

# PHARMACY INSPECTORS'

ISSUE 6 • December 2010

Newsletter



Department of  
**Health, Social Services  
and Public Safety**

[www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

AN ROINN

**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydënter Heisin  
an Fowk Siccar**

Welcome to the sixth Inspectors' Newsletter which highlights a number of key issues relating to legal requirements and best practice. Of particular note is the advice on the need for vigilance when dispensing products with similar livery and when dealing with monitored dosage systems. Pharmacists, in general, do operate very safe systems of work and I would encourage you to continue to regularly review your processes to ensure that all appropriate procedures are in place to ensure a safe dispensing environment.

Two changes to note. As from the 1st November 2010, the investigation and enforcement team became known as the Medicines Regulatory Group and, also with effect from 1st November, the group has a newly appointed Senior Investigator, Mr Peter Moore. Peter comes to the Group with a wealth of investigative experience and we are indeed fortunate to have gained a colleague of his knowledge and expertise.

**Prof. M Mawhinney - Head of Medicines Regulatory Group**

## Private CD requisitions and PCD1 forms

As you will be aware a small number of practitioners have requested PCD1 prescription forms for the private prescribing of Schedule 2 and Schedule 3 controlled drugs. Please remember, if any of these forms have been submitted to your pharmacy, that it has been a requirement from 1st April 2010 to submit the forms to BSO on the modified HS30 form. Very occasionally practitioners or licence holders may proffer private requisitions for controlled drugs. Where S2 or S3 CDs are concerned, the requisitions must be submitted to BSO, marked indelibly with the supplier's name and address. The required records for supply against PCD1 and private requisitions must be made in the CD register and Prescription Only Register. For fuller details please see the Society's *General Legal Requirements* guidance, and the 1st March 2010 letter from Dr Mawhinney and Mrs Turner, available on the Department's website - <http://www.dhsspsni.gov.uk/controlleddrugs-pcd1-forms.pdf>



## Dispensing Error - Risk of confusion of Amitriptyline/Atenolol/Amlodipine

A number of dispensing errors have come to our attention recently. In particular there have been several incidents involving **amitriptyline and atenolol**. (Also be aware of potential risk with other similarly named products e.g. amlodipine).

During visits we have also been made aware of possible confusion arising as the result of similarly packaged generic products. Caution should be exercised when putting such items on to shelves following receipt of deliveries, and the staff responsible for this activity should be made aware of the potential problems. The location on shelves of similarly named and/or similar packaged products should be reviewed in order to minimise the possibilities of dispensing errors.

The maintenance of a near miss log will help to highlight the areas of potential

problems within your practice and allow preventative action to take place.



## Monitored Dosage Systems Supplies

Paragraph 3.12 of the Society's Professional Standards and Guidance for the Sale and Supply of Medicines states that: "the pharmacist must ensure that: appropriate systems and procedures are in place if he prepares monitored dosage systems." The Medicines Act specifies that certain categories of medicines are available on prescription only i.e. with certain exceptions, a prescription is necessary for supply.

Pharmacists are reminded of their professional and legal responsibilities with respect to MDS. An essential element of such systems and associated procedures must be that



prescriptions are obtained before any supply of the medication takes place. Any changes to medication or dosage must be acted upon before the supply is made.

Errors have occurred where discontinued medication has been included in an MDS

tray; additional medication has been omitted; or an altered dose has remained unchanged. Vigilance must clearly be exercised when filling MDS trays, or indeed any other dispensing containers, and checking procedures should be in place and be adhered to. The assembly and checking procedures should be separated in time, particularly if carried out by the same person.

Labelling of MDS trays must conform to legal requirements and the obligation to supply Patient Information Leaflets (PILs) must be complied with.

## Private prescribing and Professional Judgement

We have become aware of concerns relating to patients receiving private prescriptions from practitioners other than their general practitioner, in particular from practitioners engaged solely in private practice. The concerns relate to the type of medicines prescribed, the frequency of the prescriptions and whether or not the general practitioner is aware that these prescriptions are being issued in addition to those he/she is issuing.

