The safer management of controlled drugs: Annual update 2016

Annex: Activity in 2016 from partner organisations of the Controlled Drugs National Group and Cross-Border Group

July 2017

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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 2016 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 2016:

- National Police Chiefs' Council
- 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 Health and Justice Commissioning)
- NHS Protect (now known as the NHS Counter Fraud Authority)
- 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. National Police Chiefs' Council

The National Police Chiefs' Council (NPCC) was formed on 1 April 2015 replacing the Association of Chief Police Officers (ACPO), which provided national police coordination and leadership. The association's remit has been 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 the police being involved in investigation, intelligence and partnership working, particularly through local controlled drugs intelligence networks, which meet regularly. See the website for further information: http://www.npcc.police.uk.

During 2016, the NPCC trained another 14 officers from around the UK through the week-long national course in Manchester for Controlled Drug Liaison Officers.

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 and works closely on the shared controlled drug agenda with other interested parties. See the website for further information: https://www.gov.uk/government/organisations/department-of-health.

During 2016, the Department of Health has facilitated work between NHS ambulance trust pharmacists and the Home Office to clarify the legal positon on licensing ambulance trust stations for holding and supplying controlled drugs and the requirements for mandatory requisition forms. In the autumn, the Department began initial work with stakeholders on the review of the Controlled Drugs (Supervision of Management and Use) Regulations 2013. Detailed work will be taken forward during 2017.

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 to protect, promote and maintain the health, safety and wellbeing of patients, the public and all those who use registered pharmacy services. See the website for further information: https://www.pharmacyregulation.org/

In 2016, 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 accountable officers in relation to concerns about controlled drugs identified during inspections and complaints involving controlled drugs.

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. It also inspects medicines and pharmacy management as part of health care provision. HMI Prisons promotes the concept of 'healthy prisons' in which staff work effectively to support prisoners and detainees to reduce re-offending or achieve other agreed outcomes. See the website for further information: http://www.justiceinspectorates.gov.uk/hmiprisons/#.U4yR31Mumjg

On most of our inspections of prison and immigration removal centres in 2016 we were accompanied by GPhC inspectors. As in the previous year, the prescribing, dispensing and administration of controlled drugs in most establishments that we inspected met regulation requirements. However, in some establishments there was insufficient supervision by officers of queues of those waiting to receive medication, which led to crowding around the administration area and created opportunities for bullying and diversion.

5. Home Office - Drug Licensing & Compliance

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 Drug & Alcohol Unit also continues to hold responsibility for the development and implementation of amendments to the Misuse of Drugs legislation. See the website for further information: https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns.

The Drug Firearms and Licensing Unit 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 the import and export of controlled drugs and precursor chemicals. The unit operates on a full cost recovery basis and strikes a proportionate balance against international and moral obligations to minimise the risk of the diversion of controlled drugs, but to ensure the availability of drugs for licit use. The aim is to visit each premises holding a controlled drug licence on a rolling three to five year basis, according to the risk posed by that site.

In 2016 the unit:

- introduced smarter compliance visit mapping techniques and a 'diary manager' function to book visits more efficiently and quickly and reduce waiting times
- issued 1,401 domestic controlled drug domestic licences, including 581 compliance visits

- served one administrative licensee contravention
- issued 22,073 import-export licences, approximately 95% of these for controlled drugs
- worked closely with MHRA following its opinion that CBD (cannabidiol) was 'medicinal' in nature.

The Psychoactive Substances Act 2016 (PSA) came into effect on 26 May 2016. The PSA 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 PSA 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 exempt from the PSA. These are bona fide research and healthcare activities, where they involve the supply of psychoactive substances for human consumption.

The renewal of the Temporary Class Drug Order for Methylphenidate based substances came into force on 26 June 2016, maintaining control of that substance as a temporary class drug. Advice from the Advisory Council on the Misuse of Drugs (ACMD) is available here. The renewal of the Temporary Class Drug Order for methiopropamine (MPA) came into force on 27 November 2016, maintaining the control of that substance as a temporary class drug. The ACMD advice is available here.

On 14 December 2016, the third generation synthetic cannabinoids was classified as a Class B controlled drug under the 1971 Act. On the same day, the anabolic steroid Dienedione was classified as a Class C controlled drug under the 1971 Act. The circular is available here. On 14 December 2016, the third generation synthetic cannabinoids was listed as a Schedule 1 controlled drug under the Misuse of Drugs Regulations 2001 and added to Schedule 1 Part 1 to the Misuse of Drugs (Designation) Order 2015. On the same day, the anabolic steroid Dienedione was listed as a Schedule 4 Part II controlled drug under the Misuse of Drugs Regulations 2001. The circular is available here.

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

The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care. Its role is to improve outcomes for people using the NHS and other public health and social care services. Further information is available at: https://www.nice.org.uk/.

