

PHARMACY INSPECTORS'

Issue 4 November 2008

Newsletter



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

www.dhsspsni.gov.uk

AN ROINN
**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O
**Poustie, Resydënter Heisin
an Fowk Siccar**

Dear Colleague,
By the publication date of this Newsletter, consultation will be closed on the Department's "Accountable Officer" paper. The next step is the enactment of regulations establishing accountability and a duty of collaboration on organisations and individuals handling controlled drugs. Our group will be hosting training events and issuing detailed guidance documents and will keep pharmacists fully informed of all legal and practice changes. However, I would reassure colleagues that, while there are new elements within the legislation, it is aimed primarily at formalising the already robust processes present in Northern Ireland.

Dr. M. Mawhinney
Head of Inspection and Investigation

Methadone solution from powder

Any pharmacist contemplating, or involved in, the extemporaneous preparation of unlicensed methadone solution, should bear in mind the following points among other important issues: an SOP must be in place ensuring safe systems and a verifiable audit trail; the prescriber and patient must be told that a product without a marketing authorisation is being supplied; there may be issues related to indemnity insurance due to increased liability; appropriate records must be maintained and retained and the use of an unlicensed product must be justified by the pharmacist when products with marketing authorisations are available.

Drug misuse and dependence

UK guidelines on clinical management – also known as the Orange Guide (UK Health Departments 2007 – available on the DH website). This document updates and replaces *Drug Misuse and Dependence – Guidelines on Clinical Management* (UK Health Departments 1999). It has the same status across the UK as the 1999 Clinical Guidelines. The 2007 Clinical Guidelines provide guidance on the treatment of drug misuse in the UK. They are based on current evidence and professional consensus on how to provide drug treatment for the majority of patients, in most instances.

Pharmacy records

Among other things the inspectors may wish to see the following records during inspections of pharmacies: Controlled Drugs Register, Patient CD Returns Destruction Record, Private Prescription Book, Fridge Temperature Record, SOPs and related staff training record and Extemporaneous Dispensing Record. They may check that you are maintaining Error and Intervention Logs that inform and refine your practice.

Locums (and employers)

If you are intending to work as a locum, please ensure that, prior to undertaking an arranged session, you have liaised with the regular manager about the activities you will be expected to undertake in the pharmacy during your session. Find out what guidance and documentation will be available in the pharmacy to inform your duties. The pharmacy SOPs should indicate what duties particular staff have been trained to do and are competent to undertake. Remember that during your session you should not increase the level of responsibility of support staff but when you are in personal control it may be appropriate to decrease the level of responsibility of staff whose qualifications or training you are unsure of. Ensure that you have adequate liability insurance for your locum activities.

From the RQIA

The **Regulation and Quality Improvement Authority (RQIA)** which, among other things inspects registered care homes, has asked for the following to be included:

"Monitored Dosage Systems (MDS) in Registered Care Facilities

"The RQIA pharmacist inspectors recently met to discuss themes emerging during the previous inspection year. Areas of good practice and of concern which emerged throughout the province were highlighted. Areas of concern included:

- "The suitability of certain medicines for packing in MDS with particular reference to hygroscopic preparations.
- "The standard of labelling of MDS with regard to identifying medicines and distinguishing tablets and capsules from each other - frequently inadequate or no descriptions of medicines are provided to facilitate this. This would also apply to medicines supplied in pharmacy-filled compliance aids in the community, which are frequently presented on admission to care homes.

"Part 3 of the Society's "Ethics and Practice - A Guide for Pharmacists in Northern Ireland" gives guidance concerning the provision of MDS to nursing and residential care homes. In this section, the following statements are made:

"3.2 "Tablets or capsules which cannot be identified and readily distinguished from each other should not be placed together in the monitored dosage system. Labelling should enable identification of individual medicinal products to be made."

"3.4 "Certain medications should not be placed in monitored dosage systems. These include effervescent tablets, dispersible tablets, buccal tablets, sublingual tablets and significantly hygroscopic preparations".

RQIA inspectors raise any relevant concerns with the registered facility on the occasion of their inspection and advise liaison with the supplying pharmacist in addressing the matter.

On the subject of MDS, the Department Inspectors remind pharmacists that provision of **PILs** must not be ignored for patients using these aids. Please note also that the **MHRA** received a report of tablets migrating from compartment to compartment in a monitored dosage unit. Please ensure that units are assembled correctly and that risk of migration is minimized by the particular design of compliance aid that you choose to use.

