

**The safer management of controlled drugs  
annual update 2018**

2018 activity report for

**Controlled Drugs National Group**  
and  
**Cross-Border Group**

Published July 2019

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# CONTROLLED DRUGS NATIONAL GROUP

The Care Quality Commission (CQC) leads the Controlled Drugs National Group, which comprises key regulators and agencies with a remit for controlled drugs in England. The group met three times in 2018 to share and discuss emerging issues and to identify ways of working together to reach solutions.

Membership of the group remained broadly the same as in 2017, with the addition of the Human Fertilisation and Embryology Authority and the Nursing and Midwifery Council. The members are:

- Care Quality Commission
- Department of Health and Social Care
- General Medical Council
- General Pharmaceutical Council
- NHS Digital
- Her Majesty's Inspectorate of Prisons for England and Wales
- Home Office
- Human Fertilisation and Embryology Authority
- Medicines Advice (Medicines and Prescribing Centre), National Institute for Health and Care Excellence
- Medicines and Healthcare products Regulatory Agency
- Ministry of Defence
- National Police Chiefs' Council
- NHS England (including Health and Justice Commissioning)
- NHS Counter Fraud Authority
- Nursing and Midwifery Council
- UK Anti-doping
- Veterinary Medicines Directorate.

This activity report highlights how these agencies contribute to the overall safer management of controlled drugs in England. CQC is grateful for their ongoing commitment and contributions to the National Group.

## Department of Health and Social Care

The Department of Health and Social Care (DHSC) supports health and social care professionals and their organisations by developing policy, legislation and guidance on the safe management and use of controlled drugs.

DHSC continued to work collaboratively in 2018 on the shared controlled drugs agenda, including with NHS England, the Care Quality Commission, the Home Office, the General Pharmaceutical Council and the National Institute for Health and Care Excellence.

New legislation on 1 November 2018 allowed patients to access cannabis-based products for medicinal use (CBPMs), where prescribed by or under the direction of doctors on the General Medical Council's Specialist Register. DHSC has worked with a range of stakeholders on measures to ensure the successful implementation of this policy.

Alongside work on medicinal cannabis, DHSC has worked with the Scottish Government (SG) on a report of the post implementation review of the Controlled Drugs (Supervision of Management and Use) Regulations 2013, and aims to publish the report by 31 March 2020. Considering the widespread support to maintain the current regulatory provisions, DHSC and SG have agreed to seek to remove the statutory expiry date (sunset clause) from the Regulations of 31 March 2020. This is to address uncertainty for stakeholders around the Regulations, and would mean that the regulatory provisions, as currently drafted, would be maintained until further legislative action is taken. This approach is subject to Ministerial agreement in both countries.

DHSC has also supported the Home Office on legislation to introduce pregabalin and gabapentin into Schedule 3 of the Misuse of Drugs Regulations 2001, making them controlled drugs, which came into effect on 1 April 2019. DHSC and NHS Digital have provided information to pharmacists and prescribers to highlight the implications of these medicines becoming controlled drugs, including that they can no longer be issued for repeat dispensing and that the length of prescriptions will be limited to a maximum of 30 days.

<https://www.gov.uk/government/organisations/department-of-health-and-socialcare>.

## General Pharmaceutical Council

The General Pharmaceutical Council (GPhC) regulates pharmacists, pharmacy technicians and registered pharmacies in Great Britain. Its role is to protect the public and give them assurance that they will receive safe and effective care when using pharmacy services.

This involves inspecting registered pharmacy premises to make sure they meet the required standards, which includes the arrangements to manage controlled

drugs. When the GPhC receives concerns about controlled drugs, or identifies concerns on inspection, they are shared with controlled drugs accountable officers.

In 2018 GPhC continued to work closely with CQC on areas of joint interest, being represented on the Controlled Drugs Cross Border Group and the cross-regulator group, which works to make sure that the public receive safe and effective care when using independent online primary medical services.

