Regulation bulletin

Practise issues

a) Extemporaneous supply of methadone

The supply of unlicensed extemporaneously prepared methadone, as an alternative to an available licensed version, is not compatible with the law. Pharmacies should observe the standards issued by the Pharmaceutical Society NI on the Sale and Supply of Medicines detail:

3.7 A product with a marketing authorisation is supplied where such a product exists in a suitable formulation and is available, in preference to an unlicensed product or food supplement;

4.1 A product is extemporaneously prepared only when there is no product with a marketing authorisation available and where he is able to prepare the product in compliance with accepted standards.

As there is licensed methadone available for pharmacies to supply to patients, there is no valid reason why any extemporaneous supply should be manufactured and dispensed by pharmacists. Any pharmacy currently producing extemporaneous methadone should cease this activity and revert to licensed product supply. Please liaise with the DHSSPS MRG inspectors or the Pharmaceutical Society NI when initiating this change. Patients should not be put at risk by making sudden changes or causing shortages in their supply.

b) Time release safes

All medicines defined in the Misuse of Drugs Regulations (Northern Ireland) 2002 as items which are to be held in safe custody i.e. Schedules 2 & 3 must be stored in an authorised cabinet defined in the Misuse of Drugs (Safe Custody) Regulations 1973. Due to the high number of robberies and assaults in pharmacies in 2001 the DHSSPS grant aided the introduction of time release safes as controlled drug cabinets into registered pharmacy premises. It is apparent that some pharmacies are still using older cabinets which are not time release compliant, to store CDs. In order to secure safe custody of relevant drugs all pharmacies must only use time release safes for the storage of medications which are controlled drugs subject to safe custody requirements.

c) Pseudoephedrine sales

The use of *Pseudoephedrine* as a precursor to crystal meths is well established in published media reports. The Pharmaceutical Society NI works in collaboration with the MHRA to review and monitor annually the sales of pseudoephedrine in NI. There have been recent incidents in the Republic of Ireland (ROI) where individuals or groups, were bulk purchasing pseudoephedrine containing products from community pharmacies in order to produce crystal meths. A nationwide alert was then raised by the pharmacy and medicines regulatory bodies in the ROI. Pharmacists in NI should remain vigilant of pseudoephedrine sales and report any unusual trends or bulk sales to the DHSSPS.

d) Emergency supplies are not loans

There have been a number of recent reports to the Pharmaceutical Society NI with regard the alleged loaning medicines to patients by some pharmacies in NI. The law is clear and unambiguous in that, there is no provision for the loan of any prescription

medicines. In an emergency, a pharmacist should operate within the emergency supply provisions. A communication was issued by the DHSSPS as recently as October 2012 on this matter and this was circulated to all pharmacists. Pharmacists should work with physicians and patients to ensure better medicines management and any request for loans should be actively discouraged by all pharmacies. The relevant communication is on the DHSSPS website.[1]

e) Patient record systems

Recent fitness to practise case histories would indicate that there is a still a trend for pharmacist practitioners to repeat dispense 'off patient records', rather than issuing labels from relevant legal prescriptions. All pharmacies should have SOPs for dispensing services, including labelling and accuracy checking. Practitioners must strictly follow these procedures.

f) Monitored dosage systems

Where patients receive drugs in monitored dosage systems, the medications must be clearly and individually labelled on the occasion of each dispensing. Multiple dispensing should be recorded on the PMR to reflect the chronology of patients supplies. Patient medication leaflets must also be issued as appropriate.

g) Loss of wholesaler exemption for registered pharmacies

The Human Medicines Regulations 2012 have removed the exemption which was previously detailed in Section 10 of the Medicine Act 1968 that allowed a registered pharmacy to conduct wholesale transactions as long as they do not amount to a significant part of the business i.e. the minimis rule <5%. This exemption has been removed on 14th August 2012 therefore to supply by wholesale, a pharmacy must now register with the MHRA for a wholesale dealers licence. MHRA has detailed the circumstances which are interpreted as being a professional supply and therefore do not require a wholesale dealer's licence - see MHRA website - www.mhra.gov.uk

h) Maintaining and checking registration status of pharmacists

The Pharmaceutical Society NI has a legal statutory responsibility for the register of pharmaceutical chemists in NI. There have been a number of incidences where a person has secured employment as a pharmacist whilst not being registered. Employers should not assume that because a person was registered previously or is registered elsewhere that they are currently registered to practise in NI. There is a professional responsibility on all registrants to check they are registered appropriately and on employers to check a person's registration status before employment. Failure to validate that a person is registered before offering employment will be viewed as professional negligence.

i) Maintaining and operating pharmacy websites

Every pharmacist who operates a pharmacy website is legally and professionally responsible for the content of that website. This must comply with all legislative and professional requirements. Recently, there have been a number of incidents reported where prescription only medicines [POM] have been advertised as being available to patients if they present with a legally valid private prescription in the pharmacy. This is considered to be a breach of the Human Medicines Regulations 2012 and has been addressed by the DHSSPS MRG inspectors accordingly. Therefore, if you operate a pharmacy website it is necessary to have robust audit procedures in place and regularly review the website content to ensure its compliance with all legislative and professional requirements.

