership of its Advisory Committees would continue until its meeting in September, with Paul Fahey acting as Chair of the Registration and Qualification Recognition Committee and Rita Purcell as Chair of the Finance, Administration and Corporate Governance Committee on an interim basis until September. A working group comprising of a number of Council members also reported on their review and recommendations on the role of the Vice-President, outlining a number of responsibilities that Council may wish to request the Vice-President to undertake.



Newly-elected President
Noeleen Harvey

Motions regarding Fees

Council considered two motions in relation to fees applied by the PSI. The first was in relation to the waiving of the fee for the cancellation of registration of a retail pharmacy business (€500) in the specific case where the same retail pharmacy business was being re-registered without a change in beneficial ownership. This motion was approved in principle by Council subject to clarification of the issue of beneficial ownership.

The second motion related to the application fee for pre-registration pharmacy students to undertake the in-service training programme. The Council approved an arrangement whereby a fee of €156 paid by the relevant students to the old PSI would be taken into consideration against the application fee of €1,500, the application fee could be paid in two instalments and the additional fee for the Professional Registration Examination due to be taken by these students in November 2010 following successful completion of the programme, would be waived.

Council also approved a proposal to request the Minister for Health and Children to vary fees relating to the restoration of a pharmacist or a pharmaceutical assistant following cancellation for failing to pay fees, to correctly reflect the intention of the PSI in respect of the fee levels to be applied.

Interim In-Service Practical Training Programme

The Chair of the Professional development and Learning Committee, Dr Paul Gallagher, outlined to Council regarding the need to empower the Registrar to pursue the establishment and management of an interim in-service practical training programme (II-SPTP) as a solution to the current difficulties faced by pre-registration students in sourcing placements. Expressions of interest are to be sought from institutes who are equipped to deliver a practical training programme, including its management and administration, with a planned start date of 01 October. It is intended that the interim arrangement would operate for three years. Council agreed that this is an urgent issue. The Registrar indicated that the Pharmacy Education and Accreditation Reviews (PEARS) project, of which interim findings will be available in the Autumn, is reviewing the area of pre-registration training.

Other Matters

The PSI is one of a number of bodies which had collaborated with the Irish Medicines Board on new Guidelines for the provision of Point of Care Testing (POCT) in primary, community and continuing care environments, including retail pharmacy businesses. These guidelines were brought to Council for their endorsement by the Chair of Standards and Practice, Noeleen Harvey. It was agreed that collaborative working and co-operation with bodies such as the IMB is an important mechanism for the delivery by regulators and statutory agencies of enhanced patient protection and public safety in the long run.

Council also discussed and approved the PSI Risk Management Policy and Guidelines document, and discussed matters in relation to the development of policy for implementation of Part 6 of the Pharmacy Act 2007. Chair of the Pharmacy Ireland 2020 working group Cathriona Hallahan updated Council on the progress to date, including discussions with the ESRI with regard to economic modeling. Council was also updated in relation to the Irish bid for a future International Pharmaceutical Federation (FIP) Congress in Ireland and which is hoped to result in a positive outcome shortly.

Council was informed that an additional meeting would be required during the summer to deal with a number of statutory matters and the next scheduled meeting is 29 September 2009.

Following the Council meeting, two development sessions for Council members were held, the first being led by Paul Turpin, governance specialist with the Institute of Public Administration on the Corporate Governance Framework document, and second on decision-making skills in relation to statutory functions being led by specialist legal training consultants La Touche Training.

Council Meeting 7 July 2009

An additional Council meeting was held on 7 July to deal with a number of statutory matters, which were dealt with by Council in private session, with an independent legal assessor and relevant PSI staff available to Council as necessary. Council was also updated on the process to develop the interim in-service practical training programme and informed that, following receipt of expressions of interest from academic institutions to develop and manage this interim programme, a preferred institution had been selected following the recommendation of an independent assessor. All information in relation to the institutions involved was anonymised and Council was informed that discussion on formalising a legal arrangement would now proceed and the result of this would be brought back to Council in due course.

Photo Requirement for Continued Registration 2010

Pharmacists and pharmaceutical assistants have been requested to submit photographs to the PSI for the purposes of their certificates of continued registration from 2010 onwards. Under rule 13(1)(g) of the Pharmaceutical Society of Ireland (Registration) Rules 2009, certificates of continued registration must display a photograph of the registrant, with effect from 01 January 2010.

Pharmacists and pharmaceutical assistants have been asked to submit two passport-type photos, by the end of August 2009, in order to facilitate the continued registration process for 2010. Application forms for continued registration will be issued by post to registrants two months prior to the expiry of current certificates of registration, which for the majority of pharmacists whose certificates expire on 31st December 2009, means these application forms will issue by end October. However, in order to facilitate the production and issue of certificates and cards with the photographic identification, it is essential that the PSI receives the photos in advance of the continued registration process and the co-operation of pharmacists and pharmaceutical assistants with this requirement is greatly appreciated.

The requirements for the photographs are in line with usual passport-type photographs and may be in colour or black and white. These photographs will be valid for a maximum period of 10 years and will be displayed on the annual registration certificates and professional identity cards from 2010 onwards. However, registrants will have the option of updating their photograph within the 10 year period if they so wish.

Online Facilities for Registrants

The PSI is pleased to inform pharmacists, pharmacy owners and pharmaceutical assistants that new online facilities will soon be available which will allow registrants update some of their personal details, such as contact details, online and also apply for continued registration, including payment of the annual fee online. This facility will also be available for retail pharmacy businesses to update contact information online and also apply and pay for continued registration online.

In order to use this facility, which will be accessible via the PSI website www.pharmaceuticalsociety.ie, registrants will shortly be sent letters containing a PIN and a password unique to themselves which will allow them to use this facility.



IMSN Notice re: Guidelines

The Irish Medication Safety Network (IMSN) has launched best practice guidelines for the safe use of intravenous potassium in Irish hospitals. Guidance is provided for the storage, prescribing, dispensing, administration and monitoring of patients on intravenous potassium, and is based on best practice as of August 2009.

A full copy of the guidance can be obtained by contacting irishmedsafety@gmail.com

IMSN is an independent group of pharmacists and other specialists working in the acute sector with the principal aim of improving patient safety with regard to the use of medicines through collaboration, shared learning and action.

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- ✓ Chickenpox
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*IMS D.P.C. Quarterly Pharmacy Sales 52 Wk 12/2008

Council Member Profiles



Stephen Boyle

Stephen Boyle is a secondary school teacher from Gowran in Co Kilkenny. Since 1995 he has worked at Kilkenny College, teaching Construction Studies, Design Communication Graphics, Materials Technology, Wood and Technical Graphics. He is also the College's President's Award Leader for An Gaisce.

Mr Boyle was appointed to the PSI Council as a Public Interest Nominee. His appointment ends 21 May 2013.



John Collins

John Collins grew up in Limerick city and studied pharmacy in Trinity College Dublin. After some initial community experience in the Dublin area, he subsequently held positions in University College Hospital London and the Royal Sussex County Hospital in Brighton. John and his wife Caoilfhionn (also a pharmacist) returned to Ireland in 1992 and opened their community pharmacy in Kinsale, Co. Cork. John is an accomplished photographer, holding a certificate in professional photography, and has combined this interest with a love of the sea in building a portfolio of underwater images over many years. John is also a crew member of the Kinsale RNLI lifeboat.

Mr Collins is a pharmacist appointee to the PSI Council. His appointment ends 21 May 2013.



Margaret Doherty

Margaret Doherty graduated from the School of Pharmacy in Trinity College in 1984. She returned to Donegal to complete her pre-reg training with the late Tom Carley in Raphoe and never left there, buying the business from him in 1994. From 1999 until 2008 she held the position of Community Pharmacy Advisor to the North Western Health Board (later HSE-West), working on such areas as out-of-hours care, smoking cessation and a DUMP campaign. During part of that time she was also a member of Co-operation and Working Together (CAWT), which is group promoting cross-border co-operation in healthcare delivery. In 2007 she received a diploma in Coronary Heart Disease Prevention in Primary Care from the University of Huddersfield.

Ms Doherty is a pharmacist appointee to the PSI Council. Her appointment ends 21 May 2013.



Paul Fahey

Paul Fahey is a Community Pharmacist from Tullamore, Co. Offaly. He holds a BSc (Pharm) Hons and a Post-Graduate Diploma (Community Pharmacy) from Queens University, Belfast. He is owner of Fahey's Pharmacy, Patrick Street, Tullamore and also works as a freelance IT/Remuneration Consultant.

Mr Fahey is a pharmacist appointee to the PSI Council. His appointment ends 21 May 2013.



(Georgina) Ann Frankish

(Georgina) Ann Frankish, having graduated from the UK, has served as Chief Pharmacist at the Rotunda Hospital, Dublin, for 23 years. She was previously a member of the Council of the old PSI.

Ms Frankish is a pharmacist appointee to the PSI Council. Her appointment ends 21 May 2013.



Paul Gallagher

Dr Paul Gallagher is a Senior lecturer at the School of Pharmacy of the Royal College of Surgeons in Ireland (RCSI). He is also Director of Education at the School of Pharmacy and a former convenor of the Research and Ethics Committee at RCSI.

Dr Gallagher was nominated to the PSI Council by the Directors of the Schools of Pharmacy at RCSI, Trinity College and University College Cork and is at present Chair of the Professional Development and Learning Committee.

Dr Gallagher was appointed to the PSI Council as Schools of Pharmacy Nominee. His appointment ends 21 May 2011.



Eoghan Hanly

Eoghan Hanly graduated from Robert Gordon University Aberdeen 1995 with a degree in Pharmacy. Since 1996 he has served as a pharmacist in the family business in Loughrea, Co. Galway, which was established by his grandfather, P.J. Killian in 1940. His mother, father and sister are also pharmacists.

Mr Hanly is a pharmacist appointee to the PSI Council. His appointment ends 21 May 2013.



Cathriona Hallahan

Cathriona Hallahan is from Kilternan in County Dublin, and is qualified as a Certified Accountant. She is Worldwide General Manager of Operations for Microsoft Business Solutions. She is also Executive Coach for Internal Microsoft Staff and External Clients, as well as holding directorships for a number of personal investment companies.

Ms Hallahan was appointed to the PSI Council as a Public Interest Nominee. Her appointment ends 21 May 2011.



Noeleen Harvey

Noeleen Harvey is a Community Pharmacist who first registered with the PSI in 1976. She is currently owner at Dargan's Pharmacy in Dublin 7 and is also a member of the Drugs & Therapeutics Committee for the Mater Hospital. She was previously a Board Member for the Eastern Regional Health Authority. She was a member of the Council of the old PSI, and served on its Drug Abuse Project Team from 2000 to 2004. Noeleen was elected President of the PSI in May 2009.

