# Registered pharmacies providing cannabisbased products for medicinal use (CBPM)

A themed review



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# **About the GPhC**

# Who we are

We are the regulator for pharmacists, pharmacy technicians and pharmacies in Great Britain.

We are a statutory organisation set up by the UK and Scottish parliaments, and we are independent from government and those we regulate. Our role and functions are set out in legislation called the Pharmacy Order.

We are funded by fees paid by the pharmacists, pharmacy technicians and pharmacies that register with us.

### What we do

Our main role is to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy.

We set standards to make sure that every pharmacy provides safe and effective care. And we provide guidance to help pharmacy owners achieve this.

We also inspect pharmacies to assess whether they are meeting our standards and to help them improve their systems and services.

# **Executive summary**

In 2018, cannabis-based products for medicinal use (CBPMs) were reclassified from Schedule 1 to Schedule 2 of the Misuse of Drugs Regulations. This change allowed CBPMs to be supplied against a valid prescription from an appropriately registered prescriber. CBPMs must be initiated by a specialist doctor listed on the GMC's Specialist Register, with expertise in the condition being treated.

Since the legislative change, CBPM prescribing has increased significantly particularly within the private sector. The most recent data shows a 130% rise in CBPM prescriptions between March 2023 and March 2024, with over 99.5% of these prescriptions issued in independent (private) healthcare settings, according to the **2024 annual update**, *The safer management of controlled drugs*.

The GPhC, along with other UK regulators and partner organisations, is working to improve the safety, accountability, and effectiveness of CBPM prescribing and supply. As part of this effort, we committed to publishing a themed review focussed on the supply of CBPMs, with a focus on the roles of pharmacists, pharmacy technicians, pharmacy support staff, and the pharmacy premises involved. We conducted a desk-based review of registered pharmacies identified as providing CBPMs as a key service.

We identified 25 pharmacies that regularly supplied CBPMs, of which 24 were actively registered and operational at the time of our review. Seventeen of the inspected pharmacies met all GPhC standards for registered pharmacies. We also reviewed 68 concerns related to the management and supply of CBPMs.

Our analysis revealed that pharmacies supplying CBPMs face a range of challenges. We also observed good practices developed by some pharmacies to mitigate risks.

Our findings show that stronger collaboration and better information-sharing between prescribing clinics, suppliers, pharmacies, and other healthcare providers is needed. Working together in this way is key to identifying and reducing the risks linked to CBPM supply.

We encourage all organisations involved in CBPM supply to review and act on the findings and recommendations outlined in this report.

This report will be shared with key stakeholders including other regulators, relevant government departments, professional leadership bodies and representative organisations in Great Britain, to help build shared understanding and support collaborative working.

# **Background**

In recent years, we have seen an increase in the use of cannabis-based products for the management of a range of medical conditions such as intractable nausea and vomiting, severe treatment-resistant epilepsy, spasticity, chronic pain, anxiety disorders, and post-traumatic stress disorder (PTSD) according to **NHS England**, and the **National Institute for Health and Care Excellence (NICE)**.

Cannabis contains many active compounds such as tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is the main psychoactive ingredient, responsible for the 'high' associated with cannabis. Even at low doses, it can cause effects such as drowsiness, euphoria, and altered time perception. These can affect cognitive and motor functions, including the ability to drive safely. Because of this, **THC is controlled under UK drug-driving laws**.

Pure CBD is not psychoactive and is not considered a CD under <u>the Misuse of Drugs Act 1971</u>. CBD products are often marketed as THC-free, but many contain varying amounts of THC and other cannabinoids. <u>CBD products are often sold as food supplements and must not make medicinal claims</u>.

The Misuse of Drugs Regulations (MDR) 2001 sets out how CDs are used legally in the UK. Schedule 1 drugs are considered to have little or no medical value. Drugs in Schedules 2 to 5 have medical uses and are controlled to different levels based on their therapeutic benefits and level of harm if misused. In November 2018, cannabis-based products for medicinal use (CBPMs) that meet the legal definition were reclassified to fall under <u>Schedule 2 of the Misuse of Drugs Regulations</u>, and could therefore be supplied against a valid prescription from an appropriate registered prescriber.

