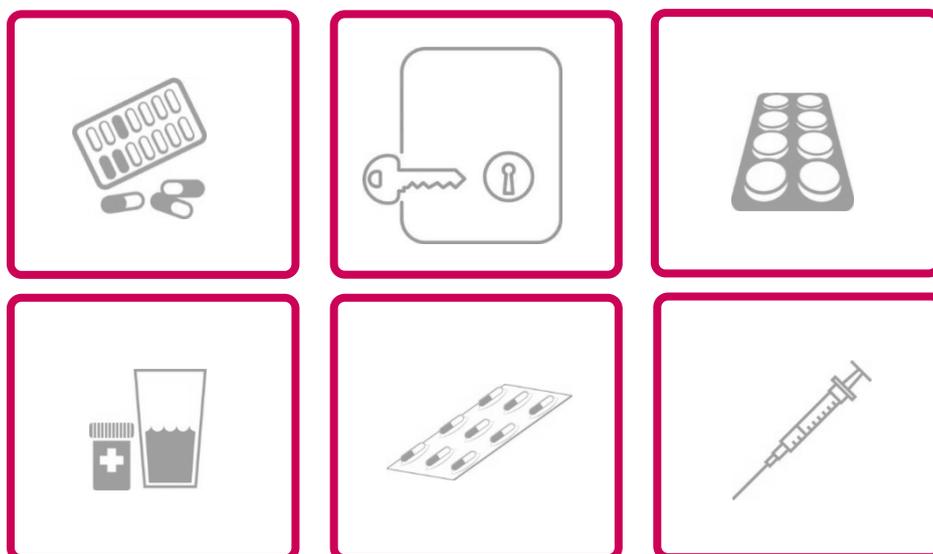


The National Group on Controlled Drugs

Report of activity in 2014 from
partner organisations

July 2015



Contents

Introduction	2
1. The Association of Chief Police Officers	3
2. Department of Health	4
3. General Pharmaceutical Council	6
4. Her Majesty's Inspectorate of Prisons for England and Wales	8
5. Home Office - Drug Licensing & Compliance	9
6. Medicines Advice (Medicines and Prescribing Centre) National Institute for Health and Care Excellence (NICE)	15
7. Medicines and Healthcare products Regulatory Agency (MHRA)	16
8. NHS England	17
9. NHS Protect	19
10. Public Health England	22
11. UK Anti-doping	24
12. Veterinary Medicines Directorate	26

Introduction

CQC's work involves leading a national strategic group of regulators and key agencies that have areas of responsibility for controlled drugs (CDs) within their remit. Membership of the National Group on Controlled Drugs Group in 2014 included:

- Association of Chief Police Officers
- Care Quality Commission
- Department of Health
- General Pharmaceutical Council
- General Medical Council
- Health and Social Care Information Centre
- Her Majesty's Inspectorate of Prisons for England and Wales
- Home Office
- Medicines Advice (Medicines and Prescribing Centre) National Institute for Health and Care Excellence
- Medicines and Healthcare products Regulatory Agency
- Ministry of Defence
- NHS England (including Patient Safety team and Pharmaceutical Adviser for Health and Justice Commissioning)
- NHS Protect
- 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.

The following are reports of the controlled drug-related activity of some of the main partners of the National Group in 2014, which illustrate the many ways in which separate groups contribute to the overall safer management of controlled drugs.

1. The Association of Chief Police Officers

The Association of Police Controlled Drugs Liaison Officers (APCDLO) was formed in 2000 by a small group of officers to improve working relationships with the rest of the police service and their partner agencies to promote best practice at both national and regional level.

Until late 2006, the association's remit was to inspect retail pharmacy outlets and some hospital pharmacies to ensure compliance with the Misuse of Drugs and Safe Custody Regulations in respect of controlled drugs. However, the Health Act 2006 puts a greater emphasis on involving the police in investigation, intelligence and partnership working, particularly through controlled drugs local intelligence networks (CD LINS), which meet regularly.

Engagement in controlled drug regulatory activity

The Police CDLO's remit is to police controlled drugs within health services and prevent controlled drugs from being diverted into the illicit drugs markets through investigations, targeted inspections and destruction of controlled drugs. APCDLO liaises and attends meetings with law enforcement and other agencies to share good practice and information, including the CD LINS.

