The safer management of controlled drugs annual update 2019

2019 activity report

Controlled Drugs National Group and Cross Border Group

Published July 2020

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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 2019 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 2018. 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.

https://www.gov.uk/government/organisations/department-of-health-and-social-care

Cannabis-based products for medicinal use

Since the law changed on 1 November 2018 to allow specialist doctors on the General Medical Council's Specialist Register to prescribe cannabis-based products for medicinal use, the level of prescribing has been low and largely restricted to the private sector. This is to be expected given the limited evidence base for the clinical and cost effectiveness of these products.

The Secretary of State for Health and Social Care asked NHS England-NHS Improvement (NHSE-I) to undertake a rapid process review to identify any barriers for patients seeking access to these medicines on NHS prescription, where clinically appropriate. NHSE-I has now reported on the findings.

The Department is working closely with NHSE-I and other delivery partners to implement the report's recommendations. These include:

- Providing further support and guidance to healthcare professionals. On 8 August 2019 Health Education England published an e-learning package for healthcare professionals across the UK. On 20 December 2019 a letter was published reminding prescribers of General Medical Council guidance on the prescribing and use of unlicensed medicines – and to clarify the procedure for prescribing and supplying cannabis-based products for medicinal use..
- Promoting research through the National Institute for Health Research (NIHR) to develop the evidence base. The Government remains determined to support the development of randomised control trials, to explore appropriate alternative study designs, and to ensure evidence is generated in way that will benefit as many patients as possible. NIHR has issued two calls for research proposals alongside its highlight notice on medicinal cannabis. NIHR, NHSE-I, DHSC, clinicians and other research experts are working together to design a study on the use of cannabis-based products for medicinal use in the treatment of refractory epilepsies. We have also contacted all producers of cannabis-based products, known to have an interest in supplying the UK market, to encourage and support research applications to develop the evidence base further.
- Establishing a new Refractory Epilepsy Specialist Clinical Advisory Network which will be launched shortly. This will make a positive addition to the current well-established clinical networks.
- Developing a patient registry with input from specialist clinicians and other advisory bodies.

On 7 December 2018, the Health and Social Care Committee launched an inquiry into the usage of medicinal cannabis. As part of this, the Department worked alongside the Home Office, MHRA and NHSE-I to produce a written evidence submission to the Committee. On 5 September 2019 the Government published its response to the Health and Social Care Committee Inquiry Report on Medicinal Cannabis.

The Secretary of State for Health and Social Care commissioned the National Institute for Health and Care Excellence (NICE) to develop guidelines on the prescribing of cannabis-based products for medicinal use. Following a public consultation, the NICE guidelines were published on 11 November 2019.

The most up-to-date data currently available from NHS Business Service Authority indicates that between January and October 2019, 2,206 licensed and unlicensed cannabis-based medicines were prescribed on an NHS prescription and dispensed in the community.

General Medical Council

The General Medical Council works to protect patient safety and support medical education and practice across the UK by working with doctors, employers, educators, patients and other key stakeholders in the UK's healthcare systems.

https://www.gmc-uk.org/

Remote consultations and prescribing

Together with other UK health organisations, the GMC issued a joint statement and co-produced high level principles for all health professionals on remote consultations and prescribing and safety tips for patients accessing healthcare online. In November 2019, the GMC launched a call for evidence on remote consultations and prescribing, which will help to inform a decision on whether it needs to review their guidance for doctors. The GMC also share intelligence with other UK healthcare organisations to ensure appropriate steps are taken to protect the public.

Cannabis-based medicinal products

The GMC gave written evidence to the Health and Social Care Committee on medicinal cannabis drugs policy (report published July 2019). GMC also produced an information resource for doctors providing information about how the guidance for doctors applies to prescribing cannabis-based medicinal products. The GMC met with MPs and the co-chairs of the All Parliamentary Group on Medicinal Cannabis under Prescription to explain the guidance.

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.

https://www.pharmacyregulation.org/

In April 2019, the GPhC began publishing pharmacy inspection reports on a new website https://inspections.pharmacyregulation.org/. The reports are published to inform and assure the public about the standards they can expect from pharmacies, and to drive improvement in pharmacy services. The website also features a 'knowledge hub', with anonymised short examples of excellent, good, and poor practice identified through pharmacy inspection activity. This knowledge hub was developed in response to feedback from the pharmacy sector about how useful they found examples of notable practice that inspectors shared during inspections. It has been designed so pharmacy owners and pharmacy teams can quickly find examples relevant for them at any time, which they can use to learn from others and to improve outcomes for patients and the public using their services.

