

# PHARMACY INSPECTORS' Newsletter

Issue 3 November 2007



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**

MANNYSTRIE O

**Poustie, Resydënter Heisin  
an Fowk Siccar**

Welcome to the third publication of the Inspectors' Newsletter. In this issue our Inspectors cover a number of pertinent areas of legal interest including reminders of the latest changes to Misuse of Drugs legislation resulting from the Shipman programme. I have also added a note about poisons... an area of pharmaceutical expertise not often called upon - but an integral part of our profession. We trust that you continue to find these newsletters useful and, as ever, we would welcome any suggestions for articles in future issues. Dr M Mawhinney

## Pharmaceutical Society of Northern Ireland



The Registrar reminds you that premises registration is due on 1st January 2008. The relevant documentation must be completed for all

registered premises and forwarded to the Registrar as directed.

The Medicines Act requires that the Registrar receives two months notice prior to the registration of new or temporary premises. Further information may be obtained from the Society and you are reminded of the information contained in our first two newsletters.

The registration of pharmacists may be checked at [www.psn.org.uk](http://www.psn.org.uk). Pharmacists **must** be registered in Northern Ireland to practice in Northern Ireland.

## Prescribing of Schedule 2, 3 & 4 Controlled Drugs

In July, the Department issued a strong recommendation that, as good practice, the quantity of Schedule 2, 3 and 4 CDs prescribed should not exceed 30 days supply. If more than 30 days supply is prescribed the prescriber should record the reasons for this in the patient's notes and be prepared to justify his/her decision.

Whilst it remains legal to dispense a prescription for more than 30 days supply, pharmacists should ensure that there is a genuine clinical need and that such prescribing does not pose an unacceptable risk to patient safety.

## Amendments to the Misuse of Drugs Regulations (MDR)

All pharmacists have been notified of a number of changes to the MDR which will come into operation over the next few months. For details of these changes you are referred to the letter from Dr Mawhinney dated 17th August 2007.

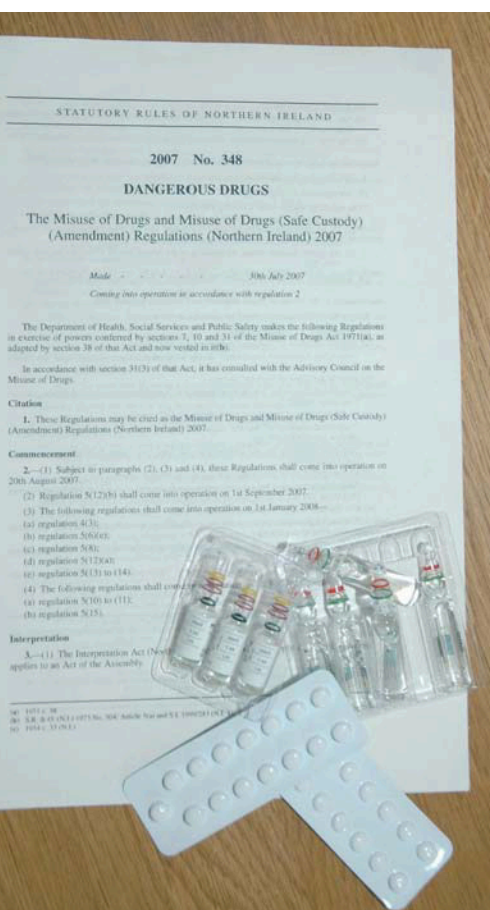
In summary the changes are:

### 20th August 2007

- Nursing homes became subject to the Safe Custody Regulations.
- The term "Senior Registered Nurse" replaced the term "Sister or Acting Sister" within the Regulations.
- Operating Department Practitioners (ODPs) are permitted to supply Controlled Drugs (CDs) for administration within the hospital in which they are working, in accordance with the directions of a prescriber.

### 1st January 2008

- Requisitions for Schedule 2 & 3 CDs must be marked with the name and address of the supplier (a pharmacy stamp may be used). Within Northern Ireland this already occurs with HS215 forms which are submitted to the CSA for payment. Dental requisitions should be similarly marked, the supply recorded in the prescription book and the requisition retained at the pharmacy.
- Midazolam will move from schedule 4 to schedule 3 of the Regulations.



### 1st February 2008

- The requirements for Controlled Drugs Registers (CDRs) will change as detailed in Dr Mawhinney's letter of 17th August. **None of the current CDRs in use meet these new requirements**, however, we understand that the NPA and others are currently revising the format of their CDRs to take account of these changes.

