

PHARMACY INSPECTORS'

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Newsletter



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

www.dhsspsni.gov.uk

AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydënter Heisin
an Fowk Siccar**

Welcome to the 5th issue of the Inspectors' Newsletter. It is published at a time of much activity in legislative matters with Responsible Pharmacist and Accountable Officer legislation coming into force on 1 October. It is pleasing to note that pharmacists in Northern Ireland, despite an ever increasing workload, have moved to fully implement the new requirements and I hope that the advice given in this Newsletter offers some further helpful guidance and links.

Dr M Mawhinney

Responsible Pharmacist

The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 came into effect on the 1st October 2009. The Regulations have been the subject of a number of training events across Northern Ireland, and have been widely publicised in the professional press. The Pharmaceutical Society of Northern Ireland (The Society) has published "Standards and Guidance on The Responsible Pharmacist Regulations" and this is available from The Society's website (www.psni.org.uk). The Society has also published, in conjunction with the RPSGB, "Guidance to Hospital Pharmacists on The Responsible Pharmacist Regulations". Again, this is available on The Society's website.

During inspection visits, the inspectors will ensure that the Responsible Pharmacist notice is displayed and correctly identifies the Responsible Pharmacist, and that the Responsible Pharmacist Record is fully and accurately maintained. SOPs will be examined to ensure they reflect the requirements of The Regulations, and you are referred to The Society's Standards document for guidance.

Entries in the Responsible Pharmacist Record are required to be contemporaneous. It therefore follows that the Responsible Pharmacist must either be present to make the required entry or, if an electronic log is maintained, the pharmacist must have secure remote access to allow the entry to be made. An electronic Record must be secure, must not be capable of being altered and must accurately record the date and time entries are made. The Record, whether paper or electronic, must be available for inspection.

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 No. 225 came into effect on 1 October 2009.

The three key elements of this legislation are:

- Accountable Officers and their duties
- Powers of entry and periodic inspections
- Co-operation between health bodies and other organisations

You can find out more about this legislation and how it affects you as a pharmacist in the PSNI Update - August 2009 Edition 5 and on our website <http://www.dhsspsni.gov.uk/index/pas/pas-practiceandadvice.htm>

The Department, as required by the legislation, has directed the establishment of a Local Intelligence Network (LIN) in Northern Ireland similar to those already operating in England, Scotland and Wales to support the co-operation between health bodies and other organisations.

The purpose of the LIN is to share information/concerns and intelligence surrounding the management and use of controlled drugs relating to 'relevant persons' as defined in the Health Act 2006. A relevant person could be a health professional, or an employee who is not a health professional, of any of the following organisations or one who provides services under arrangements made with the organisation and who is

engaged in any activity related to controlled drugs:

- HSC Board
- A HSC Trust
- Northern Ireland Ambulance Service
- An Independent Hospital

These concerns may also be shared with other responsible bodies including professional regulatory bodies, the police, Counter Fraud Unit and the Regulation and Quality Improvement Authority.

The first meeting of the network was held on 1 December 2009. In addition to sharing information and intelligence, the network will actively work towards strengthening systems and building on good practice by reviewing the learning points raised through investigation of these concerns.

You can find out more about the role of the Accountable Officer by visiting our website: <http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm>

This is updated regularly and contains, amongst other matters, practice guidance, training slides and useful links. FAQs will be added early in 2010

If you have any concerns about controlled drugs these should be addressed either to the Department Inspectors or to the Accountable Officer of the relevant Designated Body.

<http://www.dhsspsni.gov.uk/accountable-officer-contact-list.pdf>



Veterinary Medicines

There are four categories of veterinary medicines. Pharmacists may prescribe POM-VPS (Prescription Only Medicine - Veterinarian, Pharmacist, Suitably Qualified Person) and NFA-VPS (Non-Food Animal - Veterinarian, Pharmacist, Suitably Qualified Person). Some ranges of veterinary medicines include POM-VPS and NFA-VPS medicines as well as general sales list veterinary medicines. POM-VPS and NFA-VPS medicines must not be on open selection to the public. Guidance for pharmacists on the Veterinary Medicines Regulations is available on the RPSGB website (www.rpsgb.org.uk) and from the Veterinary Medicines Directorate (www.vmd.gov.uk).

Codeine Controls

New warnings and controls on the sales of OTC medicines containing codeine or dihydrocodeine have been introduced. This guidance is available from the MHRA website (<http://www.mhra.gov.uk/index.htm>) and features in their Drug Safety Update for September. The Society has also issued guidelines on this matter and this may be obtained from their website and within the PSNI Update for October 2009. The guidelines clearly indicate that packs containing more

than 32 tablets (including effervescent tablets) are for dispensing use only. (<http://www.psn.org.uk/documents/376/PSNI+Advice+on+Codeine.pdf>)

Doctors Licence

From the 16th November 2009, all doctors wishing to practice in the UK must be both registered with and licensed by the GMC. The registration and licence status of a doctor may be checked at the GMC website. (<http://www.gmc-uk.org/doctors/index.asp>)

The Society has issued guidance on this matter which is available at: (<http://www.psn.org.uk/documents/440/Guidance+on+Doctors%27+Licence+to+Practise+changes.pdf>)

Prescriptions from the EEA and Switzerland

Since October 2008 doctors and dentists registered in EEA countries and Switzerland have been recognised as prescribers under the Medicines Act. The Society has produced guidance which is available at (<http://www.psn.org.uk/documents/430/Dispensing+European+Economic+Area+prescriptions+2009-05.pdf>).

It should be remembered that only UK or EU licensed medicines may be supplied against European prescriptions. If the prescription calls for a branded generic product which is not available in the UK, as is common with Rol prescriptions, then the prescription cannot be filled. Substitution with an alternative generic product is not permitted.

A prescription for S2 and S3 controlled drugs must be written by a prescriber who is both registered and licensed in the UK, and has an address in the UK. Prescriptions for S4 and S5 controlled drugs require the prescriber to be registered and licensed in the UK.

However, we are anticipating changes in legislation relating to the dispensing of these prescriptions within the United Kingdom. Any updates on this matter will be posted on the PAS website (detailed below) and we would further anticipate that such changes will be highlighted in the Professional Press.

Pharmacy Advice and Services (PAS) Webpage

The PAS webpage is contained within the DHSSPSNI website and may be viewed at (<http://www.dhsspsni.gov.uk/index/pas.htm>). The page contains a great deal of useful information and links. Advice letters issued by the PAS Branch are located within the page and Inspectors' Newsletters are also available. If guidance is required to be issued urgently it will be published on this page (e.g. special guidance in relation to pandemic 'flu).

In particular your attention is drawn to Dr Mawhinney's advice letter in relation to "loans" of prescription only medicines. (http://www.dhsspsni.gov.uk/letter_from_mike_mawhinney_to_pharmacists_emergency_supply_poms_loans_.pdf).

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