### Definition

A cannabis-based product for medicinal use in humans as per Regulation 2(1) of the Misuse of Drugs Regulations 2001 (MDR) (as amended) means a preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4, or paragraph 10 of Schedule 5, applies, which:

- a) is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers);
- b) is produced for medicinal use in humans;
- c) is a product that is regulated as a medical product, or an ingredient of a medicinal product

CBPMs are unlicensed, meaning the Medicines and Healthcare products Regulatory Agency (MHRA) has not assessed their quality, safety, or effectiveness. In the UK, the Home Office, the Department of Health and Social Care (DHSC) and the MHRA are responsible for regulating unlicensed CBPMs.

### Forms of medicinal cannabis

There are 3 licensed products of medicinal cannabis available, which are not classified as CBPMs:

- Sativex® (Schedule 4 CD) used for moderate to severe spasticity in multiple sclerosis (MS)
- Nabilone (Schedule 2 CD) for nausea and vomiting associated with chemotherapy
- Epidyolex® (Schedule 5 CD) used for seizures associated with Lennox-Gastaut or Dravets Syndrome

Unlicensed CBPMs are available in several forms and contain different ratios of THC and CBD. These include oils which are used orally or sublingually (under the tongue), dried cannabis flower for inhalation

using a dry-heat or vaporiser device, and oral products like capsules and pastilles. MHRA approved vaporisers should be used as the smoking of cannabis-based products are still prohibited under <u>the</u> <u>Misuse of Drugs Act 1971</u>

# **Prescribing and supplying CBPMs**

CBPMs are unlicensed medicines, which means that prescriptions must be issued on a named-patient basis and initiated by a specialist doctor listed on the GMC's specialist register with expertise in the condition being treated. If a doctor is on the Specialist Register, their registered status is listed on the **GMC medical register**.

For the treatment of children and young people, the initiating prescriber should be a tertiary specialist experienced in the relevant condition they are advising CBPM for use in, as set out in guidance from NHS England and NICE. Other clinicians, such as Pharmacist Independent Prescribers, can continue prescribing if the specialist doctor who initiated the prescribing asks them to do so under a shared care agreement<sup>1, 13</sup>. Licensed cannabis-derived medicines such as Sativex®, Epidyolex® and nabilone are not classified as CBPMs and are not subject to the same prescribing restrictions for initiation.

MHRA guidance states that CBPM prescribing should be based on unmet clinical need, and not influenced by cost, convenience, or operational factors. Prescribers should always first consider prescribing medicines that are licensed for the specific condition that a patient presents with. They must follow relevant guidance on prescribing unlicensed medicines and clearly explain to patients that their treatment is unlicensed.

Private prescriptions for CBPMs must comply with Schedule 2 CD requirements and be issued on relevant CD prescription forms. The prescriptions should include the prescriber's six-digit identification number. Pharmacies should submit private CD prescriptions for CBPMs to the relevant authorities at the end of each month to enable prescribing to be monitored.

# Regulatory oversight and concerns

Although the government committed to reviewing the impact of the 2018 legislative change, the Advisory Council on the Misuse of Drugs (ACMD) noted in 2020 that meaningful data on CBPMs would take time to emerge. In June 2025, the Home Office asked the ACMD to carry out a further review of CBPM supply. The review will examine the current evidence, assess how effective existing supply and prescribing systems are, identify any unintended consequences, and recommend improvements.

The Care Quality Commission (CQC) identified CBPMs as a key area of concern in its **2024 annual update**, *The safer management of controlled drugs*. The report highlighted a 130% increase in CBPM prescriptions between March 2023 and March 2024.

Over 99.5% of CBPM prescribing is in the independent (private) healthcare sector, with the top 5 prescribers accounting for 55% of prescriptions. NHS primary care prescribing remained very limited, averaging fewer than five items per month since 2018.

We noted the report also states that pharmacist prescribers undertake the majority of CBPM prescribing. From information shared with us by NHS England, we also know that 98% of all CBPM products in England were supplied by 10 registered pharmacies during this period.

We, along with other UK regulators, have recognised the need to strengthen oversight of CBPM activity across the UK. We are working together with government departments and other organisations including other regulators to improve the safety, accountability, and effectiveness of CBPM prescribing and supply.

# What we did

We committed to publishing a themed review on the supply of cannabis-based products for medicinal use (CBPM), with particular focus on the roles of pharmacists, pharmacy technicians, pharmacy support staff and the pharmacy premises involved.

We carried out a desk-based review of registered pharmacies identified as providing CBPM as a key service, using targeted keyword searches of our inspection webpages. We also analysed data from the NHS Business Services Authority (NHSBSA) which listed the top ten dispensing pharmacies of CBPMs and reviewed all GPhC concerns received in relation to CBPM supply from these pharmacies.

