

Safer Management of Controlled Drugs

A Guide to Strengthened Governance Arrangements in Northern Ireland

Introduction

1. This guidance sets out strengthened governance arrangements for the management and use of controlled drugs in Northern Ireland. These new arrangements are underpinned by the Health Act 2006 and the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (the Regulations).

The guidance has been developed from original guidance issued by Department of Health (DH) (England) and the Scottish Executive to support the work of their Accountable Officers. The Department of Health, Social Services and Public Safety (the Department) is grateful to DH (England) and the Scottish Executive for the use of their guidance documents and for the support provided to the Department in the preparation of this document.

2. The Fourth Report of the Shipman Inquiry¹ identified a number of serious shortcomings in the systems used for the management of controlled drugs and made recommendations to improve their management. The Northern Ireland response to the Shipman Inquiry's Fourth Report was set out in "Improving Patient Safety – Building Public Confidence"². It is recognised that the recommendations within the Fourth Report related, in the main, to the situation in Great Britain at the time of the Inquiry and that the controlled drug monitoring arrangements operating in Northern Ireland were most favourably commented upon by the Inquiry Chair at that time.

3. The Shipman Inquiry identified the key strengths of the current Department's Medicines Regulatory Group (formerly known as the Medicines Inspection and Investigation Team) as its centralised nature, integration within the Department, expertise and multi-disciplinary nature, existing integration and collaboration with other professional bodies and investigation/enforcement authorities.

4. 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.

5. It was anticipated that the new procedures would result in a significant improvement to existing arrangements, being better co-ordinated and integrated within the overall framework for improving quality in healthcare. They are 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.

¹ See *The Regulation of Controlled Drugs in the Community, The Fourth Report of the Shipman Inquiry* (<http://www.the-shipman-inquiry.org.uk/4rpage.asp>)

² "Improving Patient Safety – Building Public Confidence"
www.dhsspsni.gov.uk/improving_patient_safety_-_building_public_confidence.pdf

Legislative changes

6. Parliament considered that new legislation was necessary to respond to a number of the recommendations in the Shipman Inquiry report. Therefore, the Health Act 2006, which received Royal Assent in July 2006, included measures to improve and strengthen the management and use of controlled drugs.

7. The Regulations made under the Health Act 2006 are called The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009³. The Regulations were made on 5 June 2009 and came into operation on 1 October 2009.

8. The new governance arrangements have been implemented in a way that supports healthcare professionals, encourages good practice and does not deter the use of controlled drugs when clinically required by patients. Furthermore it is essential that the new arrangements ensure potential criminality is identified and reported to the police at the earliest opportunity.

9. This guidance describes the implementation of the requirements in Northern Ireland.

Implementation

10. The three key elements of the legislation are:

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

11. The Health Act 2006 requires “Designated Bodies” to appoint or nominate an Accountable Officer, either one per organisation or, within parameters, shared between organisations. For the purposes of the Act, “Designated Bodies” are those that are “directly or indirectly concerned with the provision of health care (whether or not for the purposes of the health service)”, or “otherwise carrying on activities that involve, or may involve, the supply or administration of controlled drugs”.

12. Designated Bodies include:

- the Health and Social Care Board (HSCB)
- Health and Social Care Trusts
- the Northern Ireland Ambulance Service Trust
- Independent Hospitals.

³ The Regulations can be accessed at http://www.opsi.gov.uk/sr/sr2009/nisr_20090225_en_1

13. The Act also introduces a duty of co-operation which requires Responsible Bodies to share information and intelligence about the management and use of controlled drugs. Responsible Bodies include:

- Designated Bodies, as above
- the Department
- the Regulation and Quality Improvement Authority (RQIA)
- Police Service of Northern Ireland
- The Counter Fraud Unit of Business Services Organisation (BSO)
- regulatory bodies (including the Pharmaceutical Society of Northern Ireland, General Dental Council, General Medical Council, Nursing and Midwifery Council, Health Professions Council)

(Refer to Annex B for full list of Responsible Bodies).