[1] http://www.dhsspsni.gov.uk/letter_-__pharmacists__emergency_____supplies_of_prescription_only_medicines.pdf

Significant legislation updated in 2012

1. The Human Medicines Regulations 2012
   The Regulations consolidate the laws of the United Kingdom concerning medicinal products for human use ("products") in relation to pharmacists.

   The Regulations also introduce the following small policy changes in relation to pharmacy to help ensure that medicines legislation is fit for purpose:

   a. Removal of statutory warnings for over the counter products, other than paracetamol; more information is available here - Labels, patient information leaflets and packaging for medicines
   b. Updating the process by which independent hospitals, clinics and agencies are able to continue using patient group directions (PGDs) to ensure processes reflect changes to the registration requirements for organisations
   c. The Regulations consolidate provisions enabling a pharmacist, if in the exercise of their professional skill and judgement they believe it is appropriate to do so, to make changes to a prescription relating to the name of the product or its common name; directions for use of the product; and precautions relating to the use of the product - the Regulations remove the requirement for the pharmacist to attempt to contact the prescriber before making such change; This aims to enable pharmacists to use their expertise and professional judgement to make such changes in a more timely way
   d. Repeal section 10(7) of the Medicines Act 1968. Section 10(7) allows pharmacists to wholesale deal medicines without a wholesale dealer's licence, where that dealing constitutes no more than an inconsiderable part of that business; more information on this is available here - Supply of medicines by pharmacy to healthcare professionals

2. The Council of The Pharmaceutical society (Continuing Professional Development) Regulations (Northern Ireland) 2012
   The Regulations were made by the Council of the Pharmaceutical Society NI ("the Council") under the Pharmacy (Northern Ireland) Order 1976 ("the Order"). The Regulations set out matters relating to non-compliance by registered persons with the requirements or conditions of the continuing professional development framework adopted by the Council under Article 4A(6)(a) of the Order. The framework relates to standards of proficiency for the safe and effective practice of pharmacy. This framework is currently out for public consultation see www.psni.org.uk/

3. The Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012
   These Regulations of the Council of the Pharmaceutical Society NI ("the organisation") set out various matters relating to the procedures to be followed by the organisation when considering; allegations that the fitness to practise of its registered persons is impaired, allegations that a person should be disqualified from inclusion in the register of pharmacy retail business premises kept by the organisation and allegations of criminal conduct that the organisation is under a duty to investigate.

4. The Council of the Pharmaceutical Society of Northern Ireland (Statutory Committee, Scrutiny Committee and Advisers) Regulations (Northern Ireland) 2012
   These Regulations set out various matters relating to the Statutory Committee and Scrutiny Committee of the Council and to the functions of advisers to the Statutory Committee and Scrutiny Committee.

5. The Council of the Pharmaceutical Society of (Northern Ireland) Appointments and Procedures Regulations (Northern Ireland) 2012
   The regulations make provision with regard the constitution of the Council of the Pharmaceutical Society NI ("the Council").

6. The Misuse of Drugs (Amendment No 2) Regulations (Northern Ireland) 2012
   The Regulations add, in regulation 3, desoxypipradrol and other pipradrol-related compounds to Schedule 1 to the Misuse of Drugs Regulations (Northern Ireland) 2002 (the "2002 Regulations").Regulation 4 adds 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one (commonly known as phenazepam), and regulation 5 adds any ester or ether of pipradrol, or any stereoisomeric form or salt or preparation or other product of such an ester or ether, to Schedule 3 to the 2002 Regulations.

7. The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2012
   The Regulations amend the Misuse of Drugs Regulations (Northern Ireland) 2002 (the "2002 Regulations") to allow a nurse independent prescriber and a pharmacist independent prescriber (defined in regulation 2(1) of the 2002 Regulations, as amended by regulation 4(b)) to prescribe, possess, supply, offer to supply, administer and give directions for the administration of any controlled drug specified in Schedules 2 to 5 of the 2002 Regulations, but not in relation to cocaine, diamorphine or dipipanone as regards persons addicted to these drugs otherwise than for the purpose of treating organic disease or injury suffered by such persons. The amendments also allow a nurse independent prescriber and a pharmacist independent prescriber to supply certain articles for administering or preparing controlled drugs.

Brendan Kerr
Registrar
22 November 2012