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Welcome message

Dear Pharmacist,

The PSI would like to thank all the pharmacists who attended the recent series of information meetings about the various ongoing reforms in pharmacy education and training. The feedback gained from pharmacists at those meetings will be helpful in shaping the next phase of implementation of these initiatives. The presentation and discussions from those meetings will shortly be made more widely available, and all pharmacists will be kept informed of the next steps of engagement on the CPD model and the new five-year fully-integrated degree programme. In addition, as discussed at the meetings, all pharmacists will receive a copy of the core competency framework for pharmacists in the coming weeks.

This month's newsletter brings details of the election process for pharmacist members for appointment to the PSI Council, as five such vacancies occur this May. Eight candidates have been declared and ballot papers will now be posted to pharmacists on the electoral register. Closing date for return of completed ballot papers is Wednesday 17th April.

This month's newsletter also has information regarding an upcoming change to EU legislation regarding the preparation of extemporaneous preparations, as well as an alert about accidental paracetamol overdose in children.

Finally, just a reminder that **1st April** is the deadline for submitting your abstract for FIP 2013!

PSI Council elections

The election process for pharmacist members to be appointed to the PSI Council gets underway next week. The list of the eight candidates has been published on the [PSI website](#) and ballot papers will now be sent by post to the electoral register. This register was established by the returning officer Ciara McGoldrick, PSI Acting Registrar, on 20th March and comprises all pharmacists on the Register of Pharmacists kept by the PSI on that date who are all entitled to vote in the election for appointment. Ballot papers will be sent to each pharmacist's address as it appears in the Register of Pharmacists.

The ballot paper will include: a list of candidates in alphabetical order, giving the name and address as published in the Register of Pharmacists; the area of practice as a pharmacist of each candidate; the name and address, as published in the Register of Pharmacists, of each candidate's proposer and seconder; the latest date and time by which ballot papers shall be returned to the returning officer; and instructions on the voting procedure or a reference to an enclosure setting out such instructions.

Completed ballot papers are to be returned to the returning officer by **5.00pm on Wednesday 17th April 2013**.

The counting of votes will take place within 2 days of the election date as per Rules. At the conclusion of the count, the returning officer will declare the results and give notice in writing to the Minister for Health of the names of those elected. The election results, including details of the poll and count, will be published on the PSI website.

Paediatric Paracetamol Overdose: Risk Management

The PSI has been made aware of a recent accidental paediatric paracetamol overdose and wishes to highlight the issue to pharmacists. As medicines experts, pharmacists are ideally placed to educate the public and raise awareness about the risk, and potentially serious consequences, of inadvertent paracetamol overdose in children.

In line with Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008, which relates to the supply and counselling of non-prescription medicines, pharmacists must be satisfied that the purchaser of any non-prescription medicinal product is aware of the safe and appropriate use of the medicine, including those medicines containing paracetamol.

Paracetamol is the most common medicine involved in poisoning enquiries made to the National Poisons Information Centre and the ease of availability and regular use of paracetamol by parents may lead to an under-appreciation of the potential risks. It is widely acknowledged that children are generally at greater risk of suffering harm from medication errors than adults. It is therefore paramount that parents and carers are educated about the safe administration of paracetamol to children and that they understand the relative ease with which a paracetamol overdose can occur and the serious consequences which can potentially result.

However, as parents or carers can also purchase paracetamol containing products in non-pharmacy outlets, and frequently purchase paracetamol in anticipation of use, pharmacists should take all reasonable steps to highlight the safe use of these medicines at every appropriate opportunity, regardless of the source of paracetamol supply.

Potential Sources of Error

Potential sources of error in the administration of paracetamol to children include:

- Use of multiple products, often with different brand names.
- Use of multiple dosage forms e.g. suppositories and oral liquid.
- Errors in dosage or dose frequency.
- Accidental use of an adult formulation/dose.
- Use of an inappropriate formulation for the child's age e.g. paracetamol 250mg/5ml rather than 120mg/5ml.
- A parent/carer believing that "more is better."
- More than one parent/carer administering medicine to a child simultaneously.
- Children drinking from unattended medicine bottles/inappropriate medicine storage.

Pharmacists should take steps to minimise the potential for these errors e.g. by the implementation of protocols designed to ensure that an appropriate product is sold and that the parent/carer has been adequately counselled on the safe and appropriate use and storage of the product. Such protocols should be regularly reviewed to facilitate the safe and effective management of the sale of paracetamol containing products from a pharmacy.

Pharmacists should ensure that, where appropriate, the parent/carer is supplied with a suitable administration device (e.g. measuring spoon) and counselled in the safe and appropriate use of the device.