Matters of interest and good practice

An NHS trust contacted the police with concerns about large amounts of tramadol being prescribed internally – especially in the gynaecology department. An investigation found that a healthcare assistant was asking different doctors to prescribe tramadol for his/her back pain. As the person became increasingly dependent, they started to steal and forge prescriptions. They were subsequently arrested and charged, and received a Community Service Order. Nineteen doctors received advice letters about the breach of the trust's policy and ethics.

The police also dealt with an agency nurse who had attended a night shift in a High Dependency Unit and disappeared regularly. After concerns were raised, the nurse was found semi-conscious in the toilet with a syringe nearby. The nurse admitted injecting lorazepam and was also found to be in possession of diazepam. The nurse has subsequently pleaded guilty at court for possession of drugs and is currently suspended by the Nursing and Midwifery Council (NMC).

For further information, see: www.npcc.police.uk/Home.aspx.

2. Department of Health

The Department of Health 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 regulatory activity

The Department of Health continues to monitor the implementation of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 and works closely on the shared agenda for controlled drugs with 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.

Matters of interest and good practice

From July to October 2014, the Department of Health, Home Office and Medicines and Healthcare products Regulatory Agency (MHRA) jointly consulted on whether to enable NHS prescribed Schedules 2 and 3 controlled drugs to be prescribed electronically in England using the electronic prescription service (EPS); and privately prescribed Schedules 2 and 3 controlled drugs to be prescribed electronically and, if so, whether this should be with an advanced electronic signature (AES) alone or with additional security (in England this would be through EPS). Preliminary responses indicated wide agreement with the proposals, and in March 2015, the necessary legislative amendments enabled the electronic prescribing of Schedules 2 and 3 controlled drugs for NHS and private prescribers. Prescriptions will be signed with an advanced electronic signature and sent through the electronic prescription service, with its additional security features. The amendments require the total quantity of the Schedules 2 and 3 controlled drugs to be dispensed to be recorded in words and figures within the electronic prescription, as is the case for paper prescriptions for these drugs.

Before 14 August 2012, under Section 10(7) of the Medicines Act 1968, a pharmacist in a registered pharmacy, or someone acting under their supervision, who sells or supplies a medicinal product through wholesale dealing, was exempt from the requirement to hold a wholesale dealer's authorisation for medicines for human use ('WDA(H)'). The exemption only existed on the basis that the wholesale dealing activity constituted no more than an inconsiderable part of that business. For a long time, the MHRA had generally regarded this to be 5% or less of the total turnover of licensed medicinal products at that registered pharmacy.

This exemption was repealed under the Human Medicines Regulations 2012 (S.I. 2012/1916), which were laid on 24 July 2012 and came into force on 14 August 2012. The exemption was outside the European Directive 2001/83/EC on medicines for human use within the community. The Human Medicines Regulations 2012 provide that any person who wishes to engage in the wholesale supply of medicines is entitled to do so only if holding a WDA(H). This means that any wholesale supply of stock medicines on a commercial basis by a pharmacy now requires a WDA(H). A small group of interested parties met in early 2014 and developed an

information sheet, *Supplementary Information on Wholesale Dealer and Controlled Drugs Licences in the Health and Justice system in England*. This was circulated widely in July 2014.

Subsequently, hospice and palliative care representatives raised concerns with Dr Keith Ridge, Chief Pharmaceutical Officer, about the difficulties they had in sourcing their medicines supplies as many suppliers including hospitals were now reluctant to apply for the necessary licences. A multi-disciplinary group including palliative care and hospice providers, together with representatives of hospital pharmacy, NHS England, Department of Health, Home Office and the MHRA met twice in 2014 to share concerns and produce possible solutions about this.

For further information, see: www.gov.uk/government/organisations/department-of-health.

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. Our 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. The GPhC 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 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 regulatory activity

GPhC inspectors continued to inspect registered pharmacy premises to ensure compliance with the Standards for Registered Pharmacies and arrangements for the management of controlled drugs were routinely examined during inspections. Information was shared with CDAOs in relation to concerns about controlled drugs identified during inspections and complaints received that involved controlled drugs.

The GPhC was represented on CQC's Controlled Drugs National Group and the Controlled Drugs Cross Border Group. GPhC inspectors attended LIN meetings, participated in critical incident panels and regularly liaised with primary care organisations and police Controlled Drug Liaison Officers to share intelligence and deal with matters that fell both above and below the regulatory bar.

The GPhC responded to the [ACMD - Diversion & Illicit Supply of Medicines Inquiry](#) call for evidence in June 2014.

