PSI Newsletter

Issue 5, 2014

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Overview

This issue of the PSI newsletter provides a range of practice and medicines notices for your information.

Following a review of all systems inspections carried out by the PSI in 2013, this newsletter highlights the findings of those reports and the levels of compliance found throughout that period. The newsletter also includes a Garda requested notice in relation to pseudoephedrine and its use in the illicit manufacture of methamphetamine 'crystal meth', and an explanatory notice around recent changes to domperidone use.

You may also wish to note that the PSI currently has two public consultations open for comment; draft Guidance on Data Protection and the draft PSI Fees Rules, both of which can be found in the consultations section of the PSI website.

Details of training workshops and other information relevant to tutor pharmacists for the upcoming 2014/2015 internship period are now available on the PSI website.

Also included is a notice from the Irish Medicines Board on its imminent name change to the Health Products Regulatory Authority. Finally, we wish to draw your attention to the recent HIQA publication on Principles of Good Practice in Medication Reconciliation. This offers guidance to healthcare professionals aimed at reducing medication errors and contains practical checklists and other useful tools.

Findings from Inspections in 2013

In 2013, 388 systems inspections were carried out by Authorised Officers (Inspectors) of the PSI. These are unannounced inspections that examine the way in which medicines are supplied from the pharmacy to ensure a legitimate and safe basis for their supply, and include the review of premises, workflow and the conditions existing for the storage and preparation of medicines, amongst other things.

An overview of some of the findings and statistics from inspections carried out in 2013 is now available on the PSI website. In this first instalment, key statistics are provided in relation to pharmacy premises and medicines storage, supply of medicines to patients in nursing homes/residential care settings and quality management systems. This information as well as relevant resources are provided to assist pharmacists and pharmacy staff in meeting the standards of compliance expected under the Pharmacy Act 2007.

Data Protection Guidance for Consultation

The PSI welcomes submissions to a public consultation on draft Guidance on Data Protection for Pharmacists. Pharmacists handle personal data every day when dispensing prescriptions, providing pharmacy services and interacting with patients and other healthcare professionals. This guidance is intended to

help pharmacists understand and meet the requirements of data protection legislation in their daily practice.

Please see the draft Guidance on the PSI website along with a link to a short online questionnaire that may be completed with your comments. Alternatively send your comments in writing, preferably by email to consultation@thePSI.ie or by post to Public Consultation, The Pharmaceutical Society of Ireland, PSI House, Fenian Street, Dublin 2. The closing date for receipt of comments is **Friday 18th July 2014.**

Gardaí Request Vigilance in the Sale of Pseudoephedrine

The Garda National Drugs Unit has requested that the PSI share the following information with pharmacists on the increased production of methamphetamine in Ireland using pseudoephedrine sourced from pharmacies. As pharmacists are aware, methamphetamine is a dangerous, highly addictive controlled drug which is associated with fatalities and a high risk of causing harm, and pseudoephedrine is commonly used as a precursor in the illicit manufacture of methamphetamine (also known as 'crystal meth').

Intelligence in possession of An Garda Síochána indicates that certain criminal networks, particularly Eastern European groups, involved in the manufacture of methamphetamine are sourcing pseudoephedrine by visiting pharmacies in certain areas or towns across the country and purchasing pseudoephedrine products, albeit in the limited amounts allowed from each pharmacy. The Gardaí request pharmacists' assistance in increasing vigilance in pharmacies and encourage pharmacists to report any suspicious activity to local Gardaí.

The following points may be useful to pharmacists in dealing with this matter in their pharmacies:

- Requests for these products should be referred to the pharmacist, particularly if the request might appear to suggest that it is not for a genuine therapeutic reason – for example, requests for multiple packs or frequent requests by the same person.
- In dealing with requests where they may have suspicions, pharmacists should use their professional judgement and discretion in deciding whether a genuine clinical need exists and that the medicine is appropriate for the patient. Pharmacists are aware that they can refuse to supply a medicine where, in their professional opinion, such supply is not appropriate.
- Pharmacy staff should be made aware of the issue and asked to be vigilant.
- Pharmacists should consider the location and storage of these medicines in their pharmacies so that they can ensure that these products are under their personal control and supervision and also to minimise the risk of theft of these products.
- Your local Gardaí should be advised if you suspect diversion of these medicines for illegal purposes.

