The safer management of controlled drugs: Annual report 2015

Annex 1: Activity in 2015 from partner organisations of the Controlled Drugs National Group

July 2016

Contents

The Controlled Drugs National Group

The CQC-led Controlled Drugs National Group comprises key regulators and agencies with a controlled drugs remit. It continued to meet quarterly in 2015 to share and discuss emerging issues and to identify ways of working together to reach solutions.

Membership of the group remained the same as in 2014:

- 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 following pages highlight the many ways in which these agencies contribute to the overall safer management of controlled drugs.

CQC is grateful to these organisations for their on-going commitment and contributions to the National Group.

1. Association of Chief Police Officers

On 1 April 2015, the National Police Chiefs' Council (NPCC) was formed. It replaced the Association of Chief Police Officers (ACPO), which previously provided national police coordination and leadership.

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, with the introduction of the Health Act 2006, there is a greater emphasis on involving the police in investigation, intelligence and partnership working, particularly through controlled drugs local intelligence networks (CDLINs), which meet regularly.

Controlled drug-related activity during 2015

- A UK resident registered with a GP surgery in Bristol was receiving medication until the end of 2014, but the GP refused to prescribe any more until they engaged with the mental health team, which they failed to do. On many occasions the patient attended the doctor's surgery and stated they were visiting the UK from abroad. They would say that they had forgotten their medication and request a private prescription, obtaining tramadol, pregabalin and naproxen. They would also return and say that their medication had been stolen, so would be given more. They would also tell the doctor that their contract for work or holiday had been extended to obtain more medication. The patient was arrested and charged with fraud offences. They pleaded guilty and were sentenced to 120 hours Community Order.
- Police were informed that there appeared to be a contaminated bottle of oramorph liquid in use on a ward at a London hospital and potentially patient safety had been compromised. It was reported that the oramorph in the bottle was different in appearance and viscosity. The controlled drug register showed that some had been administered to a patient, who subsequently died. The Murder Investigation Team attended and the death was treated as unexplained. The contaminant was identified as being a small amount of oxycodone. Investigation by the CDLO team showed that a prior incident where 5mls of oxycodone was 'lost' was unreported as a serious incident. The investigation also revealed the unacceptable practice of reconstituting unused controlled drugs back into their bottles. In November 2015, a Coroner's inquest recorded the death of the patient as natural causes, but the investigation highlighted numerous areas of poor governance that required immediate action, especially in the areas of record keeping. These were adopted by the NHS trust.
- Police attended a South Manchester hospital following a number of thefts of diazepam and lorazepam from a controlled drug cabinet on a ward. Enquiries made with the hospital authorities eventually identified a nurse who was the only person on duty at the times of all the thefts. Police found packets of the medication at the nurse's house and they were arrested. The nurse made a full admission and received a police caution. They were immediately suspended by the hospital and are currently on suspension by the NMC, awaiting a decision. CDLOs were involved in addressing safeguarding issues and advising on stricter management of controlled drugs.

- A GP practice manager contacted police to report that an 89 year old male was the subject of a telephone scam where he paid £300 for medication that was not needed. Police attended the victim's address for reassurance. The matter was then forwarded to Trading Standards, who carried out their own investigation.
- The National Crime Agency seized a quantity of tramadol that had been purchased online. Research on the potential recipients found that both occupants worked for the NHS. The police visited the prospective buyers, who both denied purchasing the tramadol online. The information was shared through the CDLIN process and they were subject of an internal disciplinary process.
- A practice manager at a GP Surgery (supported by Controlled Drugs Liaison Officer at North of England Commissioning Support) informed the police about a temporary patient at their surgery, who they believed to have been previously been subject to an alert from NHS fraud. The patient used false identities to present at 13 surgeries as a temporary patient and had been prescribed approximately 100 tramadol tablets per visit. They were linked to other surgeries and arrested while attending a pre-arranged appointment elsewhere. They admitted obtaining tramadol by deception on 13 separate occasions because they had become dependent on the drug. They pleaded guilty at court and received a 12-week prison sentence suspended for 12 months, were placed on a supervision order for 12 months and 16 weeks curfew with electronic monitoring.