Through this review, we aim to:

- clarify the GPhC's regulatory remit in relation to CBPM activity for stakeholders and registrants
- identify trends and themes to support better understanding of:
  - the challenges in providing these services, including which standards pharmacies find difficult to meet
  - areas requiring improvement
  - examples of good practice

By identifying the above, we hope this report will:

- provide the GPhC inspection team with an overview of key focus areas relating to the supply of CBPM, including areas of risk, examples of good practice, and gaps in current inspection methodology
- highlight gaps in GPhC data which could be addressed through closer collaboration with relevant stakeholders (e.g. the CQC and the relevant local lead Controlled Drugs Accountable Officers)
- contribute evidence to the ACMD's ongoing evaluation of the CBPM supply landscape

# What we found

We identified 25 pharmacies which regularly supplied CBPMs. Of these 24 were actively registered and operational at the time of review. Seventeen of these pharmacies focused primarily or exclusively on supplying CBPMs as a core part of their service. We reviewed 68 concerns related to the management and supply of CBPMs from these 25 pharmacies.

Of the 17 pharmacies which supplied CBPM as a core service, five did not meet all the required inspection standards. We imposed conditions on one pharmacy, and four received improvement action plans. At the time of writing this document, three of these pharmacies have since met standards and one is awaiting re-inspection after implementing changes.

Of the eight pharmacies where CBPM supply was not a core service, three did not meet all standards at the time of inspection and were issued with improvement action plans. At the time of writing this document, one pharmacy has since met standards and the remaining two have planned re-inspections.

Inspection data focused on the 26 <u>standards for registered pharmacy premises</u> which are grouped under five key principles: **governance**, **staffing**, **premises**, **services**, and **equipment and facilities**. This review analysed themes and trends from inspection reports and concerns received, with a focus on the first four principles.

### Governance

Seven pharmacies failed to meet standards under this principle, including four where CBPM supply was a core service.

# Identifying and managing risk

Our inspections assessed how effectively pharmacies identified and managed service-related risks. Those which managed risks well typically used tailored risk assessments for each aspect of their CBPM services. These commonly covered key areas such as:

- risks associated with providing services at a distance, with mitigation strategies such as how to prevent oversupply
- how third-party prescribers are verified and monitored
- oversight of prescribing practice and checking if prescriptions are clinically suitable
- risks from look-alike/sound alike (LASA) CBPM products
- accuracy and ease of dosing and administering cannabis oils
- secure storage of CBPMs
- managing short shelf lives
- obtaining products from approved suppliers
- · safe and appropriate destruction of CBPMs

### What worked well

We saw good practice in a number of pharmacies, including:

- rolling plans for reviewing their risk assessments, with one pharmacy conducting quarterly reviews by an external pharmacy consultant
- relevant, regularly reviewed standard operating procedures (SOPs) for CBPM-related services, with version control were seen in most pharmacies. These covered areas such as the assessing clinical need of CBPMs, safe handling and record-keeping of CDs, and onboarding and verification of prescribers
- processes for staff to flag discrepancies between SOPs and actual practice, prompting timely updates to ensure they remained accurate

## **Areas for improvement**

Some pharmacies had gaps in their risk management processes:

- one had no formal risk assessments in place
- some risk assessments were missing key details such as implementation or review dates, or systems for identifying the severity of the risk
- some risk assessments failed to address CBPM-specific issues, such as setting limits on the supply quantities of unlicensed CDs
- some pharmacies were unable to demonstrate that team members had read and followed the most up-to-date SOPs

### **Our recommendations**

We recommend that pharmacies conduct and document robust risk assessments for all aspects of the CBPM-related services they provide. These should cover the whole process from start to finish and be supported by SOPs. Both risk assessments and SOPs should include a clear plan for regular review, with all updates clearly documented.

### Oversight of third-party prescribers

Pharmacies are expected to ensure that any third-party clinics and prescribers they work with operate safely, are regulated within the UK and follow relevant UK guidelines. We found varying levels of due diligence checks by pharmacies of the third-party clinics and the prescribers they work with. Most had onboarding processes to check that partner clinics were registered with relevant regulators such as the CQC. Most pharmacies also confirmed whether prescribers were listed on the GMC Specialist Register or had appropriate shared care arrangements in place.

