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

The Accountable Officers' Report

1 April 2014 – 31 March 2015

January 2016

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INTRODUCTION

This is the fifth report of the Accountable Officers in Northern Ireland concerning the governance of controlled drugs and the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009[1] ("the Regulations"). The report is written to record, inform, and provide assurances to patients and the public, Designated and Responsible Bodies, healthcare professionals and other stakeholders of the progress made between 1 April 2014 and 31 March 2015. It highlights some key developments during this period and reflects on prescribing patterns for a range of controlled drugs (CDs).

While the report provides an overview of the Northern Ireland situation, it also recognises the position of Accountable Officers and does not detract from their accountability to their own Designated Bodies or indeed the totality of assurances that they would be expected to give over the extent of the legislation. Accountable Officers are answerable to the senior management within their own organisation for implementing the requirements arising out of the Regulations. This report, in conjunction with each organisation's own internal

[1] http://www.legislation.gov.uk/nisr/2009/225/pdfs/nisr_20090225_en.pdf

reporting mechanisms, will support Accountable Officers in providing the necessary assurances to their senior management team or Board.

Background to the Regulations can be found in Appendix 1.

ACCOUNTABLE OFFICERS

There were 18 Designated Bodies and 17 Accountable Officers in Northern Ireland between 1 April 2014 and 31 March 2015 The Northern Ireland Children's Hospice has jointly nominated one person to be Accountable Officer for both their hospices (Newtownabbey (Horizon House) and Fermanagh (Horizon West).

Figure 1

The Department of Health, Social Services and Public Safety (the Department) continues to maintain the list of Accountable Officers. An up-to-date contact list can be found on the Accountable Officer section within the Department's website and accessed through the following link: http://www.dhsspsni.gov.uk/accountable-officer-contact-list.pdf.

Each Designated Body is responsible for informing the Department of the removal and appointment of an Accountable Officer. Between 1 April 2014 and 31 March 2015 a total of 2 Designated Bodies made changes to their nominated Accountable Officers.

Consultation On Proposed Amendments To The Controlled Drugs (Supervision Of Management And Use) Regulations (Northern Ireland) 2009

On 26 January 2015 the Department launched a consultation on proposals to amend the Regulations.

The 2009 Regulations had largely replicated those in force in England, Scotland and Wales for the supervision of management and use of CDs.

In 2013 England and Scotland reviewed and amended their equivalent Regulations, the Controlled Drugs (Supervision of Management and Use) Regulations 2006 introducing a range of measures to strengthen CD governance.

The Local Intelligence Network (LIN) reflected on the changes which have been brought into force in England and Scotland and considered the need for similar changes to the Northern Ireland Regulations.

Transfer of Operational Responsibility for the Local Intelligence Network

The 2009 Regulations came into operation at a time of major re-organisation for HSC organisations and, as a result, the Department assumed operational responsibility for the LIN.

On 1 December 2014 responsibility for the Local Intelligence Network (LIN) was transferred from the Department to the Accountable Officer for the HSC Board.

This now mirrors arrangements in England, Scotland and Wales. The Department and the Board worked collaboratively to ensure a seamless transition.

Furthermore it has been proposed that the amended Regulations would enshrine the Accountable Officer of the Health and Social Care Board as the lead Accountable Officer in Northern Ireland with operational responsibility for the LIN.

Work will continue during 2015 to review both content and ownership of the Accountable Officer website. The website, currently maintained by the Department, does and will continue to manage the list of Accountable Officers in Northern Ireland.

The Department will liaise with the Board to consider the on-going provision of training materials and other LIN related documents.

DATABASE

As a result of the decision to transfer operational responsibility for the LIN from the Department to the Board, responsibility for the development of the database was likewise transferred.

The Board continues to make progress and anticipates that the database will ‘go live’ in mid-2016.

NATIONAL AND CROSS BORDER MEETINGS

NATIONAL GROUP

The National Group meets quarterly and is a strategic group of regulators and key agencies that have areas of responsibility for controlled drugs within their remit. The meetings are hosted by the Care Quality

Commission and the Department has been granted permission to attend the meetings as an observer. Being present as an observer enables Northern Ireland to keep abreast of matters relating to controlled drugs elsewhere.

THE CROSS-BORDER GROUP FOR SAFER MANAGEMENT OF CONTROLLED DRUGS IN THE DEVOLVED ADMINISTRATIONS

The Cross Border Group is also hosted by the Care Quality Commission and meets twice yearly. Representatives include England, Scotland, Wales, Republic of Ireland, Northern Ireland, Isle of Man, Jersey and Guernsey. The Department, RQIA and the Pharmaceutical Society of Northern Ireland represent the interests of Northern Ireland. Like the National Group, the Cross Border Group receive updates from the various countries represented to ensure that all parties keep abreast of important updates relating to controlled drugs and allows best practice to be shared and implemented where appropriate.

The aims of the Cross Border Group are to:

a) Provide a forum to promote the sharing of general controlled drugs concerns (rather than specific issues or named individuals) across national borders

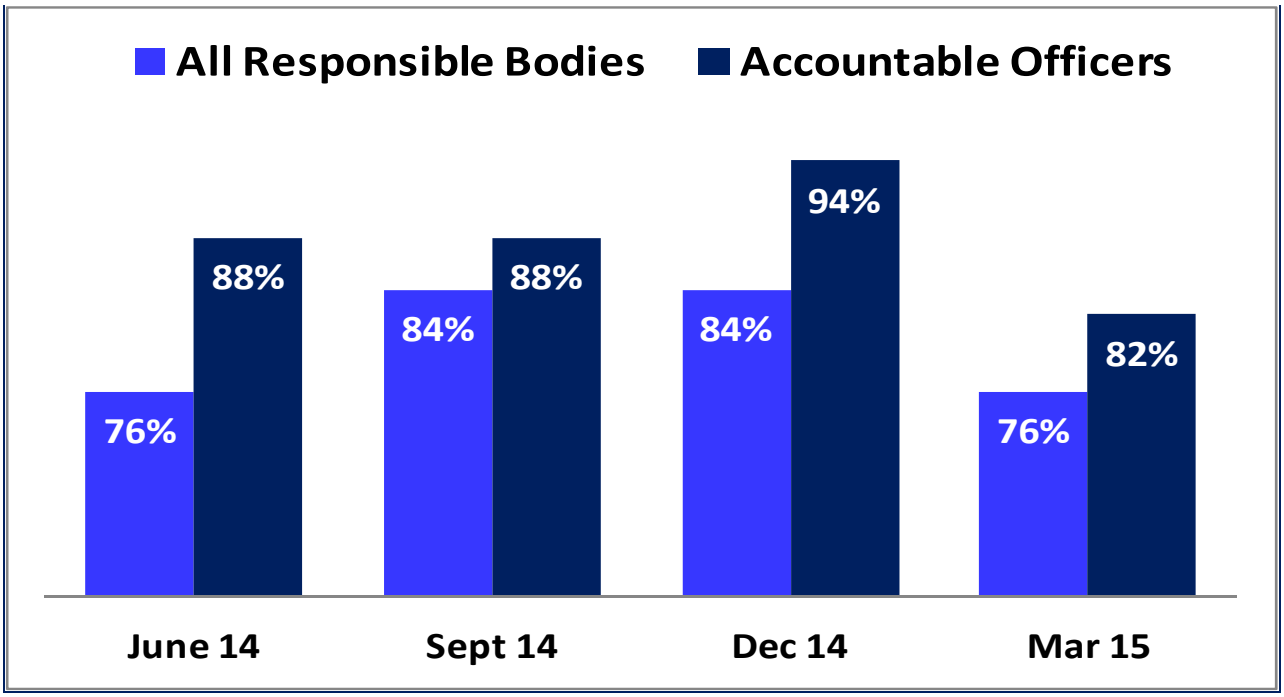
b) Share learning and best practice methodologies that support the safer management of controlled drugs in each nation