In March 2019, the GPhC published its new enforcement policy setting out how it uses the range of enforcement options. The overall approach is to support and encourage pharmacy owners to meet the standards for registered pharmacies. Statutory powers include issuing improvement notices and imposing conditions. These options may be used where there is a serious risk to patient safety.

In April 2019, the GPhC published updated guidance for registered pharmacies providing pharmacy services at a distance, including on the internet. The guidance included new safeguards to help make sure that people can only obtain medicines from online pharmacies that are safe and clinically appropriate for them.

During 2019, GPhC took enforcement action against several pharmacies, including several online pharmacies that were linked to prescribing services. In some of these cases there was evidence that opioids and other high-risk medicines were being supplied without adequate safeguards in place to prevent misuse. Conditions were imposed on some pharmacies to prevent them from supplying controlled drugs. Other enforcement options were also used alongside referrals to fitness to practise for several pharmacy professionals.

In November 2019, the GPhC published guidance for pharmacist prescribers to ensure that they provide safe and effective care when prescribing. The guidance emphasises that pharmacist prescribers must be able to justify their decisions and use their professional judgement in the best interests of the person receiving care, in all contexts. For example, when providing a pharmacy service online or when

working as part of a multidisciplinary team in a hospital, or in a community mental health team. The guidance also sets out when prescribers should consider whether any extra safeguards are needed, for example, when prescribing medicines likely to be abused or misused.

Health and Care Professions Council (HCPC)

HCPC was established by the Health Professions Order 2001 to protect the public. To do this, it sets standards for education, training and behaviour of professionals, and keeps a Register of professionals, known as 'registrants', who meet the standards. HCPC can also take action where concerns are raised about our registrants' fitness to practise. The Health and Care Professions Council (HCPC) regulates 15 health and care professionals, including several non-medical prescribers (chiropodists/podiatrists, dietitians, paramedics, physiotherapists and diagnostic and therapeutic radiographers). Several registered professions have rights to administer a limited list of controlled drugs.

https://www.hcpc-uk.org/

In March 2019, the HCPC signed up to a joint statement with NHS England, the Chartered Society of Physiotherapy, the College of Podiatry and the Institute of Chiropodists and Podiatrists on the reclassification of gabapentin and pregabalin. A statement informed physiotherapist and chiropodist/podiatrists with independent prescribing rights that they would no longer be able to prescribe these medicines.

The HCPC works closely with CQC on areas of joint interest and is represented on the Controlled Drugs National and Cross Border Group and Online Cross Regulatory Forum.

Read more about the medicines and prescribing rights.

Home Office - Drug Licensing & Compliance

The first duty of the government is to keep citizens safe and the country secure. As such, the Home Office plays a fundamental role in the security and economic prosperity of the United Kingdom.

https://www.gov.uk/government/organisations/home-office

Paramedic independent prescribing

In October 2019, the Advisory Council on the Misuse of Drugs (ACMD) published its recommendation to amend the Misuse of Drugs Regulations 2001 to allow independent prescribing and administration of six controlled drugs by paramedics. The Government will respond in due course.

Synthetic cannabinoids

The ACMD provided advice in December 2017 recommending that the generic definition of 'third generation' synthetic cannabinoids be amended to reduce the scope, removing compounds from the definition that were not intended for control. On 15 November 2019, the Misuse of Drugs Act 1971 was amended to rectify the generic definition of synthetic cannabinoids. On the same date, such compounds removed from control under the Act were also removed from the Misuse of Drugs Regulations 2001, whereby they were inadvertently captured under Schedule 1. Amendments were also made to de-designate them under the Misuse of Drugs (Designation) Order 2015.

In summer 2020, the ACMD will complete an updated harms assessment of synthetic cannabinoids. This will cover the ACMD's previous reports on synthetic cannabinoids and any recommendation on the classification and scheduling of synthetic cannabinoids under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.

The amendment does not change the classification of synthetic cannabinoids, which remain as Class B Drugs. amendment. The impact of the change is limited to the pharmaceutical and healthcare research sector and only removes controls over compounds that are not harmful.

Pregabalin and gabapentin

On 1 April 2019, pregabalin and gabapentin were controlled 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).

Cannabidiol (CBD) oil

The Home Office continues to monitor the growing CBD market and is working closely with other government departments. A number of interested departments and agencies (including HO, DHSC, Food Standards Agency) maintain an interest in developments on this issue, which the Home Office will keep under review.

Cannabis-based products for medicinal use (CBPM)

The Advisory Council on the Misuse of Drugs was commissioned to commence the longer-term review of cannabis-based products for medicinal use. The first part of this review was published in December 2019, which provided an outline for an assessment framework regarding the impacts of rescheduling cannabis-based products for medicinal use.

