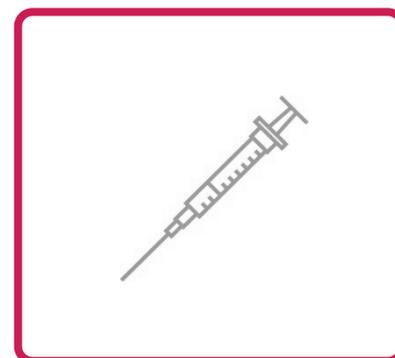
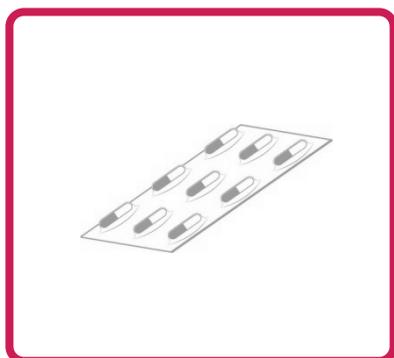
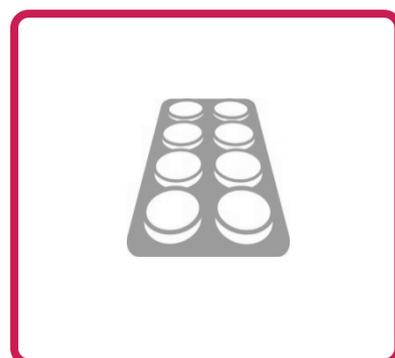
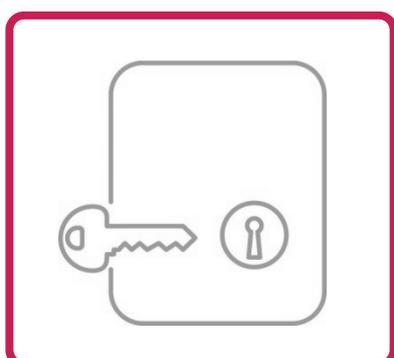


# The safer management of controlled drugs

Annual update 2016

Published July 2017



## The Care Quality Commission

**The Care Quality Commission is the independent regulator of health and adult social care in England.**

We make sure that health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

### Our role

- We register health and adult social care providers.
- We monitor and inspect services to see whether they are safe, effective, caring, responsive and well-led, and we publish what we find, including quality ratings.
- We use our legal powers to take action where we identify poor care.
- We speak independently, publishing regional and national views of the major quality issues in health and social care, and encouraging improvement by highlighting good practice.

We also have a statutory duty to oversee the safe management arrangements for controlled drugs in England.

### Our values

- Excellence – being a high performing organisation.
- Caring – treating everyone with dignity and respect.
- Integrity – doing the right thing.
- Teamwork – learning from each other to be the best we can.

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# This report

Under the Controlled Drugs (Supervision of Management and Use) Regulations 2013, the Care Quality Commission (CQC) is responsible for making sure that health and adult social care providers, and other regulators, maintain a safe environment for the management of controlled drugs in England. We do this by reporting annually to Government. This came in response to the findings of the Fourth report of the Shipman Inquiry and the Government's response to the inquiry's recommendations

In this report we make recommendations that ensure ongoing robustness of controlled drug arrangements in England. The report and its recommendations are pertinent to all controlled drugs accountable officers in England and their support teams; organisations that handle controlled drugs; healthcare professionals with a controlled drugs interest; commissioners of healthcare services and professional healthcare and regulatory bodies.

## Summary and recommendations

In this update, we make three recommendations:

- The first recommendation is for NHS England controlled drugs accountable officers to be aware of new models of care across their area. We are seeing new and innovative ways of providing healthcare, and these changes have resulted in a new range of healthcare service providers with controlled drugs responsibilities. It is therefore important that these organisations are included within the wider controlled drugs local intelligence networks.
- Our second recommendation focuses on sensitive handling of diversion by work colleagues. Through our attendance at controlled drug local intelligence network meetings, we have become aware of an increasing number of incidences of healthcare staff diverting or misusing controlled drugs. Controlled drug accountable officers must encourage work colleagues to report concerns regarding other members of staff. The investigation must be handled sensitively and support be made available where the health and welfare of members of staff are affected – both during and after an investigation.
- Our third recommendation concerns ongoing review of controlled drug prescriptions. Through the prescribing monitoring sub-group, we are aware of some high volume prescribing of oral morphine solution 10mg/5ml. Although prescribing a high volume may be clinically appropriate for some patients, others may benefit from a review of their medicines and a slow release preparation considered instead. We encourage all controlled drug prescribers to regularly review the clinical needs of their patients, to ensure that the prescribed drugs and length of treatment continues to be the most appropriate for their condition, to reduce opportunities for over prescribing and diversion.

During 2016, we continued to maintain and publish a register of controlled drug accountable officers, who are responsible for all issues around handling and governance of controlled drugs in their organisation. Some small organisations are exempt from the need to have a controlled drugs accountable officer; there was still a low uptake of this exemption during 2016.

We chaired the National Group on Controlled Drugs, which met four times during 2016, and the four sub-groups that focus on a number of key areas – namely thefts and frauds, patient safety, policy and operational issues and prescribing. We also met with our cross-border colleagues in Wales, Scotland, Northern Ireland, Republic of Ireland, the Channel Islands and the Isle of Man, to share good practice and discuss strategic controlled drugs-related issues across our borders.

We continued to attend and have oversight of how well controlled drug local intelligence networks across England are working. NHS England's controlled drugs accountable officers continued to work collaboratively in controlled drugs local intelligence networks during 2016, resulting in greater consistency across England when sharing both concerns and good practice. At the end of 2016, NHS England controlled drugs accountable officers agreed a controlled drug occurrence reporting template, which will help to build a better national picture.