Policy Framework Development on 'Temporary Absence'

Pharmaceutical Assistants are persons who have passed the examination prescribed for that purpose by the Council of the "old" Pharmaceutical Society of Ireland (PSI) and whose names are included in the register of such assistants now kept under Section 13(1) of the Pharmacy Act 2007 ("the Act"). By virtue of Section 30(1) of the Act, a person whose name is entered in the register of pharmaceutical assistants is entitled to act on behalf of a

registered pharmacist during the temporary absence of the registered pharmacist. Further information in relation to pharmaceutical assistants is available on the PSI website.

Under Section 30(2) of the Act, the Council of the PSI may, for the purposes of the exercise of this entitlement, make Rules to provide for what may or may not be done by a registered pharmaceutical assistant when acting on behalf of a registered pharmacist, and also on what constitutes the temporary absence of a registered pharmacist.

The PSI is now examining this issue and has commenced a process of engagement with selected stakeholders and interested parties, to inform the development of policy and an applicable legislative framework in this regard. The PSI will be writing to individuals and organisations in the coming weeks, to seek their input into this policy framework development.

Notice for Tutor Pharmacists for NPIP 2014/2015

The PSI website now contains details for those pharmacists intending to act as tutors for the 2014/2015 internship period. All prospective tutor pharmacists for that period will be invited to attend the mandatory face-to-face training which will be provided by the RCSI on behalf of PSI Council. You are asked to register your attendance for this training by 4th July 2014. Further details, including training locations are available on the PSI website.

Additionally, the eligibility criteria for recognition as a tutor pharmacist or as a training establishment were amended and approved by the PSI Council on 15th May 2014. The revised eligibility criteria policy is also available on the PSI website.

Current Update on Domperidone

Pharmacists will be aware of recent new advice on the safe use of domperidone products. Due to concerns regarding cardiac adverse effects associated with domperidone use, an evaluation of the benefits and risks of domperidone was recently undertaken by the European Medicines Agency (EMA). This review has now been completed and the full outcome of that review is available here.

Following the EMA review the IMB issued updated advice on the use of domperidone. In addition, the National Medicines Information Centre has also issued an update in their recent newsletter. Pharmacists have a key role in the safe supply of this medicine to patients and therefore pharmacists should be aware of all the changes to the indications and use of domperidone containing products as highlighted in these communications.

In particular the PSI would like to highlight the following points:

- Domperidone should now only be used in the relief of **nausea and vomiting** symptoms, and not in other indications.
- Non-prescription domperidone products are **not recommended for use in patients with underlying cardiac disease** without medical supervision.
- Domperidone should be recommended at the **lowest effective dose for the shortest possible period** (not usually exceeding 1 week).
- The new recommended dose of domperidone in adults and adolescents ≥ 35 kg is **10 mg orally up to 3 times daily with a maximum dose of 30 mg per day** or 30 mg twice daily when used in a suppository.

The EMA decision will be sent to the European Commission, which will take an EU-wide, legally binding position. At this point, it is expected that the product information for domperidone will be amended appropriately to reflect these recommendations. Ahead of this change to the product information,

pharmacists should be supplying domperidone products and counselling patients in accordance with the new revised clinical information.