Ms Harvey is a pharmacist appointee to the PSI Council. Her appointment ends 21 May 2011.



John Hillery

Dr John Hillery is a consultant psychiatrist and former President of the Medical Council of Ireland. He is also currently the Chair of the International Association of Medical Regulatory Authorities (IAMRA).

Dr Hillery was appointed to the PSI Council as a Public Interest Nominee. His appointment ends 21 May 2013.

contd. next page

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*Thomas E et al. ISHP. Sep 08, Milwaukee, Wisconsin

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Supply Classification: sale through pharmacy only

Date of Preparation: August 2007.

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Item No: GIIE-02-09 **Prep. Date:** May 09



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Aidan Horan

Aidan Horan is a qualified accountant, who specialises in the area of governance of state bodies and public benefit entities. He has been nominated to a number of board and audit committee roles in Ireland and he is currently a board member of the Public Finance and Management Board of the Chartered Institute of Public Finance and Accountancy (CIPFA) in London. He is a former member of the PSI Audit Committee.

Mr Horan was appointed to the PSI Council as a Public Interest Nominee. His appointment ends 21 May 2013.



Sean Hurley

Sean Hurley is Head of Process and Organisation for the HSE, Wilton Road, Cork.

Mr Hurley was appointed to the PSI Council as HSE Nominee in May 2009. His appointment ends 21 May 2013.



Ita Kelleher

Ita Kelleher is a retired Community Mental Health Nurse. She is also Treasurer of the Friedrich's Ataxia Society in Ireland.

Ms Kelleher was appointed to the PSI Council as a Public Interest Nominee. Her appointment ends 21 May 2013.



Deirdre Larkin

Deirdre Larkin is a Chartered Accountant from Templeogue in Dublin. She is a member of the Institute of Chartered Accountants of Ireland and has a BSc in Business Management (Accounting). Previously she has served as a Board Member for the Irish Health Services Accreditation Board.

Ms Larkin was appointed to the PSI Council as a Public Interest Nominee. Her appointment ends 21 May 2013.



Bernard Leddy

Dr Bernard Leddy is a pharmacist from Lismore, Co Waterford. He is Director and General Manager of pharmacy chain, Mari Mina Pharmacies. Born, reared and educated in England, he qualified as a pharmacist and attained a PhD there, before emigrating to Ireland. He subsequently undertook post-doctoral work in the chemistry department of UCC. Following this, he began his career in community pharmacy. He is a member of Lismore Town Council and is currently Mayor of Lismore. He has served as both President (2008–2009) and Vice-President (2007–2008) of the PSI.

Dr Leddy is a pharmacist appointee to the PSI Council. His appointment ends 21 May 2011.



Kate Mulvenna

Kate Mulvenna is Chief Pharmacist with the Primary, Community and Continuing Care pillar within the HSE. A community pharmacist of 20 years' experience, Kate also worked in a hospital environment for some time. She took up position as a Primary Care Pharmacist with the Health Services in 1997. She was previously a member of the Council of the old PSI immediately prior to the enactment of the Pharmacy Act 2007.

Ms Mulvenna is a pharmacist appointee to the PSI Council. Her appointment ends 21 May 2013.



Michelle Ní Longáin

Michelle Ní Longáin is a solicitor who qualified with LLB (Honours) from Queens University, Belfast. She is from Dublin and is currently a Partner at BCM Hanby Wallace Solicitors. She is also a member of the Council of the Law Society of Ireland and serves on two of its regulatory committees: Complaints & Client Relations and Education. In addition, she is a member of the Litigation and Labour Law Committee for Dublin Solicitors' Bar Association. She previously worked as a solicitor in England, Wales and Northern Ireland and was formerly a member of the Research Ethics Committee for the NEHB.

Ms Ní Longáin was appointed to the PSI Council as a Public Interest Nominee. Her appointment ends 21 May 2013.



June Nunn

June Nunn is Professor of Special Care Dentistry, Dublin Dental School and Hospital. There she also holds the post of Head of Division, Public and Child Dental Health, and is the hospital's Director of Teaching and Learning (Postgraduate). She previously worked as Senior Lecturer, Child Dental Health at the University of Newcastle upon Tyne, in the UK.

Ms Nunn was appointed to the PSI Council as representative of the provision of continuing professional development in relation to pharmacy. Her appointment ends 21 May 2011.



Darragh O'Loughlin

Darragh O'Loughlin is a Community Pharmacist from Tuam, Co. Galway. His previous positions as a pharmacist include community pharmacist in Salthill, Galway; pharmacy manager, in Cork City and basic grade pharmacist at Our Lady of Lourdes Hospital, Drogheda.

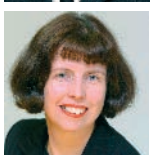
Mr O'Loughlin is a pharmacist appointee to the PSI Council. His appointment ends 21 May 2011.



Noirin O'Sullivan

Assistant Commissioner, Noirin O'Sullivan, joined An Garda Síochána in 1981. Originally from Coolock, Dublin, she became Superintendent in 2000. She was promoted to Chief in 2003, and became an Assistant Commissioner in 2007. Currently Assistant Commissioner of Crime and Security, she has previously served as Assistant Commissioner in the Technical Bureau, Garda National Drugs Unit and as Assistant Commissioner, Western Region.

Ms O'Sullivan was appointed to the PSI Council as a Public Interest Nominee. Her appointment ends 21 May 2013.



Rita Purcell

Rita Purcell is a Chartered Accountant, who holds a Bachelor of Law and a Diploma in Professional Accountancy. She is a Fellow of the Institute of Chartered Accountants. She is currently Director of Finance and Corporate Affairs for the Irish Medicines Board. Her previous positions were as Head of Internal Audit for the Irish Dairy Board and as a manager at Price Waterhouse Coopers.

Ms Purcell was appointed to the PSI Council as the IMB Nominee. Her appointment ends 21 May 2013.



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virus kept in reference laboratories show that it originated in swine, and has presumably been evolving there for some time. But, unlike H5N1, the ease with which Pandemic (H1N1) 2009 is transmitted from one human to another shows that it has become completely adapted to humans and there is no evidence that contact with swine or consumption of swine tissues causes infection. Pandemic (H1N1) 2009 is now officially considered to be a human influenza, but is named human swine influenza to reflect its origins.

These two mechanisms for antigenic change give influenza the capability to produce epidemics and pandemic in the human population. Small changes mean the immune system can still detect and respond to a virus relatively quickly, since the virus is similar to the one(s) for which it has built up immunity, and this usually results in mild symptoms in a limited proportion of the population and serious complications in a much smaller group. Epidemics of seasonal influenza occur every year and strains of Pandemic (H1N1) 2009 viruses have circulated as recently as 2006-2007. Its characteristics were only slightly different to other H1N1s from previous years and so its impact was limited. In contrast, antigenic shift, with big changes in the H and N proteins enables the virus to infect many cells and to pass from host to host before the immune system has time to mount a substantial response. The Human Swine Influenza of this pandemic is the result of antigenic shift and crucially, its H and N proteins are substantially different to those seen in seasonal influenzas. This usually results in more severe symptoms in a larger proportion of the population and also leads to a significant number of this larger total infected population at risk of developing serious complications. If the combination of these two groups is sufficient, the numbers of patients seeking treatment and care could overwhelm the capacity of the health service.

Antiviral drugs

The main class of antiviral drugs is the neuraminidase inhibitors, and both oseltamivir and zanamivir have been stockpiled by the government, and the distribution of a portion of those stocks to community and hospital pharmacies has now taken place. Both are authorised by the Irish Medicines Board for the treatment and prevention of influenza in adults and children.

They inhibit the working of the neuraminidase enzyme, the N protein referred to earlier, thus preventing any new viral particles from being released from the cell surface into the surrounding tissue fluid. This localises the infection, but it can only do so efficiently if the drug is taken within 48 hours of infection, since the virus replicates and spreads quickly in the body. Both types A and B of influenza, and all nine types of neuraminidase proteins, are susceptible to oseltamivir and zanamivir. Some studies, including a recent clinical trial in general practice in Japan, provide evidence that zanamivir may be more effective against influenza B than oseltamivir.

Randomised, controlled clinical trials have shown that both drugs are effective against seasonal influenza virus strains, when used to treat infected adults and also when used in post-exposure prophylaxis. Systematic reviews in the Cochrane library have shown that, when used as treatment, they reduce the severity of symptoms and the duration of symptoms in adults by approximately 1 day and in children by around 36 hours. Notably, oseltamivir also reduces the incidence of complications, which include bronchitis and pneumonia. An updated Cochrane Review shows that oseltamivir may only reduce the complication of otitis media in children between 1 and 5 years of age. Viral shedding, the excretion of virus into the nasal mucus, is reduced, thus potentially limiting the spread of virus from one person to another.

Both drugs can reduce the spread from cases (people with an infection) to contacts (those who look after, live or work with them), and there is good evidence that oseltamivir reduces the spread of seasonal influenza among groups, such as would be found in residential homes, and there is rather less evidence that zanamivir is effective in this form of prophylaxis as well.

However, all of this evidence was obtained in cases in which the infecting virus was one of a number of seasonal influenza strains. Observational evidence from this pandemic suggests that oseltamivir, the drug that has been most frequently used, is effective against Pandemic (H1N1) 2009, and so for the moment it can be assumed that the drug's characteristics will be the same as those reported in clinical trials involving other influenza A strains.

Oseltamivir

Oseltamivir is orally active and available in capsules and as a suspension. The two dose forms seem, from a small study to be bioequivalent. It is quickly and almost completely absorbed from the gastro-intestinal tract and

its absorption is not significantly affected by food, or by the common ingredients of antacid preparations, magnesium and aluminium hydroxides and calcium carbonate. It has low protein binding and distributes rapidly into the tissues of the respiratory tract. It is converted in the body to a carboxylate, which is the pharmacologically active molecule, and this is excreted unchanged in the urine by a combination of glomerular filtration and tubular secretion. There is evidence that the pharmacokinetic properties of the drug are similar in patients suffering from an influenza infection to the properties established in studies in healthy volunteers. The conversion to the active metabolite is catalysed by hepatic esterase enzymes of which there are a substantial excess and, consequently, in studies with patients with impaired liver function no change in the conversion of oseltamivir into the carboxylate was found. However, in patients with moderately impaired renal function (creatinine clearance >10 to ≤ 30 ml/min) the dose for treatment of an adult should be reduced to 75mg once daily or 30mg twice daily, while in patients with poor renal function (creatinine clearance ≤ 10 ml/min) the drug is not recommended.

