

PSI Newsletter Issue 4, 2015

In This Issue

- Reminder of Responsibilities under the Pharmacist Code of Conduct
- Inspection Findings 2014
- Reminder: Inspection Policy Update and Call for Participants in Focus Group Meetings
- ► Internet Supply of Non-Prescription Medicines
- New Pharmacy Practice Guidance Folder
- Guidance for Pharmacists on Extemporaneous Dispensing
- Public Consultation on Draft Guidelines on the Sale and Supply of Prescribed Medicinal Products from a Retail Pharmacy Business
- Reminder: ellaOne Guidance
- PSI Council approves 2015-2016 Seasonal Influenza Vaccination Training and Provider of Training Programmes
- Interprofessional Learning Conference
- Changes in the Continued Registration Process
- ► Alert: Blackrock Clinic Prescription Pad Theft

Overview

The Council of the PSI elected a President, Dr. Ann Frankish, pictured here with Kathleen Lynch, T.D., Minister of State at the Department of Health with special responsibility for Primary Care, Social Care (Disabilities & Older People) and Mental Health. Minister Lynch PSI's recently visited the premises and addressed the first meeting of the new PSI Council.



In this newsletter, we highlight a number of items relating to pharmacy practice guidance and development, as well as provide an overview of plans for a new inspection model. Inspection statistics for routine inspections carried out in 2014 have also been published.

The new Pharmacy Practice Guidance Folder has now been distributed to retail pharmacy businesses and is also available to access electronically on the PSI website. This practical tool is intended to assist practitioners in meeting their professional obligations. We also draw your attention to new PSI Guidance on Extemporaneous Dispensing, and seek comments through public consultation on draft Guidelines in relation to the Sale and Supply of Medicinal Products from Pharmacies.

Finally, we take this opportunity to highlight a conference, due to take place in October, on Interprofessional Learning which the PSI is jointly hosting with other Irish health and social care regulators. Interest in attending and/or submitting an abstract for participation is welcomed.

Reminder of Responsibilities under the Pharmacist Code of Conduct

The PSI would like to remind all pharmacists of their responsibilities under the Code of Conduct to patients and members of the public with regard to the products they sell and the services they provide in their pharmacy.

Pharmacists should consider the appropriateness of selling products and providing services where no clinical evidence exists to confirm their efficacy. Care should be exercised with regards to the promotion of any such products to ensure that it is not misleading. When sold from a pharmacy, members of the public may perceive products to be medicines and therefore it is essential that clear and accurate advice is provided regarding their perceived mode of action and potential benefits.

The Code of Conduct requires pharmacists to exercise their profession in a manner that is directed to maintaining and improving the health, wellbeing and safety of patients and the public. A pharmacist must also provide honest, relevant, accurate, current and appropriate information to patients regarding the nature, cost, value and benefit of medicines, health-related products and

- Alert: Attempts to obtain medicines illegally using forms originating in Northern Ireland
- PSI Council Appointments
- Pharmacy Benevolent Fund Update
- HPRA Drug Safety Newsletter
- Upcoming CPD Opportunities

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services provided by them. Pharmacists must consider this responsibility in the context of all products and services provided or offered in the pharmacy.

Inspection Findings 2014

In 2014, 624 routine systems inspections were carried out by Authorised Officers (Inspectors) of the PSI. During routine inspections, the PSI Inspectors examines the way in which medicines are supplied from pharmacies to ensure a legitimate and safe basis for their supply. They also review premises, workflow and the conditions existing for the storage and preparation of medicines, amongst other things.

An overview of the findings and key statistics from the routine systems inspections carried out in 2014 is now available on the PSI website. These details are provided for information, in order to assist pharmacy staff in continuing to improve standards of compliance.

Reminder: Inspection Policy Update and Call for Participants in Focus Group Meetings

As communicated earlier this week, the PSI is continuing the development of a new Inspection Policy. The full update, as issued to registrants, is available on the PSI website.

The PSI is looking for pharmacists and pharmacy owners to participate in focus group meetings to assist the project team in the design and development of the self-audit tool for pharmacies. These meetings will be conducted in July 2015, with details (including locations and dates) to be confirmed. By participating in one of these focus group meetings, you will have the opportunity to submit input into the design and development of the self-audit tool for pharmacies.

