

The safer management of controlled drugs: Annual update 2023

Introduction

CQC is responsible for making sure that health and care service providers, and other regulators, maintain a safe environment for the management and use of controlled drugs in England.

We do this under the <u>Controlled Drugs (Supervision of Management and Use) Regulations</u> 2013.

The responsibilities under these regulations include reporting every year about what we find through our oversight. We use this information, along with our regulatory activities under the Health and Social Care Act 2008, to make recommendations to help ensure that the arrangements for managing controlled drugs safely in England continue to be effective.

The information in this report is important for:

 all controlled drugs accountable officers (CDAOs) in England and their support teams

- organisations that manage controlled drugs
- health and care professionals with an interest or remit in controlled drugs
- commissioners of health and care services
- professional healthcare and regulatory bodies
- police controlled drugs liaison officers.

Data in this annual update relates to the calendar year 2023, but we also include relevant information for the first part of 2024.

Our oversight activity in 2023

Register of controlled drugs accountable officers

We maintain and publish an <u>online register of controlled drugs accountable officers</u> (CDAOs) across England for those organisations that are registered with us and are required under the 2013 Regulations as amended to have one. These organisations are defined as 'designated bodies' under the regulations and are required to notify CQC of their CDAO appointment. We update this register monthly. At the end of 2023, there were approximately 1,000 CDAOs listed. We approved 13 requests to be exempt from the requirement during 2023.

We remind all designated bodies that it is a legal requirement to tell us about any changes to the contact details for your CDAO so they are up-to-date on our published register. Designated bodies also need to notify us where a temporary CDAO is going to be in post for longer than 6 weeks. See more information for CDAOs.

NHS England regional teams and controlled drug local intelligence networks

The Senior Responsible Officer in NHS England for the controlled drugs accountable officer function is the National Medical Director. NHS England controlled drugs accountable officers (CDAOs) worked effectively and collaboratively during 2023. They held regular meetings for members of local intelligence networks (LINs) – both nationally and regionally. Local intelligence network meetings are an effective way to deliver consistent messaging, raise concerns, and share intelligence and learning. They also provide valuable networking opportunities for members.

NHS England CDAOs led local intelligence network meetings across England with each network meeting held online at least twice in the year. Several regions also held in-person or hybrid meetings. As well as sharing the details of controlled drugs incidents, most LIN meetings also include how the learning from these, and from other aspects, can help to improve local management of controlled drugs.

Participants in local intelligence network meetings can be unsure about what they are able to share relating to concerns over individual people or services. NHS England CDAOs provide a regular reminder about what information can be shared appropriately, and within the law.

NHS England CDAOs hosted 2 national controlled drugs learning events for all local intelligence network members across the country, which received good feedback from attendees. Regional CDAO teams also produced newsletters to share information and maintain contact with LIN members between the network meetings.

Given the helpful work from CDAOs across the regions, it may be useful for NHS England to consider how this valuable learning might be shared more widely, particularly to organisations that are not part of the LIN, across both health and social care settings.

Key concerns discussed at local intelligence network meetings

- Poor governance processes, although more organisations reported that they are now carrying out regular audit and monitoring checks.
- Controlled drugs governance in relation to paramedics and independent ambulance services.
- Home Office controlled drugs licences.
- Prescribing of cannabis-based products for medicinal use (CBPMs); how services support people if they have been prescribed, and consideration of what governance arrangements need to be in place.
- Closures of community pharmacies or a reduced service, specifically for people who receive support from substance misuse services.
- The diversion of controlled drugs in lower schedules. It is particularly challenging to identify diversion for organisations that use these in larger volumes.
- Diversion of controlled drugs by health and care professionals.
- Ongoing fraud with private prescriptions, often for controlled drugs in lower schedules.
- Arrangements for using oral liquids safely including balance checking.
- Controlled drug patches, such as those containing fentanyl and buprenorphine.
 This includes inappropriate prescribing, where people don't need constant pain relief, as well as problems with administration.

Controlled drugs reporting tool

NHS England updated its <u>CD reporting tool</u> in December 2022. This update has helped to further standardise processes across all regions through 2023. Users have welcomed the more streamlined process to report concerns and incidents. The reporting tool now also includes links to relevant guidance and short training videos, and resources to carry out other controlled drug functions such as requests for authorised persons to witness the destruction of obsolete Schedule 2 controlled drugs.

Information requests from NHS England CDAOs

When NHS England CDAOs request information, organisations need to respond and submit this as soon as possible. This could include quarterly performance reports, improvement frameworks, details of incidents or investigations and self-declarations.

Controlled Drugs National Group

CQC leads the Controlled Drugs National Group, which met in March, June and November 2023. Membership comprises government departments, key regulators and agencies with a controlled drug remit in England, Scotland, Wales, Northern Ireland, Ireland and the Channel Islands.

Key discussion topics and issues of shared interest between our cross-border members included:

- controlled drugs governance
- Home Office controlled drugs licences
- controlled drug destruction
- cross-border and remote prescribing
- the rise in the use of nitazenes, including treatment of exposure to these
- non-medical prescribing
- cannabis-based products for medicinal use (CBPMs)

controlled drugs and medication safety.

A separate summary of activity from the past year shows how member organisations contributed to the overall safer management of controlled drugs. If you would like a copy of this summary, email medicines.enquiries@cqc.org.uk.

Operational Sub-group

The operational sub-group to the National Group also met regularly in 2023. Membership comprised:

- NHS England lead CDAOs
- specialist pharmacists and medication safety officers
- NHS Business Services Authority
- chief pharmacists
- integrated care system (ICS) prescribing leads
- other government bodies.

Where appropriate, we also invited other healthcare professionals with relevant expertise to contribute.

Key issues in 2023

Reflecting on the Shipman and Gosport inquiries and risks in current practice

Next year will mark 20 years since the publication of the final report of the **Shipman Inquiry**.

Since the reports were published, we have seen a significant shift in clinical and governance practices in relation to controlled drugs to support better care for patients both in the NHS and independent sector. Legislative changes, such as the 2006 and 2013 updated versions of the Safer Management of Controlled Drugs (Supervision and Use) Regulations, have also helped.

However, with capacity demands on the health and care system at an all-time high, it is important not to be complacent about the significance of the learning from this Inquiry, or from the events at <u>Gosport War Memorial Hospital</u>. In Gosport, poor culture, lack of clinical challenge and a failure to speak up meant that patients were placed on an end of life pathway indiscriminately and irrespective of their individual clinical needs.

Risks associated with controlled drugs are still present within health and care systems, which are constantly changing. Commissioning arrangements can also be complex and opportunities for communication and collaboration are sometimes reduced because of capacity constraints or incompatible digital systems. Closed cultures and clinical isolation can increase risks associated with the use of controlled drugs. We are also aware of the significant pressure on health and care staff, including those who are not registered with a professional regulator. This can lead to tragic outcomes for all involved, including the staff and the people they are caring for.

Within services, safer care can be promoted through a combination of a welcoming attitude towards professional challenge and speaking up, combined with the approach that the safer management of controlled drugs needs to be "everyone's business," – not just that of medicines or pharmacy teams.

In our 2022 report, we emphasised the importance of working collaboratively to improve the prescribing, managing and monitoring of controlled drugs, particularly through partnership working as part of local integrated care systems. The systems we now have in place should help us to identify concerning behaviour or practice sooner. It is vitally important to make the most of these systems, with collaborative working, effective communication and information sharing central to their effectiveness. This includes those organisations providing frontline health and care services, but also other local, regional and national level stakeholders, such as integrated care boards (ICBs), regulators, commissioners and professional bodies.

