



Dear Colleague,

Welcome to the first Inspectors' Newsletter. Through this medium the Department's Inspectorate aim to bring to pharmacists' attention new legislation and practice, and to underscore existing best practice and legal requirements. We hope you find them useful.

The format of the newsletter will facilitate its retention for future reference, possibly along with the Code of Ethics and Practice.

Constructive feedback relating to the form, content and possible subjects for future newsletters is welcomed.

Dr Michael Mawhinney
Head of Inspection and Investigation

CURRENT ISSUES

Registration of Premises

Pharmacists are reminded that any change of ownership or relocation of premises (including temporary relocations) must be notified to the Pharmaceutical Society prior to that change taking place.

All new or relocated premises (including temporary relocations) must be inspected and approved by an inspector before registration. The relevant Health Board must also approve the relocation of a contract, and all new contracts, before opening.

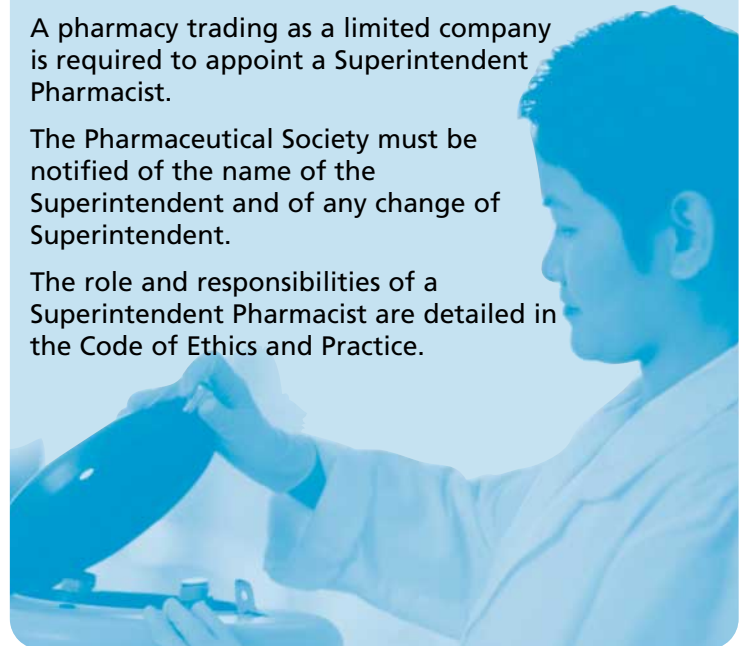
Failure to have premises inspected and registered prior to the commencement of trading will result in trading taking place from unregistered premises, which is an offence under the Medicines Act and as such is liable to prosecution.

SUPERINTENDENT PHARMACISTS

A pharmacy trading as a limited company is required to appoint a Superintendent Pharmacist.

The Pharmaceutical Society must be notified of the name of the Superintendent and of any change of Superintendent.

The role and responsibilities of a Superintendent Pharmacist are detailed in the Code of Ethics and Practice.



CONTROLLED DRUGS PRESCRIPTIONS

The Department has circulated a letter to all registered pharmacists outlining recent and anticipated changes to Misuse of Drugs Regulations.

The amendments already implemented on 16th January 2006 covered a number of areas:

- Handwriting requirements
- Electronic record keeping
- Preservation of records
- Extended formulary nurse prescribing
- Supply of ascorbic acid to addicts
- Cocaine preparations

These amendments were detailed to pharmacists in early January in circular CPh1/06 from the Chief Pharmaceutical Officer.

NB: No system for electronic CD registers has yet been approved.

It should be noted that, in respect to prescriptions, only the handwriting requirements have been changed and the other requirements such as words and figures remain.

It should also be noted that it is a requirement to enter the date of dispensing on a prescription for schedule 2 and 3 controlled drugs at the time of dispensing.



The statutory rule implementing these amendments is - *The Misuse of Drugs and the Misuse of Drugs (Notification of and Supply to Addicts) (Amendment) Regulations (Northern Ireland) 2005 - SR 2005 No.564* - and may be accessed at: www.northernireland-legislation.hmsa.gov.uk

It should be borne in mind that Northern Ireland has its own MDR and, whilst these mirror those in Great Britain, implementation dates of amendments to the Regulations may not be concurrent. If you require further advice please contact one of the Inspectors.

Standard Operating Procedures

The Pharmaceutical Society has required pharmacists to have SOPs in relation to the dispensing process since January 2005. There will be a requirement for all those who store, administer or supply CDs to have SOPs in relation to CDs when further changes to the MDR are introduced in summer 2006. Guidance for drawing up SOPs in respect of CDs may be obtained from the NPA.

Compliance Aids

The Pharmaceutical Journal of 21st January contained an article "How stable are medicines moved from original packs into compliance aids?" This article includes a table of the stability of drugs in compliance aids, based on information supplied by manufacturers. The article may be obtained from: www.pjonline.com

All pharmacists filling compliance aids, both for individual patients or as part of an MDS system, should be aware of this information and take it into account when filling such aids.

Nostrums

The RPSGB reminded pharmacists in a Law and Ethics Bulletin in the PJ of 27/08/05 that products containing CDs are Prescription Only Medicines unless a Marketing Authorisation has been granted classifying the product as Pharmacy Only or GSL.

The Bulletin gave the example of a nostrum containing Pholcodine being classified as a Prescription Only Medicine.

This would also apply to, for example, a strip of Co-Codamol Effervescent, which does not have a Marketing Authorisation, however labelled, and would therefore be a Prescription Only Medicine. (As well as the issues relating to Marketing Authorisations and PILs, the repackaging of any medicinal product for OTC sale requires the pharmacist to meet their obligations under the labelling requirements, which in practice may be difficult. The matter of product liability must also be seriously considered).

The supply of a Prescription Only Medicine other than against a prescription from a prescriber is an offence.

NEWS POINTS

Ephedrine and Pseudoephedrine

There is a growing illicit demand for Methamphetamine or "crystal meth". The increased popularity of crystal meth as a drug of abuse has encouraged the establishment of illegal manufacturing plants. The precursors for manufacture are simple substances such as Ephedrine and Pseudoephedrine. Pharmacists should closely monitor the supply of preparations containing these substances. Any unusual patterns should be reported to the Department.

Cyclizine

We have received a report from Merseyside where Cyclizine is being sold on the street to Heroin users. The tablets are crushed and added to Methadone for injecting. The abuse potential of Cyclizine is well known and pharmacists should exercise caution when responding to requests to purchase Cyclizine.

Tramadol

We have received a number of reports concerning individuals attempting to obtain Tramadol by deception. A pharmacy will receive a telephoned request purporting to be from a GP surgery, usually for an antibiotic and Tramadol. A short time later a person (usually female) will arrive to collect the medicines. Pharmacists should have robust protocols in place for dealing with such requests.



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