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

The Accountable Officers' Report

1 January 2012 - 31 December 2012

March 2013

Contents

Introduction

This is the third report of the Accountable Officers (AOs) in Northern Ireland concerning the governance of controlled drugs. The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. 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 during the year 2012.

While the report provides an overview of the Northern Ireland situation it also recognises the position of AOs 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. AOs are answerable to the senior management within their own organisation for implementing the requirements arising out of the Regulations[1]. This report, in conjunction with each organisation's own internal reporting mechanisms, will support AOs in providing the necessary assurances to their senior management team or Board. Background to The Regulations can be found in Appendix 1.

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

Accountable Officers

Within Northern Ireland there were, on 31 December 2012, 18 Designated Bodies with a total of 17 Accountable Officers. The number of Designated Bodies increased from 17 to 18 in the 3rd quarter of 2012 with the registration and opening of a new childrens' hospice. The number of Accountable Officers remains unchanged as the Accountable Officer for that organisation is jointly nominated by a second Designated Body.

Figure 1

The Department of Health, Social Services and Public Safety (the Department) continues to maintain the register of Accountable Officers. Each Designated Body is responsible for informing the Department of the removal and appointment of an Accountable Officer. During 2012 there were changes to the nominated Accountable Officers for 2 Designated Bodies. Accountable Officers are periodically asked to check the accuracy of their details held on the Department website contact list. An up-to-date contact list can be found on the Accountable Officer section within the Department website and accessed through the following link: http://www.dhsspsni.gov.uk/accountable-officer-contact-list.pdf.

A contact list is also held for the representatives of all the Responsible Bodies. This list includes contact details and job title of the individuals representing organisations such as the regulators in addition to those of the Accountable Officers.

Presentations

AOs and other Responsible Bodies continue to make presentations to the LIN about their organisation where they describe matters such as the types of services provided the extent to which controlled drugs are used within that organisation and the impact of the Regulations. This continues to promote a better understanding of their individual roles, responsibilities and processes and to further the collaborative work of the LIN.

Local Intelligence Network (LIN)

1	18	17
Local Intelligence Network	Designated Bodies	Accountable Officers

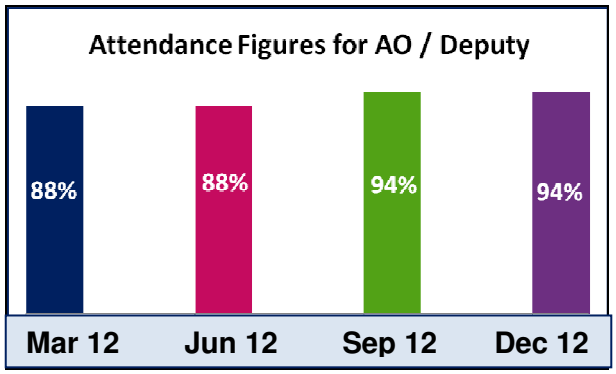
Review of the Period

1 Jan 2012 - 31 December 2012

Meetings

The Local Intelligence Network met on four occasions between 1 January and 31 December 2012 and attendance by AOs or their deputies is shown in Figure 2

Figure 2



Occurrence Report

Organisations are required to make and to keep records of controlled drug incidents which happen both in their organisation and in any organisation providing services on their behalf. 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 Local Intelligence Network meetings. During the period 1 Jan 2012 and 31 December 2012 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 2012, 24 of the 70 Occurrence Reports received had concerns recorded.

It is important to note that not all reported concerns raise issues about relevant person(s). Practice and system breaches are often recorded as concerns. This provides opportunity for all Designated Bodies to reflect on the likelihood of a similar occurrence in their organisation(s) and thereby to strengthen local systems.

Learning Points

The Occurrence Report includes a section 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 Local Intelligence Network. 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 all Designated Bodies within the Local Intelligence Network. In addition there are a small number which the Local Intelligence Network considers should be disseminated more widely. During 2012

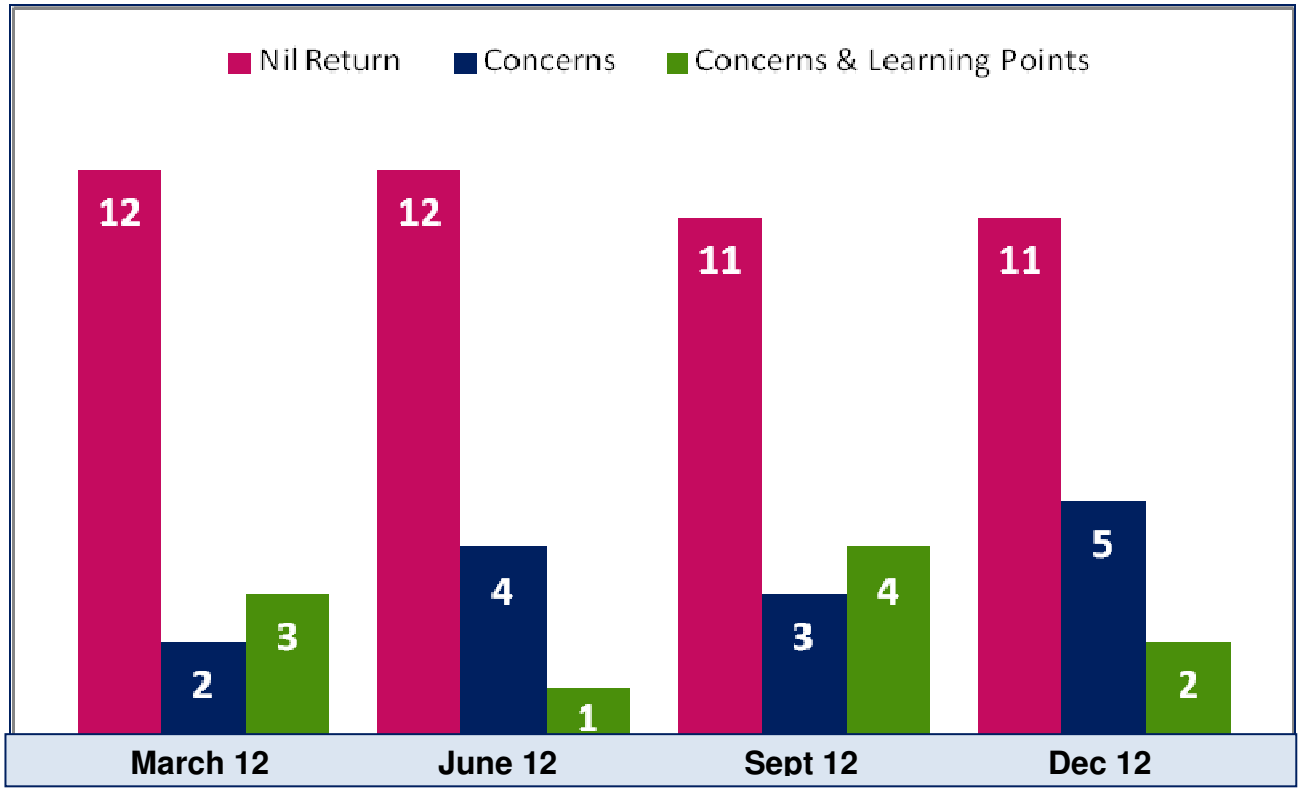
the Local Intelligence Network has debated how these regional learning points should best be managed.