Drugs Licensing Team

In 2019, the team:

- issued 2,184 domestic controlled drug domestic licences, including 418 compliance visits
- maintained casework lead-in times

- considered 75 ‘Theft and Loss’ reports and served three administrative licensee contraventions
- issued 21,495 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 cannabis-based products for medicinal use in humans (CBPMs).

Human Fertilisation and Embryology Authority

The Human Fertilisation and Embryology Authority (HFEA) aims to ensure that everyone who steps into a fertility clinic, and everyone born as a result of treatment, receives high-quality care. HFEA licenses, monitors and inspects fertility clinics and provides free, clear and impartial information about fertility treatment, clinics and egg, sperm and embryo donation.

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

In 2019,HFEA worked with CQC to update the memorandum of understanding (MOU) to reduce the regulatory burden for clinics jointly registered with both organisations.

HFEA publishes and maintains a register of accountable officers for centres in England that are not registered with CQC.

HFEA encourages clinics to ensure the information provided to CQC is up to date, and where a clinic has received confirmation of being exempt from having a CDAO, it reviews this on inspection to ensure the clinic continues to meet the exemption criteria.

Through its inspection of medicines management (which includes controlled and non-controlled drugs) in 2019, HFEA has identified this to be one of the top four areas of non-compliant practice in the fertility sector. Strategies to support knowledge of the regulatory requirements and best practice guidance within the sector are planned for early 2020, which could include development of a non-compliance reference table and some learning workshops.

Collaborative links have been made with colleagues in Scotland to support the governance of controlled drugs in clinics in Scotland and HFEA expects to develop work here to ensure a consistent and proportionate approach to controlled drugs governance and practice

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

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.

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

Relevant NIVE guidance relating to controlled drugs:

- NICE guideline on controlled drugs: safe use and management (NG46) was published in April 2016. This is due for review in 2021.
- NICE guideline on Cannabis-based products for medicinal use was published in November 2019. The prescribing, handling and monitoring arrangements for medicinal cannabis under Schedule 2 of the Misuse of Drugs Act is included in the guidance.
- Medicines optimisation: key therapeutic topics (KTT) summarises the evidence base on topics identified to support medicines optimisation but is not formal NICE guidance. The 2019 update includes Medicines optimisation in chronic pain as a topic. This includes advice on the safe prescribing of controlled drugs such as opioids.
- Safe prescribing and withdrawal management: Scheduled to publish November 2021.
- Chronic pain: assessment and management: Scheduled to publish August 2020.

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.

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

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 2019. 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 have been indications that this activity has significantly reduced the demand for benzodiazepines and non-benzodiazepines from manufacturers and large wholesale dealers, but the market for unauthorised generic versions, predominantly from India, has become stimulated. 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. A number of cases investigated and prosecuted as part of the enquiry have reached Court stages.

- David Ihenagwa was convicted of supplying Class B and C Drugs, using his mother's pharmacy as a conduit for criminal activity and sentenced to six years imprisonment.
- Registered pharmacist Jasper Ojela was convicted of supplying Class B and C drugs and sentenced to 28 months imprisonment.
- Two pharmacists have pleaded guilty to charges of selling controlled drugs from registered pharmacy premises. Trial is set for July 2020 and a further charge (where a not guilty plea was entered by one defendant) will be heard.
- Sarfraz Hussain, a pharmacist who has subsequently been suspended by GPhC, pleaded guilty to supply of Class C drugs. Sentencing was scheduled for 19 February 2020.

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.

Updates

In November 2019, GPHC published the principles of good practice in remote consultations and prescribing that are expected of UK regulated healthcare professionals when prescribing medication online.

The GMC asked its members for their views on remote consultations and prescribing to decide if its guidance needed to change.

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 2019. The MHRA is working with CQC, GPhC and healthcare partners in Scotland, Wales and N Ireland to resolve outstanding issues and assist in bringing actors in the supply chain into compliance.

Ministry of Defence (MoD)

The MoD works for a secure and prosperous United Kingdom with global reach and influence. It protects people, territories, values and interests at home and overseas, through strong armed forces and in partnership with allies, to ensure security, support and national interests.

https://www.gov.uk/government/organisations/ministry-of-defence

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 Ministry of Defence (MoD) does not manage controlled drugs in secondary care.

Controlled drugs are governed and assured through a network of empowered accountable officers who report quarterly on activity. Each reported incident involving a controlled drug is thoroughly investigated, any concerns are escalated through the Chain of Command or Military Police as appropriate, and mitigations put in place to prevent recurrence. Standard operating procedures are reviewed and updated regularly, and training delivered to support implementation.