## Prescribers self-prescribing or prescribing for someone close to them

In July the Department issued a letter reminding prescribers of professional guidance in relation to self-prescribing or prescribing for someone who has a close personal relationship with the prescriber. In essence such prescribing should only occur in exceptional circumstances where no other prescriber is available and where a delay in prescribing would put the patient's life or health at risk or cause the patient unacceptable pain. The prescriber must be prepared to justify his/her actions. For further information you are referred to the letter sent to all community pharmacists and Health Boards (dated July 2007).

## Security and Safe Custody

There have been a number of robberies of pharmacies in the past few months. The main drugs targeted have been diazepam and dihydrocodeine. We would advise that excess stock of these items be stored in the CD safe, as recent experience has demonstrated that this can greatly reduce the quantity of drugs stolen.

With this in mind, it should be remembered that **all** items subject to the Safe Custody Regulations must be stored in the CD safe, which should remain locked and time-delayed when access is not required, and that the key to the safe should be in the possession of the pharmacist.

Pharmacists should periodically review the security of their premises. This may be carried out in conjunction with local crime prevention officers.

## Substitution Therapy

Those pharmacists providing substitution therapy for addicts are reminded of the need to have appropriate Standard Operating Procedures (SOPs) in place for the service. SOPs should address all aspects of the service including:-

- how to establish the identity of the client;
- whether the client is to be supervised and by whom; and
- what action is to be taken in the event of missed doses.

Before taking control of a pharmacy, locums should establish, amongst other things:-

- if substitution therapy is provided;
- which clients are to be supplied during their period of control;
- which clients are to be supervised during this period; and
- how the identity of the client may be established.

NICPPET has a distance learning pack available, "Pharmaceutical Care in Substance Misuse", and a two day accredited training programme (for information contact NICPPET). [www.nicppet.org](http://www.nicppet.org)

## Patient Information Leaflets (PILs)

The Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 require that all medicines with marketing authorisations in the UK have an approved leaflet, which will be included in the packaging before the medicines are sold or supplied. The only exceptions are where packing includes all the information that would otherwise be in the leaflet.

When dispensing, supplying or selling medicines to patients, you must at the same time supply the approved PIL for that medicine unless all the required information is included on the immediate or outer packaging.

The leaflet must be supplied even if the medicine is to be used for an off-licence indication.

You must supply the relevant PIL even if you dispense, sell or supply the medicine outside its original packaging. This may require you to obtain a duplicate copy of the relevant leaflet from the marketing authorisation holder or your immediate supplier. Failing that, you may choose to photocopy the relevant leaflet (bearing in mind that it may be copyrighted) or download it from a reputable source such as the Electronic Medicines Compendium at [www.medicines.org.uk](http://www.medicines.org.uk), the company website or from a disc which may be supplied by the company.

Care must always be taken to supply the most up-to-date PIL for the product concerned.

For further information see Fact Sheet 3 from the RPSGB ([www.rpsbg.org.uk](http://www.rpsbg.org.uk))

## News Points

### Sale of chemicals

Pharmacists may on occasions receive requests for the purchase of chemicals. If a pharmacist supplies any chemical all relevant regulations, including Poisons Regulations, CHIP Regulations and COSHH Regulations (see Ethics and Practice Guide), must be complied with.

It may be legal to sell a chemical, but the sale may be inappropriate (e.g. volatile chemicals such as acetone or carbon tetrachloride). Pharmacists should be aware of, and satisfied with, the end use of the chemical before completing a sale.

### Sale of Part 1 Poisons

Within legislation aimed at controlling the sale of non-medicinal poisons, pharmacists find themselves in a very unique position being one of the main sources of supply for the most potent substances – those designated as 'Part 1 Poisons'. We do not need to be reminded of the potential toxicity of this group of preparations and pharmacists should be aware that sales **must only** be made in accordance with the stringent parameters laid down in the Poisons Order and attendant Regulations. In accepting our position within statute, we must be prepared to make supplies but only where we are sure that the supply is lawful and appropriate. Pharmacists are encouraged to seek guidance from the Codes of Ethics published by both Societies and to contact the Department if further direction is needed.

### Lactose tablets

We have received information that homeopathic, or other lactose containing tablets, are being used to "cut" illegal substances. If you have any concerns regarding the purchase or attempted purchase of such tablets please inform the relevant authorities.

## CONTACTS



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agus Sábháilteachta Poiblí

MINISTRE D

Poistie, Resydènt Heisin  
an Fowk Siccar