Since oseltamivir is not metabolised by any of the enzymes most commonly associated with drug metabolism (cytochrome P450), and since studies show that it does not bind significantly to these enzymes, drug interactions of this sort have not been reported. Studies of patients who took paracetamol or amoxycillin on the fifth day of a course of oseltamivir did not show any evidence of interactions. However, if a patient were concomitantly taking probenecid, this would reduce the tubular secretion of oseltamivir carboxylate and increase the serum concentration of the drug, although the size of this effect is not considered clinically significant. Oseltamivir's low protein binding eliminates the possibility of drug interactions from this route. However, the SPC for Tamiflu (oseltamivir) recommends that care should be taken with 'co-excreted agents with a narrow therapeutic margin (e.g., chlorpropamide, methotrexate, phenylbutazone)'.

Oseltamivir is well-tolerated. Pre-clinical studies showed that the drug was of low toxicity and that the difference between the concentration required to inhibit neuraminidase and the concentration required to cause cytotoxicity was several orders of magnitude. In clinical trials and from subsequent pharmacovigilance reports it is apparent that nausea, vomiting and headache are the most frequently experienced side effects. Nausea and vomiting can be significantly reduced by ensuring that patients take the drug with food and since food does not alter the absorption of the drug this will not affect the drug's activity. Headache will be noticed by patients using the drug for prophylaxis but has not usually led to discontinuation. Neuropsychiatric and neurological events are discussed below.

Zanamivir

This drug is not orally active. Its bioavailability by the oral route is approximately 2%. It is available in this country as an inhaled formulation, as a dry powder in blister packs, for use with the Diskhaler®. Zanamivir is active within minutes of being taken and is well tolerated, partly because it has low toxicity for mammalian cells and partly because only trace amounts are absorbed into the circulation. The drug does not seem to be metabolised and shows low protein binding thus having very little potential for drug interactions. No reduction in dose is required for patients with impaired kidney or liver function.

The principal limitation on the use of zanamivir is that patients must be able to use the Diskhaler effectively, hence the drug is not approved for use by children below the age of five and frail patients may not be capable. The European Medicines Agency has approved, in principle, the distribution of Relenza® (zanamivir) with a Rotacap®/Rotahaler® inhalation device during influenza pandemic, but it is up to the Irish Medicines Board to decide whether to authorise, temporarily, the national distribution and use of the Relenza Rotacap/Rotahaler during the pandemic.

Dosing and use in special groups of patients

Oseltamivir has been authorised for use in adults and children over 1 year of age for treatment and prevention. Infants over 1 year and children under 13 years of age may be dosed according to their body weight. In all age groups, two doses are taken daily for 5 days for a course of treatment, whereas one dose is taken daily for 10 days for prophylaxis. There has been no change to these dosing recommendations and they can be found in the SPC and PIL for the product Tamiflu®.

Oseltamivir capsules, 30mg, 45mg and 75mg are all available and for those who are unable to swallow capsules, they may be opened and the contents mixed with a teaspoon of a liquid food such as yoghurt or a similar

pandemic (h1n1)

food, as described in the PIL for Tamiflu®. There are also instructions on how to dissolve in the product in water, oseltamivir is water soluble, and these can also be found in the PIL or as a single page printable sheet on the Health Protection Surveillance Centre's website (<http://www.hpsc.ie/hpsc/> —> Advice for Health Professionals —> Pharmacists and Pharmaceutical Information). Information on an extemporaneous preparation is available (www.extemp.ie).

In May the European Medicines Agency published an opinion of certain aspects of the Market Authorisations of Tamiflu® and Relenza®. A group of experts assessed evidence from the Market Authorisation Holders, from ongoing and unpublished studies and reports and evaluations from within the EMEA. Based upon this review they recommended that, in the event of a pandemic being declared by the WHO that;

- Infants below 1 year of age with A/H1N1 influenza could be treated with oseltamivir at a dose of 2-3mg/kg body weight twice daily for 5 days. The paediatric suspension or the use of capsules as outlined above would be suitable for this age group.
- The use of the drug for prophylaxis of A/H1N1 at the same dose for 10 days would be acceptable if this was in line with national policy.
- Side effects of diarrhoea and vomiting were reported in the studies, so administration with food would be advisable.
- Both oseltamivir and zanamivir would be suitable for use in women who are pregnant or breastfeeding in cases of A/H1N1 infection. The EMEA did not consider that there were additional risks to the foetus based on pre-clinical studies and case reports and case series of the use of the drugs in pregnancy.

The IMB has discretion in the measures it adopts in this country and together with the EMEA may change the conditions of the Market Authorisation of the products as new information and evidence alters their assessment of the benefits and risks and any changes can remain in force only while a Pandemic criteria are considered to be fulfilled.

An older drug, amantadine, which is licensed for prophylaxis of seasonal influenza, is of limited usefulness because of side effects (mainly CNS and GIT) and because resistance occurs easily, is widespread and is probably inherited by influenza strains before exposure to the drug. The Pandemic (H1N1) 2009 influenza carries a genetic marker of resistance. However, in these special circumstances it may be used in hospital practice in serious cases in combination with other antiviral drugs.

In the US and some other countries, rimantadine, a derivative of amantadine, is licensed.

Distinguishing influenza from the common cold and responding accordingly

The symptoms and signs of minor upper respiratory tract infections are well known to pharmacists and their staff but it is essential that this knowledge is reviewed by the pharmacist with their staff team, whether pharmaceutically qualified or not. Distinguishing between the different conditions is based upon a combination of the symptoms experienced and the timing of those symptoms. Influenza produces its symptoms within a few hours and they are noticeable, discomforting and even disabling. A fever of 38°C or more, prominent headache, muscle aches and pains (myalgias), cough (dry) and sore throat accompanied by the feeling of fatigue are the most common symptoms with influenza infections. Pandemic (H1N1) 2009 also seems to produce rather more gastro-intestinal disturbance than seasonal influenza and estimates of up to 25% of patients experiencing nausea and diarrhoea have been reported.

By contrast, the adenoviruses and corona viruses that cause coughs and colds have a gradual onset over a day, with runny nose (rhinorrhoea) and sneezing as prominent symptoms early on, with sore throat and cough (dry or productive) and occasionally fever (never as high as 38°C), but rarely myalgia and fatigue. Patients can usually keep on going about their normal activities for a day or so as the symptoms are annoying rather than incapacitating.

Medicines such as paracetamol and ibuprofen are recommended as symptomatic relief for fever and myalgia in otherwise healthy patients. There is a reluctance in official pandemic planning documents to discuss other non-prescription medicines, probably because the evidence base for their use and efficacy is much less substantial than that for the antipyretics. However, patients clearly obtain relief from their symptoms since they make repeated requests for such products. If dry cough is a problem then suitable antitussive preparations are available, bearing in mind that dextromethorphan and pholcodeine do not possess the constipating effect

of codeine, and that patients taking an analgesic preparation, whether prescription or non-prescription, need to know its constituents so that they do not unwittingly take two doses of codeine or two of paracetamol. Products for sore throats can be recommended, while those for other symptoms require some confirmation of the history. For example, antihistamines such as diphenhydramine and triprolidine are used to dry up secretions in colds and are likely to be less needed in influenza since excessive respiratory tract secretions are not usually a notable feature of the illness. Preparations containing these ingredients might be suitable for otherwise healthy patients, but in those with COPD or a history of bronchitis, particularly elderly patients, it would be prudent to avoid using these drugs since any generalised drying up of respiratory secretions might adversely affect mucus production and clearance. Although Pandemic (H1N1) 2009's capacity to damage the respiratory mucosa in these patients is somewhat greater than seasonal influenza, it still seems to be moderately active, and patients with COPD and other chronic obstructive respiratory conditions are at risk of complications. In addition the anticholinergic activity of the sedating antihistamines produces some degree of cognitive slowing and this too should be avoided in elderly patients who may live alone and have to care for themselves.

Advice about the treatment of young children was updated in the letter to medical practitioners from Public Health that was circulated via the PSI in July. Teenagers and children over 6 years of age with mild to moderate symptoms and without a concomitant condition can take an antipyretic.

In young children, those under 6 years of age, without any other conditions, antipyretics, such as paracetamol, should be used alone rather than in combination with other drugs, and the recommended dose and frequency of dosing should be followed.

Children under two years of age are a risk group and should be offered paracetamol and referred for assessment and monitoring.

Patients at these younger ages (under 5 years) present with different symptoms/combinations of symptoms to adults and so these cases should be considered by the pharmacist and referred to a GP if there is any uncertainty about their cause or course; fever, cough and rhinitis may be the only symptoms – myalgia, headache, chills and sweats and fatigue are more often absent. Non-specific symptoms such as, irritability, unwillingness to feed, vomiting, diarrhoea, abdominal pain, difficulty breathing and lethargy, may be present, but may be attributed to other possible causes.

Several complementary and alternative approaches have been promoted for their 'antiviral' activity over the years, but almost all of the studies reported have involved the common cold and not influenza. Echinacea, Chinese medicinal herbs, garlic, vitamin C, and zinc have all been the subject of Cochrane Reviews.

Echinacea is widely used as a prophylactic by patients and is being extensively promoted at the moment, largely upon the results of individual studies. However, as a systematic review of all the clinical trials has found, there is no substantial evidence for any efficacy. There is no standardisation of echinacea products and those available at the moment contain extracts of different types, varying amounts of different echinacea varieties and different components of the plant. Some of the products that are available have no clinical studies to support their use. This is not to say that the right components of the right variety at the right dose may not, one day, demonstrate efficacy, but at the moment, recommending echinacea as an effective prophylactic for Pandemic (H1N1) 2009 infection or as an alternative to rest and symptomatic relief would be inappropriate. Patients may choose to use the products in this way but it should be in the knowledge that there is no evidence of efficacy. The German Medicines Regulatory Authority recommends that echinacea products should not be used for longer than eight weeks. Rash has also been reported as a side effect of echinacea use.

In Chinese medicine, mixtures of herbs are used to treat acute upper respiratory illness; the permutations used depending upon the nature of the condition. A Cochrane Review has reported that the poor quality of the evidence currently available does not allow a judgement for or against to be made.

Garlic has not been extensively studied and, although the only trial of suitable quality for assessment showed some reduction in incidence, the number of days to recovery was similar. Not surprisingly, odour, but also rash were the side effects reported.

Vitamin C has long been put forward for the treatment and prevention of the common cold, there is no substantial evidence to support its use, although regular use may slightly reduce the severity and duration of common cold symptoms.

Zinc deficiency is known to impair the immune response but unless the patient has been severely malnourished for some time they are highly



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unlikely to be deficient and, if not, there is no evidence that additional zinc intake will augment the immune response.

Promotional material for some products containing these ingredients imply that they have antiviral activity or improve the functioning of the immune system and so would be effective against viruses and other infectious agents. There is, however, no evidence for this and a pandemic influenza, such as Pandemic (H1N1) 2009, is, by its very nature, substantially different and so may well be an exception to this hierarchy of assumptions.