Some innovations in 2019 include:

- promoting a quality improvement culture to successfully improve assurance of controlled drugs management
- introducing a controlled drugs register audit to target training and development
- establishing the Controlled Drug Import Licensing Cell to support import and delivery of controlole drugs to overseas locations.

National Police Chiefs' Council

The National Police Chiefs' Council (NPCC) brings together police forces in the UK to help policing coordinate operations, reform, improve and provide value for money.

https://www.npcc.police.uk/About/AboutNPCC.aspx

Controlled Drug Liaison (CDLOs) can be found in most Police Forces throughout England but there are gaps in some areas such as central and southern England. Most forces have a named contact and following a letter to Chief Officers from the new National Police Chiefs Council (NPCC) lead Assistant Chief Constable O'Doherty (Thames Valley Police) some forces are now carrying out reviews into the role.

Areas of concern are similar to previous years. They include thefts by healthcare professionals, from care establishments, the theatre environment and oversight in weight loss clinics. The growth in distant selling pharmacies has been problematical with enquiries involving cross border co-operation between forces, regulators, and other partners.

CDLOs report increased work and contact with the Medicines and Healthcare products Regulatory Agency (MHRA), sometimes resulting in the investigation of large-scale pharmacy fraud. Some CDLOs are attending HM Coroner's Inquests in assisting investigating officers where deaths particularly in the care system have occurred. They are attending Local Intelligence Networks and report good outcomes where they work closely with the NHS England CDAO teams.

The Association of Police Controlled Drug Liaison Officers (APCDLO) continues to hold a Best Practice Event annually at Stratford upon Avon and has a website: https://www.apcdlo.org/.

NHS England

NHS England and NHS Improvement

NHS England and NHS Improvement 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 wellbeing, health and social care.

www.england.nhs.uk/

NHS England has a statutory duty to provide assurance on the safe use of controlled drugs across the health system, including private providers locally. NHS England and NHS Improvement appointed Controlled Drugs Accountable Officers (local lead CDAOs) are operationally responsible for discharging the function. A local lead CDAO's duties are set out in regulation and include the operation of a

Local Intelligence Network (LIN) where concerns about systems and/or individuals can be raised and where information is shared across Responsible and Designated Bodies. This statutory function is aligned with pharmacy and medicines optimisation, patient and professional safety, surveillance and resolution. There are close links to primary care contracting, revalidation, patient safety, quality surveillance, medicines management and wider system issues.

Since the 2018 annual controlled drug report, NHS England and NHS Improvement have undergone a significant internal change programme and have taken the opportunity to review the arrangements to discharge the functions under the Controlled Drugs (Supervision of Management and Use) Regulations 2013 (as amended).

Leadership and governance

We have clarified the accountability, governance and leadership of the function in relation to the structural changes in the organisation and the emerging architecture of the wider NHS. We have considered the resource (capacity, capability and financial) required at national and regional levels to ensure that the local lead CDAOs can continue to effectively support the safe management and (clinical) use of controlled drugs.

Local intelligence networks (LINs)

CQC carried out an Overview of the NHS England Controlled Drugs Local Intelligence Network Effectiveness Survey as part of NHS England's response to the Report of the Gosport Independent Panel to review the 'effectiveness' of the LINs in England.

Analysis of responses was broadly positive when considering the effectiveness of how the LINs operated in England. The overview demonstrated that the LINs in England provided the opportunity to share good practice and network with colleagues from across the health system.

The report of the Gosport Independent Panel

Every LIN in England has considered the Report and its recommendations, and the broader themes in individual, cultural and organisational behaviours that are identified. The importance of the National Guardian's Office and the 'Freedom to speak up' is supported by NHS England and Improvement CDAOs.

Services to manage dependence on prescribed medicines; substance misuse services

NHS England and Improvement identified that where patients have become dependent on prescribed medicines, there is often a gap in services commissioned to manage this group.

Cannabis -based products for medicinal use in humans (CBPMs)

Following the re-scheduling of cannabis-based products for medicinal use as Schedule 2 controlled drugs, NHS England [and Improvement] CDAOs have advised both NHS and independent healthcare organisations on the governance

arrangements to support the safe management and clinical use of these products as they are introduced.

In March 2019, the Secretary of State for Health and Social Care commissioned NHS England and NHS Improvement to review NHS systems and processes to identify and recommend any action necessary to address any barriers to clinically appropriate prescribing of cannabis-based products for medicinal use (CBPMs) on the NHS. The findings and recommendations are available in the document 'Barriers to accessing cannabis-based products for medicinal use on NHS prescription'.