A representative from the GPhC attended two working group meetings as an observer at the Clinical guidelines working group for the review of the Drug Misuse and Dependence: UK Guidelines on clinical management, in October and November 2014.

Data collected

The GPhC has 14,371 pharmacy premises registered, of which 341 are 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. All pharmacy premises due a renewal in 2014 were renewed by their owner and the mandatory controlled drugs declaration was completed as part of the renewal process, or the owner submitted an application for voluntary removal.

At the end of 2014, 51,172 pharmacists and 22,876 pharmacy technicians were registered with the GPhC.

Matters of interest and good practice

In May 2014, the GPhC published [*Guidance for registered pharmacies preparing unlicensed medicines*](#), which is available on its website. The guidance includes an update about the preparation of unlicensed extemporaneously prepared methadone for supply in accordance with a prescription, as an alternative to an available licensed version.

For further information, see: www.pharmacyregulation.org/.

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 health services including medicines and pharmacy management. In 2014, GPhC inspectors supported HMI Prisons on the inspection of 48 prisons and three immigration removal centres.

The reports comment on the facilities associated with, and management of controlled drug prescribing, dispensing and administration within each establishment inspected. Most establishments inspected met regulation requirements, however a small number of establishments had non-compliant registers and the controlled drug cabinets in some establishments were screwed rather than bolted to the wall. There was also the potential for diversion of controlled drugs in some establishments due to inadequate supervision during administration. The number of prisoners prescribed tramadol reduced significantly following its reclassification in June 2014.

For further information, see: www.justice.gov.uk/about/hmi-prisons/.

5. Home Office - Drug Licensing & Compliance

Drugs Licensing & Compliance is part of the wider Drug and Alcohol Unit within the Home Office.

The Home Office has responsibility for the Misuse of Drugs Act 1971 and its associated Misuse of Drugs Regulations 2001; the latter provide the framework for lawful activity with controlled drugs 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.
- 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 CD regulatory activity- Development activity

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

The regime is well-regarded and we have made concerted efforts to continue to work collaboratively with other regulatory bodies to strengthen relationships and appropriate information sharing with those parties. It strikes a proportionate balance against our international and moral obligations to minimise the risk of the diversion of Controlled Drugs, but to ensure the availability of drugs for licit use. We strive to ensure any burdens placed on

licensees are proportionate and kept to a minimum and have built upon the positive assurance received following an internal audit in 2013 as to the integrity, sustainability and proportionality of our regime. We aim to visit each premises holding a controlled drug license on a rolling three to five-year basis, according to the risk posed by that site.

Additionally Drug Licensing & Compliance:

- Cooperates as necessary with enforcement/regulatory agencies at national and international level. During 2014 we have worked collaboratively with MHRA and GPhC to support compliance activities.
- Collects and process 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 Declaration process, integrated within the annual licence application renewal forms, and robustly applying administrative sanctions- ranging from noting contraventions against a licensee to considering licence revocation.

Currently there are 22 staff (eight import/export licensing & fees management, two Finance, 10 domestic licensing & compliance, one Head of Unit, one Project Manager). In 2014 we issued 955 controlled drug domestic licences, which included 261 compliance visits.

All domestic controlled drug domestic licence applications are lodged electronically. In February 2014, we launched our 'iCasework' domestic licensing application portal and associated Case Management System to make a more intuitive and customer focused application portal for licensees, enabling them to provide more information 'up front' to streamline the consideration process, and to provide us with better Management Information and support us in our aim of continued improvement to process licence applications more efficiently. For the first time it enable Precursor Chemical Licensees and Registrants to apply online and guidance to support users through the application process has been published on our website.

An online licensing portal for all import and export licence applications (approximately 19,000 transactions per year); designed by the United Nations has been fully operational for nearly four years and integrates all controlled drug and precursor licensing activity into a single system. By the end of 2014 the 'shipping endorsements' process to confirm the details of each drug shipment from the UK will be fully electronic.

Interface with the healthcare sector

Limited general licences or 'authorities' covering some activities of paramedics, NHS ambulance trusts and St John Ambulance with morphine and diazepam are in existence. We also licence mountain rescue bodies to ensure casualties can receive prompt and efficient pain relief in a trauma situation often in inaccessible locations.

Drug Licensing & Compliance also licences the import and export of controlled drugs by patients and practitioners travelling abroad for periods longer than three months, or travelling with more than three months' supply of controlled drugs.

