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## Overview

As 2014 draws to a close, we bring you this final newsletter of the year and in it a number of important updates.

Earlier this week the PSI was delighted to welcome Minister Varadkar to PSI House where he **officially launched** the new integrated MPharm programme that will see its first intake of students to the Schools of Pharmacy in September 2015. In addressing attendees, the Minister acknowledged the important contribution and accessibility of pharmacists, and spoke of the potential for further developing the services offered by the profession.



This issue includes information on the new online application system, the Central Application and Selection Process (CAASP), that has been developed by the RCSI to support students with finding training placements.

PSI Inspectors provide clarification around balance checks for methadone products, and highlight appropriate key-holding procedures for pharmacies. This is in response to a number of queries received.

We also draw your attention to updated information around the use of ibuprofen in children and adolescents.

At its most recent meeting, PSI Council approved in principle amendments to the PSI (Council) Rules 2008, and those draft Rules are now presented for public consultation. In accordance with a decision by Council, we also publish the findings of a recent hearing before the Professional Conduct Committee.

Finally, from all at the PSI, we wish you a safe and peaceful festive season.

*Photo: At the 15th December launch at PSI House were representatives from the Schools of Pharmacy at RCSI, UCC and TCD pictured with the Minister for Health, Leo Varadkar T.D., alongside PSI President, Registrar and Chair of the PSI's Professional Development and Learning Committee.*

## Public Consultation on draft PSI (Council) (Amendment) Rules

At its meeting on the 16<sup>th</sup> December, Council adopted in principle draft Rules amending the Pharmaceutical Society of Ireland (Council) Rules 2008 (S.I. No. 492 of 2008) for the purpose of enabling all members of the Council to participate in the annual election of the President and Vice-President, including by postal ballot.

These draft rules 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 who are deemed to have been selected by the members of the Society as being eligible for appointment to the Council in the event that casual vacancies arise on the Council.

A copy of the draft Rules is available now on the [PSI website](#) and comment is welcomed by public consultation until **Friday 16<sup>th</sup> January 2015**.

Responses should be made in writing, preferably by email to [info@thepsi.ie](mailto:info@thepsi.ie), or by post to the Registrar marked Council Rules Consultation, Pharmaceutical Society of Ireland, PSI House, Fenian Street, Dublin 2.

## Practice Update

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### **Updated information on the use of ibuprofen in children and adolescents**

The PSI would like to highlight updated information on the use of ibuprofen in children and adolescents. These changes were brought to our attention by the Health Products Regulatory Authority (HPRA) following a public assessment report for ibuprofen at European level. [That full report is available to view here.](#)

Pharmacists and pharmacy staff should be aware of the following guidance and counsel parents and carers accordingly.

**When oral or rectal ibuprofen is supplied for symptomatic treatment of mild to moderate pain and/or fever, parents and carers should be advised that:**

- Medical advice should be sought for children aged 3 - 5 months if symptoms worsen, or not later than 24 hours if symptoms persist.
- Medical advice should be sought for children aged from 6 months upwards and in adolescents if symptoms worsen, or if this medicinal product is required for more than 3 consecutive days.

The Summary of Product Characteristics (SmPC) and Package Leaflet of all affected medicines are being updated to reflect this information.

## National Pharmacy Internship Programme

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### **Sourcing of Placements: Central Application and Selection Process (CAASP)**

In order to support students with finding training placements for their internship year, an online application system, the Central Application and Selection Process (CAASP), has been developed by the RCSI at the request of, and with funding provided by, the PSI. The system was developed in direct response to the needs of both students and training providers and is designed to alleviate much of the administrative burden hitherto associated with the selection process. The system will be in use in 2015 for those seeking and providing intern placements (NPIP programme).

The process requires **students and training establishments** to register their details online, where they can then submit and review CVs and indicate their preferences in ranked order. The new CAASP system then manages the matching of students with training establishments in accordance with the preferences of each party.

All aspects of the process will be undertaken online with one exception – face

to face interviews will still be conducted. While it is possible for the system to accommodate pre-existing arrangements, it is important to note that there will be no facility for placements to be agreed between training establishments and students outside of CAASP. Full details on the CAASP system are available on the [PSI website](#). Any queries on CAASP should be directed to the RCSI at [caasp@rcsi.ie](mailto:caasp@rcsi.ie).

## **Inspectors' Advice on Balance Checks & Reconciliation for Methadone Products**

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The PSI has recently received a number of queries regarding managing balance checks in relation to methadone 'overages' that may occur in the pharmacy. To assist pharmacists in maintaining the controlled drugs register for methadone products, PSI Inspectors have provided advice that is now available on the [PSI website](#).