Home Office licences

We continue to receive a number of questions about Home Office controlled drugs licences. Some services need these to enable them to treat people with essential medicines, including those used as painkillers, and for surgical procedures.

In last year's report, we recommended that providers allow enough time when applying for a licence. Working with the Home Office, we are producing guidance for providers when applying or re-applying for a Home Office licence.

Legislation update

In December 2023, a range of amendments were made to the Misuse of Drugs Regulations 2001. These have an impact on which practitioners can prescribe controlled drugs.

Paramedic independent prescribers are now able to prescribe and administer 5 specified controlled drugs:

- morphine sulfate by oral administration or by injection
- diazepam by oral administration or by injection

- midazolam by oromucosal administration or by injection
- lorazepam by injection
- codeine phosphate by oral administration

Therapeutic radiographer independent prescribers are now able to prescribe and administer:

- tramadol by oral administration
- lorazepam by oral administration
- diazepam by oral administration
- morphine by oral administration or by injection
- oxycodone by oral administration
- codeine by oral administration

All prescribers must work within their scope of practice. Guidance from the <u>College of Paramedics</u> and <u>Society of Radiographers</u> is available to support registrants.

Codeine: risks and re-classification

Codeine linctus has been re-classified from a pharmacy only medicine to a prescription only medicine due to the risk of dependence, addiction and overdose. This means that people will need to be prescribed codeine linctus and will not be able to buy it over the counter as previously without a prescription.

The Medicines and Healthcare products Regulatory Agency provides <u>information for</u> <u>healthcare professionals</u>, in relation to both the background review of the safety profile of codeine linctus, as well as useful advice for patients.

Risks around diversion of codeine are still current. For several years, we have heard about incidents of diversion involving codeine in services where it is held as a stock medicine. In some cases, providers have responded to risks by increasing auditing of stock and usage, or increasing recording requirements within their organisation, or a specific part of their organisation if risks are localised.

We also continue to hear about forged private prescriptions for codeine, both in linctus and tablet formulations. Although forgeries are becoming more elaborate, common issues on forged prescriptions may include:

- unclear or vague prescriber details
- mis-spellings
- unusually high quantities or doses
- out-of-area addresses (of the doctor, service and/or patient)

Incidents relating to forged prescriptions should be reported to the local <u>NHS England</u> <u>CDAO</u> and/or controlled drugs liaison officer (<u>CDLO</u>).

Nitrous oxide reclassification

In November 2023, possession of nitrous oxide was made illegal if it is, or is likely to be, "wrongfully inhaled". It is now a Class C drug under the Misuse of Drugs Act 1971 and a Schedule 5 controlled drug under the Misuse of Drugs Regulations 2001.

The term "wrongful inhalation" means inhalation that is not for medical or dental purposes, nor accidental inhalation of nitrous oxide that has been released into the atmosphere (such as in industrial processes).

Services need to be aware of the risks of theft and diversion from areas where medical gases are used and/or stored. This can include static as well as mobile storage areas, such as doctors' and paramedics' cars and ambulances.

Nitazenes

<u>Nitazenes</u> are synthetic opioids. They have been identified previously in the UK, but their use has been more common in the USA. They are psychoactive and their potency and toxicity may be similar to, or more than fentanyl. For context, fentanyl is in turn about 100 times more potent than morphine.

Nitazenes are often mixed with other street drugs and their use can be fatal. They are also sometimes found to be present in counterfeit medicines. An investigation by the Advisory Council on the Misuse of Drugs (ACMD) found that one nitazene, isotonitazene, was responsible for 24 fatalities in the UK in 2021. This particular nitazene is 500 times more potent than morphine.

Although nitazenes are illicit substances, we have chosen to include them in this report as we have received questions from healthcare services about where to find guidance on treating people for nitazene exposure or overdose. In July 2023, the Office for Health Improvement and Disparities issued a <u>useful alert relating to staff awareness of synthetic opioids</u>, and the treatment of overdose. This alert is important for organisations where staff may encounter people who use drugs and those who provide emergency care for opioid overdose.

Overseas prescribing of controlled drugs

Prescribing of controlled drugs from outside England continues to be an issue that is raised with us. Practitioners who can legally produce a prescription in their European Economic Area (EEA) home country for controlled drugs in Schedules 4 and 5 can also legally prescribe these for someone in England. This is not a reciprocal agreement with the EEA.

As a result of this regulatory gap, people have accessed a range of inappropriately prescribed medicines, including controlled drugs, and continue to do so. This includes large quantities of Schedule 4 and 5 controlled drugs, which have resulted in both harm and death.

There are important considerations in relation to people visiting England who require continuity of treatment, and legitimately use this avenue of care. However, we also need to consider how the risks associated with this open avenue for inappropriate prescribing practices can be minimised.

Designated bodies

The role of the controlled drugs accountable officer

Visibility of the controlled drugs accountable officer (CDAO) is important because it can help to encourage both proactive conversations about making the use of controlled drugs safer as well as an open reporting culture. We have seen some good examples of CDAOs making time to promote their role and visibility within their organisation. This is especially helpful in larger organisations with multiple locations, where it might not always be easy to identify and locate the CDAO.

As pressures in the healthcare sector continue, we are hearing that not all CDAOs have access to the resources they need. This is a crucial role, and the Controlled Drugs (Supervision of management and use) Regulations 2013 are clear that designated bodies must provide the funds and resources necessary to enable the CDAO to effectively discharge their <u>responsibilities</u>.

Board-level oversight of controlled drugs

The function of a CDAO is often viewed as a 'pharmacy team responsibility' within designated bodies such as NHS trusts and independent hospitals. Over the last year, we have heard about a range of incidences where employees of designated bodies at director level – including those who sit on boards – have not been proactively engaged with CDAOs who have raised controlled drugs concerns with them.

CQC expects that issues and concerns raised by the CDAO are discussed at board level and that these will be prioritised and scrutinised as appropriate for the specific circumstances.

It is also important that other leaders working in designated bodies engage effectively with the CDAO – including the chief nurse and medical director. Where NHS trusts take the view that 'controlled drugs are everyone's business', we often observe a much more open approach to raising concerns and problem solving.

Resourcing of controlled drugs liaison officers

Each police force has a controlled drugs liaison officer (CDLO). This role was created by the 2006 Health Act and provides an important link between the police and partner agencies, and with stakeholders such as health and social care providers, regulators and NHS England. Their work is focused on the safe management of controlled drugs and can involve preventing or even prosecuting offences in relation to them. CDLOs are important members of controlled drug local intelligence networks (CDLINs) and will share information and intelligence, where appropriate, with partners.

CDLOs provide organisations with invaluable advice on the safe management and use of controlled drugs. They can also provide basic advice on security and more sophisticated law enforcement and intelligence gathering techniques. Although the criminal justice system is vitally important, most CDLOs will adopt a problem-solving approach to the issues and challenges facing healthcare providers.

We again emphasise the importance of knowing the identity of your CDAO and CDLO. It is always better to make early contact with your CDLO. Unless the matter is an emergency, this is preferable to calling the police directly, as CDLOs have the time, experience and knowledge to more effectively assist health and care providers.

CDLOs and partner organisations have raised concerns with us regarding the lack of national coverage of CDLOs across the country. Some CDLOs have a number of other roles and a few forces have long-term vacancies, which reduces the service provided to health and care providers. This issue is being addressed at a national level with the National Police Chiefs' Council (NPCC).

