



Department of

Health, Social Services and Public Safety

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poustie, Resydënter Heisin
an Fowk Siccar**

Registered Pharmacies
Registered Pharmacists
Trust Heads of Pharmacy & Medicines Management
HSCB – Asst Director - Pharmacy & Medicines Mgt
Registrar Pharmaceutical Society NI
Chief Executive PCC
President UCA
Lead Pharmacist RQIA

**From: Head of Inspection and Investigation
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Date: 28 January 2010

Dear Colleague,

RE: THE CONTROLLED DRUGS (SUPERVISION OF MANAGEMENT AND USE) REGULATIONS (NORTHERN IRELAND) 2009.

This letter is for the attention of and action by registered pharmacists and pharmacies in relation to **Standard Operating Procedures (SOPs)** and **Declarations and Self-assessments** arising from the above Regulations and should be completed no later than 31 March 2010.

The above Regulations, which are sometimes referred to as the Accountable Officer Regulations, came into effect on 1 October 2009. Appendix A outlines the background to the Regulations and details how they will affect pharmacists and pharmacies.

Standard Operating Procedures

All pharmacies are required to have adequate and up-to-date SOPs covering the following matters:

- (a) who has access to the controlled drugs;
- (b) where the controlled drugs are stored;
- (c) security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;
- (d) disposal and destruction of controlled drugs;
- (e) who is to be alerted if complications arise; and
- (f) record keeping, including—
 - (i) maintaining relevant controlled drugs registers under misuse of drugs legislation, and
 - (ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations (Northern Ireland) 2002 that have been returned by patients.

The Inspectors will seek to have sight of these SOPs during their inspections and they must be made available on request.

Declarations and self-assessments

Declarations and self-assessments may be a useful tool in monitoring and auditing systems. In relation to community pharmacy, declarations and self-assessments will be issued and monitored by the Departmental Inspectors in conjunction with their established inspection arrangements. The Departmental Inspectors will, through their reporting arrangements, provide assurances to the Board Accountable Officer relating to the management and use of controlled drugs in contracted community pharmacies.

The arrangements for declarations and self-assessments are as follows:-

For all community pharmacies and HSC Trust pharmacies, a declaration and self-assessment form in relation to the management of controlled drugs must be completed annually. The completed form must be retained in the front of the Controlled Drug register and will become part of the routine record-keeping which will be examined by the Pharmacy Inspectors during their visits.

A copy of the declaration and self-assessment is enclosed for completion in readiness for your next pharmacy inspection visit.

A copy of this form can also be found on the DHSSPS website at the following link *
<http://www.dhsspsni.gov.uk/pas-cd-dsa.pdf>

If you have any queries, regarding the completion of this form, please contact either:
Joe Gault (028 9052 0768 joe.gault@dhsspsni.gov.uk) or Tony Wallace (028 9052 8688 anthony.wallace@dhsspsni.gov.uk).

Yours sincerely



Dr M Mawhinney
Head of Inspection and Investigation
Enc: Appendix A
Enc: Declaration and Self-assessment Form

* This link was revised on 3 March 2010

Appendix A

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

Background

The Fourth Report of the Shipman Inquiry identified a number of serious shortcomings in the systems used for the management and use of controlled drugs and recommendations were made to improve the systems in place at that time. The Chair of the Inquiry, Dame Janet Smith, praised the inspection arrangements in Northern Ireland and said that the centralised nature of the Inspectorate and its integration within the Department conferred undoubted benefits.

The Department favoured a system which would work within and alongside the existing governance arrangements and build on, and use, the expertise of the current inspection and investigation resources.

Following two separate consultation periods, [The Controlled Drugs \(Supervision of Management and Use\) Regulations \(Northern Ireland\) 2009 \(SR 2009/225\)](#)¹ (the Regulations) were drafted. The Regulations were made on 5 June 2009 and came into operation on 1 October 2009.

The new procedures will result in a significant improvement to current arrangements, being better co-ordinated and integrated within the overall framework for improving quality in healthcare. It is intended to encourage good practice in the management of controlled drugs as well as help to detect unusual or poor clinical practice or systems, criminal activity or risk to patients.