## **Key legislation changes and national trends in the use and management of controlled drugs during 2016**

The Psychoactive Substances Act 2016 (PSA) came into effect on 26 May 2016 and bans the sale, supply, production and distribution of psychoactive substances for human consumption and gives police and local authorities greater powers to tackle the trade. The act does not cover products that are already regulated by existing laws, for example, medicinal substances, controlled drugs, caffeine, nicotine, alcohol and food. The act also excludes certain bona fide research and healthcare activities, any healthcare professional in the course of his or her profession where they involve the supply of psychoactive substances for human consumption.

The renewal of the Temporary Class Drug Order for Methylphenidate based substances, such as ethylphenidate, came into force on 26 June 2016. This is to continue to restrict their supply to prevent harm.

## **Recommendations**

- 1. NHS England controlled drugs accountable officers should be aware of new models of care across their area and, where appropriate, include them in the controlled drugs local intelligence network meetings.**
- 2. Controlled drugs accountable officers should ensure that all staff in their organisation know how to report concerns about diversion and abuse of medicines by fellow colleagues, and that these issues are handled sensitively and appropriately.**
- 3. Prescribers must make sure that they review patients regularly, depending on their clinical need. This is to ensure that the prescribed controlled drugs and length of treatment continues to be the most appropriate for their condition and to reduce opportunities for over prescribing and diversion.**

### **Action for CQC**

**We have agreed to collate a national summary from the occurrence data collected by NHS England controlled drug accountable officers to build a better national picture and support the review of the 2013 regulations.**

## Progress on recommendations made in the 2015 report

In our report on activity during 2015, we made three recommendations to improve the management of controlled drugs.

Recommendation	Progress
<p>NHS England controlled drugs accountable officers should agree on and collect consistent information about controlled drug-related issues to provide a national picture.</p>	<p>During 2016, NHS England controlled drugs accountable officers agreed and updated the occurrence report template, to be used from April 2017.</p>
<p>All controlled drugs accountable officers should support the NHS England controlled drugs accountable officers by responding to requests for information in a timely way so that the controlled drugs local intelligence networks function effectively and productively.</p>	<p>This is ongoing, and NHS England controlled drugs accountable officers, or their support teams, are sending timely reminders.</p>
<p>Local authorities, through their Public Health and Adult Social Care Directors, should engage with their controlled drugs local intelligence networks to share concerns about controlled drugs that relate to the services they commission – in particular, social care organisations and drug and alcohol services.</p>	<p>Engagement with local authorities at controlled drugs local intelligence networks across the country remains variable. During 2016, NHS England controlled drugs accountable officers engaged with those local authorities that did not participate in the controlled drugs local intelligence networks.</p>

# The Care Quality Commission's activity in 2016

## CQC's website

We have updated the [dedicated controlled drug section](#) on CQC's website to include [guidance](#) that explains the exemptions for the need to have a controlled drugs accountable officer, the criteria that must be met to be appointed as a controlled drugs accountable officer, and how different types of organisations can notify us about changes.

The web pages also include the online [register of controlled drugs accountable officers](#), [links to legislation and supporting information](#) and [newsletters from sub-groups of the Controlled Drugs National Group](#). We also provide information regarding controlled drugs in primary medical services in the form of [controlled drugs 'mythbusters'](#).

## Register of controlled drug accountable officers

CQC maintains and publishes a register of controlled drugs accountable officers (CDAOs) across England for those organisations that are required under the 2013 Regulations to have one. We update this monthly. These organisations are defined as designated bodies under the regulations and are required to notify CQC of their CDAO appointment. We received approximately 28 notifications each month in 2016.

Throughout 2016, there were on average 963 organisations on our CDAO register. Of those organisations, 724 CDAOs were from independent healthcare organisations, 250 were from NHS organisations and the remainder were from other organisations, such as social care providers that fall within the designated body status.

We continued to grant exemptions for the need to have a CDAO where it is disproportionate to appoint one in independent healthcare organisations that have more than 10 employees but have a low use of controlled drugs. Organisations with fewer than 10 employees are automatically exempted. The uptake of the exemption by eligible organisations continues to remain low, and in 2016 we received and approved nine CDAO notification exemptions.

## NHS England-led controlled drug local intelligence networks

During 2016, NHS England controlled drugs accountable officers (CDAOs) met four times to share intelligence, best practice, concerns and ensure national consistency. In June, each NHS England CDAO completed a self-assessment for the NHS England central team, who shared the findings with CQC to provide updates and assurance.

NHS England's CDAOs currently run 39 controlled drug local intelligence networks across England, which meet up to four times a year. Membership of the networks includes a wide range of organisations, including clinical commissioning groups (CCGs) and CDAOs from local NHS trusts (community, acute, secondary, and mental health), private hospitals and hospices, along with the responsible bodies such as CQC, the General Pharmaceutical Council, police and local authorities. Attendance at controlled drugs local intelligence network meetings was managed well through all the local NHS England CDAOs. Non-attendance is formally followed up through letters, phone calls and reminders before being reported to CQC.

NHS England held 127 controlled drugs local intelligence network meetings across England during 2016. CQC attended 60% of these spread across all NHS England regional teams, which is broadly similar to the number attended in 2015. Although meetings of some regional NHS England CDAOs were held less often (twice or three times a year), the meetings lasted longer to cover all issues. Where this was the case, members continued to have good attendance and engagement and benefitted from additional associated learning.

The range and depth of issues discussed at controlled drugs local intelligence network meetings during 2016 remained broadly similar to previous years. The most commonly reported and discussed incidents were reported theft, amended or wrongly dispensed prescriptions and general governance issues. However, we have noted an increase in incidents involving healthcare staff diverting controlled drugs for personal use. controlled drugs accountable officers need to be vigilant within their own organisations – not only in the investigation into the missing controlled drugs, but also making sure that support is available where the health and welfare of staff may be affected.