Prescriber identification numbers

The current system for issuing prescriber identification numbers (PINs) for private prescribing and requisitioning of controlled drugs would benefit from a review. This could potentially help achieve better national oversight of prescribing and manage areas of risk.

There is currently no expiry date for PINs and practitioners are only required to provide one main address of work, even when they may also practise in a wide range of settings.

Not all practitioners requesting PINs will be required to be registered with CQC to undertake their work. This might be because they are an independent medical practitioner or a non-medical prescriber, such as a pharmacist, and may therefore fall outside CQC's scope of registration. This means they are not subject to the regulations we enforce and our assessment processes, and we therefore cannot check the quality of service being provided to people.

During the year, we have also seen that prescribers sometimes write private prescriptions using another prescriber's ready-printed pad, and they don't correct the PIN number or details to accurately reflect who actually prescribed the controlled drug.

There has been debate around whether the PIN application process is purely an administrative one, as prescribing privileges are from professional registration. However, checks by NHS England CDAO teams as part of prescriber PIN applications have previously identified governance risks that may not otherwise have been recognised, which demonstrates the value of the process. This is especially important in cases where the prescriber or service offered does not fall into scope of CQC registration.

Trends in recent years also show that prescribing of controlled drugs by non-medical prescribers is increasing, and any review of the PIN process should take account of this.

Learning from incidents

When we speak with organisations about medicines incidents, we focus on understanding the circumstances surrounding them and what has been done to investigate, follow up and reduce the chance of future recurrence.

Over the last year, we have heard about a range of cases that relate to 2 particular medicines: alfentanil and morphine. We share some of the learning from these incidents here.

Alfentanil medication errors

We have seen a recent increase in incidents relating to the incorrect selection of alfentanil – either in terms of prescribing or physically selecting a vial for administration. Alfentanil is a potent injectable opioid with a range of uses, including during anaesthesia and for some patients receiving palliative care. It is available as 500 micrograms/ml strength and 5 milligrams/ml strength (sometimes referred to as 'intensive care' or 'high' strength). The cases we have heard about involved wrongly selecting the 'high' strength.

Contributory factors have included poor knowledge and awareness of higher strengths, the competency of staff when making dose calculations, and storage of the high strength preparation on wards where it is not commonly needed or used.

Organisations have shared the following points of learning:

- It is important to make staff aware of the existence of a higher strength.
- Pharmacy teams and ward leaders should have oversight of where alfentanil is needed, used and stocked, and should query requests for stock from wards where it is not normally used.
- Risk assessments of the use of alfentanil can be useful, especially as it helps services to develop ways of mitigating risks of mis-selection or incorrect prescribing.
- Some services remove the higher strength from the ward when it is not needed.

Morphine sulfate – infant overdose

We are also aware of tragic circumstances surrounding overdoses of morphine in infants. In one example, morphine sulfate oral solution was administered at a dose 20 times higher than the intended dose. This happened because the infant's parents were supplied with a 10 milligrams/5ml oral solution after discharge from the hospital, and not a 100 micrograms/ml solution. NHS England North East and North Yorkshire has produced a helpful case study with details of the causative factors and learning points to reduce the risk of future occurrences.

Points of learning included:

Making morphine a 'red' drug in paediatrics so that responsibility for a
prescription cannot be transferred to the community. This means supply
would come from hospitals and specialist centres only.

- Discharge summaries should contain the full name of the drug, formulation, strength, and clear dose instructions with consideration of daily maximum doses for PRN (when required) medication.
- The importance of speaking directly to the prescriber for medication queries with high-risk drugs, and/or patients with complex conditions.
- When counselling, ask patients to summarise and recall main points back to you to check their understanding.

Remote prescribing of controlled drugs

Remote consultations resulting in the prescribing of controlled drugs are becoming more common, both across NHS and private settings. The pandemic triggered more widespread prescribing in this way, and we have seen this expand further over the last few years. When undertaken appropriately, remote prescribing can be convenient for people who need treatment and can enable prescribing clinicians to offer treatment in a timely way.

However, we have heard of examples where healthcare professionals are not adhering to safe practices when prescribing remotely, including non-medical prescribers.

When services contract healthcare professionals to undertake prescribing, including for controlled drugs, they must be assured that this is happening in a safe and effective way. This includes those employed as a member of staff or as a locum or independent contractor.

Services must ensure that those prescribers:

are working within their scope of practice

- have enough time to undertake consultations
- have appropriate access to medical histories of patients they are prescribing for
- are able to assure themselves that they can fulfil any monitoring requirements for people during ongoing periods of treatment and prescribing
- effectively communicate relevant information with other health and care providers, such as GPs, as appropriate.

Professional regulators such as the <u>General Medical Council</u>, <u>General Pharmaceutical</u> <u>Council</u> and <u>Nursing and Midwifery Council</u> issue professional guidance for their prescribers.

Cannabis-based products for medicinal use

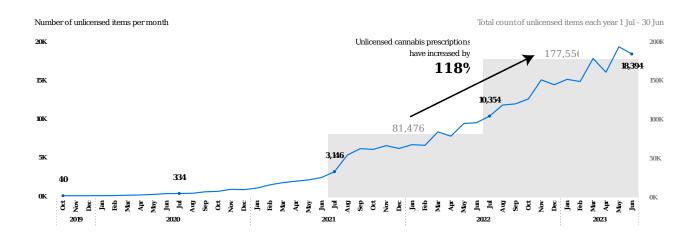
Cannabis-based products for medicinal use (CBPMs) are Schedule 2 controlled drugs under the Misuse of Drugs Regulations 2001. They can be prescribed by, or under the direction of, a doctor who is on the specialist register of the General Medical Council to treat patients on a case-by-case basis to meet an unmet clinical need.

During 2023, we continued to register clinics in the independent sector that provide treatment with CBPMs. At the time of publishing, 22 providers that prescribe unlicensed CBPMs were registered with CQC.

Over the last year we have seen instances where providers have not always communicated treatment plans and information on prescribed products in a timely way with other healthcare professionals involved in a person's care. It is vitally important to share information effectively with people's regular prescribers (normally their GP) to keep them safe. In some cases, this may also include liaising with secondary care and other independent services.

As in previous years, almost all prescribing continues to be for unlicensed CBPMs in the independent sector (figure 1).

Figure 1: Private unlicensed CBPM prescribing in England, October 2019 to June 2023



Note: Figure 1 does not include data before October 2019 because of low numbers.

Prescriptions for CBPMs are processed manually because CBPMs are not included in the <u>Dictionary of medicines and devices</u>. This means there is a time lag in the prescribing data available to present day. The most current available prescribing data for independent services has shown an increase of 118% across the following periods:

- 1 July 2021 to 30 June 2022: 81,476 items dispensed
- 1 July 2022 to 30 June 2023: 177,566 items dispensed.

This data relates specifically to prescriptions dispensed in a community setting.

Some non-medical prescribers can prescribe CBPMs under the direction of the specialist doctor. We have seen that most of the non-medical prescribing for CBPMs is undertaken by pharmacist independent prescribers, who work in clinics in the capacity of shared care with specialist doctors.

We are not able to publish the data for NHS prescribing of unlicensed CBPMs. This is because the number of items prescribed in the NHS is so small that this could potentially breach patient confidentiality.

It has been over 5 years since the change in legislation that permitted the prescribing of CBPMs. This change allows specialist clinicians to prescribe unlicensed CBPMs on a case-by-case basis, to meet an unmet clinical need. We have since seen a significant increase in prescribing to treat a wide range of medical conditions, as well as changing models of care, including those involving non-medical prescribers. People can also find it difficult to access joined-up care from all their healthcare providers. The number of unlicensed CBPMs prescribed each year continues to increase by at least 100% annually. A multiagency review of the impact of this change would be beneficial.

