

The National Group on Controlled Drugs

**Reports of activity in 2013 from
partner organisations**

August 2014

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The National Group on Controlled Drugs

Reports of activity in 2013 from partner organisations

This is a strategic group of regulators and key agencies who have areas of responsibility for controlled drugs within their remit. Membership of the Group in 2013 included:

- Association of Chief Police Officers
- Care Quality Commission
- Department of Health
- General Pharmaceutical Council
- Health and Social Care Information Centre
- Her Majesty's Inspectorate of Prisons
- Home Office
- Medicines Advice (Medicines and Prescribing Centre) National Institute for Health and Care Excellence (NICE)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Ministry of Defence
- NHS England
- NHS England Patient Safety Team
- NHS Protect
- Ofsted
- Public Health England
- UK Anti-doping
- Veterinary Medicines Directorate.

The Care Quality Commission (CQC) is grateful to these organisations for their on-going commitment and contributions to the Controlled Drugs National Group.

Reports of activity from some of the main partners illustrate the many ways in which separate groups contribute to the overall safer management of controlled drugs.

1. The Association of Police Controlled Drugs Liaison Officers

The Association of Police Controlled Drugs Liaison Officers (APCDLO) brings together the expertise and experience of Controlled Drugs Liaison Officers (CDLOs) from Scotland, England, Wales and Northern Ireland, providing a professional forum to share ideas and best practice, coordinate resources and help deliver effective policing.

Engagement in controlled drug activity in 2013

- Carried out investigations concerning any criminality or breaches of regulations relating to controlled drugs (CDs) within the healthcare arena.
- Undertook 'Targeted Inspections' at pharmacies and other health care premises and collated and disseminated key intelligence. Prevented the diversion of CDs into the illicit drugs market through investigations, targeted inspections and destructions of CDs. Premises inspected included GP surgeries, pharmacies, dentists, vets, hospitals, slimming clinics, hospice care units, ambulance stations and other healthcare premises, to ensure the safe management of CDs. Developed links with partner agencies to share information and develop processes to tackle drugs more effectively and engaged in multi-agency liaison as directed by the Health Act.
- Liaised with law enforcement and other agencies to identify wanted/missing persons from intelligence and information gained during CDLO work.

Matters of interest

The following are two examples of recent investigations carried out by the Metropolitan Police CDLOs that had successful outcomes:

- A responsible pharmacist, whilst acting as a locum for a large chain of retail pharmacies, was found to be ordering in and then stealing CDs and 'prescription only' medicines and supplying them to the local community. The investigation included liaison with the professional and regulatory bodies, including the pharmacy multiple in a joint approach that greatly enhanced the outcome.
- A senior nurse working in the theatre department of a large hospital was caught stealing large amounts of fentanyl ampoules and falsifying records to hide addiction. The nurse was summoned to court and pleaded guilty. The nurse is now receiving counselling and treatment and the case is being considered by their professional body.

2. The Department of Health

The Department of Health (DH) supports health and social care professionals and their organisations, through developing policy, legislation and guidance on the safe management and use of controlled drugs as part of patient care.

Engagement in controlled drug activity in 2013

As a consequence of the changes to the NHS structure set out in the Health and Social Care Act 2012, the Department of Health amended the Controlled Drugs (Supervision of Management and Use) Regulations 2006. The 2013 regulations came into force on 1 April 2013 and continue to apply in England and Scotland. These regulations carry forward a number of measures in the 2006 regulations that underpin the arrangements to ensure safe management and use of CDs. A copy of the 2013 regulations can be found [here](#).

To support the changes made in legislation and continue to promote good governance concerning the safe management and use of CDs across England and Scotland, the Department of Health published supporting information *The Controlled Drugs (Supervision of Management and Use) Regulations 2013 – Information about the regulations*, which can be found [here](#). This updates earlier guidance and complements other relevant information and guidance published by professional and regulatory organisations.

Since 1 April 2013, the Department of Health has been monitoring the implementation of the 2013 Regulations. Throughout 2013, the Department continued to work closely on the shared CDs agenda with other interested parties such as NHS England, the Care Quality Commission, the National Institute for Health and Care Excellence, Home Office, NHS Protect, the General Pharmaceutical Council, Association of Chief Police Officers and the NHS Business Services Authority.

During 2013, the Department of Health has been working on preparing further amending legislation that would extend electronic prescribing to include controlled drugs within Schedules 2 and 3 of the Misuse of Drugs Regulations. This work is ongoing.

3. General Pharmaceutical Council

The General Pharmaceutical Council (GPhC) is the independent regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales. Its remit is to protect, promote and maintain the health, safety and wellbeing of patients, the public and all those who use registered pharmacy services.

The GPhC sets out the standards of conduct, ethics and performance that pharmacy professionals must follow. It also publishes standards for education and training, continuing professional development (CPD) and the safe and effective practice of pharmacy at registered pharmacies.

The GPhC responds to allegations of impairment of fitness to practise and may impose restrictions on registration in accordance with the provisions of the Pharmacy Order 2010 and the rules made under it. In addition, the GPhC has enforcement duties and powers under the Medicines Act 1968, the Poisons Act 1972, and the Veterinary Medicines Regulations. These enforcement duties and powers are mainly in relation to registered pharmacy businesses.