As the boundaries between traditional types of healthcare services are becoming less distinct and services are more integrated, we are starting to see a range of new and emerging healthcare service providers that handle controlled drugs. We therefore encourage all NHS England CDAOs and their teams to be aware of those organisations that currently fall outside the scope of The Controlled Drugs (Supervision of Management and Use) Regulations 2013, and to be mindful that they may need to be included in the wider controlled drugs local intelligence networks.

## Recommendations

**NHS England controlled drugs accountable officers should be aware of new models of care across their area and, where appropriate, include them in the controlled drugs local intelligence network meetings.**

**Controlled drugs accountable officers should ensure that all staff in their organisation know how to report concerns of diversion and abuse of medicines by fellow colleagues, and that these issues are handled sensitively and appropriately.**

## Controlled Drugs National Group

The CQC-led Controlled Drugs National Group met quarterly in 2016. It comprises government departments, key regulators and agencies with a controlled drugs remit that shared and discussed emerging issues and identified ways of working together to reach solutions. Following positive feedback, we continued to share summarised meeting notes with NHS England's CDAOs, to enable them to update controlled drugs local intelligence network members about developments and policy initiatives.

Membership of the group remained the same as in 2015. We have published a separate [summary of the activity](#) from the group's main members, which highlights the many ways in which these agencies contribute to the overall safer management of controlled drugs.

The sub groups met in person or by teleconference every few months as required. Membership comprised relevant stakeholders, such as NHS Protect (now known as the NHS Counter Fraud Authority) and the police, specialist pharmacists and Medicine Safety Officers, other government bodies, NHS Digital, NHS England CDAOs and chief pharmacists. Other healthcare professionals with relevant expertise were also invited as required.

The sub group's newsletters include links to relevant guidance and case studies, and are published on the controlled drug pages on [CQC's website](#).

## Cross-Border Group

The Cross-Border Group for safer management of controlled drugs in the devolved administrations met in March and September 2016. It included 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 provided a forum to discuss controlled drug matters at a strategic level and we have published a [separate summary](#) of their major activities during 2016.

# National trends in the use and management of controlled drugs

During 2016, the total number of controlled drug items prescribed in NHS primary care was 60,117,271, which was a decrease of 0.8% compared with 2015. The cost of this was £526,941,061, which is a decrease of 6.2% on the £561,872,674 spent in 2015.

In addition, 1,042,925 controlled drug items across Schedules 2 to 5 were prescribed in hospital using an FP10(HNC) or FP10SS form, to be dispensed in the community during 2016. Hospital prescribing was broadly in line with that for 2015 although the number of items prescribed decreased by 7% with a corresponding decrease in cost of 9% to £15,747,543.

However, it is important to point out that the number of items does not take account of the quantity prescribed on a single prescription. It has come to light through the work of our prescribing monitoring sub-group that some patients are prescribed very large doses of controlled drugs to manage their pain. In particular we have seen volumes of morphine sulfate oral solution 10mg /5ml prescribed that exceeds six litres. While this may be clinically appropriate for some patients, others may benefit from a review of the medicines they take and a slow release preparation considered instead. We want to highlight the importance of ongoing review to ensure that the preparation prescribed and the length of treatment is the most appropriate and effective for the patient to reduce opportunities for over prescribing and diversion.

## Recommendation

**Prescribers must make sure that they review patients regularly, depending on their clinical need. This is to ensure that the prescribed controlled drugs and length of treatment continues to be the most appropriate for their condition and to reduce opportunities for over prescribing and diversion.**