Administration of CBPMs in health and social care settings

The number of enquiries we receive about supporting the administration of unlicensed CBPMs in health and social care settings is increasing. CBPMs must have been prescribed for an unmet clinical need. They come in a range of preparations including oils, capsules and flowers that are vaped and it is illegal for these products to be smoked.

To help support staff when caring for patients prescribed CBPMs, providers' policies and processes should consider:

- ensuring the product has been prescribed
- how to support patients with ongoing supplies, if required
- safe storage, records and appropriate authorised access, as with other Schedule 2 controlled drugs

- appropriate training for staff if they are required to support with administration
- the position on vaping, and the possible need to obtain prescribed alternatives
 where people are not able to vape
- whether a risk assessment is required

Storage of prescription stationery

We have seen during inspections that some services are not following guidance when managing prescription stationery (prescription forms) – this includes green FP10 forms and pink FP10PCD forms for private prescribing.

These problems are more apparent where prescription forms are ordered centrally to be delivered to a provider's main office but they are not logged as received, not stored securely and not tracked when they are sent to prescribers. Unauthorised access to stationery and an inability to identify when prescription forms have been lost or stolen can and does lead to diversion of controlled drugs and harm to people. Where individual prescribers have access to prescription stationery in their own homes, they also have a responsibility to store these securely. Incidents of prescription stationery loss or theft should be reported to NHS Counter Fraud and NHS England CDAOs. Both NHS counter fraud and CQC provide guidance on prescription security.

Managing unknown substances in services

More providers are asking us for advice about how to manage unknown substances that people hand in when they are using services, such as in a hospital setting.

Services need to have a clear policy and process to manage this issue and the risks associated with it, and there must be a robust documented audit trail. Unknown substances must be put into a secure, sealed container. Quantities that indicate personal use only can be destroyed locally as an unknown substance. Services should assess and manage the risk of exposure to unknown substances during the destruction process.

Larger quantities, which are indicative of supply (not for personal use), will need to be notified to the police. CDLOs are a good first point of contact for concerns in relation to this. Any trends should also be communicated to the NHS England CDAO so they can share the issue and any learning with the CDLIN.

It is important to note that dispensed supplies of cannabis-based products for medicinal use are legal to possess when they have been prescribed.

We have seen some good policies and learning points in relation to handling suspected unknown substances shared at CDLINs, so this could be a good starting point for services that are looking to develop or update their policies.

Identity badges, cards and uniforms

We continue to hear about theft and/or misuse of ID badges and cards, and how these have been used after a member of staff has been dismissed from, or left a service, to access and illegally obtain controlled drugs. We have also heard about the theft or sales of genuine staff uniforms, which have been used to create a credible story for people to request access to controlled drugs. This underlines the importance of ensuring that ID cards and uniforms are returned, and that access cards are de-activated as quickly as possible when staff change roles or leave employment.

Delays in submitting private controlled drug prescriptions to NHS Business Services Authority

We have been made aware of delays in sending private controlled drugs prescriptions to the NHS Business Services Authority (NHSBSA). This trend was highlighted in our annual update in 2019 but has again been raised with us. Any service, including community pharmacies, that dispenses Schedule 2 and 3 controlled drugs against private prescriptions must send these to the NHSBSA as soon as possible. See <u>information on the submission process on the NHSBSA website</u>. This also includes pharmacies that dispense against prescriptions for cannabis-based products for medicinal use.

Keeping controlled drugs after someone has died

When a person dies, their medicines may need to be kept for 7 days in case the coroner requires them for an investigation. This may include a supply of controlled drugs, including those of a high strength, and in injectable form.

Over the last year, concerns have been raised about the risks associated with instructing bereaved relatives to keep these medicines, especially when healthcare professionals involved in care of the family have concerns that medicines could be used for self-harm. This is often made more complex when a range of different care providers have been involved in treating or caring for the person and their family members. We hear that healthcare professionals are also concerned about removing these medicines from people's homes, in terms of legality, creating records, considering where to take the medicines for safe destruction and what to do if a family member or carer refuses permission to remove them.

Clear professional guidance would be useful in this area in both reducing risks for people who may be storing these medicines, as well as for helping healthcare professionals and service providers to understand their role and remit in these circumstances.

Incorrect use of controlled drugs disposal kits

When we inspect services, we sometimes see that controlled drugs disposal kits containing resin are not used properly. This results in a range of controlled drugs being left open to diversion. Examples of incorrect use include:

- Assuming the kits can be used more than once, by adding more medicines to the kit container after water has already been added and the resin has already set.
- Overfilling the kits, so that the resin does not set.
- Storing waste controlled drugs in the kit container on open shelves rather than locking away in a controlled drugs cabinet.

Each manufacturer has its own instructions, and we encourage services to read these before using the kits.

Electronic controlled drugs registers and medicines storage

Electronic controlled drugs registers and electronic medicines storage solutions can offer many benefits to patients and providers in terms of safety, assurance and convenience. Over the last few years, more NHS trusts have contacted us about rolling out electronic registers and/or electronic controlled drugs storage. However, at the same time we had heard concerns about the risks of doing this and navigating the roll out process.

In February 2024, we held an online forum to discuss concerns and learning in relation to these issues. A range of trusts, including those that had successfully rolled out these systems and others that were scoping roll-out, kindly gave up their time to attend this forum. Although we recognise that the complexity of rolling out electronic registers and storage systems is different across organisations, we share the learning from this forum to benefit providers.

Learning from our forum

Good planning and engagement

It's important to engage early to successfully implement electronic systems. Staff need to feel ownership and be able to actively contribute – from planning to completion. This includes having representation from each staff group that would be using the systems.

One trust spoke about the importance of engaging and involving nurses throughout the planning and rollout phase, as they were the primary users. Most trusts emphasised the importance of not under-estimating the range of stakeholders that need to be involved in collaborative working to ensure success. For example, we heard about the need to work with colleagues in estates teams as electronic storage cabinets may need a room re-configuration to accommodate them, as well as IT teams to ensure sufficient WiFi connection or the right electronic connectivity.

Good working relationships were crucial to success. Project boards that bring stakeholders together regularly, including with IT development teams, had been valuable. These helped to co-ordinate planning and enabled different people to ask questions relevant to their department and governance systems.

One trust told us it holds a weekly forum for staff to share experiences of the electronic registers and storage systems, as well as fortnightly meetings with senior staff, including senior nurses, to escalate concerns and feedback.

Trusts told us in our forum that they would find it helpful to link in with other trusts more regularly, to pick up on best practice and learning from their engagement work and user groups.

Technical expertise and training

Several trusts told us about the benefits of providing training from technical experts ('superusers') from pharmacy teams to other departments on electronic registers. Training nurses as superusers had also worked well in some trusts, so that learning was facilitated by nurses, for nurses.

We heard that staff training is an ongoing process, especially following staff turnover or changes to electronic systems. Trusts also spoke about the importance of planning the optimal time to deliver training. This makes sure that superusers are available in roll-out phases to provide effective support to frontline staff, and that the training is not delivered too far in advance or too close to rollout.

Governance, system integration and risk management

It's important to have good governance systems in place before any rollout as governance can be more difficult to develop once systems are implemented. We heard that governance can and will change during the initial and subsequent installation phases of electronic registers and storage. This can affect medicines-related governance and policies as well as wider trust policies.

We also heard about the importance of completing physical checks and audits when needed – and that although technology is beneficial, it should not be relied on entirely.