The GPhC maintains a team of inspectors under article 8 of the Pharmacy Order 2010. The inspectors regularly inspect all registered retail pharmacy premises in England, Scotland and Wales for the purpose of ensuring compliance with the GPhC's standards and the relevant legislation that the GPhC enforces.

Engagement in controlled drug activity in 2013

The GPhC's inspectors continued to inspect registered pharmacy premises on a three-year cycle, and examined arrangements for the management of controlled drugs (CDs) during inspections. Information was shared with Controlled Drugs Accountable Officers (CDAOs) in relation to any concerns about CDs identified during inspections and any complaints received that involved CDs.

GPhC monitored controlled drugs in pharmacy services in prisons as part of the work carried out on behalf of Her Majesty's Inspectorate of Prisons.

The GPhC was represented on CQC's Controlled Drugs National Group and the Controlled Drugs Cross Border Group. GPhC Inspectors attended NHS England's local intelligence network meetings, participated in critical incident panels and regularly liaised with primary care organisations and police controlled drug liaison officers (CDLOs) to share intelligence and deal with matters that fell both above and below the regulatory bar.

The GPhC Standards Team responded to phone calls, emails and letters, to provide advice to pharmacy professionals, patients and the public, about the standards set and the medicines legislation relating to pharmacy.

The GPhC continued to publish a bi-monthly bulletin called 'Regula+e', which is sent to all registrants and pre-registration trainees. Copies of Regula+e are also available to download from the GPhC's website [here](#).

Throughout the year advice in relation to CDs was provided in Regula+e. One of the regular features details fitness to practise cases that the GPhC has dealt with, and identifies learning points that registrants may find of use. This feature is entitled 'Fitness to Practise – learning'.

Fitness to practise learning case articles in 2013 included:

- Issue 9 of Regula+e in February 2013: a case involving the supply of a different amount of methadone to that requested on the instalment prescription.
- Issue 10 of Regula+e in May 2013: a case of methadone prescriptions not marked or endorsed at the time of supply.
- Issue 11 of Regula+e in July 2013: a case of the theft of morphine sulphate tablets, codeine and dihydrocodeine.

Data / information collected

At the end of 2013 the GPhC had 14,571 pharmacy premises registered, of which 536 were hospital pharmacies. The GPhC operates a 'rolling register' which means that the registration of all pharmacy premises must be renewed annually, starting one year from the date of first registration.

As part of the renewal process, 13,945 premises had renewed and completed the CD declaration. This represented renewal of over 99% of premises for which renewal was due, the remaining 11 premises were removed from the register. The GPhC Standards Team responded to 3,405 enquiries in 2013, of which 432 related to CDs.

Matters of interest

GPhC has moved away from a prescriptive or rules-based approach and has developed standards for registered pharmacies that focus on achieving results for patients. In accordance with this GPhC has reviewed the approach to inspection, and launched a prototype of the new inspection model on 4 November 2013.

The new model adopts a 'show me, tell me' approach, whereby inspectors look at the way a pharmacy works and engages with the whole pharmacy team, not just the responsible pharmacist, to obtain evidence to provide assurance that each individual standard is met.

Inspectors no longer use the CD monitoring forms that were previously completed during inspections in England and Scotland. However, they still look at the arrangements pharmacies have in place for handling CDs and will continue to pass any concerns to NHS England's Area Team Lead CDAO.

Further information about the new inspection model and the Standards for Registered Pharmacies is available [here](#).

4. Her Majesty's Inspectorate of Prisons for England and Wales

Her Majesty's Inspectorate of Prisons for England and Wales (HMI Prisons) is an independent inspectorate that scrutinises conditions for, and treatment of, those in court and police custody, prisons, young offender institutions, and immigration detention facilities. HMI Prisons promotes the concept of 'healthy prisons' in which staff effectively work to support prisoners and detainees to reduce reoffending or achieve other agreed outcomes.

HMI Prisons inspects medicines and pharmacy management. The reports comment on the facilities associated with, and management of controlled drug (CD) prescribing, dispensing and administration within each establishment inspected. Overall, inspections generally see adherence to national guidelines in the prescribing, dispensing and administration of CDs with facilities being, in the main, adequate for purpose. However, some concerns related to the storage and security of CDs remain in places of detention, where CDs at the point of administration could, potentially, be diverted for illicit use. The advent of pain clinics in some prisons has supported more systematic approaches to prescribing.

5. Home Office - Drug Licensing & Compliance

Home Office (HO) Drug Licensing & Compliance is part of the Drug and Alcohol Unit within the Home Office.

The HO has responsibility for the Misuse of Drugs Act 1971 and the associated Misuse of Drugs Regulations 2001; the latter providing the framework for lawful activity with controlled drugs (CDs) and drug precursor chemicals by the pharmaceutical industry and healthcare professionals.

The Drug and Alcohol Unit is part of the Crime and Policing Group, holding responsibility for the delivery of the Government's Drug Strategy, which aims to reduce illicit and other harmful drug use; and increase the numbers recovering from their dependence.

The 2010 Strategy has recovery at its heart. It:

- Places emphasis on providing a more holistic approach, by addressing other issues in addition to treatment to support people dependent on drugs or alcohol, such as offending, employment and housing.
- Aims to reduce illicit and other harmful drug use.
- Takes an uncompromising approach to crack down on those involved in the drug supply both at home and abroad, and
- Puts power and accountability in the hands of local communities to tackle drugs and the harms they cause.