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.

Controlled drug-related activity during 2015

The Department of Health continued to monitor the implementation of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 and worked closely on the shared controlled drug agenda with other interested parties such as NHS England, the Care Quality Commission, the National Institute for Health and Care Excellence, the Home Office, NHS Protect, the General Pharmaceutical Council, Association of Chief Police Officers and the NHS Business Services Authority.

The Department also worked with the Home Office on the introduction of the mandatory requisition form for Schedule 2 and 3 controlled drugs and on the Psychoactive Substances Act 2016.

A multi-disciplinary group of palliative care and hospice providers, together with representatives from ambulance trusts, hospital and community pharmacies, NHS England, the Department of Health, Home Office, CQC and the MHRA, met twice in 2015. The group was set up in 2014 to share concerns and discuss the implications of the Human Medicines Regulations 2012 and the existing Home Office Regulations on the supply of medicines to these providers, which were previously provided by NHS trusts.

Some hospice providers reported that they are pursuing solutions, but there are still ongoing concerns for hospices and ambulance trusts, and discussions are seeking a practical solution. The Home Office has also developed guidance to help providers apply for a Home Office Licence.

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 main job 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 investigates 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. The GPhC also 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, to ensure compliance with its Standards for Registered Pharmacies, arrangements for the management of controlled drugs and the relevant legislation that it enforces.

Controlled drug-related activity during 2015

Inspectors shared information about controlled drugs concerns identified during inspections, and complaints involving controlled drugs, with accountable officers.

The GPhC was represented on the Controlled Drugs National Group and the Controlled Drugs Cross Border Group. Inspectors attended CD 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 Standards Advisory Team received 54 controlled drugs related enquiries in 2015 (50 were from England and four from Scotland. There were none from Wales).

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

In May 2015, the GPhC published Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet. The guidance covers the need to manage risks involved in supplying medicines safely, including assessment of the suitability and timescale of the method of supply, dispatch and delivery for controlled drugs.

4. 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 staffs effectively work to support prisoners and detainees to reduce reoffending or achieve other agreed outcomes. HMI Prisons works closely with partner organisations including the General Pharmaceutical Council and CQC. HMI Prisons and CQC have produced joint reports for the prison and immigration detention inspections that we have completed together since April 2015.

Controlled drug-related activity during 2015

HMI Prisons inspects the treatment of and conditions for those detained in court and police custody, prisons, young offender institutions, and immigration detention facilities in England and Wales including medicines and pharmacy management as part of health provision. In 2015, GPhC inspectors supported HMI Prisons on inspections of 44 prisons and four immigration removal centres. The reports comment on the facilities associated with, and management of controlled drug prescribing, dispensing and administration within each establishment inspected. In places of detention the potential for the diversion and trafficking of medication, including controlled drugs, is high and consequently opiate substation treatment with methadone and buprenorphine is always supervised. A recent thematic report highlighted a significant demand for illicit medication, illegal drugs and some new psychoactive substances in most adult prisons, and many prisons have struggled to effectively reduce the demand and supply particularly of synthetic cannabis (HMI Prisons December 2015 Thematic report by HM Inspectorate of Prisons Changing patterns of substance misuse in adult prisons and service responses).

The prescribing, dispensing and administration of controlled drugs in most establishments inspected met regulation requirements. However, there were issues in a small minority of establishments inspected relating to non-compliant controlled drug storage facilities, inconsistent timing of drug administration and poor drug administration recording practices. Additionally in some establishments inflexible prescribing of opiate substitution treatment, including the unavailability of buprenorphine, resulted in poorer outcomes for some detainees and inadequate supervision of controlled drug administration increased the opportunities for bullying and diversion. The number of detainees prescribed tramadol remains comparatively low following its reclassification in June 2014.

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 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 delivering 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:

- Puts 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.
- 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.

