Pharmacist Monthly Update September 2012

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Welcome message

Dear Pharmacist,

An important aspect of the PSI's complaints, inquiries and discipline processes is that relevant learnings and observations are disseminated to the profession at large. This to assist pharmacists in reviewing and reflecting on their own practice. This month's newsletter contains a number of such observations.

This month we also update on some recent decisions by the PSI Council – the approval of flu vaccination training programmes for pharmacists and also guidelines on premises and equipment. Further details below on both these matters, as well as a guidance note relating to extemporaneous dispensing.

Finally, you are kindly asked to support the national carbon monoxide awareness campaign – information packs will be arriving in pharmacies in the coming weeks.

Vaccination Training Update

In recent days, the PSI Council has approved three seasonal influenza vaccination training programmes for pharmacists for 2012/2013, which have been accredited by the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin.

These are (a) the training programme developed by Boots Ireland Ltd; (b) the 'refresher' training programme developed by Hibernian Healthcare Ltd in conjunction with the Irish Pharmacy Union (specifically for pharmacists who successfully completed training in 2011) and (c) the full (*ab initio*) training programme developed by Hibernian Healthcare and the IPU.

Pharmacists who successfully complete these training programmes will receive certificates recognised by the PSI Council in accordance with the regulations. Pharmacists should note that these certificates, and the associated accreditation and approval, are valid until 31 August 2013.

While it is appreciated that the deadlines have been challenging for those involved in the planning and preparation for the 2012/2013 season, it is important for everyone that pharmacists are appropriately competent and confident to provide the service this year, especially in light of the extended patient cohort for which pharmacists can administer a vaccine from the national stockpile and/or receive reimbursement from the HSE.

The PSI welcomes the extension of the patient cohorts who may choose to be vaccinated by their pharmacist and supports the further integration of the pharmacy profession into this important public health initiative.

The PSI hopes and expects that the challenging timelines experienced this year and last, which were very particular to the introduction of the service and to the events of last year, should not be an annual feature. In future years, as the service becomes a more usual part of pharmacy practice, the process should become more streamlined with information about training requirements or in relation to service provision being available to pharmacists at an earlier stage.

Fitness-to-Practise Observations

In its annual report for 2011, the Preliminary Proceedings Committee (PPC) made some observations in relation to practice issues that arose during their consideration of complaints to the PSI.

(The PPC is the disciplinary committee which advises the PSI Council on whether there is sufficient cause to warrant further action being taken in relation to complaints received about registered pharmacists or registered retail pharmacy businesses.)

The PPC made observations in relation to two issues in particular: (i) the need for dosage instructions for liquid measures to be documented in both words and figures

on medicine labels to reduce the risk of dosing errors; and (ii) many complaints concerning the refusal to sell codeine to patients related to the manner in which the refusal was communicated to the patient.

In light of these observations, superintendent and supervising pharmacists are therefore requested to review any relevant policies or procedures in the pharmacies under their control to see if any improvements in practices or in patient care need to be made.

Dosage Instructions for Liquid Medicines

The PPC observation was that dosage instructions for liquid measures should be documented in both words and figures; for example, that "*give 2.5ml (half a 5ml spoonful)"* was preferable to "*give 2.5ml*". The Committee observed that if a decimal point on a label wasn't very clearly marked and legible, there was a risk of a ten-fold or other significant overdosage, where for example 2.5ml would be interpreted by a patient or their carer as 25ml.

Given that liquid formulations are more commonly prescribed and dispensed for infants and children, who are often at greater risk of harmful consequences of overdosage, the need for clear and legible labels is critical, along with clear and practical counselling for parents or carers administering medicines to children.

Managing Codeine Consultations

In 2011, 12 out of the 61 complaints considered by the PPC related to issues surrounding the refusal to supply codeine. The PPC observed that for the most part the complaints did not arise from the actual refusal of the product but related to how the patient felt they were treated when the codeine product was refused and the manner in which the refusal was communicated to the patient.

Robust local complaint handling procedures should be in place in a pharmacy so that complaints which may be amenable to local resolution are resolved at the pharmacy level and these procedures should provide for complaints to be escalated to the supervising and/or superintendent pharmacist where necessary.

Pharmacists are increasingly engaging in more complex consultations with patients and should therefore reflect on their existing individual confidence and competence in dealing with patient consultations, particularly in relation to what they feel may be challenging scenarios.

The PSI has noted that in relation to complaints received so far in 2012, the number of these which relate to this particular issue has significantly decreased compared to 2011. This improvement is welcome and pharmacists are thereby encouraged to continue to improve practice in this area as it appears to be having an impact.

Accuracy of PMR information

In a recent inquiry by the Professional Conduct Committee (PCC) [PCC hearing 27 January 2012], the PCC made certain observations regarding the inputting and recording of certain information in the electronic Patient Medication Record (PMR).

The PCC specifically raised the issue of accurate recording of the prescriber details into the PMR and noted that in some systems this is a 'default' field which may lead to an incorrect prescriber being recorded for a particular prescription.

Therefore pharmacists are reminded that they should always check that they have recorded the prescriber details accurately in the PMR.

Where systems record a 'default' usual prescriber, introducing a prompt into the dispensing procedure to remind the pharmacist to check and change the prescriber details may be useful.

It is important that all details in a PMR are recorded accurately as this information may be relied on for other purposes which may impact on patient care and safety.

Premises & Equipment Guidelines

Guidelines to facilitate compliance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008 which relate to premises and equipment have been approved by the PSI Council.

These guidelines are intended to assist pharmacy owners (those applying to open a pharmacy and owners of existing pharmacies), as well as superintendent and supervising pharmacists, in ensuring that their premises meet required standards, and with planning for changes in their premises such as refurbishments. These guidelines are also intended to assist pharmacy owners, superintendent and supervising pharmacists in the delivery of pharmacy services using equipment that is

fit for purpose and well maintained.