With regards to devolved powers, the coverage of the new strategy is as follows:

- Health, education, housing and social care – confined to England.
- Policing and the criminal justice system – England and Wales, and
- The work of the Department for Work and Pensions – England, Wales and Scotland.

The Drug & Alcohol Unit also continues to hold responsibility for the development and implementation of amendments to the Misuse of Drugs legislation.

Engagement in controlled drug activity in 2013

The Drug Licensing & Compliance Unit operates a risk-based domestic licensing regime to enable the licit use of CDs (and precursor chemicals). A complimentary licensing system is in place to enable import and export of CDs and precursor chemicals.

The regime is well-regarded with concerted efforts made to continue working collaboratively with other regulatory bodies to strengthen relationships and appropriate information sharing with those parties. It strikes a proportionate balance against international and moral obligations to minimise the risk of the diversion of CDs but to ensure the availability of drugs for licit use. The Drug and Alcohol Unit strives to ensure any burdens placed on licensees are proportionate and kept to a minimum and has received positive assurance from Internal Audit during 2013 as to the integrity, sustainability and proportionality of the regime.

Additionally the Drugs and Alcohol Unit:

- Co-operates as necessary with enforcement/regulatory agencies at national and international level,
- Collects and processes statistical information on production, consumption, import, export and stocks of drugs controlled under the Conventions for the International Narcotics Control Board in Vienna,
- Responds to problematic activity by licensees through an annual Compliance Statement process and robustly applying administrative sanctions ranging from noting contraventions against a licensee to considering licence revocation, and
- Issued in excess of 850 CD domestic licences in 2013.

All domestic CD licence applications are lodged electronically. An online licensing portal for all import and export licence applications; designed by the United Nations, has been fully operational for nearly three years and integrates all CD and precursor licensing activity into a single system.

In 2013, the Unit reviewed the domestic licensing application portal and developed a new Case Management System to make a more intuitive application portal for licensees, enabling it to provide more information 'up front' to streamline the consideration process, and to provide better management information and support for continued improvement to process licence applications more efficiently. This system will roll out in 2014, and for the first time will enable precursor chemical licensees and registrants to apply online.

Interface with the healthcare sector: licences are issued to privately owned or operated hospitals and care homes to cover possession of Schedule 2 CD stocks for administration to patients.

There are general licences or 'authorities' covering the activities of paramedics, NHS ambulance trusts and St John Ambulance with morphine and diazepam, which include mountain rescue bodies to ensure casualties can receive prompt and efficient pain relief in a trauma situation often in inaccessible locations. There are also licences covering import and export of CDs by patients and practitioners travelling abroad for periods longer than three months, or travelling with more than three months' supply of controlled drugs.

The Unit individually licences doctors at specified premises in England & Wales (in consultation with the Department of Health) to administer cocaine, diamorphine and/or dipipanone for the treatment of addiction. This function was devolved on 31 October 2012 to Scottish Ministers for practitioners wanting to prescribe cocaine, diamorphine or dipipanone in Scotland for the treatment of addiction.

Matters of interest

Licence Replacement Programme; on 1 January 2012 a 'Licence Replacement Programme', was launched, which affected holders of open ended controlled drug and precursor chemical licences and registrations issued between 2007 and before 15 November 2010. All holders of open-ended licences were required to review their licensing requirements and apply for a time-limited replacement if they intended to continue handling CDs or precursor chemicals. Failure to apply will lead to revocation of open-ended licences.

The Unit has produced a set of frequently asked questions and information about the programme and the phase breakdowns are available on the Home Office website [here](#).

All companies holding open-ended licences were required to review their controlled drug requirements and, if they continued to need licensing, submit an application for a time limited licence by the end of their phase. All phases have now closed.

Response to the programme has been positive. The Unit is visiting a proportion of licensees in the course of their 'reapplication' on a risk assessed basis. The programme is ongoing, and so far the Unit has completed approximately 647 licence replacement project cases (from March 2012- December 2013), and 139 licences holders have surrendered their licences. This equates to around 62% of cases being resolved. Those sites not visited on this cycle will be visited in subsequent years.

Licencees who are not visited at this renewal point should expect to be visited at some point in the next three years. The Unit is reviewing, on a phase-by-phase basis, those who have failed to re-apply and have initiated a two-stage revocation process, a final letter indicating that the Unit is intending to revoke a licence as the person has failed to re-apply, and a second communication at the point of revocation. No revocations have yet taken place but the Unit is working through those licensees who have failed to apply and are liable to revocation, in conjunction with driving down numbers of outstanding cases, before actually undertaking those revocations.

Compliance visits identified some common issues, which have been shared with other regulators and the Unit worked closely with licensees to ensure compliance standards were met. This included incidents of poor key security procedures and a handful of 'unlawful supply' issues.

Contracting-out of services: An emerging theme for 2013 has been the contracting-out of services that were previously carried out by crown servants or police constables. This includes but is not limited to healthcare provision in custody and prison settings, and provision of addiction treatment services, often by different providers in the same physical location. In some cases, the implications for CD licensing, and the need to hold a licence may not have been considered at the time and these activities may have been occurring unlawfully. The Unit have worked closely with all parties concerned to regularise these situations and ensure all parties are treated equally and proportionally.

Looking forward, the Unit are trying to encourage parties considering contracting out, or tendering for such contacts, to flag and give early consideration to the potential need for licensing. Early engagement is essential from prospective licensees and they are encouraged to think from the premise that licensing will be required and to factor in timescales and costs to their planning.