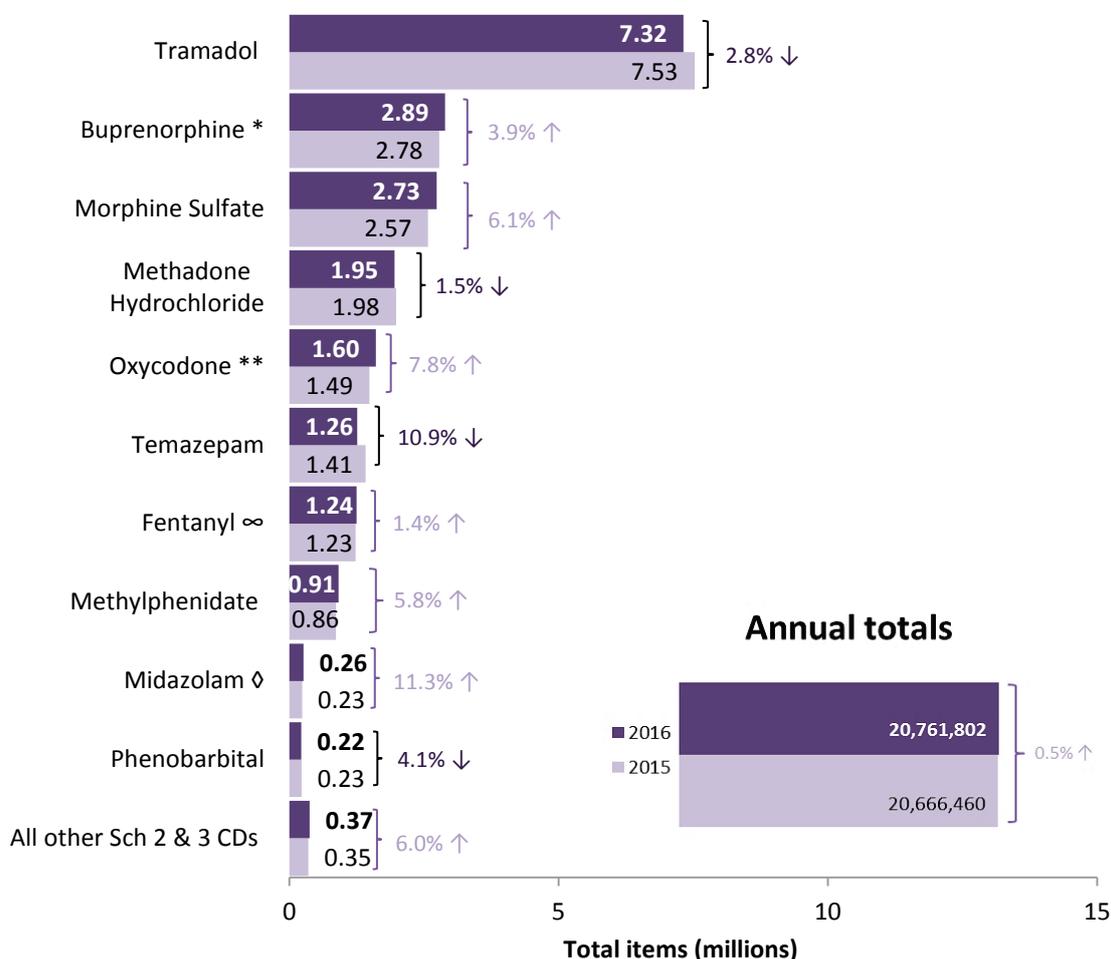
## Schedule 1 controlled drugs

Currently, no controlled drugs in Schedule 1 are used for medicinal purposes.

## Schedules 2 and 3 controlled drugs

Prescribing of Schedules 2 and 3 controlled drugs in primary care in 2016 stayed broadly comparable with 2015 (figure 1).

**Figure 1: Top 10 Schedules 2 and 3 controlled drugs prescribed in NHS primary care in 2015 and 2016 (by millions of items)**



\* Buprenorphine figures include the combination buprenorphine/naloxone.

\*\* Oxycodone figures include the combination product Targinact (oxycodone and naloxone).

∞ Fentanyl figures include fentanyl transdermal patches and small amounts of other fentanyl products.

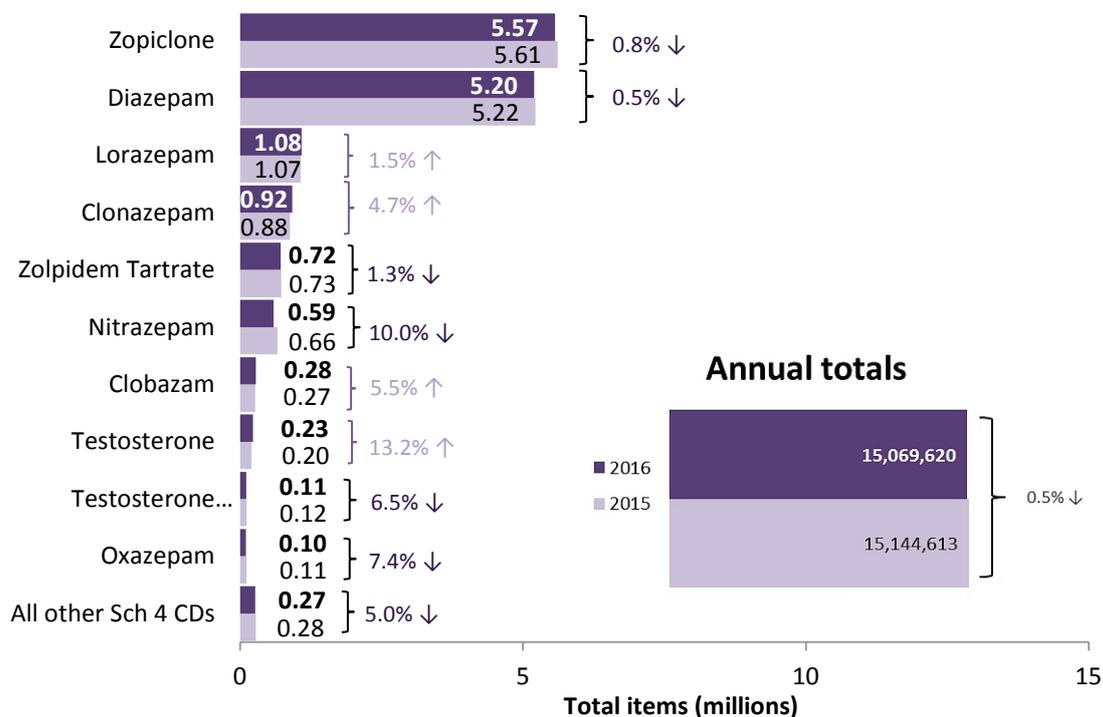
◇ Midazolam figures include oral and injectable midazolam, midazolam hydrochloride and midazolam maleate.

As in 2015, there was an increase in prescribing of oxycodone, midazolam, methylphenidate, morphine sulfate, buprenorphine and fentanyl, and a decrease in prescribing of temazepam, phenobarbital, tramadol and methadone.