Opioids

The use of opioid analgesics may be appropriate in some patients. However, there is now considerable evidence that the use of high-dose opioids (>120mg oral morphine equivalence (OME)) in the treatment of difficult to treat pain is often ineffective. The risk of side effects and patient harm is also increased where >120mg OME opioids are prescribed over a longer period. The potential for harm is increased when they are prescribed in combination with other medicines such as gabapentinoids, benzodiazepines or Z-drugs.

NHS England [and Improvement] CDAOs have led and/or facilitated an audit in several areas in England to identify the number of patients prescribed >120mg OME for difficult to treat pain and encourage the clinical review of these patients.

Online prescribing and supplies of controlled drugs

In several cases, patients have accessed inappropriate volumes of medication, particularly from online prescribers and pharmacies in the independent private sector. This is of concern in relation to medicines at risk of misuse or dependence, such as opioid based medicines, which can result in greater risk of harm, including death. We have received several "Report to Prevent Future Deaths" issued by Coroners in England and Wales where the prescribing and supply of controlled drugs online has been the primary matter of concern.

Patients co-prescribed medicines such as opioids (including those often considered 'weak' such as codeine), benzodiazepines and/or gabapentinoids are at greater risk of harm. This is especially true where co-prescribing is undertaken by two [or more] prescribers.

There is evidence of the significant harm to patients where information concerning the treatment of an individual, involving the prescribing of controlled drugs or other medication at risk of misuse / dependency [of any Schedule], is not shared promptly and accurately with other healthcare professionals involved in their care.

Since February 2020, the NHS has been focused on its response to the COVID-19 pandemic and the CDAO function has supported the NHS in this providing rapid assistance and advice on maintaining patient care while ensuring the safe management and [clinical] use of controlled drugs in unprecedented scenarios such as the NHS Nightingale Hospitals.

NHS England Health and Justice

NHS England and Improvement 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 (HJ) commissioning team is part of the Specialised Commissioning Directorate. There is a central support team with regional commissioning hubs within the seven NHS regions.

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

In 2019, the Health and Justice (H&J) Medicines Optimisation in the Long-Term Plan Programme contributed to activities involving controlled drugs.

A letter published in January 2019 describes handling of gabapentin and pregabalin for H&J sites following rescheduling as Schedule 3 (without safe custody). These will be handled and follow the same guidance as for tramadol.

In June 2019 there was a report from a national H&J audit against the Royal Pharmaceutical Society's Professional standards for optimisation of medicines in secure environments (which include standards relating to handling controlled drugs). Supply of medicines on transfer and release, including controlled drugs, are a priority for service improvement identified from the audit.

In June 2019, the ACMD published a report with recommendations about the availability of naloxone for released prisoners. Some strategic work to support the regions in improving access to naloxone has followed. NHS E&I are also working with PHE and HMPPS to identify how hostel managers in approved premises can hold naloxone for use if a resident has a suspected opioid overdose.

HJ and PHE submitted a request to the NHS Regional Medicines Optimisation Committee (RMOC) to develop guidance on the introduction of injectable buprenorphine into community and HJ substance misuse care pathways. This will focus on Buvidal but will apply to future products. This guidance is being developed through the South RMOC and publication was expected in spring 2020.

HJ leads and a small group of NHS England CDAOs, led by the East of England, have had a focus on CDs in HJ. This involved:

- audits of high dose opioids and gabapentinoids
- a regional event to share good practice to describe LIN engagement and incident reporting expectations
- proposals to develop information for CDAOs and HJ providers about good practice in CD handling in HJ.
- This work will be developed further in 2020 in collaboration with national and regional CDAO and HJ leads.

In 2019 NHS England HJ worked with the HO CD team and the MHRA to provide advice about the licencing requirements when the service provider in a HJ setting changes. This approach enables a CD ownership transaction to the new provider and prevents the need to dispose of CD stock. This advice was published in the July 2019 CQC CD newsletter.

Nursing and Midwifery Council (NMC)

NMC regulates nurses, midwives and nursing associates (England) in the UK. They exist to protect the public. They set standards of education, training, conduct and performance so that nurses, midwives and nursing associates can deliver high quality care throughout their careers. They maintain a register of nurses, midwives and nursing associates allowed to practise in the UK. Ensure nurses, midwives and nursing associates keep their skills and knowledge up to date and uphold their professional standards. Having clear and transparent processes to investigate nurses, midwives and nursing associates who fall short of our standards. Alongside a focus on keeping people safe, we're committed to putting patients and families at the heart of everything they do.

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

In January 2019 NMC introduced new standards of proficiency for nurses. One of the changes enables early access to prescribing programmes after registration, more knowledge on prescribing practice, pharmokinetics, pharmacology and whole systems assessment is now included within the standards of proficiency. The new standards have been updated to take into account the changes taking place in society and health care, and the implications these changes have for registered nurses.

