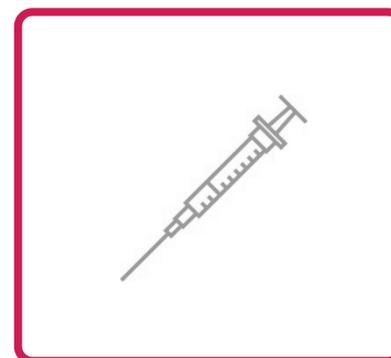
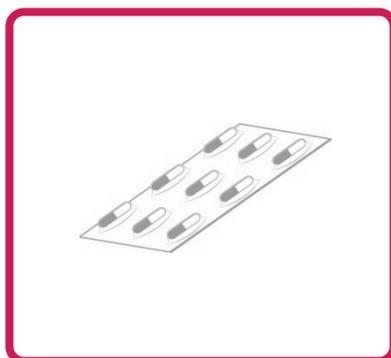
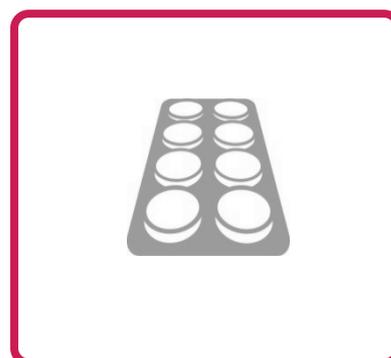
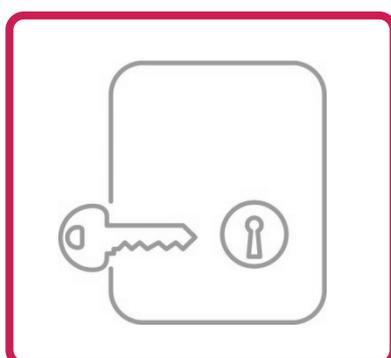


# The safer management of controlled drugs

Annual update 2017

Published July 2018



## 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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# Introduction

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 under the Controlled Drugs (Supervision of Management and Use) Regulations 2013.

This is our annual report to Government, in which we make recommendations to help ensure the continuing effectiveness of the arrangements for managing controlled drugs in England. These are important for all controlled drugs accountable officers (CDAOs) in England and their support teams, as well as organisations that handle controlled drugs, healthcare professionals with an interest in controlled drugs, commissioners of healthcare services and professional healthcare and regulatory bodies.

## Overview and recommendations

CQC chairs the National Group on Controlled Drugs and the four sub-groups. This enables us to share information and discuss issues with other organisations, with a focus on key areas such as thefts and frauds, patient safety, policy and operational issues, and prescribing. We also met with cross-border colleagues in Wales, Scotland, Northern Ireland, the 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.

As part of our oversight activity, we monitor the effectiveness of controlled drug local intelligence networks across England. NHS England's CDAOs have worked collaboratively in these networks and are using a newly-agreed controlled drug occurrence reporting template. This improves consistency when sharing both concerns and good practice, and has helped to build a better national picture of issues related to controlled drugs. NHS England's electronic occurrence reporting tool was rolled out to all regions in late 2017.

Based on our learning from work in all these areas, we make four recommendations.

Our first recommendation relates to prescribing controlled drugs outside of NHS general practice, for example by independent healthcare professionals, and the importance of informing a patient's own GP when this happens. This helps to ensure that patients are kept safe and that GPs maintain an overview of all the medicines prescribed to their patients.

Because of the growing complexity of new and emerging models of care, our second recommendation is relevant for commissioners of health and care. All those involved in commissioning need to be aware of the responsibilities and governance arrangements for controlled drugs as part of any new commissioning arrangements.

The third recommendation highlights the importance of vigilance and security for healthcare professionals and of reporting any losses of personal identification mechanisms such as badges and passwords. This follows a rise in personal identity theft, sometimes to fraudulently obtain controlled drugs.

We also highlight the importance of monitoring controlled drugs in the lower schedules, such as Schedules 4 and 5, which comprise more than 67% of controlled drugs prescribed in primary care. Regular monitoring will help to identify diversion and to take swift action to reduce it.

## Recommendations

1. Prescribers should ask patients about their existing prescriptions and current medicines when prescribing controlled drugs. Where possible, prescribers should also inform the patient's GP to make them aware of treatment to minimise the risk of overprescribing that could lead to harm.
2. Commissioners of health and care services should include the governance and reporting of concerns around controlled drugs as part of the commissioning and contracting arrangements so that these are not overlooked.
3. Healthcare professionals should keep their personal identification badges and passwords secure and report any losses as soon as possible to enable organisations to take the necessary action.
4. Health and care staff should consider regular monitoring and auditing arrangements for controlled drugs in the lower schedules, such as Schedules 4 and 5, to identify and take swift action on diversion.

# Progress on recommendations from the 2016 report

In our report on activity during 2016, we made three recommendations to improve the management of controlled drugs.

Recommendation	Progress
<p>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.</p>	<p>NHS England controlled drugs accountable officers have continued to review and broaden the membership of local intelligence networks. As part of this ongoing review, they are taking into consideration new models of care and the subsequent new range of healthcare services that have responsibility for controlled drugs.</p>
<p>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.</p>	<p>Feedback on this recommendation has been positive, with many organisations welcoming the recognition of this often difficult but neglected part of a controlled drugs accountable officer's role. This recommendation has helped to influence organisational processes.</p>
<p>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.</p>	<p>Most local intelligence networks have discussed high volume prescribing following this recommendation. Many CCGs have commissioned local data studies and presented their findings at network meetings. In general, this found that high volume prescribing is associated with patients with complex needs.</p>

# Activity in 2017

## Register of controlled drug accountable officers

CQC maintains and publishes an online register of controlled drugs accountable officers (CDAOs) across England for those organisations that are registered with CQC and are required under the 2013 Regulations to have one. We update this register monthly. These organisations are defined as designated bodies under the regulations and are required to notify CQC of their CDAO appointment.

A very small number of organisations are registered solely with the Human Fertilisation and Embryology Authority (HFEA), and not with CQC. Our website also provides a link to HFEA's register of CDAOs.

Throughout 2017, there was an average of 996 organisations on our CDAO register. Of these, 750 CDAOs were from independent healthcare organisations, 246 were from NHS organisations and the others from organisations such as social care providers that fall within the designated body status.

To keep the CDAO register up to date, it is important that organisations tell us about any changes to their CDAOs' details. If an organisation re-registers with CQC, it needs to submit a new CDAO notification. In 2017, we received approximately 30 notifications each month. Notifications can be made using the [online webform](#). Changes to contact details such as email address or phone numbers can be emailed to [CDAORegisterData@cqc.org.uk](mailto:CDAORegisterData@cqc.org.uk).

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 2017 we received and approved six CDAO notification exemptions.

The [controlled drugs section](#) on CQC's website now includes [guidance](#) about the exemptions, the criteria that must be met to be appointed as a CDAO, and how different types of organisations can notify us about changes. Revised self-assessment tools will also be available on our website.

## Updates for providers

All information about CQC's activity in relation to controlled drugs is available on our website: [www.cqc.org.uk/controlleddrugs](http://www.cqc.org.uk/controlleddrugs). This includes links to relevant legislation, information and tools for controlled drugs accountable officers, notifications forms, and information about the Controlled Drugs National Group.

## Controlled drug issues found on inspection

In response to feedback on our previous annual reports on safely managing controlled drugs, we have summarised some of our findings from inspections in relation to controlled drugs and the arrangements that we would expect to see in place.

Our findings	Our expectations
<b>GOVERNANCE ISSUES</b>	
<b>CDAO notifications</b>	
We sometimes find that the details of the CDAO on the register do not match those of the CDAO in post – particularly when the CDAO has recently moved to a new role.	We expect a <a href="#">timely notification</a> so that the register is up to date to enable the CDAO to be contacted as required.
<b>Home Office licences for controlled drugs</b>	
There is often a lack of understanding of when a Home Office licence is required and for what schedules.  Also, there is a lack of awareness that there are licences for both Home Office possession and Home Office supply, which providers may need to apply for.	Organisations must seek their own advice. We expect to see evidence on inspection to show that the Home Office has been contacted where a <a href="#">licence</a> might be required.
<b>Lack of awareness of relevant guidance and safety alerts</b>	
Many queries to CQC can easily be answered by referencing the <a href="#">NICE guidance NG46</a> , safety alerts and other sources of information and evidence-based resources such as PresQIPP.	Organisations should be familiar with relevant guidance and ensure that they cascade it where required.  We would like to see on inspection how this has been implemented in wards or departments.
<b>Reporting incidents and concerns</b>	
There is a general lack of awareness of who to report incidents to (either to the organisation's CDAO, the MSO, the NHS England lead CDAO for the area, CQC, other professional and regulatory bodies, the police or the NRLS).	We expect organisations to have a standard operating procedure in place that explains all ways to report and that encourages open reporting and a non-blame culture. We also expect to see evidence of incidents and the learning from them.