<https://www.pharmacyregulation.org/>.

## **Her Majesty's Inspectorate of Prisons for England and Wales**

Her Majesty's Inspectorate of Prisons for England and Wales (HMI Prisons) inspects the treatment of and conditions for people detained in court, police custody, prisons, young offender institutions, and immigration detention facilities in England and Wales. As part of this, HMI Prisons inspects all health and social care provision, including medicines optimisation and pharmacy services. HMI Prisons also jointly inspects and reports with CQC and GPhC inspectors in prison and immigration removal centres (IRCs).

During 2018, joint inspections of prisons and IRCs with registered pharmacy provision found that the potential for the trading, diversion and misuse of controlled drugs remains high in places of detention. The implementation of smoke free prisons appears to have triggered increased drug seeking behaviour to compensate the loss of tobacco. All controlled drugs and most tradeable medicines that are prescribed within the establishments are administered as supervised consumption. Mandatory drug testing indicates that control drugs remain a proportion of the illicit medicines used, so where some services are moving towards the use of espranor (a substitution treatment for opioid drug dependence), HMI Prisons has welcomed this.

The prescribing, dispensing and administration of controlled drugs in most establishments inspected has continued to meet regulatory requirements. However, a small minority did not meet regulations on storage, record-keeping and/or transport of controlled drugs. Of the inspections carried out in 2018, supervision of medicine queues was inadequate in approximately 50% of the sites. This situation continues to create opportunities for bullying and diversion.

Issuing controlled drugs at cell doors by nurses is a risky practice and remains the exception on most sites, but it continues to be custom and practice in units where higher risk prisoners are held.

The increasing use of psychoactive substances, and use of them on top of other potent medicines, has resulted in an increasing number of serious incidents and near misses. The report of the Prisons and Probation Ombudsman indicates an increasing number of drug-related deaths in custody.

Some sites have seen high levels of prescribing tradeable medicines for pain management, but these prescribing trends are often monitored at local medicines management and quality review meetings with robust pharmacy oversight. HMI Prisons welcomes where this is taken a step further with complex cases managed under a pain management process.

### **Good practice initiatives**

HMP Manchester: “The use of espranor increased efficiency and helped to reduce the risks associated with opiate substitute therapy”.

HMP Highdown: “The pain clinic provided excellent support for prisoners with chronic pain and had helped to manage the prescribing of tradeable medicines. The bespoke application for medicine reviews was innovative and helped prompt clinicians when further tests were needed”.

<https://www.justiceinspectrates.gov.uk/hmiprison/about-hmi-prison/#>.

## **Home Office - Drug Licensing & Compliance**

Cannabis-based products for medicinal use were scheduled as Schedule 2 drugs under the Misuse of Drugs Regulations 2001 on 1 November 2018. To constitute a ‘cannabis-based product for medicinal use in humans’, products must satisfy three requirements:

1. It needs to be a preparation or product that contains cannabis, cannabis resin, cannabidiol or a cannabidiol derivative.
2. It is produced for medicinal use in humans; and
3. It is a medicinal product, or a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product.

To order and supply these products for administration there are three access routes, which are that the product must be:

- a special medicinal product that is for use in accordance with a prescription or direction of a specialist medical practitioner
- an investigational medicinal product without a marketing authorisation that is for use in a clinical trial, or
- a medicinal product with a marketing authorisation.

On 1 April 2019 pregabalin and gabapentin were classed as Class C drugs under the Misuse of Drugs Act 1971 and Schedule 3 drugs under the Misuse of Drugs Regulation 2001. They were also added to the list of exempt drugs in Schedule 1 to the Misuse of Drugs (Safe Custody) Regulations 1973 ([Explanatory Memorandum](#) and [Advisory Council on the Misuse of Drugs advice](#)).

