



## In This Issue

- ▶ **Epilepsy Ireland Raises Concerns about the Supply of Anti-Epileptic Medicines**

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- ▶ **Learning from Fitness to Practise Inquiries, No. 2**

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- ▶ **Evaluation of the Seasonal Influenza Vaccination Service 2014/2015**

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- ▶ **Food Intolerance Testing – Guidance from HPRA**

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- ▶ **Learning Points from the PPC Annual Report 2014**

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- ▶ **Pharmacy Practice Guidance Folder Updates**

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- ▶ **New Payment Option for Continued Registration of Retail Pharmacy Businesses**

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- ▶ **Reminder – Professional Indemnity Insurance**

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- ▶ **Consultation on the Draft National Competency Framework for Pharmacists Working in Cancer Care**

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- ▶ **National Cancer Control Programme Toolkits**

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- ▶ **Upcoming CPD Opportunities**

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- ▶ **HPRA Drug Safety Newsletter**

## Overview

This issue of the PSI newsletter highlights concerns raised by Epilepsy Ireland and the Health Products Regulatory Authority (HPRA) about the supply of anti-epileptic medicines and the need to ensure appropriate counselling of patients taking these medicines. We also provide guidance from the HPRA on food intolerance testing, and remind pharmacists about their professional indemnity insurance requirements.



A recent fitness to practise inquiry, which involved an error in the supply of a medicine to an infant, is highlighted to prevent similar potential risks and errors and to improve practice. In addition, learning points from complaints made to the PSI during 2014 are included with the publication of the Preliminary Proceedings Committee's Annual Report.

The introduction of a new electronic fund/bank transfer payment option for postal applications for continued registration of pharmacies is outlined. Also included is the evaluation report of the seasonal influenza vaccination uptake in pharmacies for the 2014/2015 season, as well as guidance for those providing vaccinations and a guide to training requirements for the 2015/2016 season.

Finally, there is a note for supervising pharmacists about additions to the Pharmacy Practice Guidance Folder that are being sent shortly. The Pharmacy Practice Guidance Folder was recently presented to Minister Kathleen Lynch, TD, pictured here with PSI President Dr Ann Frankish and Chair of the Pharmacy Practice Development Committee, Ms Caroline McGrath.

## Epilepsy Ireland Raises Concerns about the Supply of Anti-Epileptic Medicines

### 1. Substitution of Anti-Epileptic Medicines

Epilepsy Ireland has brought to our attention, concerns relating to the substitution of anti-epileptic medicines, without consulting the patient or the prescriber.

The PSI would like to remind all pharmacists that:

- Generic substitution by pharmacists is only permitted for medicinal products included on the Health Products Regulatory Authority (HPRA) [List of Interchangeable Medicines](#);
- Medicines indicated to treat epilepsy are not included on the list of interchangeable medicines; therefore the product prescribed by the

doctor should not be substituted with a different product, without prior discussion with the patient and prescriber regarding the potential risks;

- [Issue 4, 2014](#) of the PSI newsletter provided information on substitution of medicines not included in the HPRA List of Interchangeable Medicines. Further information on interchangeable medicines can be found on the [HPRA website](#).

## **2. Risk of Abnormal Pregnancies in Women taking Valproate Containing Medicines**

In December 2014, the HPRA highlighted important [Safety Information on Medicines containing Valproate and the Risk of Abnormal Pregnancy Outcomes](#).

The HPRA and Epilepsy Ireland have brought to our attention that many women of child bearing age who take medicines containing valproate (generally prescribed for the treatment of epilepsy or bipolar disorder) have not been informed by their healthcare professional that they are at an increased risk of abnormal pregnancy outcomes. Pharmacists should ensure that female patients, of child bearing age, are informed of and understand:

- the risks associated with valproate during pregnancy;
- the need to use effective contraception;
- the need for regular review of treatment;
- the need to rapidly consult a healthcare professional if they are planning a pregnancy or if they become pregnant.

Further information and educational materials, available to healthcare professionals and patients, can be found in this HPRA notice on [Medicines Containing Sodium Valproate](#). Pharmacists are encouraged to bring these, and any other appropriate educational materials, to the attention of relevant patients presenting in the pharmacy.

## **Learning from Fitness to Practise Inquiries, No. 2**

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### **A complaint involving the dispensing of Zantac Syrup 75mg/5ml (ranitidine) for an infant.**

The PSI shares learnings from fitness to practise inquiries with the aim of preventing similar incidents from happening again, and to help improve practice by highlighting potential errors and risks.