Drug Licensing & Compliance operate 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. We continue to operate on a full cost recovery basis and strike 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 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. In 2015, Drug Licensing & Compliance:

- Increased 'Compliance Officer' capacity by 20% at the end of 2015.
- Issued 1,030 domestic controlled drug domestic licences, including 270 compliance visits.
- Served four administrative licensee contraventions.
- Issued 21,750 import-export licences, approximately 90% of these for controlled drugs.

- Announced that the Licence Replacement Programme, commenced in late 2012, had concluded with 301 licence surrenders and 55% of 'open-ended' licensees choosing to replace their licences.
- Published the oxycodone import policy consultation response on 26 September 2015, with a phased implementation for the policy change. We do not envisage this will have any impact on the supply or availability of oxycodone containing medication to patients.

Drug control

- A Temporary Class Drug Order to control Methiopropamine (MPA) came into force on 27 November 2015. The ACMD advice is available at: https://www.gov.uk/government/publications/acmds-temporary-class-drug-order-report-on-methiopropamine.
- The Psychoactive Substances Act 2016 came into effect on 26 May 2016. This bans the sale, supply, production and distribution of psychoactive substances for human consumption and gives police and local authorities greater powers to tackle the trade. The new legislation does not cover products that are already regulated by existing laws, for example, controlled drugs, caffeine, nicotine, alcohol and food will not be covered by this Act. Certain activities are also exempted from the Act. These are bona fide research and healthcare activities, where they involve the supply of psychoactive substances for human consumption.

Misuse of Drugs Regulations

- The review of specific provisions under the Misuse of Drugs Regulations 2001 is now completed. The statutory instrument implementing the changes was laid in Parliament and came into force on 1 June 2015, apart from delayed coming into force dates for changes relating to a mandatory requisition form for Schedule 2 and 3 controlled drugs (CIF 30 November), inclusion of RCVS number on veterinary prescriptions for Schedule 2 and 3 CDs (CIF 1 July) and the rescheduling of ketamine to Schedule 2 to the 2001 Regulations (CIF 30 November). The amendments proposed were outlined in the associated consultation, summarised at: http://www.homeoffice.gov.uk/publications/about-us/consultations/misuse-drugs-regulations/
- The legislative provisions introducing independent prescribing of a limited number of controlled drugs by physiotherapists and chiropodists were included in the global SI that came into force on 1 June 2015. The ACMD advice on the changes is available at: http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/independ-prescribing-advice
- Legislative changes to remove the exemption applicable to temazepam prescriptions to bring it in line with all other Schedule 3 drugs was also included in the global SI which came into force on 1 June 2015. The ACMD advice on the legislative change is available at: https://www.gov.uk/government/publications/temazepan-advice.
- Ketamine was rescheduled to Schedule 2 to the Misuse of Drugs Regulations 2001 following international rescheduling by the UN and a public consultation to assess

the impact of Schedule 2 status. The amending provisions were included in the global SI which came into force on 1 June 2015. The ACMD advice is available at:

https://www.gov.uk/government/publications/rescheduling-of-ketamine-and-patient-group-directions

- Legislative changes were implemented in June 2015 to enable the electronic prescribing of Schedules 2 and 3 controlled drugs under the NHS Electronic Prescription Service (EPS). The ACMD advice on electronic prescribing of Schedules 2 and 3 CDs is available at:

  https://www.gov.uk/government/publications/electronic-prescribing-service-for-schedules-2-and-3-controlled-drugs

  The global SI and explanatory memorandum are available at http://www.legislation.gov.uk/uksi/2015/891/resources.

  A Home Office circular introducing the above changes is available at; https://www.gov.uk/government/publications/circular-0192015-a-change-to-the-misuse-of-drugs-regulations-2001.

- The Home Office issued a new and improved set of 'approved wording' for instalment prescribing in November 2015. The new wording replaces the old wording and is expected to be phased in over the coming months when prescribing software is updated. The new wording is flexible and simple to use and can be mixed and matched to express the prescriber's intent.