In December 2018, the Minister accepted the advice from the Advisory Council on the Misuse of Drugs to enable independent prescribing of six controlled drugs (tramadol, lorazepam, diazepam, morphine, oxycodone and codeine) by therapeutic radiographers ([Ministerial Response](#) and [Advisory Council on the Misuse of Drugs advice](#)).

### **Drugs Licensing Team**

- Reduced waiting times for licensees.
- Issued 2,268 domestic controlled drug domestic licences, including 607 compliance visits.
- Considered 104 'Theft and Loss' reports and served three administrative licensee contraventions.
- Issued 21,562 import-export licences, approximately 95% of these for controlled drugs.
- Continued working closely with the Medicines and Healthcare products Regulatory Agency and other regulators in respect of CBD oils and in the later part of the year on cannabis-based products for medicinal use in humans (CBPMs).

<https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns>

## **Human Fertilisation and Embryology Authority**

In 2018, a team of HFEA inspectors has continued to inspect licensed fertility premises to ensure compliance with the legislation set out in HFEA's [Code of Practice](#), which includes arrangements for the management, safe storage and administration of controlled drugs.

Where relevant, HFEA shared post-inspection information with CQC at the National group meetings. HFEA holds a register of all controlled drugs accountable officers in the fertility sector, which is continually updated and shared with CQC.

<https://portal.hfea.gov.uk/knowledge-base/other-guidance/controlled-drugs-accountable-officers/>

HFEA supported NHS England in reminding private prescribers to use their Prescriber Identification Number and to address this at inspections. A notification has gone out to the sector through a Clinic Focus article to provide further reminders to controlled drugs prescribers.

<https://www.hfea.gov.uk/>

## 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 NHS and other public health and social care services.

A NICE guideline on [controlled drugs: safe use and management](#) (NG46) was published in April 2016. This is due for review in 2021.

A NICE guideline on [Cannabis-based products for medicinal use](#) is being developed and is due to publish in October 2019. The prescribing, handling and monitoring arrangements for medicinal cannabis under Schedule 2 of the Misuse of Drugs Act is included in the scope.

[Medicines optimisation: key therapeutic topics \(KTT\)](#) summarises the evidence base on topics identified to support medicines optimisation but is not formal NICE guidance. The 2018 update includes Medicines optimisation in long-term pain: high-risk medicines as a topic. This includes advice on the safe prescribing of controlled drugs such as opioids.

<https://www.nice.org.uk/>.

## Medicines and Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health and Social Care with regulatory responsibility for medicines for human use and medical devices in the UK. The MHRA also acts as the law enforcement authority for these products and officials from the Enforcement Group carry out criminal investigations into illegal activity using powers available in the Human Medicines Regulations and Medical Devices Directive.

The investigation into the large-scale diversion of specific class C controlled drugs or prescription-only (POM) medicines, including diazepam, zopiclone and zolpidem from the authorised UK supply chain to an illegal market has continued throughout 2018. Evidence has shown that they were being sold either online or distributed through the black market and instances of historic diversion have been identified and investigated. There is an indication that this activity has reduced the demand for benzodiazepines and non-benzodiazepines from manufacturers and large wholesale dealers by up to 73%. There is no legal restriction on pharmacists purchasing unlimited quantities of these medicines, but dispensing is restricted to a prescription being submitted and, 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 POMs) to be sold online – provided existing legal requirements are met. This is a contributory factor in the remote prescribing services offered through some pharmacy websites. Patients are offered an online consultation where a doctor conducts the consultation by telephone, Skype™ or an online questionnaire and may opt to provide a prescription. The online consultation and prescribing are not MHRA's remit – the General Medical Council and CQC lead, but the four regulators involved (CQC, GPhC, GMC and MHRA) have been collaborating to address safety concerns raised by online-only healthcare services, map the regulatory landscape and, importantly, identify gaps. Many of the companies are registered in other EEA Member States and this sits outside the regulatory remit of UK authorities.