c) Share analysis of trends and associated risks pertinent to safer management and use of controlled drugs.

LOCAL INTELLIGENCE NETWORK (LIN)

1 April 2014 - 31 March 2015

Figure 2 **MEETING ATTENDANCE**



See Appendix 2 for the attendance record for individual Responsible Bodies

OCCURRENCE REPORTS

Organisations are required to make and to keep records of controlled drug incidents. The Accountable Officer must then ensure that any such incidents are fully and properly investigated and that those which raise concerns about any relevant person such as a healthcare professional are recorded on an Occurrence Report.

Legislation requires that every Accountable Officer submits a quarterly

Occurrence Report to the Chair of the Local Intelligence Network. Submission of Occurrence Reports is aligned to scheduled LIN meetings. During the period 1 April 2014 and 31 March 2015 every Accountable Officer submitted an Occurrence Report in each quarter.

An Accountable Officer must submit an Occurrence Report even if there are no concerns to report and the Occurrence Reports are categorised as follows:

1. Nil return: No concerns reported
2. Concerns: The Accountable Officer has reported a concern(s)

The Occurrence Report template also includes sections for the Accountable Officer to record:

- Learning Points arising from an occurrence
- Updates on previous occurrences

CONCERNS

During the period 1 April 2014 – 31 March 2015, of the 72 Occurrence Reports received 25 had concerns recorded.

It is important to note that not all the concerns reported raise issues about relevant person(s). Each Accountable Officer determines which CD issues are to be reported on their quarterly Occurrence Report. Accountable Officers will often use the Occurrence Report and the opportunity of discussion within the LIN to highlight identified system weakness for example and to share their learning.

LEARNING POINTS

The Occurrence Report includes a section specifically for learning points and Accountable Officers are asked to identify potential learning from their incidents and concerns. This could include, for example, changes to practice or protocols which have been introduced by the reporting organisation to strengthen their arrangements.

Learning points are shared and discussed within the LIN. Organisations can therefore learn both about a concern and, wherever possible, learn from these concerns. This supports Accountable Officers, and indeed other Responsible Bodies, deliver continual improvements in relation to the management and use of controlled drugs.

While the majority of learning points have particular relevance to the originating organisation alone, many have application to other Responsible Bodies within the

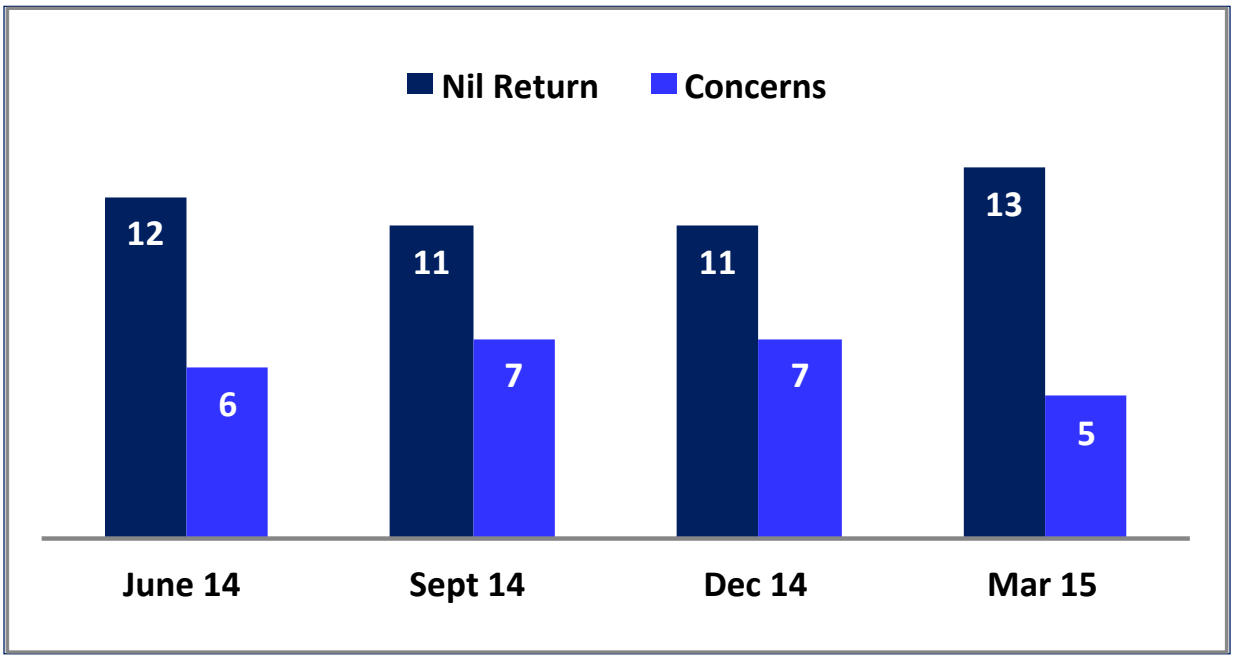
LIN. In addition there are a small number which the LIN considers should be shared more widely. These regional learning points are sent to the Chair of the Medicines Safety Sub-Group for consideration by the Group and dissemination as appropriate.