It was therefore agreed that the most effective and efficient way to share medicines safety related learning would through engagement with the multi-disciplinary regional forum provided by the Medicines Safety Sub-Group. A sub-group of the Local Intelligence Network was set-up in December 2012 to categorise all learning points recorded since October 2009 and to establish a threshold for submission to Medicines Safety Sub-Group.

Figure 3

Occurrence Reports by Type

N.B. The number of Designated Bodies increased from 17 to 18 in 3rd quarter 2012



Updates provided by Accountable Officers and other Responsible Bodies

Health & Social Care Board (HSCB)

SUMMARY OF WORK COMPLETED DURING 2012

1. Secure the safe management and use of controlled drugs

GPs

All General Practitioners (GPs) and Out Of Hours (OOHs) practices were sent a declaration and self-assessment form during 2011 to assess whether they had appropriate systems and processes in place to ensure the safe management of controlled drugs. Their responses have now all been collated and assessed: non-respondents have been contacted with a further request to return their form; all forms have also been assessed, and any outstanding issues or matters of concern addressed with the practice for further action and assurance of completion. Currently there are a small number of practices who have either still not returned their forms or have outstanding issues (see Figure 4 below). The most common outstanding issues are lack of a Standard Operating Procedure (SOP) or process to make locums aware of practice controlled drug arrangements. These practices will now be referred to Local Management Teams for discussion about the most appropriate way to manage them.

Figure 4 Summary of controlled drug self-declaration and assessment responses by GP practices in Northern Ireland

LCG area	No. GP practices	No. of responses from practices (%)	No. practices with queries (%)	OOHs return received (Y/N)
Belfast	87	85 (98)	2 (2)	Y
SE	54	54 (100)	8 (15)	N
Northern	78	77 (99)	4 (5)	Y
Southern	77	77 (100)	11 (14)	Y
Western	56	55 (98)	1 (2)	Y
NI	352	348 (99)	26 (7)	4 out of 5

A template for follow-up inspection visits to practices has been developed and piloted in a number of practices. This will build on the information gathered during the declaration and self-assessment process, and provide an opportunity to follow-up on any issues identified from that process. Roll-out of this work will take place during 2013-14, with visits being undertaken by HSCB pharmacists. It is envisaged that all practices will be visited over a 5 year period.

A meeting took place with locum representatives to discuss the issues around the safe management and use of controlled drugs by locums and sessional doctors, and a follow-up meeting is planned with Northern Ireland Medical and Dental Training Agency (NIMDTA) to agree how these issues should be managed. A controlled drug guidance summary document primarily aimed at locums and sessional GPs has also been drafted as a result of the meeting.

Community Pharmacists

A declaration and self-assessment form is issued to all community pharmacies annually and reviewed by Inspectors of the Medicines Regulatory Group (MRG) of the Department during pharmacy inspection visits. A Memorandum of Understanding has been put in place between MRG and HSCB. This has been operational since April 2011 and has allowed the formal transfer of information between both organisations.

Dentists

HSCB worked with the Regulation and Quality Improvement Authority (RQIA) in 2011 and had input to a dental questionnaire to start to look at the management of controlled drugs by dentists in Northern Ireland. The results from this were incomplete and an HSCB dental declaration and self-assessment was therefore developed by Dental Advisers and Medicines Governance Advisers (MGAs). This was sent to all dentists towards the end of 2012 to seek an assurance that adequate systems are in place for the management and use of controlled drugs. To date, there has been a 70% response rate and non-responders are being followed up. These returns will be reviewed and an action plan around visits or other follow up will then be agreed.

2. Adequate destruction and disposal arrangements for controlled drugs

General medical and dental practices have been advised to return unwanted and out of date controlled drugs to the supplying pharmacies for destruction. GPs have been advised to include a section on this in their SOP. However all HSCB Medicines Governance Advisers have now been trained and accredited to witness the destruction of expired controlled drugs. As part of the programme of follow-up visits to practices outlined above, any expired controlled drugs will be identified by HSCB pharmacists, in conjunction with the prescriber, and arrangements made for the Medicines Governance Adviser to witness the destruction of these controlled drugs.

For sessional GPs, locums or those not attached to a specific practice, discussions are underway with NIMDTA to agree the most appropriate way to manage supervised destruction and put arrangements in place to facilitate this.

3. 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 HSCB prescriptions for controlled drugs (either patient prescriptions or 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. The HSCB SOPs governing this monitoring process have recently been updated, including the provision of guidance about the monitoring of non-medical prescribing of controlled drugs. Training on the revised guidance has been provided to all staff. Work is still proceeding to include Electronic Prescribing and Eligibility System (EPES) data in the routine monitoring of controlled drugs.
GPs are also asked to provide assurances about their controlled drug prescribing in their declaration and self-assessment form.

Monitoring of privately ordered controlled drugs is also now undertaken regularly, at least quarterly, with scans of all PCD1 forms sent to relevant HSCB staff (to include Accountable Officer and deputy) for review and follow-up as needed.

Dentists

A monthly review and follow-up of dental controlled drug prescriptions continues to operate in the HSCB. A preliminary assessment of dental midazolam prescribing was undertaken in 2012 and the process for further and on-going review will be determined, based on the information obtained from the dental declaration and self-assessment.

Community Pharmacies

This is undertaken by the Department on behalf of the HSCB.