The provisions of the Falsified Medicines Directive requiring POMs to have safety features (a unique identifier and tamper-proof evidence) took effect on 9 February. The MHRA is monitoring developments and is working with GPhC to resolve any issues in pharmacies.

<https://www.gov.uk/government/organisations/medicines-and-healthcareproducts-regulatory-agency>

## National Police Chiefs' Council

Controlled drug liaison officers (CDLOs) in most forces continue to engage with local intelligence networks, but coverage in some areas is still unclear.

Reports from CDLOs show that the number of offences and investigations into non-medical and independent prescribers have increased. Most involved nurses but incidents also occurred with pharmacists and private paramedics. CDLOs have seen an increase in the number of requests for safe custody exemption certificates; these are often in respect of automated systems and keyless entry storage.

Incidents in nursing and residential care homes are perceived to be on the increase and involve both missing medication and administration errors. Officers report a number of incidents involving arrests of both nurses and carers. Many of these investigations uncover serious concerns about safeguarding and neglect.

Veterinary requests for destructions continue to be an issue and although some CDLOs do assist, some forces do not have the capacity. Practices are advised to contact another independent practice to act as authorised witness, but with the recent trend for all practices in an area to be under the same ownership this is not always possible.

The 2018 CDLO national course was held in Manchester and attended by 14 CDLOs. The 2019 course will run in the week of Monday 18 November.

The Association of Police Controlled Drug Liaison Officers (APCDLO) has a new website [www.apcdlo.org](http://www.apcdlo.org).

<http://www.npcc.police.uk>.

## 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.

NHS England lead controlled drugs accountable officers (CDAOs) have responsibilities for leading the controlled drug local intelligence networks (CDLNs) across their area.

In the 2017 annual controlled drug report, CQC recommended that commissioners of health and care services should include the governance and reporting of concerns around controlled drugs as part of commissioning and contracting arrangements. In response, the NHS England Controlled Drug Development Group has made an annual declaration available on the online reporting tool. These annual declarations can be completed by all healthcare organisations, including those in the independent sector, and help to provide assurance of compliance to the NHS England CDAOs. The online declaration makes it easier for services to make a declaration and standardises the approach across England.

There has been a continued increase in the reporting of controlled drug incidents through the online reporting tool. Ease of reporting, the standardised process across most NHS England areas and the supportive approach of the CDAOs, encouraging reflections and learning from incidents, have all contributed to this increased reporting and associated learning.

The NHS England CDAOs have contributed to national workstreams around the legislation changes for cannabis-derived medicinal products. They have distributed information to CDLNs and shared guidance that sets out expectations of what this regulatory change will mean in practice for clinicians working in the NHS and in private practice in England. Prescription monitoring arrangements for NHS and private prescriptions have been implemented.

NHS England CDAOs have also worked collaboratively since the publication of the Gosport Independent Panel Report, to ensure that the key actions from the report have been discussed and considered across CDLNs. Following the Government response to the report, the CDAOs have jointly contributed to the development of an assurance process for all designated bodies, to ensure that organisations have reflected on the learning from the report and reviewed arrangements in their organisation.

<https://www.england.nhs.uk/>

## NHS England Health and Justice

NHS England has responsibility for directly commissioning 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 Specialised Commissioning Directorate in NHS England. There is a central support team and nine commissioning hubs within the four NHS England regions. In 2018, the Health and Justice (H&J) Medicines Value Programme contributed to activities involving controlled drugs.

