The safer management of controlled drugs

Annual report 2009

August 2010

About the Care Quality Commission

The Care Quality Commission is the independent regulator of health care and adult social care services in England. We also protect the interests of people whose rights are restricted under the Mental Health Act.

Whether services are provided by the NHS, local authorities or by private or voluntary organisations, we make sure that people get better care by:

- Driving improvement across health and adult social care.
- Putting people first and championing their rights.
- Acting swiftly to remedy bad practice.
- Gathering and using knowledge and expertise, and working with others.

Contents

Summary

In December 2004, the Government gave the Healthcare Commission the responsibility for making sure that providers of health and social care and regulators were creating a safer environment for the management of controlled drugs. This responsibility transferred to the Care Quality Commission on 1 April 2009.

This is the third annual report on the regulation of controlled drugs, covering the year ended 31 December 2009. It describes how the new arrangements for safer management of controlled drugs have continued to mature and consolidate, it reports on the progress with the recommendations made in the 2008 report, and identifies examples of good practice. We also make further recommendations to safeguard the safety of people who use services.

Key features of the current arrangements

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 were designed to ensure that controlled drugs were managed effectively without interfering with their appropriate clinical use. Good governance of controlled drugs should apply in all health and social care settings and individual practices where controlled drugs are prescribed, stored, administered or transported.

Key features of the legislation are:

- The appointment of an individual within each designated healthcare body to take organisational responsibility for controlled drugs. This person is called the accountable officer (AO).

- The establishment by each primary care trust accountable officer of a local intelligence network (LIN) comprising accountable officers from local NHS and independent healthcare organisations, along with regulatory bodies and agencies.

The LIN's task is to share information about the use, management and any concerns relating to controlled drugs, including those involving individuals who give cause for concern and, when necessary, to set up incident panels to investigate serious concerns.

Safe management of controlled drugs in health and social care organisations

There is a steady turnover of accountable officers in post, but the system for keeping the central register (held by CQC) up-to-date appears to be working satisfactorily.

The number of LINs has increased marginally and there is evidence that working systems are developing and maturing. We have included two examples of good practice from LINs in this report.

It will be important to ensure that the safety gains made over the first three years are not lost in the current drive for cost-savings, and we have reminded chief executives that safer management of controlled drugs should remain high on organisations' agendas.

Care Quality Commission activity in 2009, and work with partner organisations

In 2009, the Care Quality Commission continued to oversee the system nationally. We maintained the register of accountable officers and continued to develop surveillance models to help to identify problem areas and target efforts constructively.

Partner organisations continued to develop systems and services to help frontline workers to manage controlled drugs more effectively and to assist the sharing of intelligence at national level. We have included the detailed reports from partner organisations in Appendix 3, and have highlighted a number of examples of useful initiatives in this report.

National trends in the use of controlled drugs

We have looked at national trends in the use of controlled drugs using national prescribing and requisition data. This is the third year of collecting data on private prescriptions and the trends of the first two years are reflected again in this third year, providing us with a clear picture as to prescribing patterns in this sector.

Overall, NHS prescribing of controlled drugs continued to increase in ways that were consistent with good clinical practice recommendations. Prescribing by nurses and pharmacists continued to increase, in keeping with policy and the Government's agenda to increase people's access to medicines through the introduction of more non-medical prescribers.

The analysis of controlled drug requisition data was complicated by the large number of requisitions from hospices and the fact that requisitions tend to be returned for analysis in large batches, making it impossible to examine detailed trends over time. We have recommended that the regulations should be revised to ensure that they enable all purchases of controlled drugs by all individual doctors and healthcare professionals to be captured. We can then monitor these areas of use, which are not being captured through the current arrangements. Monitoring trends would be clearer if the use by designated bodies was excluded.

The detailed information about private prescriptions once again showed that the profile of private prescribing is markedly different from that of NHS

prescribing, particularly in the volume and use of dexamfetamine. We noted that in 2008, there were issues that needed further investigation at a local level and there has been some progress with additional monitoring when high volume prescribing is identified. The different prescribing profile may in part represent unusual prescribing practices, and we have recommended that the Royal Colleges (Royal College of Physicians, Royal College of General Practitioners and Royal College of Psychiatrists) should be invited to draft guidance on appropriate use of opioids and amphetamines, to support practitioners.

Overall conclusions and next steps

Our overall conclusions for 2009 are that:

- All stakeholders, at both local and national levels, have continued to engage with enthusiasm and have made constructive efforts to improve the safe management and use of controlled drugs.
- The role of the accountable officer has now become embedded in health care organisations. However, it will be important to ensure that the gains that have been made in the safe management and use of controlled drugs are not lost in the current drive to save costs.
- Local intelligence networks have an improved understanding of their intelligence-sharing function.
- We have continued to make more and better use of national prescribing data to monitor trends and identify weaknesses. Now that we are in the third year of data analysis, we feel confident that some consistent trends are emerging and we have been able to make recommendations to bring about further improvements.

In 2008, we noted that health and social care staff had increased awareness of both good practice and potential problems, which had led to improvements in the therapeutic use of controlled drugs and earlier identification of adverse events. Our findings in 2009 suggest that this trend has continued. Increased prescribing of controlled drugs in the NHS broadly reflects good practice and improved access for patients. The many examples of good practice reflect an appropriate level of concern for the safe management and use of controlled drugs.

However, we still wish to emphasise that managing and monitoring the systems for controlled drugs at both national and local levels will require ongoing activity and vigilance to sustain the positive developments that have been achieved in the past three years.

Recommendations

1. Chief executives and accountable officers should continue to keep the safe management of controlled drugs a high priority on their organisation's agenda.

2. The Royal Colleges should develop guidance on appropriate use of opioids and amphetamines for all sectors, to ensure best practice across all areas.

3. The Department of Health should revisit the requisition regulations and guidance to ensure that they capture and identify the purchase of controlled drugs by all individual doctors and healthcare professionals, in line with the original policy intent.

1. Introduction

Background

The Care Quality Commission has responsibility for making sure that health and social care providers and regulators are creating a safer environment for the management of controlled drugs. This arose from the findings of the Fourth Report of the Shipman Inquiry[1] and the Government's response to the inquiry's recommendations.[2]

This is the third annual report on the regulation of controlled drugs, covering the year ended 31 December 2009.

Controlled drugs legislation

Controlled drugs are a group of medicines that have the potential to be abused. For this reason, they are 'controlled' by The Misuse of Drugs Act 1971. Many controlled drugs are essential to modern clinical care. They include narcotics, such as morphine and diamorphine, which are used in a wide variety of clinical situations such as the relief of severe pain and the treatment of drug dependence. Controlled drugs also include benzodiazepines (tranquillisers and sleeping tablets), anabolic steroids and growth hormones.

The main purpose of the Act is to prevent the misuse of controlled drugs by imposing restrictions on their possession, supply, manufacture, import and export, as detailed in regulation.

The legitimate, clinical use of controlled drugs is governed by the Misuse of Drugs Regulations 2001.[3] These divide controlled drugs into five 'schedules' according to the level of control they need. Appendix 1 has more information on the Act and the Regulations.

Legislative changes in 2009

Misuse of Drugs: Cannabis (including cannabis resin and other derivatives) was reclassified from Class C to Class B, with effect from January 2009.[4]

The Shipman Inquiry

The Shipman Inquiry was an independent public inquiry set up in 2001 to examine the issues arising from the case of Harold Shipman.

The inquiry's Fourth Report focused on the methods Shipman used to divert large quantities of controlled drugs for his own purposes, and considered how he was able to do it for so long without detection. It concluded that there

were serious shortcomings in the systems for regulating the governance of controlled drugs. In response, the Controlled Drugs (Supervision of Management and Use) Regulations 2006 were introduced.[5] They included provision for:

- The appointment of accountable officers in healthcare organisations described as 'controlled drug designated bodies'. The accountable officer is responsible for all aspects of the safe and secure management of controlled drugs in the organisation.
- Formal, on-site inspections of providers of health and social care by various bodies. Figure 1 shows an overview of the arrangements in place in 2009 for the safe management of controlled drugs.
- The sharing of information, including a legal duty of collaboration among all 'responsible bodies', and making accountable officers in primary care trusts responsible for establishing local intelligence networks.

The regulations came into force in England on 1 January 2007. The Government published additional guidance, *Safer management of controlled drugs: (1) guidance on strengthened governance arrangements,* in March 2006 and reissued it in January 2007.[6]

The current governance arrangements for controlled drugs and the monitoring and inspection functions are summarised in appendix 2.

The inquiry's Fifth Report, *Safeguarding Patients: Lessons from the Past - Proposals for the Future*[7] recommended better use of routine monitoring data, improved arrangements for making and responding to complaints and concerns and better regulation of doctors including revalidation. A key role in the process of revalidation will be the appointment of a local responsible officer.

The role of the Care Quality Commission

The 2006 regulations for controlled drugs[5] and subsequent guidance from the Department of Health[6] set out the responsibilities of the Healthcare Commission in relation to controlled drugs. The Care Quality Commission took on these responsibilities on 1 April 2009.