<b>Illicit substances</b>	
This issue is becoming more apparent and we are aware of more frequent and increasing quantities being brought onto healthcare premises.	Organisations need to have a clear procedure and maintain a robust audit trail with secure, sealed containment of unknown substances. A small amount can be destroyed locally as an unknown substance. Larger quantities (not for personal use) will need to be notified to the police.
We are aware of some emerging trends, such as patients bringing in their own supply of cannabis containing products such as CBD oil.	If there is a particular trend, this should be communicated to the NHS England CDAO so they can share the issue and any learning with the CDLIN.
<b>ORDERING ISSUES</b>	
<b>Controlled drug mandatory requisition form</b>	
There is a general lack of understanding of when to use the form.	Providers need to follow <a href="#">guidance</a> on the NHS BSA website.
Services are also sometimes unaware that a doctor must sign the requisition if supply is from a separate legal entity.	We expect the organisation to be aware of the requirements set out in <a href="#">MDR 2001</a> .
<b>RECORD KEEPING ISSUES</b>	
<b>Records</b>	
These are generally completed well, although there is sometimes confusion between the controlled drug register and controlled drug record books in wards and departments.	There should only be one controlled drug register at the premises.
<b>Controlled drug record books</b>	
Not all theatres follow the good practice requirement to complete the amount used/amount wasted.	We expect organisations to adopt good practice initiatives.
<b>STORAGE ISSUES</b>	
We find that some organisations still store controlled drugs in wooden cupboards, which do not meet the minimum standard.	We expect organisations named in <a href="#">The Safe Custody Regulations 1973</a> to comply with the regulations, and organisations outside the scope to use the requirements as a minimum standard.
Sometimes the contents of the cupboard do not match what is in the register. This is not usually a stock issue but related to a patient's own or 'just in case' medicines for end of life care.	All drugs stored in a controlled drugs cupboard must be recorded appropriately.

<p>Not all organisations separate high and low strength preparations or those intended for different routes such as epidurals and intravenous injections, which can increase the risk of selecting and administering the wrong preparation.</p>	<p>We expect organisations to carry out their own risk assessment and incorporate relevant guidance into their processes.</p>
<p>Some organisations are unsure how to manage situations where neither the legislation nor guidance covers the exact situation they are dealing with, for example, where controlled drugs are stored in a fridge or robot, or where there is no solid wall to affix the cupboard.</p>	<p>We expect a documented risk assessment to be in place. Above all, controlled drugs must remain secure, for example, a separate secure container for controlled drugs that need refrigeration, or secure storage within a robot. An exemption certificate issued by the police may also be required.</p> <p>Where there is no solid wall, other measures should be considered, for example, strengthening an internal wall or reviewing the location of the cupboard, and the decision recorded in a risk assessment that is reviewed regularly.</p>
<p><b>Access to controlled drugs</b></p>	
<p>Access to keys and cupboards is generally managed well.</p>	<p>We expect a standard operating procedure to be in place that covers access to keys, and staff to adhere to it. We also expect to see monitoring in place as we are aware that controlled drugs are often diverted by those with legitimate access.</p>
<p><b>PRESCRIBING ISSUES</b></p>	
<p>Nationally, there is a general naivety regarding diversion issues.</p>	<p>It is important to minimise the quantity of a controlled drug prescribed and to regularly review the patient's ongoing need. It is particularly important to consider the quantity issued in an emergency and for temporary residents until checks are carried out.</p>
<p>Organisations do not always consider the need for a reversal agent (a medicine that reverses the effect of the medicine administered to the patient).</p>	<p>We expect this to be considered as part of the prescription where appropriate, and it may need to form part of a clinical protocol.</p>

<b>ADMINISTRATION ISSUES</b>	
There is some uncertainty regarding administration of controlled drugs by a single nurse and the need for two signatures, and some organisations are unclear whether single nurse administration is allowed.	A single nurse can administer a controlled drug unless the local policy says otherwise. If a second checker is not a registered nurse, they must understand or be familiar with what they are being asked to check. We would expect to see that a competency assessment had been completed.
Dose calculations are a common cause of errors – particularly with new formulations or devices.	It is important to have training and competency assessments for difficult calculations or unfamiliar devices. Clinicians should be encouraged to ask for a second check if they are unsure or unfamiliar with the product or formulation.
Body maps are not always in place when applying transdermal patches. There is also a lack of awareness of the effect of heat, the importance of removing a previous patch and the need to check the patch every day.	Application and removal of transdermal patches continues to cause concern, and we expect to see appropriate arrangements in place to ensure that patches are managed safely.
<b>AUDITING AND MONITORING ISSUES</b>	
Some organisations are unaware of the importance of recording and auditing all stages of the controlled drug journey, and the need for standard operating procedures and ongoing regular review.	We expect the standard operating procedures to cover all aspects of controlled drug management and for these to be kept under review with supporting audits.
We find insufficient monitoring and audit, and are aware of thefts and diversion of controlled drugs, particularly those in lower schedules where there is less control, for example dihydrocodeine or morphine sulphate solution 10mg/5ml.	We expect organisations to risk-assess their controlled drug arrangements, with regular monitoring according to their organisational needs, to keep losses to a minimum.
<b>DESTRUCTION ISSUES</b>	
Some organisations are unaware of the requirement to hold a T28 exemption form for denaturing controlled drugs.	Organisations that denature controlled drugs must obtain a <a href="#">T28 exemption form</a> from the Environment Agency.
There is also uncertainty around disposing of large volume infusions (for example, hospital PCAs etc).	Large volume controlled drugs should be discarded using an absorbent material to soak up the liquid.
Organisations are also not always clear what to do with completed denaturing kits.	These must be stored securely until removed for incineration.

## Issues identified when prescribing from multiple sources

In our last update we highlighted the increasing volumes of controlled drugs being prescribed for patients. There are also risks when patients obtain controlled drugs from more than one provider, which can enable them to stockpile controlled drugs. This increases the potential for diversion and misuse, risk of accidental death, and of suicide from overdose, which is particularly pertinent for patients with long-term pain, a group at high risk of suicide.

All services should consider these risks, as well as the benefits of informing the patient's GP when prescribing opiate-containing painkillers, to enable them to ensure that patients are kept safe and that GPs maintain an overview of all the medicines prescribed to their patients.

This applies to independent providers as well as NHS providers, including GP out-of-hours, secondary care services and those offering online-only consultations with clinicians using video or questionnaire-based modalities. Safety measures should include prescribing a minimum supply according to the patient's individual needs and enquiring whether the patient already has an existing stock at home.

### Recommendation 1

Prescribers should ask patients about their existing prescriptions and current medicines when prescribing controlled drugs. Where possible, prescribers should also inform the patient's GP to make them aware of treatment to minimise the risk of overprescribing that could lead to harm.

## NHS England's area teams and controlled drug local intelligence networks

NHS England's lead CDAOs currently run 39 controlled drugs local intelligence networks (CDLNs) across the 14 NHS England areas, with membership from a wide range of organisations.

There were around 200 meetings of CDLNs during 2017 and membership continued to include a wide range of organisations. Meetings were held between two and four times a year, with many areas meeting three times a year. CQC continued to attend these, and contributed a written meeting update when unable to send a representative.

There was good attendance during 2017, but we noted an over-reliance by some organisations on sending different deputies to meetings, which led to a lack of continuity and ability to contribute fully to the meeting. Some members commented that they have found their CDLIN meetings too large and felt this had also hampered discussion.

The range and depth of issues discussed during 2017 remained broadly similar to previous years. The most commonly reported and discussed incidents were reported thefts, amended or wrongly dispensed prescriptions and general governance issues.

We summarise some of the ongoing concerns below.