In 2019 NMC received 373 referrals relating to prescribing errors and medicines management. Within this number were:

- 47 prescribing errors
- 30 theft of medication
- 26 breaches of controlled drugs procedures.

NMC's Regulatory Intelligence Unit analyses data and identifies themes and areas of serious regulatory concern.

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.

https://www.gov.uk/government/organisations/department-of-health-and-social-care

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

- **Drug-related deaths and medicines:** Illicit drugs are by far the biggest contributor to drug misuse deaths and continuing increases in these. However, there are a number of deaths from controlled and prescribed drugs, especially opioids. PHE's review of the evidence on medicines that can lead to dependence and withdrawal, some of which are controlled drugs, was published in September 2019 and has led to programmes of work by NHS England and others to reduce inappropriate prescribing: https://www.gov.uk/government/publications/prescribed-medicines-review-report
- **Opioids Aware:** The PHE-supported online resource on opioid pain medication has been updated by the Faculty of Pain Medicine: http://www.rcoa.ac.uk/faculty-of-pain-medicine/opioids-aware
- **Diamorphine licensing and prescribing:** PHE continues to provide clinical advice to the Home Office on applications from suitably-competent doctors in England for licences to prescribe diamorphine in the treatment of addiction. PHE has been working with an expert group of advisers to develop guidance on supervised diamorphine treatment for opioid misuse and dependence (often called heroin assisted treatment or HAT). The guidance is due to be published in early 2020.
- **Report Illicit Drug Reactions (RIDR):** PHE and MHRA's system to allow health professionals to make online reports about the effects of new psychoactive substances (NPS) and other drugs was closed due to a lack of reporting. Other systems for collecting this intelligence are being strengthened by PHE, including funding the Identification of Novel Psychoactive Substances (IONA) project to identify and characterise the clinical toxicology of NPS in biological samples of drug users presenting at hospitals.

UK Anti-doping

Intelligence plays a vital role in the work of UKAD, and led to 35% of all published Anti-Doping Rule Violations (ADRVs) in 2019. Working in partnership with other agencies such as MHRA, Border Force and Law Enforcement has yielded several positive results resulting in the recovery of controlled substances and the arrests of persons involved (cases sub-judice).

https://www.ukad.org.uk/

A key operation in collaboration with Kent Police in July 2019 resulted in two warrants being executed through which four individuals were arrested. A large-scale steroid lab was discovered and £10k cash, 20 mobiles and 10 computers were seized. Research into a download containing WhatsApp messages between two of the suppliers is ongoing but has so far revealed 18 links to sport of varying levels. Investigations continue in the pursuit of ADRVs with multiple athletes being tested as well as other disruption techniques being deployed. One of those arrested had been an absconder from prison 20 years ago who had been previously convicted for similar offences.

UKAD has undertaken a body of research looking into Image and Performance Enhancing Drugs (IPEDs) use in the UK. The report, published in January 2020, provides a holistic overview of IPEDs including: a breakdown of types of IPEDs, the prevalence of IPEDs in the UK, how they are obtained, the demographics of users, and the impact of using IPEDs.

UKAD's primary focus will always be to maintain clean sport through testing and educating athletes, but the issue of IPEDs is an important public health concern. UKAD has therefore commissioned this report and hopes to better understand the motivations behind drug use in both athlete and recreational populations. The key findings from this report are:

- 34% of gym goers surveyed were aware of IPED use in their gym or club
- it is estimated that there are nearly a million regular steroid users in the UK
- the most common demographic for the onset of IPED use was males aged 20-24
- roughly five million doses of anabolic steroids are seized each year at the border
- the top five countries of origin for IPEDs seized at the border are Hong Kong, China, India, USA and Thailand.

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 2019, the VMD inspected over 600 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.

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 work of Healthcare Improvement Scotland (HIS) to discharge its statutory role in relation to controlled drug governance, as defined in the Controlled Drugs (Supervision of management and use) Regulations 2013, is becoming increasingly clinically focused. The work to understand the clinical context in which controlled drugs are being used to obtain assurance of safe, effective and appropriate use, has been transferred to the Medicines and Pharmacy team, HIS.

The relocation will ensure access to the clinical resources required, sharing controlled drug intelligence with the appropriate Scottish and UK groups, and sharing best practice for governance.

HIS has established an internal group to consider the impact of diverted and illicit supply of medicines (DISMs), including controlled drugs, on the medicines supply chain. The group has mapped out the various areas where DISMs could compromise patient safety, identified opportunities for closer collaborative or partnership working between agencies to protect the public, and the supply chain integrity.