We individually licence doctors at specified premises in England and 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.

Individual premises and company specific licences are needed in many healthcare settings, including privately owned/operated hospitals, healthcare in many detention environments and some care homes to cover possession of Schedule 2 drug stocks for administration to patients. In 2014 we published a downloadable Home Office Licensing in Healthcare Settings' A4 chart to outline the general provisions/ licensing requirements which would be applicable in various healthcare sectors.

The Healthcare sector has undergone significant diversification in recent years, and the impacts of 'contracting out' or 'competitive tendering' for services is becoming apparent. This is particularly relevant for NHS bodies delivering services in non-hospital environments, or supplying drugs to other entities from a hospital pharmacy, as Home Office licensing is likely required in both cases. We would ask, looking forward, for licensing implications, and the fees associated with the issue of licences, to be considered in the course of any tendering activities.

Licence Replacement Programme

The project launched in January 2012; phases were launched as follows and the application window has closed:

Phase	Start	Close
COMMUNICATIONS	1 January 2012	31 March 2012
PHASE 1	2 April 2012	30 June 2012
PHASE 2	31 July 2012	31 October 2012
PHASE 3	1 November 2012	31 January 2013
PHASE 4	1 December 2012	28 February 2013

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.

Approximately:

- 59% of licensees in phase 1 re-applied.
- 48% of licensees in phase 2 re-applied.
- 55% of licensees in phase 3 re-applied.
- 69% of licensees in phase 4 re-applied.
- Overall 55% of licensees re-applied.

We have issued 888 time limited licences to replace existing time limited licences so far. This equates to around 80% of applications being resolved at the close of 2014.

286 licences holders have surrendered their licences.

We have reviewed, on a phase-by-phase basis, those who have failed to re-apply and implemented a two stage revocation process a final letter to indicate that we intend to revoke a licence as the person has failed to re-apply, and a second communication at the point of revocation. Final letters have been sent (stage one) and 120 formal revocation letters have been served. We are working to conclude the remaining cases where an application has not been received.

In a small number of cases, licence holders have applied for a new licence, but have persistently failed to supply requested information and/or make DBS applications while attempting to continue to trade on their open ended licences. We will be issuing warning letters to these licence holders, before formally withdrawing their applications and revoking their licences.

We made a public announcement concerning revocations early in 2015.

Legislation

Order to control the NBOMe and benzofuran compounds, lisdexamphetamine, tramadol, zopiclone and zaleplon, and reclassify ketamine

The Composite Order that subjected the NBOMe and benzofuran compounds, lisdexamphetamine, tramadol, and the Z-drugs to control, and reclassified ketamine under the Misuse of Drugs Act 1971 came into force on 10 June 2014.

The 2014 Order controlled:

- the NBOMe compounds, via generic definition, as Class A drugs
- the Benzofuran compounds, via generic definition, as Class B drugs
- lisdexamphetamine as a Class B drug
- tramadol as a Class C drug, and
- zopiclone and zaleplon as Class C drugs.

The 2014 Order also:

- reclassified ketamine as a Class B drug under the 1971 Act.

Following control:

- The NBOMe and Benzofuran compounds (advertised for sale as 'legal highs') were listed in Schedule 1 to the 2001 Regulations and designated as drugs to which section 7(4) of the 1971 Act applies as they have no known legitimate uses outside of research. This means they can only be possessed or supplied etc under a Home Office licence for research of other special purpose.
- Lisdexamphetamine (a drug which converts to dexamphetamine when administered orally and used as second line treatment for ADHD) was listed in Schedule 2 to the 2001 Regulations alongside dexamphetamine.

- Tramadol was listed in Schedule 3 to the 2001 Regulations but exempted from the safe custody requirements. Full prescription writing requirements under regulation 15 currently apply to its use in healthcare.
- Zopiclone and zaleplon were listed in Part 1 of Schedule 4 to the 2001 Regulations alongside zolpidem.

Control of khat

On 24 June 2014, khat became a Class C and a Schedule 1 controlled drug under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 respectively. The Home Office circular introducing the change in legal status is available at:

<https://www.gov.uk/government/publications/circular-0112014-changes-to-misuse-of-drugs-act-1971-and-criminal-justice-and-police-act-2001-khat>.

Order to control AH-7921, a number of LSD related compounds and extend the definition used to capture tryptamines under the 1971 Act.