Issues of concern	Solutions to consider
<b>LACK OF CENTRALISED SYSTEMS</b>	
<p>There is a risk that private prescriptions and requests for controlled drugs could be forged. This is because community pharmacies do not have access to a national register of controlled drugs personal identification numbers (CDPINs), which means they cannot verify legitimacy of private prescriptions and requisitions for Schedules 2 and 3 controlled drugs.</p>	<p>An up-to-date national register of CDPINs would be beneficial.</p>
<p>There is a risk of inappropriate use and theft of controlled drugs in dental practices. This is because dentists do not use a unique identifier for requesting and prescribing them, therefore NHS England CDAOs and commissioners cannot monitor their prescribing for outlying or potentially dangerous practice.</p>	<p>It is important that dentists have their own unique identifier.</p>
<p>There is a risk of inappropriate and duplicated prescribing of controlled drugs to temporary residents, as there is no central register of temporary residents for prescribers to check.</p>	<p>A central patient database accessible to prescribers would be welcome, so that patients who try to access controlled drugs from more than one service could be easily identified and supported where required.</p>
<p>Because of changes in primary care support services there are risks associated with lack of oversight and control of secure stationery to private prescribers.</p>	<p>The governance arrangements for issuing prescription pads need to be strengthened to avoid over-ordering and potential misuse.</p>

<b>RESOURCES</b>	
In some areas there is a risk that NHS England CDAOs will not be able to fulfil their statutory obligations and deliver responsibilities effectively because of a general lack of resource and small support teams. This may mean less monitoring of prescribing, leading to concerns being missed.	The inconsistency in resourcing requires a national review.
Similarly, some areas do not have access to and support from a controlled drugs liaison officer.	This also requires a national review so that all areas are supported.
<b>INFORMATION GOVERNANCE</b>	
There is a general lack of clarity on issuing controlled drug alerts, particularly regarding the level of detail that should be included.	NHS England CDAOs would welcome a national view on this, particularly following new data protection legislation. There is also a need to consider sharing alerts with cross-border colleagues.

Through our attendance at CDLNs we are aware of new organisations and mergers of existing organisations. Ongoing changes to the ways in which health and care are now being delivered have resulted in increasing complexity of commissioning arrangements and consequently controlled drug governance arrangements. It is important to include the oversight of controlled drug governance and reporting arrangements when commissioning services.

### **Recommendation 2**

Commissioners of health and care services should include the governance and reporting of concerns around controlled drugs as part of the commissioning and contracting arrangements, so that these are not overlooked.

With regard to thefts of controlled drugs, we have noted some increasingly sophisticated methods, which include stealing identification badges from healthcare professionals and impersonating them in order to obtain controlled drugs.

### **Recommendation 3**

Healthcare professionals should keep their personal identification badges and passwords secure and report any losses as soon as possible to enable organisations to take the necessary action.

## Controlled Drugs National Group

The CQC-led Controlled Drugs National Group comprises government departments, key regulators and agencies with a controlled drugs remit. The group met three times in 2017 to share and discuss emerging issues and identify 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 members of CDLNs about developments and policy initiatives.

In 2017, the National Group welcomed two new member organisations – the Nursing and Midwifery Council and the Human Fertilisation and Embryology Authority. We have published a separate summary of highlights from the past year showing how member organisations contribute to the overall safer management of controlled drugs.

## Sub-groups

The sub groups met three times during 2017, either in person or by teleconference. Membership comprised relevant stakeholders, such as NHS England lead CDAOs, specialist pharmacists and medicine safety officers, other government bodies, NHS Business Services Authority, and chief pharmacists. Other healthcare professionals with relevant expertise were also invited as required.

We introduced a new style joint newsletter of the sub-groups, which replaces the four separate newsletters previously produced by the Policy, Vigilance, Prescribing and Patient Safety sub-groups. This was developed using the new GovDelivery system and circulated in September and December to over 3,000 subscribers with an interest in controlled drugs.

You can [subscribe to newsletters](#) on our website.

## Cross-Border Group

The Cross-Border Group for safer management of controlled drugs in the devolved administrations met in March and September 2017. 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 alongside this update of their major activities during 2017.

# National trends in the use and management of controlled drugs

During 2017, NHS primary care services prescribed a total of 61,440,701 controlled drug items, which was a decrease of 2% compared with 2016. The cost of this was £495,105,901.46, a decrease of 7% on the previous year.

Additionally, 1,045,052 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 2017. Hospital prescribing was broadly in line with that for 2016.

**Please note:** Data on prescribing is collected by an online application, which provides analyses of prescribing data held by NHS Prescription Services to authorised users. The previous ePACT system has now been replaced by [ePACT2](#), which has resulted in some differences in data. In this report we provide year-on-year data comparisons for 2016 and 2017 by extracting both years from ePACT2. This means that some data for 2016 is different to that published in last year's update, which was extracted from the legacy system (ePACT). Any data referenced in this report that is before 2016 will be as previously published, using the legacy ePACT system.

## Primary care prescribing of controlled drugs

### Schedule 1 controlled drugs

No controlled drugs in Schedule 1 are licensed for medicinal purposes.

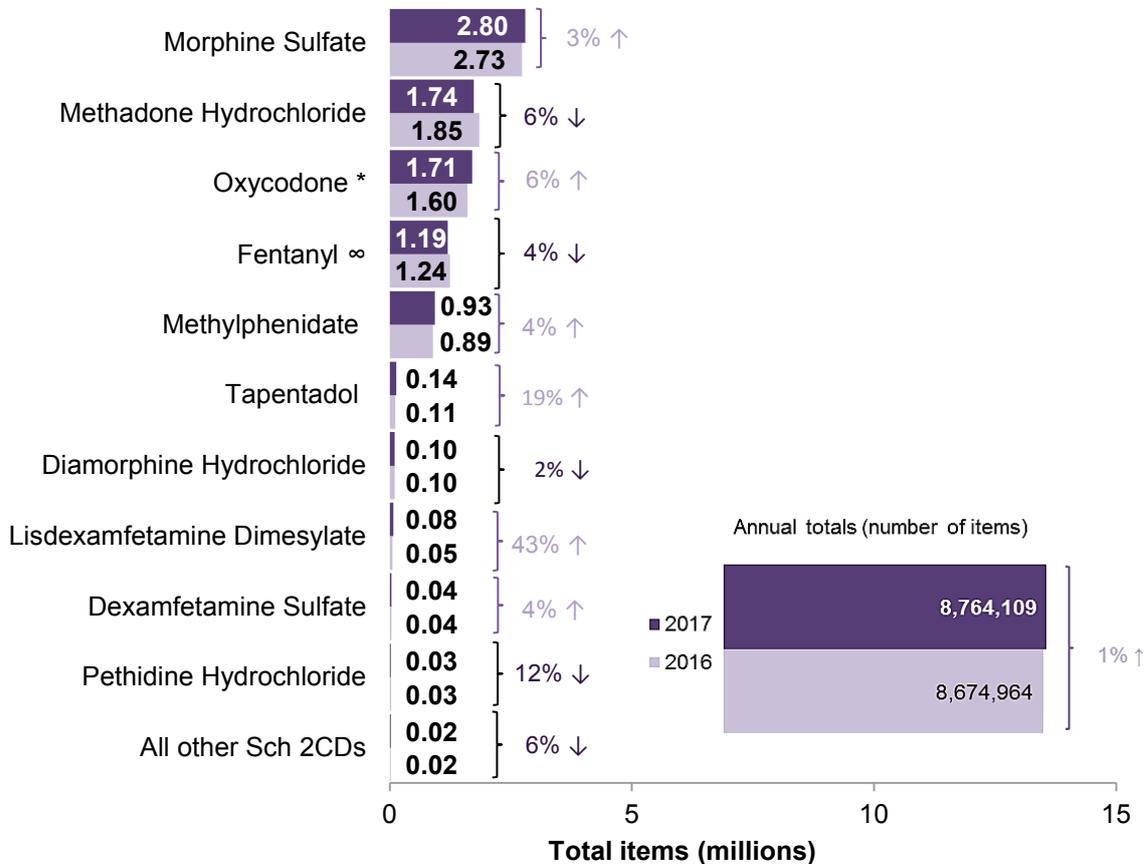
### Schedule 2 controlled drugs

This year, we have separated Schedules 2 and 3 so that we can look at the trends more closely.

Although the pattern of prescribing of Schedule 2 controlled drugs was broadly comparable with 2016, there was a 19% increase in prescribing of tapentadol. Similarly, prescribing of morphine and oxycodone continued to increase. However, prescribing of fentanyl decreased by 4% and pethidine prescribing continued to decrease as in previous years.

Prescribing of all controlled drugs for the treatment of attention deficit hyperactivity disorder (ADHD) increased compared with 2016: methylphenidate prescribing increased by 4%, lisdexamphetamine prescribing increased by 43%, and dexamfetamine prescribing increased by 4%.

