



PSI Newsletter Issue 3, 2015

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Overview

The PSI has been engaging in a number of expressions of interest processes already this year, and welcome the considerable interest shown to date. Vacancies are now arising in relation to the PSI's disciplinary work. We are asking individuals to consider their interest in sitting as part of one of the PSI's Disciplinary Committees or for appointment as an expert witness.



We highlight in this issue a test purchase exercise conducted in recent months that focussed on the sale and supply of domperidone containing products. The outcomes of that exercise and advice for pharmacists is contained on the website.

This newsletter also provides useful information in relation to changes in shareholding of limited companies and how this may impact a pharmacy's registration, and a legislative update that requires health professionals providing cross-border healthcare to hold professional liability insurance.

Pharmacists are also reminded of their obligations when dispensing prescriptions presented by patients who have obtained them through the use of online doctor services.

Finally, we take this opportunity to remind you that comments are welcomed to the ongoing public consulation on the draft Statutory Instrument (SI) relating to Continuing Professional Development for pharmacists.

Expressions of Interest Sought

Future Pharmacy Practice Project

We remind you of the recent call for expressions of interest to participate in the Future Pharmacy Practice Projectthat will be commenced by the PSI this summer, and which requires the input of pharmacists and others as part of a Steering Group and two practice subgroups. You will find information relating to the project and requirements on the PSI website. The closing deadline to register interest is this Friday, 1st May at 5pm.

Vacancies for Disciplinary Committees and Panel of Experts

In addition, there are vacancies now arising for individuals willing to sit as part of the PSI's disciplinary committees to hear matters relating to complaints received to the PSI about pharmacists and pharmacies. The PSI is also seeking expressions of interest from suitably qualified pharmacists willing to join a panel of experts. Experts are called upon to provide their independent opinion and report in relation to fitness to practise matters, as part of an inquiry process.

The key attributes required for these disciplinary-related vacancies are outlined on the PSI website and you are asked to give consideration to these before applying. There is a requirement for particular documentation to accompany an expression of interest. Submissions of interest are welcomed

to to info@thepsi.ie and should be received no later than 5pm on Monday, 18th May 2015.

Share Transfers - How does this affect a pharmacy's registration?

Changes in the shareholding of a limited company which owns a pharmacy can affect the pharmacy's registration. In some cases these changes can have the effect of automatically cancelling the pharmacy's registration and the pharmacy will have to re-register with the PSI. Therefore, it is very important that the PSI is informed of all transactions involving the disposal or acquisition of shares in limited companies which are registered as pharmacy owners on our registers.

The PSI website has been updated to provide clarity to pharmacy owners in relation to this matter and to assist pharmacy owners who may be considering making changes to their pharmacy's ownership structure. [Continue reading.]

Domperidone Test Purchase Exercise

The results of a European Medicines Agency (EMA) evaluation of the benefits and risks of domperidone, due to concerns of cardiac adverse effects, were published in April 2014, and found that people who take the drug may have an increased risk of serious cardiac adverse drug reactions. A higher risk was observed in patients over 60 years old, adults taking daily oral doses of more than 30mg and those concomitantly taking QT-prolonging medicines or CYP3A4 inhibitors.

In light of the findings of this evaluation, there were a number of changes to the treatment advice for domperidone containing medicines, and the package leaflet and Summary of Product Characteristics (SmPCs) of affected products were updated. In October 2014, the PSI published updated Guidance on the Safe Supply of Non-Prescription Medicinal Products Containing Domperidone, to highlight these changes to pharmacists. This guidance was circulated to all pharmacists in Issue 8, 2014 of our newsletter.

The PSI carried out a mystery shopper exercise in December 2014 to check whether non-prescription medicines containing domperidone were being supplied in accordance with the updated marketing authorisation for domperidone and the PSI Guidance. A test sample of 50 community pharmacies were selected at random for inclusion in the exercise and the findings of this are now available on the PSI website, along with advice for pharmacists. [Continue reading.]

Dispensing Prescriptions from Online Doctor Services

It has been brought to the PSI's attention that there are an increasing number of companies providing online doctor services to patients. The PSI would like to remind pharmacists of the importance of complying with their legal and professional requirements when dispensing a prescription from an online doctor.

Pharmacists are particularly reminded of the requirement to have a legally valid prescription for the supply of a prescription only medicine. The Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) detail the format a prescription must adhere to for it to be legally valid. A fax or photocopy of a prescription, or a prescription which has been emailed either to the patient or pharmacy, is **not** a legally valid prescription.