4. Relevant individuals receive appropriate training

A number of learning resources were developed and shared during 2012:

- Newsletter highlighting learning from incidents involving controlled drugs was issued to GPs and Community Pharmacists. Articles are included in on-going newsletters as required
- Dental newsletter highlighting relevant issues around controlled drug prescribing
- A letter of clarification on when a PCD1 form should be used
- New controlled drug legislation and relevant controlled drug issues highlighted at Clinical Governance training for reception staff
- Training on appropriate controlled drug prescribing provided to dentists as part of overall training on dental prescribing
- Ongoing training is provided to HSCB pharmacists on controlled drug -related issues as required
- Practice specific training on controlled drug related issues such as SOPs is provided as needed to GPs and their staff.

5. Maintain a record of concerns regarding relevant individuals

A database continues to be maintained to allow all controlled drug monitoring and auditing by HSCB pharmacists to be recorded. Additionally, the Accountable Officer keeps a database where all controlled drug concerns and their status is recorded. All dispensing errors that relate to controlled drugs are recorded and managed as adverse incidents by the HSCB Medicines Governance Advisers.

6. Assess and investigate concerns

After the Accountable Officer has been advised, concerns are investigated locally in the first instance by the HSCB pharmacist with support from other HSCB staff, such as the Medicines Governance Adviser and Medical Adviser, as required. Those that breach the agreed threshold level are reported to the Local Intelligence Network.

Where there are concerns, these are followed up and an action plan is developed. 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.

7. 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.

Controlled Drug Prescribing Data

Controlled drugs are divided into five Schedules, which dictate the degree to which a controlled drug's use is regulated. The Schedule in which a controlled drug is placed depends upon its medicinal or therapeutic benefit balanced against its harm when misused. Schedule 1 controlled drugs are subject to the highest level of control, whereas Schedule 5 controlled drugs are subject to a much lower level of control.

Supplies of controlled drugs for individual patients are written on a prescription and these prescriptions, both Health Service and private, are routinely monitored to identify concerns and trends. The vast majority of controlled drugs are prescribed by Health Service practitioners with very little being prescribed privately.

Figure 5 illustrates that, overall, the level of prescribing of controlled drugs in primary care has shown very little increase since 2010. This is against a background of increased demand to meet the needs of chronic pain management in a growing and ageing population, the increasing involvement of specialists in the management of pain conditions and an increase in the management of pain in a primary care setting.

Figure 5

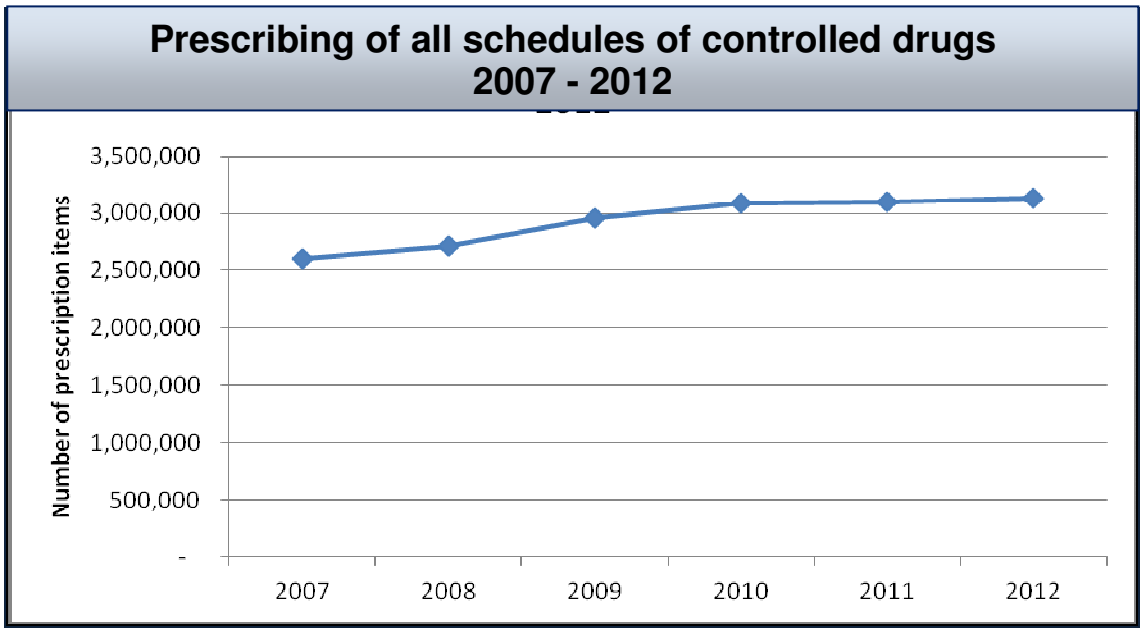


Figure 6 shows the overall prescribing broken down further, and indicates that prescribing of Schedule 2 has increased and Schedule 3 has decreased.