14. The Act 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.

Training and development

15. Learning and developmental material is available through the Department.

16. More detailed information on the above aspects of the legislation can be found in the following Annexes.

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| Annex A | - Accountable Officer |
| Annex B | - Duty of Co-operation/Local Intelligence Network |
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Annex A

Accountable Officer

1. The Health Act 2006 and the Regulations require Designated Bodies to nominate or appoint an Accountable Officer (regulation 4) to be responsible for a range of measures relating to the monitoring of the safe management and use of controlled drugs within the organisation and take appropriate action where necessary. Designated Bodies include the Health and Social Care Board, Health and Social Care Trusts, Northern Ireland Ambulance Service Trust and Independent Hospitals.

2. An Accountable Officer of a Designated Body that is not an Independent Hospital must be:

- an officer or employee of the Designated Body, and

(i) a member of the board of directors, or the management or executive committee of the Designated Body; or

(ii) a member of the body (howsoever it may be called) that has responsibility for the management of the Designated Body; or

(iii) is answerable to a person referred to in (i) or (ii) above.

3. Two or more Designated Bodies that are not Independent Hospitals but which are of the same type may jointly nominate or appoint one person to be their Accountable Officer so long as that person meets the criteria at paragraph 2 above in relation to one of the Designated Bodies. Each Designated Body must be satisfied that the Accountable Officer can discharge his/her responsibilities in relation to both.

4. In the case of an Independent Hospital, the Accountable Officer must be its registered manager⁴ or one of its officers or employees who is answerable to its registered manager. If the Accountable Officer is the registered manager, he must be answerable to the Chief Executive, Chairman or Managing Director of the hospital.

5. Two or more Independent Hospitals can nominate or appoint one registered manager to be the Accountable Officer for both or all the hospitals if the registered manager is the registered manager of both or all the hospitals.

6. The Accountable Officer must be a "fit, proper and suitably experienced person" who does not routinely supply, administer or dispose of controlled drugs as part of their duties. A Designated Body can nominate or appoint an Accountable Officer who has an occasional, exceptional role in the use of controlled drugs (for example, in emergencies). However, their use of controlled drugs should be open to the scrutiny of another person to whom

⁴ "registered manager", in relation to an independent hospital, means the person who is registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the manager of the hospital.

they are answerable. They should have credibility with all healthcare and social care professionals and be of a sufficient seniority to be able to take action regardless of how a concern is raised. Individuals at levels equivalent to Medical Directors, Pharmacy Directors or Directors of Nursing, can be appointed as Accountable Officers if they meet the above criteria. The Accountable Officer can be a stand-alone or additional role depending on local circumstances. Designated Bodies should make it clear, as part of their monitoring systems whom people should approach if they have concerns about the practice of their own Accountable Officer.

7. A Designated Body (or, in the case of a joint appointment, the Designated Bodies acting jointly) must remove its Accountable Officer if he no longer satisfies the conditions set out above or if he is no longer considered fit to be an Accountable Officer (regulation 6). For the purposes of the Regulations, an Accountable Officer is found to be unfit if he wilfully, negligently or through lack of competence breaches his duties as an Accountable Officer. A Designated Body must have in place a procedure (which may be part of its internal disciplinary procedures) for due consideration of matters which may lead to the removal of its Accountable Officer.

8. The Regulations set out Accountable Officers' responsibilities. The Accountable Officer will hold a senior post in the Designated Body and will carry overall responsibility for ensuring compliance with the arrangements in relation to the management of controlled drugs. Regulation 7 requires that a Designated Body must provide its Accountable Officer with the funds and other resources necessary to enable him to carry out his responsibilities. Resources may include staff and it is anticipated that the Accountable Officer may identify individuals to assist them in the day-to-day discharge of their responsibilities.

9. Designated Bodies must inform the Department in writing of their nominations or appointments of Accountable Officers and of any subsequent changes. The Department maintains an up to date list of Accountable Officers in Northern Ireland which is published on the Departmental website (regulation 4(5)) and can be accessed at www.dhsspsni.gov.uk/accountable-officer-contact-list.pdf

Accountable Officer Responsibilities

10. As set out in Regulations 8 -18, Accountable Officers need to ensure that they have systems in place for routinely monitoring the management and use of controlled drugs through pro-active analysis, identification of triggers for concern, and taking action (regulation 11). They also need to ensure that appropriate arrangements are in place for assessing and investigating concerns and that they are alerted to any significant findings (regulations 11 and 16). Where criminality is suspected the police should be notified.