Complications of influenza and at risk patients

In most people's minds, the terms epidemic and pandemic imply the seriousness of the situation, and the WHO number scale has probably helped reinforce this. In fact, these terms are used to describe the geographical spread of the disease, not its seriousness. All influenza viruses can produce complications and mortality rates from influenza have increased in most industrialised countries over the past 30 years, probably because of an ageing population and of increased numbers of 'at risk' patients as a result of more effective treatment of their conditions.

Antivirals such as neuraminidase inhibitors act rapidly and treated patients develop less severe and fewer noticeable symptoms than untreated patients. Mitigation of symptoms should occur within 48 hours, if it does not and the severity of the symptoms does not diminish or if the patient deteriorates then they should be referred immediately because they may be developing a more serious infection and be at risk of complications. The warning signs for adults shown below are indications for immediate referral:

- shortness of breath, either during physical activity or while resting
- difficulty in breathing
- turning blue
- bloody or coloured sputum
- chest pain
- altered mental status
- high fever that persists beyond 3 days
- low blood pressure.

Bronchitis, sinusitis, otitis media and pneumonia are all obvious potential complications of influenza. Although influenza damages cells in the respiratory tract directly, particularly through the actions of neuraminidase, elsewhere in the body another mechanism(s) may be responsible. It is thought that some of the other genes of the virus are responsible for the complications and that they may act in two ways to bring about their effects. First of all, when the virus enters the respiratory tract it elicits a response from the immune system that helps to begin the process of containing the infection and of producing antibodies to the virus. Highly pathogenic virus strains interfere with this early phase of the immune response and this gives the virus a head start. Secondly, it has been shown that later on in the course of the infection, an excessive, dysfunctional immune response floods the tissues with immune system messengers, cytokines, and that it is these molecules that cause much of the additional damage. This 'cytokine storm', as it is known, has been shown to occur with the 1918 pandemic influenza strain ('Spanish Flu') and other highly pathogenic strains.

Complications occur in a small proportion of otherwise healthy patients and some of those who are at risk, even with strains of influenza that cause mild disease, and they occur every year with seasonal influenza. However, in strains that produce more severe symptoms, these complications occur with greater frequency and in patients who are otherwise healthy. Pandemic (H1N1) 2009 has some of the characteristics of a highly pathogenic virus in laboratory experiments but it has not produced these complications very frequently so far in the populations infected. In 'at risk' patients their concomitant conditions and/or their drug treatment make them especially vulnerable to the complications of influenza and their conditions can deteriorate rapidly if the functioning of other major organs, such as the liver or kidneys, is affected by the excessive cytokine concentrations.

Patients with risk factors who remain at home and are being monitored can use paracetamol as an antipyretic. As a precaution, pharmacists should ensure that whichever prescriber is monitoring the patient, reconciles the list of medicines in their records with the PMR kept in the Practice.

The most common forms of complications, those in the respiratory system, frequently involve other infectious agents. Respiratory Syncytial Virus and Parainfluenza viruses cause acute respiratory illnesses by themselves to varying extents in different age groups. Additional, initially empirical,

antiviral drug use, particularly ribavirin, often in combination with a neuraminidase inhibitor and possibly also amantadine, will be considered in tertiary referral centres and published reports suggest benefit in some patient groups. More frequently, secondary bacterial pathogens, *Streptococcus pneumoniae*, *Staphylococcus aureus* and *Haemophilus influenzae*, are detected. However, other organs and tissues may also be affected and myocarditis, myositis, encephalopathy and Reye's syndrome are among other potential complications.

Treatment of the complications of influenza involves intensive monitoring and support of the respiratory, renal, hepatic and cardiovascular systems. Where bacterial infection occurs, either as secondary infection or as mixed viral and bacterial pneumonia, antibiotics will be used. In the National Pandemic Influenza Plan, drawn up in 2007, a standard approach using certain antibiotics and dose regimens was envisaged, based upon the common bacterial pathogens listed below (Table 1). Some purchase ordering and stockpiling of antibiotics have been undertaken but whether the antibiotics listed in the table are the ones that will be recommended for this pandemic is not yet clear, and what arrangements may be used to distribute these medicines to hospital pharmacies around the country or whether hospital pharmacists should be taking the initiative are also unanswered questions at the time of writing.

Table 1: Antibiotics for Secondary Infection

Preferred	Alternative
Doxycycline 200mg immediately, then 100mg daily	Clarithromycin 500mg bd for penicillin allergy
— or —	
Co-amoxiclav 625mg tds for 1/52	

Patient groups who are at risk are shown in the table below (Table 2). Most of these groups are familiar, since they are patients with chronic disease and they are usually the groups who are encouraged to seek vaccination against seasonal influenza. The extremes of age are risk factors in themselves and add to the risk of chronic disease.

Children in the first year of life and adults over 65 years of age have essentially similar risks of hospitalisation for influenza-related complications. A high fever, without any other signs in an infant of 6 months or less, or a persistent or recurrent fever and cough in a child of less than 2 years of age, may be warning signs of complications and are all indications for referral. Prematurity and cardiopulmonary disease predispose children to exacerbations of pulmonary disease and to complication of influenza. Exacerbations of asthma and antibiotic use do not seem to be reduced in oseltamivir-treated children, nor was the incidence of otitis media altered in children of 6–12 years of age according to the most recent Cochrane Review. Table 3 is an appendix from the US Committee on Infectious Diseases regarding antiviral therapy and prophylaxis for influenza in children, published in 2007, which outlines the paediatric patients at high risk from complications from influenza.

Several clinical trials of oseltamivir, some in patients from risk groups are underway and so new information and guidance may be released.

One group of patients in particular, those receiving drugs that produce immunosuppression (e.g. oral corticosteroids, azathioprine, mycophenolate), can be easily identified by pharmacists from their Patient Medication Records and may otherwise be overlooked. In immunosuppressed patients the symptoms and signs of infection are masked and the consequences of infection are much more serious than in immunocompetent patients.

Another group who should be actively monitored are pregnant women, and so far those with asthma have comprised many of the reported cases. Rapid referral and frequent monitoring are essential. Conflicting advice has already been given out in the UK which added to a feeling of unease there about the NHS response. Oseltamivir, because of its systemic activity, would be the drug of choice and is the drug recommended in the US; in Ireland it is recommended that, pregnant women in the first trimester with severe symptoms, and those in the second and third trimester with influenza-like illness should receive the drug. A letter has been sent to obstetricians from the national committee about this issue and there is also guidance for GPs about 'at risk' groups on the Health Protection Surveillance Centre's website. An example of one of the cases reported by the Centers for Disease Control in May in the USA is given in Box 1.

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NEXIUM Tablets: Gastro-resistant tablets containing 20mg or 40mg esomeprazole. **Dosage and administration:** Adults (including the elderly) NEXIUM IV: Prevention of rebleeding of gastric and duodenal ulcers: Following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers, 80 mg should be administered as a bolus infusion over 30 minutes, followed by a continuous intravenous infusion of 8 mg/h given over 3 days (72 hours). The parenteral treatment period should be followed by oral acid-suppression therapy. Administration (refer to SPC for full instructions): The reconstituted solution should be inspected visually for particulate matter and discoloration prior to administration. Only clear solution should be used. The reconstituted solution for injection or infusion is clear and colourless to very slightly yellow. For single use only, any unused solution should be discarded. For the 80 mg bolus dose, the reconstituted solution should be given as a continuous intravenous infusion over 30 minutes. For the 8 mg/h dose, the reconstituted solution should be given as a continuous intravenous infusion over a period of 71.5 hours (calculated rate of infusion 8 mg/h). **Infusion 80 mg:** A solution for infusion is prepared by dissolving the content of two vials of esomeprazole 40 mg in up to 100 ml of 0.9% sodium chloride for intravenous use. **Infusion 40 mg:** A solution for infusion is prepared by dissolving the content of one vial with esomeprazole in up to 100 ml 0.9% sodium chloride for intravenous use. Shelf life after reconstitution: Chemical and physical in-use stability has been demonstrated for 12 hours at 30°C. From a microbiological point of view, the product should be used immediately. 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Elderly: No dose adjustment needed. **Contraindications:** Known hypersensitivity to esomeprazole, substituted benzimidazoles or any other constituents of NEXIUM. Esomeprazole, like other PPIs, should not be administered with acyclovir. **Precautions:** In the presence of any alarm symptoms and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment may alleviate symptoms and delay diagnosis. NEXIUM Tablets patients on long-term treatment should be kept under regular surveillance. NEXIUM Tablets contain sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take NEXIUM Tablets. Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter. **Interactions:** (See SPC for full information) Medicinal products with pH dependent absorption: Ketoconazole or itraconazole absorption may be reduced. When NEXIUM is combined with drugs metabolised by CYP 2C19, such as diazepam, citalopram, imipramine, clomipramine, phenytoin, voriconazole etc., their plasma concentrations may be increased and a dose reduction could be needed. Plasma concentrations of phenytoin should be monitored when treatment with NEXIUM is introduced or withdrawn. In warfarin, or other coumatine derivative-treated patients, monitoring is recommended when initiating and ending concomitant treatment. AUC and half-life of dispride increased/prolonged. CYP 3A4 and CYP 2C19 inhibitors e.g. clarithromycin and voriconazole may increase exposure to NEXIUM. Acyclovir use is contraindicated. The effect of esomeprazole on drugs metabolised by CYP 2C19 may be more pronounced during the high dose IV regimen (80mg/8mg/h). Patients should be monitored closely for adverse effects during the 3-day IV treatment period. **Pregnancy & Lactation:** (See SPC for full information) Exercise caution when prescribing NEXIUM to pregnant women. It is not known whether esomeprazole is excreted in breast milk. Do not use NEXIUM during breast-feeding. **Undesirable effects:** Common: Nausea/vomiting, headache, abdominal pain, diarrhoea, flatulence, and constipation. Administration site reactions (NEXIUM IV only) Uncommon: dermatitis, pruritus, urticaria, rash, dizziness, dry mouth, peripheral oedema. Insomnia, increased liver enzymes, paraesthesia, somnolence, vertigo and blurred vision (NEXIUM IV). For less common side effects refer to SPC. **Package quantities:** NEXIUM IV: 5ml vial. 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pandemic (h1n1)

Box 1: Extract from Case Report

A 29-year old woman at 23 weeks' gestation had a one-day history of cough, sore throat, chills, subjective fever and weakness. One of her sons, aged 10 years, had similar symptoms a week before the mother and another son, aged seven years, had become ill on the same day as the mother. A specimen from the mother was confirmed positive for A(H1N1)v. After being prescribed oseltamivir her pregnancy proceeded normally.

