

# PHARMACY INSPECTORS'



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

www.dhsspsni.gov.uk

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## Newsletter

Welcome to the 7th edition of the Inspectors' Newsletter. As you will read below, it is likely that 2012 will herald new Medicines Regulations, consolidated Misuse of Drugs Regulations and the amendments to the Pharmacy Order allied to the regulation of pharmacy in Northern Ireland. Recognising that these contain complex and important provisions, pharmacists can be assured that this Department along with HSCB and PSNI will continue to keep you abreast of the changes and continue to offer you support as they roll out in practice.

Prof. M Mawhinney - Head of Medicines Regulatory Group

## Near-miss/Error log

Good pharmacy procedures related to the dispensing process should, when they are followed, prevent errors reaching the patient. Mistakes do happen but when they are identified prior to supply as near-misses by good procedures, there is an opportunity to learn and, hopefully, avoid the same thing happening again. Unfortunately dispensing errors occur when mistakes remain undetected to the point where the patient or their representative takes possession of the medicine.

One way of learning from incidents, and thus improving practice, is to maintain near-miss and error logs and to regularly analyse their contents. In that light, practice may be reviewed and procedures amended if necessary. In a similar vein recently, the HSCB wrote to pharmacies and provided forms for the purpose of gathering anonymised data about near-misses and dispensing errors. Through this mechanism the learning experience of individual pharmacies can be shared and be of benefit to all pharmacies.

the idea of learning from errors and near-misses in its *Standards for the Supply of Prescribed Medicines*: "3.14 **The pharmacist must ensure that procedures are in place to minimise the risk of dispensing errors or contamination of medicines and a record of errors and 'near-miss' incidents must be made and practices reviewed in light of such incidents.**"

The Royal Pharmaceutical Society (RPS) has generously provided guidance about near-miss error logs in the public section of its website. There is an

excellent analysis tool with suggestions for categorising incidents and some downloadable material. Knowledge of the RPS material will complement the HSCB's initiative.

Community pharmacists are dedicated to operating safe dispensing processes but the potential for learning from incidents and improving practice is so important that time spent in recording and analysing errors should be professionally rewarding. Participation in the HSCB's sharing scheme should multiply the benefits.

HSCB Health and Social Care Board

AIF1(PharmacyAnon)

Had the error gone unnoticed, please indicate the level of harm you think could have occurred to the patient:

Insignificant  minor  moderate  major   
Catastrophic  unknown/unpredictable

Please indicate your perceived likelihood that this could happen again, in your or another pharmacy:

Rare  unlikely  possible  likely   
almost certain

17. Possible Cause / Contributory Factors

17a Please indicate how busy the pharmacy was at the time of the incident

Very busy  busy  average  quiet  very quiet

17b Action taken by contractor with regard to this event:

17c Action taken by contractor to prevent recurrence:

Please tick the box(es) that best describe(s) this error/near miss tick as many as are applicable:

<input type="checkbox"/> Dose or strength was wrong or unclear	<input type="checkbox"/> Verbal direction to patient was wrong or omitted
<input type="checkbox"/> Expiry date wrong, omitted or passed	<input type="checkbox"/> Wrong/transposed/omitted medicine label
<input type="checkbox"/> Formulation of medication was wrong	<input type="checkbox"/> Wrong drug/medicine
<input type="checkbox"/> Frequency for taking of medication was wrong	<input type="checkbox"/> Wrong method of preparation or supply
<input type="checkbox"/> Medication incorrectly stored	<input type="checkbox"/> Wrong quantity
<input type="checkbox"/> Mismatch between patient and medicine	<input type="checkbox"/> Contra-indication to the use of the medication
<input type="checkbox"/> Omitted medicine or ingredient	<input type="checkbox"/> Medication prescribed to which patient had a known allergy
<input type="checkbox"/> Other medication incident	<input type="checkbox"/> Omitted dose
<input type="checkbox"/> Patient information leaflet wrong or omitted	<input type="checkbox"/> Wrong route of administration of medication

HSCB Use Only: FPS Reference No \_\_\_\_\_  
Logged by \_\_\_\_\_ Date \_\_\_\_\_

\* PLEASE NOTE THAT THIS INFORMATION WILL BE TREATED ANONYMOUSLY AND WILL NOT BE USED FOR ANY PURPOSE OTHER THAN LEARNING.  
Please post completed document to:  
Medicines Governance Adviser, Integrated Care, Local HSCB Office