You are reminded that Principle 1 of the Society's Code of Ethics states that a pharmacist must **"Make the safety and welfare of patients your prime concern"**. Paragraph 3.2 of the Society's Professional Standards and Guidance for the Sale and Supply of Medicines states that: "a pharmacist must ensure that: **a clinical assessment of every prescription is undertaken, by a pharmacist, to determine the suitability of the medication, the appropriateness of the quantity and its dose frequency for the patient.**"

Pharmacists who have concerns about private prescribing can contact the Health and Social Care Board (HSCB), Pharmaceutical Society of Northern Ireland or the Medicines Regulatory Group.



## Pharmacists and the AO legislation

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 came into operation on 1st October 2009. This legislation introduced the role of Accountable Officer (AO) for certain organisations known as Designated Bodies.

The AO has overall responsibility for the safe management and use of controlled drugs within their Designated Body and must ensure that any person providing services to their organisation also has appropriate arrangements in place.

The Designated Bodies include, amongst others, the HSCB and the Trusts. If a pharmacist has a concern

about a controlled drug, no matter which schedule, these concerns should be notified to the relevant Accountable Officer for their area of practice. For hospital pharmacists this will be the Trust AO and for community pharmacists the HSCB AO. A list of AOs and their contact details can be obtained from the Department's website. <http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer/pas-contact-details.htm>

In January/February 2011, a declaration and self-assessment form was sent by the Department to all community and Trust pharmacies. These completed forms are reviewed by the Inspectors during their visits. If you have any concerns about the management or use of controlled drugs, including matters such as prescribing practices of healthcare professionals or their fitness to practise, please contact the inspectors at the earliest possible opportunity.

On a quarterly basis, the Inspectors send a summary of any controlled drug matters which have arisen from visits to community pharmacies to the HSCB AO for his consideration.

Under the above legislation, a Local Intelligence Network (LIN) meets on a quarterly basis to discuss controlled drug concerns and to consider learning points. Those attending the LIN include all AOs, the Department, the police, the regulatory bodies, (including the Pharmaceutical Society), Counter Fraud and RQIA.



## SOPs

Amendments to the Medicines Act, The Responsible Pharmacist Regulations and the "Accountable Officer" (AO) Regulations have enshrined Standard Operating Procedures (SOPs) in law. The Responsible Pharmacist (RP) must establish (if not already established), maintain and keep under review procedures to secure the safe and effective running of the pharmacy business so far as concerns the sale and supply of medicines (including GSL products). The AO Regulations attracted a duty to community pharmacy contactors (among many others) to have SOPs in place for the management and use of controlled drugs. Both sets of regulations specify the matters that must be covered by the respective SOPs. Many pharmacists address the matter of SOPs very well.

However a minority of businesses have been noted to have defective SOPs. Some of the noted defects have been:

- templates from trade organisations, or others, have been presented but these were not tailored in the least to the circumstances of the business concerned;
- the range of matters specified in the regulations has not always been covered;
- lack of procedures which identify members of staff who are competent, in the view of the RP, to perform certain tasks relating to the relevant part of the pharmacy business.

Guidance is available on the Society's website, on the Department's website and from the Department of Health in London (agreed by the four Administrations) among other places.

## Codeine containing products

Pharmacists will be aware of the recent changes affecting the OTC sale of codeine containing analgesics, in particular co-codamol effervescent. The Society has issued advice relating to the sale and supply of codeine and this may be accessed at:

<http://www.psnl.org.uk/documents/376/PSNI+Advice+on+Codeine.pdf>

Addiction services are encountering individuals who are consuming greatly excessive daily co-codamol, with serious implications for the individuals' health.

Codeine linctus has long been associated with misuse and we would also advise caution when supplying Terpin and Codeine. This product has increased potential for misuse due to its high codeine and alcohol content.