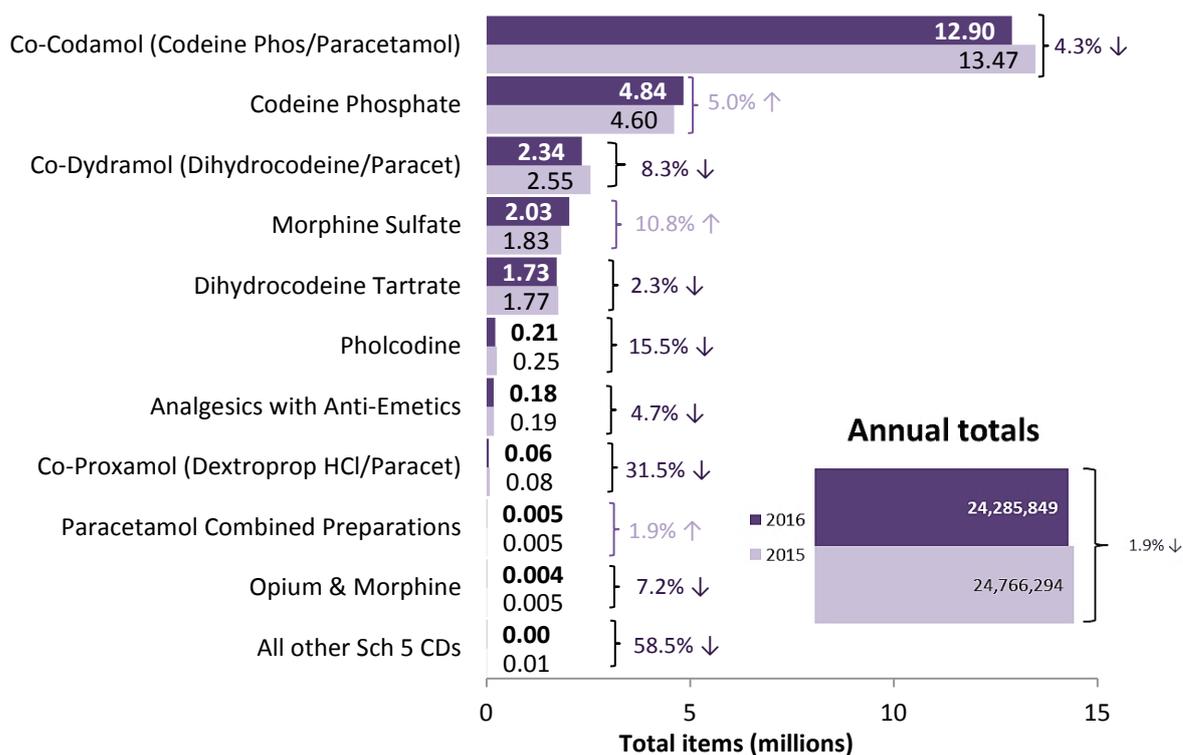
## Schedules 4 and 5 controlled drugs

The pattern of prescribing for Schedules 4 and 5 controlled drugs during 2016 remains broadly similar to 2015 (figures 2 and 3 on the next page).

**Figure 2: Top 10 Schedule 4 controlled drugs prescribed by NHS primary care in 2015 and 2016 (by millions of items)**



**Figure 3: Top 10 Schedule 5 controlled drugs prescribed in NHS primary care in 2015 and 2016 (by millions of items)**



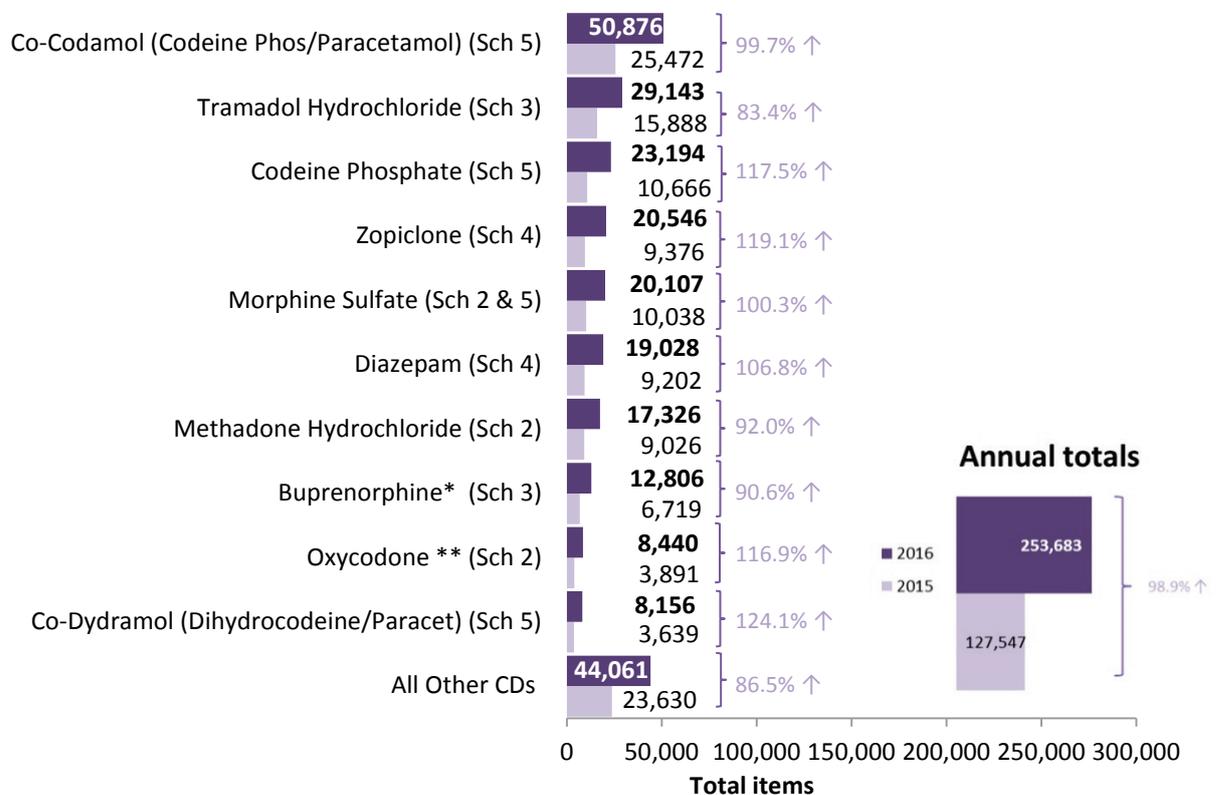
The most commonly prescribed Schedule 4 controlled drug in 2016 continued to be zopiclone, although the amount prescribed fell slightly (by 0.8%) compared with 2015. As in 2015, there was an increase in prescribing of clonazepam, clobazam and lorazepam, while prescribing of nitrazepam and oxazepam continued to decrease.