The HSC Board has used its Medicines Safety newsletters to raise the awareness of health care professionals to CD concerns an example of which can be found through the link below:

http://www.medicinesgovernance.hscni.net/download/primarycare/medicines-safety-matters/prescribers-community-pharmacists/Medicines_Safety_Matters_vol4_issue2_May14.pdf

OCCURRENCE REPORTS BY TYPE

Figure 3



UPDATES PROVIDED BY ACCOUNTABLE OFFICERS AND OTHER RESPONSIBLE BODIES

1 HEALTH & SOCIAL CARE BOARD (HSCB)

SECURE THE SAFE MANAGEMENT AND USE OF CONTROLLED DRUGS

Work continues in the HSCB to secure the safe management and use of controlled drugs by doctors, dentists and pharmacists as outlined below.

GPs

Work is still on-going to increase capacity in order to put in place an inspection schedule which will result in CD inspection visits to practices over a five year rolling programme of visits, to cover all GP practices. This will build on the information gathered during the self-declaration and assessment process, and provide an opportunity to follow-up on any issues identified from that process and any other concerns that may have arisen in the interim.

CD inspection visits to GP practices have been carried out by HSCB staff on a number of occasions during 2014 in response to potential concerns identified as part of routine CD monitoring or adverse incidents reported to the Board. Action plans were developed and reviewed as necessary following the visits.

HSCB guidance around the safe management and use of CDs continues to be promoted to GPs, with key messages being reinforced both regionally and locally as opportunities arise.

COMMUNITY PHARMACISTS

A declaration and self-assessment form was sent to all community pharmacies in February 2015 and this form is subject to review by the Medicines Regulatory Group (MRG). A Memorandum of Understanding has been put in place between MRG and HSCB which sets out organisational and partnership arrangements with respect to monitoring contracted community pharmacies in terms of their legislative requirements pertaining to controlled drugs. The working arrangements between the MRG and HSCB is characterised by regular contact and the exchange of information (subject to all regulatory requirements).

DENTISTS

A Controlled Drugs Self Declaration has been received in 2014 from each dental practice as part of their annual Quality Assurance return. This declaration relates

to their handling and management of CDs, as required by the Accountable Officer regulations. The Quality Assurance form also now includes a piece which allows for ready identification of dentists who are providing conscious sedation to facilitate development of any further monitoring that is required in this area.

MANAGEMENT OF CDS IN THE COMMUNITY

One of the areas of risk in the management of CDs in the community is when they are stored in the patient's home for individual patient use, but are then administered to the patient by nursing staff. A number of incidents have been reported to HSCB and Trusts where CD ampoules or patches appear to have gone missing between nursing shifts, but current recording systems do not lend themselves readily to verification of this data. A regional piece of work was carried out during 2013 and 2014 to develop a Controlled Drug Record Card (CDRC) and supporting guidance and patient information. The CDRC is intended to be used by nursing staff from all organisations to record stock received by, and administered to, patients and will go some way to protecting and providing assurances to nursing staff. The documents have been finalised by the Local Intelligence Network (LIN) and are now going through Trust Drugs and Therapeutics committees to agree implementation.

ADEQUATE DESTRUCTION AND DISPOSAL ARRANGEMENTS FOR CONTROLLED DRUGS

General Medical and Dental practices are advised to return unwanted and out of date controlled drugs to a community pharmacy for destruction, and GPs have been advised to include a section on this in their SOP for the safe management of CDs.

MONITORING AND AUDITING OF THE MANAGEMENT AND USE OF CONTROLLED DRUGS

GPS AND NON-MEDICAL PRESCRIBERS

HSCB pharmacists continue to undertake quarterly monitoring of all HSC prescriptions for controlled drugs (both patient prescriptions and stock orders) and follow up with prescribers where appropriate. All concerns are recorded on a database and discussion of these is encouraged at local team meetings.
An SOP has been developed for the regular monitoring of all privately ordered controlled drugs (for both private stock

requisitions and PCD1 prescription forms). Scans of all private stock requisitions and PCD1 forms are sent to relevant Board staff from the BSO for review and follow-up as needed.

A process has also been established for the ordering of PCD1 forms, to ensure that these are only ordered where there is an identified need and when there are no concerns about the prescriber. Information on the ordering process for PCD1 forms has been sent to all GPs, dentists and community pharmacists and posted on the three practitioner sections of the BSO website/intranet.

DENTISTS

Controlled drug prescribing is monitored on a monthly basis by a Dental Adviser with support from a Medicines Governance Adviser. The Standard Operating Procedure (SOP) for this monitoring has been updated in conjunction with the Accountable Officer to support the work.

COMMUNITY PHARMACISTS

Monitoring is undertaken by the DHSSPS on behalf of the HSCB. Following a concern in relation to alleged diversion of Schedules 3, 4 and 5 Controlled Drugs, a project is currently being undertaken which will test whether routine reconciliation of wholesale records against dispensing claims will strengthen the security of the supply chain.

RELEVANT INDIVIDUALS RECEIVE APPROPRIATE TRAINING

Training continues to be provided to a range of staff on issues relating to CDs. During 2014, the following training was carried out:

- CD Frequently Asked Questions (FAQs) bulletin was issued to GPs, community pharmacists and dentists following the change in legislation around tramadol, when it became a schedule 3 CD in June 2014.
- A Regional Learning Letter was issued to all GPs, Community Pharmacists and Trusts highlighting the risks with prescribing and dispensing of buccal midazolam. This was in response to further adverse incidents being reported which involved buccal midazolam products.
- A letter was issued to all GPs and Community Pharmacists, in response to an adverse incident, advising of the risks of incomplete

cross-tolerance when switching between opioids

- Training on the safe management and use of CDs was provided for the ST3 trainee GPs, facilitated through NIMDTA
- Training on safe dispensing of CDs was delivered to final year pharmacy students as part of High Risk Medicines' training.
- Learning from incidents involving CDs is included in newsletters to GPs and CPs on an on-going basis as required
- CD legislation and relevant CD issues were highlighted at Clinical Governance training for reception staff in the Western area.
- On-going training is provided to HSCB pharmacists on CD-related issues as required
- Practice specific training and guidance on CD related issues, such as SOPs, is provided on an on-going basis as needed to GPs and their staff e.g. in follow-up to CD inspection visit. .The annual dental prescribing newsletter has included articles on various aspects relating to CDs. These publications are sent to all dental practitioners in Northern Ireland and are posted on the dental section of the Business Services Organisation (BSO) website.
- Any Dental Practitioner applying to be on the dental list in Northern Ireland has to attend a "New Starts" information presentation. This includes information on the prescribing of CDs. All new dental graduates who are Vocational Trainees also receive this presentation in the first month of their vocational training year.

MAINTAIN A RECORD OF CONCERNS REGARDING RELEVANT INDIVIDUALS

A database continues to be maintained to allow all CD monitoring and auditing by HSCB pharmacists to be recorded. Additionally, the Accountable Officer keeps a database where all controlled drug concerns and their status are recorded. All prescribing, dispensing and administration errors/concerns that relate to CDs are recorded and managed as adverse incidents by HSCB Medicines Governance and Medicines Management Advisers where necessary. This is to ensure learning and/or more serious concerns are identified and shared as appropriate.