Updated guidance: *General Security Guidance* and *Security of Controlled Substances in Transit*.

These two guidance documents for existing and prospective licensees have been given a substantive re-vamp, to ensure clarity and consistency but there are no changes to the underlying legislation (Misuse of Drugs (Safe Custody) 1973 Regulations). These are available on our website and we have worked closely with Department of Health, Social Services and Public Safety Northern Ireland (DHSSPNI) to ensure consistency across the UK in terms of expectations.

Supply of CD stock from the NHS to other organisations (separate legal entities) - emerging issue.

There have been no legislative changes to the (MDA/MDR) in this regard and 'supply' of CD stock (from NHS hospitals) to separate sites or legal entities is technically always something that has required licensing (as a wholesale activity). Changes to the Medicines Act in 2012, specifically the repeal of S10(7), has brought this issue to the fore. It is a related but not identical issue. There has been some dissatisfaction expressed at this situation but we do not envisage making any legislative changes in this regard.

During 2014, representatives of Medicines and Healthcare products Regulatory Agency (MHRA), Department of Health and Home Office will meet NHS representatives to discuss the situation further. The Unit recognises the need to ensure healthcare needs are met and is prioritising applications accordingly, but we do not envisage any consequential changes to drug legislation or policy.

Legislative updates during 2013

- Review of provisions under the Misuse of Drugs Regulations 2001: Work on proposals to review specific provisions under the Misuse of Drugs Regulations 2001 is continuing with proposed regulatory amendments expected to come into force during the second half of 2014, subject to Ministerial approval.

The amendments proposed were outlined in the associated consultation, which can be found [here](#).

- Re-scheduling of 'Sativex: Following the Advisory Council on the Misuse of drugs (ACMD) advice, 'Sativex' was re-scheduled from Schedule 1 to Part 1 of Schedule 4 to the 2001 Regulations in April 2013.

- ACMD advice on methoxetamine, and related compounds, o-desmethyltramadol and a further group of synthetic cannabinoids: The ACMD provided further advice on methoxetamine (at the time a temporary class drug) and related compounds, o-desmethyltramadol (found in the 'legal high' Kratom), and a further group of synthetic cannabinoids. The ACMD advice is available [ACMD advice here](#).

The Government accepted the ACMD's advice and the above drugs were brought under the control of the Misuse of Drugs Act 1971 on 26 February 2013.

- ACMD further advice on two groups of new psychoactive substances ('legal highs'). The ACMD provided further advice on the two groups of new psychoactive substances – 'NBOMe' and 'Benzofury', which were subjected to temporary control under the Misuse of Drugs Act on 10 June 2013.

The ACMD recommended that the NBOMe compounds should be controlled as Class A drugs, and the Benzofuran compounds as Class B drugs. The Government accepted the ACMD advice. The temporary Order is in force until 09 June 2014. None of these drugs have any identified legitimate medical or industrial uses besides 25I-NBOMe currently used in research for use in PET Scanners.

Legislation controlling these drugs permanently was expected to come into force on 10 June 2014.

- Tramadol: Following consultation on scheduling, tramadol was brought under the control of the Misuse of Drugs Act 1971 on 10 June 2014 as a Class C and schedule 3 drug, but exempt from the safe custody requirements.
- Independent prescribing by Allied Health Professionals: The legislative changes introducing limited independent prescribing authorities for chiropodists and physiotherapists is expected to come into force in the second half of 2014 when the first batch of prescribers come online, subject to Ministerial approval.

The ACMD advice is available [here](#).

- Lawful provision of foil: The ACMD recommended in 2011 that legislative changes should be made to enable the provision of foil by persons employed or engaged in the lawful provision of drug treatment services for use in smoking instead of injecting.

The Government accepted the ACMD's advice but on the strict conditionality that such provision should only be lawful if foil is provided "*as part of structured efforts as to get individuals off drugs, whether for the purpose of getting them into treatment in the first place or in the initial stages of their treatment and recovery plan*".

Legislative changes implementing the ACMD advice under the strict conditionality is expected to come into force in the second half of 2014, subject to ministerial approval.

The ACMD advice is available [here](#). The government response to the ACMD advice is also available [here](#).

- Lisdexamphetamine, zaleplon and zopiclone: The ACMD published advice on lisdexamphetamine, zaleplon and zopiclone in September 2013. The ACMD recommended that lisdexamphetamine should be controlled as a Class B Schedule 2 drug and the two Z-drugs as Class C and Schedule 4 Part 1 drugs, under the 1971 Act and the 2001 Regulations.

The ACMD advice is available [here](#). The government has accepted the ACMD advice. Legislative changes implementing the recommendations came into force on 10 June 2014.

- Rescheduling of GHB (Xyrem): Following international rescheduling by the United Nations the ACMD recommended that GHB should be rescheduled to Schedule 2 to the 2001 Regulations. The Government has accepted the ACMD advice. Schedule 2 status is not expected to impact or burden prescribers and dispensers as about a thousand prescriptions are issued for the GHB-based medicine, Xyrem, in the UK annually. Legislative changes are expected to come in late 2014.
- Reclassification and rescheduling of ketamine: Following a review, the ACMD has recommended (December 2013) that ketamine should be reclassified as a Class B drug under the 1971 Act and, subject to the outcome of a public consultation, rescheduled to Schedule 2 to the 2001 Regulations. Legislation reclassifying ketamine as a class B drug came into force on 10 June 2014. It is expected that a full public consultation on the impact of schedule 2 status will be undertaken over the summer of 2014 prior to a decision on scheduling being made.