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

The NICE Medicines and prescribing centre (MPC) provides a Controlled Drugs Accountable Officer (CDAO) support programme.

Controlled drug-related activity during 2015

In October 2014, NICE started developing a guideline on the safe use and management of controlled drugs, which was scheduled for publication in March 2016. Information about the guideline is at www.nice.org.uk/guidance/indevelopment/gid-cdgpg.

NICE communities of practice

With agreement from NHS England and the Department of Health, the secure area for CDAOs that included a closed discussion forum was closed in September 2015 due to inactivity.

7. Medicines and Healthcare products Regulatory Agency (MHRA)

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

Controlled drug-related activity during 2015

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' took effect from 1 July 2015. All Member States are required to have in place national arrangements to register legal suppliers of medicines to the public.

All websites supplying medicines at a distance must 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. MHRA is the UK Competent Authority and processes applications from registered pharmacies and other suppliers. MHRA works with the GPhC to raise awareness.

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 (MoD)

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 management procedures across primary care. Apart from operations and the Defence Medical Rehabilitation Centre (DMRC), the MOD does not manage controlled drugs 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 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 issued in 2014.

Controlled drug-related activity during 2015

MOD has revised its internal policy on Management of Medicines, which includes a detailed chapter on controlled drugs. This was published in December 2015 (JSP 950 leaflet 9-2-1).

2014/15 saw significant deployment of military forces in support of the international ebola crisis, with UK activity centred in Sierra Leone. The medical facility for non-ebola cases operated under routine MOD procedures that comply with UK legislation wherever possible. The combined Ebola Treatment Facility operated in partnership with Save the Children had international Pharmacy staff. Differing national legislative requirements and working practices led to a pragmatic approach to managing controlled drugs, complying with UK legislation where possible. However, MOD did relax the record keeping requirements, at this facility only, for other drugs that would normally be deemed 'accountable' and therefore secured and accounted for in a register in the same way as controlled drugs. This was based on a risk assessment and the requirement to develop coherent, streamlined processes to enable timely and safe patient care.

MOD has introduced the off–label use of Oral Transmucosal Fentanyl Citrate, 800 micrograms, as part of the spectrum of pre-hospital care analgesics available for operational use. This is currently only available to medically-trained personnel but will replace morphine 10mg autoinjector as self-administered analgesia in due course. All stock will be managed and accounted for in accordance with MOD policy, which is based on UK legislation.

9. NHS England

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

Our vision: 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.

Our purpose: 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.

Controlled drug-related activity during 2015

NHS England introduced new regional structures from April 2015 resulting in further changes to the controlled drug accountable officer role. NHS England has reduced the number of lead CDAOs but has, in general, retained the original local intelligence networks to ensure that the considerable work done to build relationships and trust and to create the environment for intelligence sharing has been maintained, as far as possible.

Taking account of CQC's recommendations in 2014, a new NHS England Controlled Drug Forum has been formed, bringing together all the lead CDAOs across England to work more collaboratively and to agree a consistent national approach to delivering NHS England's responsibilities with respect to the safe use of controlled drugs. Good progress has been made towards ensuring a more consistent approach and ensuring wider sharing of learning from incidents and near misses.

During 2015, NHS England clearly outlined expectations of clinical commissioning groups (CCGs) regarding the safe use of controlled drugs as part of the delegation agreement for co-commissioning. This requires that a CCG assists NHS England's CDAO to carry out its functions under the Controlled Drugs (Supervision of Management and Use) Regulations 2013. A CCG must designate a CCG CD Lead and the delegation agreement outlines their responsibilities in supporting the NHS England Lead Controlled Drugs Accountable Officer. This includes a requirement to analyse controlled drugs prescribing data.

10. NHS England Health and Justice

NHS England has responsibility for directly commissioning services for people receiving healthcare services or facilities for people who are detained in a prison or in other accommodation of a prescribed description.