A Parliamentary Order to control the so-called 'legal highs' AH-7921, a number of LSD related compounds and extend the tryptamine generic definition successfully passed through both Houses of Parliament in November and was approved by the Privy Council in December. The Order came into force on 7 January 2015.

The Order:

- controls the synthetic opioid AH-7921 and the LSD related compounds - AL-LAD, ETH-LAD, PRO-LAD, ALD-52 and LSZ as Class A drugs, and
- extends the generic definition used to capture tryptamines to bring compounds such as AMT and 5-MeO-DALT that currently fall outside of the existing definition under control.

These drugs have no legitimate uses as medicines and are therefore listed in Schedule 1 to the 2001 Regulations and designated as drugs to which section 7(4) of the 1971 Act applies as they have no known legitimate uses outside of research.

The ACMD's AH-7921, LSD and Tryptamine advice is available at

<https://www.gov.uk/government/publications?departments%5B%5D=advisory-council-on-the-misuse-of-drugs>.

Order to control the synthetic opioid MT-45 and the synthetic stimulant 4,4'-DMAR

A Parliamentary Order to control the so called 'legal highs' MT-45 and 4,4'-DMAR has been laid in Parliament following Ministerial acceptance of ACMD advice. The Order is expected to come into force in March subject to Parliamentary approval. Both compounds have no legitimate medicinal uses and will therefore be designated as drugs to which section 7(4) of the 1971 Act applies and placed in Schedule 1 to the 2001 Regulations.

The ACMD advice on MT-45 and 4,4'-DMAR are available at

<https://www.gov.uk/government/publications/report-summary-synthetic-opioid-mt-45> and <https://www.gov.uk/government/publications/report-summary-synthetic-stimulant-44-dmar>.

Rescheduling of GHB

Following international rescheduling by the UN in June 2013, the ACMD recommended that GHB should be rescheduled to Schedule 2 to the 2001 Regulations. This recommendation was accepted by the Ministers. The ACMD advice is available at <https://www.gov.uk/government/publications/acmd-advice-on-the-scheduling-of-ghb>.

GHB was rescheduled from Part 1 of Schedule 4 to Schedule 2 to the 2001 Regulations on 7 January 2015. As a result of its rescheduling GHB is now subject to the prescription writing, requisition, destruction and safe custody requirements when used in healthcare.

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. The developed statutory instrument implementing the changes is now going through final quality assurance. The proposed regulatory amendments are expected to come into force by April 2015 at the earliest, subject to Ministerial approval.

The amendments proposed were outlined in the associated consultation, summarised at <http://www.homeoffice.gov.uk/publications/about-us/consultations/misuse-drugs-regulations/>.

ACMD advice; independent prescribing by physiotherapists and chiropodists, and removal of temazepam prescribing exemptions

Independent prescribing by AHPs: work on the legislative changes introducing AHP independent prescribing is still continuing and expected to come into force in 2015, subject to Ministerial approval. The ACMD advice is available at <http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/independent-prescribing-advice>.

Removal of temazepam prescribing exemptions: the ACMD recommended that the exemptions applicable to the prescribing of temazepam in the public sector should be removed to bring temazepam in line with all other schedule 3 drugs.

The ACMD advice is available at <https://www.gov.uk/government/publications/temazepam-advice>. Ministers accepted the ACMD's advice. Implementation of the removal of the exemption is being delayed to consider issues raised around the impact on the secondary care sector in the consultation responses. Removal of the existing exemptions is expected to be implemented in 2015.

Ketamine rescheduling consultation

The consultation on the rescheduling of ketamine ended on 3 November 2014. Nearly 100 responses were received. The responses are being analysed to inform policy advice to Ministers. A Ministerial decision on the outcome of the public consultation will be implemented at the earliest opportunity in 2015.

For further information, see: <https://www.gov.uk/government/organisations/home-office>.

6. Medicines Advice (Medicines and Prescribing Centre) National Institute for Health and Care Excellence (NICE)

A controlled drugs accountable officer (CDAO) support programme is provided by the NICE Medicines and prescribing centre (MPC).

During 2014, NICE has continued to deliver the programme through a specific NICE community of practice, which includes a secure discussion forum.

In October 2014, NICE started to develop a guideline on the safe use and management of controlled drugs. You can see information about the guideline development at <http://www.nice.org.uk/guidance/indevelopment/gid-cdqpg>. The guideline is scheduled for publication in March 2016.