## **Key-Holding for Pharmacies**

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It has come to the attention of the PSI that certain pharmacies permit wholesaler delivery drivers to access the pharmacy premises before or after opening hours, without a pharmacist being present, in order to facilitate the delivery of orders. The PSI would like to provide clarifications to pharmacy owners and pharmacists in relation to these arrangements.

The Pharmacy Act 2007 provides that the sale and supply of medicines, including the keeping of medicines, must be carried out under the personal supervision of a registered pharmacist. This means that non-pharmacists, including non-pharmacy employees, may not have access to the pharmacy premises in the absence of a registered pharmacist.

It is not lawful or appropriate for wholesaler delivery drivers to be key-holders for pharmacies, and to have access to areas of pharmacy premises where medicines, patient records and other confidential records are stored.

The Superintendent Pharmacist, acting through the Supervising Pharmacist, is responsible for the management, control and safe keeping of all medicines, patient records, and other confidential records kept in pharmacies. The Superintendent and Supervising pharmacist, in conjunction with the pharmacy owner, are accountable for making sure that unauthorised access to medicines and pharmacy records is prevented at the pharmacy.

## **Pharmaceutical Assistant Qualification**

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The National Framework of Qualifications (NFQ) was established in 2003 as the framework through which all learning achievements may be measured and related to each other. The qualification to become a Pharmaceutical Assistant ceased in Ireland in the late 1980s long before the establishment of the NFQ. Today, most qualifications are mapped to the NFQ and this allows for easy recognition of a qualification.

As the Pharmaceutical Assistant qualification is not aligned to the NFQ, at the request of the Pharmaceutical Assistants' Association, the PSI agreed to submit an application to Quality and Qualifications Ireland (QQI) to have the qualification evaluated for placement on the NFQ. Over the past 12 months, the PSI has undertaken significant archival work to develop a comprehensive overview of the qualification in order to make a submission to QQI. Further to this work, a survey has been developed by the PSI which will be sent out shortly to former lecturers and tutors involved with the final iteration of the Pharmaceutical Assistant qualification in order to have complete information available for the purposes of the application to QQI. The PSI expects to submit the application to QQI in early 2015 with a view to the qualification being placed on the NFQ by end of June 2015. (Further information on the

NFQ can be found on the [Quality and Qualifications Ireland website](#).)

## HPRA Drug Safety Newsletter

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The latest HPRA Drug Safety Newsletter (DSN), issues 64 and 65, are now available on the [HPRA website](#) and include updates on the following:

- **Newer Oral Anticoagulants (NOACs):** Updated information about the increased risk of bleeding and haemorrhage during the use of NOACs such as apixaban, dabigatran and rivaroxaban.
- **Adverse Reaction Reporting:** Reminder to pharmacists to report any suspected adverse reactions to the HPRA in order to facilitate the continued surveillance of the safety of medicines.
- **Valproate – Containing Medicines:** Updated information about the recommendation to further restrict the use of valproate in women and girls.
- **Ivabradine (Procoralan):** Updated recommendations to minimise the risk of cardiovascular events and severe bradycardia.
- **Agomelatine (Valdoxan):** Reminder of the importance of liver function monitoring to reduce the risk of serious hepatic adverse reactions.

## Pharmacy Benevolent Fund Draw

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The Pharmacy Benevolent Fund is now gratefully accepting subscriptions to its annual confined draws for 2015. This facilitates the Fund's support of pharmacists and their families who are experiencing difficult times. The annual draw form and further information is available on the [Pharmacy Benevolent Fund website](#).

## Upcoming CPD Opportunities

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

A new offering at UCC's School of Pharmacy provides opportunity for 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 and information is available on the [UCC website](#). [Closing date for applications](#) is Monday 2nd February 2015.

### All-Ireland Pharmacy Conference 2015

The 7th All-Ireland Pharmacy Conference will take place in Ballymascanlon House Hotel, Dundalk on the 26th and 27th January 2015. The focus is to share good practice in pharmaceutical care and practice development across the primary and secondary care sectors. Registration to attend is now open to all those working as part of the pharmacy team, and further information is available on the [IIOP website](#).

### Irish Institute of Pharmacy (IIoP)

A reminder that the [IIOP website](#) provides access to information on courses offered by the IIoP, and on courses and events from other providers. Pharmacists can also connect with the IIoP on their social media platforms to keep up-to-date on all CPD opportunities.