Figure 6

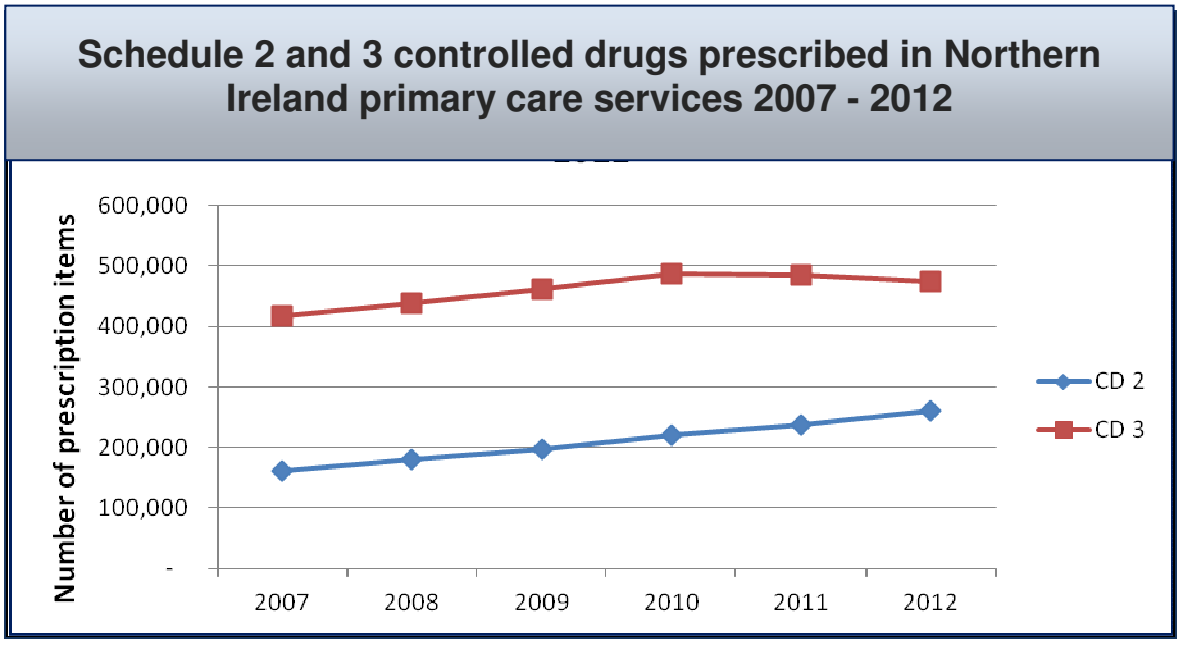
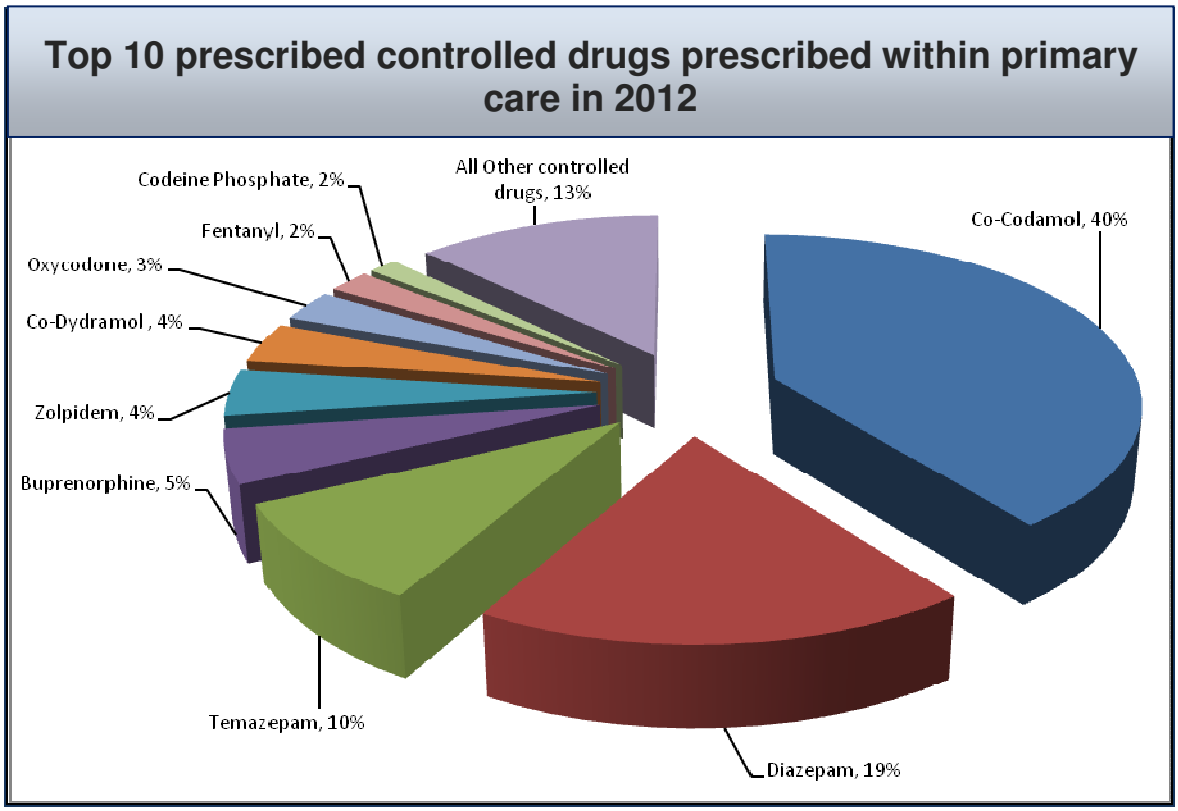


Figure 7 shows the controlled drugs that are most commonly prescribed in primary care. The profile of prescribing for 2012 is very similar to that for 2011

Figure 7



Benzodiazepine and Z drug prescribing

The graphs below show benzodiazepine and Z drug prescribing in terms of Northern Ireland Prescribing Units (NIPUs). These units are used to weight prescribing information to allow the comparison of practice/Local Commissioning Group (LCG) information. The weighting is applied by taking account of the gender and age of all patients on the patient list for each practice.

Benzodiazepines and Z drugs are used to treat conditions like anxiety and insomnia. They should usually only be prescribed for short courses of treatment. The Northern Ireland trend shows that overall the prescribing levels of benzodiazepines in primary care continue to reduce slightly (Figure 8). However the trend of prescribing levels of Z drugs in primary care has remained fairly constant over the past 2 years. (Figure 9).

