Dear Colleague

Welcome to the 10th issue of the Inspectors’ Newsletter. There are a range of key regulatory matters covered in this issue, a number of which reflect matters raised by or with the Inspectors during the inspection process. I would, in particular, draw your attention to the article on SOPs which highlights the requirement to establish, maintain and review your pharmacy procedures. These are an essential tool in ensuring that your pharmacy is adhering to legislative and best practice requirements.

Prof Mike Mawhinney – Head of MRG

Legislation update

Misuse of Drugs Regulations (Northern Ireland) 2002 - Amendments during 2014/early 2015

Since the last Inspectors’ Newsletter, there have been five sets of amending regulations up to February 2015. (SRs 2014/21, 2014/158, 2014/261, 2014/288, 2015/53.) Many of the amendments were in regard to adding new substances liable to misuse to Schedule 1 of the regulations. In addition, lisdexamphetamine was added to Schedule 2, tramadol to Schedule 3, zaleplon and zopiclone to Schedule 4-1. 4-Hydroxy-n-butyric acid (‘GHB’) was moved from Schedule 4-1 to Schedule 2. (Tramadol was added to the list of exempted drugs in Schedule 1 to Safe Custody Regulations i.e. storage in the CD safe is not required by law.) An amendment allows for the provision of aluminium foil by persons employed or engaged in the lawful provision of drug treatment services. Such provision is permitted as part of structured steps to bring individuals into treatment or as part of such treatment.

Human Medicines Regulations 2012 – Amendments during 2014

There were two sets of amending regulations during 2014. Firstly, SI 2014/490 addressed certain corrections and omissions from the time of consolidation of the Medicines legislation. Further to that, EU Directives in relation to cross border healthcare were implemented. The definition of “EEA health professional” was substituted with a new one, and a definition of “product subject to special medical prescription” was inserted in the Medicines Regulations (any substance or product specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations 2001/2002, GB and NI respectively). The expression “Products subject to special medical prescription” then replaced certain references to “controlled drugs” in the Medicines Regulations; this achieved compatibility with European prescribing terminology. Such products are not dispensed in the UK under a prescription issued by an EEA member State. A new provision was inserted that requires prescriptions issued in the UK for dispensing in another EEA State to contain certain details. Existing provisions for incoming EEA prescriptions were amended, specifying details to be included that now accord with the new European requirements.

SI 2014/1878 made some provisions in relation to parallel import licences, advertising and the wording of package leaflets in regard to adverse event reporting. Furthermore, amendment was made to clarify that rules about prescriptions issued by healthcare professionals in EEA States also apply to prescriptions issued in Switzerland. Provision was made for schools to obtain inhalers containing salbutamol, subject to the presentation of an order signed by the principal, and make supply in an emergency, by persons trained to administer the relevant medicine, to pupils who are known to suffer from asthma and require such medication.

Many of the amendments have an impact on the practice of pharmacy and the detail of the changes described above may be reviewed on the legislation website www.legislation.gov.uk which can be searched using the SI or SR number. Further assistance may be available from professional bodies and trade associations.
SOPs – reviewed, signed, dated, version controlled?

The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008, established that the Responsible Pharmacist has a statutory duty to establish, maintain and review Pharmacy Procedures. The procedures covered are specified within the regulations and are generally referred to as the Responsible Pharmacist SOPs. The procedures should reflect the actual practice within the pharmacy. Templates are useful in drafting the SOPs, but these should be suitably amended or tailored to reflect the practices within the pharmacy. The SOPs must be signed and dated by the Responsible Pharmacist and all appropriate members of staff, including all pharmacists, locums, pre-registration pharmacists, dispensers, technicians and counter staff.

All SOPs should be reviewed every two years as a minimum, or when legislation or guidance changes or at any time when an incident, which may potentially have led to a compromise of patient safety, occurs. Any amendments should be noted and the SOPs signed by the reviewer and all appropriate members of staff as detailed previously. Separate versions of the old and new SOPs should be referenced and retained. The Society’s guidance states that:

“There is a system of document control to make clear:
• What Pharmacy Procedures are currently in place;
• What Pharmacy Procedures have previously been in place during any given period of time;
• The Responsible Pharmacist who amended or revised the Pharmacy Procedures and the date of which the amendment or revision was made and the date it is valid until.”