The ACMD advice is available [here](#).

6. National Institute for Health and Care Excellence

The Controlled Drugs Accountable Officer (CDAO) support programme is provided by the National Institute for Health and Care Excellence (NICE) Medicines and prescribing centre. The programme was originally commissioned by the Department of Health to provide a comprehensive programme of support materials, tools and resources to enable CDAOs in England to undertake their statutory duties effectively.

During 2013, NICE has continued to deliver the programme through specific NICE communities of practice, including a secure discussion forum and through networking and learning events.

Engagement in controlled drug activity in 2013

NICE's communities of practice continues to be a secure online area for CDAOs to access a closed discussion forum and share learning with other CDAO colleagues.

NICE hosted four half day networking and learning events in March 2013 for CDAOs in the UK. The events were held in Leeds and London and were attended by 234 CDAOs in total. The half day events included presentations from the Department of Health, CQC, NHS England's Patient Safety Team and Association of Chief Police Officers. The learning event included interactive case studies, which were considered on small working group tables and allowed delegates to share their learning and discuss how they would approach particular scenarios about controlled drug (CD) practice.

NICE continued to cascade news alerts about significant developments or important information around the safe management and use of CDs.

7. Medicines and Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency (MHRA), an Executive Agency of the Department of Health, is responsible for the regulation of medicines (for human use) and medical devices on the UK market.

There are specific enforcement powers under the Human Medicines Regulations 2012 and authorised officers at MHRA undertake the enforcement function on behalf of Secretary of State for health.

Engagement in controlled drug activity in 2013

Medicines legislation applies to controlled drugs (CDs) which are prescribed as Prescription-Only Medicines (POMs).

Data / information collected

European Directive on Falsified Medicines was implemented in the UK in August 2013. The first tranche of the legislation places more robust control over the regulated UK supply chain. A second tranche, concerning medicines supplied “at a distance” will introduce a common logo for pharmacies and retailers that offer to supply medicines electronically. The Implementing Act is expected from the European Commission in spring 2014.

Matters of interest

The MHRA monitors medicines being sold online. In cases where medicines legislation is breached, the Internet Service Provider (ISP) is contacted with a view to the website being suspended.

8. Ministry of Defence

From April 2013, the majority of primary care delivered to Her Majesty’s Armed Forces came under the single command of Defence Primary Healthcare (DPHC). This provides consolidated and consistent controlled drugs (CDs) management procedures across primary care. Apart from operations and the Defence Medical Rehabilitation Centre (DMRC), the MOD does not manage CDs in secondary care.

The Controlled Drugs (Supervision of Management and Use) Regulations 2013 introduced the MOD as a Designated Body for the first time and a single Controlled Drugs Accountable Officer (CDAO) has been appointed for the MOD. Each of the Commands has a deputy Controlled Drugs Accountable Officer (CDAO) who reports annually up the chain of command to the CDAO.

Internal MOD policies are under review to reflect the changes in legislation and are expected to be issued in 2014.

Engagement in controlled drug activity in 2013

The MOD has robust policy and standard operating procedures in place for the management and use of CDs. This includes operations at home and overseas. These ensure that the MOD conducts management checks beyond what is required in legislation, and also on a separate category of “Accountable Drugs” (Schedule 3-5 and some other medicines where there is risk of misuse). It is also a routine procedure to report incidents via an automated Significant Events system.

This system is being amended to allow a better search function for CD related events. Additional occurrence reports are raised as necessary. Inspections are undertaken by MOD’s Assurance teams who look at the management of CDs as a distinct feature of the Common Assurance Framework.

Data / information collected

Work is underway to develop a robust reporting system on CDs usage and prescribing analysis in primary care. Significant event trend analysis is underway.

Matters of interest

The MOD manages Schedule 3-5 and other valuable medicines as a separate entity, prescribed and accounted for in the same way as CDs. This is over and above legislation but provides the CDAO and the chain of command with additional assurance. The main issue for the MOD in 2013 was the difficulty in obtaining FP10(PCD) and the MOD and DH worked in liaison with NHS England to provide a solution.

9. NHS England

NHS England was established in April 2013 to deliver high quality care for all, now and for future generations with a vision and purpose to:

- Ensure everyone has greater control of their health and their wellbeing, supported to live longer, healthier lives by high quality health and care services that are compassionate, inclusive and constantly improving, and
- Create the culture and conditions for health and care services and staff to deliver the highest standard of care and ensure that valuable public resources are used effectively to get the best outcomes for individuals, communities and society for now and for future generations.