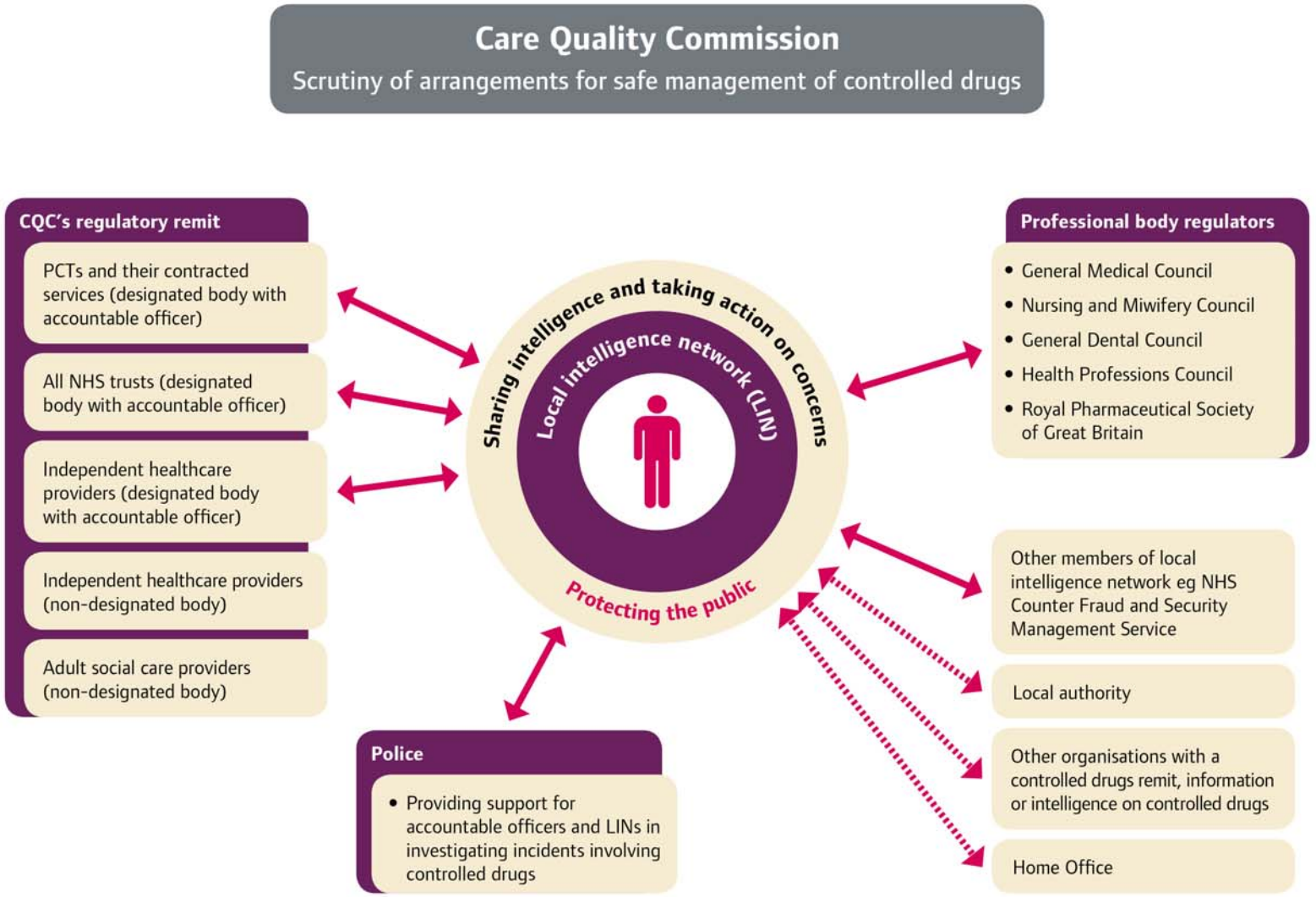
The Care Quality Commission is responsible for external scrutiny of the arrangements for the safer management of controlled drugs that were introduced after the Shipman Inquiry. We use our regulatory powers to inspect or investigate systems failures in NHS organisations that are registered under the Health and Social Care Act 2008 and in organisations currently registered under the Care Standards Act 2000 in the independent health and adult social care sector.

The role of CQC in addition to external scrutiny

CQC has national oversight of the arrangements for the safer management of controlled drugs. This includes:

- Providing assurance of the new system of regulation of controlled drugs.
- Leading a national group of the regulators and agencies involved in different aspects of the management and use of controlled drugs.
- Providing external scrutiny on how other regulators and agencies work together.
- Reporting annually to Government on the safer management of controlled drugs, including findings on the management of controlled drugs and sharing trends both in good practice and in common system errors, to promote improvement.
- Assessing and overseeing how health and social care providers manage controlled drugs through the ongoing assessment of controlled drug handling.
- Maintaining and publishing a register of accountable officers.
- Participating in and monitoring the effectiveness of local intelligence networks (LINs) led by primary care trusts, and ensuring that local governance arrangements and provisions for incident panels are satisfactory.

Figure 1: Arrangements in place for the safe management of controlled drugs



2. Safe management of controlled drugs in health and social care organisations

Introduction

There are two main elements in The Controlled Drugs (Supervision of Management and Use) Regulations 2006 to assure the safe management of controlled drugs:

- The appointment and effective functioning of an accountable officer in controlled drug designated bodies (primary care trusts, other NHS trusts including foundation trusts, and private hospitals), or the responsible health or social care professional in non-designated bodies.
- Sharing of information between organisations, regulators and agencies involved in handling controlled drugs through the local intelligence network.

All health and social care organisations are responsible for making sure that they have systems in place to ensure the safe and effective management of controlled drugs and for making sure that these systems are working effectively. In addition, all healthcare professionals have a duty to ensure that controlled drugs are managed safely and correctly. The requirements are set out in detail in The Controlled Drugs (Supervision of Management and Use) Regulations 2006.[5]

The Health and Social Care Act 2008

The Care Quality Commission has responsibility under the new Health and Social Care Act for the new registration system in England of all regulated health and adult social care services. All providers of health and adult social care who provide regulated activities will be required by law to be registered with CQC (from April 2010 for NHS providers, and from October 2010 for adult social care and independent healthcare providers). To do so, they must show that they are meeting new essential standards of quality and safety across all of the regulated activities they provide.

The management of controlled drugs is included in Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. Our *Guidance about compliance: Essential standards of quality and safety*[8] translates the regulations into expected 'outcomes' that describe quality and safety from the perspective of people who use services. Management of controlled drugs is included in Outcome 9 'Management of Medicines'.

When assessing how well an organisation is managing its controlled drugs, we consider all of the related legislation and we follow up and investigate when necessary (see appendix 2).

The role of accountable officers

The accountable officer is the person within 'controlled drug designated bodies' (primary care trusts, other NHS trusts including foundation trusts, and private hospitals) who has organisational responsibility for controlled drugs. During 2009, we continued to maintain the register of accountable officers. We receive an average of 20 notifications for changes each month.

Smaller organisations that do not meet the criteria to be a designated body are not required to appoint an accountable officer. However, if they hold stocks of controlled drugs, they must still make arrangements for their safe handling. The fact that an organisation does not need to appoint an accountable officer does not alter any of the requirements to comply with the Misuse of Drugs Regulations and to make arrangements for the safe management of controlled drugs.

The responsibilities of the accountable officer are set out in detail in the 2006 Regulations.[5]

Controlled drug designated bodies must inform the Care Quality Commission of the appointment of, and changes of, their accountable officer.

Key findings

Accountable officers

At the end of December 2009, 1,138 controlled drug designated bodies with accountable officers were registered with CQC (table 1).

There is a steady turnover of accountable officers (as noted in the previous year's report) and this trend has continued during 2009. This is one reason why it is important for organisations to have good internal governance to ensure that the accountable officer post is always filled, therefore ensuring that there is always someone with organisational responsibility for controlled drugs.

Table 1: Controlled drug designated bodies registered with CQC (December 2009)

Organisation	Number
NHS acute trusts	166
NHS primary care trusts	152
NHS mental health trusts	60
NHS ambulance trusts	11
Total NHS organisations	389
Independent healthcare organisations	**749**
Total	**1,138**

Local intelligence networks

Local intelligence networks (LINs) enable organisations, regulators and agencies to raise concerns about the activities of any healthcare professional or organisation in relation to the management and use of controlled drugs and to share these at the earliest stage with other agencies who may also be affected or who may have additional information. Accountable officers in primary care trusts are responsible for establishing and operating local intelligence networks.[5]

Organisations analyse their own concerns through a process of root cause analysis and, if necessary, alert LINs of the outcomes in occurrence reports. Urgent items are notified to the LIN immediately rather than waiting for the next quarterly occurrence report.

Where concerns need further scrutiny, the primary care trust's accountable officer should take the lead in setting up an incident panel of the relevant agencies or individuals. Each agency retains the responsibility for taking appropriate action within their regulatory remit.

At the end of December 2009, there were 102 LINs, compared with 96 in December 2008. Some LINs have now found it more efficient to operate as 'single-PCT' LINs, only involving organisations within their geographical primary care trust area.

The following examples show how local intelligence networks are developing reporting arrangements.

Good practice example 1

Online occurrence reporting

NHS Tees LIN is developing an online occurrence reporting tool that will allow accountable officers to report any occurrence directly and will permit others a 'view only' access. This is designed to allow real time rather than retrospective reporting. It will also help in the analysis of trends.

Good practice example 2

Learning from previous incidents

Cornwall and Isles of Scilly LIN has developed an improved occurrence report form that includes a section to capture the learning from each reported event. The aim is to distribute this information to avoid recurrence of similar incidents in future. Using the new template has enabled all accountable officers in Cornwall to outline the learning from an incident and explain how this has been used to improve practice within their own organisation. Key learning is included in the Cornwall and Isles of Scilly Controlled Drugs Newsletter, which is published quarterly.

Inspections by CQC

CQC's pharmacist inspectors carried out 1,158 inspections of care homes, and identified a concern involving controlled drugs at 266.

There were three areas of particular concern:

1. Compliance of controlled drug cupboards with the Misuse of Drugs (Safe Custody) Regulations 1973. The issues related more to the way in which cupboards were fixed to walls rather than the actual construction of the cupboard. Examples included loose cupboards within an outer cupboard, cupboards fixed with tiny screws, and cupboards nailed to walls. Where it was unclear whether the actual cupboard was compliant, the pharmacist inspector requested the provider to confirm this with the manufacturer of the cupboard and provide the supporting documentation as evidence.

2. Fentanyl transdermal patches. Although there have been improvements, we still have concerns about the timing of application of these patches, which are used to treat severe pain. The patches last for 72 hours and if the interval between replacements exceeds this, patients could be left in pain. Conversely, if there is too short an interval, the patient could receive a higher dose than required and the patches could be used wastefully.

3. Controlled drugs awaiting destruction – There have been some instances where patients' own controlled drugs which are no longer required have been stored inappropriately while awaiting destruction. This has occurred mostly in care homes without nursing where all of the patient's medicines have been stored together rather than the controlled drugs being segregated and stored in accordance with the Misuse of Drugs (Safe Custody) Regulations 1973.

We continue to respond to external queries on the safer management of controlled drug governance arrangements, and these average at over 40 a month.

Our field force staff and pharmacist inspectors continue to represent CQC at local intelligence networks, and follow up newly-registered organisations when they are slow to provide us with the name of their new accountable officer.

We have been developing a new surveillance model for identifying and following up PCT prescribing outliers for controlled drugs, which we will be reporting on in 2010.

Pharmacist inspectors have identified a number of compliance issues during their inspections which have been resolved at the time of the visit.

Conclusions

There is a continuing steady turnover of accountable officers in post, but the systems for keeping the central register (held by CQC) up to date appear to be working satisfactorily.

The number of LINs has increased marginally and there is evidence that working systems are developing and maturing.

It will be important to ensure that the gains in safety made over the first three years are not lost in the current drive for cost-savings.

Recommendation 1

Chief executives and accountable officers should continue to keep the safe management of controlled drugs a high priority on their organisation's agenda.

3. Work with partner organisations

National Group on Controlled Drugs

The National Group on Controlled Drugs consists of regulators and key agencies that have areas of responsibility for controlled drugs.