The  
Pharmaceutical  
Society (PSNI) has enshrined

# Risk Based Inspection System

A review into "Reducing Administrative Burdens: Effective Inspection and Enforcement" by Philip Hampton, introduced a number of principles to be followed by regulators when carrying out inspection and enforcement activities. The Department of Business Enterprise and Regulatory Reform consolidated these principles into "The Regulators' Compliance Code". Whilst the Code does not, strictly speaking, apply to Northern Ireland, it does set standards of good practice for inspection and regulation and it is appropriate that these standards are reflected in the inspectors' activities

The principle from the Hampton Review which pertains is:

**Hampton Principle: No inspection should take place without a reason.**

**Inspections can be an effective approach to achieving compliance, but are likely to be most effective when they are justified and targeted on the basis of an assessment of risk.**

In order to reflect these standards of good practice, a new risk-based inspection system for pharmacies was introduced in April of last year. The system allows:

- a computerised report to be completed at the time of the inspection;
- any agreed action points to be noted on the report;
- an evaluation of risk to be calculated;
- signatures of the inspector and pharmacist to be recorded; and
- a summary of the report to be e-mailed to a business e-mail address.

The "Risk Areas" inspected reflect:

- legal requirements;
- the Society's Standards;
- good practice; and
- areas of potential risk identified by the inspectors.

Specifically the areas covered are:

- Buildings and Facilities – *Security, Building Condition, Cleanliness and Emergency provisions.*

- Personnel – *Staff Training, Staffing Levels and Staffing Profile.*
- Record Keeping – *Prescription Book, Extemporaneous Dispensing and Fridge Temperature.*
- Controlled Drugs – *Register, Safe Custody, Diversion, SOPs, Record of Disposals, Stock Audit and Annual Self-Assessment form.*
- Responsible Pharmacist – *Display of notice and maintenance of record.*
- Incident Management – *Error Log, Near Miss Log and Intervention Log.*
- SOPs – *Relating to the RP and AO Regulations.*
- Wholesale Dealing – *When a Wholesale Dealer's Licence has been issued.*
- MDS Dispensing – *Prescription Management, SOPs for Assembly and Delivery Protocols.*
- Internet Pharmacy – *These reflect the Society's Standards for Internet Pharmacy.*
- Other Matters – *Nostrum manufacture, Poisons, Sales of Chemicals, Veterinary Medicines, Other Services (such as Oxygen), Substitution Therapy, Equipment/Reference Sources, which Pharmacist/s was/were present and if a Pre-registration Graduate is being trained.*

The inspection report will contain comments on all of the areas inspected and an acknowledgement of those areas not inspected. These comments and any action points are agreed between the inspector and pharmacist before the report is signed by both.

**Once the report has been signed and saved it cannot be altered and it will automatically be sent to the e-mail address provided when the inspector is next in the office.**

Should the agreed action points require information to be forwarded to the inspector, a facility exists which allows a record to be made of the information received or an action completed. This allows the inspection to be logged as complete. Should the inspector require no further information then the report is considered complete.

This system has now been in use for over nine months and almost 200 inspections have been completed. It

Risk Area	Not Inspected	Comments
Buildings and Facilities		
Security		Electric shutters fitted at front and rear. Monitored alarm system and CCTV installed. Rear door lubricated of metal.
Building Condition		The premises were refurbished in the past 3 years and are well maintained.
Cleanliness/Tidiness		Dispensary area is limited and must be well managed. Date checking and cleaning notes are in place.
Emergency Provisions		A fire assessment has been completed, exits are clearly marked and extinguishers serviced.
Dispensary Equipment		N/A
Reference Sources		N/A
Personnel		
Staff Training		Dispenser has completed NVQ level 3 training and counter staff have completed internet training.
Staffing Levels		1 full-time pharmacist, 1 full-time dispenser, 2.5 FTE counter staff.
Staffing Profile		See above.
Record Keeping		
Prescription Book		Prescription book generally well maintained. Discussed EEA prescriptions with pharmacist.
Extemporaneous Dispensing		Extemporaneous dispensing record maintained, last entry 07/12/11.
Fridge Temperature		Record of medicine fridge temperatures maintained, some marginal highs noted.

has been extremely well received and pharmacists have commented that it is helpful to know exactly what is being inspected, to have direct feedback on all of the areas inspected, to know what actions are required of them and to receive a detailed report of the inspection.