Integrating electronic registers and storage into existing IT systems can sometimes be difficult, as it means having to run 2 systems concurrently. It also means assessing and managing the risks associated with this.

It is vital to have robust systems to handle IT failures. This includes ensuring a 'back-up of information from systems. Trusts told us they worked with IT teams to ensure they had robust back-up plans for both routine and unexpected events, which included considering which servers were used for different electronic systems.

It's also important to consider at the beginning of the design process who should be authorised to access electronic registers and how access can be removed as soon as possible, for example if people leave employment with the trust.

Additional learning points

- It's important to reflect on the success of each phase of rollout, to improve planning for the next phases.
- When developing an electronic controlled drugs register, as well as recording statutory information, it's important not to forget to routinely collect other information that is needed to manage controlled drugs safely.
 Many paper registers already do this.
- Electronic registers can restrict which people can investigate incidents and discrepancies, as each username can have different levels of authorisation for viewing and editing. This can stop any unauthorised editing of the register.

 Electronic registers and storage can provide new, more detailed information about the management of controlled drugs. This will require further consideration as to how to use the data in the best way to manage risk and encourage improvement.

What CQC expects

We are often asked about our expectations in relation to both electronic storage and registers. We understand the diversity among providers, including NHS trusts, in their size, how they work and the populations they serve. The general principles that we expect providers to consider are:

- The system should meet legal requirements.
- It should be fit for purpose for the provider's needs, which may involve bespoke elements to meet this. For example, it could mean additional data fields in registers.
- Systems should be covered by the provider's governance processes, including audits.
- Access to the systems should be assessed, appropriately restricted and monitored.
- Staff should be trained at the point of implementation, and on an ongoing basis, for example when there are system updates.
- There should be robust processes for back-up and/or IT failures.
- Ongoing use and development should be monitored and any emerging risks appropriately assessed and managed.

We understand that legislation governing safe custody of controlled drugs is 50 years old, and that there may be some circumstances in which new electronic storage systems do not meet the technical requirements of the legislation (such as where the storage is going to be sited). In these cases, we recommend a risk assessment combined with discussion and advice from local police controlled drugs liaison officers before implementation.

National trends in the prescribing of controlled drugs

Notes on data:

Data on prescribing is collected by <u>ePACT2</u> – an online application that provides authorised users with access to prescription data held by NHS Business Services Authority. For prescribing in the NHS, including hospitals and dental services, we have extracted data from this application for the years 2021, 2022 and 2023 to provide overall figures and trend analysis. For non-medical prescribing, the NHS Community Pharmacist Consultation Service, and requisitions and prescribing in independent primary care, the data for 2023 was supplied directly by NHS Business Services Authority.

In this report, we compare current data for 2023 with the data published in our report for 2022. There may be changes to overall figures for 2022, as ePACT2 may be updated over time.

Prescribing trends in primary care

In this section, we highlight trends of the most prescribed controlled drugs.

Overall prescribing of controlled drugs in Schedules 2 to 5 in 2023

Total controlled drug items prescribed by NHS primary care services:

73,830,666 items in 2023

73,880,442 items in 2022 (a small decrease of less than 0.5%)

The cost of this was £572,477,393 in 2023 compared with £547,248,678 in 2022 (an increase in cost of 5%) even though the number of items had decreased.

The most notable prescribing trends in NHS primary care in 2023 include:

- Continued increases in prescribing volumes of medicines that are licensed to treat attention deficit hyperactivity disorder (ADHD), such as dexamfetamine, lisdexamfetamine and methylphenidate. This trend is also echoed in NHS hospital prescribing for dispensing in the community, as well as in the private prescribing trends, which may reflect a lack of access to NHS care. Figure 14 shows the NHS hospital prescribing trends over the last 5 years.
- Similar to last year, an increase in testosterone prescribing, which could be linked to increased awareness of its use for women experiencing menopause.
- A reduction in prescribing of pholcodine (after changes to clinical guidance and availability), pethidine, co-proxamol, fentanyl and diamorphine. We have also seen reduced fentanyl patch prescribing in certain age groups.

- An increase in non-medical prescribing. Similar to last year, pharmacists account for over half of non-medical prescribing.
- A continued trend in reduced prescribing by NHS dentists, possibly linked to dental access issues.

Figure 2 shows overall prescribing levels in 2023 compared with the previous year.

Figure 2: Prescribing of controlled drugs by schedule in 2023

Schedule	Change	Total items prescribed in 2023	Total items prescribed in 2022
Schedule 2	up by 1%	9,345,681	9,226,618
Schedule 3	up by less than 0.5%	26,108,803	26,008,549
Schedule 4	down by less tha n 2%	12,844,589	13,062,052
Schedule 5	up by less than 0.5%	25,531,593	25,583,223

Of all prescribing of controlled drugs in primary care in 2023:

- **Schedule 2** accounted for 13%
- **Schedule 3** accounted for 35%

- **Schedule 4** accounted for 17%
- **Schedule 5** accounted for 35%

Patterns of prescribing in NHS primary care

Of the most prescribed controlled drugs in 2023, there was a **reduction in prescribing** for a number of controlled drugs compared with 2022 (figure 3).

Figure 3: Reductions in prescribing of controlled drugs in 2023

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Pholcodine (Schedule 5)	down by 82%	5,744	31,264
Pethidine (Schedule 2)	down by 72%	2,035	7,157
Temazepam (Schedule 3)	down by 40%	335,122	555,427
Co-proxamol (Schedule 5)	down by 25%	5,078	6,728
Fentanyl (Schedule 2)	down by 8%	746,026	812,439

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Diamorphine (Schedule 2)	down by 8%	8,279	8,979
Co-dydramol (Schedule 5)	down by 7%	1,324,448	1,426,820
Oxazepam (Schedule 4)	down by 7%	48,850	52,267
Phenobarbital (Schedule 3)	down by 5%	153,148	161,063
Methadone (Schedule 2)	down by 5%	1,697,505	1,785,152
Zopiclone (Schedule 4)	down by 4%	4,486,235	4,681,170
Diazepam (Schedule 4)	down by 3%	4,189,107	4,339,653
Dihydrocodeine (Schedule 5)	down by 3%	1,390,020	1,432,483

At the same time, of the most prescribed controlled drugs, there was an **increase in prescribing** in 2023, compared with 2022 (figure 4).

Figure 4: Increases in prescribing of controlled drugs in 2023

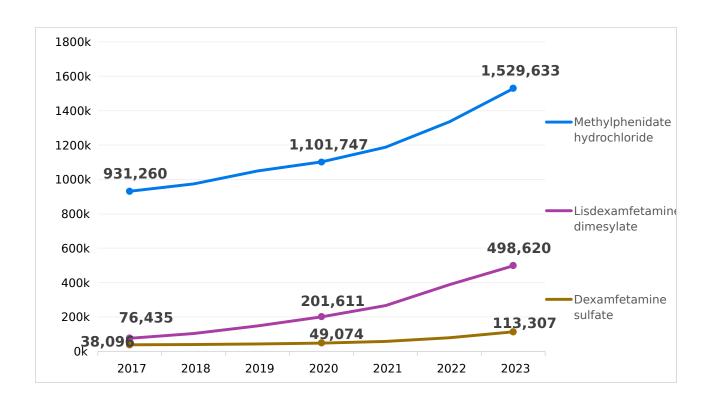
Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Dexamfetamine (Schedule 2)	up by 44%	113,307	78,824
Lisdexamfetamine (Schedule 2)	up by 29%	498,620	387,490
Testosterone (Schedule 4)	up by 15%	606,002	526,876
Methylphenidate (Schedule 2)	up by 15%	1,529,633	1,334,860
Zolpidem (Schedule 4)	up by 6%	625,656	591,436
Pregabalin (Schedule 3)	up by 5%	9,053,848	8,636,909
Midazolam (Schedule 3)	up by 3%	365,538	354,614