- The handling of gabapentin and pregabalin following rescheduling of these as Schedule 3 (without safe custody) has been agreed for H&J sites. These medicines will be handled as for tramadol, and follow the same [guidance](#). An exception to the requirement to have all doses of these medicines as not-in-possession (supervised) has been agreed for Category D open prisons. This is because they do not have seven-day healthcare services and prisoners are able to leave the prison to complete work placements and have authorised leave. Prisoners in Category D prisons will be able to have a maximum of 7-day in-possession of these medicines, but the prisons will be introducing additional safeguards to reduce the risk of diversion/abuse. These safeguards will be published during 2019/20.
- A national H&J audit against the Royal Pharmaceutical Society's [Professional standards for optimisation of medicines in secure environments](#) received a 99% return rate and a report on the outcomes (which include standards relating to handling controlled drugs) will be published in 2019/20.
- NHS England H&J are working towards integrating prescribing data into ePACT 2. This will enable controlled drug prescribing to be monitored and allow use of the controlled drug indicators and dashboards in ePACT.
- H&J has been included in the proposals (previously just for secondary care) to enable electronic prescription transfer of controlled drugs. This is being led by DHSC and NHS England. The next stage is for the Advisory Council on the Misuse of Drugs to consider the proposal.

<https://www.england.nhs.uk/commissioning/health-just/>

## Nursing and Midwifery Council (NMC)

The Nursing and Midwifery Council (NMC) exists to protect the public by regulating nurses, midwives and nursing associates in the UK, and setting standards of education, training, conduct and performance to enable them deliver high-quality care throughout their careers.

The NMC makes sure nurses, midwives and nursing associates keep their skills and knowledge up to date and uphold professional standards, and have clear and transparent processes to investigate those who fall short of standards.

NMC maintains a register of nurses, midwives and nursing associates allowed to practise in the UK. In 2018, NMC published new standards of proficiency for nurses, which were updated to take into account the changes in society and health care, and the implications of these for registered nurses.

The standards for medicine management guidance were withdrawn from 28 January 2019. The medicines management webpage contains links to several useful documents and websites that should be used instead.

<https://www.nmc.org.uk/standards/standards-for-post-registration/standards-for-medicines-management/>

NMC continues to establish a Regulatory Intelligence Unit, which analyses data and identifies themes and areas of serious regulatory concern.

<https://www.nmc.org.uk/>

## Public Health England (PHE)

Public Health England (PHE) is an executive agency of the [Department of Health and Social Care](#), with a mission to protect and improve the nation's health and to address inequalities.

PHE's alcohol, drugs, tobacco and justice division, located within the Health Improvement 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.

PHE supports the commissioning and provision of drug treatment services in line with relevant NICE guidance and the 2017 UK guidelines on clinical management of drug misuse and dependence. This helps ensure the safe prescribing of controlled drugs for opioid dependence.

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

**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 and prescribed drugs, especially opioids, so PHE contributed to national and international summits to better understand how to prevent such deaths.

**Prescribed medicines review:** PHE was commissioned by the public health minister to review the evidence on medicines that could lead to dependence and withdrawal, some of which are controlled drugs. In 2018, the review collected evidence through analysis of prescription data and a literature review. It will report in 2019.

**Opioids Aware:** The PHE-supported online resource on opioid pain medication is being updated by the Faculty of Pain Medicine: <http://www.rcoa.ac.uk/faculty-of-pain-medicine/opioids-aware>

**Diamorphine licensing:** PHE took over the role of DHSC in considering and providing clinical advice to the Home Office on applications from suitably competent doctors in England for licences to prescribe diamorphine, cocaine or dipipanone in the treatment of addiction. In reality, licence applications are only ever for diamorphine and there are very few of these, but the system that requires doctors to be licensed in this way continues to be an important safeguard in the UK.

**Report Illicit Drug Reactions (RIDR):** A joint project between PHE and the MHRA allows health professionals to make online reports about the effects of new psychoactive substances (NPS) and other drugs, in a similar way to how adverse effects of pharmaceutical drugs are reported to the MHRA's Yellow Card Scheme. Many of these are controlled drugs but few are medicines.

## 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.

UKAD's Intelligence and Investigations team liaises directly with law enforcement agencies. As part of its role, the investigator liaises with UK Border Force and police forces regarding seizures of controlled drugs, in particular performance enhancing drugs. The team assesses whether there are any links to sport and investigates accordingly.