The three key elements of the new legislation are:

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

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, which were made under The Health Act 2006, require “Designated Bodies” to appoint or nominate an Accountable Officer. The Designated Bodies include the Regional Health and Social Care Board (the Board), the Health and Social Care Trusts, the Northern Ireland Ambulance Service Trust and Independent Hospitals. Each of the Designated Bodies has appointed an Accountable Officer who will be supported, in some cases, by a Designated Officer(s).

The Health Act also introduces a duty of co-operation that requires Responsible Bodies to share information and intelligence about the management and use of controlled drugs. The Responsible Bodies include the Designated Bodies, the Department, the Regulation and

¹The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009
http://www.opsi.gov.uk/sr/sr2009/nisr_20090225_en_1

Quality Improvement Authority, the Police Service of Northern Ireland, the Regional Business Services Organisation and regulatory bodies (including the Pharmaceutical Society of Northern Ireland).

The Act also contains a new power of entry and inspection for certain authorised persons to inspect controlled drugs and associated records. The inspection process is intended to monitor compliance, improve quality and support individual and organisational development. It may identify concerns which will be brought to the attention of the Accountable Officer.

How will this affect me as a pharmacist?

In Northern Ireland, controlled drug inspections are already an integrated part of the routine visit by the Departmental Inspectors. You should therefore notice little change in the format of the routine inspection when the Inspector visits. The Department will send community pharmacies a declaration and self-assessment form which should be completed and retained at the premises. The Inspector will ask to look at this form when he visits. This form will be sent to community pharmacies every year and the Inspector will request to look at the most recent form received although all previous forms should be retained as part of the audit trail.

Under the above Regulations, the Departmental Inspectors will provide assurances to the Board Accountable Officer relating to the management and use of controlled drugs in community pharmacies. Similar assurances will be given, in conjunction with the RQIA, to the Trust Accountable Officers following inspection visits to the Trust pharmacies. The Department will send declarations and self-assessments to Trust pharmacies while the RQIA will have responsibility for co-ordinating declarations and self-assessments relating to the wider responsibilities of the Trust.

Any concerns about controlled drugs should be addressed either to the Department or to the Accountable Officer of the relevant Designated Body.

Further information about the role of the Accountable Officer and the contact details are available on the Department's web-site at <http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm>.

DECLARATION AND SELF ASSESSMENT 2010
ALL QUESTIONS MUST BE ANSWERED

	Yes/No		Yes/No
1. Do you have specific written SOPs covering the management of CDs, appropriate to the activities carried out at the premises and as required by the Accountable Officer regulations?		7. Do you transport CDs in accordance with an SOP (e.g. patient deliveries)?	
2. Are the staff involved in activities related to CDs appropriately trained and competent?		8. Are all CDs appropriately labelled?	
3. Do you have procedures in place to identify, deal with and learn from significant incidents involving CDs?		9. Are regular date checks of CD stock carried out?	
4a. Have you noted any signs of unusual, excessive or inappropriate supply or prescribing patterns?		10. Is the CD Register maintained in accordance with the Misuse of Drugs Regulations and any relevant guidance?	
4b. If yes , have these issues been fully addressed?		11. Are running balances of CDs maintained and is there evidence that they are audited?	
5a. Are there any signs of, or do you have concerns about, the diversion of CDs?		12. Are all relevant CDs stored in accordance with the Safe Custody Regulations and are procedures in place to prevent unauthorised access to CDs?	
5b. If yes , have these issues been fully addressed?		13. Is date expired and patient returned medication appropriately marked and segregated?	
6a. Have there been any complaints or significant incidents involving CDs in the last 12 months of which you are aware?		14. Are out of date or patient returned CDs destroyed in accordance with legislation and published guidance?	
6b. If yes , have these issues been fully addressed?			

DECLARATION

I declare that to the best of my knowledge and belief that the handling, management and use of Schedules 2 and 3 controlled drugs at these premises complies with the provisions of the Misuse of Drugs Act 1971, its associated regulations and the Health Act 2006 and its associated controlled drugs regulations.

Signed

Date

Name		Registration Number	
Position within organisation		Name of organisation and address of premises	

PAS-CD-DSA