**Figure 1: Top 10 Schedule 2 controlled drugs prescribed in NHS primary care in 2016 and 2017 (by millions of items)**

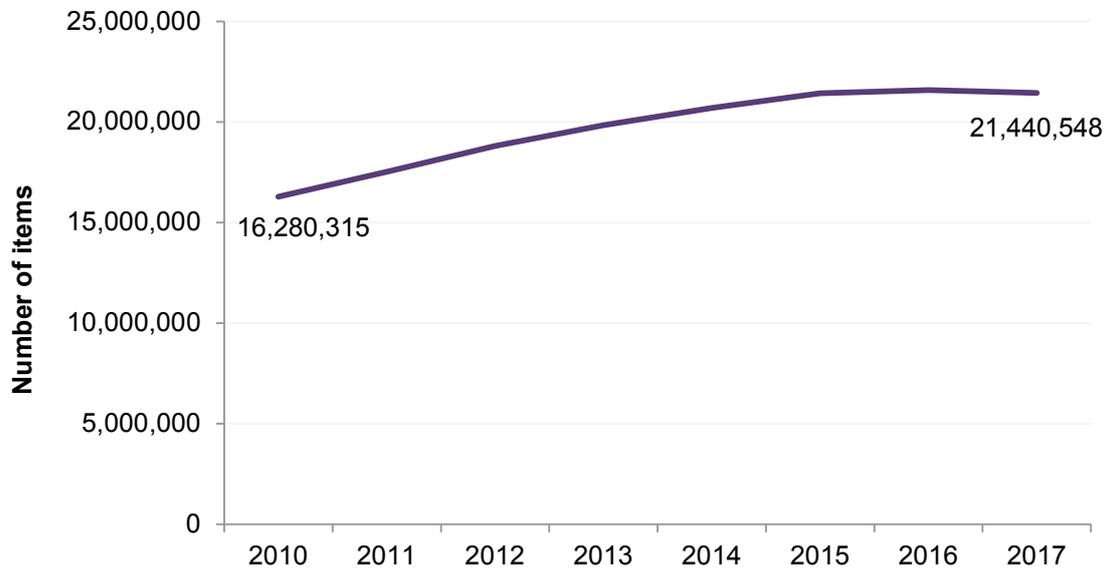


\* Oxycodone figures include the combination product Targinact (oxycodone and naloxone).

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

Although prescribing of opiates is broadly similar year on year, the trend when reviewed over an eight-year period clearly shows a steady long-term increase in the overall prescribing. Figure 2 shows the increase for controlled drugs commonly prescribed for the management of chronic pain. The percentage increase from 2010 to 2017 is 32%.

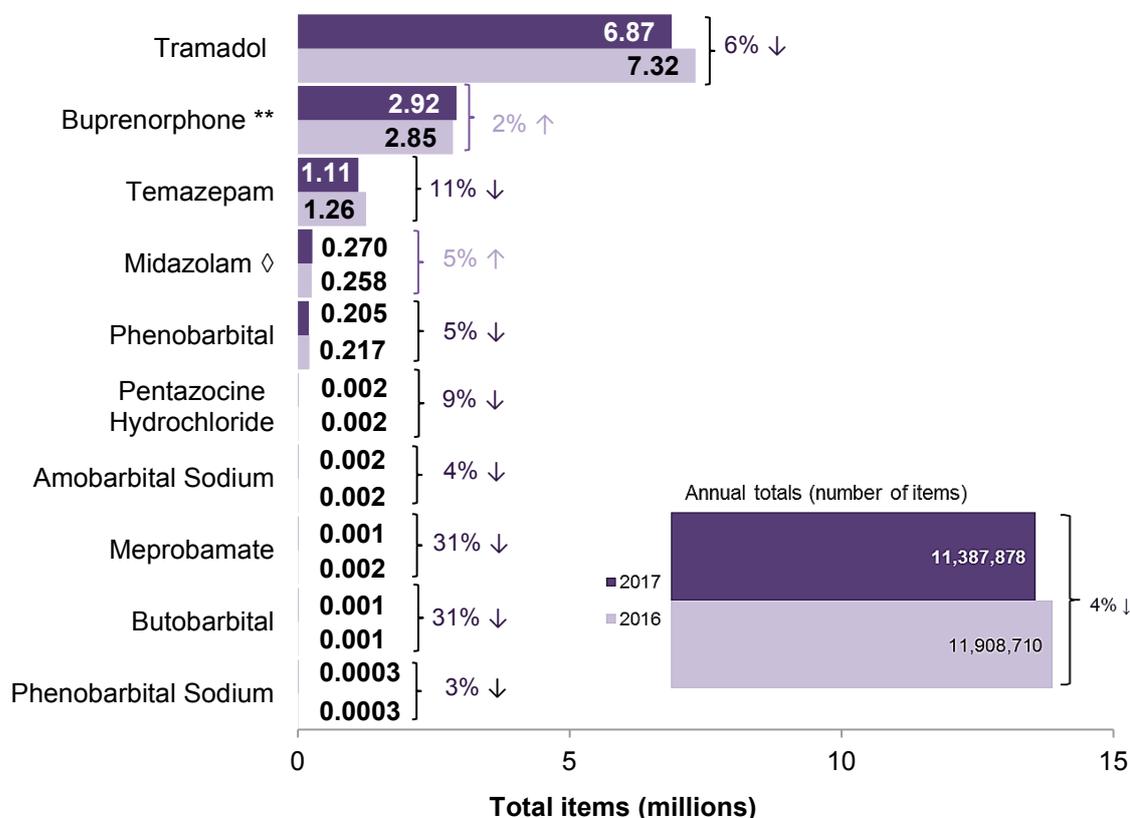
**Figure 2: Controlled drugs prescribed to manage chronic pain 2010 to 2017**



### **Schedule 3 controlled drugs**

The pattern of prescribing of Schedule 3 controlled drugs was broadly comparable with 2016 (figure 3). Tramadol and temazepam prescribing continued to fall as in 2016, and buprenorphine and midazolam prescribing continued to increase. We have not previously looked at some of the barbiturate preparations such as amobarbital sodium, butobarbital and phenobarbital sodium, but their use, as anticipated, is decreasing. Meprobamate use is also declining.

**Figure 3: Top 10 Schedule 3 controlled drugs prescribed in NHS primary care in 2016 and 2017 (by millions of items)**



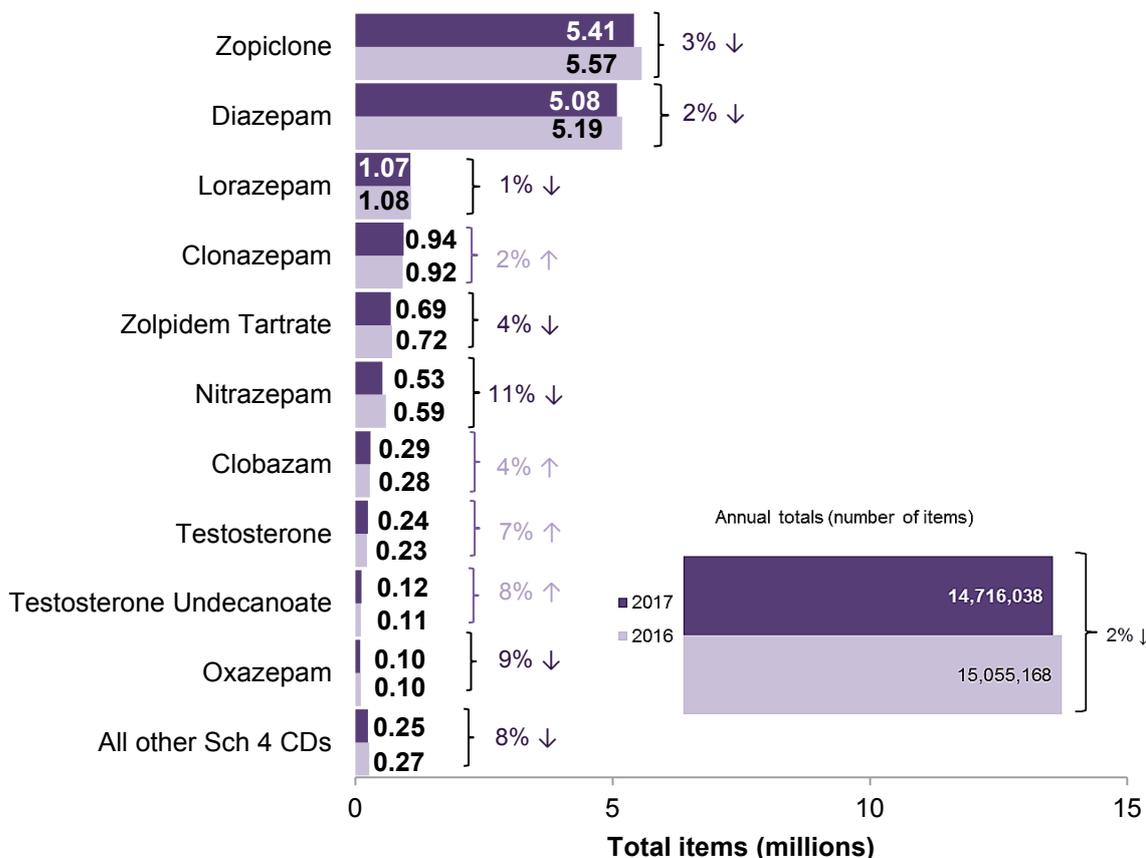
\*\* Buprenorphine figures include the combination buprenorphine/naloxone.