Figure 8

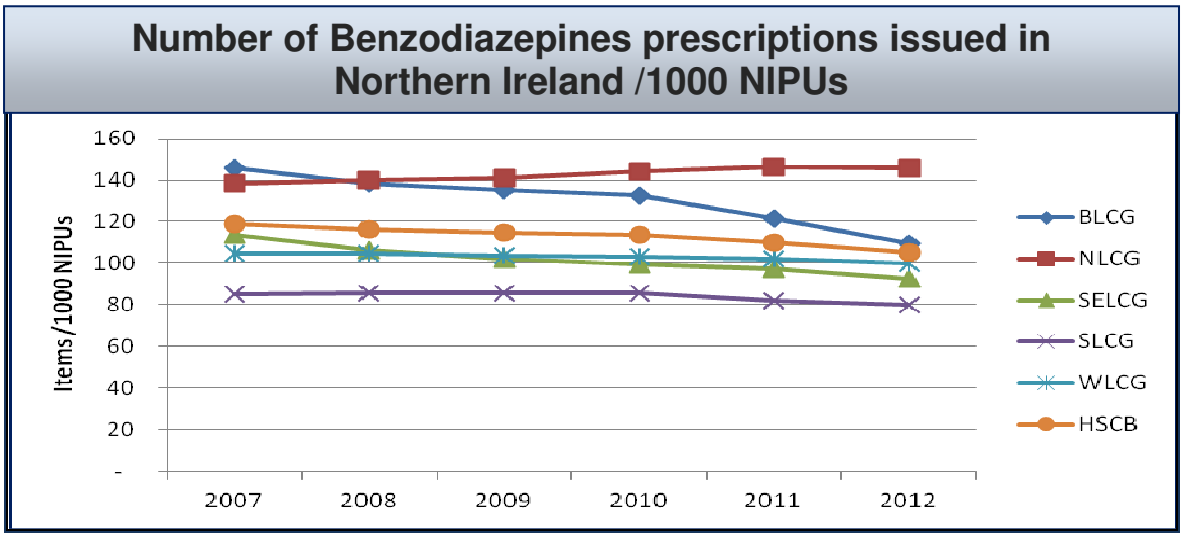
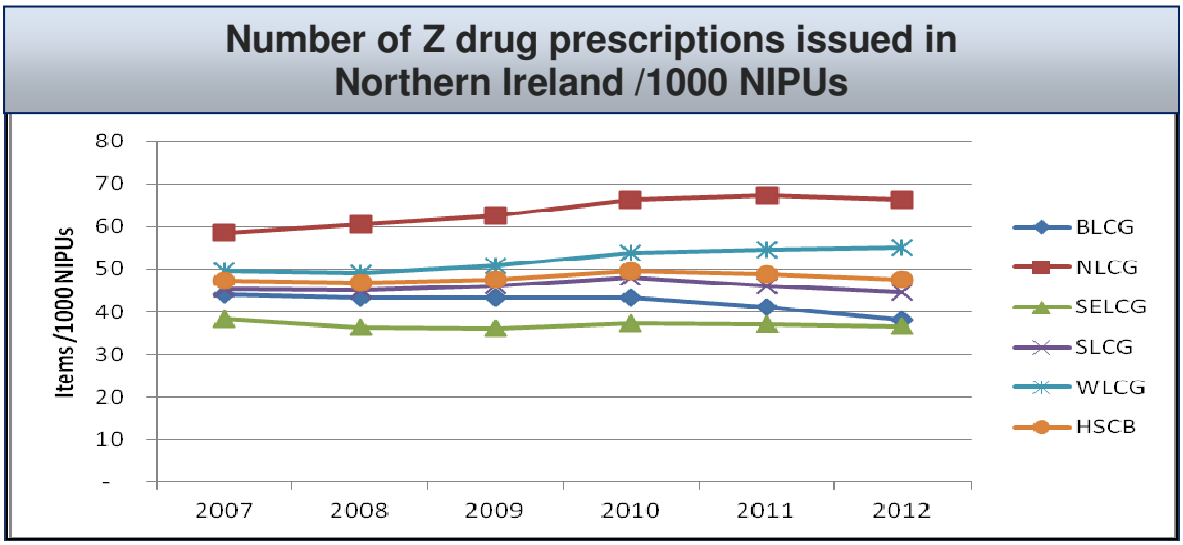


Figure 9

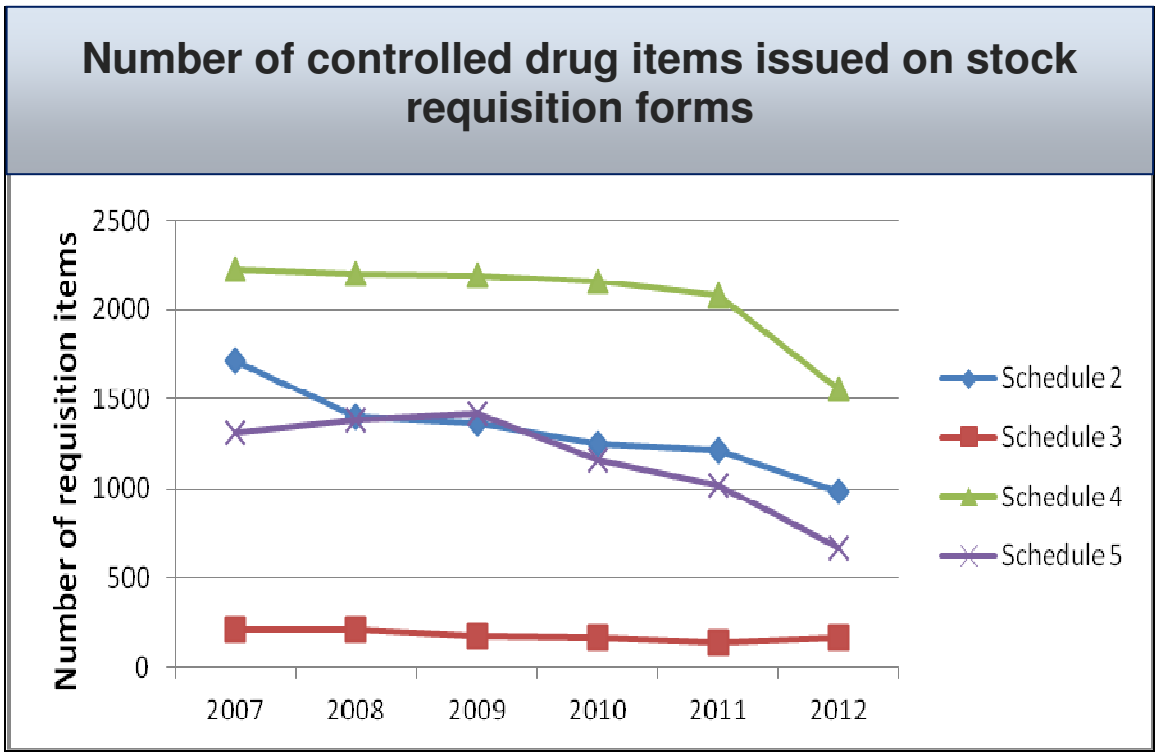


Stock Requisitions

Practitioners such as doctors can obtain a stock of controlled drugs for use in their surgery or on home visits.

General Practitioners use the HS21S requisition (stock order) form to obtain stock of Schedule 2 and 3 controlled drugs from registered community pharmacies. It is interesting to note that there has been a marked reduction in the overall number of controlled drugs issued on stock requisition forms in 2012. In addition to CD prescriptions for named patients, the Board also monitors these stock orders.

