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## Overview

This month's newsletter includes an update on a proposed legislative amendment to the Regulation of Retail Pharmacy Businesses Regulations 2008 (SI No. 488 of 2008), and guiding principles which the PSI Council has approved for pharmacists in order to ensure clarity and transparency in the pricing of prescription medicines.



This issue also contains advice from the National Immunisation Advisory Committee, in relation to the use of prophylactic antipyretics at the time of vaccination in children, and a guide to selling medical devices from the IMB.

In follow up to the survey sent to all pharmacists seeking feedback on topics to be included as part of learning events focusing on fitness to practise and inspection and enforcement processes later this year, this issue highlights useful PSI information resources that are currently available to the profession.

Finally, a reminder that the Irish Institute of Pharmacy (IIOP) information events commence in April. The aim of these sessions is to provide pharmacists with information about the new CPD model and the IIOP. You can register your attendance on the [IIOP website](#).

## Transparency in the Pricing of Prescription Medicines

The PSI receives queries on pricing in pharmacies on an ongoing basis from pharmacists, patients, other healthcare professionals and state agencies. While the area of pricing of medicines is out of the remit of the PSI, the PSI considers that transparency in pricing for patients and members of the public is desirable in line with the Code of Conduct for Pharmacists. Consequently, PSI Council has requested that pharmacists ensure that their practice is guided by the following **principles relating to pricing transparency for prescription medicines**:

- The role of the pharmacist is to ensure the rational and responsible use of medicines. Therefore any information provided by pharmacists, on the pricing of medicines supplied on prescription, should encourage the rational use of the medicine(s).
- In line with principle three of the [Code of Conduct](#), pharmacists are required to "provide honest, relevant, accurate, current and appropriate information to patients regarding the nature, cost, value and benefit of medicines, health-related products and services provided by them." Pharmacists should therefore ensure that patients are facilitated in the provision of information concerning prices for medicines and services in pharmacies.
- Transparency of prices of prescription medicines for patients is desirable and any information on pricing provided to patients must be meaningful. The final (retail) price of the medicine is the most meaningful information for patients.
- Where requested by a patient/their representative, pharmacists should provide the price to the patient/their representative in advance of dispensing their medicine(s). It is acknowledged that the final accurate

price may not be possible unless the pharmacist has the prescription.

- Following the dispensing of medicine(s), pharmacists should provide the patient/their representative with a receipt which itemises the price charged i.e. sets out the price per item dispensed.

In addition, pharmacists are reminded that the PSI published a Medicine Price Listing Clarification in the [PSI Pharmacist Newsletter of May 2012](#). This clarification stated that factual information regarding the prices of prescription only medicines may be lawfully displayed. The advertising of prescription only medicines to the general public is not permitted by the [Medicinal Products \(Control of Advertising\) Regulations 2007](#); however these regulations do not apply to factual informative announcements, including price lists, provided they include no product claims (i.e. any information should just include the name of the product, its pharmaceutical form and strength, and its price).

The display of such information must not imply that the prescription-only products concerned are available without the presentation of a prescription (or that the emergency supply arrangements would be availed of for the purposes of making a supply). The display should not compare prices of different products, or offer discounts for patients that might encourage them to obtain larger quantities of prescription only medicines than are needed, or than have been prescribed for them.

## Proposed Legislative Change

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The PSI wishes to inform pharmacists of a proposed legislative amendment to the Regulation of Retail Pharmacy Businesses Regulations 2008 (SI No. 488 of 2008).

This proposed legislation states that pharmacy-only medicines '**are stored in a part of the premises to which the public does not have access.**' This amendment reflects the existing practice in pharmacies where pharmacy-only medicines are stored behind the pharmacy/medicines counter. Please note that this provision does not mean that all pharmacy-only medicines will be required to be stored in the dispensary. Therefore, this should not result in any change in current practice.