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

## Schedule 4 controlled drugs

The pattern of prescribing of Schedule 4 controlled drugs also remains broadly comparable with 2016, with use of most of the benzodiazepines and zopiclone and zolpidem decreasing (figure 4). Use of clonazepam and clobazam continued to increase as in 2016, and both testosterone and testosterone undecanoate use also increased compared with 2016.

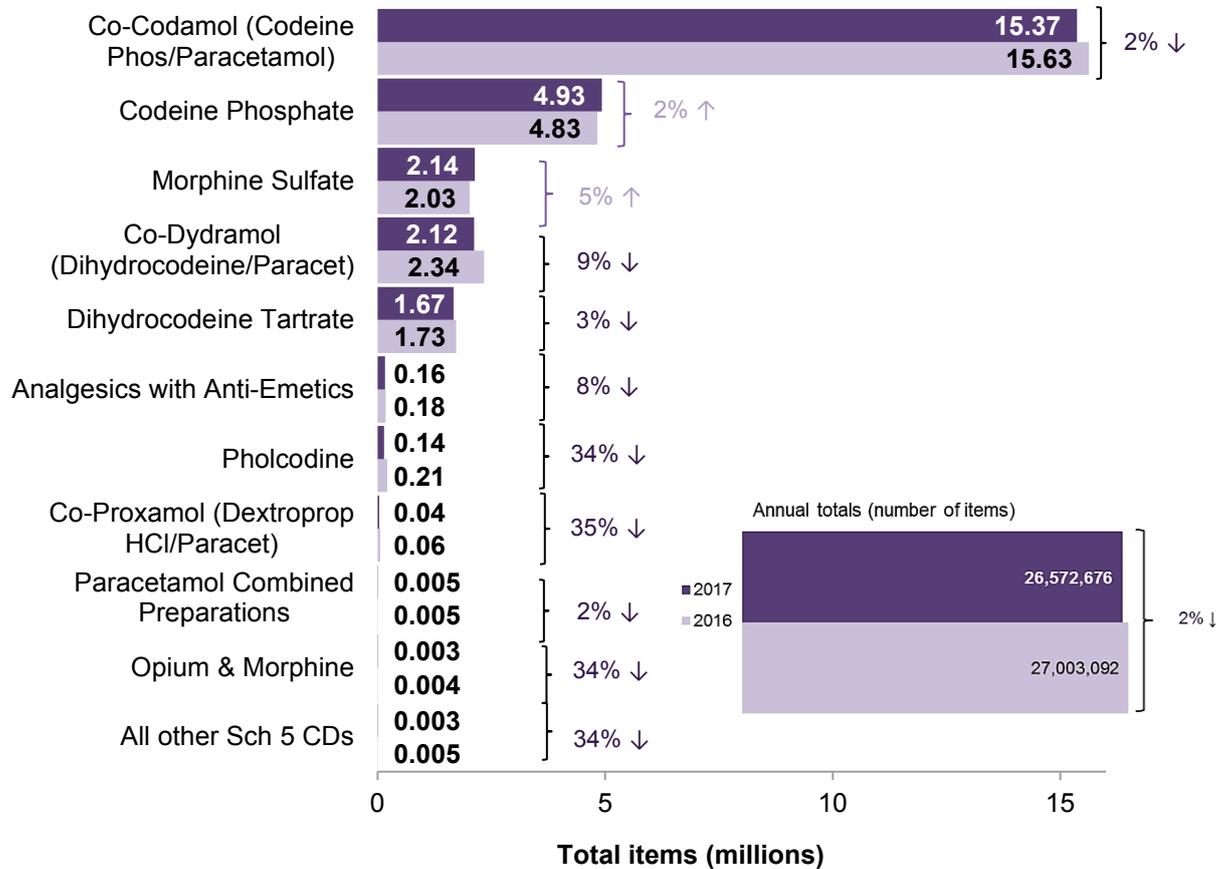
**Figure 4: Top 10 Schedule 4 controlled drugs prescribed in NHS primary care in 2016 and 2017 (by millions of items)**



### Schedule 5 controlled drugs

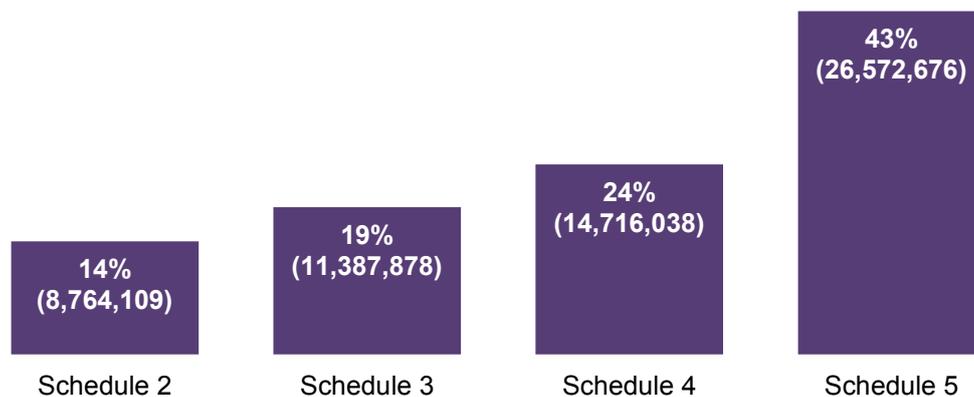
Although the general pattern of prescribing of Schedule 5 controlled drugs remains broadly comparable with 2016, co-dydramol has now dropped to fourth position and is replaced by morphine sulphate oral solution as the third most prescribed Schedule 5 controlled drug. Similarly, analgesics with anti-emetics (to treat the side-effect of nausea) have replaced pholcodeine in sixth position. Use of co-proxamol and opium and morphine products continues to fall, as expected.

**Figure 5: Top 10 Schedule 5 controlled drugs prescribed in NHS primary care in 2016 and 2017 (by millions of items)**



## Summary of controlled drug prescribing by Schedule

**Figure 6: Summary of controlled drug prescribing by schedule for 2017 (percentage and number of items)**



Discussions both in controlled drug local intelligence networks (CDLINs) and our National Prescribing Sub-group have brought to light concerns regarding misuse by health and care professionals across all settings of lower schedule controlled drugs, such as codeine and dihydrocodeine.

Because the controls are less stringent, misuse can go unnoticed potentially for a long period and can be difficult to trace. When we look at the breakdown of prescribing in primary care by schedule, 67% of all the controlled drugs prescribed are in Schedules 4 and 5. We therefore encourage health and care providers to be vigilant and put in place monitoring arrangements for lower schedule controlled drugs where required, particularly where previous audits have identified unexplained losses.

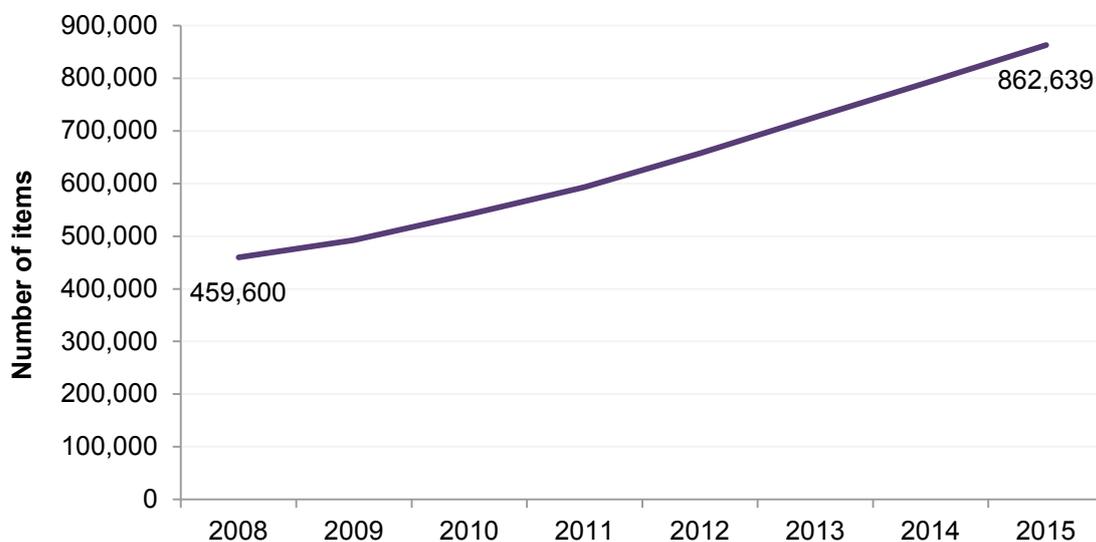
#### Recommendation 4

Health and care staff should consider regular monitoring and auditing arrangements for controlled drugs in the lower schedules, such as Schedules 4 and 5, to identify and take swift action on diversion.