Processes have been put in place for HSCB to work more closely with staff in BSO Counter Fraud and Probity Services around identification of potential fraudulent activity, particularly as it relates to CDs, and to ensure that there are systems in place in general practice and community pharmacy to reduce the risks associated with this.

ASSESS AND INVESTIGATE CONCERNS

After the AO has been advised, any concerns are investigated locally in the first instance by the HSCB pharmacist with support from other Board staff, such as the Medicines Governance Adviser and Medical Adviser, as required (annex 1). Some eighty seven errors/concerns were reported in 2014 compared with sixty eight in 2013 and sixty in 2012. Those that breech the agreed threshold level are reported to the Northern Ireland Local Intelligence Network (LIN) (annex 2).

All concerns are followed up and an action plan is developed where necessary. If the concern is not resolved the Accountable Officer will, either solely or in partnership with other agencies, investigate or prepare a file for referral to the appropriate regulatory body.

TAKE APPROPRIATE ACTION IF THERE ARE WELL-FOUNDED CONCERNS

Action has been taken where appropriate with individual practitioners. Any local or regional learning from these has been identified and shared.

ESTABLISH ARRANGEMENTS FOR SHARING INFORMATION

Each of the organisations' Accountable Officers (AO), as well as regulatory bodies, meets as part of the NI LIN. The group meets quarterly to share information about potential CD offences and potential or actual systems failures. In December 2014, the HSCB took over the responsibility for the LIN, with the chairmanship passing from the DHSSPS to Mr Joe Brogan, who is the HSCB's AO. As part of this new arrangement, HSCB is reviewing the data and information governance arrangements of the LIN to minimise the risks to the Board:

- The HSCB is now responsible for centrally co-ordinating all the Occurrence Reports that are received from member organisations, and sharing these as appropriate. The current infrastructure relies heavily on

paper based mechanisms which are slow and administratively burdensome, and consequently funding has recently been secured to develop a secure database to replace the paper based system. Work is currently underway with Hewlett Packard to develop this electronic secure records management system and database which will ensure the effective operational management of the LIN. This is expected to go live during 2015.

- A revised information sharing arrangement for all organisations involved with the LIN has been drafted and sent to all LIN members for comment. This is currently being finalised and will be sent to all member organisations in the near future.

Training on the revised information sharing arrangements was provided at the December 2014 LIN meeting.

Further details of the LIN membership and arrangements for sharing information are available at (http://www.dhsspsni.gov.uk/index/pas/pas-accountable-officer/pas-lin.htm).

The Health and Social Care Board can provide extensive monitoring information on the use of controlled drugs in primary care and this information has also been shared within the LIN to help inform risk management arrangements

HEALTH AND SOCIAL CARE TRUSTS

There are 6 Health and Social Care (HSC) Trusts in Northern Ireland. Five of these are acute and community HSC Trusts and the sixth is the Northern Ireland Ambulance Service.

2. HSC TRUSTS (ACUTE AND COMMUNITY)

The five HSC (acute and community) Trusts in Northern Ireland are:

- **BELFAST HSC TRUST**

BHSCT continued to review and implement the recommendations from the RQIA review of the management of controlled drugs in hospitals. A community Controlled Drugs policy has been approved by BHSCT D&T. Further work is underway developing a policy for the RBHSC Palliative Care Boxes which will have a regional application. A process for monitoring the usage of all schedules of controlled drugs has been developed. Audits are also conducted to verify the

ordering process of controlled drugs, in particular Schedule 4 and Schedule 5 drugs.

- **NORTHERN HSC TRUST**

The DHSSPS Medicines Inspectorate carried out annual inspections at Antrim, Causeway, Holywell and Mid-Ulster sites. There were no significant deficiencies identified during the inspection at any of the sites but some recommendations were made to further improve processes at the sites as below:

ANTRIM

Currently a wholesale dealer licence is held but in order to ascertain if a DHSSPS CD licence may also be required, any wholesale CD transactions are being reviewed to enable a decision to be made.
The SOP for CD prescriptions should be reviewed after the launch of the new prescription form and on the basis of learning from the MacMillan Unit pilot.
In relation to Scheduled 2 or 3 CDs, the date of supply should be endorsed on the prescription at the time of supply and this should be verified by staff.
Consideration should be given as to whether up-dating the authorised nurse signature lists during the four-monthly Pharmacist led ward CD inspection would save time rather than undertaking as separate exercise.
Consideration should be given to assessing the level of security provided at the reception area (other hospital pharmacy departments have reinforced transfer screens with “speak through hole” as a secure transfer mechanism for order books / medicines. Staff are to be reminded of the need to mark the date of opening on oral liquid medicines.

CAUSEWAY

All discharge CD prescriptions must comply with the regulations. It is acknowledged that the new prescription form is being introduced and will help significantly in this regard.
Any infrequent small supplies of CDs to the Out Of Hours (OOH) Doctor service must fall within the limits allowed by MHRA when no licence is required.
Consideration should be given as to whether up-dating the authorised nurse signature lists during the four-monthly Pharmacist led ward CD inspection would save time rather than undertaking as separate exercise.
Wards should not keep non-stock CDs in their cabinets for longer than is necessary and should return these to pharmacy as soon as possible. Ensure obsolete stock is segregated from live stock.

HOLYWELL

The SOP documents for the pharmacy should be reviewed in the light of the fact that only S4 or S5 substances are managed at the pharmacy and thus the process applicable to S2 and S3 medicines is not relevant.

MID-ULSTER

Prescriptions forms for S2 and S3 CDs must be endorsed with the date and the time of supply.

Consideration should be given as to whether up-dating the authorised nurse signature lists during the four-monthly Pharmacist led ward CD inspection would save time rather than undertaking as separate exercise.

To ensure that pharmacist-led ward CD inspections are carried out at the agreed frequency.