The group met four times during 2009, and the main partners submitted reports of activity that are available in appendix 3. The group continues to be a useful forum to identify and discuss emerging issues. Membership of the National Group on Controlled Drugs in 2009 included:

Association of Chief Police Officers
Care Quality Commission
Department of Health
Health and Social Care Information Centre
Her Majesty's Inspectorate of Prisons
Home Office
Medicines and Healthcare products Regulatory Agency
National Clinical Assessment Service
National Patient Safety Agency
National Treatment Agency
NHS Counter Fraud and Security Management Service
Ofsted
Royal Pharmaceutical Society of Great Britain

(The Healthcare Commission and the Commission for Social Care Inspection were members until they were superseded by the Care Quality Commission on 1 April 2009).

Initiatives from partner organisations

During 2009, partner organisations continued to refine management systems and support front-line workers with a variety of useful initiatives.

Partner initiative 1: National information sharing scheme

The Department of Health and the Association of Chief Police Officers (ACPO) have begun the initial stages of a joint work programme to consider how the requirements of the police's information sharing agreements will affect the role of accountable officers and local intelligence networks. This will continue across 2010 to ensure that all are clear about what is required. It will also build on the good practice in terms of information sharing between the NHS and police as highlighted in our 2008 annual report, and the Department of Health's policy development following on from the 5th report of the Shipman Inquiry.

Partner initiative 2: Standard investigation processes

The National Clinical Assessment Service (NCAS) has prepared guidance on the processes for investigating apparently idiosyncratic prescribing of controlled drugs in general practice. It also suggests ways in which the less common causes of poor professional performance, fraud and criminal behaviour may be identified. The standardised processes that are recommended should help to ensure that procedures in primary care trusts are robust, able to withstand legal challenge and are linked to local clinical governance and risk management processes.

The guidance has been placed on the National Prescribing Centre's (NPC) controlled drugs website.

Partner initiative 3: Department of Health working groups

The Department of Health has set up working groups in partnership with the National Prescribing Centre (NPC) to identify key issues, solutions and priorities to support the safer management of controlled drugs in the following areas that are not covered by the current primary and secondary care guidance publications:

- Private prescribing.
- Ambulance trusts and paramedics.
- Offender health in prisons.
- Controlled drug record cards.

These programmes will continue to develop in 2010 and will be supported by engagement with stakeholders.

Partner initiative 4: Support website for accountable officers

The Department of Health commissioned the National Prescribing Centre (NPC) to develop and provide a comprehensive programme of support for accountable officers in England. As part of this initiative, the NPC developed and launched a dedicated, interactive website in April 2009 (www.npci.org.uk/cd).

The website has two tiers; tier one has open access and provides signposting for guidance and legislation alongside educational resources for anyone involved in the management and prescribing of controlled drugs. These include:

- The third edition of the NPC guide to good practice in the management of controlled drugs in primary care.
- FAQs with quality-assured responses from the Department of Health, the Home Office and the Care Quality Commission, as appropriate.
- Guidance on legislation.
- Podcasts discussing current guidance.
- Signposting to news and updates from other relevant organisations

- A regular quarterly newsletter.

Tier two is a password-protected area restricted to accountable officers and those professionals supporting them, and includes:

- A secure discussion forum to discuss current hot topics and post questions.
- An area to share resources which may include:
  - Guidance documents.
  - Leaflets.
  - Standard operating procedures (SOPs).
  - Monitoring forms.
  - Presentations.
  - Memoranda of understanding.
  - Terms of reference for LINs.
  - Template documents for controlled drugs inspections.
- A list of accountable officers with authorised groups of people to witness the destruction of controlled drugs in multiple bodies prior to onward disposal.

Registered users receive regular email alerts to notify them of key developments, new resources and other relevant issues relating to controlled drugs.

Partner initiative 5: Regional events for accountable officers

During 2009 the National Prescribing Centre hosted three, one-day regional events focusing on key issues relating to accountable officers. The events also provided a forum for networking with colleagues and sharing good practice.

Feedback from delegates at these events showed that 85% rated the events 'good' or 'excellent'. To help improve future events, delegates also suggested that events should differentiate between new and more experienced accountable officers and that practical skills training would be useful.

4. Progress on recommendations in the 2008 report

Following on from our recommendations in the 2008 annual report, we summarise the progress in table 2 below.

Table 2: Progress against recommendations in the 2008 report

Recommendation	Progress
1. Healthcare organisations should ensure that they have accountable officers in place at all times. They should have mechanisms to replace accountable officers immediately when they leave and notify the Care Quality Commission of the change.	The Chief Pharmacist, Dr Keith Ridge, wrote to all NHS chief executives to remind them of their responsibilities. (See http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_109091.pdf)
2. A robust, workable method should be devised to ensure that 72-hour (three-day) fentanyl patches are applied at appropriate intervals to ensure that patients are not left in pain (because of too long an interval) and that the patches are not used wastefully (because of too short an interval).	A number of local initiatives have been developed to remind prescribers about the problem. One practical measure that has been adopted in some places is to write the date of application onto the patch.
3. PCT accountable officers should collaborate more effectively with other primary care trusts and national bodies, to ensure that suitable numbers of authorised witnesses are available for destroying obsolete drugs. There should be a robust mechanism for recognising authorised witnesses, and healthcare professionals need to be made aware of the purpose of having authorised witnesses.	There is a list of accountable officers who have authorised groups of people to witness the destruction of controlled drugs in multiple bodies on the National Prescribing Centre's controlled drugs website. It remains important that accountable officers ensure they have sufficient witnesses available to prevent the build-up of expired or unwanted controlled drugs.
4. Local intelligence networks (LINs) must make sure that all their designated bodies are kept up to date with the formation and leadership of the network, and that they know where to submit their reports. Networks should be reminded to keep their membership and working arrangements under review, and to keep everyone informed.	There has been some progress, but LINs will need to keep this on the agenda.

5. National trends in the use and management of controlled drugs

During 2009, the Care Quality Commission monitored the overall use and management of controlled drugs, by analysing national prescribing and requisition data, feedback on routine activity in controlled drugs monitoring and reports from members of the National Group.

All data on prescribing in NHS primary care (including prescribing by GPs and other non-medical primary care prescribers) is collected by NHS Prescription Services. Private prescriptions for Schedule 2 and 3 controlled drugs are also analysed by NHS Prescription Services. The output from the database is known as ePACT (electronic prescribing analysis and costs).

By analysing the data on prescribing, we are able to examine the whole picture and identify areas where the prescribing of controlled drugs deviates from the normal pattern. As 2009 is only the third year that the prescribing data have been analysed and published in this way, the tables and graphs presented in this chapter should be interpreted with this in mind.

Key findings

Prescribing of controlled drugs in primary care

In 2009, the total number of controlled drugs items prescribed in NHS primary care was 45,351,382 at a cost of £417,310,734. These figures represent increases of 2.5% and 6% compared with 2008.

However, the total number of controlled drug items that were prescribed privately was 43,436, a decrease of 14% compared with 2008. Therefore, private prescribing accounts for about 0.1% of overall controlled drug prescribing. We have analysed private prescribing in greater detail on page 27.

A detailed breakdown of prescribing by Misuse of Drugs Regulations (MDR) schedule is shown in table 3.

Table 3: Overall picture of private prescribing compared with primary care prescribing in 2009		
Controlled drug schedule	**Controlled drug items prescribed privately**	**Controlled drug items prescribed in primary care**
1	39	1,880
2	36,858	6,185,280
3	6,539	4,906,445
4	0	9,178,570
5	0	25,079,207
Total	**43,436**	**45,351,382**

Opioids and cannabis products

Table 4 shows the most commonly prescribed opioids, including analgesics (pain killers) and drugs used in treating substance dependence (drug addiction), and Sativex, the only licensed cannabis product (used in the management of multiple sclerosis). These are grouped together because they are all in Schedules 1 and 2 of the Misuse of Drugs Regulations.

The trend for prescribing in primary care mirrors that in 2008 with methadone (drug addiction), morphine, fentanyl, oxycodone, and methylphenidate being the most frequently prescribed Schedule 2 controlled drugs in primary care during 2009. Methadone for pain relief and dexamfetamine are the first and third most common privately prescribed Schedule 2 items during 2009. We believe that this reflects their use in the management of chronic pain and substance misuse, respectively.

The NHS prescribing of Sativex has remained constant over the period 2008 to 2009.

Table 4: Most commonly prescribed (private and primary care) opioid and cannabis products 2008-2009						
	No. of private items 2008	**No. of private items 2009**	**% change**	**Primary Care 2008**	**Primary Care 2009**	**% change**
Cannabis Oromucosal spray 5.5ml VI (Sativex)	32	39	+22%	1,881	1,880	-0.05%
Total Schedule 1 items	**32**	**39**	**+22%**	**1,881**	**1,880**	**-0.05%**
Methadone (drug addiction)	9,623	7,817	-19%	2,097,732	2,341,870	+12%
Methadone (analgesic)	15,579	13,474	-14%	68,926	71,178	+3%
Dexamfetamine	8,034	7,414	-8%	40,124	40,038	-0.2%
Morphine	4,133	3,000	-27%	1,193,614	1,338,062	+12%
Methylphenidate	2,317	2,581	11%	459,600	492,247	+7%
Oxycodone	954	1,089	14%	619,078	755,669	+22%
Fentanyl	506	687	36%	791,250	897,900	+13%
Other	971	796	-18%	220,135	248,316	+13%
Total Schedule 2 items	**42,117**	**36,858**	**-12%**	**5,490,459**	**6,185,280**	**+13%**

Buprenorphine, temazepam and phenobarbital

Buprenorphine, temazepam, and phenobarbital are grouped together because they are all in Schedule 3 of the Misuse of Drugs Regulations (MDR). Suboxone is a combination product containing buprenorphine and naloxone (a narcotic antagonist) that is used in the management of substance misuse. Temazepam is a hypnotic drug (or sleeping tablet), a class of drugs for which regular prescribing is discouraged. Phenobarbital is mainly used to control epilepsy.

Table 5 shows that temazepam and buprenorphine remain the most common privately prescribed Schedule 3 controlled drugs in 2009 as in 2008. The use of Suboxone has increased substantially in 2009 in both primary care and, in particular, in private prescribing.