Engagement in controlled drug activity in 2013

The 2013 Regulations require the NHS Commissioning Board (now known as NHS England) to have robust systems in place for the safe and effective management and use of controlled drugs (CDs) and to ensure that these systems are working effectively. Since 1 April 2013, NHS England has:

- Appointed Sir Bruce Keogh as the senior responsible officer but responsibilities are carried out by the operations directorate across area teams.
- Addressed and mitigated any areas identified as a significant risk or issue.
- Developed a comprehensive assurance process to assess how well area teams are executing their controlled drugs responsibilities.
- Ensured that all area teams have appointed their Controlled Drugs Accountable Officer (CDAO) and their Local Intelligence Networks are operational.
- Conducted the first annual assurance process to monitor area teams' progress in relation to the "Controlled Drugs (Supervision of Management and Use) Regulations 2013". A report outlining the main findings will be made available and will be shared with CQC to provide an annual review of any issues that require national resolution. The first report was published in October 2013.
- Established a short life working group, co-chaired by the Deputy Chief Pharmacist and Head of Primary Care Commissioning with representation from DH, CQC, NICE, Health and Social Care Information Centre and NHS Business Services Authority to ensure that area teams' are well supported to carry out their statutory functions.
- Published a comprehensive Single Operating Model in November 2013 to help area teams with their responsibilities. The Model can be found [here](#).
- Agreed terms of reference for a permanent NHS England CD national forum, and
- From April became a member of CQC's Controlled Drugs National Group.

10. NHS Protect

NHS Protect is a division of the NHS Business Services Authority. It is an intelligence-led organisation and is responsible for tackling fraud and managing security in the NHS.

Engagement in controlled drug activity in 2013

Throughout 2013, NHS Protect sought to collate and analyse data and supporting information regarding the nature of crime risk across the NHS in the form of a strategic intelligent assessment. The assessment identified theft of controlled drugs (CDs) as one of the strategic priority areas for the organisation in 2013. There is an incomplete picture on the extent of CD losses in England as a result of theft or fraudulent activity. Reports on CD losses to NHS Protect

are low. Theft of prescription forms and their consequent misuse is also an area of concern for NHS Protect, as these can be used to illegally obtain CDs. This is also an area of low reporting.

In response to the strategic intelligent assessment, NHS Protect arranged an internal CD working group led by a member of its senior management team with representatives from all its internal units. The CD working group identified three objectives for the organisation:

- To develop a consistent organisational approach to undertaking NHS Protect's responsibilities as a named 'responsible body' in the "*Controlled Drugs (Supervision of management and use) Regulations 2013*".
- To explore a mechanism with stakeholders to enable national collation of CD losses and where possible analyse data to identify potential criminality, and
- To develop a toolkit to address medicine security in designated healthcare providers.

Reporting on progress against these objectives, the first objective has been completed. An internal organisational policy on how NHS Protect undertakes its responsibilities as a named 'responsible body' in the 2013 Regulations has been developed. This allows a more coordinated approach across the organisation.

For the second objective NHS Protect undertook work to improve the reporting of CD losses with the development of its Security Incident Reporting System (SIRS). The system is designed to gather information either from local risk management systems, or via an online form.

NHS Protect met with CQC and NHS England to explore existing reporting mechanisms for CD losses. As a result of this meeting, NHS Protect and CQC submitted a joint proposal to NHS England's Controlled Drugs Short Life Working Group outlining a proposed framework for the collection of occurrence data reported into the NHS England controlled drug accountable officers. This was to gain a clearer national picture of safer management arrangements for CDs within England, in particular, the extent of CD prescribing and administration errors, CD losses and governance related issues. The proposal was accepted by NHS England and is now a part of the NHS England document *The Controlled Drugs (Supervision of Management and Use) Regulations 2013 NHS England Single Operating Model*. The CQC will share this collated information with NHS Protect and other responsible bodies.

As reported in 2012, NHS Protect began work on developing a toolkit to address medicine security at hospital-based pharmacy services in acute, mental health, community and hospice providers; the continuation of this work was absorbed into the CD working group as the third objective. A medicines security self-assessment tool, as part of an overall medicines security toolkit, has been developed and was published on 31 January 2014. The tool focuses on the security of all medicines, including CDs and patients' own medicines, and aims to help providers assess the security and governance arrangements of all medicines within their organisation.

Responsibility for the tool is focused on the provider organisation's chief pharmacist but completion should be undertaken as a multi-disciplinary exercise, with the controlled drugs accountable officer (CDAO) and the local security management specialist (LSMS) having co-signatory status in the sign-off of the document in relation to their specific remit and duties.

The self-assessment tool has been developed with the support of the Chief Pharmaceutical Officer at the Department of Health and in consultation with the CQC, Royal Pharmaceutical Society, pharmacy leads and security specialists at NHS organisations. The self-assessment tool

was successfully piloted in November 2013 and the final version will be for hospital based pharmacy services in the acute, mental health and community settings. Further work is needed for the hospice setting; this will be examined in 2014.

Care was taken to avoid duplication with the Care Quality Commission's (CQC's) 'CD governance self-assessment tools', which specifically looks at governance arrangements around CDs. However, it is the intention that the completion of the medicine security self-assessment tool may be used to provide evidence of the robustness of medicine governance arrangements during the CQC's inspection process.

A review of the Pharmacy Reward Scheme data from February 2003 to December 2013 showed 127 reports of counterfeit prescriptions. The Pharmacy Reward Scheme allows pharmacists to claim a reward of £70 if they identify a fraudulent prescription (for example a form which is not a genuine order for the person named on it, stolen, counterfeited or illegitimately altered) and thereby either prevent fraud or contribute with valuable information to the investigation of fraud. From this data 50 claim forms were recovered and examined, seven of these were identified as correctly recorded counterfeit prescriptions. These were all for different drugs, in different areas of the country and from different periods over the last three years. Four other reports were recorded as counterfeit but a pharmacy reward claim was not received after the initial telephone report. Thirty-nine reports had been marked as counterfeit but were actually prescriptions that had been stolen and/or amended.