## In the matter of Part 6 of the Pharmacy Act 2007

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### Mr Adrian Conlon MPSI (Registration No.5781)

Following the submission of a report of the Professional Conduct Committee, the Council, at its meeting on the 26<sup>th</sup> June 2014, decided to censure and attach the following conditions to the registration of Mr Adrian Conlon MPSI, Registration Number 5781, in relation to the findings of professional misconduct and poor professional performance made by the Professional Conduct Committee in its report of the 23<sup>rd</sup> May 2014 which are set out in

*Appendix 1* attached to this notice:

1. That Mr Conlon shall not act as a superintendent pharmacist for a period of twelve months.
2. That Mr Conlon should promptly enter into a mentoring programme with a senior experienced pharmacist to be nominated by the Registrar of the PSI. The mentor will assist Mr Conlon in his efforts to improve his practice of pharmacy, he shall comply with all advice, guidance and recommendations (to include a programme of self-audit) to the satisfaction of the mentor. He shall authorise the mentor to provide reports on his progress to the Registrar every two months. His mentorship shall continue for a period of twelve months and within that period he shall satisfy the mentor that he has successfully and adequately addressed the deficits in his professional performance.
3. Mr Conlon shall discharge the costs associated with the implementation and in compliance with these conditions.

**The reasons for the Council decisions were as follows:**

- (i) The serious nature of the professional misconduct and poor professional performance;
- (ii) Mr Conlon's admissions of a number of the matters alleged and his full co-operation in all aspects of the Inquiry process;
- (iii) The need to safeguard the public interest,
- (iv) To facilitate his rehabilitation as a pharmacist;
- (v) To send the appropriate message to the public and to the profession in the context of continued public confidence in the profession.

**Appendix 1:**

**Findings:**

1. Failed to ensure that part of the retail pharmacy business that consists of the management and administration of the sale and supply of medicinal products was carried out under your personal control and/or in accordance with all legal requirements and/or in so doing acted in breach of Regulation 5 (1)(a) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) (hereinafter called "SI 488/2008") in that you;

- Failed to preserve or keep readily available a Prescription Register and/or in so doing caused a breach of Regulation 10 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (SI no. 540 of 2003)(as amended) (hereinafter called "SI 540/2003 (as amended))

**FINDING: POOR PROFESSIONAL PERFORMANCE**

- Failed to adequately and/or properly ensure the segregation of out of date medicinal products from other medicinal products and/or failed to ensure that out of date medicinal products were removed for disposal or destruction and /or failed to ensure that there were adequate systems in place for medicines waste management

**FINDING: POOR PROFESSIONAL PERFORMANCE**

- Failed to ensure that medicinal products were stored in an adequate or appropriate environment or manner

**FINDING: POOR PROFESSIONAL PERFORMANCE**

2. Failed to keep or adequately keep a controlled drugs register in the prescribed manner and/or in so doing caused a breach of Regulation 16 of the Misuse of Drugs Regulations 1988 (SI328/1988)(as amended) and/or Regulation 10 of the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations, 1998 (S.I. No.225 of 1998) and/or Regulation 12 (1) (b) of SI 488/2008

**FINDINGS: POOR PROFESSIONAL PERFORMANCE and PROFESSIONAL MISCONDUCT**

3. Failed to ensure that schedule 2 and schedule 3 controlled drugs were

stored in a locked fixed receptacle and/or in so doing caused a breach of Regulation 4 (4) of SI 488/2008 and/or Regulation 4 (1) of the Misuse of Drugs (Safe Custody) Regulations 1982 (S.I. No. 321 of 1982) (as amended)

**FINDINGS: POOR PROFESSIONAL PERFORMANCE and PROFESSIONAL MISCONDUCT**

4. Failed to preserve and keep readily available for inspection at the premises for a period of 2 years from the relevant date a prescription for 60 units of the medicinal product Oxycontin 5mg dispensed on the 31<sup>st</sup> day of December 2011 to Patient A and/or in so doing acted in breach of Regulation 10 of SI 540/2003 (as amended).

**FINDING: POOR PROFESSIONAL PERFORMANCE**

5. Failed to preserve and keep readily available for inspection at the premises for a period of 2 years from the relevant date a prescription for 30 units of the medicinal product Oxycontin 20mg dispensed on the 21<sup>st</sup> day of December 2011 to Patient B and/or in so doing acted in breach of Regulation 10 of SI 540/2003 (as amended)

**FINDING: POOR PROFESSIONAL PERFORMANCE**

6. Failed to preserve and keep readily available for inspection at the premises for a period of 2 years from the relevant date a prescription for 30 units of the medicinal product Equasym XL 10mg dispensed on the 23<sup>rd</sup> day of March 2012 to Patient C and/or in so doing acted in breach of Regulation 10 of SI 540/2003 (as amended)

**FINDING: POOR PROFESSIONAL PERFORMANCE**

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