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Overview

This issue of the PSI newsletter contains a number of practice guidance updates as well as notice of several relevant legislative changes.

Since last issue, PSI Council has elected a new President, Ms. Leonie Clarke and a new Vice-President, Dr. Ann Frankish. Additionally, the PSI's Annual Report and Financial Statements for 2013 have been published and are available to view and download on the [PSI website](#).



This issue also highlights the second instalment of findings from inspections carried out by the PSI in 2013. Part two of these key statistics relate to the supply of prescription only medicines and the management of controlled drugs in pharmacies.

Guidance on the Delivery of Prescription Medicine from a Pharmacy was approved by Council at its most recent meeting as were the training requirements, training providers and guidance for the 2014/2015 flu season, and this information is provided.

This issue also has notice of recruitment opportunities in the PSI's Pharmacy Practice Development and Inspection units. We also remind registrants of the imminent closing date for your comment in relation to PSI inspection policy as part of the ongoing strategic review. Finally, we ask you to 'save the date' for PSI learning events to consider inspection and fitness to practise topics this October.

Findings from Inspections in 2013 (Part 2)

The second instalment of compliance statistics for inspections carried out in 2013 are now available on the [PSI website](#). Part two of findings for 2013 relate to prescriptions and control of supply and the management of controlled drugs so as to ensure legitimate and safe basis for supply from the pharmacy. As with the statistics provided in the previous PSI newsletter, relevant resources are also provided to assist pharmacists and pharmacy staff in meeting the standards of compliance expected under the Pharmacy Act 2007.

PPC Annual Report and Learning Points for Pharmacists

Along with the publication of the PSI's Annual Report 2013, the PSI's Preliminary Proceedings Committee (PPC) has also published its 2013 Report, making observations from complaints considered by it during the year. The role of the PPC is to consider all complaints made to the PSI and to make recommendations to Council as to whether those complaints warrant further action or not. The PPC's Report is available to [view here](#).

Some of the practice issues observed in the PPC Report are now highlighted on the [PSI website](#) along with what pharmacists can learn from these observations in order to minimise the risk of these errors occurring in their pharmacies. These include [observations and learnings](#) on dispensing errors, high risk dispensing practices (eg. dispensing for children and the dispensing of methotrexate), and a variety of communication issues.

Practice Updates

Guidance on the Delivery of Medicines Dispensed on Foot of a Prescription from a Retail Pharmacy Business

The PSI Council has approved [Guidance on the Delivery of Medicines Dispensed on Foot of a Prescription from a Retail Pharmacy Business](#) (Pharmacy). The purpose of the guidance is to outline the requirements that must be fulfilled when a pharmacy provides a delivery service for medicines dispensed on foot of a prescription to their patients. Many pharmacies have traditionally provided a delivery service for dispensed medicines whenever this was necessary in the interest the health, safety and convenience of the patient. This guidance document therefore sets out the obligations of pharmacy owners and pharmacists including superintendent, supervising and registered pharmacists, in assuring the security and safety of delivery systems and ensuring compliance with legal and professional requirements.

The approval of the guidance follows a public consultation process on the initial draft guidance which closed on the 13th June. The PSI would like to thank all those who contributed to the consultation. The submissions received and responses to those are available on the [PSI website](#).

PSI Council approves 2014-2015 seasonal influenza vaccination training and the Report on the Evaluation of the Seasonal Influenza Vaccination Service in Pharmacies 2013-2014

Training 2014-2015 Season

In May 2014, the Council of the PSI agreed the mandatory training requirements for pharmacists wishing to participate in the delivery of the 2014-2015 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 here on the [PSI website](#).

The PSI Council has approved and recognised two training providers, **Hibernian Healthcare Ltd.** and **Boots Retail (Ireland) Ltd.** for the provision of seasonal influenza vaccination training for pharmacists for the 2014-2015 season for the vaccination of adults aged 18 years and over. At its meetings held on 26 June and 31 July 2014, the PSI Council approved a number of training courses for the purposes of the 2014-2015 'flu season. The list of approved training providers and courses can be found [here](#).