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Buprenorphine (Schedule 3)	up by 3%	3,343,768	3,255,662

Looking at the proportions of controlled drugs in different schedules prescribed in 2023:

- pregabalin and gabapentin accounted for 63% of all Schedule 3 prescribing
- diazepam and zopiclone accounted for 68% of all Schedule 4 prescribing
- co-codamol accounted for 59% of all Schedule 5 prescribing
- methylphenidate, lisdexamfetamine and dexamfetamine accounted for 23% of all
 Schedule 2 prescribing (see figure 5)
- morphine sulfate accounted for 29% of all Schedule 2 prescribing

Figure 5: Number of items of methylphenidate, lisdexamfetamine and dexamfetamine prescribed in NHS primary care in England, 2017 to 2023



NHS non-medical prescribing

Overall prescribing of controlled drugs by non-medical prescribers (healthcare professionals other than a doctor or dentist) increased during 2023:

5,440,585 items prescribed in 2023

5,152,958 items prescribed in 2022 (an increase of 6%)

Figure 6: Non-medical prescribing of controlled drugs in 2023

Prescribed by	Change	Total items prescribed in 2023	Total items prescribed in 2022
Pharmacists	up by 10%	2,908,340	2,645,819
Nurses	up by 1%	2,524,854	2,499,873
Paramedics	down by 13%	5,116	5,897
Physiotherapists	up by 79%	2,098	1,171
Radiographers	up by 10%	111	101
Podiatrists	down by 35%	63	97

Prescribing by pharmacists accounted for 53% of all non-medical prescribing in 2023 (2,908,340 items) compared with 51% in 2022. Given the year-on-year increasing volume of non-medical prescribing, this year we provide some more detailed information about the range of controlled drugs being prescribed by pharmacists and nurses (figures 7 and 8).

Pharmacist prescribing

Figure 7 shows the controlled drugs prescribed by pharmacists at volumes in excess of 10,000 items during 2023.

Figure 7: Pharmacist prescribing of controlled drugs in 2023

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Co-codamol (Schedule 5)	up by 10%	563,232	510,178
Pregabalin (Schedule 3)	up by 12%	401,398	357,374
Gabapentin (Schedule 3)	up by 10%	299,679	272,078
Tramadol (Schedule 3)	up by 6%	212,149	201,032
Codeine (Schedule 5)	up by 12%	195,183	174,538
Zopiclone (Schedule 4)	up by 7%	160,604	150,109
Diazepam (Schedule 4)	up by 7%	157,141	147,107
Buprenorphine (Schedule 3)	up by 12%	124,265	111,294

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Morphine sulfate (Schedule 2)	up by 7%	112,692	105,097
Oxycodone (Schedule 2)	up by 12%	85,593	76,634
Methadone (Schedule 2)	up by 6%	70,092	66,392
Methylphenidate (Schedule 2)	up by 31%	57,770	44,141
Dihydrocodeine (Schedule 5)	up by 7%	56,920	53,276
Co-dydramol (Schedule 5)	up by less than 0.5%	51,554	51,469
Clonazepam (Schedule 4)	up by 12%	46,095	41,073
Lorazepam (Schedule 4)	up by 10%	40,195	36,668

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Fentanyl (Schedule 2)	up by less than 0.5%	28,689	28,660
Lisdexamfetamine (Schedule 2)	up by 55%	25,625	16,538
Zolpidem (Schedule 4)	up by 12%	22,356	19,953
Clobazam (Schedule 4)	up by 12%	18,781	16,765
Testosterone (Schedule 4)	up by 46%	16,970	11,627
Nitrazepam (Schedule 4)	up by 6%	13,266	12,506
Temazepam (Schedule 3)	down by 38%	12,337	19,786

Nurse prescribing

Figure 8 shows controlled drugs that were prescribed by nurses at volumes in excess of 10,000 items during 2023. It is important to note that the high volume of items of methadone prescribed is likely to reflect nurses practising in services that offer opioid substitution therapy.

Figure 8: Nurse prescribing of controlled drugs

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Methadone hydrochloride (Schedule 2)	down by 6%	536,072	568,063
Co-codamol (Schedule 5)	up by less than 0.5%	391,431	389,667
Buprenorphine (Schedule 3)	up by 5%	328,009	311,681
Pregabalin (Schedule 3)	up by 7%	181,212	169,410
Codeine (Schedule 5)	up by 3%	159,539	154,276
Gabapentin (Schedule 3)	up by 1%	151,814	150,254

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Tramadol (Schedule 3)	down by 2%	113,710	115,994
Diazepam (Schedule 4)	down by 3%	103,938	106,974
Zopiclone (Schedule 4)	down by 1%	91,282	92,230
Morphine sulfate (Schedule 2)	up by 5%	77,796	74,411
Methylphenidate (Schedule 2)	up by 34%	57,536	42,845
Oxycodone (Schedule 2)	up by 3%	46,708	45,209
Dihydrocodeine (Schedule 5)	down by 5%	29,986	31,687
Lorazepam (Schedule 4)	up by 5%	28,182	26,853

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Co-dydramol (Schedule 5)	down by 7%	25,404	27,205
Midazolam (Schedule 3)	up by 13%	25,210	22,242
Lisdexamfetamine (Schedule 2)	up by 28%	19,201	15,045
Clonazepam (Schedule 4)	up by 4%	17,929	17,251
Fentanyl (Schedule 2)	down by 5%	17,011	17,902
Zolpidem (Schedule 4)	up by 11%	11,468	10,357

We have also seen a range of controlled drugs prescribed by other non-medical prescribers. The vast majority of this appears to be consistent with the expected scope of practice of these healthcare professionals, such as paramedics and physiotherapists. However, we have noted several instances where medicines such as dexamfetamine, lisdexamfetamine and methylphenidate have been prescribed by healthcare professionals who are unlikely to have expertise in this specialist area.

Last year we looked at the importance of ensuring that non-medical prescribing is undertaken appropriately, including ensuring it is within the prescriber's scope of practice. Professional regulators all have expectations of their registrants and provide guidance for safe and effective prescribing. We also provide guidance on <u>supporting non-medical prescribers in primary care</u>, and many elements of this are transferable to other settings.

NHS dental prescriptions for controlled drugs

Total controlled drug items prescribed by NHS dentists:

28,819 items in 2023

30,790 items in 2022 (a decrease of 6%)

Dentists working in the NHS can prescribe 3 controlled drugs on NHS dental prescription forms to patients:

Dihydrocodeine: as in previous years, this was the most prescribed medicine, accounting for 82% of total dental prescribing in 2023.

23,714 items prescribed in 2023

25,826 items prescribed in 2022 (a decrease of 8%)

Diazepam: Between 2022 and 2023 prescribing increased by 6%

Temazepam: Between 2022 and 2023, prescribing decreased by 14%

Reduced access to dental treatment continues to be a national issue. These patterns in decreased prescribing could be a result of this.

ePACT2 Opioid comparators dashboard

Last year, we looked at prescribing of opioids in a specific geographical area. When we looked at this data again, we found the number of patients receiving opioid pain medicines per 1,000 patients in early 2024 remained similar compared with the same period in 2023 (figure 9). Prescribing is still highest in the north of England, which reflects previous years.