11. Accountable Officers must have arrangements in place for the review of the management and use of controlled drugs within their Designated Body or ensure that the Designated Body does so. They must also ensure that any

person or body acting on behalf of, or providing services under arrangements made with their Designated Body, establishes, operates and reviews appropriate arrangements for the management and use of controlled drugs.

12. The Accountable Officer will need to have or be able to access certain skills and expertise, including data analysis, investigative skills and networking. They may require investigative and administrative support and support from others such as the clinical governance lead, Medicines Management Adviser, the Department or the police as appropriate (see Annex C).

13. Designated Bodies may wish to consider consortia arrangements to support Accountable Officers in areas such as data analysis and investigative skills. These arrangements will be for local determination and should take into account any previous history of concerns about controlled drugs misuse and predictions of the likely workload.

15. The Accountable Officer should also make sure that their Designated Body and contractors have suitable arrangements in place for the disposal of controlled drugs (regulation 10).

16. Accountable Officers are required to ensure that appropriate training is received by those carrying out their responsibilities under the Regulations and this should include regular and comprehensive training applicable to the role of the person involved in the prescribing, supplying, administering and disposal of controlled drugs.

17. Accountable Officers shall provide appropriate training on local standard operating procedures and ensure that anyone involved in working under the standard operating procedures is informed when a formal review takes place e.g. after the designated time period or after a critical incident.

18. The structures set up for the Accountable Officer should integrate with existing local performance structures and should relate to groups such as Drug and Therapeutic Committees and clinical governance committees. Accountable Officers are encouraged to share best practice and learn from each other through contact with other Accountable Officers both regionally and throughout the UK.

Annex B

Duty of Co-operation

1. To maximise the effectiveness of the Regulations it is important that healthcare organisations, the police service, and others work together to share intelligence on controlled drugs issues. The Regulations place a statutory duty of co-operation on specified organisations (“Responsible Bodies” set out in regulation 22) to share information giving rise to concerns about the management or use of controlled drugs by any “relevant person”. The Health Act 2006 (Section 19) and the Regulations (regulation 23) made under the Act define the term “relevant person” and include any individuals whether or not healthcare professionals who are involved in any way (HSC or private) with the management or use of controlled drugs⁵.

2. Under the arrangements the following are Responsible Bodies:

Primary Care

- Health and Social Care Board

The Accountable Officer may liaise with key members of staff including prescribing, medical, dental, nursing advisers and HR where appropriate to collate detailed information for the Local Intelligence Network (LIN).

Secondary Care

- Belfast Health and Social Care Trust
- Northern Health and Social Care Trust
- Southern Health and Social Care Trust
- South - Eastern Health and Social Care Trust
- Western Health and Social Care Trust

The Accountable Officer may liaise with key members of staff including clinical directors, pharmaceutical directors and HR, where appropriate, to collate detailed information for the LIN.

Other Designated Bodies

- Northern Ireland Ambulance Service Trust
- Independent Hospitals

The Accountable Officer may liaise with key members of staff within their Designated Body to collate detailed information for the LIN.

⁵ See clause 19 of the Health Act 2006 and regulation 23 of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

Other bodies

- Department
- RQIA
- Counter Fraud Unit of BSO
- Police Service of Northern Ireland
- Pharmaceutical Society of Northern Ireland
- General Medical Council
- General Dental Council
- Nursing and Midwifery Council
- Health Professions Council

Information-Sharing

3. A Responsible Body may disclose to any other Responsible Body any information which may help identify cases where action may need to be taken in respect of the management or use of controlled drugs. This enables bodies that have a concern to share it as soon as possible with any other bodies who may be affected or who may have complementary information.

4. Confidential information about patients must be removed where possible (regulations 25 & 26). If it is not possible to remove patient identifying details from confidential information, then the patient's consent should be sought wherever practicable (regulations 25 & 26).

5. In sharing such information, Responsible Bodies must have regard to the Data Protection Act 1998 and codes of practice on confidentiality - in particular the Caldicott principles i.e.

- Justify the purpose
- Do not use patient identifiable information unless it is absolutely necessary
- Use the minimum necessary patient identifiable information
- Access to patient identifiable information should be on a strict need to know basis
- Everyone should be aware of their responsibilities
- Understand and comply with the law.