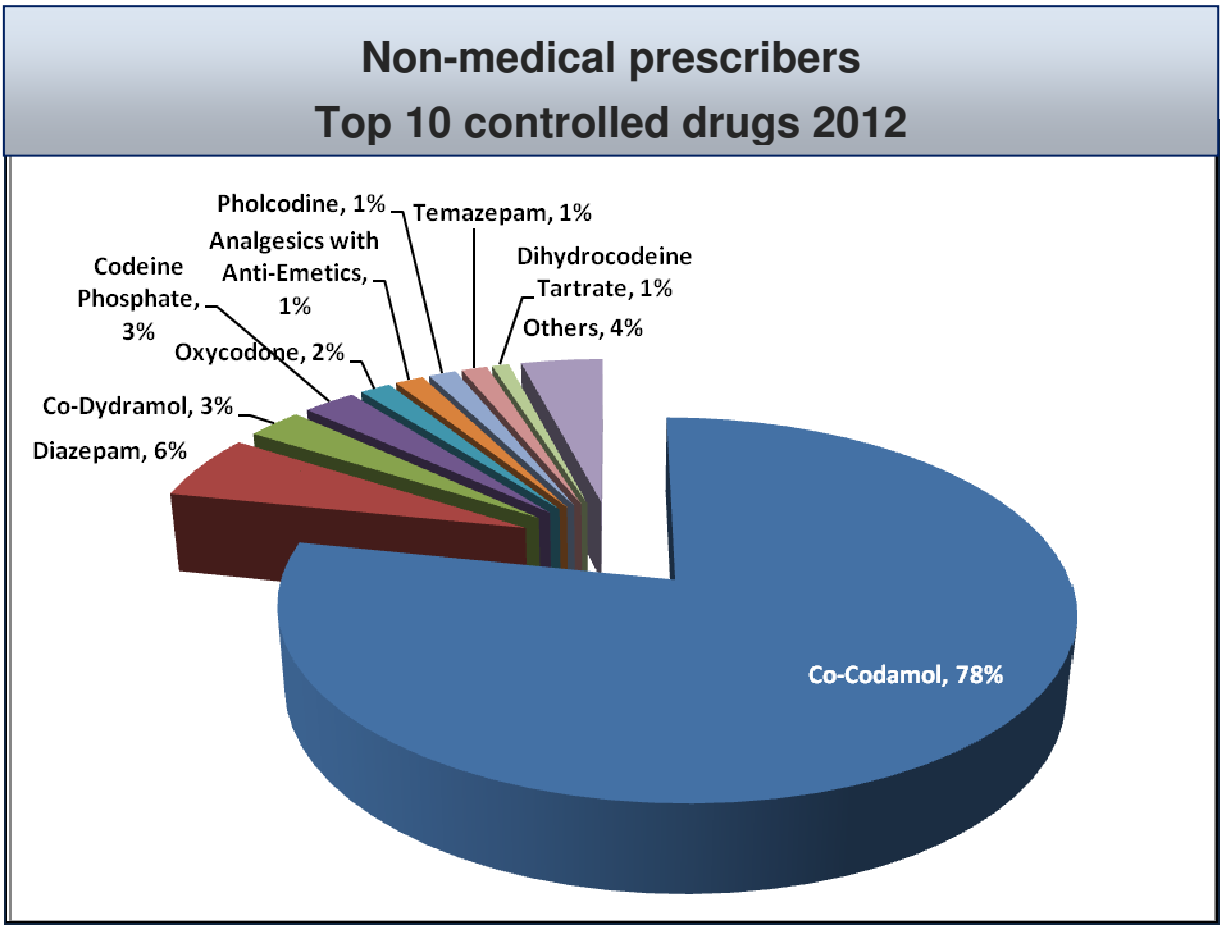
Figure 10



Non-medical prescribers

Changes to Misuse of Drugs Regulations in May 2012 mean that nurse independent and pharmacist independent prescribers are now able to prescribe any controlled drug in Schedule 2, 3, 4 or 5. The chart above shows the CDs prescribed by nurse and pharmacist prescribers during 2012. (Figure 11)

Figure 11



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.

1. HSC Trusts (acute and community)

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

- Belfast HSC Trust
- Northern HSC Trust
- Southern HSC Trust
- South- Eastern HSC Trust
- Western HSC Trust

Regular standardised audits of quality and accuracy of controlled drug registers at ward level are undertaken by pharmacists on the acute sites. Pharmacy continues to work with their nursing and medical colleagues to improve compliance with regard to record-keeping and Trust SOPs.

The five Trusts have now moved to the same modern pharmacy IT system for Northern Ireland. This has allowed some Trusts to progress with drugs of potential abuse reporting to identify excessive or unusual prescribing.

Some examples of good practice include:

- BHSCT has appointed a lead pharmacist for controlled drugs which has been beneficial in progressing with the current gaps in compliance and driving consistency throughout the Trust.
- The WHSCT has a pharmacy controlled drug monitoring group which meets to review incidents, concerns and share learning. The Accountable Officer attends the Trust's Medicines Governance Working Group every two months to discuss incidents relating to controlled drugs, the results of investigations and how learning is being disseminated. The new South West Hospital in Enniskillen opened in June 2012 and the Designated Officers and Accountable Officer ensured that controlled drugs were managed appropriately during the move. Systems were also put in place to manage controlled drugs during the fire and flood in Altnagelvin Hospital in October 2012.

RQIA is undertaking a controlled drugs review within the acute hospital sites. The purpose of the review is twofold.

- To assess that systems and processes in place within Trusts for the safe and effective management of controlled drugs are robust and working effectively.

- To assess the effectiveness of communication and partnership working between relevant bodies within the Local Intelligence Network (LIN)

A report is expected in 2013/14 which should identify gaps in the system as well as areas of good practice.

2. Northern Ireland Ambulance Service HSC Trust

Intravenous morphine for administration by Northern Ireland Ambulance Service (NAIS) paramedics was introduced at the end of March 2011. The procedures relating to the storage, use and associated documentation of controlled drugs by ambulance staff were developed by NIAS in conjunction with the Medicines Regulatory Group (MRG) of the Department and the UK Home Office. The use of morphine by ambulance crews has seen significant clinical benefit for patients although the required documentation trail has impacted on paramedic workload, particularly at the start and finish of shifts. However the procedures put in place were designed in such a way that adherence to them would offer staff a significant degree of protection in the event of any adverse incident relating to controlled drugs. To date, no controlled drugs have been lost by NIAS crews, and despite two attempts by members of the public, no controlled drugs have been stolen from ambulance vehicles or stations. Genuine errors have occurred in the recording of controlled drug stocks but the robust procedures have allowed these to be identified and a rapid resolution achieved.