There was also a similar pattern to 2015, with codeine-containing preparations continuing to be the most commonly prescribed Schedule 5 controlled drugs. Co-codamol was the most commonly prescribed Schedule 5 controlled drug in 2016, although prescribing reduced by 4.3%. Codeine phosphate was the second most commonly prescribed and prescribing continued to increase, as in 2015. Conversely, the number of items prescribed of dihydrocodeine and dihydrocodeine in combination with paracetamol had both decreased. The number of morphine sulfate items also continued to increase.

## Non-medical prescribing

In 2016, controlled drug prescribing by pharmacists almost doubled from 127,547 items to 253,683, continuing the trend from the previous year. However, nurse prescribing only increased by around 5% to 1,068,296. We will continue to monitor the trend in prescribing of controlled drugs by non-medical prescribers.

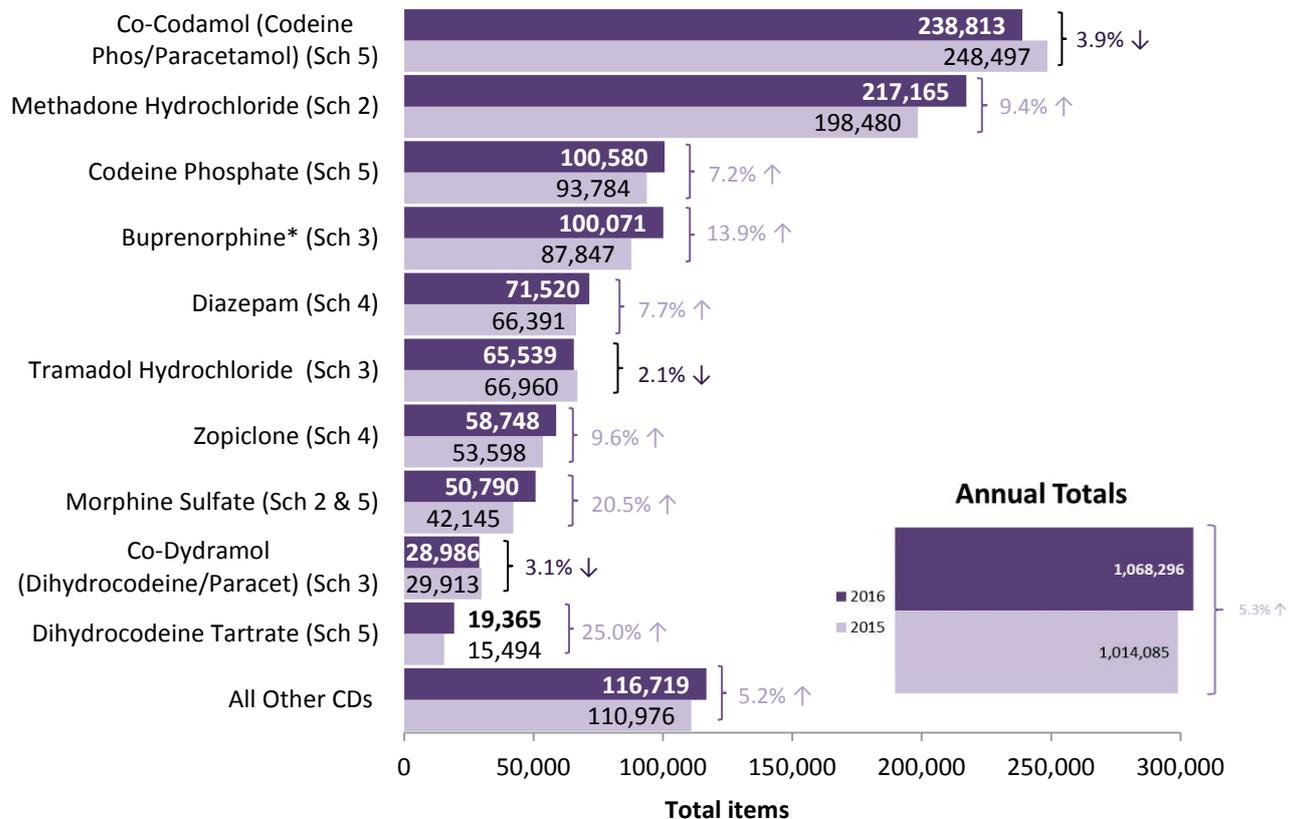
**Figure 4: Top 10 pharmacist prescribed controlled drugs in NHS primary care in 2015 and 2016**



\* Buprenorphine figures include the combination buprenorphine/naloxone.

\*\* Oxycodone figures include the combination product Targinact (oxycodone and naloxone).

**Figure 5: Top 10 nurse prescribed controlled drugs in NHS primary care in 2015 and 2016**



\* Buprenorphine figures include the combination buprenorphine/naloxone.