However, there is an exemption from the requirements of the Data Protection Act 1998 relating to the investigation of crime. Section 29(3) of that Act includes exemptions for the prevention or detection of crime and for the apprehension or prosecution of offenders.

6. Care should also be taken when sharing information about identifiable relevant persons and, where possible, individuals should be made aware of concerns raised about them unless, for example, disclosure would jeopardise the conduct of an investigation.

The Code of Practice on Protecting the Confidentiality of Service User Information www.dhsspsni.gov.uk/confidentiality-code-of-practice0109.pdf may be a helpful resource.

Local Intelligence Network (LIN)

7. The Department has directed Accountable Officers to establish a network (a Local Intelligence Network) for sharing information regarding the management and use of controlled drugs. Responsible Bodies participate in a single Local Intelligence Network, covering Northern Ireland.

8. Membership of the LIN is described in the Regulations and involves key agencies (regulation 18). The LIN will facilitate timely and appropriate sharing of information, and enable agencies that have a concern about the activities of any healthcare professional or organisation to liaise at an early stage with other local agencies who may be affected or who have complimentary information.

9. The LIN includes, but is not limited to, the following types of bodies:

- Department
- HSC Board
- HSC Trusts
- the NIAS
- Independent Hospitals
- RQIA
- the Counter Fraud Unit of BSO
- the Police Service of Northern Ireland
- regulatory bodies

Members of the LIN may also want to involve others as appropriate such as Drug Action Teams and Local Supervising Authority Midwifery Officers. However, this list is not exhaustive and it is crucial that this forum takes account of the diversity of interests both within and outwith the health service including manufacturers, wholesalers and Veterinary Practitioners.

10. The LIN meets on a quarterly basis under the agreed chairmanship of the Department and members have agreed their Terms of Reference and guidance to support the managing and sharing of concerns. An Accountable Officer may request that an incident panel be convened by the Chair of the LIN to investigate a concern and to make recommendations. Each body will retain responsibility for taking appropriate action where required.

11. In addition to the quarterly meetings, members of the LIN may develop a centrally maintained, confidential database to support the effective sharing of information throughout the network.

Occurrence Reports

12. Accountable Officers must provide the Chair of the LIN with a quarterly occurrence report (regulation 29). This report shall provide details of any

concerns that the Designated Body may have identified regarding the management or use of controlled drugs or confirm that it has not identified any such concerns.

Request for Additional Information

13. There may be instances when a Responsible Body considers that it may require additional information from another Responsible Body in order to determine whether or not action is necessary (regulation 26). This additional information may be specific to the management or use of controlled drugs or could be, for example, fitness to practise information. Where a Responsible Body has received such a request in writing it must decide within a reasonable period of time whether or not to disclose the additional information. The decision about disclosure should take account of issues of confidentiality.

Restrictions Relating to Disclosures

14. Where a Responsible Body has an Accountable Officer, any information disclosed under the Regulations must ONLY be made by or to the Accountable Officer or his staff. The information may ONLY be used for identifying cases, considering and taking action in respect of concerns relating to the management or use of controlled drugs (regulation 27). In particular, the Responsible Body must ensure that appropriate measures are taken to prevent unauthorised access, processing, or disclosure of the information.

Record Keeping

15. Responsible Bodies must keep records (either paper or electronic) of any decisions to disclose information, details of the nature of the information disclosed, details of the Responsible Body to which the information was disclosed and any other relevant details (regulation 28).

16. Responsible Bodies must also keep a record (either paper or electronic) of any requests received from another Responsible Body to disclose information, details of the nature of the information disclosed, details of the Responsible Body to which the information was disclosed and any other details considered to be relevant (regulation 28).

17. Responsible Bodies should refer to “Good Management, Good Records” for guidance on managing records in Health and Personal Social Services organisations in Northern Ireland. www.dhsspsni.gov.uk/dhs-goodmanagement.pdf

Taking Action

18. Responsible Bodies have a duty to co-operate in identifying cases, considering action and taking action, in respect of matters arising in relation to the management or use of controlled drugs by a relevant person (regulation

24). Action might include further investigation of issues of concern or the initiation of processes to protect the safety of the public, including professional disciplinary processes. Each organisation will be separately accountable for action within its own remit.