Table 5: Buprenorphine, temazepam and phenobarbital (and other Schedule 3) prescribing 2008-2009						
	Number of private items 2008	**Number of private items 2009**	**% change**	**Primary care 2008**	**Primary care 2009**	**% Change**
Temazepam	5,121	4,143	-19%	3,091,328	2,940,796	-5%
Buprenorphine (analgesic)	451	442	-2%	758,970	987,397	+30%
Buprenorphine (drug addiction)	1,992	1,382	-31%	478,994	519,330	+8%
Phenobarbital	114	83	-27%	279,500	273,148	-2%
Suboxone	11	48	+336%	43,143	71,893	+67%
Other	515	441	-14%	90,600	113,881	+26%
Total Schedule 3 items	**8,204**	**6,539**	**-20%**	**4,742,535**	**4,906,445**	**+3%**

Although the volume of temazepam has declined during 2009 for both private and primary care prescribing, analysis of ePACT data has provided information about primary care trusts where there are outliers with unusually high prescribing levels. Where we have identified outliers, we are undertaking some surveillance work to gather intelligence and identify how this might be accounted for, whether the primary care trust is aware of any particular issues, and whether any monitoring is currently in place. We plan a similar follow up on methylphenidate.

Benzodiazepines and zolpidem

Benzodiazepines, such as diazepam, nitrazepam and zolpidem are grouped together because they are all in Schedule 4 of the Misuse of Drugs Regulations (table 6).

As in 2008, prescribing of nitrazepam continued to fall in 2009 and there was again a slight increase in the prescribing of zolpidem. This is in keeping with current guidance provided in the British National Formulary.

Diazepam continues to be used as an adjunct in the management of substance misuse and lorazepam, a short acting benzodiazepine, is used in the treatment of anxiety. Clonazepam is used in the treatment of epilepsy.

Table 6: Benzodiazepines and zolpidem - most commonly prescribed drugs, 2008-2009			
	2008	2009	% change
Diazepam	4,721,877	4,877,343	+3%
Nitrazepam	1,154,030	1,083,746	-6%
Lorazepam	877,629	909,010	+4%
Zolpidem	689,340	705,544	+2%
Clonazepam	510,663	563,491	+10%

Weak opioids

Codeine, dihydrocodeine and dilute oral morphine solution are grouped together because they are all in Schedule 5 of the MDR (table 7).

The top five drugs in this group are all analgesics (pain killers). The trends in 2009 are consistent and of a similar order to those seen in 2008.

Low-strength morphine oral solution is often used to manage breakthrough pain in people taking regular pain-relief medication and, as such, is an essential 'safety net'. Prescribing of low-dose morphine oral solution has risen substantially compared to 2008. Again, this is consistent with good practice guidance on pain management.

Table 7: Most commonly prescribed weak opioids (Schedule 5 controlled drugs) 2008-2009			
	2008	2009	% change
Co-codamol	13,832,907	14,110,172	+2%
Co-dydramol	3,921,808	3,678,636	-6%
Codeine	2,589,513	2,784,753	+8%
Dihydrocodeine	2,091,759	2,048,456	-2%
Morphine oral solution	713,664	823,735	+15%

Nurse and pharmacist prescribing

The numbers of controlled drug items most commonly prescribed by nurses and pharmacists are shown in tables 8 and 9.

Overall, there was a 19% increase in nurse prescribing of controlled drugs in 2009 compared with 2008, with the biggest contribution coming from methadone and buprenorphine (Schedule 2 controlled drug) prescribing. There has also been a 54% increase in pharmacist prescribing of controlled drugs in 2009 compared with 2008, and prescribing of methadone (Schedule 2 controlled drug) has more than doubled from 2008 to 2009 (1,124 to 2,307 items).

In both cases, this is mainly attributable to nurses and pharmacists being involved in prescribing for the treatment of addiction in line with policy to improve access to treatment for patients.

Table 8: Nurse prescribing of controlled drugs (top four items, numbers of prescriptions) 2008-2009

Drug	2008	2009	% change
Methadone	88,888	113,022	+27%
Buprenorphine (drug addiction)	37,045	44,507	+20%
Diazepam	43,309	52,331	+21%
Co-codamol	190,490	219,342	+15%
Total	**359,732**	**429,202**	**+19%**

Table 9: Pharmacist prescribing of controlled drugs (top four items, numbers of prescriptions) 2008-2009

Most common drug	2008	2009	Change
Methadone	1,124	2,307	+105%
Buprenorphine (drug addiction)	650	1,009	+55%
Diazepam	1,574	2,113	+34%
Co-codamol	2,352	3,366	+43%
Total	**5,700**	**8,795**	**+54%**

Private prescribing of controlled drugs

Table 10 summarises the private prescribing of controlled drugs during 2009 for Schedules 1 to 3, as classified under the Misuse of Drugs Regulations 2001 (MDR). Overall, there has been a more marked decrease in the number of controlled drugs prescribed privately in 2009: 43,436 in 2009 compared with 50,353 prescription items in 2008 and 51,643 in 2007.

The main decrease was in Schedule 2 controlled drugs. Within this group of drugs, methadone – used principally for analgesic purposes and then drug addiction – continues to be the most common privately prescribed item, followed by dexamfetamine and morphine.

Table 10: Private prescribing of controlled drugs 2008-2009

MDR schedule	Items prescribed privately 2008	Items prescribed privately 2009
1	32	39
2	42,117	36,858
3	8,204	6,539
Total	**50,353**	**43,436**

Table 11: Top 10 most common controlled drugs prescribed privately

	Number of items 2008	Number of items 2009	% change
Methadone (analgesic)	15,579	13,474	-13.5%
Methadone (drug addiction)	9,623	7,817	-18.8%
Dexamfetamine	8,034	7,414	-7.7%
Temazepam	5,121	4,143	-19.1%
Morphine	4,133	3,000	-27.4%
Methylphenidate	2,317	2,581	11.4%
Buprenorphine (drug addiction)	1,992	1,382	-30.6%
Oxycodone	954	1,089	14.2%
Fentanyl	506	687	35.8%
Buprenorphine (analgesic)	451	442	-2.0%

By contrast, in primary care, methadone for drug addiction was the most common Schedule 2 controlled drug prescribed, and for analgesic purposes, it was the seventh most common (table 11).

In both NHS primary care and in private prescribing, the volumes of methylphenidate, oxycodone and fentanyl increased during 2009. The private prescribing of Methylphenidate requires further assessment by individual primary care trusts as it is unlikely that the increase is entirely attributable to the treatment of ADHD in children.

Table 12 shows that the London region accounted for 86% of all privately prescribed controlled drugs in England. Table 13 breaks this down further, showing that Westminster Primary Care Trust had the highest number of privately prescribed items (22,561) representing 52%. Together with four other primary care trusts in London, they privately prescribed the highest number of items in total, accounting for 80% of all privately prescribed controlled drugs for 2009. By comparison, the volume of private prescribing in primary care trusts outside the London region was very small, ranging from 1% to 4% of the total volume.

Table 12: Private prescribing of controlled drugs by region in 2008 and 2009

Regions	Number of privately prescribed items 2008	Number of privately prescribed items 2009	% change
London	43,885	37,138	-15%
Eastern	1,816	1,638	-10%
South East	1,579	1492	-6%
Northern & Yorkshire	762	949	+25%
West Midlands	924	818	-11%
South West	651	748	+15%
North West	614	516	-16%
Trent	94	129	+37%
Unidentified doctors	42	8	-81%
Total	**50,367**	**43,436**	

Table 13: Private prescribing of controlled drugs by PCT in 2009		
Prescriber	**Total private controlled drugs prescribed**	**% of total**
Westminster PCT	22,561	52%
Islington PCT	6,708	15%
Haringey Teaching PCT	2,181	5%
Camden PCT	1,885	4%
Kensington & Chelsea PCT	1,355	3%
All other PCTs (116)*	**8,746**	**20%**
Total	**43,436**	**100%**

*Number of all other PCTs who privately prescribed controlled drugs during 2009.

The composition of the top five controlled drugs prescribed privately in Westminster PCT mirrors those prescribed privately nationally (methadone, dexamfetamine, morphine are the top Schedule 2 controlled drugs privately prescribed and temazepam is the top Schedule 3 controlled drug prescribed privately). Some collaborative working is taking place between Westminster and Islington primary care trusts to identify the underlying reasons for this high volume and to ensure that appropriate monitoring is in place.

However, the rationale for the private prescribing of dexamfetamine is currently unclear. Further breakdown of ePACT data confirms that dexamfetamine sulphate is the most common CNS stimulant controlled drug prescribed privately in 2009. Similarly, the rationale for privately prescribed methylphenidate also requires further review.

Given the uneven distribution of private prescribing for controlled drugs, some guidance on good practice and appropriate prescribing may be needed.

Recommendation 2

The Royal Colleges should develop guidance on appropriate use of opioids and amphetamines for all sectors, to ensure best practice across all areas.

Controlled drugs requisitions

In order to obtain a stock of a Schedule 2 and 3 controlled drug from a pharmacy, practitioners must use a written requisition form. There were 18,289 controlled drug requisitions during the period January to December 2009. By contrast, the figures were lower in 2008, when 10,657 controlled drug items were requisitioned.

Table 14 shows the most frequently requisitioned controlled drug items during 2009. Oxycodone was the most commonly requisitioned controlled drug followed by diamorphine, morphine and fentanyl, all of which are used for pain relief. The requisition volume of oxycodone has almost doubled from 1,800 in 2008 to 3,569 in 2009.

Of the 149 primary care trusts in England, the five in table 15 had the highest volume of controlled drug items requisitioned in 2009. The high volume of requisitions for these five PCTs was largely attributed to requisitions from hospices for pain relief in palliative care. As a designated body, each hospice has its own accountable officer who is responsible for monitoring its controlled drug handling, including ordering. The original policy intent was to capture the number of purchases of controlled drugs for practice use. The original policy intent behind the introduction of standardised requisitions was to capture a record of purchases of controlled drugs for practice use. However, large numbers of requisitions are generated by some hospices and it is not possible to distinguish between hospice use and use by individual practitioners with current methods of data capture. A more robust system is required to capture CD requisitions from individual doctors and healthcare practitioners

Table 14: Controlled drug items most frequently requisitioned during 2009

Controlled drug	Total 2008	Total 2009
Oxycodone	1,800	3,569
Diamorphine	2,227	3,229
Morphine	1,478	2,687
Fentanyl	1,277	2,393
Methadone	744	1,538
Midazolam	762	1,426
Buprenorphine	459	931
Temazepam	408	588
Pethidine	345	415
All other CD items	**1,157**	**1,513**
Total	**10,657**	**18,289**

Table 15: Top five PCTs with highest volumes of controlled drug requisitions			
PCT code	**PCT name**	**Total 2008**	**Total 2009**
5D7	Newcastle PCT	790	1,274
5C3	City & Hackney Teaching PCT	1,053	970
5HP	Blackpool	1	845
5PH	North Staffordshire	609	816
5F1	Plymouth Teaching	677	744

Good practice example:

Obtaining controlled drugs for non-NHS paramedics

A routine audit by the accountable officer in Dorset PCT uncovered a misunderstanding about the application of the Misuse of Drugs Regulations to private paramedics, which provided an opportunity to clarify the position regarding controlled drug requisitions.