The PSI has previously issued Advice on Emergency Supply which outlines

the limited circumstances, provided for in the legislation where an emergency supply can be made at the request of a patient or at the request of a prescriber.

Additionally, pharmacists are reminded of their obligation to comply in full with the PSI's statutory Code of Conduct. The Code mandates that the health, wellbeing, care and safety of the public must be the primary concern of every pharmacist. If the pharmacist has any concerns with regard to the appropriateness of the medicine prescribed for the patient they should contact the prescriber.

Training Placement Registration (CAASP)

Phase 1 of the National Pharmacy Internship Programme's Central Application and Selection Process (CAASP) has concluded and we are pleased to note that it was very successful, with RCSI confirming that nearly 80% of all students have secured a training placement. The PSI and the RCSI wish to acknowledge the central role that pharmacists and training establishments have played in the success of CAASP to date and would like to thank everyone for their co-operation and engagement with the new process.

The registration period for training establishments is now underway for Phase 2. Phase 2 is essentially a repeat of Phase 1, providing another opportunity for those training establishments that did not recruit an intern, or did not participate during Phase 1, to offer a training placement for 2015/2016. All students who did not secure a training placement in Phase 1 of CAASP will be automatically engaged in Phase 2.

The CAASP office at the RCSI has sent direct communications to all training establishments with details of Phase 2. If you did not receive an email from CAASP or would like further details about registering and listing an internship placement for the 2015/16 training year, please contact CAASP Admin at the RCSI (Michael Cresswell) at caasp@rcsi.ie or phone 01 402 5129.

PSI Council Election Results 2015

Following the counting of votes on 16th April, and in accordance with PSI (Council) Rules 2008 and 2015, the Returning Officer Marita Kinsella, PSI Registrar, has declared the following four pharmacists as elected for the purposes of Section 10(3)(f) of the Pharmacy Act 2007, for appointment by the Minister for Health to the PSI Council: Rory O'Donnell, Muireann Ní Shuilleabháin, John Corr, and Joanne Kissane. A panel has also been established for the filling of any vacancies that might arise.

The full election results, including details of the number of ballot papers issued (total electorate), the total valid poll and the votes and transfers at each count are published on the PSI website.

New Pharmacy Practice Guidance Folder

In the coming weeks, every retail pharmacy business in Ireland will receive a folder which contains current PSI guidance documents. The guidance will assist all pharmacists and pharmacy owners in ensuring that their pharmacy is operating safely, in line with legislation and good practice requirements.

All documents included in this folder have been previously published on the PSI website. While the overall content of the guidance has not changed, these documents have been reformatted to make them more consistent in layout and easier to read.

The PSI will continue to produce guidance to help facilitate compliance with

the Regulation of Retail Pharmacy Businesses Regulations 2008, and the safe and effective practice of pharmacy in Ireland. As new guidance is published, as well as highlighting it in this newsletter and placing it on our website, it is intended to send a copy of the new guidance to every registered retail pharmacy to add to the folder. In this way, each pharmacy will have a suite of up-to-date documents on the premises that can be referred to at any time, by both pharmacists and other pharmacy staff members.

An electronic version of all documents will also be available to view and download from the PSI website.

Public Consultation: CPD Statutory Instrument

A draft statutory instrument (SI) relating to CPD for pharmacists has been published on the PSI website and comments continue to be invited to the public consultation until 5pm on Monday, 18th May 2015.

These Rules are necessary to give statutory effect to the PSI's CPD model agreed by the Council of the PSI in June 2010 and set out the system of CPD for pharmacists, the establishment of the Irish Institute of Pharmacy to oversee the management and operation of the CPD system on behalf of the PSI, the associated quality assurance review processes, and the recognition and approval of CPD programmes and courses.

A copy of the draft SI is available on the PSI website along with the online questionnaire for receipt of submissions. Consideration will be given to all comments, and your participation is appreciated.

Obligations in relation to Cross-Border Insurance

Last month, the Minister for Health signed into law, legislation that requires health professionals providing cross-border healthcare to hold professional liability insurance.

Regulation 15 of the European Union (Application of Patients' Rights in Cross-Border Healthcare) (Amendment) Regulations 2015 (S.I. No. 65 of 2015) implementing Article 4 (2)(d) of the European Union Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, came into force on 31st March 2015.