The Society’s guidance in relation to the Responsible Pharmacist Regulations may be found at: http://www.psni.org.uk/documents/352/Standards+on+the+Responsible+Pharm_.pdf

Guidance in relation to the controlled drugs SOPs may be found at: http://www.dhsspsni.gov.uk/guide-sops-td-dgs-ni.pdf
From the Registrar- Single labels on multiple packs, managing risks

There has been an increasing incidence of pharmacies placing a single label on multiple dispensing packs which may or may not be sealed together. There have been adverse incidents reported and also some near misses in relation to this practice. Good professional practice would require that each and every product should be supplied with its own discrete dispensing label to aid patients and carers in ensuring the safe and correct usage of the product.

Possible exceptions to this may be the supply of dietetic products or surgical products where outer packaging could be labelled once. There is risk that where multiple packs are bound together and one label applied, if these become separated then the patient or carer might not be aware of how the medicine should be used.

NHS National Patient Safety Agency guidance reads ‘Medicines supplied in multiple packs may result in patients not realising that each pack contains the same medicine. Multiple packs can become separated if taped or boxed together, potentially resulting in unlabelled containers. Always label each container when a medicine is supplied in multiple packs. Include information to indicate that each container is one of a number holding the same medicine.’

Good practice therefore is to label each product and if this is not the case then to justify the reason not to do so. If the patient falls to any harm through the receipt of unlabelled medicinal products then the pharmacist will be asked to justify the apparent deviation from safe practice. Professional standards are issued to supplement statutory regulations and patient safety and welfare should always be the pharmacist’s primary consideration, not saving on labels.

Rebalancing Project

On 12 February 2015 a joint consultation was launched with the other Departments of Health on the first phase which includes important proposals that will be of interest to pharmacy professionals, patients and members of the public alike. The Department welcomes responses to this important piece of work and the consultation details can be found at https://www.gov.uk/government/consultations/pharmacy-legislation-on-dispensing-errors-and-standards

The proposals include changes relating to dispensing errors and registered pharmacy standards. It is anticipated the dispensing error changes will address the fear of criminal prosecution of pharmacists who make inadvertent dispensing errors. By removing this fear, pharmacists will be encouraged to report errors which will lead to a greater understanding and learning from errors.

In relation to registered pharmacy standards, the Section 60 Order makes provision for the Pharmaceutical Society of Northern Ireland to set standards for the safe and effective practice at registered pharmacies. These changes are crucial to promoting high-quality patient care, improving safety and developing pharmacy practice.

Two information events were held in Belfast on 23 March 2015 prior to the consultation closing on 14 May 2015. The afternoon session explored the proposals and sought views from patients/public with the evening session aimed at pharmacy professionals.

Further information on the events will be published on http://www.dhsspsni.gov.uk/index/pas/pas-lie/pas-rebalancing-project.htm in the near future.
Pharmacists are reminded of their responsibilities when processing private requisitions and prescriptions for Schedule 2 and 3 controlled drugs (CDs). **Private prescriptions for named patients for CDs** For the purposes of private prescribing for **named patients**, Schedule 2 or 3 CDs can only be written on PCD1 forms which are available to practitioners from BSO (for further information, please see http://www.medicinesgovernance.hscni.net/primary-care/controlled-drugs/private-cds/) Pharmacists are not permitted to supply Schedule 2 or 3 CDs which have been prescribed privately for named patients on any form other than a PCD1. Pharmacists are required to submit PCD1 forms to BSO using the modified HS30 form as part of the normal prescription submission process.

It should be noted that in an emergency situation, when treatment is considered to be both immediately necessary and clinically appropriate for a patient who is not otherwise eligible to receive Health Service prescriptions, it is acceptable to prescribe the required Schedule 2 or 3 CDs under NHS arrangements on an NHS prescription form. A private prescription is not necessary in these circumstances.

The Regulations, as far as possible, replicated measures for the supervision of management and use of controlled drugs which came into force in England, Scotland and Wales and have not been subject to amendment until now. England and Scotland reviewed their equivalent Regulations in 2013 and a range of additional governance arrangements were introduced. These additional governance arrangements have been considered in the context of Northern Ireland healthcare services and a number of amendments have been proposed. The consultation on these proposed amendments runs for 14 weeks and responses must be received no later than 5pm on 1 May 2015. The consultation can be found at: http://www.dhsspsni.gov.uk/consultation_on_the_proposed_amendments_to_the_controlled_drugs_supervision_of_management_and_use_regulations_northern_ireland_2009.pdf

In response to recommendations arising from the Shipman Inquiry the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (“the Regulations”) came into operation on 1 October 2009. The Regulations were designed to improve controlled drug governance without hindering patients from accessing the treatment they needed.
Private stock requisitions for CDs

Private stock requisitions for Schedule 2 and 3 CDs should be written on the prescriber’s headed notepaper (PCD1 forms should NOT be used) and must be marked indelibly with the supplier’s name and address. The original should be submitted to BSO (a photocopy should be kept in the pharmacy) as part of the normal prescription submission process. Pharmacists should be aware that there are proposals to amend Misuse of Drugs legislation which may make it a statutory requirement that requisitions are written on a standardised form.