Controlled drugs were held in the base/home of the owner of a private paramedic company. The individual was neither a registered paramedic nor a health professional and did not have a Home Office licence, and was therefore not in a position to lawfully supply or possess the controlled drugs concerned. The drugs had been obtained and unlawfully supplied by the company's medical director and were given to paramedics working for the company when on duty.

A group authority issued by the Home Office authorises registered paramedics to supply, offer to supply, and possess morphine sulphate (in the form of morphine sulphate injection to a maximum of 20mg and oral) and diazepam to administer for the immediate necessary treatment of sick or injured persons. However, the authority covers the individual paramedics and not the company or body corporate employing them.

It is the paramedics' responsibility to source their own individual supplies of morphine sulphate and diazepam. They are also responsible for the safe-keeping of the drugs in their possession at all times, and for keeping a record of their use and appropriate disposal/destruction.

In this case, it was agreed that the drugs would be obtained from a nominated community pharmacy using the standard requisition forms (FP10CDF) provided by the PCT. The accountable officer provided a pack of supporting information to the community pharmacy to ensure that the process ran smoothly.

The standard requisition forms are processed by NHS Prescription Services in the usual way and the accountable officer is able to track use through the reports.

Recommendation 3

The Department of Health should revisit the requisition regulations and guidance to ensure that they capture and identify the purchase of controlled drugs by all individual doctors and healthcare professionals, in line with the original policy intent.

Conclusions

NHS (primary care) prescribing of controlled drugs continued to increase in ways that were consistent with good clinical practice recommendations. Prescribing by nurses and pharmacists continued to increase in keeping with policy and the Government's agenda to increase people's access to medicines through the introduction of more non-medical prescribers.

The analysis of controlled drug requisition data was complicated by the large number of requisitions by hospices and the fact that requisitions tend to be returned for analysis in large batches, making it impossible to examine detailed trends over time. Accordingly, we have recommended that the regulations should be revisited to ensure that they capture and identify the small scale ad-hoc use (by non-designated bodies) of controlled drugs.

The detailed information about private prescriptions once again showed that the profile of private prescribing is markedly different from that of NHS prescribing, with high amounts of dexamfetamine prescribed privately that is not seen in NHS practice.

In the report for 2008, we noted that the private prescribing profile required further clarification and investigation at a local level. The different prescribing profiles may in part represent different approaches to prescribing for some client groups and therefore we have recommended that the Royal Colleges (RCP, RCGP and RCPsych) should be invited to draft guidance on appropriate use of opioids and amphetamines.

Conclusions and recommendations

Our overall conclusions for 2009 are that:

- All stakeholders, at both local and national level, have continued to engage with enthusiasm and have made constructive efforts to improve the safe management and use of controlled drugs in the widest perspective.

- The role of the accountable officer has now become embedded in health and social care organisations. With the current national measures to make efficiencies in budgets, it will be important to ensure that the gains made in the safe management and use of controlled drugs are not lost in the drive for cost-savings.

- Local intelligence networks have an improved understanding of their intelligence-sharing function.

- National prescribing data is allowing us to monitor trends and identify weaknesses. Now that we are in the third year of data analysis, we can see some consistent trends emerging, and we have been able to make recommendations to bring about further improvements.

- Last year, we noted that awareness of both good practice and potential problems had increased among health and social care staff, which had led to improvements in the therapeutic use of controlled drugs and earlier identification of adverse events. Increased prescribing of controlled drugs in the NHS broadly reflects good practice and improved access for patients. The many examples of good practice reflect an appropriate level of concern for safe management and use of controlled drugs.

- However, we still wish to emphasise that managing and monitoring the systems for controlled drugs at both national and local levels will require ongoing activity and vigilance to sustain the positive developments that have been achieved in the past three years.

Next steps

A new registration system for health and adult social care providers will come into place during 2010, which will focus on outcomes for patients. This involves ongoing monitoring of providers' compliance with new essential standards of quality and safety, which includes the management of controlled drugs.

Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 requires the registered person of a service to protect service users against the risks associated with the unsafe use and management of

medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines.

There are additional prompts in the underpinning guidance to investigate incidents and share concerns on controlled drugs to further embed the steps introduced by safer management of controlled drug to protect people who use services.

Recommendations

1. Chief executives and accountable officers should continue to keep the safe management of controlled drugs a high priority on their organisation's agenda.

2. The Royal Colleges should develop guidance on appropriate use of opioids and amphetamines for all sectors, to ensure best practice across all areas.

3. The Department of Health should revisit the requisition regulations and guidance to ensure that they capture and identify the purchase of controlled drugs by all individual doctors and healthcare professionals, in line with the original policy intent.

Appendix 1: The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001

The Misuse of Drugs Act 1971 (the Act) and the Misuse of Drugs Regulations 2001 (the Regulations) restrict the possession, supply, administration and disposal of controlled drugs.

The Misuse of Drugs Act 1971

Controlled drugs are categorised into three classes as specified under schedule 2 of the Act. This classification is designed to enable the control of particular drugs according to their comparative harmfulness, either to individuals or to society at large, when they are misused. The classes determine the level of penalties (fine and/or imprisonment) applicable to offences (as defined in the Act) involving the different drugs in a descending order of severity, from A to C.

Class A (the most harmful)

Includes: Ecstasy, LSD, heroin, cocaine, crack, magic mushrooms (whether prepared or fresh), methylamphetamine (crystal meth), and other amphetamines if prepared for injection.

Penalties for possession: Up to seven years in prison, an unlimited fine or both.

Penalties for dealing: Up to life in prison, an unlimited fine or both.

Class B (an intermediate category)

Includes: Cannabis, amphetamines, methylphenidate (Ritalin), barbiturates, pholcodine.

Penalties for possession: Up to five years in prison, an unlimited fine or both.

Penalties for dealing: Up to 14 years in prison, an unlimited fine or both.

Class C (the least harmful)

Includes: Tranquilisers, some painkillers, GHB (gamma hydroxybutyrate), ketamine, anabolic steroids, benzodiazepines, growth hormones.

Penalties for possession: Up to two years in prison, an unlimited fine or both.

Penalties for dealing: Up to 14 years in prison, an unlimited fine or both.

The Misuse of Drugs Regulations 2001

Controlled drugs are also categorised into five schedules by the Regulations, corresponding to their therapeutic usefulness and misuse potential. The drugs listed in Schedule 1 have limited medicinal use and may only be lawfully possessed under licence from the Home Office.

Schedule 1

Schedule 1 includes cannabis and cannabinoids.

Schedule 2

Schedule 2 controlled drugs include the opiate-based drugs used in acute and palliative care. They are subject to regulations determining their supply and storage.

Supply: Supply is restricted to licensed wholesalers, practitioners, hospitals and registered pharmacies. Wholesalers are permitted to supply only to a person authorised to possess. Practitioners are restricted to supplying their patients. Hospitals (in so far as it represents the business of the hospital) may supply patients, wards and practitioners. Pharmacies may supply on receipt of a valid prescription or signed order. Additional prescription writing requirements exist.

Record: A record of all Schedule 2 controlled drugs obtained and supplied must be kept in a register, the form of which must comply with the relevant regulations.

Storage: Schedule 2 controlled drugs are subject to safe custody requirements (The Misuse of Drugs (Safe Custody) Regulations 1973, amended 2007). They must be stored in a locked receptacle, usually in an appropriate controlled drug cabinet or approved safe, which can be opened by a person in possession of the controlled drug or a person authorised by that person.

Destruction: The destruction of Schedule 2 controlled drugs must be appropriately authorised and the person witnessing the destruction must be authorised to do so. Schedule 2 controlled drugs must be denatured before being placed into waste containers.

Schedule 3

Schedule 3 contains a number of substances that are perceived as being open to abuse, but less likely to be so than Schedule 2 controlled drugs. It includes a number of synthetic opioids together with other substances.

Supply: The regulations concerning supply (and the additional prescription writing requirements) are similar to Schedule 2 controlled drugs.

Record: There is no statutory requirement to record the supply of Schedule 3 controlled drugs.

Storage: The majority of Schedule 3 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf. Certain Schedule 3 controlled drugs are exceptions to this exemption.

Destruction: The requirements relating to witnessing of destruction do not apply to Schedule 3 controlled drugs (unless the controlled drugs are manufactured by the individual). However, Schedule 3 controlled drugs must be denatured before being placed into waste containers.

Schedule 4

All Schedule 4 controlled drugs are prescription only medicines (POMs) and are divided into two parts. Part 1 contains most benzodiazepines and zolpidem. Part 2 contains most of the anabolic steroids.

Supply: Supply is restricted to supplies against practitioners' prescriptions or in accordance with Patient Group Directions (PGDs) but there are no additional requirements as to the form of prescription other than those that apply to all POMs.

Record: There is no statutory requirement to record the supply of Schedule 4 controlled drugs.

Storage: Schedule 4 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf.

Destruction: The requirements relating to witnessing of destruction do not apply to Schedule 4 controlled drugs (unless the controlled drugs are manufactured by the individual). However, Schedule 4, part 1 controlled drugs must be denatured before being placed into waste containers.

Schedule 5

Schedule 5 controlled drugs, which include POMs and over-the-counter medicines, contain preparations of certain controlled drugs such as codeine, pholcodine, cocaine and morphine which are exempt from full control when present in medicinal products of low strength. They are excepted from the prohibitions on importation, exportation and possession.

Supply: Some of the controlled drugs in Schedule 5 are available for over-the-counter sale in registered pharmacies. It is for the pharmacist to use their professional judgement to determine the appropriateness of any supply and be alert to potential misuse of products.

The Schedule 5 controlled drugs that are prescription only medicines (including codeine, dextropropoxyphene and dihydrocodeine tablets) can only be supplied in accordance with a valid prescription or Patient Group Direction.

Record: There is no statutory requirement to record the supply of Schedule 5 drugs.

Storage: Schedule 5 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf.

Destruction: The requirements relating to destruction do not apply to Schedule 5 controlled drugs.

