In This Issue

- Revised Methotrexate Guidance
- Guidance on non-Rx Curanail
- PSI Inspectors Advice on Animal Remedies
- IMB Communication on Metoject
- CPD: All-Ireland conference; PhD opportunity
- Tutor Pharmacists Update

Print Version »

Welcome message

Dear Pharmacist,

This month's newsletter features revised guidance for pharmacists in the safe supply of oral methotrexate.

Medication errors resulting in inadvertent overdose, either by daily intake of a weekly dose or through confusion between different strength tablets, can have extremely serious and potentially fatal consequences for patients.

Pharmacists play a critical role in minimising the risks of these errors occurring and also in ensuring that patients and their carers are appropriately informed and aware about the safe use of this drug.

This revised guidance for pharmacists aims to assist pharmacists in carrying out this important medication safety role and supporting their management of the key issues.

The PSI would like to thank colleagues on the Medication Safety Forum, Dr Aisling O'Leary in RCSI and Arthritis Ireland for their contribution to the revision of this guidance.

Revised Methotrexate Guidance

The PSI, in collaboration with the Medication Safety Forum, has revised and updated its guidance to pharmacists in relation to the supply of oral methotrexate.

A recent EU review of the issue, aimed at further minimising the risk of medication error with oral methotrexate, has highlighted the importance of emphasising the once-weekly dosing for rheumatology and dermatology indications and advised that prescribers should specify the day of intake on the prescription for clarity.

Pharmacists play a critical role in ensuring the safe use of methotrexate, through their participation in the educating, counselling and monitoring of patients. The revised PSI guidance highlights the key safety messages for pharmacists in supplying this medicine, including that only 2.5mg strength tablets are dispensed and that patients are actively encouraged and supported in taking one strength only. The importance of making patients and their carers aware of the signs and symptoms of methotrexate toxicity and of seeking medical attention should they develop symptoms is also highlighted. The guidance contains a template for a patient information notice which may be helpful to provide to patients.

The revised guidance is available to view and download from the PSI website.

Guidance on non-Rx Curanail

The Irish Medicines Board recently granted a marketing authorisation for Curanail Medicated Nail Lacquer containing 5% w/v of Amorolfine, as a non-prescription medicinal product for the treatment of mild cases of fungal nail infections in adults. The product is expected to be available to pharmacies in Ireland shortly.

The PSI welcomes this latest move of a medicine, previously available on prescription, to direct supply from a pharmacist, and has issued guidance in respect of the supply of non-prescription Curanail.

This guidance states that the supply of Curanail, and the associated assessment and consultation with a patient, should only be carried out by a pharmacist and that this consultation and discussion should take place in the pharmacy's patient consultation area.

Each time this medicine is supplied, the pharmacist must be satisfied that, in the exercise of his or her professional judgment, the supply of such a medicine is safe and appropriate for the individual patient. Pharmacists should be familiar with the product SmPC and patient information/package leaflet in order to satisfy themselves that the patient's condition meets the product indications and that there are no contra-

indications or cautions regarding use of this product for the individual patient. Patients will seek the pharmacist's advice in relation to their particular symptoms or condition, so familiarity with the diagnostic criteria is important.
The guidance in full is available to view and download from the PSI website.

PSI Inspectors Advice on Animal Remedies

PSI inspectors have found that the management of animal remedies (veterinary medicines) is an area of community pharmacy practice that is often inadequately understood. We hope to cover some of the recurring issues found at inspection in this and future newsletters and hope this information will help pharmacists to better understand the relevant regulations and requirements.
The main requirements are primarily set out in the European Communities (Animal Remedies) (No.2) Regulations 2007 (S.I. No.786 of 2007) (as amended), which can be accessed via www.irishstatutebook.ie. or via the PSI website www.thePSI.ie. All pharmacists engaging in the sale and supply of animal remedies should ensure they are familiar with these regulations.
This month we will review:

- The classification of animal remedies
- The storage of animal remedies
- Record keeping requirements

Classification:
The route of sale or supply of an animal remedy depends on the category it belongs to. The classification or category can be readily identified as it is indicated on the labelling or outer packaging of the product. If you are ever in doubt as to the classification of an animal remedy, information can be checked at www.imb.ie.
A veterinary practitioner (vet) can supply all remedy classifications; however there are other restrictions on who can sell or supply each class of product and under what circumstances as outlined below.
Animal remedies are classified into 6 categories:

1. Veterinary Practitioner Only (VPO-1/VPO):

These medicines may only be sold or supplied by a vet. The symbol **VPO-1/VPO** will be displayed on the labelling or outer packaging of the product.
Pharmacists/pharmacies are not permitted to have these animal remedies in stock and/or to sell or supply these medicines.

2. Prescription Only (POM)

These medicines may only be supplied by a pharmacist, from a pharmacy on foot of a veterinary prescription. The symbol **POM** will be displayed on the labelling or outer packaging of the product.
Certain POM animal remedies may also be sold or supplied by a responsible person from 'licenced merchant' premises, in accordance with a veterinary prescription.