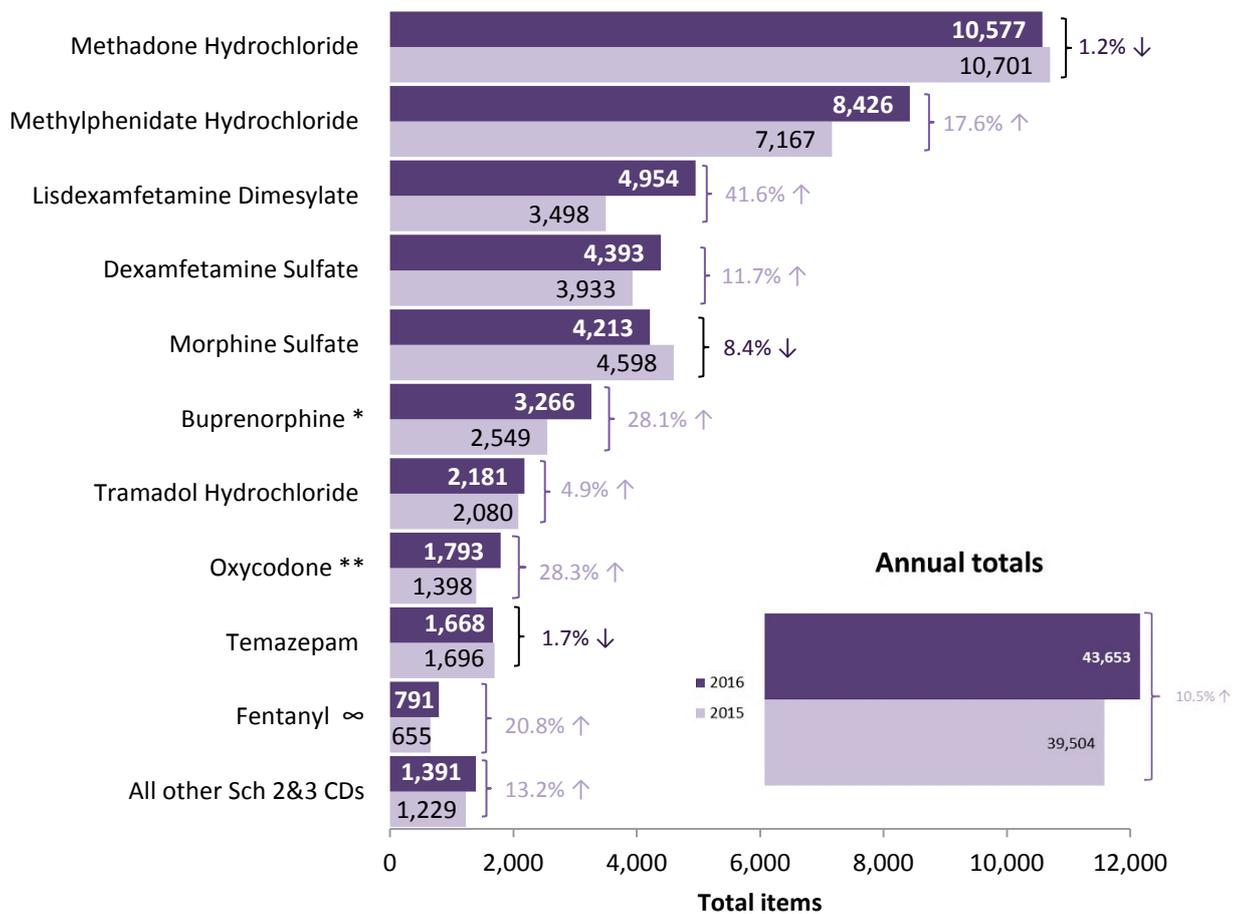
## Physiotherapist and podiatrist prescribing of controlled drugs

This continued to be at minimal levels during 2016, with the total number prescribed collectively amounting to less than 150 items.

## Private prescribing

Privately prescribed controlled drugs continue to account for a small proportion (0.1%) of overall controlled drug prescribing. The top 10 Schedules 2 and 3 controlled drugs stayed broadly similar to 2015. However, lisdexamfetamine (used in the treatment of attention deficit hyperactivity disorder (ADHD)) replaced morphine sulphate in third place. Methadone (used in the treatment of substance misuse) continues to be the most common controlled drug prescribed privately but, as in 2015, its use has continued to decrease, whereas the number of items of buprenorphine (also used to treat substance misuse) continued to increase.

**Figure 6: Top 10 Schedules 2 and 3 controlled drugs prescribed privately in 2015 and 2016**



\* Buprenorphine figures include the combination buprenorphine/naloxone.

\*\* Oxycodone figures include the combination product Targinact (oxycodone and naloxone).

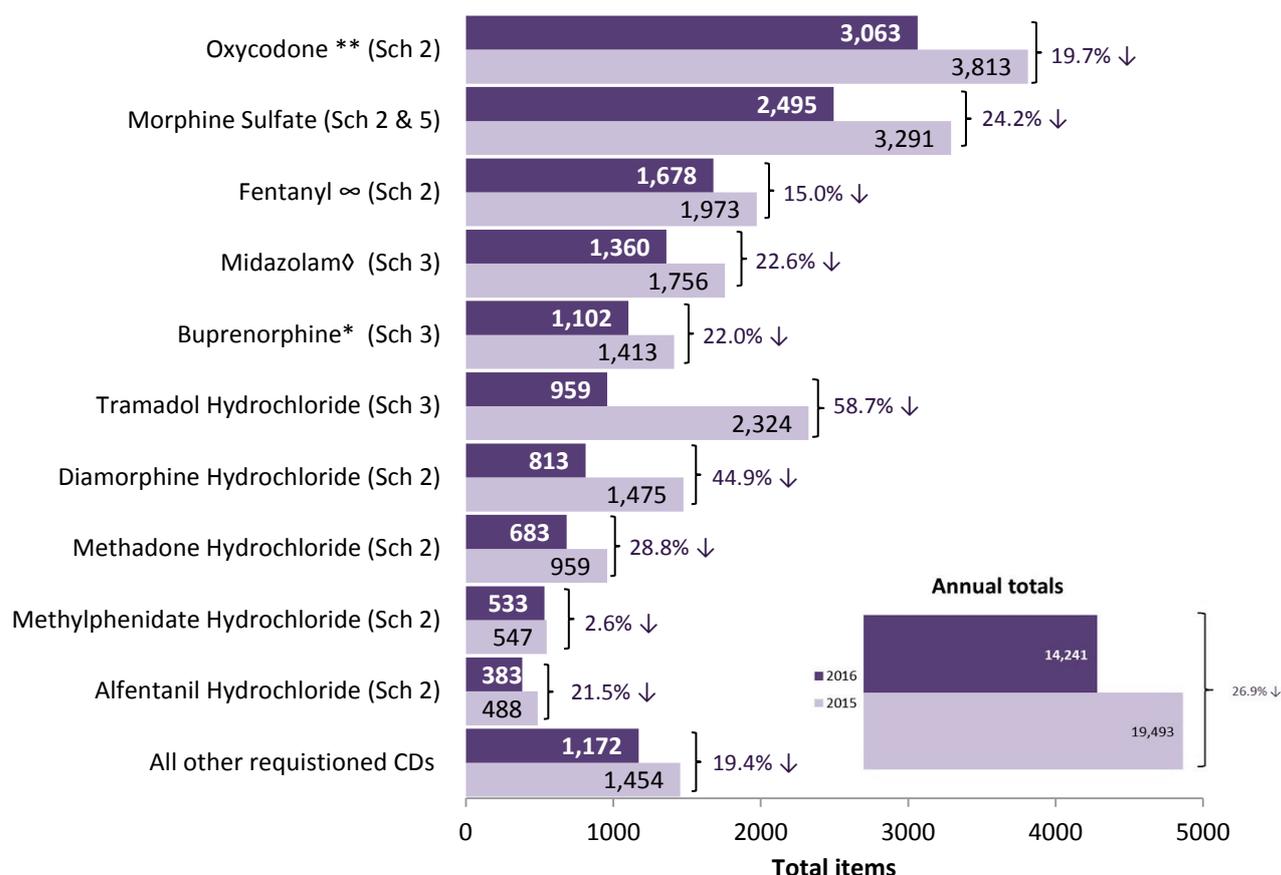
∞ Fentanyl figures include fentanyl transdermal patches and small amounts of other fentanyl products.