Obesity has not been identified as a risk factor for influenza complications previously. Reports of case series in the US have raised this possibility. In July, the US authorities published a report of 10 Intensive Care Cases, 9 of whom were obese. These patients were treated with antivirals even though more than 48 hours had passed since their symptoms began and they received higher than recommended doses (up to 150mg bd), depending upon their kidney function. None of the cases had evidence of bacterial infection in the respiratory tract. Empirical antiviral treatment outside the usual guidelines, coupled with intensive monitoring has been effective in many of these hospital cases.

Table 2: At-risk Patient Groups

- 65+ years of age
- Chronic respiratory disease – including asthma, COPD, cystic fibrosis
- Chronic heart disease – hypertension with cardiac abnormalities, congestive heart failure
- Chronic renal disease
- Chronic liver disease
- Diabetes mellitus and chronic metabolic disorders
- Immunosuppression and malignancy – HIV+ve, chemotherapy patients, corticosteroid (prednisolone/equivalent) 20mg or more for longer than one month
- Long-stay residents – nursing homes

Referral of patients who may be at risk should be made quickly and clearly, i.e. pharmacists should not worry about overloading the health service. It would be better to assess 20 patients and find one who needs specialist care rather than have that patient delay and present as an acute, deteriorating case, and referral made with justification – a note of the symptoms, patient's report of their history and their medicines use and, of course, include the pharmacist/pharmacy contact details – is the appropriate action. Consider this case (Box 2):

Box 2: Extract from Case Report

In February 2007, fever developed in a previously healthy 15-year-old girl, with a peak temperature of 102°F (38.9°C) and mild upper respiratory congestion. The next day she was seen by her primary care physician. A rapid screening test for group A streptococcus was negative, and oseltamivir was prescribed. After two doses, she continued to have fever and also had nausea and emesis, malaise, and restlessness but could not get out of bed. Two days later, she was taken to the local emergency room, where she was found to be hypotensive.

It is easy to be wise in hindsight, but this patient was taken to the emergency room (A&E in an Irish context), three days after starting oseltamivir (2 doses plus two days). The recommended period during which symptoms should be monitored for improvement is two days, and if no response has occurred, the patient should be re-assessed. In this case the outcome was tragic (Box 3).

Box 3: Extract from Case Report

Despite intensive resuscitative efforts, she died 12 hours later; the postmortem examination showed necrotizing pneumonia and extensive alveolar hemorrhage. A viral culture confirmed an influenza A (H1N1) infection, and methicillin-resistant *Staphylococcus aureus* was isolated from a tracheal aspirate.

The case report shown above is taken from the seasonal influenza cases of 2006–2007 in Texas, USA.

Table 3: Infants and Children at High Risk of Complications from Influenza³

- High-risk children during the 2 weeks after influenza immunisation, if influenza is active in the community
- High-risk children for whom influenza vaccine is contraindicated
- Family members or healthcare providers who are unimmunised and are likely to have ongoing, close exposure to (1) high-risk, unimmunised children or (2) infants who are younger than 6 months
- Control of influenza outbreaks for unimmunised staff and children in a closed institutional setting with high-risk pediatric residents (e.g., extended-care facilities)
- As a supplement to immunisation among high-risk children
- Post-exposure prophylaxis in a family setting
- High-risk children and their family members and close contacts, as well as healthcare workers, when circulating strains of influenza virus in the community are not matched with vaccine strains
- Ages between 6 and 24 months (no antiviral agent is currently approved for infants younger than 12 months)
- Asthma or other chronic pulmonary diseases such as cystic fibrosis
- Haemodynamically significant cardiac disease
- Immunosuppressive disorders or therapy
- HIV infection
- Sickle cell anaemia and other haemoglobinopathies
- Diseases requiring long-term aspirin therapy, such as rheumatoid arthritis or Kawasaki disease
- Chronic renal dysfunction
- Chronic metabolic disease such as diabetes mellitus
- Neuromuscular disorders, seizure disorders, or cognitive dysfunction that may compromise the handling of respiratory secretions

Pharmacies in the pandemic

Pharmacists and pharmacy owners need not just to plan but to act now to be able to operate effectively throughout the autumn period and up to the end of the year. To operate effectively, all of the team, those with responsibility for medicines and those responsible for other goods and services, full-time and part-time, need to be informed, equipped and motivated. This is an opportunity to manage a series of changes in the pharmacy that could produce a lasting alteration in the way in which patient and staff interactions occur. In particular, superintendent pharmacists need to consider how the procedures and tasks relevant to the management of the pharmacy, to medicines acquisition, storage, supply, documentation, recall, disposal and stock control, as well as patient care procedures will be managed in the event that a pharmacist, pharmaceutical assistant or pharmacy technician is unavailable and to what extent training of suitable staff in some of these skills is appropriate and feasible. A discussion needs to take place to determine how the pharmacy is to be organised while the staff are being informed about the pandemic and being trained to carry out the tasks and roles that they have been allocated. Crucial to the success of communications skills training in these circumstances will be how well the rationale for the actions and messages is understood, since once people appreciate that there is a reason, and that it has been arrived at through careful thought, they will not only accept the consequences but take responsibility for their role and the effectiveness of the team. The agenda topics for this discussion should include:

- Communication message: tone and content – knowledgeable, calm, reassuring
- Communication skills: face-to-face, telephone, public, parents and children, prescribers
- Advice about antivirals: frequently asked questions, referral criteria
- Advice about medicines for symptomatic relief: responding to symptoms, suitable products, responding to product requests



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pandemic (h1n1)

- Referral procedures for: those with symptoms that may need assessment, those whose circumstances may make them vulnerable
- Hand hygiene and cough etiquette: for everyone, every morning, afternoon and evening
- Possible setting aside of consultation area as the 'respiratory symptoms area' during the pandemic – the clearing out of extraneous items and arrangements for its regular cleaning with an appropriate disinfectant

There are many challenges in this: the message is clouded by the sheer volume of material and diversity of media sources delivering different stories and 'angles' on the issues. The provenance of the information is the crucial guarantee of the quality of the content and of the appropriateness of the tone. The websites of the PSI and the IPU, the National Plan and the documents and links to other organisations available from the Health Protection Surveillance Centre are the most reliable sources and are the basis of the advice offered here.

A pandemic in abstract is a distant and unthreatening phenomenon. As it affects those around us, it becomes an emotive and worrying reality. This is why staff need to understand and to be convinced that the right information and procedures will, ultimately, produce the best outcome. For example, an important message for staff today is, "Antivirals will not be used for everyone because it does not make sense to use them in that way – most cases will be mild – and the stock must be managed so that antivirals will be available for use by those at risk of complications in the later stages of the pandemic."

Compliance with antivirals

As is the case with other medicines, when antiviral drugs are used for treatment, compliance tends to be high, the main problem is making sure that patients finish the course of drug. When they are used for prophylaxis however, compliance is less and is more variable. The benefits of treatment, when they may be noticeable and what side effects are likely and how to deal with them, are the principal points that need to be made. The recommendations about which adults should receive oseltamivir for treatment and for prophylaxis at this stage of the pandemic clearly target those with severe symptoms and those at risk of serious illness or complications; patients in these groups can be reassured that the benefits outweigh the risks. Patients who feel confident that they have been told why they need a medicine and what to expect from it will also feel secure about making the decision whether or not to take the medicine. Even if they decide not to take the medicine they should be advised about warning signs, so they can seek help if necessary, and they should be told that they can get further advice if they want it.

Treatment of children should focus on those with severe symptoms and those at risk of complications. Although the recent Cochrane Review was able to consider the most common complication, otitis media, and to assess the reduction of episodes of asthma exacerbations, there are other complications and other chronic respiratory conditions that could not be addressed in the review. Two UK studies from the early stages of this pandemic provide some ideas about children's and parent's experiences and attitudes.

In a group of 95 school children, 41 in Primary School and 54 in Secondary School, just over 40% reported a GIT adr (nausea, stomach pain) and 18% a neuropsychiatric adr (sleeping problems).¹ Less than half of those primary school children (48%) who started oseltamivir prophylaxis, while three quarters (76%) of secondary school children completed the course. Comments from parents clearly indicated that they were sceptical of the need for prophylaxis in asymptomatic children and its scientific basis, that prophylaxis would not provide long-lasting benefit or immunity and that more information about side effects should be provided so that they, the parents, could make a fully informed choice about whether or not to use the drug.

A study in the first secondary school in the UK to be closed when a case of Pandemic (H1N1) 2009 occurred, found that compliance with the full course was high (77%), while 91% of pupils took at least seven days. Half experienced side effects, particularly nausea, headaches and stomach-ache while fewer reported tiredness and difficulty in concentrating.

It is clear from these two reports that insufficient information about side effects, even the most common and noticeable, nausea, was provided. Younger children were less likely to be given oseltamivir as prophylaxis and recent media stories will increase parent's feeling of uncertainty. In the first of the studies, apart from scepticism about the official recommendations, parents were also influenced by two other factors: (i) changing advice from the health authorities – this was viewed as evidence of unreliability of

official scientific evidence and (ii) advice from healthcare professionals that was in conflict with the official recommendations – in particular private physicians.

In advising people about non-prescription medicines, the familiarity of these products and of the symptoms can lead to complacency. A high fever can produce effects that worry young, inexperienced parents, and may lead them or their relatives in the context of the pandemic to take risks that they are unaware of. Discussing with staff that people will need reassuring of the effectiveness of antipyretics, that it is not necessary to keep dosing a child until their temperature is back to 37°C, that aspirin should not be used because of the risk of Reye's syndrome, will help them to have the confidence to deliver these messages appropriately. Similarly, the use recommendations of medicines for coughs and colds in young children (from 2–6 years of age in particular) have changed, and these should be revisited as the labelling of some products has been revised.

Smoking damages the respiratory tract and predisposes a person to respiratory infections. Even though smokers view smoking as one of their consolations in life, they need to be told that in an influenza pandemic it increases their risk of serious infection and of complications. Furthermore, it is essential to reinforce with all smokers that passive smoking increases the risks to other people in a pandemic, especially children and those with respiratory conditions. Communicating both of these messages is an opportunity to ask a smoker if they are ready to quit and to counsel them about smoking cessation – and pharmacy staff should be the first to think about this.

The whys and wherefores of referral, of the person or of their question, within the pharmacy as much as to a GP or hospital, must be clearly worked out and communicated. Patients and the public should be told that they are being referred because it is appropriate, otherwise they may conclude it is because of the ignorance of the staff or the unwillingness of the staff member to help.

Pharmacies, through their close contact with the local community and through their Patient Medication Records, have the ability to identify and approach people who are likely to have to stay at home and may have no-one to help them get their medicines, food or other important supplies. Simply checking that these people, or their neighbours, have made arrangements or have thought about the issue may help, because once significant numbers of people are affected, there will more urgent work and less time for the rest to devote to this.