3. Prescription Only Exempt POM(E)

These medicines may be sold from a pharmacy without a prescription, but the sale must be personally made by a pharmacist. The symbol **POM(E)** will be displayed on the labelling or outer packaging of the product.

4. Pharmacy Only (PS)

These medicines may be sold from a pharmacy, without a prescription, under the personal supervision of a pharmacist. The symbol **PS** will be displayed on the labelling or outer packaging of the product.

5. Licensed Merchant (LM)

These medicines may be sold from a pharmacy, without a prescription, under the supervision of a pharmacist. The symbol **LM** will be displayed on the labelling or

outer packaging of the product. The sale of these medicines is not restricted to pharmacies. They are also available from other 'licensed merchant' premises, e.g. farmers' co-ops.

6. Companion Animal Medicines (CAM)

These medicines may be sold from a pharmacy, without a prescription, under the supervision of a pharmacist. The symbol **CAM** will be displayed on the labelling or outer packaging of the product. The sale of these medicines is not restricted to pharmacies. They are also available from 'licensed merchants' and 'companion animal remedies sellers' (e.g. pet shops)

Pharmacists should ensure that appropriate advice is given every time an animal remedy is sold or supplied. This will enable animal owners to use the products safely and effectively.

Storage:

Animal remedies should be stored in a pharmacy in a manner which meets all relevant requirements as set out in the PSI's *Guidelines on Storage of Medicinal Products within a Retail Pharmacy Business*, and in particular Section 3.5. They should be stored separately from human medicines and the parts of the premises used for the storage of animal remedies should be clearly identified as such.

POM animal remedies must be stored in the dispensary, and must not be stored in an area where they would be accessible to the public for selection. POM (E) animal remedies should also be stored in the dispensary to ensure the sale is personally made by a pharmacist. PS, LM and CAM animal remedies should be stored in an area of the pharmacy under the personal control of the pharmacist, such as behind the pharmacy counter.

Pharmacists should check the pharmacy shelving in the public areas of the pharmacy to ensure that no animal remedies are inadvertently inappropriately located. We have previously found, for example, that certain prescription only pet wormers, 'spot-on' flea preparations and ear drops have been mistaken as being LM remedies.

All animal remedies must be stored in accordance with the requirements of their marketing authorisations. The storage conditions for a medicinal product, including the temperature requirements, are normally specified on the outer packaging of the product. All animal remedies requiring storage between 2-8°C must be kept in a separate animal medicines pharmaceutical grade refrigerator.

You are also reminded that extra precautions are needed if an animal remedy has a strong odour which may compromise other medicines/products at the pharmacy. These products should be stored in a part of the premises isolated from other medicinal products.

Please ensure that all expired, damaged or 'patient-returned' animal remedies are segregated from active stock and promptly disposed of.

Record Keeping:

A record of all purchases and sales of POM, POM(E), PS and LM animal remedies (both incoming and outgoing transactions) must be maintained in the pharmacy.

This record must contain:

a) The date the transaction occurred

b) The precise identity of the animal remedy (i.e. name, form, strength) or medicinal product

c) The quantity received or supplied

d) The name and address of the supplier or purchaser

e) The manufacturer's batch number of the product received/supplied, and

f) Where the transaction relates to the supply of a prescription only medicine (POM), the serial number of the veterinary prescription.

You don't have to keep this record for purchases and sales of companion animal medicines (CAM).

Invoices received for animal remedies may contain all of the relevant information for 'incoming' transactions. These animal remedies invoices should be kept separate from other pharmacy invoices.

The record can be maintained as a daily printed computer record or in a separate register or folder. However you choose to keep the record, it must contain all the details listed above and be available for inspectors to review at inspection. Please note that some of these details may not be automatically recorded on a computer-generated record. The legislation requires the record to be kept for five years.

Future Newsletters

Pharmacists should also note that a vet may prescribe human medicinal products for an animal under the 'cascade' system where there is no animal remedy authorised for the treatment of the condition and the animal is under the care of the prescribing vet. The cascade system will be covered in a future newsletter.

The requirements related to veterinary prescriptions will also be covered in a future newsletter.

IMB Communication on Metoject

The IMB wish to highlight that there is currently a shortage of 'Metoject 10mg/ml solution for injection, prefilled syringe' PA623/7/1 on the Irish marketplace. The Marketing Authorisation Holder (MAH - Medac) has informed the IMB that they intend to supply the UK licenced product 'Metoject 50mg/ml solution for injection, prefilled syringe' as an exempt medicinal product during this stock shortage period, if healthcare professionals wish to use a 'prefilled syringe' presentation.

'Metoject 10mg/ml solution for injection, prefilled syringe' is the only authorised Methotrexate product in a pre-filled syringe presentation on the Irish marketplace. The IMB wish to point out that the unlicenced UK product is a **significantly** higher concentration (five times higher) than the authorised 10mg/ml product. The labelling and package leaflet of the unlicenced product have not been approved by the IMB and healthcare professionals are advised to **exercise extreme caution** when dispensing and administering this higher concentration product, in order to avoid medication errors and potential harm to patients.

