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## Overview

This newsletter provides notice of a call for nominations for pharmacist members for appointment to PSI Council. A number of terms of office of Council members will come to an end this June, and an election for pharmacist appointees will be held on Wednesday 15th of April.



Additionally, pharmacists are asked to consider their interest in contributing to the work of PSI Advisory Committees. Expressions of interest are now welcomed for a variety of positions on Committees, so as to ensure that a broad range of skills and expertise are available to the PSI.

This issue also provides a number of inspection related updates: notice of verification inspections as well as Inspectors' Advice on the segregation and destruction of controlled drugs.

We take this opportunity to remind you of the ongoing public consultation on the draft extemporaneous dispensing guidance and welcome any comment through the survey below or by email. Finally, the published Guidelines on the Premises and Equipment Requirements of a Retail Pharmacy Business are made available following earlier consultation and can be found on the PSI website.

## Elections for Pharmacist Members of Council 2015

Terms of office of a number of Council members will come to an end on 14<sup>th</sup> of June this year. The four pharmacist vacancies on Council will be filled through a defined selection process, and the Registrar, Marita Kinsella, in her capacity as Returning Officer, now requests nominations from pharmacists on the Register of Pharmacists held by the PSI who may wish to stand for selection for appointment to the PSI Council.

Nomination papers are available on the [PSI website](#) or by request from the Registrar. If the number of nomination candidates received is greater than the number of vacancies, then an election will be held on Wednesday 15<sup>th</sup> April, in accordance with Section 10(3)(f) of the Pharmacy Act 2007.

The closing date for receipt of nomination papers is **Wednesday 18th March 2015 at 12 noon**. Nomination papers should be returned to: Returning Officer, PSI House, 15-19 Fenian Street, Dublin 2. The electoral register will be established on that date. Election timelines and additional information is available on the [PSI website](#).

The 21 member PSI Council is responsible for ensuring the delivery of the functions of the PSI as set out in the Pharmacy Act 2007. Appointments to Council by the Minister for Health are made for a four year term. Members appointed to the Council act in the public interest to ensure the statutory functions of the PSI, to regulate the profession and practice pharmacy, are effectively performed. Information on the responsibilities of Council including practical information on Council meetings and workload is available [here](#).

## Expressions of Interest for PSI Committees

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Expressions of Interest are being sought from pharmacists, public interest representatives and healthcare professionals to participate in the ongoing work of four of the PSI's Advisory Committees.

PSI Advisory Committees are established by PSI Council to assist it in the performance of its functions, and to ensure that a broad range of contributions, skills and qualities are available to it in the interest of patients and the public. Committees are composed of Council and non-Council members who demonstrate knowledge, skills and/or expertise in the primary area of focus and responsibility of a particular Committee.

Individuals are asked to consider their interest in contributing to the work of the PSI through its Committees. The eight areas of skill and expertise are set out in the [recruitment section of the PSI website](#), and requires pharmacists from different practice settings; employee pharmacists and pharmacy owners; those with experience with another healthcare regulator; and those with experience of quality and risk management systems. Non-pharmacist roles will also be circulated separately.

Suitably qualified persons, possessing the key attributes and experience required are invited to **register their interest by email** to [info@thepsi.ie](mailto:info@thepsi.ie) **by Friday 6<sup>th</sup> March 2015**. Please mark the subject as '**Committee Expressions of Interest**'. In applying, please refer to the reference number of the position that interests you, and outline with specific examples how you hold the key attributes and experience for that position. All applications received will be acknowledged. Detailed information on these Committee positions are available on the [PSI website](#).

## PSI (Council)(Amendment) Rules 2015

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As notified in the previous newsletter, in December Council adopted in principle the draft Rules amending the Pharmaceutical Society of Ireland (Council) Rules 2008 (*S.I. No. 492 of 2008*). As is required a [public consultation](#) on the proposed amendments was conducted until 16<sup>th</sup> January and those comments have been taken into consideration. Council approved the Rules on 29<sup>th</sup> January, and the proposed statutory instrument will be provided to the Minister for Health for his signing.

The amendments set out the changed procedures for the conduct of the elections of the President and Vice-President of Council, and also establish arrangements for the formation of a panel of pharmacist candidates at the time of Council elections, to be drawn from in the event that casual vacancies arise on Council.

## PSI Guidelines on the Premises and Equipment Requirements of a Retail Pharmacy Business

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The PSI has published Guidelines on the Premises and Equipment Requirements of a Retail Pharmacy Business to facilitate compliance with the requirements specified in the Regulation of Retail Pharmacy Businesses Regulations 2008 (*S.I. No. 488 of 2008*).

The [Guidelines on the Premises Requirements of a Retail Pharmacy Business](#) are intended to assist pharmacy owners (those applying to open a pharmacy and owners of existing pharmacies), as well as all pharmacists, but in particular superintendent and supervising pharmacists, in ensuring that their premises meet required standards. It will also assist those planning for changes in their premises, such as refurbishments.