The style of pharmacy inspections may have changed to reflect current best practice, but the philosophy which underpins the inspectors' work has not. It remains our purpose to ensure that pharmacists are practising legally and professionally. The inspectors will continue to actively support and guide pharmacists in their efforts to improve practice.

## Medicines Legislation

The MHRA has consulted on the matter of consolidating Medicines legislation. Pharmacists will be aware that the body of legislation has grown considerably since the introduction of the Medicines Act in 1968. Presently, with the Act, there are about 200 related statutory instruments. The intention is to replace the current body of material with one set of Human Medicines Regulations, removing much obsolete law in the process. The result, anticipated in July 2012, should be shorter, simplified law that is easier to understand and apply. Although the main focus of the process is consolidation, a number of policy changes are also proposed. The MHRA website may be consulted for further information.

# Accountable Officers and controlled drugs

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (sometimes referred to as the "Accountable Officer" Regulations) came into operation on 1 October 2009. This legislation introduced the role of Accountable Officer (AO) for certain organisations which included, amongst others, the HSCB and the Trusts. The AO has overall responsibility for the safe management and use of controlled drugs (Schedules 1 to 5) within their organisation and must ensure that any person providing services to their organisation also has appropriate arrangements in place. If a pharmacist has a concern about a controlled drug matter, these concerns should be notified to the relevant AO. For hospital pharmacists this will be the Trust AO and for community pharmacists the HSCB AO. A list of AOs and their contact details can be obtained from the Department's website. <http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer/pas-contact-details.htm>.



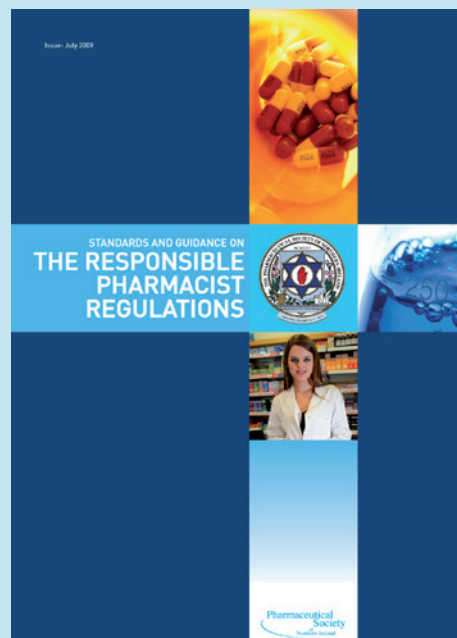
In January 2012, a declaration and self-assessment form was again sent by the Department to all community and Trust pharmacies. The completed forms are reviewed by the Inspectors during their visits. On a quarterly basis, the Inspectors send a summary of any controlled drug matters which have arisen from visits to community pharmacies to the HSCB AO for consideration.

Under the above legislation, a Local Intelligence Network (LIN) meets on a quarterly basis to discuss controlled drug concerns and to consider learning points. Those attending the LIN include all AOs, the Department, the Police, the Regulatory Bodies, (including the Pharmaceutical Society), Counter Fraud and RQIA.

# Review of Standard Operating Procedures

As you are aware, the Responsible Pharmacist Regulations and the "Accountable Officer" Regulations enshrined Standard Operating Procedures (SOPs) in law and both sets of regulations specify the matters that must be covered by the respective SOPs.

The guidance regarding the Responsible Pharmacist regulations states that the SOPs should be reviewed at least once every two years. Review of the SOPs should therefore occur, as a minimum, every two years or at any time that an incident occurs which may potentially have led to a compromise of patient safety (<http://www.psn.org.uk/documents/352/Standards+on+the+Responsible+Pharm.pdf>)



As the legislation came into operation on 1 October 2009, if they have not already done so, the Responsible Pharmacist should be considering a review of their SOPs to ensure that they continue to be appropriate for the business of the pharmacy.