Evaluation Report 2013 -2014

The PSI has published a Report on the [Evaluation of the Seasonal Influenza vaccination Service in Pharmacy 2013-2014](#). The report notes that the seasonal influenza vaccination service provided in pharmacies continues to operate effectively and no quality or safety concerns were identified in the evaluation. It was also reported that the numbers of patients who were vaccinated in pharmacies more than doubled from approximately 19,000 in the 2012-2013 season to 40,908 during the 2013-2014 season.

Guidance

The PSI [Guidance on the provision of the seasonal influenza vaccination service by pharmacists](#) has been approved by PSI Council and is re-issued

unchanged for the 2014-2015 influenza season. The guidance is intended to support pharmacists in providing a seasonal influenza vaccination service in line with the legislation and will be reviewed and revised as necessary going forward in light of any practice changes in this area. As pharmacists prepare for the delivery of vaccination services in pharmacies for the 2014-2015 season, they should ensure that they are aware of the requirements in the [PSI Guidance](#) which includes a self-assessment checklist for the pharmacy.

The PSI carried out inspections on the provision of 'flu vaccination services in a number of pharmacies during the 2013-2014 season. Areas highlighted for improved compliance included the need for improved and complete recording of vaccine administration in the patient's medication record and the prescription register, together with the name and registration number of the vaccinating pharmacist. At the start of a new season pharmacists are advised to undertake an internal review of the service in the pharmacy, including the review and updating of relevant SOPs. Practice runs within the pharmacy, together with internal sign off of the service should also be reviewed and updated prior to the commencement of the service for 2014-2015. Full details of the requirements can be found in the PSI guidance and self-assessment checklist. All related information is available in the [Pharmacy Services guidance section](#) of the PSI website.

Important New Information on the Clinical Efficacy of Levonorgestrel and Ulipristal

The PSI wishes to draw pharmacists' attention to important new information from HPRA (formerly IMB) and the European Medicines Agency (EMA) on the clinical efficacy of the emergency hormonal contraceptives containing levonorgestrel and ulipristal.

The EMA has concluded that levonorgestrel and ulipristal are suitable emergency contraceptives for all women, irrespective of body weight. This follows a review of emergency contraceptives to assess whether increased body weight affects the effectiveness of these medicines in preventing unintended pregnancy following unprotected sexual intercourse or contraceptive failure. The full outcome of the EMA review can be found [here](#).

This [HPRA statement](#) has been issued providing advice to healthcare professionals, on this issue, prior to the updated product information being available.

In light of this new information, the product information will be revised and updated by the medicines agencies, and the PSI will also now review and update PSI guidance to pharmacists on the safe supply of Norlevo products, in line with updated product (SmPC) and patient information being approved.

Save the Date – PSI Learning Events

The PSI will hold learning events for pharmacists this Autumn that will focus on the PSI's inspection and enforcement and fitness to practise processes. These will consider learnings useful to pharmacists and include practical group input and discussion. Further information including how to book your place for the evening meetings will be communicated in due course.

The learning events will be held at these locations:

Tuesday 7th October: PSI House, Dublin 2

Wednesday 8th October: PSI House, Dublin 2

Thursday 9th October: Silver Springs Moran Hotel, Tivoli, Cork

Tuesday 14th October: Clayton Hotel, Ballybrit, Galway

Wednesday 15th October: Clarion Hotel, Clarion Road, Sligo

Thursday 16th October: City West Hotel and Conference Centre, Saggart, Co. Dublin

PSI Inspection Policy Survey

The PSI has commenced a strategic review of the current PSI inspection policy with a view to developing a new inspection policy for routine pharmacy inspections for the next cycle of routine inspections commencing in 2015.

This is a reminder to pharmacists, pharmaceutical assistants and pharmacy owners of the surveys recently circulated for your input and which remain open for any final submissions this Friday, 8th August. Comment is welcomed from the profession in relation to the current PSI inspection process whether you have or have not yet experienced a PSI pharmacy inspection. Further information on the project and access to the surveys is available on the [PSI website](#).

Legislative Updates

The PSI would like to inform pharmacists of the following updates to legislation:

Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) Regulations 2013

Pharmacists should be aware of the commencement of the Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) Regulations 2013 on 1st July 2014. These Regulations relate to the provision of care and welfare of residents in designated centres for older people, together with provisions to govern the management of such centres.