NHS Protect collated and reviewed available intelligence to update its understanding of issues relating to the theft and diversion of CDs. This review included an evaluation of reporting to the Pharmacy Reward Scheme; including counterfeits and reports of lost and stolen prescription forms.

Data / information collected

Through the work of NHS Protect's operational staff and local counter fraud specialist (LCFS) and LSMS networks, information on incidents involving CDs including any means by which inappropriate access is obtained is shared with the CQC's Controlled Drugs National Group.

SIRS underwent extensive development, with a view to creating a national information gathering resource for security incidents, including the theft of CDs. Alongside this development, engagement with NHS healthcare providers has commenced as a means to assisting with the mapping process that will allow them to upload records from their system directly onto SIRS.

Matters of interest

The security of CDs remained an issue of concern, with incidents involving the loss and theft of CDs being reported to NHS Protect via the LSMS and LCFS networks. Examples include:

- A local security management specialist in the South West was contacted by a matron about unexplained use of Schedule 5 CDs, Dihydrocodeine and Codeine Phosphate 30mg, in a community hospital. An audit of stock levels identified discrepancies against stock records over a period of three weeks. An analysis of the discrepancies against staff attendance resulted in a registered nurse being arrested on suspicion of theft, which was admitted, along with admissions of theft of the same type of medicine from patients. The

staff nurse also admitted to the offences taking place over three years. The staff nurse was formally cautioned by the police and was dismissed for gross misconduct. The trust referred the matter to the Nursing and Midwifery Council and proceedings are ongoing. To prevent reoccurrence, the trust put in place a standard operating framework for community sites to ensure appropriate stock management and monitoring arrangements.

- A local counter fraud specialist in the North West has contributed to a website solution for recording all CD incidents across Greater Manchester. The website provides a platform so that local intelligence including information on criminal activity can be shared with the NHS England CDAO through an incident reporting system. The system enables the NHS England CDAO to compare incident data and where appropriate refer suspicions to LCFS or LSMS for investigation. It also assists the lead CDAO in determining the risk posed as a result of an incident, for example the risk posed by a 'frequent flyer', as well as users being able to flag the potential to issue a local alert. The website also has a link so users can also report fraud and corruption directly to NHS Protect.

11. Public Health England

Public Health England (PHE) is an executive agency of the Department of Health, with a mission to protect and improve the nation's health and to address inequalities. PHE is responsible for:

- Making the public healthier by encouraging discussions, advising government and supporting action by local government, the NHS and organisations.
- Supporting the public so they can protect and improve their own health.
- Protecting the nation's health through the national health protection service, and preparing for public health emergencies.
- Sharing information and expertise with local authorities, industry and the NHS, to help them make improvements in the public's health.
- Researching, collecting and analysing data to improve our understanding of health and come up with answers to public health problems.
- Reporting on improvements in the public's health so everyone can understand the challenge and the next steps, and
- Helping local authorities and the NHS to develop the public health system and its specialist workforce.

One of PHE's priorities for 2013 was reducing the burden of disease and disability in life by focusing on preventing and recovering from the conditions with the greatest impact, including dementia, anxiety, depression and drug dependency.

PHE's Alcohol and Drugs Team, located within the Health and Wellbeing directorate, works across PHE and the alcohol and drugs sector to deliver the government's recovery ambition by promoting a balanced, effective and ambitious prevention and treatment system. They support local commissioners by providing high quality information and intelligence about drugs and alcohol, expertise, bespoke support, and by benchmarking performance and sharing good practice.

Engagement in controlled drug activity in 2013

PHE supported the commissioning and provision of drug treatment services in line with relevant NICE guidance and the 2007 UK guidelines on clinical management of drug misuse and dependence. This helps ensure the safe prescribing of controlled drugs (CDs) for opioid dependence.

In 2013 PHE was involved in a number of activities related to CDs. These included:

- Reviewing opioid substitution treatment: a guide to best practice in reviewing treatment for drug users, based on supplementary advice provided by the Recovery Orientated Drug Treatment Expert Group, chaired by Professor John Strang, which produced the Medications in Recovery report in 2012.
- Addiction to medicines: PHE published a commissioning guide for the NHS and local authorities on how to respond to the needs of people who are addicted to medicines. The guidance sets out PHE's expectation that support should be available in every area for people with a dependency on prescription or over-the-counter medicines, based on a full assessment of local need. Also, as part of its work on addiction to medicines, PHE held discussions with NHS England about the role of pharmacists in identifying and responding to possible dependence, and ensuring that repeat prescribing is reviewed.
- Prison pain management: a guide that gives an overview of best practice in managing persistent pain and describes how this might be implemented in secure environments, including prisons, police custody and immigration removal centres. It offers advice on confirming a diagnosis of persistent pain in a secure setting. The guide was written in association with the Faculty of Pain Medicine of the Royal College of Anaesthetists, the Royal College of General Practitioners and the British Pain Society, and is supported by the Department of Health.
- Optimising opioid substitution treatment: good practice guide which focuses on elements of opioid substitution treatment (OST) that can be optimised to improve recovery outcomes: a comprehensive recovery framework; adequate opioid levels; a range of medications; supervised consumption; biological testing; and contingency management.
- Pain management: PHE is supporting a national expert group to develop a core resource on opioid pain medication, in part to reduce the risks of misuse and dependence.
- Advice to local authorities: Through its center teams, PHE provided advice to local authorities on their new responsibilities for meeting dispensing costs, and the importance of maintaining investment to allow daily pick-up/containers and supervised consumption of opioid substitution medicines.
- Safe use of OST: PHE is currently reviewing, with the Department of Health, the need for additional guidance to ensure the continued safe use of opioid substitution medicines, and
- CQC Controlled Drugs National Group: PHE was further involved in CD regulatory activity in 2013 through the involvement of Dr. Michael Kelleher (clinical psychiatrist advisor to the PHE alcohol and drugs team) and Steve Taylor (Programme manager, alcohol and drugs) who attend the CQC's Controlled Drugs National Group.