19. If a Responsible Body shares information under Regulations 25 and 26 that indicates a concern about inappropriate or unsafe use of controlled drugs by a “relevant person”, the Accountable Officer(s) concerned may make recommendations to the Responsible Body as to the actions that should be taken. For these purposes, the relevant Accountable Officer would be the Accountable Officer of the Designated Body responsible for entering into any arrangements (either directly or through another individual or body) with the person to provide services. The Responsible Body is any Responsible Body that could take appropriate action, including regulatory bodies and the police. Where the person does not provide services to a Designated Body, the chair of the LIN must seek to take reasonable steps to protect the safety of patients and the general public. If appropriate, the Chair must refer the matter to a relevant Responsible Body, e.g. a regulatory body or the police (regulation 30). Further information about undertaking investigations can be found in Annex E.

Annex C

Monitoring

Routine monitoring

1. Accountable Officers must establish and operate or ensure that their Designated Body and any persons or bodies acting on behalf of, or providing services under arrangements made with the Designated Body, establishes and operates arrangements for monitoring and auditing the management and use of controlled drugs (regulation 11). This can be through normal governance and management arrangements. Where one organisation provides services to another, the commissioner of the services has responsibility for ensuring that appropriate governance arrangements are specified in the contract.

2. The arrangements made by the Accountable Officer in relation to controlled drugs must include provision for the following:

- monitoring and analysing of prescribing
- ensuring that the Designated Body (or its service providers⁶) has systems in place to alert the Accountable Officer of any complaints or concerns
- ensuring that the Designated Body (or its service providers⁶) has an incident reporting system in place for untoward incidents
- ensuring that the Designated Body (or its service providers⁶) has appropriate arrangements in place for analysing or responding to untoward incidents

Monitoring of prescribing may include COMPASS Prescribing Reports and allied data analysis tools. The COMPASS prescribing reports are produced from data that are captured by the Business Services Organisation from dispensed prescriptions. Prescribing reports are generated for individual practices, locality groups and the Board as a whole for each quarter and each financial year. Practice reports are circulated to all practices each quarter. The report allows practices to see how their prescribing compares to that of other practices in NI and how they have changed compared to the previous year. The COMPASS system is also used to generate control charts which allow Medicines Management Advisers to identify "out-lying" practices which require follow up in relation to their prescribing of Controlled Drugs.

Monitoring in secondary care can include, but is not restricted to, analysing:

- ward/department usage
- in-patient/out-patient discharge dispensing
- use in out of hours services.

The responsibility for prisons lies with the AO of the South Eastern Health and Social Care Trust

⁶ any persons or bodies acting on behalf of, or providing services under arrangements made with the Designated Body

3. The Care Quality Commission (formerly the Healthcare Commission) produced a Controlled Drug Governance Self-Assessment Toolkit⁷ to allow Designated Bodies to assess how they are doing in terms of controlled drug governance and to suggest actions for areas of improvement. The toolkit was developed predominantly for general practice in England, but can be used in other settings.

Controlled drug declarations and self assessments

See Annex F

Standard Operating Procedures (SOPs)

4. The Accountable Officer must ensure that his Designated Body (and related bodies or persons⁶) has adequate and up-to-date SOPs in place in relation to the management and use of controlled drugs.

Regulation 9 requires the SOPs to cover:

- who has access to the controlled drugs;
- where the controlled drugs are stored;
- security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;
- disposal and destruction of controlled drugs;
- who is to be alerted if complications arise, and
- record-keeping, including –
 - (i) maintaining relevant controlled drugs registers under the 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) 2002⁸ (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

⁷ See http://www.cqc.org.uk/db/downloads/CDToolVersion5PCT_bis.xls

⁸ SR 2002/1 as amended

Annex D

Entry and Inspection

Routine periodic inspections

1. Inspections of a wide range of relevant premises are already undertaken by the Department's Medicines Regulatory Group and the Regulation and Quality Improvement Authority (RQIA). In addition to this, the Health Act 2006 contains a power of entry and inspection, subject to certain criteria, for constables and certain authorised persons to enter any relevant premises to inspect controlled drugs and any associated records. These authorised persons include Accountable Officers and persons authorised by the Designated Body.