The [Guidelines on the Equipment Requirements of a Retail Pharmacy Business](#) are intended to assist pharmacy owners, as well as all pharmacists, but in particular superintendent and supervising pharmacists, in the delivery of pharmacy services using equipment that is fit for purpose and well maintained.

A public consultation was carried out on these guidelines in 2012 and the submissions received along with the PSI responses may be viewed in the Consultation section of the PSI website. These and related guidelines are available together in the [practice guidance section](#) of the PSI website.

These guidelines have been formatted into two separate documents for inclusion in the 'Pharmacy Practice Guidance Folder'. As highlighted earlier, the Pharmacy Practice Guidance Folder will be a hard copy resource containing all recently published PSI guidance for ease of reference. The PSI intends to send this folder in hard copy to all retail pharmacy businesses in the coming months.

## Practice Update

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### Levonorgestrel 1500mcg tablets

#### **1. Brand Name Change and POM to P Switch**

From 1<sup>st</sup> March 2015, Levonorgestrel 1500 mcg Emergency Contraception, will be available from Consilient Health under the brand name Prevenelle 1500® (formerly known as Levonelle®). In addition, Prevenelle 1500® has been reclassified from a prescription only medicine (POM) to pharmacy only (P), not subject to medical prescription.

#### **2. Body Weight and Efficacy**

Following the outcome of an EMA review in 2014, it was concluded that there is limited and inconclusive data on the effect of body weight and BMI on the contraceptive efficacy of Levonorgestrel 1500mcg, ([PSI Newsletter, Issue 6 2014](#)). Patients should be advised to take emergency contraception as soon as possible after sexual intercourse regardless of their BMI or body weight. This information is now reflected in the specific products' SmPCs and PLs. Pharmacists are asked to consult the [HPRA website](#) for up-to-date SmPCs and PLs for all relevant Emergency Contraception products available for pharmacy only supply on the Irish market.

#### **3. Updated Guidance**

In light of these developments, the PSI has updated its *Guidance for Pharmacists on the Safe Supply of Non-Prescription Medicinal Products Containing Levonorgestrel 1500mcg for Emergency Hormonal Contraception*, reflecting the updated SmPCs and PLs. The updated guidance is available here on the [PSI website](#).

## Learning from Fitness to Practise Inquiries, No. 1

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One of the ways in which the PSI carries out its function to regulate the profession of pharmacy is by handling complaints raised about pharmacists and pharmacy owners. Part 6 of the Pharmacy Act 2007 sets out the process to be followed when a complaint is made, and the sanctions that can be imposed on a pharmacist or pharmacy owner if the complaint is substantiated. More information on the PSI's complaints process can be found on our [website](#).

The PSI intends to share learnings from fitness to practise inquiries in order to help prevent similar incidents from happening again, and to help improve practice by highlighting potential errors and risks. All registrants should consider how they can use these learnings to review and improve their own practice and policies.

In this issue we include [a complaint involving the dispensing of a High Tech medicine](#).

## Inspectors' Advice on Controlled Drug Segregation and Destruction

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The management of controlled drugs (CDs) is reviewed during all inspections. This review examines, amongst other matters, the manner in which date-expired or damaged controlled drugs and patient returned controlled drugs are managed at the pharmacy.

Please remember that a pharmacy is **never** permitted to sell or supply a medicinal product which has previously been supplied to a patient, is damaged or is out of date. Controlled drugs that have been returned by patients, that are damaged or out of date should be segregated from 'live'/'active' stock and clearly labelled as 'CDs for destruction'. These must be stored in the CD safe until they are destroyed. These medicines should be promptly destroyed and should not be allowed to accumulate as this will increase the risk for error.

To assist pharmacists and pharmacies, PSI inspectors highlight important information on appropriate destruction and record keeping on this topic. This is available on the [PSI website](#).

## Inspection Updates

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### Inspection Policy Update

An independent Project Expert Group was appointed by the Council of the PSI in June 2014, to undertake a strategic review of the current inspection policy and to consider PSI inspection policy for the future. The report of the research findings, together with recommendations for a new inspection policy for routine inspections, is currently under consideration by the Council. The decision on the new Inspection Policy will be communicated once agreed by the Council.

### Notice of Verification Inspections

By end of December 2014, the PSI had completed the first full cycle of inspections under the Pharmacy Act 2007. This involved conducting at least one formal inspection in each community pharmacy. The PSI has now commenced the process of conducting follow-up inspections. The primary purpose of these follow-up inspections is to verify the confirmations submitted in response to the previous inspection. These inspections will be unannounced.