Pharmacists here have been most vigilant in monitoring the sales of such preparations and are reminded that all staff involved in the sale of OTC products should be aware of the abuse potential of certain OTC medicines, and should be alert to over-frequent requests or requests for large quantities. Such requests should be referred to the pharmacist who must exercise his/her professional judgement as to whether or not to supply and if professional advice would be helpful to the prospective buyer. Owners of pharmacies should consider whether it is appropriate to stock products that are known to be liable to misuse.

## MHRA advice

The MHRA has published advice from the Commission for Human Medicines (CHM). Following its review of cough and cold medicines for children, the CHM



has advised that OTC liquid medicines containing codeine should no longer be used in children under 18 years.

Further detailed information is available on the MHRA's website.

<http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con096756.pdf>

## Ephedrine/pseudoephedrine sales

Pharmacists should be aware that there have been a number of requests for the supply of pseudoephedrine in circumstances which may cause concern or arouse suspicion. You are referred to the guidance issued by the Society relating to the sale of pseudoephedrine.

<http://www.psnl.org.uk/press-releases/pseudoephedrine-guidance.php>

## EEA prescriptions

The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 were recently amended to omit the requirement for prescriptions provided by EEA or Swiss doctors and dentists to contain details of the address and the age, if under 12, of the person for whose treatment the prescription is given. (The requirement for UK prescriptions is unchanged.) Other amendments, effective from 20 December 2010, provide that EEA prescriptions for S4 and S5 controlled drugs are not automatically excluded from being dispensed in the UK. Also, emergency supplies of S4 and S5 controlled drugs, at the request of EEA prescriber or patient, are provided for in the legislation on the same basis as for UK prescribers and patients.

Pharmacists should ensure that they are satisfied that they are in possession of all information necessary for good clinical governance before making supplies against EEA prescriptions. Fuller details are available in the Society's Professional Guidance.

<http://www.psnl.org.uk/documents/731/Microsoft+Word+-+Dispensing+European+Economic+Area+prescriptions+december+2010.pdf>

## Veterinary Products

During recent visits to pharmacies we have noted that some brands of pet wormers are becoming more widely distributed. Some of the products within these brand ranges are licensed as NFA-VPS products and therefore should not be openly displayed for public self-selection.

These products, and indeed all products designated POM-VPS, may be supplied by a pharmacist following a request from the keeper of the animal. The pharmacist may not diagnose the animal's condition, this may only be done by a veterinary surgeon. In response to a request for a product, for example to treat worms, the pharmacist must recommend the most appropriate product, irrespective of any promotions which may be available.

**Pharmacists should also be aware that it is an offence to possess and/or supply a veterinary medicine which is not licensed for use within the UK.**



## Drug Donations

We have been made aware of an issue where unused patient medicines were stored for the intention of drug donation and humanitarian relief.

It is important that all healthcare professionals are aware of their legal, professional and ethical responsibilities attached to drug donations.

Guidance has been produced by the World Health Organisation - *Guidelines for Drug Donations - Revised 1999* - which lists the four core principles for drug donation shown below.

*"The first and paramount principle is that a drug donation should benefit the recipient to the maximum extent possible. This implies that all donations should be based on an expressed need and that unsolicited drug donations are to be discouraged.*

*"The second principle is that a donation should be made with full respect for the wishes and authority of the recipient, and be supportive of existing government health policies and administrative arrangements.*

*"The third principle is that there should be no double standards in quality: if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.*

*"The fourth principle is that there should be effective communication between the donor and the recipient: donations should be based on an expressed need and should not be sent unannounced."*



In relation to patient returns they state that *"No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere"*.

Additionally they advise that *"All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date."*

Would-be donors should also ensure that they comply with UK and destination country legislation regarding transactions in medicines or export/import activities that they may be considering. Professional bodies and trade associations may be able to give advice and MHRA should be consulted about licence requirements.

Guidelines for Drug Donations - Revised 1999 can be found at <http://apps.who.int/medicinedocs/en/d/Jwhozip52e/>

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