### Working in partnership

UKAD's Intelligence and Investigations work during 2018 has spanned a number of areas, from operations with UK police forces to international partnerships with other national anti-doping organisations (NADOs).

The focus in 2018 was to build on existing partnerships in line with UKAD's strategic plan, and on maximising the use of intelligence and investigative resources, with an additional investigator employed to help increase investigatory capacity.

To have an effective intelligence-led anti-doping programme, UKAD works closely with the public and the sports community, and the Intelligence and Investigations team continues to maintain strong partnerships with members of CQC's National Group on Controlled Drugs, as well as agencies such as:

- the Food Standards Agency
- the Gambling Commission

- pharmaceutical companies and health regulators
- law enforcement partners, such as the National Crime Agency, UK Border Force, Interpol and other police partners
- the Government Agency Intelligence Network
- other National Anti-Doping Organisations and WADA.

These partnerships have yielded several positive results, with Operation Greyskull being a notable success. In July 2018, the team collaborated with Cambridgeshire Police, the NCA, UK Border Force and the Eastern Region Special Operations Unit (ERSOU). This operation resulted in two search warrants being executed on domestic and commercial premises, where over £30,000 worth of steroids were seized.

A key focus of UKAD's intelligence work is to promote and engage in inter-agency information sharing about doping in sport. In partnership with Crimestoppers, UKAD also manages Report Doping in Sport, a 24-hour confidential phone line for anyone to report information or suspicions about doping in sport.

UKAD's strategic plan places more emphasis on disruption techniques, and the Intelligence and Investigations team are using a new matrix, in collaboration with the NCA and law enforcement teams. The Disruption Techniques Matrix will be introduced to some key NGB stakeholders to help act on intelligence received from the team.

### **Socio-cultural**

Public health bodies and drug misuse charities have warned of an increase in image and performance enhancing drug (IPED) use in the UK. The growing social issue of IPED use outside of organised sport, particularly in gyms, has a trickle-down effect on UKAD's work especially in amateur sport.

UKAD has commissioned a report into IPED use that will help to develop partnerships and education programmes to address the issues.

[www.ukad.org.uk](http://www.ukad.org.uk)

## **Veterinary Medicines Directorate**

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

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. Responsibility for enforcing the Veterinary Medicines Regulations at Practice Standards Scheme premises remains with the VMD. In 2018, the VMD inspected over 630 veterinary practice premises.

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

VMD conducted a survey on the disposal of controlled drugs in May 2018 to understand the extent of the problem vets face when getting controlled drugs witnessed for disposal. The results of the survey and the responses will help the VMD with any future possible policy development.

<https://www.gov.uk/government/organisations/veterinary-medicines-directorate>.

## **CROSS BORDER GROUP ON CONTROLLED DRUGS**

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

## **Controlled Drugs Accountable Officers' Network, Scotland (CDAON)**

The Network is now established as a forum for education and learning and sharing good practice between NHS staff and other stakeholders, and will take the form of an annual assembly. The meeting in September 2018 discussed the report from the Gosport Independent Panel and considered the implications for health services in Scotland.

A major focus of the work in 2018 involved developing information for service providers around cannabis-based medical products and cannabidiol.

The Information sharing protocol with Police Scotland is still in development with the current spotlight being on developing a Privacy Impact Assessment.

In NHS Greater Glasgow and Clyde, the Heroin Assisted Treatment facility has progressed, and a temporary site has been identified. In addition, discussion with the Scottish Government around prescribers and licensing of prescribers has been successful.

The CDAON has been actively involved as stakeholders in various consultations including the Home Office Consultation – pregabalin and gabapentin: Proposal to schedule under the Misuse of Drugs Regulations 2001: The Controlled Drugs (Supervision of Management and Use) Regulations 2013 and on changes to the Human Medicines Regulations 2012.