If you are interested in participating in the focus group meetings, the PSI would like to hear from you and you can register your interest by emailing your details to inspectionproject@psi.ie on or before **Friday**, **3rd July 2015.**

Further opportunities to participate in this project, including involvement in the pilot inspections, will be communicated to stakeholders in due course. The PSI will provide regular updates and information on this project as it progresses over the coming months, via the PSI website, this Newsletter and other communications.

The PSI will continue to conduct pharmacy inspections in accordance with Section 67 of the Pharmacy Act 2007 during the course of the project.

Internet Supply of Non-Prescription Medicines

As of Wednesday, 24th June 2015, anyone in Ireland who wishes to sell non-prescription medicines over the internet must make an application to the PSI to be entered on the Internet Supply List. They must also display a new EU-wide common logo on every page of their website offering medicines for sale. The common logo can only be used by suppliers who are entered on the list.

The common logo will enable the public to identify legitimate online suppliers of non-prescription medicines, so that they are assured that they are purchasing safe and genuine medicines online.

These requirements apply to pharmacies and other retailers who supply non-prescription medicines online. Pharmacies can sell all categories of non-prescription medicines online (ie pharmacy-only and general sales list). Other retailers can only sell general sales list medicines online.

Prescription medicines are still not permitted to be sold over the internet in Ireland.

Further details and application forms are now available in the Internet Supply section of the PSI website. Queries should be directed to internetsupply@psi.ie.

New Pharmacy Practice Guidance Folder

The PSI has published a Pharmacy Practice Guidance Folder which contains current PSI guidance documents. This is intended as a practical resource to be used by pharmacists and pharmacy owners to assist in ensuring that their pharmacy is operating safely, in line with legislation and good practice requirements.

The folder should, by now, have been received by supervising pharmacists in all registered retail pharmacy businesses. The folder should be made available in the pharmacy for all pharmacists and staff members to reference in their daily practice.

A hard copy of guidance that is approved since finalising the Pharmacy Practice Guidance Folder will be sent to all retail pharmacy businesses in the coming months so that these can be added to the folder.

This will include:

- Guidance for Pharmacists on the Safe Supply of ellaOne®
- Guidance for Pharmacists on Extemporaneous Dispensing

All documents are also available electronically to download and/or print in the Pharmacy Practice section of the PSI website. If you have any queries in relation to any of the guidance documents included in this folder, please contact the Pharmacy Practice Development Unit, by email at info@psi.ie.

Guidance for Pharmacists on Extemporaneous Dispensing

Following a period of public consultation, the PSI Council has approved **Guidance for Pharmacists on Extemporaneous Dispensing**. The purpose of this guidance is to assist pharmacists in discharging their legal and professional obligations to patients in the area of extemporaneous dispensing, and to help to ensure the safe and appropriate preparation and supply of these products.

The guidance outlines the legislation that permits a pharmacist to extemporaneously prepare a medicine in limited circumstances; specifies the decision-making process that the pharmacist should follow when considering how best to meet the patient's needs; and details the records which must be made and kept each time a medicine is extemporaneously prepared.

As always, the PSI appreciates and thanks all those who contributed to the consultation in February. A report summarising the comments received during the consultation is available on the Consultations section of the PSI website.

The final guidance can be viewed and downloaded from the PSI website, as part of the electronic version of the Pharmacy Practice Guidance Folder.

Public Consultation on Draft Guidelines on the Sale and Supply of Prescribed Medicinal Products from a Retail Pharmacy Business The PSI is seeking comments on Draft Guidelines on the Sale and Supply of Prescribed Medicinal Products from a Retail Pharmacy Business. The purpose of these guidelines is to facilitate compliance with the personal supervision requirements of the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations (S.I. No. 488 of 2008), and in particular, Regulation 9. Regulation 9 provides a legislative basis for the therapeutic and pharmaceutical review that must be undertaken by a registered pharmacist upon receipt of a prescription. As a recognised expert in the use of medicines, pharmacists have a unique opportunity and duty to discharge that responsibility in the course of his or her interaction with patients.

A copy of the draft guideline is available to view or download from the PSI website. In order to participate in the consultation process, please complete the following short online questionnaire.