UPDATE ON ACTION PLAN FOR RQIA REVIEW OF THE MANAGEMENT OF CONTROLLED DRUG USE IN THE TRUST

Work is on-going to address the recommendations made by the RQIA:

1. There is currently no designated officer to supply the AO and this is on the directorate risk register

2. In relation to monitoring of controlled drug usage further, Crystal reports have been developed from the JAC pharmacy computer and other software packages are being considered at a regional level

3. In relation to further raising awareness of the abuse potential of controlled drugs in the hospital setting it is hoped to have a LIN police liaison officer to do a presentation in this regard

4. A programme of unannounced observations will be undertaken to ensure that ward Kardexes for controlled drugs are in line with SOPs

5. In relation to appropriate training for medical staff in relation to use and management of controlled drugs a new pharmacy post in medical education is being created which will ensure that this is addressed

6. In order to ensure that appropriate pharmacy resource is available on all wards, further work is being undertaken to ensure that the One Stop Dispensing (OSD) service is extended to remaining wards

7. In relation to patient's own drugs, a new CD register for these CDs has been introduced to ensure appropriate management

8. In relation to the sharing of information when it is felt appropriate – regional guidance is being finalised

The Accountable Officer (AO) attended all four of the meetings held during the 14/15 financial year. In relation to the occurrence reports for the year a total of three concerns were named and a final update of the outcome of a concern from 13/14 was reported.

During the year the responsibility for the management of the LIN was transferred from DHSSPS to the HSCB.

Key Tasks

1. Work is in its final stage with regard to the production of the regional controlled drug LIN guidelines for disclosing names

2. A database is being developed for use by the LIN in terms of receiving occurrence reports and learning updates. Thus, when in place will mean an end to the paper-based reports

3. Guidance for the management of parenteral and transdermal controlled drugs in the community setting by nurses and GPs has been under development and it is hoped to issue in early 15/16

Controlled Drugs Policy

The new Controlled Drugs Policy was launched during the year with a morning seminar on key aspects of the policy being held to facilitate dissemination.

- **Southern HSC Trust**

The Trust's Accountable Officer (AO) attended all four meetings of the LIN during this period.

The Accountable Officer submitted four Occurrence Reports to the LIN. These reports contained three concerns.

During the year the Trust pharmacy staff were trained on the updated controlled drug Pharmacy Standard Operating Procedures.

A new Patient's Own Drug (POD) Controlled Drug register was introduced to the Trust wards and departments.

- **South Eastern HSC Trust**

A number of initiatives relating to CDs were progressed during 2014/15:

Implementation of New CD Legislation

The Misuse of Drugs (Amendment No. 2) and Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern

Ireland) 2014 came into effect on 26th June 2014. This required a few changes to how we manage some medicines in particular tramadol which is now a schedule 3 CD with CD prescription writing requirements. These changes have seen a 37% reduction in the use of tramadol across the Trust.

CD Dashboard

The dashboard to record compliance with the CD SOPs continues to be modified to provide a tool for monitoring improvement in documentation. Pharmacists now enter directly onto the Sharepoint folder. Wards/clinical areas are assigned a pass or fail for compliance with :

- Completion of the CD register
- Managing CD register anomalies
- Completion of the CD Patients Own Drugs (POD) register
- Recording of discharge prescriptions for Schedule 2 CDs
- Ordering of CDs

An overall pass or fail is also assigned to each ward. Clinical Managers have access to these reports and receive a summary for their directorate to allow them to address any concerns with the ward managers/sisters. Compliance has increased from 27% in April 2014 to 57% in Jan 2015. Work continues with ward managers/sister to improve compliance.

RQIA Action Plan

An action plan to address the 15 recommendations from the RQIA Independent Review of the Management of Controlled Drug Use in Trust Hospitals (reported June 2013) was agreed. By 1 April 2015, 12 of the recommendations have been implemented, 1 is in progress and the 2 remaining are dependent on staffing resources.

Observational Audit of CD Administration and Twice Daily Stock Checks

The RQIA review in 13/14 recommended observational audits to ensure compliance with the SOPS for the preparation, administration and recording of CDs and also for the twice daily stock check at ward level. This is now a time limited nurse KPI and data is audited by the ward sister/manager on a monthly basis.

- **Western HSC Trust**

There were four meetings of the LIN throughout this twelve month period. The Accountable Officer (AO) attended all four of these.

The Accountable Officer submitted four Occurrence Reports to the LIN in line with the legislation. In these, a total of 22 concerns relating to the use of controlled drugs were raised. Three of these concerns related to incidents that occurred in March 2015 which were reported to the LIN in May 2015's Occurrence Report. This was an increase from the 18 concerns raised in 2013/14.

All concerns were investigated, changes made to procedures and additional staff training provided as necessary.

No individual's name was shared with the LIN by the Trust's AO during this period.

Key Actions during 2014/15

- Trust Principal Pharmacists met with the Accountable Officer five times during the year to review all incidents related to the management of controlled drugs. This meeting ensures that learning is shared and that each incident has been followed through and closed.

- Trust standard operating procedures (SOPs) for the management of controlled drugs at ward/department level were reviewed and updated in January 2015. This review was carried out by Pharmacy and Nursing staff, taking into account the learning from recent incidents.

- The use of drugs of potential abuse is monitored by the named pharmacist in collaboration with the Ward Manager each month. The use and effectiveness of this process was reviewed during 2013/14 and a revised process was put in place during 2014/15. This includes asking each Ward Manager to sign that the quantity of drugs of potential abuse that was supplied to their ward reflects the level of use.

- The AO has worked closely with the Trust's Responsible Officer during the year with respect to the safe management of controlled drugs.

- The Principal Pharmacist, SWAH/TCH worked with a regional group to develop new guidance for the management of parenteral and transdermal controlled drugs in primary care. Some additional Trust changes were made to this document in collaboration with the Trust's Assistant Director, Nursing Governance and it will be approved for use in the Trust in 2015.

- The AO, in collaboration with the Trust's Assistant Director, Nursing Governance and Assistant Director, Human Resources drafted and piloted tools for risk assessing whether to share the details of relevant individuals with the Regional Local Intelligence Network and also when to remove a relevant individual's name from the regional data base.

- The Trust's AO has worked closely with the AO from the HSCB with respect to incidents relating to the management of controlled drugs in the community/primary care as appropriate. The number of such incidents reported appears to be increasing.

The AO is notified of all controlled drug incidents reported on DATIX. The AO attended three meetings of the Trust's Medicines Governance Working Group during the year to discuss incidents relating to controlled drugs and how learning can be disseminated across the Trust. Pharmacists and Ward Managers have been reminded of the role of the AO and the requirement to notify her of incidents relating to controlled drugs, in line with RQIA recommendations.

A request to increase support for the Accountable Officer was taken through the Acute Directorate's Governance Committee and will be considered as a corporate risk on the Trust's corporate risk register.

External Inspections and Audits

The following external inspections and audits relating to controlled drugs were carried out during the time period.

Regulation and Quality Improvement Authority (RQIA) - Theatres

The RQIA reports for visits to Altnagelvin and South West Acute Hospitals were published in June 2014. They highlighted areas of good practice and made the following recommendations:

1. The Trust should ensure that two nurses or trained personnel witness when the controlled drug is removed from the CD cabinet and both should check the stock balance - implemented.
2. The anaesthetist should record in the CD book the actual quantity administered on each occasion - implemented.
3. The Trust should consider maintaining a list of the sample

signatures of anaesthetists who sign the CD record book – not implemented.