NICE communities of practice

Continues to be a secure area for CD AOs to access a closed discussion forum and share learning with other CD AO colleagues. On 31 December 2014 there were 146 people registered on the forum.

Medicines evidence commentary

NICE published a medicines evidence commentary (MEC) in June 2014, on [Amendments to The Misuse of Drugs Act 1971 affecting tramadol, zaleplon, zopiclone and lisdexamfetamine](#) alerting health professionals to changing controlled drugs legislation.

For further information, see: www.nice.org.uk/about/nice-communities/medicines-and-prescribing.

7. Medicines and Healthcare products Regulatory Agency (MHRA)

The Medicines and Healthcare products Regulatory Agency (MHRA), an Executive Agency of the Department of Health, is responsible for the regulation and medicines (for human use) and medical devices on the UK market. The MHRA also acts as the law enforcement agency in the UK and has specific enforcement powers under the Human Medicines Regulations 2012 and the 1968 Medicines Act.

Engagement in controlled drug regulatory activity

The requirements of medicines legislation apply to controlled drugs that are prescribed as prescription-only medicines (POMs).

Analysis of data collected

The European Directive on Falsified Medicines was implemented in the UK in August 2013. The first tranche of the legislation placed more robust control over the regulated UK supply chain.

Provisions concerning medicines supplied 'at a distance' will be implemented from 1 July 2015. Member States are required to introduce national arrangements to register legal suppliers of medicines.

This will involve establishing a national website and the adoption of the common EU logo. All websites supplying medicines at a distance will be required to display the EU logo and provide a hyperlink to the national website of the Member State in which the person offering to sell medicines at a distance is established.

Matters of interest and good practice

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.

Operation Pangea Results for 2014

- UK seizures of counterfeit and unlicensed medicines totalled £9.5 million.
- This UK activity resulted in the seizure of 3.6 million doses of counterfeit and unlicensed medicines including huge hauls of potentially harmful slimming pills and controlled drugs such as diazepam and anabolic steroids.
- 5 arrests made.
- 1,862 websites closed down.
- For the first time, illegal adverts on social media websites were targeted, with 18,671 YouTube videos removed and 356 YouTube accounts terminated.
- Press coverage in: BBC Fake Britain, the Daily Telegraph, Reuters, Herald Scotland, Manchester Evening News, and the Yorkshire Post.

For further information, see: www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency.

8. NHS England

NHS England was established on 1 April 2013 and its aim is to deliver high quality care for all, now and for future generations.

Vision and purpose:

- 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.
- We 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 regulatory activity

The Controlled Drugs (Supervision of Management and Use) Regulations 2013 make clear that the NHS Commissioning Board (known as NHS England) must ensure that systems are in place for the safe and effective management and use of controlled drugs and that these systems are working effectively.

NHS England is responsible for

- Ensuring that systems are in place for the safe and effective management and use of controlled drugs and that these systems are working effectively.
- Formally determining how many Local Intelligence Networks there are to be in England and how many lead controlled drug accountable officers are required to cover them.
- Ensuring adequate governance arrangements for its lead controlled drug accountable officers and for notifying CQC of the name of each controlled drug accountable officer.

Collaboration

During 2014, NHS England and CQC have continued to work in collaboration around controlled drugs.

- CQC is formally represented at the NHS England National Controlled Drugs Forum.
- NHS England continues to build on its annual assurance process to monitor progress in relation to the Controlled Drugs (Supervision of Management and Use) Regulations 2013 and shares outputs of this with CQC.
- CQC and NHS England continue to in work in partnership to deliver two training events a year to support the NHS England Controlled Drugs Accountable Officers. These were delivered on 17 June and 2 December 2014 and were highly valued by attendees.

Achievements in 2014

- NHS England CDAOs succeeded in embedding the Controlled Drugs Single Operating Model, improving consistent systems and processes across England.
- Formally established a Controlled Drugs Forum to continue to oversee its responsibilities for the safe use of controlled drugs.
- Embedded its assurance process in relation to the safe use of controlled drugs and produced its first annual report.
- Began to plan for changes that would be brought about by its Organisational Alignment and Capacity Programme and the impact of these on its statutory responsibilities with respect to the safe use of controlled drugs.

Matters of interest and Good practice

Produced a Single Operating Model to help area teams with their responsibilities.

<http://www.england.nhs.uk/wp-content/uploads/2013/11/som-cont-drugs.pdf>.

For further information, see: www.england.nhs.uk.