Similarly, it should be possible to identify patients who may be at risk and to check whether they have made arrangements, or wish to make arrangements and to discuss some of these situations with their GP practice. Some, despite their obvious need, will not want 'to bother' anyone.

Hand and Respiratory Hygiene

- Wash your hands with soap and water thoroughly and frequently. Alcohol-based hand cleaners are also effective if washing facilities are not available.
- Avoid unnecessary close contact with people who have influenza or have symptoms such as coughing, sneezing, fever or shivering.
- Avoid touching your eyes, nose or mouth.
- Cover your nose and mouth with disposable tissues when sneezing, coughing, wiping and blowing your nose.
- Dispose of used tissues in the nearest waste bin.
- Wash your hands after coughing and sneezing.
- It is important to ensure that all household surfaces that are touched by hands are kept clean, especially bedside tables, surfaces in bathrooms and kitchens and children's toys. Such surfaces should be wiped regularly with a household disinfectant according to directions on the product label.

Apart from the clinical issues, the pharmacy must be able to operate as a business. Forfás has produced a useful guide to Business Continuity Planning (http://www.forfas.ie/media/forfas070228_business_continuity.pdf) including a checklist, with four headings: Planning Activities, Business Issues to Address, Measures to Underpin Continuity and Responding to Workplace Risks, that should form the basis of any pharmacy's strategy. It is necessary to try to envisage who will work and what they can do when a staff member is ill, or one of their children is ill, or the children's crèche or school closes down because of illness. These periods of absence will be

measured in units of a week since that will be the recommendation. It is vital that in areas with widely dispersed pharmacies, if one or more has to close, contingency plans can be made, now, for a rota system, or a process for the referral of vulnerable patients, to cope with that eventuality, and consider who else among the area's health service providers should be informed. Finally, when the arrangements have been agreed, they should be published to the patients and local communities affected.

Pandemic-specific issues

The first tranche of oseltamivir from the national stockpile has been distributed to community and hospital pharmacies to coincide with a change in strategy. The initial approach in any epidemic is to try to contain the infection by identifying cases using specific diagnostic tests, treating cases and tracing contacts and if necessary prophylaxis of contacts. This can be effective in small localised groups but once the infection is sufficiently widespread to make this approach unfeasible then mitigation (also referred to as treatment in some sources here and overseas – it is probably a more easily understood term) is the next strategy. Treatment involves identifying cases according to clinical symptoms and treating as warranted, and identifying those at risk. For these cases the national stock is to be used and is provided free of charge to patients. This stock should be identified and a copy of the prescription sent to the HSE to enable tracking of the pandemic through antiviral drug use. Those not at risk but experiencing influenza-type symptoms should be told to stay at home since social distancing, as it is called, can limit the spread of infection.

Parallel-imported product cannot be used in place of the national stockpile and will not be reimbursed by the PCRS.

The national stockpile should not be diverted for non-approved use. In Norway and the US there has been evidence of personal stockpiling for prophylaxis, particularly by private prescribers and their patients. Any stockpiling diminishes the availability of drug for cases in need. Prescribers have been asked to resist demand for antivirals to have as personal stock from people without risk factors, but anecdotal and press reports suggest that it is a significant issue in private practice.

In addition, the recent letter from the HSE to clinicians noted that "anecdotal comments from GPs and pharmacists would suggest that there is a pressure from the public to obtain antiviral drugs for those going on holidays or for those with minor illness. This is inappropriate and needs to be resisted. Antiviral drugs are a valuable resource and need to be used judiciously so as to avoid the development of resistance and to ensure that those who need them can avail of them".

The decision to prescribe is always based upon the balance of the risks of the infection, the benefits and risks of the treatment and the specific needs and wants of the patient. Inevitably therefore, each decision is different because each patient is unique. However, the guidelines in the National Plan are an accepted consensus view.

What is complicating this pandemic is the fact that, although they have been available for some time, oseltamivir and zanamivir have never been used on this scale in so many diverse at-risk groups before. The relative mildness of the presentation of the infection in most patients lessens the potential benefits and proportionately increases the potential seriousness of the side effects of the drugs. This has become particularly evident for the option treating of children with oseltamivir. The apparent absence of benefit, particularly in a reduction of otitis media in children above 5 years of age, will cause parents and prescribers to reconsider their position.

Adverse drug events can be reported to the Irish Medicines Board online or by fax. It is important that pharmacists understand that, in reporting a suspected event, they are not required to present clear evidence that the drug is directly responsible and nor should they be concerned that the event may be reported by two different healthcare professionals, leading to double counting. The Irish Medicines Board collates all of the reports it receives and assesses them. They will be able to eliminate any duplicates and ultimately, from their country-wide view, they will judge the nature and strength of the relationship between the drug and the event. The Irish Medicines Board issued a special advisory notice about reporting suspected adverse effects of antiviral medicines on May 15th of this year.

Suspected adverse effects of oseltamivir in patients with influenza are neuropsychiatric or neurological events, such as convulsions and delirium, hallucinations and abnormal behaviour. These have been reported mainly in paediatric and adolescent patients, sometimes serious or fatal injuries were associated with the events. These serious effects are thought to be rare, whereas disturbed sleep, bad dreams and difficulty concentrating are more common. Initial anecdotal reports and the small surveys of school children in the UK confirm that these effects occur and, although transient, they are

unsettling. Seasonal influenza is also associated with encephalitis or encephalopathy and Reye's syndrome (this can also occur in the absence of aspirin) in children. Four cases of neurological complications, including seizures in two of the cases, have been described in the USA in patients with confirmed Pandemic (H1N1) 2009 infection. The duration of the neurological symptoms ranged from one to seven days; all four cases recovered without any consequences and all four received oseltamivir without any apparent effect. It is hard to distinguish between the events linked to the drug, those linked to the illness and those linked to the combination of drug and illness, particularly since there are no easily discernible risk factors.

As with all chemotherapeutic drugs, there is concern that Pandemic (H1N1) 2009 could become resistant to the antiviral drugs used against it. In the past, a number of different influenza strains have demonstrated resistance to amantadine and this has been one of the reasons for its very limited use.

Oseltamivir and zanamivir target the neuraminidase enzyme of the virus. However, they bind to it in different ways. Zanamivir binds directly to the active site of the enzyme without any alteration in the site's topography, while oseltamivir requires a shape change in the site before it can bind. To date, oseltamivir resistance seems to have occurred more frequently. However, it also seems to have occurred without the use of the drug, in other words, it arose spontaneously. Nevertheless, reports, particularly for the US, seem to indicate that the resistant virus is not associated with greater pathogenicity. It had been assumed that, since the neuraminidase is essential to the virus's ability to spread to other cells, any change in its structure that conferred resistance would also probably reduce infectivity, but this may not be the case with some variants. Nevertheless, many countries have been typing and testing Pandemic (H1N1) 2009 virus samples from patients and so far no pattern of resistance and/or increased pathogenicity has been detected. It may be that extensive drug use does not promote resistance for this class of drugs, but that much of the resistance arises spontaneously, since it has been recorded in the absence of drug use, and decays spontaneously.

Vaccination

As soon as it is feasible, vaccination will begin. In patients with COPD influenza vaccination reduces 'flare-ups' of the disease according to a Cochrane Review. In patients with Cystic Fibrosis, vaccination results in an immune response but there is no direct evidence to show that it protects against influenza infection or prevents lung damage. An immune response to vaccination occurs in children with cancer although it is poorer than that in healthy children but there have been no studies that examined the clinical efficacy of vaccination in this group of patients. In all of these groups, apart from some instances of local, injection site reactions, vaccination was not associated with any severe adverse reactions. Vaccination against influenza is very effective in elderly patients despite their reduced immune response, hence the need for adjuvants. In this group it reduces mortality from all causes by around 70% and complications (exacerbations of lung disease, pneumonia, heart failure, angina and myocardial infarction) by around 50%. In patients with cardiovascular disease it helps prevent heart failure, brain infarction, recurrent myocardial infarction and primary cardiac arrest and in patients with diabetes mellitus it reduces hospital admission because of loss of diabetes control by approximately 79%.

Pregnant women are also candidates for vaccination since this will pass on immunity to the newborn, an immunity that will last until the infant is around 6 months old, after which, they become candidates for vaccination themselves. Parents and carers (such as those in crèches) of young children also pose less of a risk to the children (as transmitter of infection) once vaccinated. Similarly, vaccination of the staff of residential homes for the elderly and chronically ill, significantly reduces the chances of influenza in those facilities. It is worth remembering that a person without significant symptoms and signs can still transmit the infection to a vulnerable patient, hence the need for everyone who has contact with patients to improve and maintain their hand hygiene procedures.

The government has placed purchase orders for enough vaccine for the population, at an estimated cost of €80m. There are several companies producing vaccines and, as a result of the deficiencies in vaccine production facilities identified by previous pandemics, there is greater capacity and new methods of production have meant that faster production is possible. However, the virus still has to be clinically evaluated in trials and these are underway at the moment. Concern has been expressed by some that speeding up the process of vaccine assessment by the European Medicines Agency and other medicines regulators could lead to exposing the

pandemic (h1n1)

population to unreasonable risks, particularly since the virus produces a mild infection in most people. However, the agencies involved are confident that their procedures are thorough and that unnecessary risks are not being taken.

Since this is an influenza virus, the formulations will be very similar to those used each year for the seasonal influenza vaccines and the details of these preparations for the purpose of authorisation are well known. As the WHO have stated; "In early June, WHO held a consultation of experts which reviewed the safety of adjuvants, or substances added to vaccines to make them more effective; no significant safety concerns were identified." Vaccine safety will be carefully monitored through post-marketing surveillance. It remains to be seen whether one dose or two of the vaccine will be required and it is likely that it will be delivered in multi-dose vials, raising anxieties that inefficient usage could lead to significant wastage. Additional clinical trials in children are likely to be conducted, especially as they are the group most susceptible to infection.

Vaccines are very often produced using eggs and the final formulation usually contains ovalbumin. Some patients are allergic to egg proteins and in the past have been excluded from vaccination. Since some of the vaccines that are being evaluated in clinical trials have been produced by new techniques using cells, they may have little or no ovalbumin in their formulations. Additional information on the constituents of the formulation of the vaccine purchased by the Irish Government will be available in the autumn. However, the British Society for Allergy and Clinical Immunology (BSACI) has suggested an approach to patients dependent upon the seriousness of their allergy, as shown below;

- 1 Patients with a relatively minor egg allergy who are able to tolerate foods containing moderate amounts of cooked egg or who only develop local symptoms after consuming a reasonable quantity of either lightly cooked or raw egg (such as a teaspoon of scrambled egg) should be vaccinated at the GP surgery with the usual precautions in place.
- 2 Patients with more severe egg allergy who have positive skin tests or RASTs to egg and with symptoms on exposure to small amounts of egg or a history of severe swelling or systemic features such as respiratory compromise or generalized urticaria should be referred to an allergy clinic for further assessment and vaccination if this is deemed appropriate.
- 3 Patients with poorly controlled asthma should also be referred to an allergy clinic regardless of the severity of the egg allergy.