## Controlled drug requisitions

Since 30 November 2015, practitioners wishing to obtain controlled drugs in Schedules 2 and 3 from a community pharmacy have been required to use a mandatory requisition form; 2016 was the first year for which we have a full 12 months' worth of data on its use.

The overall number of items decreased by 26.9% from 19,493 items in 2015 to 14,241 items in 2016. This could be a consequence of increased regulation but it is difficult to make a judgement based on only one year's data. The split between NHS requests (66%) and private prescribing (34%) is broadly in line with last year where the split was 65% and 35%

**Figure 7: Top 10 requisitioned controlled drugs in 2015 and 2016**



\* Buprenorphine figures include the combination buprenorphine/naloxone.

\*\* Oxycodone figures include the combination product Targinact (oxycodone and naloxone).

∞ Fentanyl figures include fentanyl transdermal patches and small amounts of other fentanyl products.

◊ Midazolam figures include oral and injectable midazolam, midazolam hydrochloride and midazolam maleate.

## Next steps

NHS England controlled drugs accountable officers worked hard in 2016 to ensure that the arrangements for the safe management of controlled drugs were maintained.

However, we need to be mindful that the way healthcare is delivered across England is changing and new types of health and care providers that cross traditional boundaries are emerging. In our next annual update we will be looking at how these providers are ensuring that any controlled drugs being prescribed or managed are done so appropriately and safely.

We will also continue to report on the work undertaken by the Medicines and Healthcare products Regulatory Agency on their ongoing investigation into the large-scale diversion of specific controlled drugs (principally diazepam and zopiclone) from the authorised supply chain to the criminal market (further information can be found in the separate summary of activity from partner organisations of the Controlled Drugs National Group, published alongside this update).

# Appendix: Further information

## Links to relevant controlled drugs legislation and guidance

[The Health and Social Care Act 2012](#)

## The Controlled Drugs (Supervision of Management and Use Regulations 2013

[The Controlled Drugs \(Supervision of Management and Use\) Regulations 2013 - Information about the regulations](#)

[The Shipman Inquiry Reports](#)

[The Human Medicines Regulations 2012](#)

[The Misuse of Drugs Act 1971](#)

[The Misuse of Drugs Regulations 2001](#)

[The Misuse of Drugs \(Amendment\) \(No. 2\) \(England, Wales and Scotland\) Regulations 2015](#)

[NHS England's Controlled Drugs Accountable Officers' Single Operating Model](#)

[NICE Guideline 46: The safe use and management of controlled drugs](#)

## Links to key changes in controlled drugs legislation during 2015

Electronic prescribing of Schedules 2 and 3 controlled drugs:

[The National Health Service \(Amendments to Primary Care Terms of Service relating to the Electronic Prescription Service\) Regulations 2015](#)

[The Human Medicines \(Amendment\) \(No. 2\) Regulations 2015](#)

[Physiotherapist and podiatrist independent prescribers](#)

[Rescheduling of ketamine](#)

[Standardised requisition forms for Schedules 2 and 3 controlled drugs](#)

## Newsletters of the Controlled Drugs National Group Sub Group

[Safe Use of Fentanyl & Buprenorphine Transdermal Patches](#)

[Supporting information](#)

[Preventing Harm from Oxycodone Medicines](#)

[Supporting information](#)

[Preventing Harm Still Occurring with CDs Administered via MS Syringe Drivers](#)

[Supporting information](#)

[Preventing harms from the use of methadone](#)

[Supporting information](#)

[Vigilance newsletter](#)

[Patient Safety newsletter](#)

Other newsletters on policy and prescribing will be available on the [website](#).

## **Links to CQC's website for controlled drugs accountable officer notifications and the controlled drugs accountable officer notifications register:**

[Controlled drugs accountable officers](#)

[Primary medical services controlled drugs myth buster](#)

[Controlled drugs governance self-assessment tool for primary care organisations](#)

[Controlled drugs governance self-assessment tool for secondary care organisations](#)

## **Information for all health and social care providers**

Our website has all you need to know about registration with CQC in our [Guidance for providers](#).

## **Registering for the first time**

Whether you own a new organisation and need to register with us, or if you work for an existing registered provider, please read the following guides:

[Step-by-step guide to applying as a new provider](#)

[Step-by-step guide to applying as a new registered manager](#)

## **Contact us**

If you have an enquiry about the register or you want to notify us of a change of contact details for your controlled drugs accountable officer notifications (phone number or email address), please email us at [CDAOregisterdata@CQC.org.uk](mailto:CDAOregisterdata@CQC.org.uk).

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