4. The Trust should ensure the CD record book includes for each occasion, the relevant signatures for the disposal of CDs - implemented.
5. The security arrangements for the movement of controlled drugs between theatre and pharmacy when medicines are being hand carried should be reviewed (SWAH) - implemented.

Visit by the DHSSPSNI's Medicines Inspector

Mr Tony Wallace, Pharmaceutical Officer from the DHSSPSNI's Medicines Regulatory Group visited the Trust's three Pharmacy Departments (Altnagelvin, South West Acute Hospital and Tyrone County Hospital) in January 2015. His key recommendations included further updates for standard operating procedures and ensuring pharmacy staff have been trained on the updated SOPs.

Follow-up from RQIA Independent Review of the Management of Controlled Drug use in Trust Hospitals 2013

The Trust has implemented twelve out of fifteen recommendations from the RQIA Independent Review of the Management of Controlled Drug Use in Trust Hospitals. The remaining three recommendations are being progressed actively. These include:

Recommendation 8

Trusts should assure themselves that appropriate training is provided for medical staff in the use and management of all schedules of controlled drugs.

Recommendation 9

Trusts should work towards providing appropriate pharmacy resource into all wards that use controlled drugs.

Recommendation 15

Each trust should confirm its policy for dealing with sharing of personal information when it is felt to be appropriate

3. Northern Ireland Ambulance Service HSC Trust

The Northern Ireland Ambulance Service has deployed morphine for administration by paramedics for the past four years. This has seen a significant benefit in terms of managing patients with moderate to severe pain particularly in the management of cardiac and severe trauma patients. Strict arrangements are in place for the recording of controlled drugs stocks at station level and when the

drugs are in the possession of individual paramedic staff. This system tracks the individual 10mg dose packs from the time of supply to administration or return to station at the end of shift. A system of unannounced inspections continues under the oversight of the MRG, with all of the NIAS premises that hold controlled drugs stocks being reviewed on a rolling basis.

A small number of controlled drug incidents have been recorded during the current reporting period. All incidents were investigated locally and, where appropriate regionally supported, as necessary, by MRG and no further concerns have been identified. Of note, no morphine has been stolen from an ambulance crew at any stage since its deployment.

The procedures for management of medicines within NIAS have been reviewed to take account of recent developments and improvements to supply, delivery and administration processes in light of new clinical guidelines.

4. Hospices (Independent Hospitals)

All four adult Hospices in Northern Ireland plus Marie Curie Community Nursing Services and the Children's Hospice have appointed Accountability Officers.

The Local Intelligence Network (LIN) has continued to meet on a quarterly basis led by the Principle Accountable Officer at the DHPSS and laterally to the HSCB.

The key purpose of the LIN is to share information about the use of CDs and about individuals who give cause for concern. The (LIN) gathers "Occurrence Reports" of significant incidents involving Controlled Drugs these are submitted quarterly by each Accountable officer occurrence reports are discussed at the next LIN meeting where action and learning points are shared and subsequently recorded and analysed.

An annual declaration and self-assessment is undertaken by all Accountable Officers. As Accountable Officers we undertake regular CD audits within our own organisations with some of us using the comprehensive audit templates from Help the Hospices.

There was only one concern and one learning point from all of the hospices within the reporting period, and whilst we cannot be complacent; these figures are indicative of good, rigorous SOPs and audits within the hospice settings. However, it should be noted that we are

smaller organisations than the Trusts with smaller numbers to manage.

In addition we have a duty to inspect and review practices within our organisation. All Standard Operation Procedures (SOPs) have been fully developed and reviewed - these included stock checks and review of procedures governing all stages of the process from ordering through to obstruction of out of date stock.

A rolling education programme has been delivered to all staff to ensure that they understand the current Regulation with regards to Controlled Drugs Management.

5. Independent Hospitals (other than Hospices)

a. Hillsborough Private Clinic

Hillsborough Private Clinic is an Independent Hospital which is regulated by the RQIA.

Medicine Management was reviewed within the clinic by the RQIA in July 2014. All issues identified have been addressed and Policies & Procedures amended to reflect these changes.

Controlled Drugs are supplied by a local Community Pharmacist.

The Clinic holds a small stock of Controlled Drugs, only one locked cupboard. All staff have had their yearly Medicine Management Training which has included Controlled Drugs.

The LIN Meetings have enabled the Clinic to avail of improvements and recent best practice which is shared by all the NHS and Private Clinics and Hospitals.

b. Fitzwilliam Clinic

Fitzwilliam Clinic is an independent hospital regulated by RQIA. There are many similarities to the arrangements within the Independent Hospitals as those within an NHS environment, depending on number of beds and clinical activities. At Fitzwilliam Clinic we do not have inpatient beds so therefore all procedures are done as a day case. We have just one theatre so require minimal range and stock of drugs. We do not have an onsite pharmacy and we have an arrangement with Antrim Area Hospital (AAH) to obtain CDs.

Doctors are self employed and must adhere to our practicing privileges. We have a small team of five nursing staff and, when required, we have other nurses employed utilizing our bank system. All nurses receive Medicines Management Training.

The LIN meetings have been well attended by the AOs from the Independent Hospitals. This has given Fitzwilliam Clinic the opportunity to share CD concerns and promote learning.

c. Ulster Independent Clinic

The safeguarding of patients with regard to controlled drugs is of prime importance across all areas of practice and we feel our involvement and regular attendance at LIN has enhanced this.

Participation in the LIN meetings enables us in the Independent Sector to keep up to date with developments, changes in practice and changes in policy. During the past year we have implemented the re-scheduling of Tramadol and retained CHKS Accreditation.

The sharing of concerns and learning outcomes from incidents throughout Northern Ireland enables us to re-examine practice with a view to making continued improvements.

d. North West Independent Hospital

The North West Independent Hospitals Accountable Officer is its Hospital Director. A representative attends the quarterly LIN meetings and also completes an Occurrence Report for the quarterly periods.

To date, the North West Independent Hospital has had no occurrences to report and is very strict on its protocols for the prescribing, administration and recording of Controlled Drugs within the Hospital.

The Accountable Officer does quarterly checks in all departments e.g. Theatre, Surgical Ward and Pharmacy to ensure all Controlled Drugs registers, order books and receipt books are all recorded properly.

As the North West Independent Hospital is one entity it is much easier to manage and coordinate the use of Controlled Drugs. Controlled Drugs would never be dispensed when discharging a patient.

The North West Independent Hospital's policies and procedures in controlling the use of Controlled Drugs are up to date and meet current legislation.