The PSI guidance to pharmacists on domperidone is that:

- The supply of non-prescription domperidone containing medicines should **only be by a registered pharmacist**.
- Requests for domperidone should be directed to the pharmacist to ensure appropriate patient review and counselling.
- **Appropriate counselling and advice** should be provided to the patient by the pharmacist in order to ensure the correct use of these products in line with the new recommendations.
- Domperidone containing non-prescriptions medicines should be stored in an area under the direct management and supervision of the pharmacist. **The recommended location is in the dispensary**, unless for justifiable reasons e.g. shortage of storage space, an alternative area of the pharmacy is used. This area must be close to the dispensary and therefore under the pharmacist's direct supervision.

Pharmacy Practice Guidance Manual Update

The PSI's Pharmacy Practice Guidance Manual was published in May 2008 as a self-audit tool following the introduction of the Pharmacy Act 2007. It was designed as a practical and educational tool for pharmacists and pharmacy owners to allow self-audit of a pharmacy practice which would help identify areas of the practice that may be in need of further attention. While the practice manual continues to be helpful to pharmacists, pharmacists should be aware that since the publication of the manual the Regulation of Retail Pharmacy Business Regulations 2008 have come into force and the PSI has issued a series of updated guidance. Therefore some sections of the practice manual have been superseded or additional information is now available. The PSI has updated the online version of the Pharmacy Practice Guidance Manual to indicate which sections are now superseded by updated regulations and guidance or where additional information is available on the PSI website.

The PSI is currently preparing a new consolidated guidance resource, which will contain all recent guidance and will be available in hard copy for the profession. All current guidance is available under the Practice Guidance section of the website. If you have any queries about PSI guidance please contact info@thepsi.ie.

Change of name for the Irish Medicines Board from 1st July

On 1st July 2014, the Irish Medicines Board (IMB) will change its name to the **Health Products Regulatory Authority (HPRA)** and launch its new website and brand identity. This change arises from the expanded remit of the IMB to include other health products as well as a number of health related functions. The organisation now has a role in regulating:

- Human and veterinary medicines
- Clinical trials
- Medical devices
- Controlled drugs
- Blood products and components
- Tissues and cells
- Cosmetic products
- The protection of animals used for scientific purposes
- Organs intended for transplantation

The IMB would like to draw your attention to these changes and note that e-alerts and other information will arrive under the HPRA name and email

address from 1st July. The mission of the **HPRA** remains: *To protect and enhance public and animal health through the regulation of medicines, medical devices and other health products.*

IMB Drug Safety Newsletter

The 61st edition of the IMB's Drug Safety Newsletter is now available. This focusses on the recent Europe-wide review recommending updates to the treatment advice for domperidone. The 60th edition issued in April contained updates relating to increased restrictions in the use of Protelos and Hydroxyethylstarch (HES) Infusion Solutions.

Upcoming CPD Opportunities

MSc (research) in Clinical Pharmacy, UCC

The School of Pharmacy at UCC has an opportunity for a research student to join its postgraduate team to conduct a M.Sc. research project funded by the Health Research Board of Ireland. Details of the project and application requirements are available on the UCC website. The deadline for applications is 31st July 2014 and informal enquiries may be made in advance by email to Dr Laura J Sahm: L.Sahm@ucc.ie.

Health and Care Law, UCC

UCC Faculty of Law is welcoming applications to its one year full-time or two year part-time postgraduate diploma/Masters in Health and Care Law. The course considers the legal and ethical principles in health and care law nationally and internationally. Applicants should ideally have experience or work in some aspect of law, health law or regulatory affairs. Applications will be accepted until 1st July and further information is available on the UCC website or from Veronica Calnan , 021 4903995 or v.calnan@ucc.ie.

MSc /Postgraduate Diploma in Preventive Cardiology, NUI, Galway

The College of Medicine, Nursing & Health Sciences at NUI, Galway is welcoming applications to its MSc/Postgrad Diploma in Preventative Cardiology. The course equips students from a variety of health science backgrounds with the knowledge and skills required to make meaningful contributions in the area of preventive cardiology. Students have the opportunity to engage with patients who are participating in programmes at the Croí Heart and Stroke Centre where teaching takes place. Further information is available on the NUI, Galway website.

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Published by PSI