Figure 9: Patients receiving opioid pain medicines by region in 2023 (12 April to 9 May 2023) and 2024 (29 February to 27 March 2024)

Region	Number of patients receiving opioid pain medicines	Number of patients receiving opioid pain medicines per 1,000 patients
London	83,861 in 202483,122 in 2023	8 in 20248 in 2023
South East	134,267 in 2024133,490 in 2023	14 in 202414 in 2023
East of England	102,437 in 2024102,000 in 2023	14 in 202414 in 2023

Region	Number of patients receiving opioid pain medicines	Number of patients receiving opioid pain medicines per 1,000 patients
South West	110,312 in 2024109,434 in 2023	18 in 202418 in 2023
Midlands	221,329 in 2024219,778 in 2023	19 in 202419 in 2023
North West	172,666 in 2024173,375 in 2023	22 in 202422 in 2023
North East and Yorkshire	243,209 in 2024242,692 in 2023	26 in 202427 in 2023

Full details about the dashboard specifications are on the <u>NHS Business Services</u> Authority website.

We also looked at prescribing of 'high oral morphine equivalent' volume of opioid prescribing, in combination with other medicines, such as gabapentinoids, antidepressants and z-drugs (figure 10). The risk of harm increases substantially at doses above an oral morphine equivalent of 120mg/day, but there is no increased benefit. Risk can be increased further when this is prescribed alongside these other medicines.

Figure 10: High oral morphine equivalent prescribing with other medicines, 29 February to 27 March 2024

Medicines prescribed	Prescribed for 1 to 84 days	Prescribed for 85 to 168 days	Prescribed for 169 days or more
Patients receiving high oral morphine equivalent volume of opioids in combination with gabapentinoids	263	440	26,525
Patients receiving high oral morphine equivalent volume of opioids in combination with antidepressants	272	463	37,332

Medicines prescribed	Prescribed for 1 to 84 days	Prescribed for 85 to 168 days	Prescribed for 169 days or more
Patients receiving high oral morphine equivalent volume of opioids in combination with benzodiazepines	109	131	7,559
Patients receiving high oral morphine equivalent volume of opioids in combination with z-drugs	63	83	5,576

The dashboard provides a useful snapshot of data that prescribers and their teams can look at to help identify and manage higher risk prescribing. This data is available at practice level to support this work. Some academic health science networks have produced <u>useful webinars</u> on the functionality of the dashboard and also compiled a <u>range of resources</u> and <u>opioid deprescribing toolkits</u> that can help to support teams working to reduce the risk of harm from opioids.

Fentanyl patch prescribing

Last year we looked at how fentanyl patches are prescribed for older adults. We have followed up on this in 2023 (figure 11).

Figure 11: Fentanyl patch prescribing by age band

Age group	Change	Total items prescribed in 2023	Total items prescribed in 2022
0-59	down by 17%	261,825	313,611
60-69	down by 8%	162,134	176,841
70-79	down by 15%	144,266	169,966
80 and over	down by 19%	156,112	192,155

Total number of items prescribed:

- 727,614 total items prescribed in 2023 (including 3,277 with ages unknown)
- 856,722 total items prescribed in 2022 (including 4,149 with ages unknown)

Overall there has been a 15% decrease in the prescribing of fentanyl patches in 2023 compared with 2022 (prescribing reduced by 8% between 2021 and 2022). This year, the biggest year-on-year reduction in prescribing (19% reduction) was in the group aged 80 and over. Although it is not possible to tell if this reduced prescribing is specifically a result of deprescribing initiatives, it may be seen as a positive trend, given the importance of ensuring that prescribing of these medicines is clinically appropriate, especially on an extended basis in older adults.

Prescribing in NHS hospitals for community pharmacy dispensing

In 2023, hospital prescribing (on FP10HP prescription forms that can be dispensed in a community pharmacy) was also broadly in line with 2022 (figures 12 and 13).

Total controlled drug items across Schedules 2 to 5 prescribed in hospital using an FP10(HNC) or FP10SS form:

978,220 items in 2023

956,529 items in 2022 (an increase of 2%)

The cost of this was £16,420,698 in 2023 compared with £15,876,710 in 2022 (an increase of 3%)

Of all prescribing of controlled drugs in hospitals for dispensing in a community pharmacy:

- **Schedule 2** accounted for 51%
- **Schedule 3** accounted for 16%
- **Schedule 4** accounted for 20%
- **Schedule 5** accounted for 12%

Note: Percentages may not add to 100% due to rounding

Figure 12: Key reductions in hospital prescribing of controlled drugs for community pharmacy dispensing in 2023

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Temazepam (Schedule 3)	down by 19%	1,752	2,152
Methadone (Schedule 2)	down by 12%	249,631	282,184
Buprenorphine (Schedule 3)	down by 7%	114,887	123,600

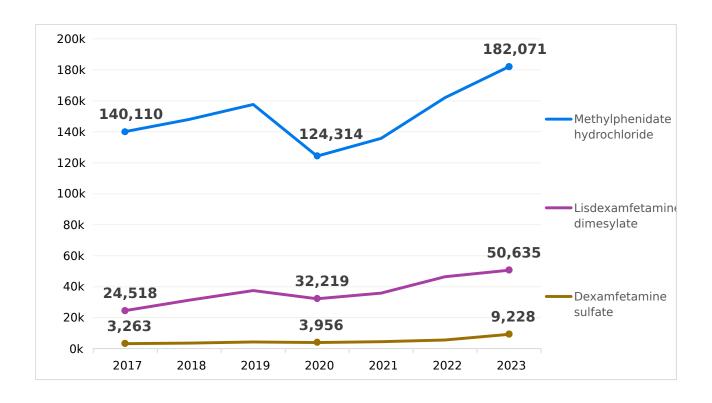
Figure 13: Key increases in hospital prescribing of controlled drugs for community pharmacy dispensing in 2023

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Dexamfetamine (Schedule 2)	up by 64%	9,228	5,627

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Co-dydramol (Schedule 5)	up by 33%	3,206	2,406
Dihydrocodeine (Schedule 5)	up by 30%	5,392	4,139
Codeine (Schedule 5)	up by 30%	43,324	33,388
Morphine (Schedule 5)	up by 25%	20,362	16,230
Co-codamol (Schedule 5)	up by 19%	47,219	39,720
Zolpidem (Schedule 4)	up by 12%	5,371	4,793
Methylphenidate (Schedule 2)	up by 12%	182,071	161,943
Gabapentin (Schedule 3)	up by 11%	5,956	5,389
Pregabalin (Schedule 3)	up by 10%	24,239	22,108

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Tramadol (Schedule 3)	up by 10%	7,571	6,903
Lisdexamfetamine (Schedule 2)	up by 9%	50,635	46,309
Oxycodone (Schedule 2)	up by 8%	4,040	3,734
Lorazepam (Schedule 4)	up by 8%	27,793	25,815

Figure 14: Number of items of methylphenidate, lisdexamfetamine and dexamfetamine prescribed in hospital for dispensing in the community in community in England, 2017 to 2023



NHS Community Pharmacist Consultation Service

The national NHS Community Pharmacist Consultation Service (CPCS) aims to reduce pressure on primary and urgent care services, including emergency departments and out-of-hours GP services. The service refers people to community pharmacies for advice, treatment, and urgent repeat prescriptions, and may supply certain controlled drugs in specific circumstances for a limited period.

Of all controlled drugs supplied in 2023, the majority supplied were in Schedule 5. We continue to see increases in the number of controlled drugs supplied through the CPCS. This could be associated with pressures in primary care, particularly in relation to timely access to GP services.