The proposed legislation is currently notified to the European Union which requires a 3 month standstill period following which the amending Regulations will be signed by the Minister for Health.

In anticipation of the enactment of the proposed legislative amendment and in consideration of the nature and purpose of these medicines, the PSI advises that all pharmacists maintain the current practice of storing pharmacy-only medicines behind the pharmacy/medicines counter and continue to supply these medicines with the appropriate supervision and advice of the pharmacist.

## Practice update: Children Should NOT be Given Prophylactic Antipyretics at the Time of Vaccination

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As medicines experts, pharmacists are ideally placed to educate the public and raise awareness about the appropriate use of medicines. This role is particularly important in the area of non-prescription medicines as pharmacists are often the sole healthcare professional involved in patient education and advice.

The PSI would like to bring to the attention of pharmacists, the advice of the National Immunisation Advisory Committee (NIAC) on the use of antipyretics at the time of vaccination. Prophylactic use of antipyretics such as paracetamol and ibuprofen, at or shortly after vaccination may result in significant reduction in the primary antibody responses to some vaccine

antigens in the childhood schedule. It is likely that this reduction in the immune response is due to interference by antipyretics with the inflammatory response at the injection site.

Fever is a normal part of the inflammatory response, and is well-known to occur after vaccination. Fever which occurs after vaccination is generally benign and self-limiting; it rarely rises above 39.5<sup>0</sup>C. Antipyretic drugs do not prevent febrile convulsions in at-risk children.

Consequently pharmacists are asked to advise parents that children should **not** be given prophylactic antipyretics at the time of routine childhood vaccination. Either paracetamol or ibuprofen may be considered for treatment of fever greater than 39.5<sup>0</sup>C or for a significant reaction at the site of vaccination.

Further information can be found in the [Immunisation Guidelines for Ireland](#) or in the [recent research](#) section of the National Immunisation Office website.

## Recent Survey and PSI Information Resources

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The recent survey to pharmacists surrounding the PSI's hosting of learning events on the fitness to practise and inspection processes was well received and we would like to take the opportunity to thank all respondents who took the time to complete the survey. Further information about the upcoming learning events for the profession will be provided in due course.

Following the responses received it may be useful to highlight and remind you of information resources that are currently available on the PSI website:

- In **preparation for a PSI inspection** the PSI has a [short guide to inspections](#) document and inspection checklists for [regular pharmacy inspections](#) and for [new opening inspections](#), and there is also a useful [podcast](#) of the inspection process. PSI Inspectors also provide advice and assistance to pharmacists and pharmacy owners through the PSI newsletter and on the [Inspectors' Advice on improving compliance](#) page of the website. This information has included advice on the adequate storage of medicines, how to write and maintain SOPs, and on the supply of veterinary medicines. All these are available in the [inspection section](#) of the website.
- **Guidelines** issued by the PSI to facilitate compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008, and other practice notices and guidance issued by the PSI including the recent guidance on testing services, and recent updates on supply to residential care settings/nursing homes are all available to download from the [practice guidance section](#) of the website.
- **For supervising and superintendent pharmacists**, in order to promote an understanding of the legal requirements and responsibilities of these roles, there are information resources for pharmacists and pharmacy owners including a useful video series available to view [here](#).
- The PSI Council shall, if satisfied it is in the public interest, give public notice of the **outcome of a fitness to practise** process. Sanctions to which the PSI Council decides to give public notice are usually made in the PSI newsletter and/or on the PSI website.
- Past issues of the **PSI newsletter** that each month contain information and events of interest to the profession including notice of legislative change, pharmacy guidance and CPD opportunities are archived to the [PSI website](#) for future reference.

The PSI also provides a query answering service for the profession, members of the public and other healthcare professionals. Last year 385 queries were received and responded to. Queries are welcomed in writing to [info@thepsi.ie](mailto:info@thepsi.ie).