The required records for supply against both PCD1 forms and private requisitions must be made in the CD register and Prescription Only Register

Management of GP returned Schedule 2 controlled drugs

Instances where CDs have been unlawfully destroyed by pharmacists have been identified. Pharmacists are only permitted to destroy CDs which have been returned by patients. Any out of date stock or stock returned by GPs, must not be destroyed without the presence of an authorised witness. Receipt of this stock must be entered in the CD register as ‘received from Dr ……… for destruction’. The stock should then be segregated from usable stock in the CD cabinet and quarantined with other out of date stock until an authorised witness visits the pharmacy.

Fraudulent Medication Reports

The Health and Social Care Board (HSCB) has been advised by the Business Services Organisation of an increase in the number of fraudulent medication incidents which have been reported by GPs and community pharmacists to their Counter Fraud and Probity Services (CFPS) department. A total of 57 reports were made to CFPS between December 2013 and September 2014. Typically these offences involved a patient attempting some form of deception or forgery, or a combination of both, in order to obtain medication in greater quantities than originally prescribed, or to obtain medication that was not prescribed for them at all. The patient may be obtaining the medication either to consume themselves or to sell onto others. Unsurprisingly, the drugs most frequently reported were those most liable to misuse or abuse, e.g. benzodiazepines, “Z” drugs, opioid analgesics and pregabalin. There are obvious risks associated with fraudulent attempts to obtain medication, either to the perpetrator themselves as a result of taking medication that was not prescribed for them or to the health of others if the medication is obtained and then diverted elsewhere.

Indicators of potential fraudulent activity

Community pharmacists are asked to be vigilant for potential fraudulent activity. Although this can often be hard to detect, the following may provide an indication of possible fraud:

- Physical alterations of a computer generated prescription. The prescription may have been obtained in good faith or as a result of a deception in a GP practice. In most cases, the script will be altered to increase the quantity/strength, or extra medication will be added to the prescription.
- Handwritten prescriptions that are not completed correctly or that raise suspicion in some other way such as spelling errors or incorrect abbreviations.
- Suspicion about the patient details provided. Previous reports have involved patients masquerading as a member of GP Practice staff, a doctor or another patient.
- Prescriptions from practices that are not from the local area, particularly when they also contain some of the warning indicators above.

Steps to take if fraudulent activity is suspected

- Contact the prescriber and establish if the prescription or information is accurate. If unable to speak to the prescriber and you have strong suspicions about its validity, the medication should NOT be dispensed.
- If you are suspicious as to the validity of the prescription, consider taking a photocopy or scan of the script in case the person demands it back and you need to return it to avoid confrontation.
- If you are suspicious about the validity of a telephone call from a GP practice, consider calling the practice back to confirm the call. Obtain the practice telephone number from a trusted source and not the caller.
- Ensure that any CCTV that may have recorded the incident is retained and not routinely copied over. Also take steps to ensure that your CCTV is operating correctly and recording an accurate date and time on a regular basis.

Health and Social Care as an organisation has a zero tolerance approach to fraud. Community pharmacists should report any suspicious behaviour or instances of alterations of prescriptions to Counter Fraud and Probity Services (CFPS) on 08000 0963396.

All confirmed attempts to obtain medication fraudulently should also be reported to the PSNI (police) on 0845 600 8000 as they are criminal offences, regardless of whether medication was obtained or not.

Further advice can be sought directly from CFPS on the above number, or via CFPS@hscni.net. Additional information on prescription fraud and the work of CFPS is available at www.cfps.hscni.net/reportfrmr

Remember: fraud against Health and Social Care (HSC) is not a victimless crime. Money lost to fraud drains the resources available for the delivery of frontline services and patient care. Now more than ever, we need to work together to stamp fraud out.

CONTACTS

Joe Gault
joe.gault@dhhspsn.gov.uk
tel: 028 9052 0768

Tony Wallace
anthony.wallace@dhhspsn.gov.uk
tel: 028 9052 8688

Canice Ward
canice.ward@dhhspsn.gov.uk
tel: 028 9052 3703