In this issue we include a complaint involving the dispensing of Zantac Syrup 75mg/5ml (ranitidine) for an infant. All registrants should consider how they can use these learnings to review and improve their own practice and policies.

Read the learning from [Fitness to Practice Inquiry, No. 2](#).

## **Evaluation of the Seasonal Influenza Vaccination Service 2014/2015**

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The PSI has published an Evaluation of the Seasonal Influenza Vaccination Service 2014/2015 which concludes that the service was operated safely and effectively during the season. The report shows that uptake of the influenza vaccine in the community pharmacy setting continues to rise. According to figures from the HSE Primary Care Reimbursement Service, 53,047 patients were vaccinated across 691 community pharmacies in Ireland between 1 September 2014 and 30 April 2015. This is an increase of 12,604 patients compared to the 2013/2014 season and an increase of 34,093 patients compared to the 2012/2013 season.

The report recommends that a more substantial evaluation of this service is carried out for the 2015/2016 influenza vaccination season, involving

engagement with a greater number of patients and pharmacists. This will provide a more in-depth analysis of how this service is being operated and potentially provide a platform to consider the further expansion of this and other vaccination services. Further information on how pharmacists and patients can contribute to this important evaluation during the 2015/2016 season will be provided later this year.

Read the full [Report on the Evaluation of Seasonal Influenza Vaccination Service in Pharmacy 2014/15](#).

### **Guidance and training**

The PSI Guidance on the Provision of the Seasonal Influenza Vaccination has been approved by the PSI Council and is re-issued unchanged for the 2015/2016 influenza season. As pharmacists prepare for the delivery of vaccination services in pharmacies for the 2015/2016 season, they should ensure that they are aware of the requirements in this guidance, which is contained already within the pharmacy's practice guidance folder.

Read the [PSI Guidance on the Provision of the Seasonal Influenza Vaccination Service by Pharmacists](#).

In order to assist pharmacists in identifying the correct training course for them, the PSI has produced a [guide to assessing training needs](#).

## **Food Intolerance Testing – Guidance from HPRA**

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In line with the recent newsletter [Reminder of Responsibilities under the Code of Conduct](#), the PSI would like to highlight the HPRA's Information Notice regarding Food Intolerance Testing.

The HPRA notice makes the following recommendations to patients: 'The diagnosis of any condition relating to the ability to digest or "tolerate" foods and the level of clinical significance of this including any planned actions, such as dietary restriction, should be made only after careful consultation with your doctor and should not be based on the use of self-testing alone and/or use of testing services that have not been recommended by your doctor'.

Any patient availing of these tests should receive appropriate counselling regarding the results and should always be told to consult their doctor before changing their diet or that of their family.

If home test kits are available or food intolerance testing services are provided in your pharmacy, you should consider the usefulness of these tests in light of the HPRA notice and a pharmacist's responsibilities under their Code of Conduct.

The HPRA is undertaking further market surveillance of these products and services across a range of settings and has indicated that they may contact pharmacies to ascertain what devices are being used in connection with this service. They would like to hear from pharmacists and patients who have encountered problems with these tests by email to [devices@hpra.ie](mailto:devices@hpra.ie).

Read the HPRA [Information Notice regarding Food Intolerance Testing](#).

## **Learning Points from the PPC Annual Report 2014**

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The PSI's Preliminary Proceedings Committee (PPC) has published its Annual Report for 2014, making observations on complaints considered by it during the year. The PPC considers all complaints made to the PSI and makes recommendations to the PSI Council whether a complaint warrants further action.

Some of the practice issues observed in the PPC Report have been highlighted and expanded, with learning points for pharmacists now on the PSI website. Topics include:

- pricing and generic substitution;
- high tech medicines;
- communication;
- accuracy of prescriptions;
- dispensing veterinary medicines.

Read more about the [learnings identified in the PPC Annual Report 2014](#) and the [Report in full](#) on the PSI website.

## Pharmacy Practice Guidance Folder Updates

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The supervising pharmacist in all registered retail pharmacy businesses will shortly be receiving hard copies of the following documents:

- Guidance for Pharmacists on the Safe Supply of Non-Prescription Levonorgestrel 1500mcg for Emergency Hormonal Contraception (Version 3 January 2015);
- Guidance for Pharmacists on the Safe Supply of Non-Prescription Ulipristal Acetate 30mg (ellaOne®) for Emergency Hormonal Contraception (Version 1 May 2015);
- Guidance for Pharmacists on Extemporaneous Dispensing (Version 1 June 2015);
- A letter entitled 'Superintendent Pharmacists and Companies Conducting Retail Pharmacy Businesses' (July 2010);
- Revised contents page.