# Drugs liable to misuse

Pharmacists will be well aware of the abuse/misuse potential of a number of drugs available over the counter. The PSNI Standards and guidance for the sale and supply of medicines states **"The pharmacist must ensure that ... 2.8 All persons involved in the sale of OTC products are aware of the abuse potential of certain OTC medicines and other products, including being alert to requests for large quantities and frequent requests, and knowing to refuse to make a supply where there are reasonable grounds for suspecting misuse and/or abuse."**

- Codeine based products continue to give cause for concern with reports from addiction services indicating that some individuals are taking excessive quantities of co-codamol tablets. Some of these products will be supplied against prescriptions (and may be diverted), some will be purchased from pharmacies and some will be obtained by other means.
- Promethazine products are both over-used and abused. Individuals have

been "de-toxed" from promethazine and you are reminded that the licence stipulates short term use only. Repeated requests by, or sales to, individual customers should be a cause for concern and must be referred to the pharmacist.

- Cyclizine has long been associated with opioid abuse. According to the Scottish Drug Forum "Cyclizine is probably the most misused antihistamine and is often injected in large quantities with opiates..."
- Pregabalin is a POM medicine which, according to the RCGP/RPS guidance, "Safer Prescribing in Prisons", has "well recognised abuse potential". Anecdotally there appears to be a growing use of pregabalin as a drug of misuse. Pharmacists should be aware of the potential for forged or counterfeit prescriptions for pregabalin, especially if the prescription originates from a source other than prescribers with whom you are familiar.

These are examples of current issues, and sales of any products with the potential for misuse and/or abuse should be closely monitored.



## Misuse of Drugs Regulations (Northern Ireland) 2002

The Home Office and the Department have both published consultations on consolidating the Misuse of Drugs Regulations, for Great Britain and Northern Ireland respectively. Since the Regulations came into operation here in 2002, a number of amendments have been made to reflect policy changes and clarify the provisions under the Regulations. This process has naturally tended to the legislation becoming fragmented and complex. The Department's objective is to consolidate the 2002 Regulations and the multiple amending statutory rules. Clarifying amendments will also be made to existing provisions in order to ensure that the consolidated regulations will be comprehensive and fit for purpose, reflecting current policy on controlled drugs available in healthcare and similar settings. It is anticipated that the consolidated regulations will be made in 2012.

## Misuse of Drugs Act 1971

Some amendments have been made to the Misuse of Drugs Act 1971 by the Police Reform and Social Responsibility Act 2011. They came into force in November 2011. The Secretary of State is provided with the new power to make a 'temporary class drug order' to control a substance that is being, or is likely to be, misused, and its misuse is having, or is capable of having, harmful effects. These orders may be made following consultation by the Secretary of State or following receipt of a recommendation from the Advisory Council on the Misuse of Drugs (ACMD) on invoking such an order.

The definition of a controlled drug is then also expanded to include a substance which is specified in a temporary class drug order. Another amendment of interest relates to the constitution of the ACMD. It removes the statutory requirement on the Secretary of State to appoint members with experience in specified activities and recent experience of social problems connected with drug misuse, in effect allowing for greater flexibility in the membership of the council. A more exhaustive, non-statutory list of likely relevant areas of expertise for membership of the ACMD has been published.

Fuller details, if desired, can be found in **Home Office Circular: 012-2011**.

## Amendment to the Pharmacy (Northern Ireland) Order 1976

Between 16 March and 22 June 2011 the Department consulted on the draft Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2011 (the draft Order). As part of the consultation process pharmacists were invited to two public meetings held by the Department. The purpose was to present the proposals in the

draft Order, to answer questions and provide clarification on any matters raised. This draft Order takes forward recommendations in the 2007 White Paper *Trust, Assurance and Safety - the regulation of health professionals in the 21st Century* which was designed to modernise and strengthen the regulation of healthcare professionals to ensure patient, public and professional confidence in the regulatory bodies.

The draft Order proposes amendments to the Pharmacy (Northern Ireland) Order 1976 which would;

- Reconstitute the PSNI's Council;
- Place a duty on the Council to set and publish standards for the safe and effective practice of pharmacy;
- Place a duty on the Council to set standards of continuing professional development (CPD);
- Reconstitute the Statutory Committee and extend the range of sanctions available to it;
- Create a Scrutiny Committee with a range of sanctions;
- Repeal Article 18 of the Order and create the power to consider health cases.

Once the draft Order has been laid in the Assembly it is anticipated that regulations to be made under the Order will be consulted upon. These regulations will provide more detailed information about the provisions contained within the draft Order.



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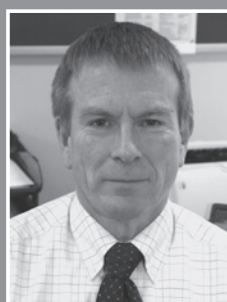
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