Appendix 2: Governance arrangements for controlled drugs in 2009

Table 15: Governance arrangements in 2009 for sites where controlled drugs are used

Controlled drug handling site	Governance arrangements
Primary care trusts.	Accountable officer with responsibility for all aspects of safe and secure handling of controlled drugs. All controlled drug activity defined in standard operating procedures (SOPs). Self-assessment and declaration to the Care Quality Commission. Collected self-assessments from contracted services. Develop and lead the local intelligence network.
NHS hospital trusts and foundation trusts.	Accountable officer with responsibility for all aspects of safe and secure handling of controlled drugs. All controlled drug activity defined in SOPs. Self-assessment and declaration to the Care Quality Commission. Member of the local intelligence network.
Independent hospitals.	Accountable officer with responsibility for all aspects of safe and secure handling of controlled drugs. All controlled drug activity defined in SOPs. Self-assessment and declaration to the Care Quality Commission. Member of the local intelligence network.
Non-statutory prescribing drug services in community and inpatient (including residential) settings.	All controlled drug activity defined in SOPs. Commissioner of service to specify assurance.
Non-controlled drug designated bodies e.g. private clinics, private doctors.	All controlled drug activity defined in SOPs. Those registered with the Care Quality Commission under the Care Standards Act 2000 to complete self-assessment and declaration. For those not registered with the Care Quality Commission, the accountable officer of the primary care trust has the right of entry to investigate reported controlled drug concerns.

Controlled drug handling site	Governance arrangements
Social care settings.	Inspection by Care Quality Commission. All controlled drug activity defined in SOPs/policies and procedures. Self-assessment and declaration to the Care Quality Commission. Care Quality Commission member of the local intelligence network. Individual duty to report concerns to the primary care trust's accountable officer/local intelligence network.
GPs	Inspection by primary care trust's accountable officer. All controlled drug activity defined in SOPs. Self-assessment and declaration to the primary care trust. Individual duty to report concerns to the primary care trust's accountable officer/local intelligence network.

Appendix 3: Reports from partner organisations

Association of Chief Police Officers

The Association of Chief Police Officers (ACPO) represents the police service throughout England, Wales and Northern Ireland.

The ACPO drugs committee appointed Assistant Chief Constable Nick Wilkinson of Sussex Police as the link in this field of policing. ACC Wilkinson also chairs the Association of Police Controlled Drugs Liaison Officers (APCDLO).

There are 39 police forces in England providing 59 designated controlled drugs liaison officers (CDLOs) who take an active part in multi-agency work with partners. The role of the police is primarily in developing intelligence and subsequently investigating criminal offences involving controlled drugs. They work in close partnership with accountable officers, partner agencies and local intelligence networks.

Regulatory activity
ACPO is represented on the National Group on Controlled Drugs and the National Accountable Officers Support Programme. In 2009, there was an increase in the number of police staff rather than police officers performing the role of CDLOs. Capturing the vast experience of retiring officers allows forces to make the best use of their resources and continues to provide partners with a high quality of service.

Matters of interest
Some examples of good partnership working across the country include CDLOs in London joining with accountable officers and medicines management departments to deliver joint training to primary care trusts and private practitioners; a CDLO working with Herefordshire Primary Care Trust and community pharmacies to develop good practices in the safer management of controlled drugs; and a CDLO in Cleveland working with numerous partner agencies to reduce deaths related to illicit and diverted-prescribed diazepam.

NHS Counter Fraud and Security Management Service

The NHS Counter Fraud and Security Management Service (CFSMS), is a division of the NHS Business Service Authority (a special health authority). The CFSMS has two main responsibilities – reducing fraud to an absolute minimum (in England and Wales) and the management of security in the NHS (in England only).

As a named responsible body within the regulations, the CFSMS continued to actively support the safer management of controlled drugs by:

- Continuing its membership of the National Group.
- Continuing to raise awareness through the established local security management specialist (LSMS) and local counter fraud specialists (LCFS) networks locally.
- Participating at accountable officer support programme events from the National Prescribing Centre (NPC), with presentations from staff.
- Contributing to the revision and update of the third edition of the NPC's *A guide to good practice in the management of controlled drugs in primary care (England)*.

Regulatory activity
Work in this area continues as reported in 2008, with the ongoing development of information and guidance for LSMSs and LCFSs on the role and responsibilities of the accountable officer for controlled drugs and the local intelligence networks (LINs).

Information collected
The CFSMS does not currently collate information on incidents concerning controlled drugs. However, through the work of its operational staff and LCFS and LSMS networks, it gathers information on incidents involving controlled drugs and issues at LINs and shares this with the National Group.

Matters of interest
The security of prescription forms remains an ongoing issue of concern. Incidents involving the loss and theft of prescription forms have been reported to the NHS CFSMS through the LSMS network.

Department of Health

The Department of Health supports health and social care professionals and their organisations by developing policy, legislation and guidance in the safe management and use of controlled drugs in providing care for patients.

Regulatory activity
The Department of Health is working in partnership with the National Prescribing Centre (NPC) to identify key issues, solutions and priorities to support the safer management of controlled drugs in the following areas:

- Offender health.
- Ambulance trusts/paramedics.
- Private prescribers.
- Controlled drug record card.

These programmes will continue to develop in 2010 and will be supported by engagement with stakeholders.

The Department of Health has worked in partnership with the Association of Chief Police Officers (ACPO) to review the process for issuing warrants to civilian police staff under section 20(5)(a) of the Health Act 2006.[9] This has resulted in a streamlined application process and producing more secure warrants.

In addition, the Department and ACPO have begun the initial stages of a joint work programme to consider how the requirements of the police's information sharing agreements will affect the role of accountable officers and local intelligence networks. This will continue in 2010 to ensure that all are clear about what is required. It will also build on the good practice in terms of information sharing between the NHS and the police, and the development of policy from the Department of Health following on from the Shipman 5 Inquiry.

Following up on CQC's 2008 report, the Chief Pharmaceutical Officer wrote to all chief executives in October 2009 to remind them of their responsibilities regarding appointing a suitable accountable officer for their organisation, and providing the necessary support to enable them to carry out their duties.

The Department of Health is continuing to monitor the impact of the Controlled Drugs (Supervision of Management and Use) Regulations 2006 to consider with Ofsted and the Ministry of Defence whether they need to be defined in regulations as a Responsible Body to enable them to participate in local intelligence networks and the duty of cooperation that it requires. The Department is also monitoring the development of the commissioner/provider split within primary care trusts to consider whether this also has implications for the governance of the role of the accountable officer. A clarifying policy statement was issued on the accountable officer website and the position is being kept under review.

Matters of interest

Accountable officer's website: The Department of Health continued to support the development of the accountable officer network by providing resources to the National Prescribing Centre (NPC) to develop and maintain the website. This was launched in April 2009 with three supporting events in May and June.

This has been supported by the update of the NPC's guide to good practice in the management of controlled drugs in primary care, a new handbook for accountable officers that was issued in early 2010, and the development of training support materials for accountable officers, which was available in early 2010.

As part of the development of the accountable officer website, the Department of Health became responsible for collecting and maintaining information for the list of witnesses for the destruction of controlled drugs in multiple pharmacies. The list is now available on the NPC's AO website.

Ambulance trust pharmacy advisers network: Many ambulance trusts now have pharmacy advisers to support them with their medicines management. A network of advisers has been established and is working together to bring consistency in the safe use of medicines. This includes helping the Department of Health to develop guidance to support the safe management and use of controlled drugs across the ambulance/paramedic sector.

Home Office Drugs Licensing and Compliance Unit

The Drugs Licensing and Compliance Unit is part of the Drug Strategy Unit at the Home Office. The Home Office has responsibility for the Misuse of Drugs Act 1971 and its associated Regulations, which provide the framework for lawful activity with controlled drugs and drug precursor chemicals by the pharmaceutical industry and healthcare professionals.

Regulatory activity
The Drug Strategy Unit is part of the Drugs, Alcohol and Partnerships Directorate, holding responsibility for the delivery of the Government's Drug Strategy, which aims to reduce the harm that drugs cause to society, to communities, individuals and their families.

The 2008-2018 drug strategy comprises four strands of work:

- Protecting communities through tackling drug supply, drug-related crime and anti-social behaviour.
- Preventing harm to children, young people and families affected by drug misuse.
- Delivering new approaches to drug treatment and social re-integration.
- Public information campaigns, communications and community engagement.

The Drug Strategy Unit is also responsible for developing and implementing amendments to the Misuse of Drugs legislation, together with operating the licensing regime for individuals and corporate bodies involved in lawful activities with controlled drugs that are not covered by the provisions of the Regulations.

Drugs Licensing and Compliance Unit
The Drugs Licensing and Compliance Unit exists primarily to provide the Competent Authority to service the functions of the 1961 and 1971 United Nations Conventions. It gives effect to the Home Secretary's responsibilities under these and the Misuse of Drugs Act 1971.

In addition to the Misuse of Drugs Act 1971, the main domestic legislation under which it operates is the Misuse of Drugs Regulations 2001, the Misuse of Drugs (Safe Custody) Regulations 1973 and The Substances Useful for Manufacture (precursor chemical) legislation.

It has a licensing team of 10 and a compliance team of eight and its main functions are:

- Administering the statutory system of controls on the legitimate production and distribution of controlled drugs including:
    - Risk assessing and authorising licence applications and other authorities.
    - Making field-based visits to applicants and existing licensees and other authorised persons.
    - Administering controls on precursor chemicals.
- Co-operation with enforcement or regulatory agencies at national and international level.
- Collecting and processing statistical information on production, consumption, import, export and stocks of drugs controlled under the Conventions for the International Narcotics Control Board in Vienna.
- Responding to concerns raised about problematic activity by licensees through an annual Compliance Statement process.

Information collected
There are approximately 2,510 current domestic licences and approximately 11,500 import and export licences issued every year.

The unit has recently completed a three-month project using 10 investigators from an agency to visit all precursor licensees and those issued with controlled drug licences during 2007/08, when no pre-issue visits were made. The visits highlighted areas of poor compliance that needed immediate remedial measures and, in a handful of cases, resulted in licences being revoked. Education was the highest risk area, with an average of 1.7 problems identified per report; brokers/traders and manufacturers were the next highest risk areas, with an average of 1.6 problems per report. Between the three of them, these sectors accounted for two thirds of licensees visited, so the problems are widely spread. Standard operating procedures were the most commonly identified problem area (25% of errors), followed by licence irregularities (23%) and records/audit (21%).

Work is currently underway to install an IT system, provided by the United Nations, which will integrate all controlled drug and precursor licensing activity into a single system. It will deliver significant efficiency savings, increase the rigour of the scrutiny of applications, and faster turnaround times for licensees. The system will also link to the pre-export notification system to strengthen controls with international partners.

Healthcare
In healthcare, licences are issued to privately owned or operated hospitals and care homes to cover possession of Schedule 2 drug stocks for administration to patients.