Updated resources in 2018 include:

- Controlled Drug Declaration & Self-Assessment Questionnaires for Individual Medical Practitioners, and for General Practice (for dispensing and non-dispensing practices)
- Guide to Good Practice in the Management of Controlled Drugs in Primary Care – Scotland Summary Guide for Community Pharmacies and Pharmacy Technicians
- Controlled drug standard operating procedure example template for GPs (dispensing and non-dispensing practices)
- Controlled Drugs Governance: Induction Handbook
- Controlled Drugs Frequently Asked Questions.

New resources in 2018 include:

- a national Controlled Drug Record Book for use in hospital wards
- a Controlled Drugs Declaration & Self-Assessment Questionnaire for use in the Scottish Prison Service Healthcare and in the Forensic Medical Service.

Work is also ongoing on developing a suite of prescribing reports.

### **Working with partner organisations**

- Cooperation continues between the CDAON with Health Improvement Scotland (HIS) and the Controlled Drugs Local Intelligence Network Terms of Reference - Best Practice Template is completed. This provides guidance including how to establish a local intelligence network, its purpose and membership.
- Scottish Health Boards provided HIS with information around incidents involving oxycodone covering all sectors of health care and the [Learning from adverse events - Report on the medicines thematic analysis of oxycodone adverse events: May 2018](#) has been completed. This identifies core learning and suggests actions to reduce further errors.
- Discussion is ongoing around the private supplies and online access to controlled drugs including those used in the treatment of mental health conditions and in slimming clinics and around the diversion and illicit supply of medicines.
- The Network has been actively involved with the National Prisoner Healthcare Network in updating the Controlled Drug SOP for use by NHS staff in the Scottish Prison Service. In addition, the re-tender process for

supplies of pharmaceutical services to the Scottish Prisons has been completed.

- The updated resources, flash reports and general information are all available on [The Knowledge Network](#) and <http://www.knowledge.scot.nhs.uk/accountableofficers.aspx>.

## Department of Health Northern Ireland

### **Responsibilities of the Department in relation to controlled drugs**

The Department's Medicines Regulatory Group (MRG) continues to be the lead regulatory authority for a wide range of controlled drug licensing, compliance, legislative and enforcement matters in Northern Ireland.

### **Legislation**

The Medicines Regulatory Group is the Departmental policy lead on a wide range of medicines, controlled drug and pharmacy-related legislation in a Northern Ireland context.

The Department worked closely with the Home Office during the year to bring into operation an amendment to the Misuse of Drugs Regulations (Northern Ireland) 2002 to allow the wider use of cannabis-based products for medicinal use in humans. This legislative change followed a period of discussion with the Home Office and relevant stakeholders relating to the prescribing of cannabis-based medicinal products.

### **Community pharmacy**

During the reporting period, MRG officers carried out 236 inspections and visits in community pharmacies, controlled drug licensees and secondary care pharmacies. While covering a wide range of professional and statutory areas, these inspections also specifically targeted the management and use of controlled drugs.

On 22 February 2018, MRG circulated the annual self-assessment and declaration form to all registered pharmacy premises in Northern Ireland. This return covers all aspects of the safe management of controlled drugs and is reviewed by the MRG Pharmacy Inspectors during pharmacy inspection visits.

A quarterly report is forwarded to the HSCB Accountable Officer detailing the pharmacies inspected during that quarter, any controlled issues that have arisen, and the actions taken to resolve the issues.

### **Responsibilities of the Department relating to Relevant Independent Hospitals and Accountable Officers**

The Department continues to make determinations under Regulation 2A of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 relating to 'relevant independent hospitals'. A range of conditions

must be met for the Department to make such determinations and for a hospital to be prescribed as a Designated Body under the Regulations. In addition, the Department continues to hold the list of Accountable Officers in Northern Ireland as required by Regulation 4 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. See <https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/accountable-officer-contact-list.pdf> for the list and contact details.