2. Formal inspection involving an 'on-site' visit is only part of the new monitoring and inspection arrangements which also include controlled drug declarations and self assessments. Nonetheless, inspection remains a useful tool to check physical arrangements for the storage, record keeping and management of controlled drugs. The inspection process is intended to monitor compliance, improve quality and support individual and organisational development.

3. For those premises that are periodically inspected by RQIA and the Department, the Accountable Officer does not have a duty to undertake **periodic** inspections (regulation 19). However, as part of his monitoring, the Accountable Officer may undertake additional inspections to give assurance that controlled drugs are being managed and used safely. The number and frequency of these additional inspections are at the discretion of the Accountable Officer. In undertaking any additional inspections, the Accountable Officer should take account of the Government's policy^{Error!} that the inspection process should not be over burdensome and should avoid duplication. RQIA and the Department will inform relevant Designated Bodies on the frequency of the routine inspections and also the format and frequency of assurances following such visits.

Primary Care

4. As part of their monitoring and auditing arrangements, the Board Accountable Officer should arrange for a small number of inspections of a random sample of "relevant premises"⁹ where controlled drugs are stored, dispensed, supplied or used. Inspections will be informed by information received by the Accountable Officer including inspection reports, declarations, and other monitoring of data. The Accountable Officer may choose to integrate controlled drug inspections into the current monitoring activities. Adverse issues may be investigated as detailed in Annex E.

⁹ See clause 20 of the Health Act 2006 and Regulations 19 and 20 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

5. The Department's Medicines Regulatory Group will undertake periodic inspections of community pharmacies and these will include an in depth audit of controlled drugs. The Board will undertake periodic inspections of General Practitioners and Dental Practitioners who are commissioned by the Board to provide medical and dental services under the health service. The RQIA may undertake periodic inspections of purely private Dental Practitioners. . These inspections may be informed by self assessment and other available information. The inspecting authority and the relevant Accountable Officer will determine the level and frequency of feedback following such visits.

Secondary Care

6. In secondary care pharmacies, periodic inspections will be carried out by the Department's Medicines Regulatory Group Inspection and Investigation Team and these will include an in depth audit of controlled drugs. Inspection of other wards and departments will be the subject of agreement between RQIA/Department and the Trust.

These inspections will be informed by self assessment and other available information. The inspecting authority and the relevant Accountable Officer will determine the level and frequency of feedback following such visits

Independent Healthcare and Care Homes

7. In Independent Hospitals the RQIA, as part of their existing inspection processes, will carry out periodic inspections. The Department also carry out controlled drug visits to the Independent Hospitals. The inspecting authority and the relevant Accountable Officer will determine the level and frequency of feedback following such visits.

8. The Regulations enable an Accountable Officer to request in writing that another Accountable Officer from a Designated Body of the same type (Health Service or Independent) inspects any relevant premises of his Designated Body (regulation 20(6)). This is intended to provide Accountable Officers with a system of mutual audit and support.

Records

9. Inspecting authorities must keep a record, either paper or electronic, of all inspections (regulation 19). Where reports of routine inspections are made available to the premises concerned these may give assurance of existing good practice and may high-light areas where improvement is necessary. The relevant Accountable Officer should make arrangements with the inspecting body in relation to the sharing of reports following inspection visits.

Annex E

Investigations

1. Accountable Officers must ensure that robust systems are in place across their areas of responsibility to enable concerns or incidents involving controlled drugs to be identified and, where appropriate, investigated (regulations 15 and 16).

Adequate records must be compiled and kept, in either paper or electronic form, in relation to any concerns expressed. Access to these records must be restricted to:

- the Accountable Officer and his staff; and
- others who need access for the purpose of ensuring the safe management and use of controlled drugs

The record must include, but is not limited to, as appropriate:

- the date on which the concern was made known to the Accountable Officer
- any dates on which the matters that led to the concern took place
- details regarding the nature of the concern
- details of the relevant individual in relation to which the concern was expressed
- details of the person who, or body which, made known the concern
- details of any action taken by the Designated Body (or a body or person acting on behalf of, or providing services under arrangements made with , the Designated Body) in relation to the concern
- the assessment of whether information in relation to the concern should be disclosed to another Responsible Body under regulation 25 or 26; and
- if information regarding the concern is disclosed to another Responsible Body under regulation 25 or 26 the details of any such disclosure, including the name of the Responsible Body to which the disclosure was made and the nature of the information disclosed to the body.