9. NHS Protect

NHS Protect is a division of the NHS Business Services Authority (a special health authority). It leads on work to identify and tackle crime across the health service.

Under the NHS Standard Contract for 2014/2015, all organisations providing NHS services must put in place and maintain appropriate counter fraud and security management arrangements. NHS Protect is committed to raising the standards of security management within the NHS and has developed a national strategy and a series of security standards for providers, which incorporates a risk-based approach to both providing a safe and secure environment for patients, staff and visitors and to protecting NHS property and assets. These standards, which are quality assured, also include a standard relating to the security of medicines and controlled drugs.

NHS Protect has in place Memorandum of Understanding and Information Sharing Agreements with all the regulators to ensure joint working and information sharing around all crime risks, including controlled drugs.

In 2014, a new Department of Health Anti-fraud Unit was established to work with NHS Protect and set the overall direction and pace of this essential work. The work will include investigation of those defrauding the Department of Health and its Arm's Length Bodies as well as preventative work across the department's group.

Engagement in controlled drug regulatory activity

In 2014, NHS Protect undertook a range of guidance development and engagement activity around the security of controlled drugs and medicines.

A Medicine Security Self-assessment Tool was launched at the beginning of 2014. The tool focused on the security of all medicines, including controlled drugs and patients' own medicines within hospital-based pharmacy services in the acute, mental health and community settings. The tool is designed to help providers in assessing the security and governance arrangements of all medicines within their organisation.

A wide range of promotional activities at national and regional events were undertaken to introduce the tool and its use directly to Chief Pharmacists and their staff. There has been positive feedback about the tool and its usefulness in highlighting potential security issues and improving governance arrangements.

Aide-memoires on prescription form security aimed at prescribers, practice managers and area teams were also developed, to reinforce key messages in keeping prescription form stock secure. These one-page documents highlight and summarise the key points for managing the security of prescription forms that provide legitimate access to controlled drugs and medicines.

NHS Protect also published guidance on the security and storage of medical gas cylinders, along with two checklists to help organisations to review their existing security arrangements for medical gas cylinders.

NHS Protect sought to improve its presence and engagement activity at CD LIN meetings and efforts were made to ensure that operational staff attended each of the area team CD LIN meetings. Key for NHS Protect is the ongoing engagement and support provided to controlled drug accountable officers (CDAOs).

NHS Protect staff have been able to provide support and advice to CDAOs on a number of issues including alerts, assistance with investigations, liaison with the Police, and implementation of security measures.

Data collected

Theft and loss of CDs, medicines and prescription forms remains an issue. The majority of thefts involving these items are not being reported to NHS Protect's Security Incident Reporting System (SIRS).

There is a need to develop further the fields within SIRS to ensure there is adequate information into thefts of controlled drugs, which includes identifying the types of controlled drugs involved, the location of the theft and other pertinent factors.

There is an ongoing long-term development programme for SIRS, which will include a review and update of the way the information on CDs, medicine and prescription form losses is captured. This controlled drug development aspect is being collated alongside all other SIRS developments, into a single version (Version 3) of SIRS, which is due to be finalised in 2015/16.

A security standard in relation to reporting to SIRS is being introduced into the 2015/16 NHS Security Standards for Providers. This standard is a pilot (and therefore not compulsory initially) and only relates to violence in the initial standard, however it is envisaged that reporting theft of controlled drugs will be added to the standard requirements at the end of this pilot.

Matters of interest and good practice

From engagement activity with NHS trusts, NHS Protect is aware of the wide variation in the way incidents involving the loss and theft of controlled drugs, medicines and prescription forms are reported and managed.

Some incidents are reported to the Local Security Management Specialist (LSMS) and/or the Police for investigation and sanctions are applied, such as prosecution and/or disciplinary action. However, some trusts do not always make use of the LSMS and investigations are undertaken by other (clinical/administrative/managerial) staff without their input. As a result sanctions are not always applied, particularly where a staff member or contractor is involved.

LSMSs are trained to undertake investigations so it is very unlikely that it would compromise a Police investigation if one were to take place at a later date. Without input from an LSMS, some incidents being investigated by other staff are being handled as a training or reflective practice issue. Late involvement of the LSMS and Police has led on occasion to evidence being inadmissible because of due process failures. Although there may be a need for training and learning, the crime risk would not have been fully explored and there would be missed opportunity for lessons to be learned or sanctions applied.