This covers community, secondary and certain specialised services provided in:

- prisons
- youth offender institutions
- courts
- immigration removal centres
- children and young people's secure estate (welfare and youth justice)
- sexual assault referral centres (43 sites).

NHS England is working in partnership with the 40 police forces in England to support the commissioning of healthcare for people in police custody.

The Health and Justice commissioning team are part of the Medical Directorate in NHS England. There is a central support team and 10 commissioning hubs within the four NHS England regions. There is also a Health and Justice Clinical Reference Group (H&J CRG), which provides advice to the commissioning team and leads on clinical programmes.

The central support team hosts a medicines optimisation (MO) programme led by a national health and justice pharmaceutical adviser. The MO programme and wider H&J CRG work streams include projects that incorporate controlled drug use, operationally and within specific care pathways.

Controlled drug-related activity during 2015

The three main outputs related to controlled drugs and medicines of abuse are:

Letter about misuse of hyoscine butylbromide (Buscopan) (June 2015). The aim of this joint letter with Public Health England is to raise awareness of the misuse of hyoscine butylbromide (Buscopan) that has been reported from HM prisons and to provide advice to clinicians on actions to minimise this risk. This was shared with CDAOs as there would be wider relevance in the community, especially for substance misuse providers.

Guidance on access to supervised doses of opioid substitution for people in police custody (September 2015) can be found here. Recent reports have revealed inconsistencies in how people in police custody access their doses of methadone and buprenorphine. These doses are usually administered under supervision by the community pharmacist or community substance misuse team. Even though it is not common that methadone and buprenorphine doses are needed for a patient in custody, procedures need to be in place to manage this. Healthcare professionals, commissioners and regulators have written this briefing to help other healthcare professionals, including community pharmacists and police custody teams, give people safe access to these medicines.

Prison Pain Management Formulary for acute, persistent and neuropathic pain (December 2015). The formulary supports clinicians in the management of acute or persistent pain and neuropathic pain, taking account of the specific challenges of prescribing pain medicines in prisons. The formulary is published as two documents, which should be used together to embed the formulary into practice:

- The Formulary – shows the recommended medicines along with advice and clinical guidance links to support these choices.
- The Implementation Guide – this provides information about:
    - The scope and development of the formulary and who should use it.
    - How medicines fit into the pain care pathway versus alternative treatment.
    - The patient perspective on their experiences of current pain care in prisons.
    - Prescribing, reviewing and continuing pain care for people coming into prison, during their stay and on release or transfer to another prison.
    - Self-care and supporting self-management of pain by prisoners.
    - How to optimise safety when prescribing and using pain medicines for people in prison.

In addition to these publications, practical implementation tools and examples of good practice in managing pain in prisons will be collated and published on the website.

For further information about these work streams please contact denisefarmer@nhs.net

11. NHS Protect

NHS Protect is part of the NHS Business Services Authority (NHSBSA), an arm's length body of the Department of Health, and works to a memorandum of understanding between these two organisations. Its remit covers England and Wales for economic crime, and only England for all other issues.

The Department of Health created an Anti-Fraud Unit (DH AFU) in 2014-15 to combat fraud within the Department and its arm's length bodies. Since DH AFU was created, the functions of NHS Protect have been reviewed, and this is continuing in 2015-16. As a result, NHS Protect has revisited its vision, purpose and strategic goals. The vision for NHS Protect is simply to deliver a service that is focused on the protection of NHS resources, including medicines, controlled drugs and prescription forms.

NHS Protect is responsible for the development of anti-crime standards and assessment services to ensure that local action to identify and tackle crime is effective. Under the NHS Standard Contract for 2015/2016, all organisations providing NHS services must put in place and maintain appropriate counter fraud and security management arrangements.

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

Controlled drug-related activity during 2015

NHS Protect continues in its remit to engage and provide support to NHS professionals, NHS organisations, NHS providers, CDAOs and CD LINs in the secure management and control of controlled drugs. This has been through attendance at CDLIN meetings by NHS Protect's operational staff and providing support and assistance to CDAOs and NHS provider organisations with investigations and liaison with the police.