The guidelines will be formally published in the coming weeks on the PSI website, sent by email to pharmacists and other stakeholders, and a printed hard copy will be sent to all registered pharmacies.

A number of issues relating to extemporaneous dispensing arose during the development of these guidelines, and the Council has formed the view that it would be timely to give closer consideration to the PSI's policy and practice guidance around extemporaneous dispensing.

Therefore it is intended that a review of this issue, taking into account international practice guidance and trends, as well as local research, will be undertaken by the PSI as part of its service plan for 2013.

In the interim, the following note on extemporaneous preparation, as well as the relevant information in the Premises and Equipment Guidelines, should be helpful.

Note on Extemporaneous Preparation

Extemporaneous preparation or manufacture refers to the process by which a pharmacist, using traditional compounding techniques, produces a medicinal product to meet the special needs of a patient when no suitable authorised medicinal product is available.

The law permits the supply of extemporaneously prepared medicinal products in certain limited circumstances:

- in response to a bona fide unsolicited order of a practitioner (i.e. on foot of a prescription), where the medicinal product is for an individual patient under the prescribing practitioner's care; or
- in response to a request from a patient where the extemporaneously produced medicinal product is not subject to prescription-only control and is produced in the pharmacy in accordance with the specifications of the Pharmacopeia. In Ireland only the European Pharmacopeia and British Pharmacopeia are official and as such are the only pharmacopoeias that are relevant for this purpose. Where an extemporaneously prepared medicinal product is supplied under this heading, the pharmacist should always make a documented record of the particular reasons that necessitated its preparation and supply.

In all cases, the pharmacist must be satisfied that the medicinal product concerned is not the subject of an advertisement and that no other authorised medicinal product of appropriate composition is available for use in the particular circumstances.

Extemporaneous preparation is not permitted in any other circumstances. The decanting, relabelling and/or altering of the presentation of an authorised non-prescription medicinal product or the combining of two or more non-prescription medicinal products is also not permitted, other than in the circumstances outlined above. As extemporaneous preparations are only permitted to meet the special needs of an individual patient, batch manufacture is not permitted.

Pharmacists are reminded that at all times the health and safety of the patient is their primary concern and, for that reason, they must be satisfied that any extemporaneously prepared medicinal product that they may supply is of appropriate quality and safety and that they have been prepared under appropriate conditions.

Alternatives to Extemporaneous Preparation when Dispensing on foot of a Prescription:

A pharmacist, who receives a prescription for a medicinal product, should only engage in the supply of an extemporaneously prepared product whenever an authorised version of the product, or of a suitable authorised alternative, is not available commercially. Pharmacists should also consider the urgency of the situation and endeavour to supply the prescribed product within an appropriate time-frame.

Prior to preparing an extemporaneous medicinal product, pharmacists should check if the prescribed medicinal product can be sourced through any of the following channels:

- From an authorised Irish manufacturer or wholesaler of medicinal products, including one of those specialising in the sourcing and supply of such products; or
- From an authorised wholesaler or manufacturer of medicinal products established in another EEA country where an authorised version of the product

in that country may be available, or if such a product is not available, an appropriately authorised alternative; or

- If it has proved impossible to source an authorised alternative from an EEA country, a medicinal product that has been authorised in a country where the standards of manufacture and control correspond with those in EEA countries (e.g. USA, Canada or Australia) should be sourced. These supplies may only be procured through manufacturers or wholesalers, established within the EEA, that are authorised to make such importations; or
- If the prescribed product or an appropriate alternative is not available through any of the above channels, consideration may be given to the sourcing of an appropriate product, as an unauthorised medicinal product, from a specialist compounding facility which holds an appropriate manufacturer's authorisation for that purpose.

In general, therefore, in the interests of patient safety and public health, only medicinal products that are the subject of appropriate marketing authorisations, should be supplied. Where this is not possible, efforts should be made to source products that are appropriately authorised in another EEA country so that the interests of patient safety continue to be met. Pharmacists should therefore, only engage in extemporaneous preparation where all these routes of procurement have been exhausted or where it is not possible to obtain the patient's prescribed medicine via any of these routes without undue delay.

Prior to the preparation and supply of an extemporaneously prepared medicinal product, particularly where an appropriately authorised alternative product may be available, the pharmacist should discuss the options available with the prescribing practitioner so that he or she is aware of the medicinal product's unauthorised status. This will enable the prescriber to consider other potential options that may be available.

PSI Guidelines on Sourcing, Storage and Disposal of Medicines also provide further guidance on 'exempt' (unauthorised) medicinal products.

Carbon Monoxide Campaign

As you will be aware, carbon monoxide poisoning is a preventable cause of death in Ireland each year, with many more people suffering non-fatal poisoning, which can lead to lasting neurological damage and other ill effects. At this time of year, the increased use of heating appliances and reduction in open windows and other ventilation sources increases the risk of carbon monoxide poisoning.

Carbon monoxide poisoning can, however, be easily prevented and greater awareness amongst health professionals of the signs and symptoms of carbon monoxide exposure in their patients will help to save lives and prevent unnecessary suffering.

An information pack, including an updated fact sheet on carbon monoxide poisoning aimed specifically at GPs and healthcare professionals, which is part of a Bord Gáis Networks sponsored information campaign, is being distributed to all pharmacies.

The pharmacy profession supported a similar campaign in 2010 and community pharmacies in particular played a valuable part in that initiative.

Further information is available at www.carbonmonoxide.ie

Your co-operation and assistance with this important public health protection initiative is much appreciated.

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Published by PSI