Alternatively comments on the draft guidelines are welcome in writing, preferably by email to consultation@psi.ie or by post marked public consultation. The closing date for receipt of submissions is **5pm 24th July 2015.**

Reminder: ellaOne Guidance

Please note the Guidance for Pharmacists on the Safe Supply of Ulipristal Acetate 30mg (ellaOne®) has been published on the PSI website. ellaOne® has been authorised as a pharmacy-only medicine for emergency hormonal contraception which allows supply of this product without a prescription, under the personal supervision of a pharmacist. The new pharmacy pack is now available to pharmacies in Ireland. Any existing packs which display 'POM' cannot be supplied to a patient without a legally valid prescription.

The purpose of this guidance is to assist pharmacists in supplying ellaOne® safely and appropriately to patients. The guidance sets out the issues to be considered by pharmacists before making a supply and should be read in conjunction with the Summary of Product Characteristics (SmPC) which is available on the Health Products Regulatory Authority's (HPRA) website.

Due to the nature of this medicine and the associated patient counselling requirements, a private consultation between the pharmacist and the individual patient is required. This consultation should take place in the pharmacy's patient consultation area. ellaOne® should be stored in the dispensary under the direct control and supervision of the pharmacist.

The full guidance can be viewed and downloaded from the PSI website as part of the electronic version of the Pharmacy Practice Guidance Folder.

PSI Council approves 2015-2016 Seasonal Influenza Vaccination Training and Provider of Training Programmes

In June 2015, the Council of the PSI agreed the mandatory training requirements for pharmacists wishing to participate in the delivery of the 2015-2016 Seasonal Influenza vaccination service. The training course that a pharmacist will be required to attend depends on both the previous training completed and the vaccination experience of the individual pharmacist. A training needs assessment guide, to help pharmacists identify the correct training course to address their training needs, is available on the PSI website.

Some pharmacists may be required to complete an additional face-to-face course 'bridging training'. This is to ensure that the national standardised injection technique is used by all pharmacists delivering the influenza vaccination in the 2015/2016 season.

The PSI Council has approved and recognised Hibernian Healthcare Ltd. as a provider for the provision of seasonal influenza vaccination training for pharmacists for the 2015-2016 season for the vaccination of adults aged 18 years and over. At its meeting on 25 June 2015, the PSI Council approved a number of training courses for the purposes of the 2015/2016 'flu season. The list of approved training providers and courses can be found here.

Interprofessional Learning Conference

A number of Irish health and social care regulators – CORU, the Medical Council, the Nursing and Midwifery Board of Ireland and the PSI, supported by the Dental Council – will jointly host a conference on 6th October 2015 focused on interprofessional education and learning for collaborative practice in the health and social care professions.

The broad theme of the conference is 'Advancing health and well-being through interprofessional learning for collaborative practice: Good practice, Dilemmas and Future Directions'.

This full day conference will take place in Dublin Castle Conference Centre and will comprise of two keynote addresses, parallel interactive workshop sessions and plenary panel discussions. For further information visit the conference website. Those interested in attending are asked to register their interest in advance of the official conference registration. The call for Abstracts for workshop presentations is now open with a submission deadline of **3rd July 2015**.

Changes in the Continued Registration Process

We would like to inform all registrants that from July 2015, the Pharmaceutical Society of Ireland will be changing the way that the continued registration renewal process operates.

The first change planned will be that the PSI will no longer issue hard copy renewal forms for pharmacists and pharmaceutical assistants. From July 2015 until January 2016, at the time of continued registration renewal, all pharmacists and pharmaceutical assistants will be issued with a single page letter by post and email advising them of the option to either apply online or to download the application form for completion. This will be the only hard copy correspondence issued in the continued registration process. Applicants may then apply and pay the registration fee directly and securely online at the PSI website.

The online system is the easiest and quickest way to apply for annual continued registration, and is available 24 hours a day.

Registrants are also asked to note the following associated changes:

- From July 2015, reminders and late fee notices will be issued in electronic form only.
- From January 2016, no hard copy letter will be issued. All
 communications regarding continued registration will be done in
 electronic form only. Similarly, where an individual wishes to obtain a
 specific form, they will have to contact the office of the PSI directly.
- Voluntary cancellation forms, checklist forms and the online guidance leaflet will be accessible on the continued registration page of the PSI website.