In 2015, NHS Protect continued to receive reports of theft and fraud involving controlled drugs. Prescription forms were also targeted, with temporary and new patients registering at multiple GP practices using their own or false details to fraudulently obtain controlled drugs. Fraudulently obtained controlled drugs are a financial loss to the NHS, as these resources are diverted from legitimate use and can potentially cause harm due to unsupervised use. Alerts were issued regionally and nationally on preventative action to be taken regarding known individuals presenting to fraudulently obtain controlled drugs. Alerts were also issued to NHS organisations and their staff, to take precautions in relation to known individuals who posed a threat of violence and aggression in their efforts to fraudulently obtain controlled drugs to misuse.

Other operational matters that have arisen regionally in 2015 include:

- A number of cases highlighting perceived weaknesses within NHS organisations around checks on bank and agency pharmacy and nursing staff. NHS Protect's operational staff have run sessions with Local Security Management Specialists (LSMSs) on pre-employment screening and document checks, and identifying false and forged documentation. Guidance was issued on preventing, detecting and investigating misrepresentation of qualifications, skills and experience.

- Assisting NHS organisations with investigations into the theft of controlled drugs, providing security advice to NHS organisations on securing their environments and controlling the movement of people in areas where controlled drugs and medicines are stored.
- Assisting trusts with search and destruction policies for illegal substances found on patients.
- Sharing good practice and learning where LSMSs have been involved in controlled drug storage spot checks, audits and investigations to improve accountability among professionals.
- Providing advice to GP practices on the security and storage of prescription form stock.
- Providing advice to community trusts on prescription printer security.
- Providing advice to CDLINs on the framework around the use of covert surveillance in accordance with the Regulation of Investigatory Powers Act 2000, as part of investigatory work to obtain evidence.
- Joint work with CDAOs on prescription security leading to the development of security checklists and risk assessment.
- Developing processes to address emerging security risks.
- Assisting in the pilot project to develop a controlled drugs cupboard security alarm and closed circuit television system.
- Supporting police investigations into people targeting medical gas cylinders for nitrous oxide gas. The cost of this to healthcare organisations is substantial. Although the number of reports has dropped significantly since the autumn, a small number of reports continue to be made. Alerts were issued on preventative action to be taken on this and other emerging crime trends.

In 2015, revised standards for both anti-fraud and security management work were issued to providers of NHS services.For the first time, anti-fraud and security management standards were also issued to NHS commissioners. In the 2015/16 revision of the security management standards for providers, Standard 3.7 from 2014/15 was re-worded and became Standard 3.8 *The organisation has clear policies and procedures in place for the security of medicines and controlled drugs.* Assessment of trusts in 2015 against this standard has shown that 11% of organisations assessed were partially compliant and 89% were fully compliant. There were no instances of non-compliance. Through its on-going Quality Assurance Programme, NHS Protect continually seeks to improve anti-crime standards across all NHS organisations inspected and aim to increase compliance and performance against this standard.

In response to intelligence and information concerning the theft and loss of NHS prescription forms, NHS Protect will be introducing a new security management standard for providers to ensure prescription forms are protected from theft and misuse. Work on this standard began in 2015 and the new standard will be launched in 2016 as part of the 2016/17 security management standards for providers. NHS Protect had considered extending the security management standard for providers on controlled drugs to include prescriptions, but after consideration the standards review group agreed to create a separate standard for prescription forms, to reflect the issue's importance.

In the latter part of 2015, NHS Protect evaluated the Security of prescription forms guidance to assess how it is used and to identify if any updates and amendments were needed based on current practices and experiences. While 75% of the respondents advised that their organisation had a policy or standard operating procedure in place for the security of prescriptions, the survey highlighted that this is still not given the high priority status that is essential for protecting this NHS resource. The introduction of the new security management standard in 2016 will hopefully address this. NHS Protect continues to champion the protection and improved security of prescription forms and will update the guidance to reflect recent changes and feedback received. The updated guidance will be published in 2016.