## Guide to Selling Medical Devices

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The Irish Medicines Board (IMB) has developed a leaflet to highlight the important role retailers (including pharmacists) can play in ensuring that medical devices sold in Ireland are safe and comply with relevant legislation. A medical device is a healthcare product or piece of equipment that a person uses for a medical purpose e.g. bandages, thermometers, pregnancy tests, blood pressure meters and blood glucose meters.

The leaflet, which includes information on what a medical device is, what a retailer should look out for when sourcing medical devices and what records they should keep in relation to medical devices, can be downloaded from the [IMB website](#). Printed versions of the leaflet can also be ordered from [brochures@imb.ie](mailto:brochures@imb.ie).

In February, the Council of the PSI approved [Guidance on the Provision of Testing Services in Pharmacies](#) which includes guidance on the sale or supply of tests and testing equipment in pharmacies.

## PSI Council Appointments

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Over recent months the Minister for Health has made a number of appointments to the PSI Council. These include Dr Paul Gorecki (ESRI Research Affiliate and part-time lecturer with Trinity College Dublin), Mr Shane McCarthy (Solicitor), Prof Kieran Murphy (Consultant Psychiatrist, Beaumont Hospital and Professor and Chairman of the Department of Psychiatry, RCSI) and Ms Deirdre Larkin (Chartered Accountant). A short biography of all Council members and dates of the next Council meetings are available on the [PSI website](#).

## Upcoming CPD Opportunities

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### MSc in Clinical Pharmacy, UCC

Applications are now invited for the two-year (part-time) distance learning Masters in Clinical Pharmacy, commencing in September 2014. The course is structured to provide specialist training to enable pharmacists working in hospital and community pharmacies to extend their professional role within the evolving clinical healthcare system. Further information and an online application facility is available on the [UCC School of Pharmacy website](#). Closing date for applications is Friday 25th July 2014.

### Irish Institute of Pharmacy

The [Irish Institute of Pharmacy \(IIOP\) website](#) will be providing course and event updates and will, in due course, allow for online bookings for certain events.

## Useful Resources

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### NMIC Bulletin

The National Medicines Information Centre (NMIC), based at St. James' Hospital in Dublin, aims to promote the safe, effective and efficient use of medicines. The NMIC produces a number of publications, in particular *Therapeutics Today* and the *Therapeutics Bulletin*. The NMIC also offers a free clinical enquiry answering service, providing evidence-based information and advice to healthcare professionals on all aspects of the therapeutic use of medicines including indications, drug interactions, adverse reactions, drug use in pregnancy/lactation etc. To contact the NMIC team or to subscribe to its electronic mailing list for publications, email [nmic@stjames.ie](mailto:nmic@stjames.ie) or see the [NMIC website](#).

### NCCP Testicular Cancer Leaflets

As you are aware the [National Cancer Control Programme \(NCCP\)](#) provides a

comprehensive programme of cancer control in Ireland, overseeing the delivering of cancer care, cancer services and awareness. NCCP provides information for health professionals, patients and the public on its website and following requests from pharmacists has published a pocket-sized [leaflet on testicular cancer](#). To have this or other information leaflets delivered to your pharmacy contact Mary McCann at [info@cancercontrol.ie](mailto:info@cancercontrol.ie).

## **'Let's Talk About' Survey**

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The All Ireland Institute of Hospice and Palliative Care (AIHPC) is seeking respondents to their 'Let's Talk About' survey which is a unique all-Ireland initiative that will provide a first time overview of experiences of living with or assisting others with serious or progressive medical conditions. It is intended that the survey results will inform policy and services for the future.

Further information is available on the [AIHPC website](#) or you can link directly to the survey [here](#).

PSI House,  
Fenian Street,  
Dublin 2  
**Phone:** +353 1 2184000  
**Fax:** +353 1 2837678  
**Email:** [info@thepsi.ie](mailto:info@thepsi.ie)  
**Web:** PSI Website

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