2. Where a concern involves a registered professional's fitness to practise or where patient safety may be compromised, information should be passed immediately to the appropriate Regulatory Body. Guidance can be found on the Regulatory Bodies websites, examples of which are listed below.

General Dental Council (www.gdc-uk.org) *Our Guide to Local Practitioner Advice and Support Schemes*

General Medical Council (www.gmc-uk.org) *Referring a doctor to the GMC: A guide for individual doctors, medical directors and clinical governance managers*

Nursing and Midwifery Council (www.nmc-uk.org) *Reporting unfitness to practise: A guide for employers and managers*

Health Professions Council (www.hpc-uk.org) *Making a complaint about a health professional*

The Pharmaceutical Society of Northern Ireland (www.psnri.org.uk)

3 Regulation 17 details where advice may be sought and what actions should be taken in response to well founded concerns..

Incident Panel

4 Where concerns have come to light, initial consultation with the members of the Local Intelligence Network (LIN) may be helpful as an alternative or prior step to requesting the Chair of the LIN to establish an Incident Panel. An Incident Panel would be convened by the Chair of the LIN and facilitates more structured consideration of a concern. The membership is drawn from the LIN and will depend on local circumstances and the nature of the concern. The Incident Panel can recommend a number of actions as detailed in regulation 17(3), including ongoing monitoring, referral of concerns to the Regulatory Body or the police.

5 In all cases, care should be taken that any evidence gathered during the course of an investigation is preserved in an appropriate manner to ensure its integrity. Such evidence may be required for proceedings instituted by the police, other enforcement agencies, Disciplinary Committees or Regulatory Bodies.

Escalating concerns

6 There may be cases where concerns cannot be resolved locally and need to be escalated or passed to another organisation. The table below summarises where issues should normally be referred. On occasion concerns may need to be passed to more than one organisation.

Concern	Refer to:
Criminality suspected	Police
Fraud suspected	Counter Fraud Unit (BSO) Department Police
Individual fitness to practise issue	Regulatory Body
Organisational/systems issue	Department

7 If a concern is passed to another organisation(s) the relevant Accountable Officer should record the referral (regulation 28).

8 When patient safety is thought to be at risk, immediate action must be taken. HSC bodies should follow their local serious untoward incident

procedures. Immediate referral to the relevant regulatory body should be considered where there are serious concerns about an individual's fitness to practise.

9 Actions taken consequent upon the investigation findings and relevant policies in the Designated Body should be clearly documented.

Targeted inspection

10. Either following an Incident Panel or as a direct result of a concern, the Accountable Officer may decide that a formal inspection at the premises is required. The Accountable Officer can seek support from the Department's Medicines Regulatory Group and RQIA in conducting such an inspection to provide independent assurance.

Raising concerns

11 Individuals raising concerns should be supported in doing so. Cases where health service fraud is suspected can be reported to Counter Fraud Unit either by contacting cfps@hscni.net or 08000 963396.

12 Individuals should also be supported where concerns have been raised about them or where they wish to raise concerns about their own performance.

Closure of cases

13. Cases considered by an Accountable Officer should be recorded with a clear account of the findings and any action taken (regulation 15). The Accountable Officer should ensure that concerns, and any lessons learned, are shared across the Local Intelligence Network. Wider sharing of information may be appropriate through the Cross Border Group¹⁰. Where there is evidence that a controlled drug has been diverted, it may also be appropriate to inform the manufacturer or wholesaler.

14 Reports containing information about the storage and movement of controlled drugs should not normally be disclosed under Freedom of Information legislation as this could aid criminal activity and so would come within the "law enforcement" exemption.

¹⁰ The Cross Border Intelligence Group comprises representatives from the UK and the Republic of Ireland. This Group has been formed as a result of the 5 Nations meeting in 2007 (under the Health Act 2006). The remit of the Group is to support the development of appropriate systems through dissemination of information and sharing of good practice in order to achieve statutory compliance and to feed back this information to members' home organisations.

Annex F

Controlled Drugs declarations and self-assessments

Those who will send declarations and self-assessments can devise forms to suit their needs. The declaration and self-assessment form for registered pharmacies can be found below (Regulation 12)

SELF ASSESSMENT 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	