Following extensive consultation with the Home Office CD Licensing teams, NHS Boards in Scotland are now completing the licence application process for storage of CDs in prisons. Initial discussions had focused on the possibility of adopting a hub and spoke licensing model between prisons and police custody suites, but it has now been agreed that controlled drug governance requirements will be best met by individual licensing for each site.

The CDAO Network Scotland engages strategically within and outside the NHS in Scotland and the UK, including the Scottish Government Medicines and Pharmacy Division and professional regulators. This ensures a focus on patient safety to promote best practice and learning from adverse events, and also identifies issues and proposes solutions to progress resolution.

The Network meeting in September 2019 was a forum for sharing learning and best practice, and was well attended by both NHS and non NHS staff.

The AO working group vice chair attended the Northern Ireland LIN in September to provide information on the workings of the AO network and to encourage a closer working relationship.

A major focus of the work in 2019 involved providing advice around cannabis-based medicinal products, cannabidiol, and the gabapentinoids

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

In NHSGGC the enhanced drug treatment service is in operation and the provision of care to vulnerable homeless people now includes the prescription of medicines and the safe supervised self-administration of diamorphine.

Opioids Review Stakeholder Group (MHRA)

The Scottish CDAOs are represented on the recently commissioned Opioids Review Stakeholder Group with a remit to provide guidance on the use of opioids across all cover all sectors.

Updated resources in 2019 include:

- A Guide to Good Practice in the Management of Controlled Drugs in Primary Care - Scotland: Summary Document for Community Pharmacists and Pharmacy Technicians
- GP Summary; A Guide to Good Practice in the Management of Controlled Drugs in Primary Care – Scotland
- CDAO Report Template.

Working with partner organisations

The cooperation between the CDAON with Health Improvement Scotland (HIS) continues and CD Local Intelligence Network Terms of Reference - Best Practice Template is now in place.

There is ongoing discussion around private supplies and online access to controlled drugs, including those used to treat 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 developing the provision of health services to prisoners.

The updated resources, flash reports and general information are all available on The Knowledge Network.

Department of Health Northern Ireland

Responsibilities of the Department in relation to controlled drugs]

The Department through its 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.

Controlled drug licensing

Unless specifically exempted by the Misuse of Drugs Regulations (Northern Ireland) 2002, any person or company that wishes to produce, supply or possess controlled drugs in Northern Ireland will need a domestic controlled drug licence issued by the Department. Healthcare organisations requiring licences include some hospital trust pharmacies, the Northern Ireland Ambulance Service Trust, private hospitals and clinics. A wide range of other licensees fall under the Department's remit that support the healthcare sector, including major pharmaceutical manufacturers and wholesale dealers, police forensic laboratories, regional toxicology laboratories and importers and exporters. All licensees are subject to pre-licensing inspections and unannounced follow-up inspections, and are required to produce for MRG's perusal enhanced criminal record checks and an annual declaration. Further information relating to this work can be found at https://www.health-ni.gov.uk/articles/controlled-drugs.

During the reporting period the Department has seen an increase in the number of queries and licence applications, particularly in relation to growing hemp and cannabis for medicinal purposes.

Cannabis

The Department continues to work alongside colleagues from Home Office, Medicines and Healthcare products Regulatory Agency, Department of Health and Social Care and the devolved administrations to manage various issues surrounding medicinal cannabis.

Compliance visits and self-assessments

During the reporting period, MRG Officers carried out 260 inspections and visits to 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 20 February 2019, the annual self-assessment and declaration form was emailed to all registered pharmacy premises in Northern Ireland. The form is reviewed by the MRG Officers during pharmacy inspection visits and covers all aspects of the safe management of controlled drugs.

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

Legislation

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

Pregabalin and gabapentin

The ACMD noted that both pregabalin and gabapentin presented a risk of addiction, potential illegal diversion and medicinal misuse. It recommended that pregabalin and gabapentin should be controlled as Class C drugs under the Misuse of Drugs Act and placed in Schedule 3 to the Misuse of Drugs Regulations (MDRs). Following a consultation exercise it was concluded that pregabalin and gabapentin be placed in Schedule 3 to the MDRs but with safe custody exemption. This was in line with the scheduling of tramadol in 2014.

As a result of these recommendations, amendments were made on 1 April 2019 to schedule both pregabalin and gabapentin as controlled drugs under the Misuse of Drugs Regulations (Northern Ireland) 2002.

Synthetic cannabinoids

On 15 November 2019, Northern Ireland, like the HO, brought in an amendment to the Misuse of Drugs Regulations regarding synthetic cannabinoids. This amendment alters the generic definition of a range of synthetic cannabinoids permanently controlled under Misuse of Drugs legislation, which has reduced the range of compounds captured by the definition of synthetic cannabinoids.