The Unit issued a general licence covering practitioners, pharmacists and patients involved in prescribing the cannabis-based medication Sativex and another covering the activities of paramedics with morphine and Diazepam.

It also licences the import and export of controlled drugs by patients and practitioners travelling abroad for periods longer than three months and the prescribing (in conjunction with the Department of Health) of cocaine, diamorphine and dipipanone for the treatment of addiction.

National Patient Safety Agency

The National Patient Safety Agency (NPSA) is a special health authority, created in 2001 to coordinate efforts to identify, and learn from, patient safety incidents. The agency was established and guided by the Department of Health publications *An organisation with a memory (2000) and Building a safer NHS for patients – implementing An organisation with a memory (2002).* Its functions include:

- Collecting and analysing information on adverse events.
- Assimilating other safety-related information.
- Learning lessons and ensuring that they are fed back into practice.
- Where risks are recognised, identifying solutions to prevent harm.

The NPSA promotes patient safety by helping to develop a more open and fair culture in which risk is proactively assessed and patient safety is a high priority for everyone. It has issued reports, alerts and notices that concentrate on high risk areas for the NHS, including work around medicines.

From 1 April 2005, the NPSA expanded, giving it greater scope to improve patient safety in the NHS. The NPSA's work now includes specific safety aspects of hospital design, cleanliness and food. It also ensures that research is carried out safely, through its responsibility for the National Research Ethics Service (NRES), formerly the Central Office for Research Ethics Committees, and is supporting local organisations in addressing their concerns about the performance of individual doctors and dentists through its responsibility for the National Clinical Assessment Service (NCAS). It also manages the contracts with the three confidential enquiries.

Full details of this work and associated resources can be found on the NPSA website at www.npsa.nhs.uk . NPSA work relating specifically to medication can be found at:
http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/

Regulatory activity
The NPSA worked with the National Prescribing Centre to provide an appendix to the Guide to good practice in the management of controlled drugs in

secondary care. The third edition was published in December 2009, which reiterated the Actions from a Rapid Response Reports and Patient Safety Notices and provided practical advice on their interpretation. This is available at: http://www.npci.org.uk/cd/public/docs/controlleddrugsthirdedition.pdf

The NPSA continues to monitor the implementation of current actions in light of several high profile cases where inappropriate dosing has harmed patients. It is also collaborating in research to support this.

Information collected
The Safe Medication team at the NPSA regularly analyses data on medication error in general, gathered from the National Reporting and Learning Service (NRLS) and other organisations. This often includes data relating to controlled drugs, which feeds into the NPSA's work programme.

Recent data from a retrospective case review recorded by community pharmacists indicates that there are still inappropriate increases in dose for a range of opioids/opiates. This is being addressed by dedicated education of community pharmacists.

Matters of interest
The NPSA continues to work with the pharmaceutical industry to help improve safety in medication packaging. Due to the inherent risks associated with controlled drugs, these often form the focus of this collaborative working.

Representatives of the NPSA also sit on a number of external committees that sometimes deal with controlled drugs issues, such as the Medicines and Healthcare products Regulatory Agency (MHRA) Patient Information Expert Advisory Group and the Dictionary of Medicines and Devices working party. The primary purpose of NPSA representatives on all of these committees and working groups is to try to make the use of medicines, including controlled drugs, safer in practice.

National Treatment Agency for Substance Misuse

The National Treatment Agency for Substance Misuse (NTA) is an NHS special health authority, established in 2001 to improve the availability, capacity and effectiveness of drug treatment in England.

The NTA's early years focused on improving access and capacity: getting people in. With this achieved, the focus shifted to retention: keeping people in treatment long enough to gain lasting benefit. The challenge is now successful completion: getting more people out of treatment, free of dependency. NTA's priorities are to:

- Help drug users to overcome addiction and regain their lives.
- Benefit communities through less crime, better health and more stable families.

- Promote a balanced treatment system, where the type of treatment people get matches their needs.
- Help build the evidence underpinning drug treatment.
- Make sure that specialist services are available for under-18s with drug and alcohol problems.

Regulatory activity
The NTA continued to work closely with key partners in 2009 on regulatory activity of controlled drugs:

- Its nine regional teams assured the delivery of drug treatment according to national guidelines, including the 2007 suite of drug misuse guidance from the National Institute for Health and Clinical Excellence (NICE) and the UK-wide clinical guidelines *Drug Misuse and Dependence: UK Guidelines on Clinical Management*.
- It published guidance for drug treatment services on clinical governance. This emphasises the importance of the accountable officer and will help ensure that drug treatment services are included in local implementation networks. Regional teams include requirements for appropriate clinical governance in their assurance of local treatment systems.
- The NTA has also advised the Department of Health and the National Prescribing Centre on the potential implementation of a controlled drug record card.

Matters of interest
The NTA has continued to work with the Department of Health and the Care Quality Commission to ensure that the new registration requirements for health and adult social care providers ensure that substance misuse treatment is safe and meets the needs of service users, especially where the handling or prescribing of controlled drugs is regulated and inspected.

Royal Pharmaceutical Society of Great Britain

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. At present, it also regulates registered pharmacy technicians on a voluntary basis. Its primary objectives are to lead, regulate, develop and represent the profession of pharmacy.

Following the 2007 Government White Paper *Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century*, the Society is continuing the work towards separating its regulatory and professional roles. It made significant progress during 2009 and the new General Pharmaceutical Council (GPhC) will launch in 2010.

In 2009, the new draft Pharmacy Order, made under section 60 of the Health Act 1999, was published. The draft standards for the GPhC were published and will be subject to consultation in 2010. The new Chair Designate, Chief Executive Designate and the GPhC Council Designate were appointed in 2009. The RPSGB also made significant progress on developing the professional leadership body.

The Society's Regulations Directorate, including the Inspectorate, will transfer to the GPhC. The Inspectorate expanded in 2009 and there are currently 27 pharmacy inspectors in Great Britain, all of whom are pharmacists with considerable experience. They each have responsibility for approximately five primary care organisations and 550 registered retail pharmacies, the large majority of which are community pharmacies. The inspectors continued with the planned programme of monitoring visits to registered pharmacy premises, ensuring that legal requirements and professional standards were being observed and promoting safe and effective practice.

Regulatory activity

Community pharmacies in England are required to make a declaration on the annual premises retention form. Each establishment is required to declare if they keep controlled drugs and if so, whether the premises comply with the provisions of the Misuse of Drugs Act 1971 and the associated Regulations in the handling, use and management of Schedules 2 and 3 Controlled drugs. The Inspectorate follows up any establishment that fails to make a declaration.

In January 2007, RPSGB inspectors took over the monitoring and inspection of controlled drugs in community pharmacies in England as part of the agreed programme of changes arising from the Shipman Inquiry.

As part of the pharmacy inspection process, the pharmacist in charge must complete a self-assessment form indicating the activities undertaken within the pharmacy and provide information on the management and use of controlled drugs at each pharmacy. This information, together with other data including information from the annual declaration and complaints, is used as a basis to target pharmacy inspections.

Inspectors completed a report of controlled drug inspections for each pharmacy visit and, if there were any areas of concern or relevant issues arising, they provided a copy to the relevant accountable officer.

Following the introduction of the Responsible Pharmacist legislation on 1 October 2009, the RPSGB issued guidance specific to hospital pharmacies and guidance on what activities can be undertaken in registered pharmacy premises, both of which included information regarding the management and supply of controlled drugs.

The controlled drug section of the Medicines, Ethics and Practice Guide was updated and revised.

In 2009, RPSGB inspectors continued their extensive involvement in the local intelligence networks operated at primary care trust level. The inspectorate worked closely with partner organisations and has undertaken joint

investigations with other enforcement agencies on issues involving the management and use of controlled drugs.

RPSGB provided information on all complaints received relating to the management and use of controlled drugs to the relevant accountable officer at the start of any investigation, together with the subsequent outcome of the investigation.

The Inspectorate and Legal and Ethical Advisory Service assisted the National Prescribing Centre (NPC) in developing e-learning material and contributed to the NPC's guide to good practice in the management of controlled drugs primary care (England) - Third Edition.

The Inspectorate contributed to the Department of Health-led working group looking at issues relevant to the safe management and use of controlled drugs in ambulance services and paramedics (NHS and private).

Information collected

The RPSGB has approximately 11,202 pharmacies registered in England, of which around 209 are hospital pharmacies that have chosen to register.

All pharmacy owners except one completed the 2009 controlled drugs declaration that formed part of the premises fees retention form. This pharmacy owner has subsequently deregistered the premises.

During 2009, 3,543 controlled drugs monitoring and inspection visits in England were undertaken by the RPSGB inspectors and reports provided to the owners of pharmacies or superintendent pharmacists, where appropriate. This brings the total number of CD monitoring visits undertaken in community pharmacies in England, since the work began, to 9,814. Where there have been issues relating to the management and use of controlled drugs during the course of the visits, reports have been provided to the relevant accountable officers.

17 'commencement of investigation' disclosures have been made to accountable officers under s25 (4) of the Controlled Drugs (Supervision of Management and Use) Regulations 2006.

47 complaints received in 2009 were been logged as primarily raising concerns about the management and use of controlled drugs. There were 15 cases of single one off dispensing errors involving schedule 2 controlled drugs that were managed through the non-referral process subject to the Society's published threshold criteria.

The inspectorate investigated 82 cases which involved controlled drugs in 2009.

During 2009, 3,285 enquiries were received centrally and answered by the Society's Legal and Ethical Advisory Service relating to controlled drugs. Of these, 2,942 were telephone enquiries and 343 were written enquiries.

Matters of interest

The Controlled Drugs Inspection programme has completed its third year and the Inspectorate has seen continuing improvement.

Most community pharmacies visited demonstrated safe management of controlled drugs and considered ensuring compliance and developing effective systems as high priority. Community pharmacist generally had a positive response to the monitoring visits and appreciated the opportunity to discuss their concerns with the Inspectors.

Overall the number of pharmacies keeping running balances in the register of controlled drugs increased in 2009. Keeping a running balance is not a legal requirement but it is good practice and the RPSGB guidance on running balances recommends regular reconciliation of stock. Where regular reconciliation took place the running balances were managed well, however there remain a number of community pharmacies that have taken the decision not to record running balances for methadone liquid.

Destruction of obsolete controlled drug stock in community pharmacies was managed well overall although accumulation of obsolete stock was observed towards the end of 2009 in organisations where destruction of controlled drugs had ceased to be a priority. The Inspectors observed a build up of patient returned controlled drugs and some community pharmacies were struggling to appropriately store items awaiting destruction. Some pharmacists remain unaware of their authority to destroy date expired Schedule 3 stock and patient returned CDs.