The controlled drugs most commonly supplied by the service in 2023 were:

- co-codamol (in a range of forms, including tablets and capsules) 30/500mg, 15/
 500mg and 8/500mg
- **codeine** 15mg and 30mg tablets

- dihydrocodeine 30mg tablets
- morphine sulphate oral solution 10mg/5ml
- clonazepam 500mcg tablets
- **clobazam** 10mg tablets
- **co-dydramol** 10/500mg tablets
- **diazepam** 2mg tablets
- **zopiclone** 7.5mg tablets

Private controlled drug prescribing in independent primary care

Total controlled drug items prescribed privately across independent primary care services:

390,788 items in 2023

225,482 items in 2022

This is an increase of 73%. As in 2022, the main contribution towards this trend comes from the increased prescribing of Schedule 2 controlled drugs licensed to treat ADHD.

Of all private prescribing of controlled drugs in independent primary care:

- **Schedule 2** accounted for 97%
- **Schedule 3** accounted for 3%

(Schedule 4 and 5 prescribing collectively accounted for less than 1% overall. Even though there is no requirement for Schedule 4 and 5 controlled drugs to be prescribed on the private prescription form FP10PCD, this sometimes still happens, which is why we always see a small percentage of these medicines in the data).

Private prescribing of Schedule 2 controlled drugs

Prescribing of Schedule 2 controlled drugs alone increased by 80%:

378,049 total items in 2023

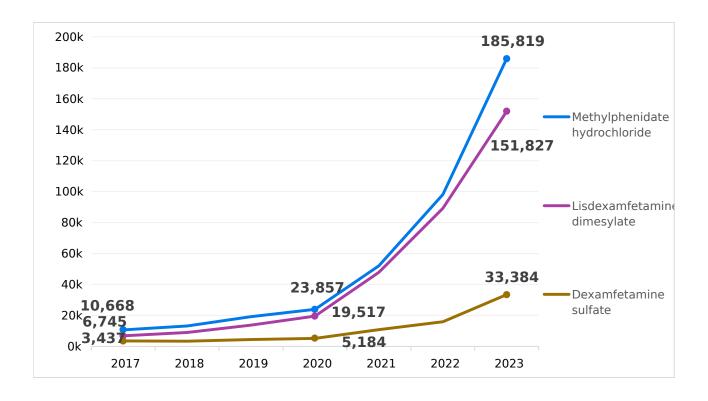
211,130 total items in 2022

This figure does not include unlicensed cannabis-based products for medicinal use and has largely been driven by the increase in prescribing for medicines licensed for ADHD (figures 15 and 16).

Figure 15: Schedule 2 controlled drugs prescribed in independent primary care in 2023

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Methylphenidate	up by 89%	185,819	98,115
Lisdexamfetamine	up by 70%	151,827	89,297
Dexamfetamine	up by 111%	33,384	15,830

Figure 16: Number of items of methylphenidate, lisdexamfetamine and dexamfetamine prescribed annually in independent primary care in England, 2017 to 2023



We continue to monitor arrangements around safe prescribing of medicines to treat ADHD for people whose care is shared between different services. Although there were shortages of these medicines during 2023 and into 2024, we continue to see increased prescribing volumes. Increasing volumes is particularly evident in the private sector, which may be a result of long waiting times for access to NHS care.

Private prescribing of Schedule 3 controlled drugs

12,411 total items prescribed in 2023

13,383 total items prescribed in 2022 (a decrease of 7%)

Pregabalin: is the most prescribed drug in Schedule 3, accounting for 56% of all Schedule 3 prescribed items:

6,922 total items in 2023

7,395 total items in 2022 (a decrease of 6%)

Prescribing of some other Schedule 3 controlled drugs has reduced in 2023 compared with 2022 (figure 17):

Figure 17: Reductions in private prescribing of Schedule 3 controlled drugs in 2023

Controlled drug	Change	Total items prescribed in 2023	Total items prescribed in 2022
Buprenorphine	down by 8%	1,988	2,150
Midazolam	down by 18%	797	977
Gabapentin	down by 10%	865	964
Temazepam	down by 9%	540	595

Requisitions

Requisitions are documents that allow the appropriate people to order medicines for use in their professional practice, such as ordering a stock of controlled drugs that are later administered to patients.

The volume of requisitions has increased in the last year:

15,739 total items requisitioned in 2023

10,725 total items requisitioned in 2022 (an increase of 47%)

Looking at where these requisitions came from in 2023:

- 74% of all requisitions were from NHS providers (compared with 65% in 2022)
- 26% were from independent organisations (compared with 35% in 2022)

The top 10 controlled drugs on requisition remained the same in 2023 as for 2022. Figure 18 shows the most commonly requisitioned controlled drugs in 2023.

Figure 18: Requisitions of Schedule 2 and 3 controlled drugs in 2023

Controlled drug	Percentage of all requisitions	Total items
Pregabalin	20%	3,105
Methylphenidate	17%	2,677
Gabapentin	7%	1,175
Morphine sulfate (Schedule 2 and 5)	9%	1,411
Midazolam	8%	1,183
Oxycodone	10%	1,571

Controlled drug	Percentage of all requisitions	Total items
Buprenorphine	7%	1,086
Fentanyl	5%	832
Lisdexamfetamine	5%	749
Tramadol	4%	616

Recommendations

These recommendations aim to raise awareness and address some of the specific issues we have identified from our work during the last year.

We continually monitor progress and change to drive improvement in the safer management of controlled drugs.

For health and care services

Share information about concerns in relation to controlled drugs with the right organisations as soon as possible, including with NHS England controlled drugs local intelligence networks

This may include sharing appropriate information about persons of concern. One of the key findings of the Inquiry into the crimes of Harold Shipman was that failure to connect key pieces of intelligence meant that his actions were not identified earlier. This is why proactive membership of CDLINs is crucial. The Controlled Drugs (Supervision of management and use) Regulations 2013 emphasise the importance of sharing information. They also take account of data protection legislation. If you are concerned about whether it is appropriate to share information, your NHS England CDAO can support you with this.

For national bodies and government

Review the national system for prescribing identification numbers (PINs)

In its current form, the system has no expiry date for PINs and practitioners are only required to provide one main address of work. Any review should take account of increases in non-medical prescribing, and the fact that not all practitioners will be required to be registered with CQC to undertake their work, so they may not be subject to checks on the services they offer to people in future.

Address online prescribing of controlled drugs in Schedules 4 and 5 by services and prescribers outside of the United Kingdom

This issue remains a risk to people in England. Although there is no national dataset that quantifies this prescribing, we continue to hear about instances where this happens and results in harm to people. Relevant national stakeholders should work together to generate an accurate and current picture of these risks to determine the best way to manage this.

Review the impact of the 2018 legislation change to allow prescribing of cannabis-based products for medicinal use (CBPMs)

The intention for this change was to support treatment for individual patients for an unmet clinical need. We have since seen a significant increase in prescribing to treat a wide range of medical conditions, as well as changing models of care including those involving non-medical prescribers. It is important that accurate and up-to-date CBPM prescribing data is available to support any review and ongoing oversight of this sector. Prescription processing procedures should be reviewed to achieve this.

For police services

Consider whether <u>controlled drugs liaison officers</u> are adequately resourced

Controlled drugs liaison officers (CDLOs) are crucial partners and sources of support and advice for services that use controlled drugs. Resourcing for these important roles is inconsistent across different constabularies. Each constabulary should consider the resourcing needs for their specific area to ensure that health and care services are able to access CDLO expertise.

© Care Quality Commission