Since 2011 members of the MRG have performed unannounced inspections of all 32 NIAS sites where controlled drugs are stored. No significant issues were identified during these inspections although NIAS did self-report an issue relating to the posting of a controlled drugs cupboard code in a public area. The latter was swiftly resolved.

The current policy and procedures for the management of medicines by NIAS is presently under review and will incorporate learning from our experience to date.

Hospices (Independent Hospitals)

During 2012, there has been little overall change regarding the management of controlled drugs in the five hospices. However, it is worth mentioning that a second facility attached to the Children's Hospice, Horizon House West, has now opened in Fermanagh and the Accountable Officer in Horizon House also has responsibility for the safe management of controlled drugs in this establishment. At the time of this annual report there are no controlled drugs stored in Horizon House West.

The hospices are regulated by the RQIA and continue to strive to maintain robust internal systems demonstrating compliance with the legislation pertaining to the safer management of controlled drugs.

Alongside this the individual Accountable Officer for each hospice continues to develop their role to face the challenges, specific to their organisation, encountered on a daily basis in the safer management of controlled drugs, with patient safety being paramount at all times. This involves working closely with all staff involved in the management of controlled drugs – pharmacists, prescribers, medical and nursing staff – to actively support the safer management of controlled drugs and to consider innovative approaches that may further enhance their safe management and use within hospices.

The Accountable Officers from the hospices have had good attendance at the quarterly Local Intelligence Network meetings in 2012 and during this period there has only been one concern reported in the occurrence reporting activity. Reflection on previous years indicate that there has been a reduction in the number of concerns reported:

While we are confident the five hospices in the region are safely managing controlled drugs, there is however no room for complacency and the robust systems and processes in place, including updated SOPs, needs to be maintained. Improvement in the safer management of controlled drugs within the hospice settings is undoubtedly attributed to the learning acquired at the Local Intelligence Network meetings.

In the past year the five hospice Accountable Officers made presentations at the Local Intelligence Network meetings, informing those in attendance about their individual organisation and the impact their role and the legislation has had on the safer management of controlled drugs, and the benefits gained

Hospices (Independent Hospitals) (contd)

from the inception of Accountable Officers and the Local Intelligence Network.

As well as continuing with regular internal controlled drug audits and RQIA Pharmacy Inspections, the five hospices have all had their recent controlled drugs inspection by the Department, in November 2012, resulting in only a small number of recommendations, an improvement from the previous inspection in 2010.

In conclusion, the Accountable Officers in the hospice settings believe there has been improved clinical practice in all aspects of controlled drug management to include, prescribing, ordering, delivery, receipt, administration and destruction of controlled drugs. This can be attributed to greater awareness, adherence to the legislation, and the benefits gained from the Local Intelligence Network, to include:

- collaborative working with all organisations in the Local Intelligence Network;
- agreed regional guidance on operational matters;
- sharing good practice alongside concerns regarding the use and possible abuse of controlled drugs;
- shared learning from all concerns reported;
- promotion and sharing of best practice with regard to monitoring and audit processes;
- improvement in training provision and policy development; and
- having a safe, confidential environment within the Local Intelligence Network meetings which facilitates openness and honesty.

Independent Hospitals (other than Hospices)

Independent Hospitals (3 clinics and 2 hospitals) are regulated and inspected by RQIA. There has been one change in Accountable Officer representation during 2012.

Whilst the Independent Hospitals include the same core elements in their policies and procedures for the management of controlled drugs, each one has adapted these to reflect the environment in which they operate.

Two of the independent hospitals are not 24 hour facilities and use controlled drugs in the operating theatre only. The Regulations state that the Accountable Officer must not routinely supply, administer or dispose of controlled drugs as part of their duties. This presents a particular challenge for Accountable Officers of the smaller organisations to provide the necessary separation from day to day controlled drug activities.

In facilities without a pharmacy department policies and procedures have been reviewed to ensure safe delivery and receipt of controlled drugs from local pharmacies.

The safeguarding of patients with regard to controlled drugs is of prime importance across all areas of practice and the Independent Hospital Accountable Officers feel that involvement with LIN has enhanced this.

Participation in LIN meetings enables Accountable Officers in the Independent sector to keep up to date with developments.

The sharing of concerns and learning outcomes from incidents across Northern Ireland supports continual improvement of all organisations and provides each organisation with the opportunity to reflect on their practice and procedures.

The Department of Health, Social Services and Public Safety

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 Inspectors of the Medicines Regulatory Group (MRG) of the Department during pharmacy inspection visits. A Memorandum of Understanding in place between MRG and HSCB allows the formal transfer of information relating to controlled drugs between the both organisations.

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 completed within a 36 month period 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.

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. In addition there is a detailed reconciliation of the stock held by the station. The inspection report is signed by the Station Officer and the Inspector and a copy forwarded to the Station Officer and the NIAS Accountable Officer. Any issues arising are resolved in conjunction with the Station Officer and the NIAS Accountable Officer. Inspections are carried out on a 24 month cycle and are prioritised following the risk-based inspection.

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. The cycle of visits which begun in late 2011 was completed during 2012. Inspectors were also consulted in relation to the construction of the controlled drugs storage facility at the new South West Acute Hospital pharmacy. MRG cooperated with the PSNI "Secured by Design" expert officer, the contractors and Western Board professional staff to arrive at a novel solution which has been deemed to exceed the security expectations in relation to the 1973 Misuse of Drugs Safe Custody Regulations.

Hospices

Again, a cycle of compliance visits by MRG inspectors takes place at these facilities. Such visits were conducted in the latter half of the reporting period, including at the Northern Ireland Hospice's temporary facility at the Whiteabbey Hospital site.

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, were conducted at two facilities conducting Phase I-II clinical trials during the inspection cycle, end of 2011/beginning of 2012.

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.

The Police Service of Northern Ireland

The procedure for Accountable Officers to report incidents to the Police Service of Northern Ireland (PSNI) is improving. The PSNI would welcome earlier referrals in order to maximise all evidence gathering opportunities. We would welcome the immediate reporting of any suspicious incidents as soon as preliminary investigations indicate a crime may have been committed.