Parent/Carer Counselling

Parent/carer counselling should include advice:

- On the amount to be administered and the frequency of administration, following confirmation of the child's age and an explanation that the dose is age-related.
- That many children's medicines contain paracetamol and that the simultaneous use of more than one product may be dangerous – therefore parents should always check if a medicine contains paracetamol and seek their pharmacist's advice if they are unsure about any aspect of a medicine's appropriate use.
- Never to give more than one medicine to a child except on the advice of a doctor or pharmacist.
- To follow the directions printed on medicine labels.
- To use the measuring device provided with their child's medicine. Household spoons are not suitable measuring devices.

- To store all medicines out of childrens' reach and sight, and to never leave medicines unattended where young children are around.

Training

All pharmacy staff should be aware of the dangers of paracetamol overdose and the potential risks to children if paracetamol containing products are not used appropriately. All staff should be appropriately trained in the necessary counselling techniques required to ensure the safe use of these medicines.

Advisory on Use of Herbal Teas in Young Children

Following recent reports to the Irish Medicines Board (IMB) of herbal tea, specifically chamomile tea, generating adverse reactions in infants, pharmacists are requested to advise the public that herbal teas should not be used in infants and young children as a precautionary measure.

A number of herbal teas are available on the Irish market, some of which may be supplied through pharmacies. Members of the public may also seek the advice of their pharmacist about what food supplements or other products they may safely give to their children.

Pharmacists should note that, for example, the European Medicines Agency's assessment report for fennel containing herbal products has a restriction on the use of fennel based teas in young children.

In both of the recent reports to the IMB about chamomile tea causing adverse reactions in infants under 12 months, the infants experienced status epilepticus secondary to hyponatraemia requiring hospitalisation.

In view of this evidence, in general herbal teas should not be used in infants and young children, as a precautionary measure. Pharmacists should be aware of the necessity to provide appropriate information on the safe use of these products to the public.

EP changes on 1st April – Implications for Extemporaneous Dispensing

The European Pharmacopoeia monograph on pharmaceutical preparations (2619) comes into force on 1st April 2013. This monograph provides guidance on, and highlights the ethical considerations surrounding, the preparation and supply of extemporaneously prepared products.

The monograph notes that when deciding to provide a pharmacy prepared product, all healthcare professionals involved have a duty of care to the patient receiving the product. It also introduces significant requirements with regard to the testing/analysis of these products in a pharmacy setting to assure the quality of the product produced.

Requirements outlined in this monograph include those relating to the production and testing of pharmacy-prepared products, and cover issues such as formulation, active substances and excipients, microbiological quality, containers, and stability. The requirements on testing deal with the appearance of products, identity and purity tests, uniformity and reference standards.

This document will be published as a monograph of the European Pharmacopoeia, in the 7th edition (supplement 7.7) on **1st April 2013**.

Additional Considerations

In addition to the European Pharmacopoeia monograph, the PSI would also like to draw pharmacists' attention to the Council of Europe Resolution 2011, which addresses important issues including:

- When pharmacy-preparations are of added value i.e. when they are needed by a specific patient or by specific population groups with particular needs.
- The responsibilities of healthcare professionals e.g. for determining whether an

extemporaneous preparation could be of added value, including where an authorised equivalent is available.

- The preparation process (including a model procedure for risk assessment).
- Preparing product dossiers (including quality control and stability testing).
- Compliance with pharmacopoeial requirements.
- Labelling.
- Communication and information for patients.

The full resolution can be accessed [by clicking here](#).

The PSI is considering the implications of the requirements and standards imposed by these documents in respect of extemporaneous dispensing, in the context of pharmacy practice in Ireland. Further guidance on this issue will be communicated to the profession in due course.

RCSI/NCPE survey on generic substitution

Pharmacists will recently have received an email inviting them to participate in a survey exploring attitudes to generic substitution. This survey is being carried out by the RCSI and the National Centre for Pharmacoeconomics, across various medical professionals and patients.

The aim of the study is to assess the attitudes of patients, pharmacists and prescribers to generic substitution before and after its introduction, through two surveys conducted in 2013. The survey, which is conducted on-line, takes 5-10 minutes to complete.

The survey is available [by clicking here](#).

All individual responses will be strictly confidential.

The RCSI/NCPE have also provided clarification to queries arising about questions 11 and 19 of the survey, which ask the respondent to rank the answers in order of preference (starting with 1 which they consider most important and 5 least important). Please note that by inserting the ranking number in the box beside the text, the text statements will automatically change order according to the ranking assigned.

Respondents who have completed the survey to date need not undertake the survey again.

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

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