In particular, regulation 29 of these Regulations relates to medicines and pharmaceutical services. The Regulations recognise the role of a pharmacist in the provision of medicines services to patients. The Regulations place an obligation on the person in charge of the centre to facilitate a pharmacist, of the resident's choice, or who is acceptable to the resident, in meeting his or her obligations under relevant legislation or guidance issued by the PSI. The Regulations are available on www.irishstatutebook.ie.

Misuse of Drugs (Amendment) Regulations 2014 (S.I. No. 323 of 2014) and Misuse of Drugs (Designation) (Amendment) Order 2014. (S.I. No. 324 of 2014)

The PSI would like to inform pharmacists of an amendment to the Misuse of Drugs Regulations 1988, as amended and the Misuse of Drugs (Designation) Order 1998, which were signed by Minister Alex White on 11 July 2014. The purpose of these amendments is to:

(a) enable authorised cannabis-based medicinal products to be legally prescribed by medical practitioners and used by patients. Following this change the cannabis-based medicinal product, Sativex®, has been authorised in Ireland by the Healthcare Products Regulatory Authority (HPRA). This authorised product is now a schedule 2 controlled drug (CD2) under the Misuse of Drugs Regulations 1988 as amended. The PSI understands that this product will be available in Ireland in early 2015.

(b) remove the handwriting requirements in respect of prescriptions for methadone. This means that the following information is no longer required to be handwritten by the prescriber for methadone: the name and address of the patient, dose, form, strength and total quantity (in words and figures). (Please note that this legislation change applies only to prescriptions for methadone; prescriptions for all other schedule 2 controlled drugs still require the details listed above to be in the prescribers own handwriting).

Further information is available in the [Department of Health press release](#) and the amendments in full: (S.I. No. 323 of 2014) www.irishstatutebook.ie/pdf/2014/en.si.2014.0323.pdf and (S.I. No. 324 of 2014) www.irishstatutebook.ie/pdf/2014/en.si.2014.0324.pdf

Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014 (SI No. 300 of 2014)

The PSI would like to inform pharmacists of an amendment to the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended which was signed by the Minister for Health on 2 July 2014. The purpose of this amendment is to:

(a) update the list of medicinal products that registered optometrists can be supplied with, hold a small stock of, and administer directly to patients in the course of a patient consultation.

(b) update the list of medicinal products that may be supplied to the various grades of ambulance personnel (i.e. advanced paramedics, paramedics and emergency medical technicians) for use in the course of their work in pre-hospital emergency care.

This amendment, Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014 (SI No. 300 of 2014), is available in full on www.irishstatutebook.ie.

Reminder Notice for Tutor Pharmacists

Pharmacists intending to seek recognition to act as a tutor pharmacist for the upcoming internship year 2014/2015 are reminded that the closing date for application to attend a mandatory tutor training workshop is **15th August 2014**. Council of the PSI has agreed that this training is compulsory for all pharmacists intending to act as a tutor for the 2014-2015 year. Full details on registration, including training locations, are available on the [PSI website](#). If you have any queries about the tutor training workshops, please contact the RCSI at mpharm@rcsi.ie.

Tutor pharmacists should also note that the earliest start date for commencement of an internship placement is Friday, 1st August 2014. Students will also be required to register for the 2014/2015 internship year on Monday, 15th September 2014. Key dates relating to the NPIP are available on the [PSI website](#).

Other Notices

Launch of Third National Clinical Guideline on *Clostridium difficile* (C. diff)

In June the Chief Medical Officer at the Department of Health, Dr Tony Holohan, launched the 3rd National Clinical Guideline – Surveillance, Diagnosis and Management of *Clostridium difficile* Infection in Ireland. This guideline was quality assured by the National Clinical Effectiveness Committee (NCEC).