In the same Statutory Rule, there were also additional amendments relating to a range of matters that were brought in in Great Britain in 2015.

These amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002, among other matters, included:

- authority for physiotherapist IPs and podiatrist IPs to prescribe a limited range of controlled drugs
- adding definitions relating to juvenile justice centres, prisons and organisations providing ambulance services
- Regulation 14 (requisition) is amended to refer to a “form approved by the Department “when requisitioning schedule 2 and 3 CDs
- A requirement that a vet must include their registration number on a prescription form when prescribing.

Maintaining the list of Accountable Officers

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. The list, including relevant contact details, can be found at https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/accountable-officer-contact-list.pdf.

Determination of Designated Bodies

The Department continues to make 'determinations' in relation to which independent hospitals registered with the Regulation and Quality Improvement Authority (RQIA) are "relevant independent hospitals" under Regulation 2A of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (as amended). Those identified as relevant independent hospitals, are prescribed as designated bodies under the legislation and must appoint an Accountable Officer. Once the process has been completed, the Department writes to the organisation to advise of its determination, which is also shared with the RQIA.

Wales

During 2019, Health Inspectorate Wales (HIW) published a review on the Wales CDLINs, based on observations made during visits to all of the LINs and securing the support of Medical Directors to make sure the recommendations were taken forward. They reported wide variation in the maturity of the LINs and variation in the way in which they operated. In particular, there were variations in the monitoring of controlled drugs and the collection and use of data and how agencies engaged with the LIN.

The findings of the report were similar to those that CQC identified in England. The report noted that a Once for Wales approach would help to benchmark controlled drug management across Wales, and should cover destruction, monitoring, CDLIN terms of reference and guidelines for managing the suspected possession of illegal substances.

As noted in last year's report, all Health Boards have continued to assure WG on oversight and governance of prescribing of controlled drugs in the palliative care setting in mitigation of issues raised in the publication of the Gosport Inquiry. Re-classification of pregabalin and gabapentin and discussions on cannabinoid products were common to the agenda of all CDLINs across Wales.

A joint meeting of CDLIN representatives with the Chief Pharmaceutical officer's team in April recommended standardisation of the activities of the CDLIN across Wales, appointment of an adequately resourced all Wales lead pharmacist to take a lead on making improvements in the management of controlled drugs. Working with Local Health boards and reporting to the CDLINs and the Welsh government through the Chief Pharmaceutical Officer. These recommendations were further endorsed by the findings of the HIW review and report. The group also expressed the need to consider the adoption of electronically embedded individual prescriber identifier that would allow prescribers to be tracked, as is already the practice in England, this too was endorsed in the HIW report.

Velindre Trust CD Oversight Group has produced Guidelines on the use of cannabinoid products at Velindre Cancer Centre and a CBD position statement, The other CDLINs are maintaining a close watch on developments involving these products not only in Wales but also in those reported through the UK cross border collaboration.

Activity during 2019

The CDLINs have reported activities relating to:

- **Hywel Dda:** the collaboration with the bio-psychosocial chronic pain management team, to address the opioid burden and high use of analgesics in the Health Board.
- **Cardiff&Vale:** review of pain pathways and educational session to prescribers on opioid use. Consideration of a primary care based prescribing audit that expands on current work and looks at the co- prescribing of benzodiazepines to opioid dependant patients.
- **Swansea Bay Health Board:** Due to organisational boundary, changes in April 2019 the CDLIN changed its name to the **West Glamorgan CD LIN** to reflect the new geographical area covered; a Health Board wide review of Controlled Drug governance during 2019 has resulted in a new CD Governance Framework which is due to go live in 2020.
- **WAST:** building on the successful rollout of automated medicines cabinets has invested in a new CD security system. The 'ABLOY' project commenced in April 2019 and involves the installation of station-based programming devices (across 95 sites), individual issue 'smart keys' for paramedics and upgraded vehicle CD safes.
- **BCUHB CDLIN** : Renamed this year as the **North Wales CDLIN** to reflect that the network represented a wide-ranging number of agencies, both Health Board and independent, from across North Wales. In-depth consideration of the scrutiny and assurance of CD prescribing and individual prescribing practice noted that this requires support at National level possibly with the introduction of an embedded personal prescriber pin and it remains an issue of high risk on the assurance agenda. The CD pharmacist and Head of Local Counter Fraud Service have designed a National Management Procedure for the Circulation of Controlled Drug Alerts to improve the sharing of intelligence across Wales and the UK. The was finalisation of the new procedure on private CD prescriptions for MOD in Wales to bring this in line with the system used in England.

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