Some Practice Issues

Incidents prompt the inspectors to raise some points of practice. Picking errors - the importance of correctly assembling prescribed medicines and having a system of accuracy checking cannot be overemphasized. Quantities supplied - instalment directions must be read carefully, particularly on substitution therapy prescriptions, and the assumption should not be made that they will be unchanged from previous prescriptions. Invalid prescriptions - check that prescriptions are not time-expired. Patient identity - patients or their representatives must be correctly identified when supplying dispensed medicines.

Legal Validity of EEA and Swiss Prescriptions in the UK

New legislation came into operation on 3rd November which relates to the validity in the UK of prescriptions written by EEA or Swiss healthcare professionals (doctors and dentists registered to practice in an EEA country or Switzerland). The Society has drawn attention to the new rules in a recent letter, information has been published in the Pharmaceutical Journal and guidance has been published by the National Pharmacy Association.

New PSNI Controlled Drugs Liaison Officer (CDLO)

Pharmacists may be aware that in Great Britain designated police officers inspect some matters related to controlled drugs in community pharmacies. Although the Misuse of Drugs Act 1971 makes similar provision for the police in Northern Ireland, no police officers have been routinely using the powers conferred. (Such controlled drugs inspections are undertaken here by the two DHSSPS Pharmacy Inspectors.) Recently Detective Constable Robin Stanex, based at PSNI Drugs Squad headquarters, has undergone the training course for CDLOs. DC Stanex however, will not routinely visit community pharmacies here and the Pharmacy Inspectors will continue to inspect controlled drugs related matters. DC Stanex is also the PSNI Chemical Liaison Officer, which involves him in the monitoring of supply of potentially dangerous chemicals. DC Stanex may be contacted at 028 9065 0222 Ext 30422 or Robert.Stanex@psni.pnn.police.uk

Over the Counter Sales

The Inspectors discuss the potential for misuse of OTC medicines' during inspection visits. Products frequently highlighted are codeine-containing analgesics, antihistamine sleeping tablets, codeine linctus and kaolin and morphine mixture. A letter was recently circulated to all pharmacists stressing the importance of the issue and acknowledging pharmacists' ongoing vigilance. Pharmacists are also asked to remind staff that some homeopathic tablets containing lactose are apparently being bought to be ground down and used to "cut" illicit substances.

FROM THE SOCIETY...

Superintendent pharmacists

"The Society is witnessing an emerging trend where a body corporate, in appointing the superintendent of the company, is not briefing the pharmacist on the full extent of the role they are being asked to fulfill and the resultant responsibilities in law. The duties are clearly stated in The Code of Ethics of the Pharmaceutical Society of Northern Ireland under Principle Six (see 6.3 and 6.4). The superintendent pharmacist must be in a position to effect and influence the quality of pharmaceutical care provided from all premises for which they have responsibility, including all aspects of clinical governance and the management of complaints processes. The superintendent may carry total responsibility if, as a result of his neglect or inactivity, poor pharmaceutical care is provided.



Pharmacist employers should also ensure that all employees are competent in the English language and can effectively communicate with patients and associated health professionals."

Excessive dispensing

"The Society reminds pharmacists of the Code of Ethics (paragraph 1.9) under Principle 1.

"A pharmacist must exercise professional judgment to prevent the supply of unnecessary and excessive quantities of medicines and other products, particularly those which are liable to misuse, or which are claimed to depress appetite, prevent absorption of food or reduce body fluid.

There are some recent examples of excessive prescribing of medications by GPs which has then been exacerbated by the pharmacist / pharmacy dispensing the full quantities of the medications to the patient without querying the rationale for prescribing, or helping to minimise the risk to the patient by not dispensing the medications. A recent example was where "100 x Levothyroxine 100mcg, Take one tablet daily," had been prescribed on each of three sequential months for an individual patient and the full quantities were dispensed to the patient on each occasion by the same pharmacy.

There is a professional responsibility for the pharmacist to refer back to the prescriber. Professional judgment should be exercised on each supply of medicines, especially where the pharmacist has the ability to access patient medication records and to establish the validity of supply."

Registration certificates for pharmacists

"The Medicines Act 1968 (Articles 70 and 71) currently requires that all pharmacists in personal control of registered pharmacies must display their certificates of registration. In Northern Ireland these certificates are distinguished by the wording "this certificate of registration is for the purpose of the Pharmacy (Northern Ireland) Order 1976 and is the property of the Pharmaceutical Society of Northern Ireland". This is the certificate which is sought during inspections by the Pharmaceutical Inspectorate. Where a certificate is mislaid, a new one can be issued by the Society's offices for an appropriate fee (currently £100 and processed within 28 days.)"

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