In the US, an expert panel (Advisory Committee on Immunization Practices) has already decided which categories of patients should be given first priority in any vaccination programme (Box 4).

Table 4: Advisory Committee on Immunization Practices recommendations on patient groups to receive the new Pandemic (H1N1) 2009 vaccine

- **Pregnant women**, because they are at higher risk of complications and can potentially provide protection to infants who cannot be vaccinated
- **Household contacts and caregivers for children younger than 6 months of age**, because younger infants are at higher risk of influenza-related complications and cannot be vaccinated. Vaccination of those in close contact with infants less than 6 months old might help protect infants by 'cocooning' them from the virus
- **Healthcare and emergency medical services personnel**, because infections among healthcare workers have been reported and this can be a potential source of infection for vulnerable patients. Also, increased absenteeism in this population could reduce healthcare system capacity
- **All people from 6 months through 24 years of age**
 - ~ **Children from 6 months through 18 years of age**, because we have seen many cases of novel H1N1 influenza in children and they are in close contact with each other in school and day care settings, which increases the likelihood of disease spread, and
 - ~ **Young adults 19 through 24 years of age**, because we have seen many cases of novel H1N1 influenza in these healthy young adults and they often live, work, and study in close proximity, and they are a frequently mobile population
- **Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza.**

Future developments

The National Plan for Pandemic Influenza, drawn up in 2007, has provided the framework for the government's actions in the face of this pandemic. It represents a logical response in an age of rapid intercontinental travel and in a population with a high proportion of patients with chronic disease living in the community. Similar plans have been developed elsewhere and are being modified to meet the challenges posed by Pandemic (H1N1) 2009.

When the main evening television news programme can lead with the story that one visiting student is being kept in isolation in a summer school in UCD, it still suggests a lack of perspective among some of the media. However, the 'clinical attack rate', the proportion of people being infected each week, is around 35–40 per 100,000 which is much lower than the 120 per 100,000 that was recorded last year for seasonal influenza.

Nevertheless, Pandemic (H1N1) 2009 still remains a readily communicable disease with properties that have come as a surprise. It has continued to spread during the summer months whereas seasonal influenza does not. Some cases do not exhibit a high fever. It continues to infect the young much more frequently than the 'old' suggesting that an even milder form may have circulated before but was not detected but has left those over 45 with substantial immunity. Evidence from Australia seems to bear this out but also to confirm that recent vaccination against seasonal influenza offers no protection against the pandemic virus. Pregnancy confers susceptibility, not just for the illness but potentially for a more severe form. Predictably, patients with one or more chronic illness, immunosuppression, obesity or poor liver function are vulnerable to complications. Although hospitalisation for the complications of influenza is usually high, the pattern of mortality is not likely to be the same. Children, especially young children and infants are probably less at risk of dying than older people who are hospitalised – this is probably because they are more likely to have a co-morbidity. At the moment, only patients with one or more risk factors need to see their GP, the rest are being, and will continue to be, advised to stay at home and self medicate and self care. This will enable GPs to provide adequate monitoring and care for those with risk factors and to continue to provide care for patients with other conditions, since all of the usual acute and chronic episodes and illnesses will continue to occur.

Pharmacy for its part must be, and be seen to be, professional and reliable in its response. In many instances, pharmacists and pharmacy staff will listen and will provide reassurance. Outside Primary Care, few health service managers and providers fully appreciate the value of reassurance in patient care. In a pandemic, reassurance, from someone the patient knows, will be even more valuable than in non-pandemic times.

Seasonal influenza will also emerge in the autumn and its pathogenicity and its response to its vaccine is unknowable. Whether seasonal influenza and the pandemic strain will interact, and if they do, what form this interaction may take cannot be predicted. If the seasonal influenza infects mostly older people and the pandemic strain mostly younger people, their combined attack rates will undoubtedly stretch the health service's capacity to respond. Certainly, the necessity of having to vaccinate against two influenzas will place a considerable strain on the Health Service. The initiative of the IPU in arranging for training for pharmacists in vaccination procedures is a welcome development and has been supported by the HSE since those in Public Health have also thought of the possible scenarios described above. In addition, vaccination against pneumonia in vulnerable patients will be promoted although there is some debate about which vaccine provides the most benefit.

Pharmacy is helping, and must help, respond to this situation. Pandemic (H1N1) 2009 still has the potential to infect a substantial proportion of the population and in subsequent waves of infection to change into a more pathogenic virus. The Expert Pharmacy Advisory Task Force (see Background) was formed to help link the profession and its practitioners with the Health Service. Primary Care in this country remains poorly resourced and fragmented and it is around medicines use that this fragmentation is most evident. The National Pandemic Expert Group has elected to deal with the structures and bodies in Primary Care as they are presently constituted since the burden of the infection is not disrupting services – the infection is classed a 'moderate' by the World Health Organisation. This means that some of the communication from the HSPC for example, in its tone and content, still reflects a subordinate role for the pharmacist, rather than that of a front line communicator and service provider. This is not that different to many other countries and is perhaps

not surprising, since in an uncertain situation people tend to be overly cautious.

This looks like it will be a long lasting pandemic. It is difficult to predict whether the virus will change much as it infects new hosts in the population and it is difficult to know how it will react to the widespread use of antivirals and how effective the vaccine will be.

However, it is a mistake to think of each of the antiviral measures as a separate tool. The drugs, the vaccine, the hand hygiene, the cough etiquette and the social distancing are a combined force, they should be thought of as such by pharmacists and used as such. Now and until the pandemic has passed, hand hygiene and cough etiquette and social distancing must be practised and antivirals and the vaccine will be added to these as appropriate.

We must expect that the virus will spread, that people will become ill, that some will become more seriously ill than anyone could have foreseen and that there will be disruption to the normal life of the local community. But if all is done that can be done and should be done, then no more illness, suffering and dislocation will occur than is unavoidable.

Pandemic (H1N1) 2009 is a world-wide infection. What other countries do, and how successful their strategies are, will materially alter the extent to which future waves of infection affect the population of Ireland. The authorities in Mexico showed great capability given that the first cases occurred in Mexico City with a population of around 20 million and large areas of high population density. What happens in the UK has an impact here, not just because of the sheer numbers of Irish people living there and travelling back and forth each day, but also because of the ubiquitous transnational media that are continuously available. The WHO has been helping low income countries with their planning and trying to obtain donations of antivirals and vaccine. Sanofi-Aventis, one of the vaccine producers, has pledged 100 million doses. Pandemics should serve as a reminder that health is global issue and that infectious disease affects us all, so everyone must help their neighbour as well as themselves.



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ETHICAL AND LEGAL ISSUES IN HEALTHCARE

Collegiality challenged?



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).

You are a part-time staff pharmacist working at one location of a five-pharmacy chain. You return from two weeks' holiday to a busy day in the dispensary, assisted by the two full-time technicians. When filling a prescription for 30 Tylenol capsules you remove a strip of ten from the outer carton and notice six empty blisters...

The likelihood that the box of capsules was returned to the pharmacy for disposal, and accidentally returned to the shelf is low, as the date-stamp identifying when they were received from the wholesaler refers to only four days prior. The possibility that the capsules were removed before delivery to the pharmacy remains. As you contemplate this latter idea, one technician takes the part-filled strip, cuts away the empty blisters, and returns the remaining product to the dispensing tray, muttering that the replacement pharmacist needed regular doses of Tylenol to cope with the hangovers...

What do you do?

At issue is the fact that a member of your professional support staff team has made allegations that a pharmacist has been consuming Tylenol, while at work, in a manner that appears to be both illegal (without having had them dispensed on a prescription) and for a use other than analgesia. "Codeine can produce drug dependence of the Morphine type, and therefore has the potential for being abused. Prolonged regular use ... may lead to physical and psychological dependence (addiction)... Codeine may impair the mental/or physical abilities required for the performance of potentially hazardous tasks." (www.imb.ie – SPC: Tylenol) The implication that this individual required the codeine to cope with regular high consumption of alcohol suggests additional risk in the context, in that 'Tylenol may exhibit an additive depressant effect'. If true, it is in the person's 'best interests' that such potential additions be addressed in a proactive manner, and there are patient-safety risks posed where a pharmacist practises while 'under the influence' of alcohol and/or codeine.

Professional practice standards and the Code of Conduct for pharmacists are also at issue, in that a pharmacist ought not to permit another person do anything which would impair or compromise his/her ability to practise professionally.¹ To be seen to condone or accept such behaviour would undermine the pharmacy practice itself; pharmacists and professional support staff. It is possible that the second technician is even more uncomfortable about the behaviour of the replacement pharmacist and is awaiting your reaction before voicing deeply held concerns.

The reality is that many of us would hesitate as to what to do next. Natural justice requires that an innocent pharmacist's reputation be protected. However, it may be that there are a number of other concerns influencing our decision-making, not least of which might include collegiality, personal risks associated with 'whistle-blowing' and a fear of 'doing the wrong thing'.

'Collegiality', a version of loyalty to a person or 'cause', is commonly used with reference to groups such as professions. The term has a 'caring' undertone, not inconsistent with the notion that in a scenario such as presented, the well being of the individual ought not to be unnecessarily sacrificed to the process used to deal with the situation responsibly. Efforts should be made to ensure that a colleague who demonstrates addictive tendencies or other mental health problems be encouraged to avail of treatment. Indeed, many larger organisations have Alcohol and Drug policies in place and the introduction of the Health, Safety and Welfare at Work Act (2005) has further stimulated development of such policies. Professional programmes are available to direct and counsel through a detoxification process. Where appropriate, organisations such as the Benevolent Fund seek to support individuals undergoing such processes. Where such supports are available the dilemma would be ameliorated.

However, 'loyalty' assumes that one's actions will be in the best interests of all concerned... the individual, the pharmacy, the professional staff therein, the profession and the patients being served. David Kline, in 'On Complicity Theory', challenges that if a pharmacist is "aware of the wrongdoing and he does not try to stop it, he is implicated in the wrongdoing". Irish society has seen serious examples of the cost of 'silence' in recent times – not least in the guise of the Neary Case², Ryan Report³ and the Anglo Irish⁴ debacle. These clearly demonstrate how healthcare, institutional care and our banking and finance systems could and can benefit if more proactive approaches are taken by those on the periphery of events.