### Ten-year trends

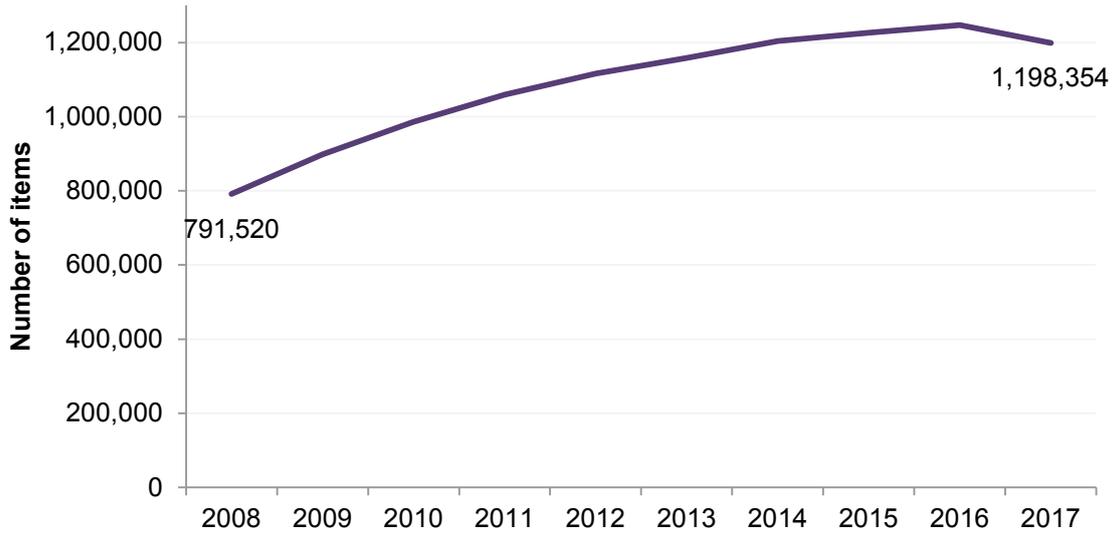
This year, we also take the opportunity to highlight prescribing trends over the last 10 years for a few commonly-prescribed controlled drugs.

**Figure 7: Methylphenidate prescribing 2008 to 2015**



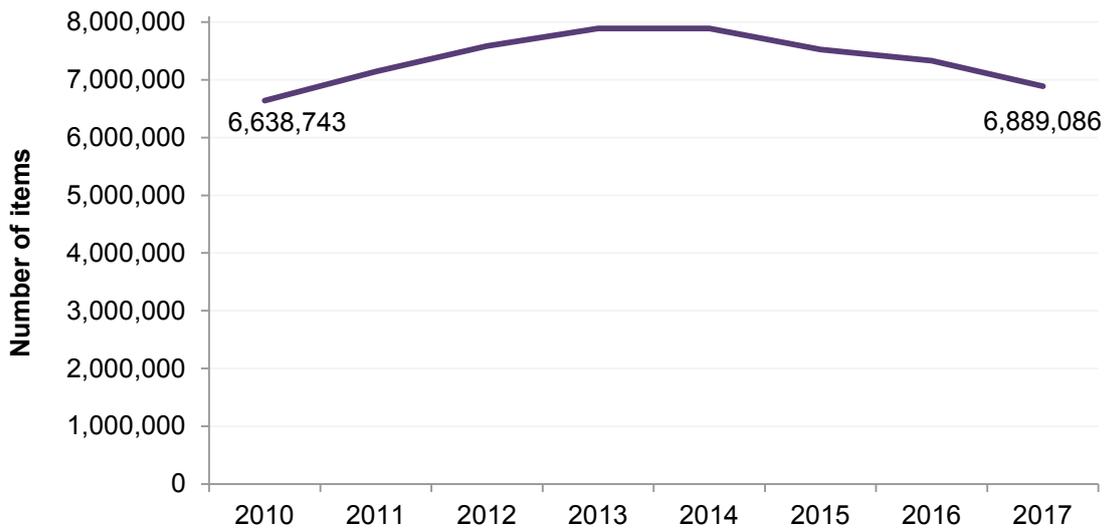
Please note, Figure 7 only shows data to 2015 because of a discrepancy in 2016 and 2017 data retrieved from the two different ePact systems. However, we know that prescribing of methylphenidate continues its increasing trend year on year.

**Figure 8: Fentanyl prescribing 2008 to 2017**



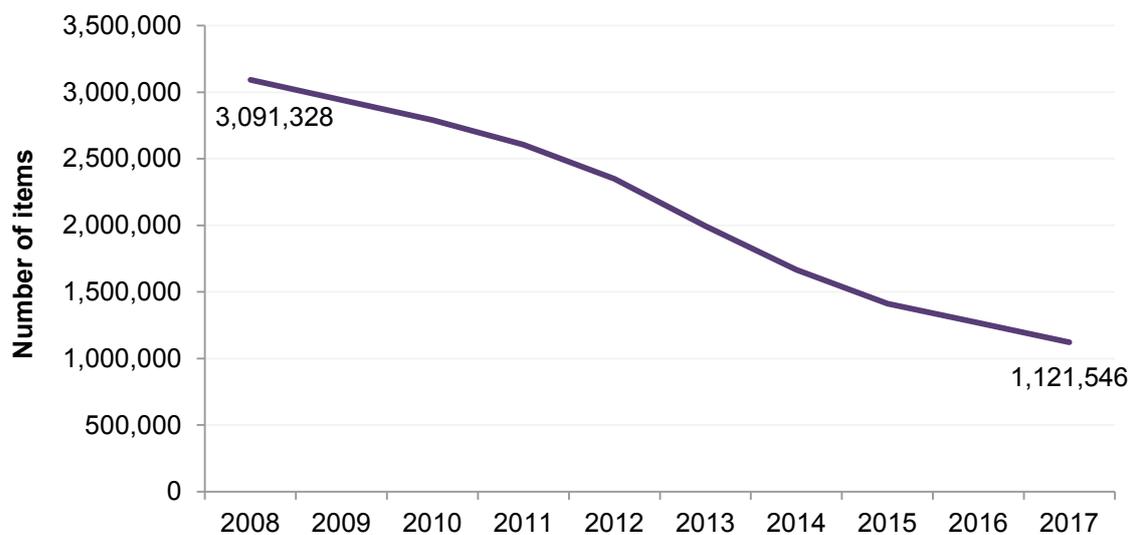
Fentanyl prescribing has increased year on year, until a decrease of 4% in 2017.