The PSI previously published a checklist and a podcast to assist pharmacy owners and pharmacists to prepare for inspections and to inform on what to expect during an inspection. The checklist and podcast are available in the [inspection section](#) of the website. Guidance issued by the PSI as well as pharmacy and medicines legislation are available on the PSI website. All relevant legislation can be found on [www.irishstatutebook.ie](http://www.irishstatutebook.ie).

Please review your previous inspection report to ensure that the required actions identified in that report have been fully addressed and that your retail pharmacy business is compliant with the Pharmacy Act 2007 and with other pharmacy and medicines legislation and guidelines.

## Comment sought on draft Extemporaneous Dispensing Guidance

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The PSI is seeking your comments on draft Guidance for Pharmacists on Extemporaneous Dispensing as part of a public consultation that issued last

week. 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 assure the safe and appropriate preparation and supply of these products.

This draft guidance is available to view and download from the [PSI website](#).

You can participate in the public consultation process by completing this [short survey](#). Alternatively, comments are welcomed in writing, preferably by email to [consultation@thePSI.ie](mailto:consultation@thePSI.ie) or by post to Public Consultation, The Pharmaceutical Society of Ireland, PSI House, 15-19 Fenian Street, Dublin 2. The closing date for receipt of comments is **Friday 27<sup>th</sup> February 2015**.

## Other Notices

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### Pharmacists for Editorial Advisory Panel

SpunOut.ie, the youth information website created by young people, for young people, is seeking up to three pharmacists willing to be part of an external Editorial Advisory Board. This is being established to ensure that relevant expertise is available to independently and voluntarily proof and comment on health-related content before publication on the website. In particular it is envisaged that pharmacists would play a role in relation to the drug harm reduction content.

SpunOut.ie is funded by the HSE and National Office of Suicide Prevention to provide information to people aged 16-25 to empower them through informed decision-making, and promote general wellbeing and healthy living. The [SpunOut.ie](#) website has 65,000 monthly readers who consume around 1.5 million pages of information each year, making this an important resource for young people.

For additional information, pharmacists should contact Ian Power, Executive Director at [ian@spunout.ie](mailto:ian@spunout.ie) or phone 01 675 3554. Applicants are asked to provide a short biography or CV outlining suitability and relevant experience for these voluntary positions by 6th March.

### New HSE QUIT Campaign

The PSI would like to bring to your attention the new QUIT support service launched by the HSE in January 2015, to help members of the public to give up smoking. The QUIT service has a new support team of counsellors available over the phone, by email, live web-chat or via Twitter or [Facebook](#), it also has a brand new interactive [website](#) and online QUIT plan. The QUIT service is evidence-based and can offer quitters a standard treatment programme, where they will be tracked and supported for 12 months. A quitter is twice as likely to quit for good if they use this service, and twice as likely again if they match the support with approved quit products or medication.

Pharmacists are in a prime position to support patients and members of the public in quitting smoking. Pharmacists and members of the pharmacy team should try to engage with smokers to encourage them to consider quitting and in doing so can signpost to the new resources provided by the QUIT campaign. Leaflets and posters are also available on [HealthPromotion.ie](#)

## Upcoming CPD Opportunities

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### IIOP Updates

The Irish Institute of Pharmacy has arranged a series of ePortfolio Information Events which will take place around the country from late March to coincide with the launch of the new ePortfolio for pharmacists; some dates are available to book now in the Events section of the IIOP website. Two new dates have also been planned for the Personal Development Training Programme in Sligo on February 17th and Cork on March 3rd. Places on



these courses can be booked on the [IIOP website](#). In addition, two more dates are planned for the Superintendent Pharmacist Training Programme in Cork and Galway. These dates will be advertised shortly. New eLearning programmes have also been made available to pharmacists recently through the IIOP Website, including programmes on Cardiovascular Disease, Diabetes and Anticoagulation.

### **IPU Academy Spring Programme**

The Spring Programme of the IPU Academy has begun and runs until early April. Details of this season's continuing education courses are now available on the [IPU Academy website](#) or you can download the [programme brochure here](#).

### **Health Literacy for Health and Social Care Settings, UCC**

A reminder that UCC's School of Pharmacy is still receiving applications from health and social care professionals to improve their understanding of health literacy and better meet the needs of patients with limited health literacy. The course commences in Spring 2015. See the [UCC website for details and application form](#).

### **Dementia Training with Elevator**

Dementia Elevator is a national education and empowerment programme developed by Dublin City University and the HSE to help individuals, communities and health systems engage appropriately with people with dementia. The Elevator project team has developed free online dementia training for customer-facing staff. A tailored resource for pharmacy staff is also in development. The training will soon be available on the [Elevator website](#) and a resource pack will also be available to facilitators who wish to deliver the training in a group setting. See this [video](#) for information and contact Elevator's development officer Ann-Marie Coen at 01 700 6190/ [ann-marie.coen@dcu.ie](mailto:ann-marie.coen@dcu.ie) should you wish to find out more.

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