Risks to whistleblowers include the underlying concern they may find themselves the subject of retaliatory complaints and disciplinary action or are "advised to keep quiet or their careers would suffer" (Varielius). A well-known example of whistleblowing, and its risks to the whistleblower, is dramatised in the 1999 film 'The Insider'... Jeffrey Wigand (Russell Crowe) exposes executives of big tobacco

companies in the USA as being aware that cigarettes were addictive and that they added carcinogenic ingredients to cigarettes. He certainly put himself at risk. There is, of course, additional risk where the pharmacist him/herself has not actually witnessed the misuse of medicines by another colleague, and is depending on information from one or more members of the professional support staff. There may be instances where an approach to the 'accused' pharmacist him or herself may be appropriate or, failing that, to the supervising or superintendent pharmacist, or owner of the business. Difficulties may arise if the replacement pharmacist is the owner or/and superintendent, or has influence over the part-time pharmacist's employment or professional position, in which case the 'Protection of Disclosures of Information' (Health Act 2007, section 14) provides a further option. This legislation provides for statutory protection in respect of disclosures made, in good faith, by "a person to a regulatory body" where such person registered with such regulatory body has posed, is posing or is likely to pose a risk to the health or welfare of the public. In the case of the PSI, Dr Cora Nestor MPSI has been appointed as the officer to accept protected disclosures.

To quote Peter Gooderham, in his editorial in the *BMJ* (May 2009), "Professional people may feel damned if they do raise concerns, and damned if they don't... a start would be for those in official positions to recognise the risks of whistle-blowing." It seems that the 2007 Protection of Public Disclosures Act does address those concerns.

Notwithstanding the direct risks to whistleblowers, "False allegations can cause hurt, distress and embarrassment", a sometimes costly affair given current controversy surrounding the €1.872 million award against Independent Newspapers for making "false claims about PR Consultant Monica Leech" (*Irish Times*, Friday June 26th). The article highlights that, "had Leech lost both her arms she could have expected damages of between €141,000 and €197,000."⁴ Such is the perceived value of one's reputation: "the purest treasure mortal times afford is spotless reputation" (Richard II). The proposed Defamation Bill (2006) clearly identifies that a defence of qualified privilege, or protection for a whistle-blower, shall fail if the whistleblower lied or acted out of spite, ill will or improper motive. Factually accurate information is essential.

Once the decision to act is made, the next question is how. It seems that the choice of action(s) must seek to minimise the risks to the reputation of the pharmacist, the profession and the business – be that in a community, hospital or other setting. Establish what 'facts' are available to you from the support team, clarifying that if an issue exists, action is required. The ideal is to use internal structures and reporting mechanisms to minimise any perceived or real risks to patient care and pharmacy practice, while seeking to care for any colleague prone to addiction. There may even be situations where the jobs/livelihoods of both the reporting pharmacist and the technicians involved are perceived to be at risk, in which cases routes to protected disclosure might be engaged.

However to 'turn a blind eye' could be to facilitate ongoing misuse of medicines, facilitate the likelihood that a registered pharmacist will work in a state of mind not conducive to safe practice, and represent a betrayal of one's professional responsibility to lead professional support staff in the practice of pharmacy. Like it or not, the colleague pharmacist in the opening scenario ought to properly be considered vulnerable on a human level, but a potential risk to patient safety on a professional level. Once a pharmacist is aware such risks exist he/she is in the difficult position of being required to take all reasonable steps to intervene in an appropriate manner.

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Further Reading ~

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Can Your Pharmacy afford to be left outside?

An exciting new initiative is offering pharmacies in Dublin a competitive edge. The Access Business Directory, recently launched by Dublin City Council, is designed to make the capital more accessible and premises in Dublin are rapidly joining. Some might find the idea of a Local Authority helping business gain a competitive edge unusual. But the growing partnership between a City Council wanting to improve Dublin and businesses hungry to gain customers is working in Ireland's capital.

The Access Business Directory features over 1,000 companies, including 29 pharmacies, that are actively marketing their premises and services as offering accessibility to people who are temporarily on crutches, to elderly people, to mothers with buggies, to those who are visually impaired, to wheelchair users and to all their families and friends.

Supporters of this initiative include the Dublin Chamber of Commerce, Dublin Tourism and the Dublin City Centre Business Association and businesses in the directory range from hotels and restaurants to banks, retail outlets and health centres.

Almost 10% of the Irish population is people with disabilities who influence the spending of others –

their families, friends and carers. In addition to an ageing demographic across Europe, the accessible tourism market is one of Dublin's fastest growing and, with this directory, these consumers can become informed and better able to select a destination or location that meets their accessibility needs.

The then Lord Mayor of Dublin, Eibhlin Byrne, called on the business community to join the campaign to make Dublin the most accessible city

in the world. "This directory will give businesses a competitive advantage over others by reaching this relatively untapped segment of the market. It is a positive initiative to promote accessibility and we would encourage all businesses to consider joining the directory. Improving access for everyone, regardless of age or ability, is of

huge economic and business importance and will make the city a better place," she says.

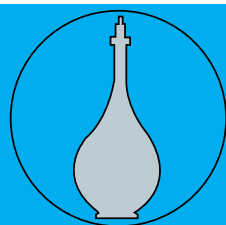
Throughout 2009 the Access Unit in Dublin City Council intends to continue to add new businesses to the Directory. Sign up for inclusion today and your pharmacy will be listed on www.accessdublin.ie as well as on an international website that informs tourists visiting Dublin of the choices available to them.



The then Lord Mayor of Dublin, Eibhlin Byrne with Eileen Corrigan of the City Pharmacy in Dame Street, Dublin City Centre, at the launch of the Access Business Directory by Access Matters



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THE HISTORY OF PHARMACY

MAY/JUNE 2009

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

1909

SALE OF WINE BY CHEMISTS

The Excise department at Belfast insisted that all chemists should withdraw all dutiable wines from sale between 10pm Saturday and 7am Monday. Many chemists readily agreed to the order, while others conceded only under protest. In some cases, the parties consulted the Revenue Supervisor, who asked that all wines should be withdrawn, excepting medicated wines containing a given percentage of quinine or other medicament.

CHEMIST EXTRACTORS (UK)

A letter was received by the C&D concerning chemists who were in the practice of extracting teeth "and also interested in 'adapting' artificial teeth". The letter asked if the Dental Association could be deterred from prosecuting individuals "for letting the public know that they are prepared to extract teeth or 'fit' a case for them". The author mentioned a society called "The Incorporated Society of Extractors and Adaptors of Artificial Teeth" whom he had been unable to contact. He wished to defend his own practice of extraction, arguing, "Surely a chemist is more fitted to extract teeth with his knowledge of antiseptic treatment and, where local anaesthetics are used, his acquaintance with the properties, dosage, etc. of the drugs used..." The author was referred to in a later issue of the C&D, where the editor received further correspondence from him stating that "he has not received sufficient encouragement to satisfy him that an association is warranted". About thirty chemists had indicated their willingness to join such an association and offered subscriptions from five shillings to one guinea. The C&D reported that the need for such an association had since passed in any case, since the British Dental Association had instructed its officials to cease prosecutions of unregistered persons for advertising "painless extractions".

SPIRIT DUTY

Mr Richard Blair wrote to the *Cork Examiner* concerning an increase in duty on spirits. He suggested the insertion of a clause in the Act exempting spirit used for strictly medicinal purposes. The June 12 issue of the C&D also raised the matter, which averred that there was no better time for striking than the present. The matter, it said, would not be closed until the Committee stage of the Finance Bill was passed, "and the case presented for hospitals and retail chemists has so impressed the Chancellor of the Exchequer that it needs but a little more pushing to get some recognition of the claims of medicine for special treatment in regard

to spirit-duty". It also remarked, "In this connection the letters received by the Irish Pharmaceutical Council are of peculiar interest." At the June Council meeting of the PSI, a letter was acknowledged as received from the Chancellor of the Exchequer. The letter in turn acknowledged the receipt of correspondence from the Council of the PSI. The Chancellor had copied the letter to Captain Craig MP, who in his reply said, "You have my fullest sympathy and support, and I am to-day (May 10) bringing the matter under the notice of the Committee formed for the purpose of amending the Budget as far as possible, and trust that our efforts will be successful in the direction in which you are interested." Other letters of support had been received from Mr Lonsdale MP, Mr John Gordon MP and Mr Idris MP. The Ulster Drug-Trade Association enclosed a copy of a letter they had addressed to the Chancellor expressing similar views.

1959

BRINGING PHARMACISTS TOGETHER

At the PSI Council meeting of April 1954 (reported on in May), a letter was read from the Post-Graduate Study Group outlining a proposal that had been adopted at its Committee meeting to bring together interested pharmacists for a course of intensive study. It was proposed that the course be held in September or thereabouts. It was suggested that the various pharmacy organisations might be encouraged to hold general meetings or functions and that manufacturing firms might be requested to hold their annual displays to coincide with the course. The letter added, "In this way, pharmacists attending the course and the other various activities would be brought together, problems of interest could be discussed, and thereby the seed of an important annual conference could be sown." It was suggested that a preliminary meeting might be held attended by representatives of the PSI, the PMRA, the Association of Hospital and Public Pharmacists, the employees' organisation, the compounds' Union and the IPSA. It was felt that this group might then act as a co-ordinating body.

Mr D.J. Kennelly noted that the post-graduate lectures had been very well received, particularly by the medical representatives' group and hospital pharmacists. A postal course was being organised for retail pharmacists in regional areas. He added that "the various groups were inclined to become so engrossed in their work that there was a possibility there would be no cohesion" and for this reason he considered an annual meeting, on social, scientific and professional levels, to be a good idea. The president welcomed the suggestion and said that the Council should give the proposal its blessing, which was agreed.

The success of the postal courses was further mentioned, more than 250 applications having been received, from all parts of Ireland, England and as far afield as Pakistan. The committee had decided, so as not to leave more than a fortnight between each lecture, not to send out the papers until three lectures had been prepared. A lot of work was involved in the preparation of the lectures, with between 15,000 and 20,000 sheets of foolscap being printed.

PILGRIMAGE TO LOURDES

The Irish Pharmaceutical Pilgrimage to Lourdes was due to depart Dublin in a chartered 'Viscount' aircraft on the evening of 3rd August, and begin its return journey on the evening of the 16th, arriving into Dublin early the next morning. A total number of nine pilgrims were expected. The airfare from Dublin to Lourdes, including French Government tax and bus transfers to and from Tarbes Airport (Lourdes), was £29 6s. A deposit of £3 was required to secure a place and the balance was to be paid before 1 June. Rooms had been provisionally reserved at the Hotel St Sauveur, each room with three beds for the fourteen days costing £22 12s, two beds £24 6s 4d and one bed £25 11s.

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