NICE guideline on controlled drugs: safe use and management (NG46) was published in April 2016. Medicines optimisation: key therapeutic topics (KTT) summarises the evidence base on topics identified to support medicines optimisation, but is not formal NICE guidance. In January 2017, NICE published Medicines optimisation in long-term pain: high-risk medicines, which includes advice on the safe prescribing of controlled drugs such as opioids.

7. Medicines and Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health and is the UK Regulatory Authority for medicines for human use and medical devices. The MHRA also acts as the law enforcement authority for these products and officials from the Enforcement Group undertake criminal investigations into illegal activity using powers available in the Human Medicines Regulations and Medical Devices Directive. Further information is available at: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Concerns have been identified for a significant quantity of class C controlled drugs, principally Diazepam and Zopiclone, which are being diverted from the legitimate supply chain and sold either online or distributed through the black market. There is no legal restriction on pharmacists purchasing unlimited quantities of these medicines, but legitimate distribution is restricted to dispensing the medicines through prescription, or if licensed by both the Home Office and the MHRA, they can be distributed wholesale within the UK and abroad.

UK medicines legislation allows medicines of all categories (including prescription-only medicines (POMs)) to be sold online – provided existing legal requirements are met. Many websites now offer the services of a doctor offering remote consultation (by telephone, Skype or a questionnaire) and a subsequent prescription. The online consultation and prescribing are not MHRA's remit – the General Medical Council and CQC lead. MHRA has received considerable complaints from authorities in other EU member states as POMs cannot be legally sold in this way. However, pharmacies are in compliance with medicines law as medicines are dispensed against a bona fide prescription. MHRA is working with CQC and other regulators in the review of digital healthcare services and supported actions are being taken through the joint statement.

Under the provisions of the Falsified Medicines Directive, all POMs are required to have safety features (a unique identifier and tamper-proof evidence). Systems must be in place by 2019 across the 28 member states of EU.

8. Ministry of Defence (MoD)

The majority of primary care delivered to Her Majesty's Armed Forces in the UK and overseas is provided by Defence Primary Healthcare (DPHC). This enables a consolidated and consistent approach to management procedures for controlled drugs across primary care. Apart from operations and the Defence Medical Rehabilitation Centre (DMRC), the MOD does not manage controlled drugs in secondary care.

MOD 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 2017. All stock will be managed and accounted for in accordance with MOD policy, which is based on UK legislation.

9. NHS England

NHS England leads the National Health Service (NHS) in England. It sets the priorities and direction of the NHS and encourages and informs the national debate to improve health and care. See the website for further information: https://www.england.nhs.uk/

NHS England has consolidated the operation of local intelligence networks across England in 2016 to continue to build relationships and trust and to further foster an appropriate environment for timely intelligence sharing. The membership of many local intelligence networks has been broadened to reflect the diverse range of partner organisations that play a role in commissioning and delivering health and social care.

Taking account of CQC's recommendations in 2015, the NHS England CDAOs have worked together to ensure the information they collect about incidents and/or concerns about the safe management and use of controlled drugs is more consistent across England. This has included a review of the information requested from designated bodies in Occurrence Reports.

During 2016, NHS England, through its CDAOs, began to explore how it could support the wider health system in learning from incidents about the safe management and use of controlled drugs. This happens through a number of mechanisms including direct communication from the CDAO, locally produced CDAO updates and wider 'learning' local intelligence networks in some areas.

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 specific accommodation. The Health and Justice commissioning team is part of the Medical Directorate in NHS England. There is a central support team and 10 commissioning hubs within the four NHS England regions. Further information is available at: https://www.england.nhs.uk/commissioning/health-just/.

The 2016/2017 Health and Justice Medicines Optimisation Programme is progressing, or has contributed to, the following activities that include controlled drugs:

- Contributing evidence and information to support the prison content and recommendations in the recently published ACMD report on Diversion and Illicit Supply of Medicines.
- Professional Standards for Medicines Optimisation in Immigration Removal Centres and other secure environments in January 2017.

Healthcare and substance misuse providers in health and justice continue to link in with CD LINs and NHS England CDAOs, which enables them to learn from and share issues with other sectors of practice and providers.

Useful Health and Justice publications that include pathways where controlled drugs are used include:

- NICE Guidance on Physical health of people in prison: This includes recommendations about medicines.
- Other NHS England H&J publications: The Health and Justice team has published it's 2017/18 commissioning intentions (under H&J resources) and Strategic Priorities for 2016-2020.

11. NHS Protect (now known as NHS Counter Fraud Authority)

NHS Protect is part of the NHS Business Services Authority (NHSBSA), an arm's length body of the Department of Health. It works to a memorandum of understanding with the NHSBSA and Department of Health, and is responsible for the development of effective local anti-crime standards and assessment services. NHS Protect has been subject to a review of its functions, which concluded in 2016. NHS Protect will continue as a single expert, intelligence-led organisation to provide centralised capacity at a national level for investigations into complex crime matters and to have oversight of and monitor anti-crime work across the NHS.