Alert: Blackrock Clinic Prescription Pad Theft

The PSI has been made aware of the theft of a prescription pad from the Blackrock Clinic in Dublin. Pharmacists are asked to be vigilant of any

Blackrock Clinic prescriptions that have been presented, particularly in the past three months, or is presented. The prescriptions serial numbers concerned are 15301 - 15350.

The Blackrock Clinic has requested that any information regarding this prescription pad, including if such a prescription is presented, to be reported to them at either the Matrons' Office on 01-2064302 or the Pharmacy on 01-2064362.

The PSI would like to remind pharmacists to remain vigilant in assessing all prescriptions.

Alert: Attempts to obtain medicines illegally using forms originating in Northern Ireland

The PSI has been made aware of an incident whereby a patient registered with a doctor's surgery in Northern Ireland has illegally obtained medicines from a number of pharmacies in the Republic of Ireland using their repeat medication list.

GP surgeries in Northern Ireland often use the right hand side of the green NHS prescription form (HS21) to provide patients with a list of their current repeat medicines. This can then be used by the patient to re-order a new prescription for their medicines from the GP surgery. It is understood that in the incident described above, the patient presented this list to community pharmacies in the Republic of Ireland as a 'private prescription' and subsequently obtained supplies of co-codamol and tramadol.

Pharmacists are reminded:

- to be vigilant in the context of the matters as raised above;
- that all private prescriptions must meet legal requirements, to include the name, address and signature of the prescriber;
- that if you are in any doubt as to whether a prescription is genuine or not, always contact the prescriber or surgery specified on the prescription.

PSI Council Appointments

The Minister of State for Primary and Social Care, Kathleen Lynch T.D., has appointed ten individuals to the Council of the PSI. These include Mr. Fintan Foy (CEO of the College of Anaesthetists of Ireland), Mr. Graham Knowles (Former CEO of the Royal Hospital Donnybrook), Ms. Ann Sheehan (Business Development Specialist), Mr. Paul Turpin (Governance specialist with the Institute of Public Administration), Assistant Professor Sheila Ryder (Assistant Professor in Pharmacy Practice, TCD), Mr. Rory O'Donnell (Community pharmacist), Ms. Muireann Ni Shuilleabhain (Hospital pharmacist), Ms. Joanne Kissane (Community pharmacist). The Minister also re-appointed Mr. John Corr (Community pharmacist) and Mr. Pat O'Dowd (Assistant National Director with the HSE). A short biography of all Council members and dates of the next Council meetings are available on the PSI website.

Pharmacy Benevolent Fund Update

The Pharmacy Benevolent Fund supports pharmacists and those who have been associated with pharmacy who are in need of assistance. The funds are put to a wide variety of uses to improve the basic quality of life of those in need. For more information, including details of how you can support the Benevolent Fund financially, through volunteering to help with fundraising and other activities, please visit the pharmacy benevolent fund website.

Upcoming Event: Helix Health Pharmacist Awards on Saturday 21st November. This event is held in association with the Benevolent Fund, which receives all the proceeds. To find out more, including details of how to nominate pharmacists for the awards, visit the pharmacist awards website.

If you know anyone who might need help from the Pharmacy Benevolent Fund, or you require help yourself, you can get in touch with the Benevolent Fund by e-mail to info@pbf.ie or by contacting the Fund's Social worker, Mary Dowd (email: marydowd@gmail.com or tel: 087 6884966). All referrals are treated in the strictest confidence.

HPRA Drug Safety Newsletter

The most recent HPRA Drug Safety Newsletter (DSN), issue 68, is now available on the HPRA website and includes information regarding:

- Ibuprofen: Review confirms small increased cardiovascular risk with daily doses at or above 2,400mg
- Codeine: Restricted use in children and adolescents for cough and cold
- Adverse Reaction Reporting: reminder
- EU Healthcare Professional Survey: have your say on how safety recommendations for medicines are communicated
- Direct Healthcare Professional Communications published on the HPRA website since the last Drug Safety Newsletter

Upcoming CPD Opportunities

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.

NUI, Galway MSc Biomed

Applications are also invited for a two-year distance learning Master's in Biomedical Science at NUI Galway's National Centre for Biomedical Engineering Science. This course allows students to remain in full-time employment while completing the full programme. Alternatively, there is also a module-by-module version of the course which allows students to take single modules of interest to them. For further information, see the webpages for the full course and for the modular option.

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