The launch of the Medicine Security Self-assessment Tool has introduced the role of the LSMS to many Chief Pharmacists who were previously unaware of or had little involvement with an LSMS. As a result, LSMSs have collaborated with Chief Pharmacists in many trusts to undertake unannounced visits and spot checks on wards and areas where medicines are stored, to review the security measures in place and staff adherence to policies and procedures. The LSMSs have been able to offer practical security advice and raise awareness on the reporting of theft.

For further information, see: www.nhsbsa.nhs.uk/Protect.aspx.

10. Public Health England

Public Health England 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 other people 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 its 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.

PHE's alcohol, drugs and tobacco division, located within the Health and Wellbeing directorate works to deliver the government's recovery ambition by promoting a balanced, effective and ambitious prevention and treatment system. With PHE centres, the division supports local commissioners by providing high quality information and intelligence, expertise, bespoke support, and by benchmarking performance and sharing good practice.

Engagement in controlled drug regulatory activity

PHE supports 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 for opioid dependence.

In 2014 PHE was involved in a number of activities related to controlled drugs. These included:

Clinical guidelines: PHE is leading the update of Drug misuse and dependence: UK guidelines on clinical management on behalf of the departments of health in England, Scotland, Wales and Northern Ireland. Work is ongoing and is being advised by a panel of clinicians and other experts and the revised guidelines will be published in 2016.

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 centre teams across the country, PHE invited local areas to put themselves forward for support to pilot improved understanding of and responses to medicines misuse and dependence.

Safe use of OST: PHE is currently reviewing, with the Department of Health, the need for guidance to ensure the continued safe use of opioid substitution medicines. This is now being considered by the clinical guidelines group.

CQC Controlled Drugs National Group: PHE was further involved in controlled drug regulatory activity in 2014 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) in the CQC Controlled Drugs National Group.

For further information, see: www.gov.uk/government/organisations/public-health-england.

11. 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, UKAD also prosecutes offenders who do not. Ultimately, UKAD is working for everyone who loves sport, whether competing, training or spectating. Together, UKAD is creating a level playing field where all athletes know they can compete fairly and in the true spirit of sport.

UKAD is responsible for ensuring that 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.

On 1 January 2015, a new World Anti-Doping Code came into effect which all UK signatories to the UK National Anti-Doping Policy must comply with, and embrace, their responsibilities under the new Code.

Changes of significance include two new Anti-Doping Rule Violations (ADRV) – 'Complicity' though involvement in an ADRV, and 'Prohibited Association' though association with a person such as a coach, doctor or physio who has been found guilty of a criminal or disciplinary violation.

Under the new Code, some sanctions have now been increased, with serious doping offences now receiving four years rather than two, and refusal or evading sample collection also carrying sanctions of up to four years.

Engagement in controlled drug regulatory activity

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

In December 2014, UKAD signed a Memorandum of Understanding with the National Crime Agency, which sets out clear guidelines for sharing information in the fight against the supply and trafficking of doping-related substances and activities in sport.

UKAD is not licensed to handle controlled drugs at the present time.

Data 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 that 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 controlled drugs are being distributed in a gym for example.

For further information, see www.ukad.org.uk.

12. 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.
- 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 and good practice

The VMD inspects 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 under an agreement with the VMD, but responsibility for enforcement of the Veterinary Medicines Regulations at those premises remains with the VMD.

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

In 2014 the VMD inspected 610 veterinary practice premises. Of these, 582 were scheduled inspections, two were enforcement visits and the remaining 26 were to follow up and ensure corrective actions had been taken following previous inspections. No enforcement actions relating to controlled drugs were required as a result of these inspections

The VMD's 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. 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. Under the MDR, VMD's inspectors are authorised to examine records and witness CD destruction. However, they do not have any enforcement powers and so if they find any critical deficiencies they refer them to the Police Controlled Drugs Liaison Officer for that area.

The VMD's Veterinary Medicines Guidance Note on controlled drugs provides guidance for veterinary surgeons and pharmacists on the prescribing and supply of controlled drugs and the additional requirements that they must meet under misuse of drugs legislation. This guidance was amended in June 2014 and is available on the GOV.UK website at the following link: [here](#).

In addition to this guidance note, the VMD provides best practice advice also on GOV.UK: [here](#).

For further information, see: <https://www.gov.uk/government/organisations/veterinary-medicines-directorate>.

How to contact us

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Email us at: **enquiries@cqc.org.uk**

Look at our website: **www.cqc.org.uk**

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459