12. 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 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 our 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
- helping local authorities and the NHS to develop the public health system and its specialist workforce.

PHE's alcohol, drugs and tobacco division, in 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.

Controlled drug-related activity during 2015

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 2015, PHE was involved in a number of activities related to controlled drugs:

- **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 nearly complete and is being advised by a panel of clinicians and other experts. The revised guidelines will be published in 2016.
- **Drug-related deaths:** Illicit drugs are by far the biggest contributor to drug misuse deaths and recent increases in these. However, there are a number of deaths from controlled drugs, and because we are increasingly concerned about these, controlled drugs were considered in a national summit to review causes and prevention of deaths in early 2015. They were also included in subsequent data analyses.
- **Addiction to medicines pilot:** PHE is working with three local authorities to oversee a pilot programme that is testing a range of responses to addiction to medicines (including opioid pain medication and benzodiazepines). Aims across the sites include identifying patients at risk of addiction and referring to treatment, reducing prescribing of pregabalin and tramadol and increasing GP confidence to identify and respond to prescribed medication misuse. PHE is also supporting other areas that are developing approaches to treating addiction to medicines and is also inputting to a research project attempting to establish prevalence of addiction to medicines, using the Clinical Practice Research Datalink.
- **Pain management:** PHE supported the development of a core resource on opioid pain medication, in part to reduce the risks of misuse and dependence. It was published on the Faculty of Pain Medicine website in late 2015: www.rcoa.ac.uk/faculty-of-pain-medicine/opioids-aware
- **CQC Controlled Drug National Group:** PHE was further involved in controlled drug regulatory activity in 2015 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 and through contact with the chair, Sarah Dennison.

13. UK Anti-doping

UKAD's Intelligence and Investigations Team liaises directly with law enforcement agencies. Part of the role of the investigator involves contacting UK Border Force and Police forces regarding controlled deliveries and the Intelligence Team assesses whether there may be any links to sport.

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.

As a result, UKAD has engaged with the Organised Crime Command (OCC) and embarked on a joint operation called Operation Underground, where the OCC coordinated the

commitment of UK police forces resulting in the dismantlement of illicit controlled substance factories within the UK and the seizure of substantial criminal assets.

UKAD is not currently licensed to handle controlled drugs but is applying for a Controlled Substance Licence to enhance its capability in this field.

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.

UKAD continues to be concerned about the rise in the number of men using steroids, not just for performance enhancement but also for cosmetic reasons. Nearly 50% of UKAD anit-doping rule violations in 2015 related to anabolic steroid use and many of those findings came from low level rugby.

The main focus for UKAD's Intelligence and Investigations in 2015 was Operation Underground, in collaboration with the National Crime Agency, as well as national and international law enforcement partners.

UKAD continues to focus on preventing doping in sport by targeting the source of the problem through anti-doping education at all levels of sport (from primary schools through to elite athletes), and by targeting the supply of illicit substances through partnership work with law enforcement partners.

14. 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.

Controlled drug-related activity during 2015

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.

VMD 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. Inspection reports point out any non-compliance and give advice and guidance on the measures required to correct this.

In 2015, the VMD inspected 512 veterinary practice premises. Of these, 509 were scheduled inspections and three were enforcement visits. No enforcement actions relating to controlled drugs were required as a result of these inspections

When necessary, 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) 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 inspectors are authorised to examine records and witness controlled drug 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 guidance on controlled drugs provides information for veterinary surgeons and pharmacists on the prescribing and supply of controlled drugs and the additional requirements that must be met under misuse of drugs legislation. This guidance was amended in June 2015 and is available on the GOV.UK website at the following link: www.gov.uk/guidance/controlled-drugs-veterinary-medicines

As well as this guidance note, the VMD provides best practice advice, also on GOV.UK: www.gov.uk/guidance/controlled-drugs-recording-using-storing-and-disposal.