The PSNI acknowledge that further work is required, particularly around providing feedback from police District investigations. PSNI Districts are primarily responsible for following up any concerns and allegations raised by Accountable Officers. One of the functions of the PSNI representative on the Local Intelligence Network is to ensure investigations are carried out by the PSNI as required.

The PSNI gave a presentation to the Local Intelligence Network Meeting in September regarding diazepam and temazepam. This brought the prevalence of such drugs into context within Northern Ireland. The PSNI share the concerns of other partner agencies around this issue and are currently commissioning some work aimed at tackling the problem from an enforcement perspective.

The PSNI is committed to using all lawful tactics and methods in order to arrest those involved in the importation, supply and distribution of such drugs

The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) routinely monitors the management of controlled drugs 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.

Dispensing and prescribing issues are referred to the Regional Health and Social Care Board.

Following the notification of incidents to RQIA which identified that staff did not always remove the 'old' fentanyl patch from patients prior to replacing it RQIA wrote to registered facilities in October 2012 highlighting the dangers associated with the use of these patches. The letter has also been placed on the website.

Following guidance issued by RQIA in June 2011, registered managers have introduced standard operating procedures (SOPs) in relation to the management of controlled drugs. The introduction of these has been monitored throughout the year as part of the inspection activity. Where inspectors have found these are not sufficiently robust, a recommendation has been made which will be monitored at the next medicines inspection.

In December 2012 RQIA began a review to assess the systems and processes in place with regard to the management of controlled drugs in Trust hospitals. The purpose of the review is twofold:

- To assess that systems and processes in place within Trusts for the safe and effective management of controlled drugs are robust and working effectively

- To assess the effectiveness of communication and partnership working between Relevant Bodies within the Local Intelligence Network (LIN).

This is on-going and the report will be published on the RQIA website when it is complete (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 (AO), 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

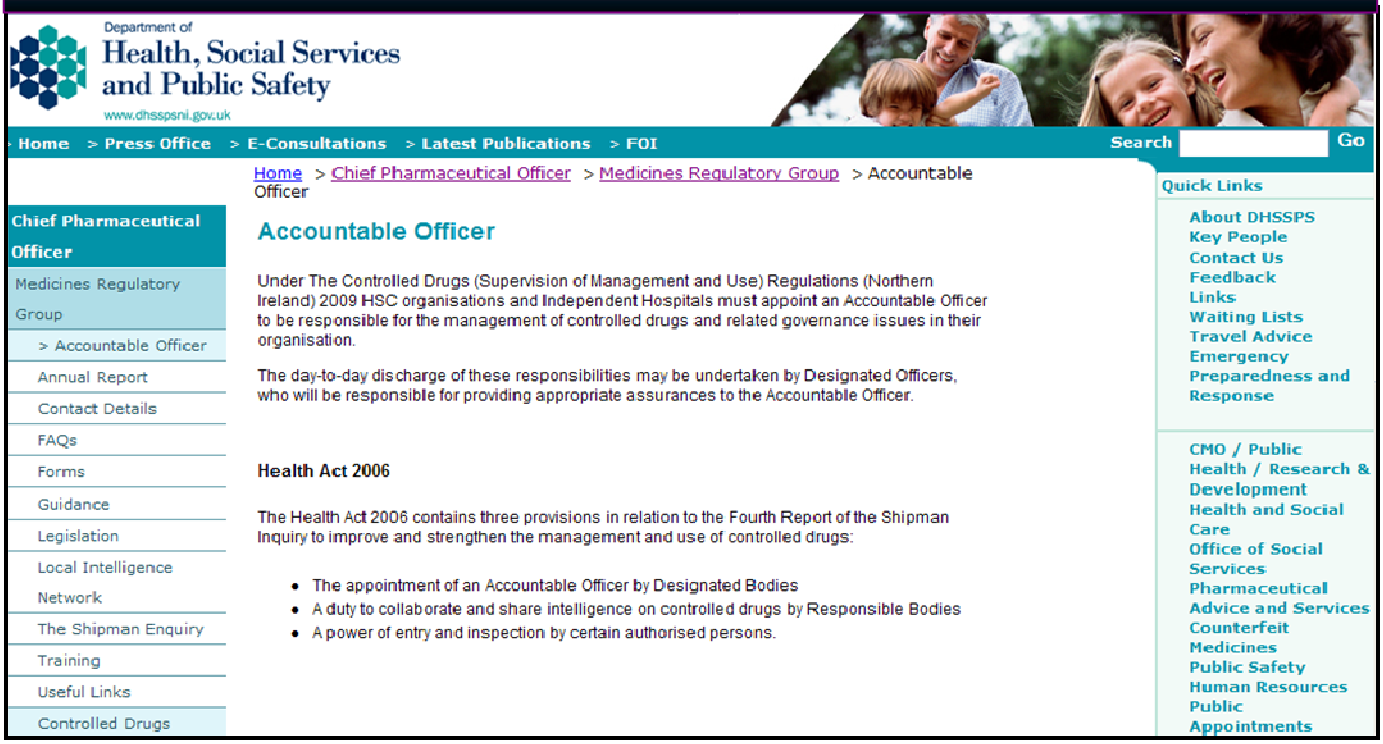
A section of the Pharmaceutical Advice and Services Departmental website has been dedicated to support the work of the Accountable Officers.

Within the contact details section, the name, address, telephone number and e-mail address is listed for each Accountable Officer and for the nominated representative for each Responsible Body.

A range of training materials have also been provided.

These 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 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 single Local Intelligence Network within Northern Ireland which meets quarterly.

The Local Intelligence Network is attended by Accountable Officers, representatives of the regulators, the Police, the Department and the Counter Fraud Unit of BSO, collectively known as Responsible Bodies.

Accountable Officers submit their quarterly Occurrence Report to the Chair of the Local Intelligence Network and concerns arising from these reports are shared within the confines of the confidential Local Intelligence Network 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. The Local Intelligence Network is chaired by Ms Shona Coy, Principal Pharmaceutical Officer of the Department. Terms of Reference can be accessed at the following link:

www.dhsspsni.gov.uk/lin-terms-of-reference.pdf

Guidance on 'Managing and Sharing Concerns' was finalised in late 2010 and will be revised in 2013. This guidance describes best practice on raising concerns, investigating these concerns and sharing of information and can be accessed at:

www.dhsspsni.gov.uk/managing-and-sharing-concerns.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 (anticipated update March 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 Inquiry's Reports. The guidance documents can also be found on the Accountable Officer website.