This National Clinical Guideline together with the guidelines No. 2 on MRSA, provides practical guidance on prevention and control measures for *clostridium* to improve patient care, minimise patient morbidity and mortality and to help contain healthcare costs. This includes the importance of organisations having an infection control and prevention programme in place with an emphasis on good hand hygiene, the use of Standard Precautions and antimicrobial stewardship. This guideline has been developed for all healthcare staff involved in the care of patients, residents or clients who may be at risk of or may have *C. difficile* in hospitals, nursing homes/long stay residential units and the community. The full guideline, summary version

and presentation from the launch are available on the [DOH website](#).

HPRA(IMB) Publishes List of Substances Suitable for Reclassification (Switching)

On July 17th 2014, the HPRA published a list of twelve active substances (or combinations of substances) contained in medicinal products currently classified as prescription-only medicines (POM) for which it considers the method of sale and supply classification could be safely switched from POM to pharmacy sale not subject to medical prescription. The list includes medicines for the treatment of migraine, acid-reflux symptoms, hay fever, cold sores, muscle pain and inflammation, fungal skin and nail infections and other inflammatory skin conditions.

The HPRA is now requesting expressions of interest from companies who are the Marketing Authorisation Holders (MAH) for these medicines to apply to the HPRA to reclassify their medicines. Following approval of any applications from MAHs, the PSI will continue to engage with the HPRA to ensure that any medicinal product switched will be supplied safely into the future. Further information is available on the [HPRA website](#) and the list itself is available [here](#).

HIQA Consultation: National Standards for Residential Care Settings for Older People

The Health Information and Quality Authority (HIQA) has begun a nationwide public consultation on new National Standards for nursing homes and residential care settings providing services to older people. With the aim of continuously improving these services, submissions are welcomed to the consultation until 5pm on Wednesday 24th September 2014 with information on the draft standards and consultation feedback forms available at www.hiqa.ie.

CPD Opportunities

Health and Social Care Priorities for Ireland - Learning with Europe

The European Union Network for Patient Safety and Quality of Care (PaSQ) together with HIQA will host a learning workshop on Thursday 2nd October 2014 in Dublin Castle. The themes for the workshop are medication safety, the deteriorating patient and the vulnerable elderly. The workshop aims to provide a platform for Irish health professionals to learn from and share their own experiences with European contemporaries presenting from the Netherlands, Norway and the UK who have successfully implemented quality improvement initiatives in these areas. Registration for the event is now open. [See the PASQ website for more about the event](#).

Postgraduate Certificate in Health Promotion, NUI Galway

NUI, Galway in collaboration with Croí, Diabetes Ireland and the Irish Heart Foundation welcomes applications to its postgraduate certificate in health promotion focusing on 'Approaches to Cardiovascular Health and Diabetes Prevention'. The course is suitable for a variety of health professionals. The deadline for applications is the 22nd of August. Further information including online application is available on the [NUI, Galway website](#) or contact Anne O'Grady: anne.ogrady@nuigalway.ie or 091 493644.

Croí Training, Galway

Croí has opportunity to avail of expert training course (Level 1 Certificate) in motivational interviewing in healthcare behavior change. The aim is to enable participants to confidently support patients with complex lifestyle behavior change. The two day course runs on 30th and 31st October 2014 in the Croí Heart & Stroke Centre, Moyola Lane, Newcastle, Galway. For further details see the [Croí website](#) or contact Alma O'Connell, alma@croi.ie.

All Ireland Pharmacy Conference 2015

The 7th All Ireland Pharmacy Conference will return to Ballymascanlon House Hotel, Dundalk in January 2015. The cross-border event encourages sharing good practice in pharmaceutical care and practice development across the primary and secondary care sectors. The conference includes panel discussions, parallel oral sessions and poster presentations. Note that the closing date for receipt of abstracts for poster or oral presentation is Friday 26th September. All further information is available on the [IIOP website](#).

PSI Recruitment

The PSI is seeking to fill four temporary senior pharmacist positions on twelve month fixed term contracts. The positions are available in the Inspection & Enforcement and Pharmacy Practice Development Units. Further information is available on the [PSI website](#). The closing date for receipt of applications is Friday 15th August 2014 at 5pm.

PSI House,
Fenian Street,
Dublin 2
Phone: +353 1 2184000
Fax: +353 1 2837678
Email: info@thepsi.ie
Web: PSI Website

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