**Figure 9: Tramadol prescribing 2010 to 2017**



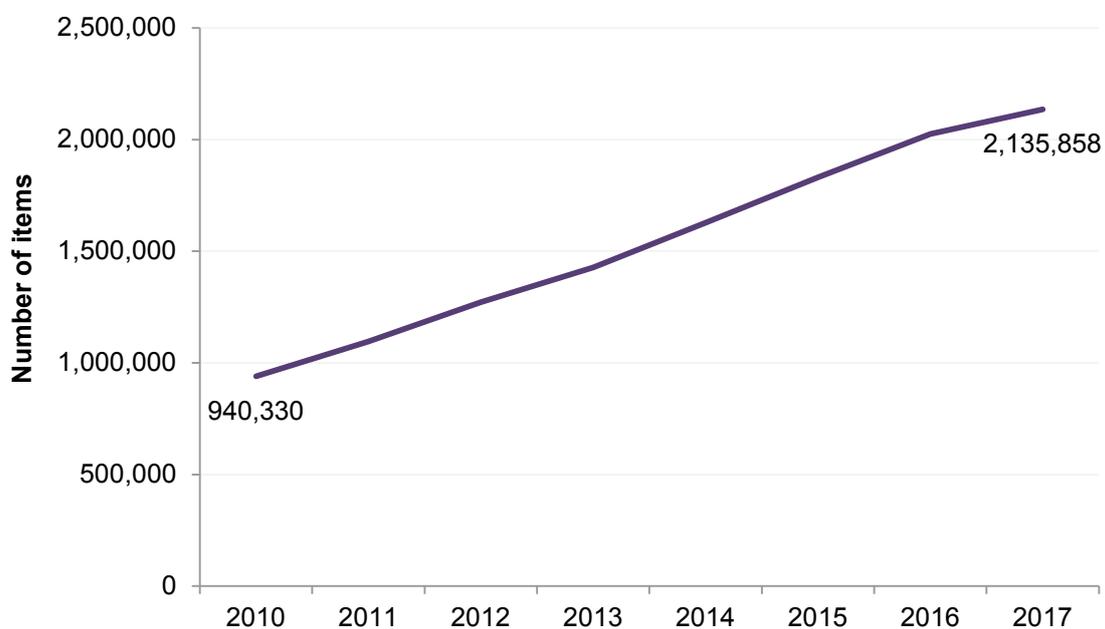
Tramadol prescribing increased year on year until it was classed as a Schedule 3 controlled drug in 2014, after which we have seen a year-on-year decrease in its prescribing.

**Figure 10: Temazepam prescribing 2008 to 2017**

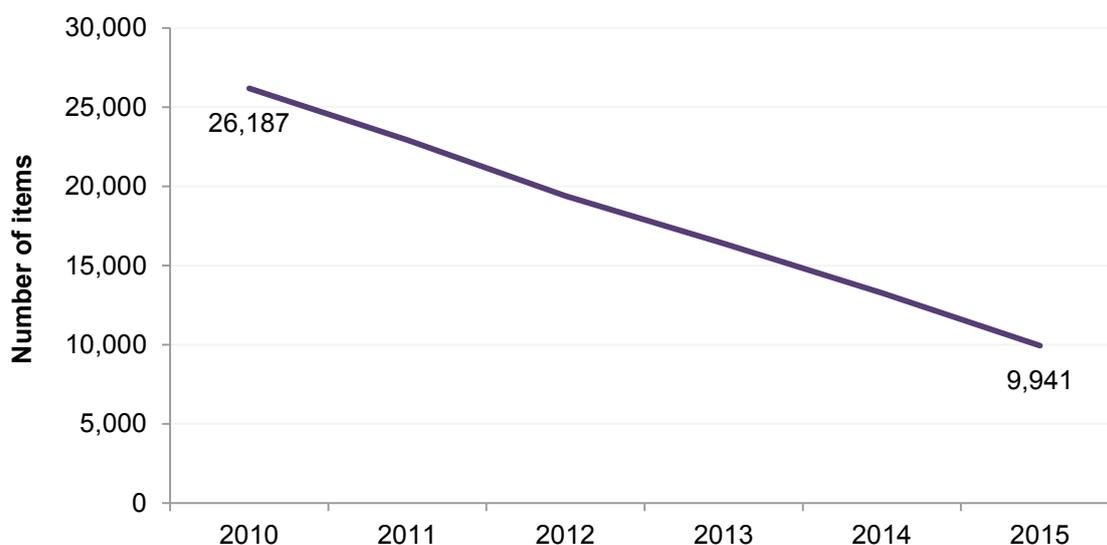


Prescribing of Temazepam has continued to decrease.

**Figure 11: Morphine sulphate oral solution 10mg/5ml prescribing 2010 to 2017**



**Figure 12: Dipipanone hydrochloride prescribing 2010 to 2015**



Our National Controlled Drug prescription monitoring sub-group has also been looking at prescribing of the opioid analgesic dipipanone. NHS England lead CDAOs have been following this up with GP practices to remind them to be vigilant when prescribing it as abuse is well documented, and to only continue prescribing it where clinically appropriate. The continuing decrease in prescribing is a welcome finding.

Although the chart only shows data up to 2015 because of the discrepancy in 2016 and 2017 data retrieved from the two different ePact systems, we know that dipipanone prescribing continues to decrease each year.

## Non-medical prescribing

As in 2016, the volume of prescribing of controlled drugs by pharmacists in 2017 almost doubled from 259,394 to 487,036 items. The increase in nurse prescribing was around 6%, which was in line with the increase in 2016, from 1,120,681 items to 1,184,802.

Physiotherapist and podiatrist prescribing of controlled drugs continued to be at minimal levels, collectively amounting to just over 200 items.

## Controlled drug prescribing in the independent sector

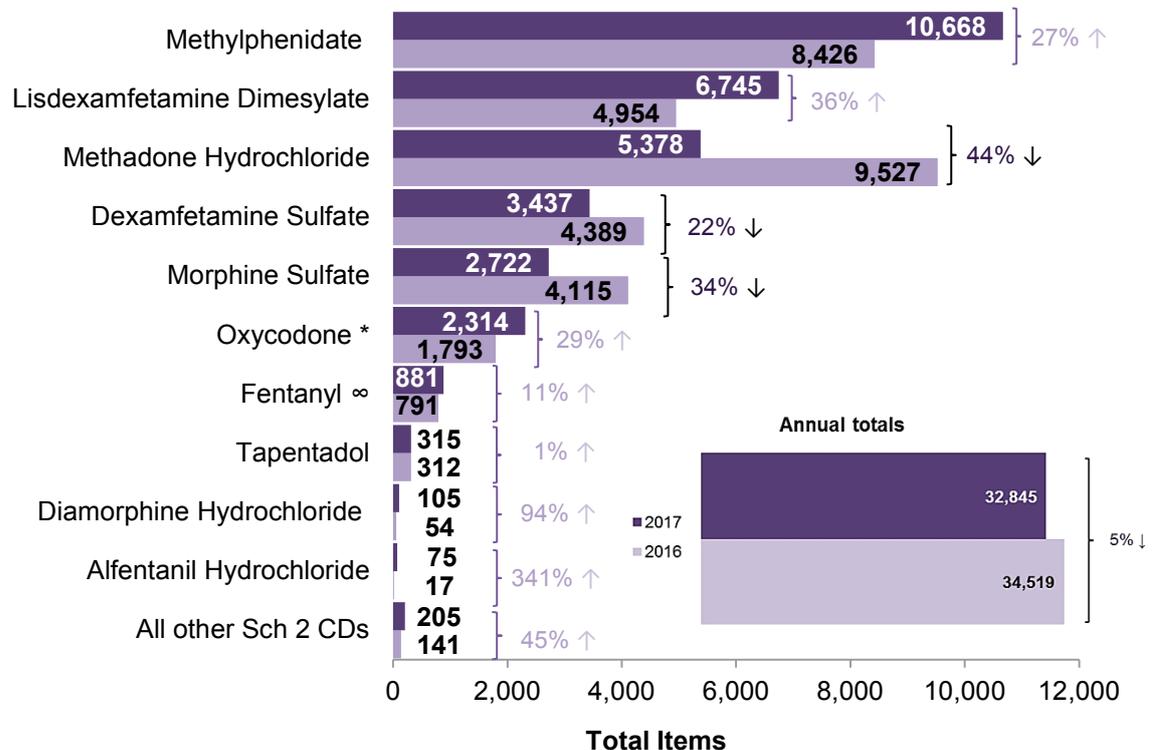
Overall prescribing of controlled drugs by private or independent healthcare providers continues to account for less than 0.1% of all controlled drug prescribing, similar to 2016.

### Schedule 2 controlled drugs prescribed privately

In 2017, the pattern of private prescribing of Schedule 2 controlled drugs stayed broadly similar to 2016, with the exception of methadone, where prescribing decreased by 44%, which moved it from first to third place. Methylphenidate and lisdexamphetamine, both used in the treatment of ADHD are now the most commonly privately prescribed Schedule 2 controlled drugs, with dexamfetamine, also used to treat ADHD, being in fourth place.

The prescribing of oxycodone and fentanyl continued to increase as in 2016, but morphine prescribing decreased by 34%. This is the first year that we have separated Schedule 2 and 3 controlled drugs. Compared with 2016, the prescribing of diamorphine increased by 94% although the overall quantity remains small. The increase may be attributable to previous supply shortages. Alfentanil also increased by 341%, some of which may be due to inappropriate prescribing as it should be reserved for use in kidney injury. However, the quantity similarly remains small. We will monitor both of these over the coming year.