The supervising pharmacist should ensure that these documents are read and understood by the relevant members of the pharmacy team.

All documents are also available to download and/or print in the [Pharmacy Practice Guidance](#) section of the PSI website. If you have any queries in relation to any of the guidance documents, please contact the [Pharmacy Practice Development Unit](#).

## New Payment Option for Continued Registration of Retail Pharmacy Businesses

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The PSI is introducing a new electronic fund transfer (EFT)/bank transfer payment method for postal applications for continued registration of pharmacies.

A guide to this new system and the EFT form will be included with all postal applications from August.

Please note that during this initial trial period, the EFT facility is not yet available for online applications, but these can still be made using a credit or debit card. Your co-operation in the making of a prompt application and payment of the prescribed fee, either online or by post is greatly appreciated.

If you intend to pay the continued registration fee for your pharmacy by postal application and would like to use this new payment option, please see the PSI website for [further information](#).

## Reminder – Professional Indemnity Insurance

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The PSI would like to remind all pharmacists that they must ensure that they are covered by professional indemnity insurance. Following the introduction of [S.I. 65 of 2015](#) relating to cross-border healthcare, the HSE has recently clarified that health professionals providing cross-border health care in the State must also have professional indemnity insurance, either

personally or through their employer.

The statutory [Code of Conduct](#) states that a pharmacist should 'ensure that all professional activities undertaken are covered by appropriate professional indemnity arrangements'.

Pharmacists are advised to clarify the status of their indemnity cover with the employer in each pharmacy where they practise, ensuring that the correct and appropriate indemnity cover is in place.

## **Consultation on the Draft National Competency Framework for Pharmacists Working in Cancer Care**

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The National Cancer Control Programme (NCCP) is seeking feedback on a [Draft National Competency Framework for Pharmacists Working in Cancer Care](#). This framework was drafted by the NCCP in collaboration with colleagues from the Irish Institute of Pharmacy, the Irish Pharmacy Union, hospital oncology pharmacy and community pharmacy. The competency framework outlines the behaviours, skills and knowledge required by pharmacists working in cancer care and as a result, will work towards improving the quality of care and outcomes for cancer patients in Ireland.

Related information and a feedback form are available on the [HSE website](#). Feedback should be returned to [orla.walsh@cancercontrol.ie](mailto:orla.walsh@cancercontrol.ie) by Monday, 24 August 2015.

## **National Cancer Control Programme Toolkits**

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### **Head and Neck Cancer Referral**

The National Cancer Control Programme (NCCP) has developed a head and neck cancer detection and referral tool in an effort to encourage the earlier detection and referral of patients with suspicious clinical features.

Pharmacists have an important role in identifying patients who may need to be referred for specialist clinical assessment, for example, patients with unexplained hoarseness, difficulty in swallowing, neck lumps, nerve palsies and non-healing mouth lesions. Such clinical features that last for more than three weeks need to be assessed by a GP or dentist in the first instance. An urgent referral may then be needed to a specialist. The tool is available at [Head and Neck Cancer Referral Advice for Primary Care](#). Email requests for hard copies to [info@cancercontrol.ie](mailto:info@cancercontrol.ie).

### **30 Seconds Stop Smoking Advice; Make every contact count.**

This simple tool aims to support health professionals in raising the issue of smoking cessation with patients to help them quit smoking. Smokers expect to be asked about their smoking by health professionals.

The tool gives simple hints on how to 'Ask, Advise, Act.' It includes support contacts that patients may find helpful and highlights the options for pharmacotherapy. Research clearly shows that the combination of advice and referral together with pharmacotherapy increases the chance of quitting four fold. The tool is available at [30 second stop smoking advice](#). Email requests for hard copies to [info@cancercontrol.ie](mailto:info@cancercontrol.ie).

## **Upcoming CPD Opportunities**

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### **Irish Institute of Pharmacy (IIOP)**

Information on upcoming learning events and courses is available on the [IIOP website](#).

## HPRA Drug Safety Newsletter

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The latest [Drug Safety Newsletter](#) from the HPRA is now available and includes:

- systemic fusidic acid and interaction with statins - a reminder of risk of rhabdomyolysis;
- risk of clinically significant arrhythmias when Harvoni (fixed dose combination of sofosbuvir and ledipasvir) or Daklinza (daclatasvir) in combination with Sovaldi (sofosbuvir) are given concomitantly with Cordarone X (amiodarone).

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