In 2016, NHS Protect engaged and provided support on the secure management and control of controlled drugs with operational staff attending CD LIN meetings. These staff provided advice on a range of issues including the design of controlled drugs room storage and participation on controlled drugs incidence panels.

12. UK Anti-doping

UK Anti-doping (UKAD) is the national organisation dedicated to protecting a culture of clean sport. It is responsible for ensuring that sports bodies in the UK are compliant with the World Anti-Doping Code by implementing and managing the UK's National Anti-Doping Policy. Further information is available at: www.ukad.org.uk.

UKAD's Intelligence and Investigations team liaises directly with law enforcement agencies. The investigator, as part of its role, contacts UK Border Force and police forces regarding controlled deliveries and the team assesses whether there are any links to sport.

In 2016, UKAD was granted a Controlled Substance Licence and was also granted an Importation Licence. Both licences have already played an important part in not only investigating cases of trafficking and supply, but also building relationships with law enforcement partners.

13. Veterinary Medicines Directorate

The Veterinary Medicines Directorate (VMD) is an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra). The VMD is the Competent Authority for veterinary medicinal products in the UK. Further information is available at https://www.gov.uk/government/organisations/veterinary-medicines-directorate.

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-compliance and giving advice and guidance on the measures required to correct them. With the rescheduling of ketamine to Schedule 2, VMD's inspectors have had an increase in requests to witness controlled drugs destruction. Under the MDR, VMD's inspectors are authorised to examine records and witness 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.

Cross Border group on controlled drugs

The Cross-Border Group for safer management of controlled drugs in the devolved administrations includes the Controlled Drugs Accountable Officers' Network Scotland (CDAON), the Health and Social Care Board of Northern Ireland, NHS Wales and the Health Products Regulatory Authority (HPRA) of Ireland. The group provides a forum to discuss controlled drug matters at a strategic level.

Controlled Drugs Accountable Officer's Network, Scotland

The Controlled Drugs Accountable Officers' Executive group operates on behalf of the Controlled Drugs Accountable Officers' Network (Scotland) to engage with key strategic stakeholders and to drive improvements in the management of controlled drugs and to ensure effective decision-making and actions. Further information is available at: http://www.knowledge.scot.nhs.uk/accountableofficers.aspx.

In 2016, the work included:

- publishing the Controlled Drugs Accountable Officers' Network (CDAON) (Scotland Controlled Drugs Governance: Induction Handbook (January 2016)
- reviewing the Standard Operating Procedure (SOP) for use in the managed and contractor services
- publishing an information booklet for administrative or clerical staff in general practice on the management and use of controlled drugs and prescription stationery in NHS Scotland

- revising and updating the Pre-Registration Pharmacist Training Package to standardise the training material used across Scotland.

Department of Health, Northern Ireland

On 8 May 2016 the number of Departments in Northern Ireland reduced from 12 to nine following the Departments Act (Northern Ireland) 2016, the Departments (Transfer of Functions) Order (Northern Ireland) 2016 and the Departments (2016 Act) (Commencement) Order (Northern Ireland) 2016. The Department of Health, formally known as the Department of Health, Social Services and Public Safety (DHSSPS), is one of these nine Departments. Its mission is to improve the health and social wellbeing of the people of Northern Ireland. Further information is available at https://www.health-ni.gov.uk/.

Northern Ireland has parallel Misuse of Drugs Regulations in operation and work continues to ensure that, where appropriate, parity is maintained with provisions in Great Britain. In respect of the proposed review of the current Misuse of Drugs Regulations and the Safe Custody Regulations in Great Britain, Northern Ireland intends to work with Home Office colleagues to progress their review in tandem.

Northern Ireland has also been working closely with colleagues in the Health Products Regulatory Authority in Dublin in respect of an Open General Licence aimed at regularising cross border movement of controlled drugs by GPs who live in the Republic of Ireland and work in Northern Ireland. Northern Ireland continued to develop and improve its processes relating to the safe and effective management and use of controlled drugs and one area being taken forward is the development of a standardised controlled drug requisition form.

NHS Wales

NHS Wales is the publically-funded National Health Service of Wales providing healthcare to some three million people who live in the country. Its key principle is that good healthcare should be available to all, regardless of wealth. Further information is available at: http://www.wales.nhs.uk/.

NHS Wales continued to focus on tramadol and opioid prescribing, with resource materials for primary and secondary care produced by the All Wales Therapeutics and Toxicology Centre (available on the All Wales Medicines Strategy Group website at: http://www.awmsg.org/medman_library.html and). There was also a continued focus on opioid analgesic prescribing across Wales.

In 2016 the All Wales Therapeutics and Toxicology Centre (AWTTC) produced a number of resource documents for healthcare professionals to support the safe management of drugs liable to misuse. Resources are available at: http://www.awmsg.org/medman_library.html?jqprselect=button1