The reason for the lack of occurrences to report is due to the staff education and stringent compliance within the Hospital.

6. The Department of Health, Social Services and Public Safety

a. Community Pharmacies

A declaration and self-assessment form is issued to all community pharmacies annually. The self-assessment covers all aspects of the management of controlled

drugs including specific written SOPs, staff training, prescribing patterns, diversion, complaints, transport, labelling, date checking and audit checks. The declaration confirms that the pharmacist, to the best of their knowledge and belief, is complying with the legal requirements in relation to controlled drugs. The declaration and self-assessment is reviewed by MRG Inspectors during pharmacy inspection visits.

A Memorandum of Understanding in place between the Department and HSCB allows the formal transfer of information relating to controlled drugs between both organisations. Inspection software has been modified to facilitate communication with the HSCB Business Services Organisation in respect of receipt by the Department of enhanced controlled drug data for use during community pharmacy inspections. This process will begin upon the signing of a data sharing access agreement between the Department and the HSCB Business Services Organisation.

A risk-based inspection process was introduced in April 2011 for the inspection of community pharmacies. In relation to controlled drugs, the inspection process covers: maintenance of the controlled drugs register, safe custody of controlled drugs, diversion of controlled drugs, SOPs for the management of controlled drugs, disposal of out of date and returned controlled drugs, stock audits and a review of the annual declaration and self-assessment form. Any action points are agreed and the completed inspection report is signed by the Inspector and the pharmacist and a copy forwarded to the pharmacist.

Inspections are targeted to be conducted within a (maximum) 36 month cycle and are prioritised following the risk-based inspection. A quarterly report is forwarded to the HSCB Accountable Officer detailing the pharmacies inspected, any controlled drug issues which have arisen and the actions taken to resolve these issues.

b. NIAS HSC Trust

The routine inspection of NIAS stations was introduced in 2011 to review the management of morphine held by the stations. The inspections are carried out by MRG officers who examine both the station records and the personal records of paramedics. These records are used to provide an audit trail for morphine within the station. Each pain pack containing morphine has a unique identification number which is reconciled with the packs received, the packs allocated to individual

paramedics and which packs have been used for patient administration. This is a detailed and robust audit which not only reconciles the number of pain packs received but also their distribution and utilisation to and by the paramedics. The inspection report is signed by the Station Officer and the Inspector and a copy forwarded to the Station Officer and to the NIAS Accountable Officer. Any issues arising are resolved in conjunction with the Station Officer and the NIAS Accountable Officer. Inspections are carried out within a 24 month cycle and are prioritised following the risk-based inspection.

c. Trust Pharmacies

Medicines Regulatory Group (MRG) inspectors conduct a cycle of compliance visits to ensure that management of controlled drugs in the Trust pharmacies complies with legislation and good practice. A cycle of visits to all Trust pharmacies was completed during the reporting period. MRG continues to cooperate with the "Secured by Design" expert Police Officer, referring Trust Pharmacy enquiries in respect of security arrangements when refurbishment of premises is undertaken.

d. Hospices

Again, a cycle of compliance visits by MRG inspectors takes place on a 36 month basis at these facilities. Routine inspections are not due again until 2015. Interim visits are made, when requested by Hospice staff, to witness the destruction of unwanted or date-expired Schedule 2 controlled drugs.

e. Contract Research Organisations

Compliance visits by MRG inspectors, in relation to Misuse of Drugs legislation and associated good practice for the management of controlled drugs, are conducted at two facilities conducting Phase I-II clinical trials. Routine inspections of the establishments were conducted in February and March 2015.

f. Authorised Witnesses

Misuse of Drugs legislation requires that date-expired or otherwise unwanted schedule 2 controlled drugs stock be destroyed only under the supervision and direction of a witness authorised by the Department. A programme for the training and authorisation of witnesses in Trusts and the larger community pharmacy chains continues to be managed by MRG.

7. The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) routinely monitors the management of controlled drugs in relevant registered facilities, through its regulatory activity. Concerns in relation to the management of controlled drugs are discussed with registered providers and when appropriate are referred to the Accountable Officer in the relevant trust.

When dispensing and prescribing issues are reported to RQIA these are referred to the Health and Social Care Board.

Following the outcomes of inspection activity and incidents reported to RQIA, managers and staff were again advised of the importance of administering prescribed controlled drug patches as directed by the prescriber. RQIA has in the past year taken enforcement action, when appropriate, in relation to this poor practice and continues to routinely monitor the administration of these medicines.

During the year RQIA wrote to all relevant registered establishments to advise them of the change in status of some controlled drugs.

Information on guidance available to registered establishments and enforcement action is published on RQIA's website (www.rqia.org.uk).

Appendix 1

Background to the introduction of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

As a result of the actions of Harold Shipman an Inquiry, chaired by Dame Janet Smith DBE, was established which published 6 reports between 2002 and 2005. In the Inquiry's Reports Dame Janet Smith considered the systems for the management and regulation of controlled drugs, together with the conduct of those who operated those systems.

The Inquiry identified some key strengths within the arrangements which already existed in Northern Ireland. These included an acknowledgement of the benefits of the centralised arrangements which were integrated within the Department of Health, Social Services and Public Safety ("the Department") providing expertise of a multi-disciplinary nature and integration and collaboration with other professional bodies and investigation/enforcement authorities.

The significant changes which have since been made in both governance and legislation surrounding the management and use of controlled drugs have sought to build on these existing governance arrangements.

Legislative changes made include:

- Introduction of Health Act in 2006
- Amendments to Misuse of Drugs Regulations (Northern Ireland) 2002
- Introduction of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (the Regulations)

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 came into operation on 1 October 2009 and apply to all healthcare settings and individual practices where controlled drugs are used covering activities such as prescribing, administering, storage, transportation and disposal.

These arrangements were designed to:

- Improve systems for managing and identifying concerns about controlled drugs
- Provide comprehensive and co-ordinated arrangements for monitoring and inspecting
- Establish a mechanism to support collaboration and information sharing

Underpinning these improvements was the determination that they would not compromise clinical care and patients' access to this care.