These regulations apply only to healthcare professionals engaged in the provision of cross-border healthcare under the Cross-Border Healthcare Directive, and not those providing treatment to European citizens under the European Health Insurance Card. Healthcare professionals employed in the public health service are already covered by the State's Clinical Indemnity Scheme.

Under these regulations, pharmacists providing cross-border healthcare, as defined in the regulations must:

- 1. have professional liability insurance which is "appropriate to the nature and the extent of the risk, for treatment provided in the State";
- 2. supply proof of professional liability insurance within 15 working days of a request to do so by an authorised officer of the HSE.

Pharmacists are not obliged to provide more extensive information to patients resident in other member states than they provide to those in the State.

Further information about the Cross Border Directive may be accessed on the HSE website.

HPRA Drug Safety Newsletter

The most recent HPRA Drug Safety Newsletter (DSN), issue 67, is available on the HPRA website and includes information regarding:

- Bisphosphonates and denosumab: minimising the risk of osteonecrosis of the jaw,
- Risk of severe allergic reactions with ambroxol and bromhexinecontaining medicines considered small,
- New restriction for hydroxyzine-containing medicines to further minimise the known risk of QT prolongation,
- The importance of Product Information for Medicines.

Upcoming CPD Opportunities

National Clinical Programme for Older People Conference

This conference entitled 'Transforming Care of Older People in Ireland' will take place on Tuesday 26th May 2015 in the Royal College of Physicians of Ireland, 6 Kildare Street, Dublin 2. Guest speaker is Professor David Oliver, President of the British Geriatrics Society and author of 'Making our health and care systems fit for an ageing population'. Registration is through the RCPI website. Places are limited so early registration is advisable.

MSc in Hospital Pharmacy, TCD

Applications are invited for a two-year (part-time) course leading to a Master's Degree in Hospital Pharmacy that commences in January 2016. Information is available on the Trinity College Dublin website and applications should be made using the online application process. The closing date for applications is 30th June 2015. Further information is available from course coordinator Niamh McMahon by email to nmcmahon@tcd.ie or telephone 01-416 2586/416 2467/896 3181. It should be noted that short-listed students will have to attend hospital interviews for clinical placements the week commencing 5th October 2015.

Cardiology in Clinical Pharmacy Practice, TCD

Applications are now being invited for the September 2015 intake of the Cardiology in Clinical Pharmacy Practice module with the TCD School of Pharmacy & Pharmaceutical Sciences. The module is open to registered pharmacists working in hospital or community practice. The course entails 12 weeks engagement, predominantly online. The closing date for applications is 30th June 2015. Application forms and additional information are available from Course Coordinator Niamh McMahon, email cardioclinpharm@tcd.ie; or Cynthia Mannion, Executive Officer, cmannion@stjames.ie or by phone 01-416 2586/2467 and 01-8963181.

MSc in Clinical Pharmacy, UCC

Applications are invited for a two-year (part-time) distance learning Master's Degree offered by the School of Pharmacy, University College Cork, commencing in September 2015. Course information including minimum requirements for application are available on the UCC website. The closing date for applications is 24th July 2015. Further information may be received by contacting Programme Co-ordinator Dr. Teresa Barbosa by email t.barbosa@ucc.ie or telephone 021 490 1792.

Postgrad Certificate in Health Promotion, NUI,G

The Discipline of Health Promotion at National University of Ireland, Galway is accepting applications to the Postgraduate Certificate in Health Promotion – Approaches to Cardiovascular Health and Diabetes Prevention that will commence in October 2015. This is a one year (part-time) distance learning course delivered in partnership with the Irish Heart Foundation, Diabetes

Ireland and the National Institute for Preventive Cardiology, and open to a variety of health professionals. Information is available on the NUI, Galway website and by contacting Anne O'Grady by email anne.ogrady@nuigalway.ie or telephone 091-493644.

Dementia Training with Elevator

Following earlier newsletter notice of the training programmes offered by the Dementia Elevator project at DCU, training is now available for health and social care staff. For pharmacists and pharmacy staff, the Elevator project has developed a specific resource training pack for use in the pharmacy setting. Information is available on the Elevator website. The programme is a national education and empowerment programme developed by DCU and the HSE to help individuals, communities and health systems engage appropriately with people with dementia. See this video for information or contact Elevator's development officer Ann-Marie Coen at 01 700 6190/ann-marie.coen@dcu.ie.

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