12. UK Anti-Doping

UK Anti-doping (UKAD) is the national organisation dedicated to protecting a culture of clean sport. Every day, UKAD raise awareness of the issues through extensive education and testing programmes. As well as helping athletes to understand and follow the rules, they also prosecute offenders who do not. Ultimately, UKAD are working for everyone who loves sport, whether competing, training or spectating. Together, UKAD are creating a level playing field where all athletes know they can compete fairly and in the true spirit of sport.

UK Anti-Doping is responsible for ensuring sports bodies in the UK are compliant with the World Anti-Doping Code through implementation and management of the UK's National Anti-Doping Policy. For more information on what we do, please go to www.ukad.org.uk.

As part of UKAD's organisational review, a new investigator post was filled in September, fitting in with the World Anti-Doping Agency's updated International Standard for testing and investigations. UKAD has also engaged with new partners such as the Care Quality Commission and is now sitting on the Controlled Drugs National Group, providing another forum to discuss intelligence on substances, such as steroids, at a national level.

Engagement in controlled drug activity in 2013

UKAD's Intelligence and Investigations Team liaises directly with law enforcement agencies. The investigator, as part of their role, contacts UK Border and Police forces regarding controlled deliveries and the Intelligence Team assesses whether links to sport may exist.

UKAD contributed to an East Midlands police force drugs profile, in order to assist in building a bigger picture around drugs and links to gyms for example. UKAD is not licensed to handle controlled drugs (CDs) at the present time.

Data / information collected

UKAD receives a wide range of data, including information from UK Border Force Agency regarding drug seizures. This information is only shared where there are links to substances featuring on the World Anti-Doping Agency Prohibited List (and those which are listed under the Misuse of Drugs Act or Medicines Act). In addition to this, UKAD receives information on people, substances and activities which may relate to doping, through its dedicated Report Doping in Sport line, powered through "Crimestoppers". This information may also be dual reported to police forces and UKAD, where CDs are being distributed in a gym for example.

13. Veterinary Medicines Directorate

The Veterinary Medicines Directorate (VMD) is an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra). The VMD is the Competent Authority for veterinary medicinal products in the UK. In this role the VMD is responsible for:

- Policy and legislation; developing and implementing the Veterinary Medicines Regulations.
- Pre-marketing assessment of product applications.
- Issuing Marketing Authorisations (licences).
- Monitoring suspected adverse reactions to veterinary medicines in animals and humans, and
- Surveying for residues in animal food products for human consumption.

The VMD also inspects and approves sites manufacturing veterinary medicines, wholesale dealers and retail suppliers of veterinary medicines, including veterinary practices. Premises where veterinary medicines are combined into animal feed are also inspected and approved.

Matters of interest

The VMD's Inspections and Investigations Team is responsible for the inspection of all registered veterinary practice premises in the UK, other than those registered with the Royal College of Veterinary Surgeons (RCVS) as Practice Standards Scheme premises. Practice Standard Scheme premises are inspected by the RCVS's inspectors under an agreement with the VMD, but responsibility for enforcement of the Veterinary Medicines Regulations at those premises remains with the VMD.

The VMD inspectors regularly advise veterinary surgeons on how to comply with the Misuse of Drugs Regulations 2001, in particular with regard to safe storage, record-keeping, disposal and requisition orders. Inspectors provide reports after an inspection pointing out any non-compliance noted and giving advice and guidance on the measures required to correct them.

In 2013 the VMD inspected 622 veterinary practice premises. As result of information passed on to the VMD from a partner organisation, one practice was investigated due to concerns over its procurement of large quantities of morphine. The VMD gave advice and guidance to the investigated practice and a follow up inspection showed that the practice had made appropriate improvement.

The VMD Inspectors liaise with other enforcement bodies including the Police, the General Pharmaceutical Council, Home Office and Department of Health, Social Services and Public Safety (Northern Ireland) when necessary to investigate allegations over the supply and misuse of controlled drugs (CDs). Working together and sharing information in this way has shown to be an effective way of addressing the wide range of cross-cutting risk factors.

Schedule 2 controlled drugs must be destroyed in the presence of an authorised witness. Specific to the veterinary sector, a VMD inspector and a veterinary surgeon independent of a practice where the destruction takes place are now authorised by the Home Office to witness destruction of CDs.

The VMD's "Veterinary Medicines Guidance Note on Controlled Drugs" provides guidance for veterinary surgeons and pharmacists on the prescribing and supply of CDs and the additional requirements which must be met under misuse of drugs legislation. This guidance was amended in July 2013 and is available [here](#). In addition to this guidance note, the VMD provides best practice advice which can be found [here](#).