Accountable Officers

The Regulations identified the organisations (Designated Bodies) which were required to nominate individuals, known as Accountable Officers, who would be responsible for the management and use of controlled drugs in their organisation. The Designated Bodies (DBs) prescribed by the legislation are as follows:

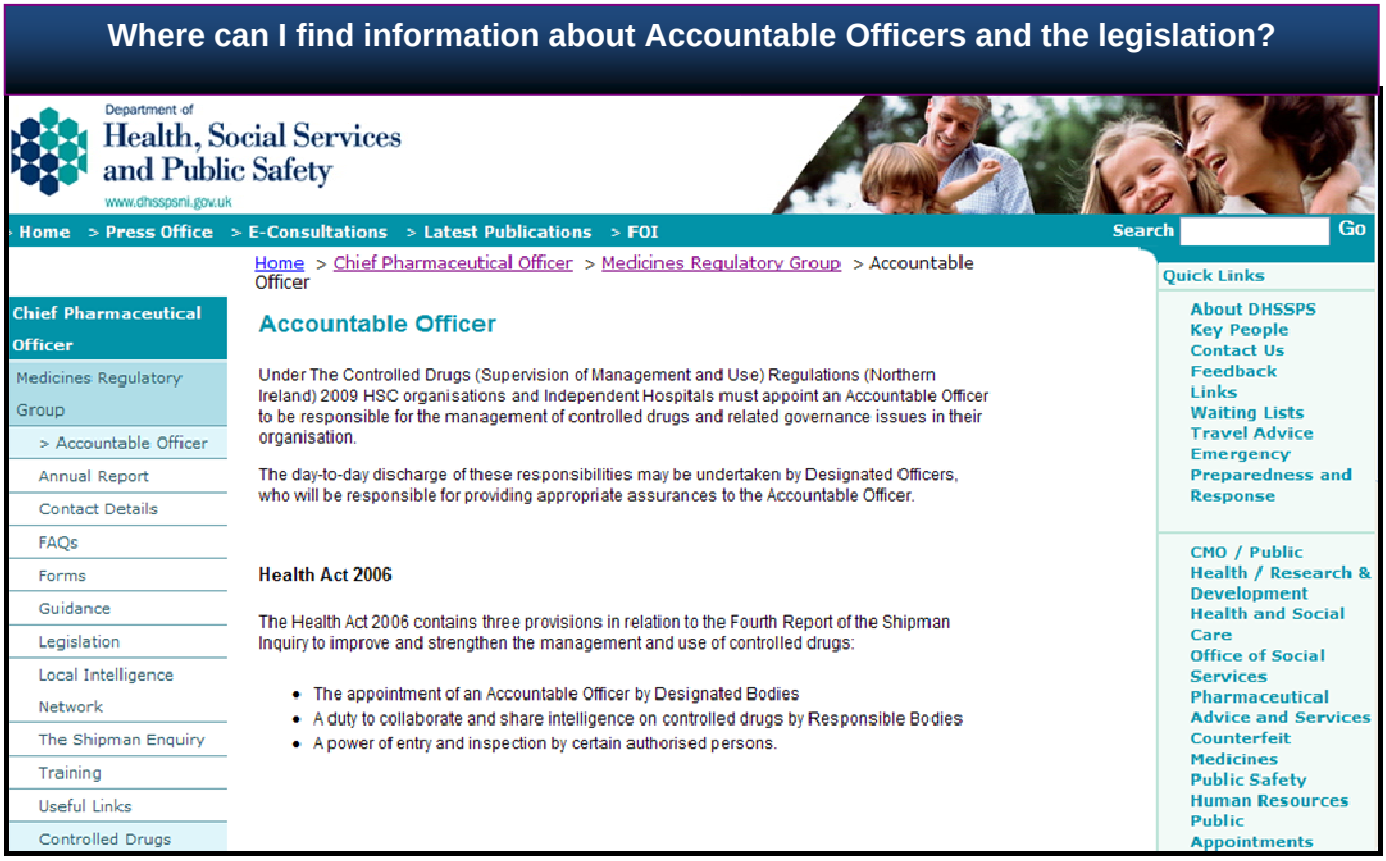
- the Board (HSCB)
- a HSC Trust
- Northern Ireland Ambulance Service (NIAS)
- an Independent Hospital.

Accountable Officer Website

A section of the Pharmaceutical Advice and Services Departmental website has been dedicated to support the work of the Accountable Officers. Responsibility for some of this content will transfer to the Health and Social Care Board during 2015.

The Department will continue to maintain the list of Accountable Officers which provides the name, address, telephone number and e-mail address for each Accountable Officer and can be found at: www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm

Where can I find information about Accountable Officers and the legislation?



The Local Intelligence Network

The concept of a Local Intelligence Network (LIN) was introduced to increase collaboration and promote information sharing between healthcare organisations, amongst others, about the use of controlled drugs and about individuals who give cause for concern.

The Northern Ireland Local Intelligence Network

There is a single LIN within Northern Ireland which meets quarterly.

The LIN is attended by Accountable Officers, representatives of the regulators, the Police, the Department and the Counter Fraud Unit of the Business Services Organisation (BSO), collectively known as Responsible Bodies.

Accountable Officers submit their quarterly Occurrence Report to the Chair of the LIN and concerns arising from these reports are shared within the confines of the confidential LIN meeting. Organisations can share well-founded concerns and, wherever possible, learn from these concerns. Designated Bodies are also encouraged to share good practice within this arena. Terms of Reference can be accessed at the following link: www.dhsspsni.gov.uk/lin-terms-of-reference.pdf

Guidance

The Department developed a range of guidance documents to promote the safe and effective use of controlled drugs in healthcare organisations. These include guides to good practice which were developed for the secondary care sector in 2009 (updated in August 2012) and the primary care sector in 2010 (updated in May 2013). These provide background to the Regulations and take account of legislative changes and developments in professional practice and accountability which have arisen as a result of the Shipman Inquiry's Reports.

Guidance on 'Managing and Sharing Concerns':www.dhsspsni.gov.uk/managing-and-sharing-concerns.pdf and 'Safer Management of Controlled Drugs - A Guide to Strengthened Governance Arrangements in Northern Ireland were revised in September 2013.

All guidance documents can be found on the Department's Accountable Officer website.

Appendix 2

Number of Meetings attended by Individual Bodies (out of a possible 4)

Designated Bodies	
Name	**Number of Meetings Attended**
Belfast HSC Trust	4
Northern HSC Trust	4
Southern HSC Trust	4
South Eastern HSC Trust	4
Western HSC Trust	4
Northern Ireland Ambulance Service	2
Regional HSC Board	4
Fitzwilliam Clinic	2
Foyle Hospice	4
Hillsborough Clinic	4
Kingsbridge Clinic	3
Marie Curie Hospice	4
North West Independent Hospital	2
Northern Ireland Children's Hospice	3
Northern Ireland Hospice	4
St John's Hospice Newry	4
Ulster Independent Clinic	4
Counter Fraud Unit of BSO	4
Department of Health, Social Services and Public Safety	4
General Medical Council	2
Health and Care Professions Council	2
Nursing & Midwifery Council	1
Pharmaceutical Society of Northern Ireland	0
Police Service of Northern Ireland	4
Regulation & Quality Improvement Authority	3