## **Enforcement**

MRG is also tasked with a range of enforcement responsibilities under the Misuse of Drugs Act 1971 and associated regulations.

Throughout 2018, MRG has carried out enforcement activities and intelligence gathering with key partner agencies with regard to the illegal supply or diversion of controlled drugs throughout Northern Ireland and, where appropriate, has prepared case files for consideration by the Public Prosecution Service. MRG has maintained active liaison with national and international medicines enforcement agencies including the Medicines and Healthcare products Regulatory Agency (MHRA), Permanent Forum on International Pharmaceutical Crime (PFIPC) and European Working Group of Enforcement Officers (WGEO).

## **Controlled Drugs Reconciliation Project**

This key project was initiated by MRG, the Health and Social Care Board and the Business Services Organisation. It has established a process for ensuring that the medicine supply chain is robust and ensures that there is less potential for fraud in the system. It is hoped that this project will help prevent more deaths from prescription drugs and raise the already high clinical governance standards within the community pharmacy network.

<https://www.health-ni.gov.uk/>

## **Wales**

NHS Wales is the publicly-funded National Health Service of Wales providing healthcare to approximately three million people who live in the country.

Controlled drug local intelligence networks (CDLINs) across Wales generally meet four times a year with a broad membership across the Health Board along with partner agencies, regulators and service providers.

CDLINs scrutinise controlled drug handling and management across the region, sharing trend analyses of incidents and establishing guidance to enable learning to better safeguard patients and public.

Most CDLINs are linked through their annual reports to the Quality, Safety, Experience and Assurance Committee of their respective Health Boards. Some CDLINs now produce bi-annual or quarterly newsletters to communicate across sectors throughout their Health Boards.

**Monitoring:** Betsi Cadwaladr Health Board (BCUHB) has developed an IT-based monitoring tool that also incorporates a concern logging tool. Work is in progress to further develop the tool to monitor controlled drug management in secondary care. The tool provides a detailed overview of prescribing at practice level in primary care and directorate level in secondary care, allowing in-depth examination of prescribing practices.

### **Activity during 2017/8**

All CDLNs have reported activities relating to:

- Response to the Gosport report: contributions from each health board were provided to the Cabinet Secretary for his Written Statement about the use of opioids within NHS Wales.
- Developing and reviewing health board policy regarding conforming with the requirements of Home Office Controlled Drugs and MHRA dealers' licences.
- Re-classification of pregabalin and gabapentin: all health boards have issued cross-sector guidance clarifying the prescription and management requirements resulting from the change.
- Reclassification of cannabinoids: all health boards are considering their position regarding prescribing of cannabis-based products.
- General Data Protection Regulations (GDPR) requirements: several CDLNs have reviewed information sharing protocols to ensure they comply with the requirements.

The CDAO for BCUHB has agreed with all CDAOs in Wales to develop revised arrangements for prescription arrangements for Ministry of Defence (MOD) personnel to bring this in line with the arrangement in England. In England, private prescriber-controlled drug forms allocated to the MOD are not restricted to the use of a single named prescriber, which allows for better provision of controlled drugs by a professional workforce that moves between geographical locations.

WAST has built on the successful roll-out of the automated controlled drug cupboards and is developing intelligence gathering to provide supporting evidence of the improved compliance with controlled drug legislation and security. A business case has been prepared to support the purchase and implementation of a new security system that uses smart key technology, to permit restricted and auditable access by users, to all of its controlled drug safes across Wales.

All Wales Therapeutics and Toxicology Centre (AWTTC) continues to contribute to the safe management of controlled drugs and drugs liable to misuse through their activities in monitoring of National Prescribing Indicators, which now include a number relating to opioids. AWTCC also continues to work with the advisory panel on substance misuse. <https://www.awttc.org/>

<https://hiw.org.uk/accountable-officers-controlled-drugs>

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