The issues identified with controlled drug instalment prescriptions continued through 2009. Dose, instalment amount and intervals were not always being stated on FP10MDA prescriptions. Some prescribers were not using the home office wording on the instalment prescriptions to allow supply of the remaining quantity if the instalment day was missed. This placed pharmacists in a difficult position when patients missed a collection date at times or attended with incorrectly written prescriptions when the prescribing services were closed.

There was a common theme for errors whereby inappropriate supplies of Methadone were made due to mistaken identity of the patient. Proof of identity, especially for methadone patients, was very rarely requested and ID was very rarely seen. There were numerous incidents where the wrong quantity of methadone was supplied to substance misuse patients because of mistaken identity.

Unlicensed methadone was still being prepared in some pharmacies with lack of storage available for housing large volumes of the licenced product being given as the main reason.

Self reporting of incidents by pharmacists increased in 2009, but there was little evidence of self-reporting by other health care professionals. Secondary care organisations were not as fully engaged with the process of reporting concerns as others which may have contributed to an unbalanced view overall.

Some LINs were still requesting the Inspectorate and other regulators to sign information sharing protocols despite being fully informed of the statutory obligations placed on responsible bodies, rendering this unnecessary.

National Prescribing Centre

The National Prescribing Centre (NPC) is a health service organisation, formed in April 1996 by the Department of Health. Its aim is to promote and support high quality, cost-effective prescribing and medicines management across the NHS, to help improve patient care and service delivery.

The Department of Health commissioned the NPC to develop and provide a comprehensive programme of support for accountable officers in England. A national steering group has been established to guide the development of the programme with representation from stakeholders including professional regulators, national bodies involved in the safe management and use of controlled drugs and accountable officers.

The support provided through the programme includes regional learning events for accountable officers and a dedicated area of the NPC website (www.npci.org.uk/cd), where a variety of resources are available (see examples of good practice from NPC on pages 18 and 19).

During 2010-2011, the NPC will be looking to further enhance the controlled drugs web pages and provide additional resources to support the safe management and use of controlled drugs.

NHS Prescription Services

NHS Prescription Services, on behalf of the NHS, pay community pharmacies and appliance contractors and calculate the payments due to dispensing doctors for prescription items they have dispensed to patients.
Using information collected from this process, NHS Prescription Services provides the NHS with information for prescribing and financial management purposes. Over the last year, NHS Prescription Services priced more than 80 million prescription items each month, paying around £800 million to 11,500 contractors, while accounting for this prescribing against approximately 40,000 separate prescribing budgets.

NHS Prescription Services is delivering significant efficiency savings in processing prescriptions. In 2009, further updates to the processing system were implemented, enabling electronic prescription messages to be accepted and improving how the information needed for reimbursing and remunerating dispensing contractors can be captured from paper forms. The use of high speed scanners and intelligent character recognition software has allowed NHS Prescription Services to reduce the amount of information that has to be captured manually. However, a large number of staff are still involved in

capturing and verifying information and pricing prescriptions, before it is passed either for payment or as information to the wider NHS.

By October 2008, all community pharmacy accounts (around 64 million prescription items per month) were being processed through the new processing system and in June 2009, dispensing doctors and personal administration contractors' accounts were moved to the new system. NHS Prescription Service plans for appliance contractors to move to the new system in May 2010 and that, in the future, all dispensing contractors' paper forms will be handled this way.

Regulatory activity
NHS Prescription Services is primarily concerned with the calculation and payment, on behalf of the NHS, to dispensing contractors for prescriptions dispensed in primary care in England.

To support the management of controlled drugs, NHS Prescription Services captures and provides information to the NHS on controlled drug requisitions and non-NHS prescriptions supplied from community pharmacies and dispensing doctor practices.

Information collected
NHS Prescription Services collects data from prescription forms dispensed in the community, controlled drug requisition forms and private controlled drug prescription forms. It produces national and primary care trust (PCT) level information reports on all Schedule 1, 2 and 3 controlled drug requisitions and non-NHS prescriptions supplied from community pharmacies and dispensing doctor practices. It also includes data on prescribing of controlled drugs in the ePACT and ePFIP information systems.

Matters of interest
The management of controlled drugs has led to closer examination of prescribing data and increased scrutiny of information provided by NHS Prescription Services.

NHS Prescription Services information systems and reports have been developed independently over the last 20 years using raw prescription data. Although NHS Prescription Services can act to ensure that correct payments are made to dispensing contractors, it has never been able to correct information reports once they have been published due to the inter-correlation and timeliness of the various reporting systems.

During 2009, NHS Prescription Services maintained targets set by the Department of Health for accuracy and timeliness of payments to contractors. NHS organisations and the NHS Prescription Services have identified various issues that are affecting the quality and accuracy of the information systems and reports supplied for a small number of products captured on the new processing system. These issues are different to those experienced using the old system which, coming from a more manual system, were more widespread and sporadic.

Its information systems are robust and of a high quality, despite issues with these few products. A team of staff analyses the reimbursement and remuneration processes and takes action where appropriate to minimise the risk of errors occurring in information systems.

From increased scrutiny of its information, NHS Prescription Services has seen an increase in the number of requests for 'original' prescriptions from accountable officers and PCT staff. It stores 14 months' worth of paper forms (560 million forms) in its warehouse in Newcastle upon Tyne. Retrieving prescriptions is resource-intensive and the NHS Prescription Services has worked with prescribing leads in strategic health authorities and the Department of Health to determine appropriate timescales for delivery. From May 2010, it is anticipated all PCT requests for prescription retrieval will be delivered within a maximum of four weeks, rather than the previous 12-week target.

In addition to the paper prescriptions stored, NHS Prescription Services has access to up to the last five months' scanned prescription images, which allow faster retrieval of information to respond to PCT requests.

NHS Prescription Services is working with key NHS stakeholders to engage with people who use information to understand how information should be provided in the future. Improved information will enable best practice to be identified and implemented, which will lead to increased value for tax-payers money.

References

1. The Stationery Office, *Fourth Report of the Shipman Inquiry: The Regulation of Controlled Drugs in the Community*, July 2004

2. Department of Health and Home Office, *Safer management of controlled drugs: The Government's response to the Fourth report of the Shipman Inquiry*, December 2004, www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4097904

3. Misuse of Drugs Regulations 2001 (SI 3998), www.opsi.gov.uk/si/si2001/20013998.htm

4. Misuse of Drugs Act 1971 (Amendment) Order 2008, UK SI 3031

5. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (SI 3148), www.opsi.gov.uk/si/si2006/20063148.htm

6. Department of Health, *Safer management of controlled drugs: (1) guidance on strengthened governance arrangements*, March 2006, updated January 2007

7. The Stationery Office, *Fifth Report of the Shipman Inquiry: Safeguarding Patients: Lessons from the Past - Proposals for the Future*, December 2004

8. Care Quality Commission, *Guidance about compliance: Essential standards of quality and safety*, March 2010 http://www.cqcguidanceaboutcompliance.org.uk/

9. The Health Act 2006, www.opsi.gov.uk/acts/acts2006/pdf/ukpga_20060028_en.pdf

Glossary of terms

Term	Abbreviation	Definition
Accountable officer	AO	The person in a healthcare organisation who takes formal responsibility for all controlled drug handling and governance issues in their organisation. This is a requirement under the Health Act 2006.[9] Details of the role are set out in the Controlled Drugs (Supervision of Management and Use) Regulations 2006.
Advisory Council on the Misuse of Drugs	ACMD	An independent expert body that advises Government on issues related to the misuse of drugs in the UK.
Analgesic		Pain-relieving medicine
Central nervous system stimulants	CNSS	e.g. dexamfetamine, methylphenidate
Controlled drugs liaison officer	CDLO	Police officer or police staff with a specific role in relation to controlled drugs intelligence and investigation.
Controlled drug designated body	CDDB	A healthcare organisation that is required to have an accountable officer under the Controlled Drugs (Supervision of Management and Use) Regulations 2006. In England this includes PCTs, NHS trusts (including foundation trusts) and independent hospitals.
Controlled drug requisitions		Standardised documents that are used when healthcare practitioners requisition supplies of controlled drugs from community pharmacies.
electronic Prescribing Analysis and Costs	ePACT	A computer system that provides an interface to analyse prescribing information held on the NHS Prescription Services' prescription information database.
FP10PCD		Standardised controlled drugs private prescription form.
Healthcare organisation	HCO	For example, a PCT, NHS trust hospital or independent hospital.

Independent healthcare		Private or voluntary healthcare delivered outside the NHS.
Local intelligence network	LIN	Defined in legislation as a network to be established by the PCT accountable officer to share information between organisations and agencies regarding the handling and use of controlled drugs.
Medicines and Healthcare products Regulatory Agency	MHRA	The government agency that is responsible for ensuring that medicines and medical devices work, and are acceptably safe.
Misuse of Drugs Act 1971	MDA	Act of Parliament that aims to control the possession and supply of various drugs.
Misuse of drugs legislation		See MDA and MDR.
Misuse of Drugs Regulations 2001	MDR	Legislation governing the legitimate, clinical use of controlled drugs.
Opiate		Naturally-occurring narcotic derived from opium, e.g. morphine.
Opioid		A synthetic narcotic that resembles the naturally occurring opiates e.g. fentanyl.
Prescribing Support Unit		Body responsible for analysis of all NHS and private prescriptions for controlled drugs dispensed in community pharmacies.
Primary care trust	PCT	Body responsible for commissioning and delivering healthcare and health improvement to the people of its local area.
Relevant person		Healthcare professionals and others whose work involves, or may involve, the supply and administration of controlled drugs on behalf of another registered medical practitioner, dentist, pharmacist, private midwife, or registered person, etc (that is, the non-professionals involved with handling controlled drugs) in assisting the healthcare person (Regulation 23).
Responsible body		Body or organisation defined in regulation with a duty to share information on controlled drugs.

Root cause analysis		A systematic approach to get to the true root causes of process problems
Serious untoward incident	SUI	An adverse incident that causes serious harm to a user of healthcare services, a member of the public or a member of staff, or that causes a serious breach of the standard or quality of service.
Strategic health authority	SHA	Bodies that manage the NHS locally. They develop plans for improving health services in their area, make sure local health services are of a high quality and making sure national priorities are integrated into local health service plans.
Transdermal patches		Adhesive patches that contain a drug (eg buprenorphine or fentanyl) and are used to deliver a drug slowly through the skin.

Published August 2010

How to contact us

Phone: 03000 616161
Email: enquiries@cqc.org.uk

Registered Office:
Care Quality Commission
Finsbury Tower
103–105 Bunhill Row
London EC1Y 8TG

Please contact us if you would like a summary of this document in another format or language.