**Figure 13: Top 10 Schedule 2 controlled drugs prescribed in private prescribing in 2016 and 2017 (number of items)**



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

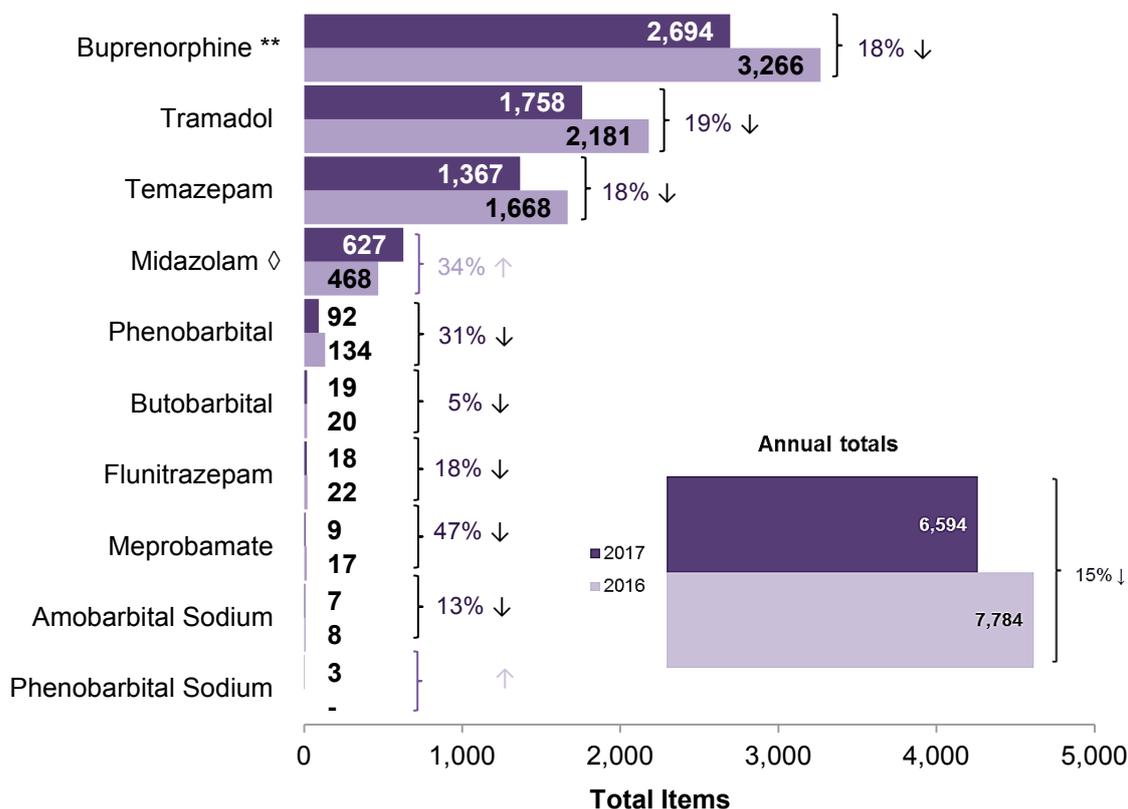
∞ Fentanyl figures include fentanyl transdermal patches and small amounts of other fentanyl products.

### Schedule 3 controlled drugs prescribed privately

In both 2016 and 2017, there was a decrease in private prescribing of methadone, and we therefore anticipated a corresponding increase in buprenorphine prescribing, as in 2016. However, this has not been the case and private prescribing of buprenorphine has instead decreased by 18%. The reasons for this are not clear and we will monitor this over the next year.

Tramadol and temazepam prescribing have decreased in line with NHS primary care prescribing. Similarly, while we have not previously looked at private prescribing of some of the barbiturate preparations such as amobarbital sodium, butobarbital and phenobarbital sodium, their use, and that of meprobamate are decreasing as expected.

**Figure 14: Top 10 Schedule 3 controlled drugs prescribed in private prescribing in 2016 and 2017 (number of items)**



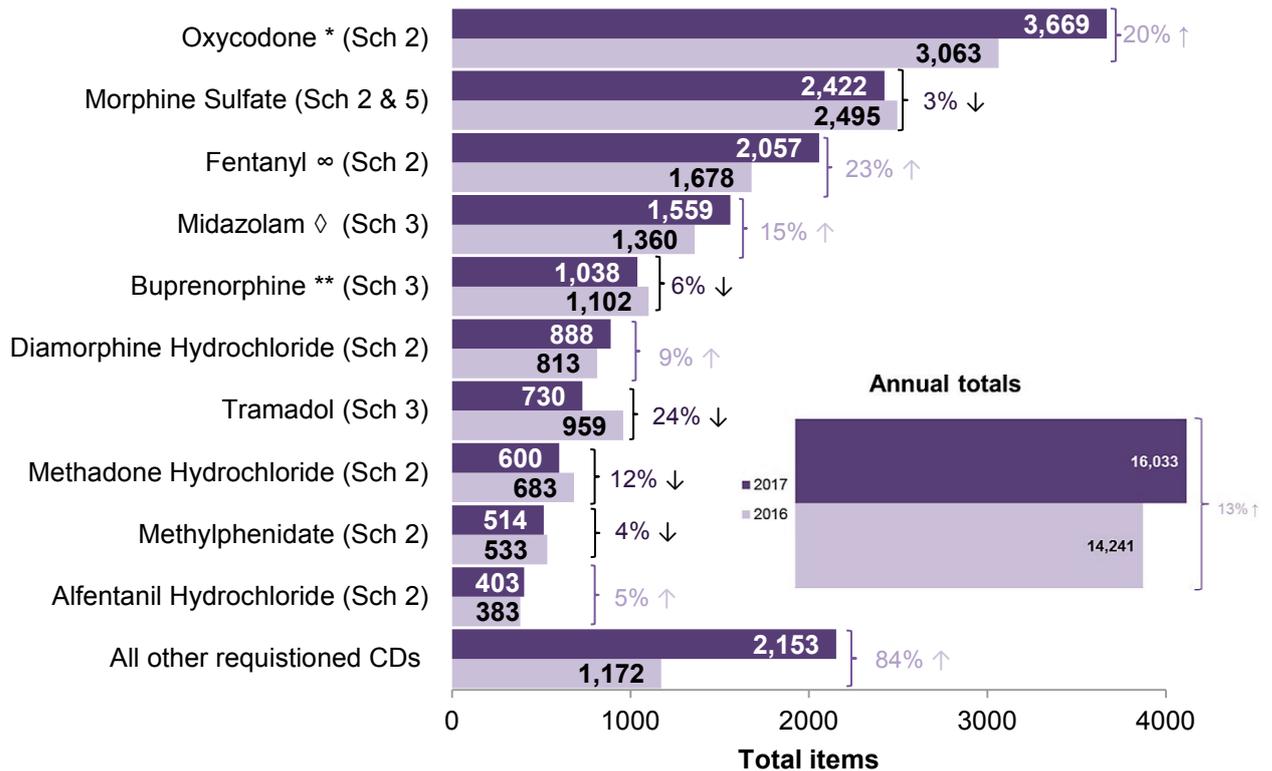
\*\* Buprenorphine figures include the combination buprenorphine/naloxone.

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

## Controlled drug requisitions

In 2017, the overall number of individual items on a requisition increased to 16,033 compared with 14,241 in 2016, an increase of 13%. The general pattern is broadly similar to 2016.

**Figure 15: Top 10 controlled drugs requisitioned in 2016 and 2017 (number of items)**



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

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

\*\* Buprenorphine figures include the combination buprenorphine/naloxone.

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

## Next steps

At the time of writing this report, we are particularly aware of the inquiry into the deaths of patients at Gosport War Memorial Hospital, which found that patients died through opioids prescribed "without medical justification". Although controlled drug governance arrangements are now strengthened compared with those in the 1980s and 1990s, there is no room for complacency. Services should think about incorporating self-assessment, monitoring and clinical audit into their controlled drug arrangements and review their reporting culture.

There has also been widespread parliamentary and media interest in cannabis products being used for medicinal purposes. Work is currently underway to consider the rescheduling and licensing requirements for cannabis products to allow wider access for certain conditions.

Moreover, health care is now being delivered across England in increasingly new and complex ways, and people are able to access services more easily across borders and through the internet. This adds additional challenges for health and care providers, and organisations need to build on the work carried out so far under the regulations, so that the arrangements for the safe management and use of controlled drugs are not overlooked in this changing landscape, and that patient safety is placed at the forefront of all decision making.

The scale of diversion of controlled drugs during 2017 is also a concern and CQC is continuing to support the work of other agencies to address this.

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