Earlier this month, the MAH was requested to issue a letter to all retail and hospital pharmacies as well as to rheumatologists, so that the potential risks associated with interim use of this product could be communicated. The letter advised pharmacists of the need to **exercise caution** when dispensing and administering this product, in light of its **significantly** higher concentration than the 10mg/ml authorised product.

All packs of the UK- authorised 50mg/ml product that are being supplied by Fannin Healthcare will be accompanied by a copy of that letter.

CPD: All-Ireland conference; PhD opportunity

Call for Abstracts for All-Ireland Conference

The ICCPE would like to remind pharmacists that this year's All-Ireland Pharmacy Conference will be held at Ballymascanlon House Hotel, Dundalk on 12th and 13th November. Abstracts for oral and poster presentation at the conference are now invited. Further information, including guidelines and a template for submitting an abstract is available on the ICCPE website www.iccpe.ie. The closing date for receipt of abstracts is Friday 3rd August 2012. Completed abstract submissions or queries regarding the conference should be sent to info@iccpe.ie

Funded PhD opportunity

The School of Pharmacy and Pharmaceutical Sciences in Trinity College Dublin is seeking applications to pursue a full-time funded PhD project, based in the School and Tallaght Hospital, and have provided the following details about the project which is entitled: *"Investigation of models of clinical pharmacy to facilitate integrated medicines management and reconciliation between secondary and primary care".*

The successful candidate will commence in September 2012 and will receive a stipend of €14,500/annum plus payment of annual PhD student fees for three years (payable on the EU scale only). Candidates should be members of the Pharmaceutical Society of Ireland, or eligible to register; hold a 1st or 2.1 degree; and hospital pharmacy experience is desirable.

Increasing prevalence of multimorbidity, polypharmacy and an aging population make medication use ever more complex. Ensuring medication safety as patients move into and out of hospital is challenging. The successful candidate will investigate the effectiveness and cost effectiveness of models of clinical pharmacy and medicines management to support safe medication use across transitions of care. This project offers an excellent opportunity to work with a multi-disciplinary team in the clinical setting and to gain training and expertise in health services research, using quantitative and qualitative methodologies.

To apply, please submit the following to tagrimes@tcd.ie:

1) A letter of introduction stating why you would be suitable for the position.

2) Your CV, including telephone numbers and e-mail addresses for three people willing to act as referee. This should include one academic and one employment related referee.

3) A 400 word document outlining your understanding of medication reconciliation.

4) University examination transcripts and, if available, a copy of your degree certificate. (Scanned copies and/or certified translations accepted in the first instance.)

5) If your first language is not English, evidence of English Language proficiency.

Informal enquiries are welcome between 9th and 20th July and should be directed to: Dr Tamasine Grimes, Associate Professor, TCD/ Research Pharmacist, Tallaght Hospital. Email tagrimes@tcd.ie.

Closing date for receipt of application is Monday 23rd July 2012. Applicants should be available to attend interview in Dublin on Monday 13th August 2012.

Tutor Pharmacists Update

The online application process for the 2012-2013 National Pharmacy Internship Programme (NPIP) is now open (from 15 June 2012).

The PSI Council recently approved revised requirements relating to the eligibility criteria for tutor pharmacists and training establishments, as well as to the Tutor Training and Accreditation Programme (TTAP).

TTAP for 2012-2013

An additional element of the TTAP is a mandatory one-day Tutor Network Meeting which has been added based on feedback from tutor pharmacists, as it was felt that certain elements of tutor training and skills development weren't particularly suited to learning in an online format.

This Meeting therefore will provide a forum for tutor pharmacists to engage in face-to-face peer learning and work through issues related to their role as a tutor using 'real-life' experiences, including performance review, coaching skills, handling difficult situations, ethical reasoning, clinical governance and risk management.

Attendance at a Meeting is mandatory for new tutors for the 2012-2013 academic year who haven't previously completed the TTAP and for those tutors who did the original TTAP in 2010-2011. Tutors who successfully completed the TTAP in 2011-2012 aren't required to do this additional training but may attend a Tutor Network Meeting if they wish. Details about the dates, times and venues for these meetings, which will be held in the autumn will be made available shortly. Further information about the TTAP is available on the PSI website at http://thepsi.ie/gns/education/cpd/TTAP.aspx

Eligibility Criteria for Tutors and Training Establishments

The PSI Council also recently approved revised eligibility criteria for the recognition of tutor pharmacists and for training establishments. These revisions primarily relate to circumstances where a pharmacist or training establishment would be deemed ineligible, for example following convictions under pharmacy or medicines legislation or sanctions arising from a fitness to practise hearing.

Further information about the details of these eligibility criteria is available on the PSI website.

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

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