### What worked well

We saw good practice in a number of pharmacies, including:

- regular checks (ranging from monthly to annually) on the registration status of third-party clinics and prescribers. This allowed one pharmacy to identify a prescriber who was no longer registered with the GMC, which they fed back to the clinic
- one pharmacy held formal interviews with clinics before agreeing to work with them
- keeping records of key documents such as proof of the clinic's indemnity insurance, prescribers' GMC registration and scope of practice, shared care agreements, prescribing policies, confirmation of information sharing with GPs, and relevant continuing professional development (CPD) records

# Monitoring safety and quality

We found varying approaches to how pharmacies reviewed and monitored the safety and quality of their services, particularly regarding near misses and dispensing errors. Some pharmacies had structured systems for recording, reviewing, and learning from mistakes.

### What worked well

We saw good practice in a number of pharmacies, including:

- pharmacy teams used electronic systems to log near misses which created a clear audit trail.
   These were reviewed regularly by the superintendent pharmacist or a designated Patient
   Safety Lead, and the outcomes shared during team huddles, daily briefings, or regular governance meetings.
- pharmacy teams proactively conducted regular audits and developed post-audit action plans to update risk assessments and SOPs.
- pharmacies separated look-alike/sound-alike (LASA) products, such as different strains or strengths of cannabis oils, to reduce the risk of selection errors
- pharmacy teams using coloured tape on shelving to visually distinguish similar products and prevent confusion during picking

# Areas for improvement

### Some pharmacy teams:

- reviewed near misses and dispensing errors inconsistently or kept incomplete records,
   making it harder to identify issues and make changes
- failed to make the changes needed to prevent dispensing errors from recurring, for example making necessary changes to workflow or drug storage to prevent dispensing errors

### Some pharmacies:

- could not show evidence of regular audits of their prescribing services, such as checking prescriber registration, or confirming prescribers were following relevant guidelines
- had poor oversight of complaints and concerns made about their services, missing opportunities to learn and make improvements

### **Our recommendations**

We recommend that pharmacies record and review incidents in a consistent manner to support learning and improvement. Regular audits can help confirm whether safe standards are being met and highlight areas for development.

# Safeguarding

CBPMs are often prescribed to individuals with complex medical needs. Because of the risk of misuse and diversion, and the vulnerability of patients who may require CBPMs, robust safeguarding measures are essential. We found that many pharmacies had systems and procedures in place to protect vulnerable people, though the effectiveness and consistency of these measures were variable.

Most pharmacies had documented safeguarding SOPs, and staff generally understood how to recognise and report concerns. We also saw that most Responsible Pharmacists (RPs) had completed Level 2 or 3 safeguarding training, and several pharmacies extended this training to all staff, including delivery drivers.

### What worked well

We saw good practice in a number of pharmacies, including pharmacy teams:

- appointing designated safeguarding leads, set out clear escalation routes, and provided visible signposting to local and national support services
- recording details of safeguarding concerns and taking proactive steps to reduce risks
- working closely with prescribing clinics to identify vulnerable patients and setting individualised limits on the amount of CBPM supplied at one time
- training delivery staff to recognise safeguarding issues and ensured their courier services used age-verification processes when delivering CDs

# Areas for improvement

In some cases, only the RP had completed safeguarding training meaning other staff were not aware of how to identify or report concerns.

One pharmacy acknowledged it didn't check for compliance with its courier's over-18 delivery policy.

One pharmacist had inappropriately prescribed CDs to a person with a known history of drug misuse, despite having completed safeguarding training.

### Our recommendations

All patient-facing staff should complete safeguarding training at a level appropriate to their role, so they can identify and report concerns. Pharmacy teams should also ensure that third-party providers follow agreed safeguarding procedures.

### **Dealing with complaints and concerns**

Most pharmacies had a documented complaints procedure and a clear process for receiving and handling feedback. Many also made this information easy to find, either via their websites or within the pharmacy premises. Some pharmacies also monitored social media and third-party review sites, such as Trustpilot, to spot service issues and gather feedback.

### What worked well

Complaints about delayed or missed deliveries of CBPMs were commonly heard by one online pharmacy. In response, the pharmacy team held regular meetings with its courier provider to highlight issues and improve service reliability. This pharmacy also set up a weekly complaints committee to review specific cases and put in place key performance indicators for handling complaints.

One pharmacy used a dashboard to track complaints from its associated prescribing clinic, which helped it stay informed about any issues.

# **Areas for improvement**

Some pharmacies did not have clear processes in place for handling complaints.

One pharmacy forwarded all complaints to third-party prescribing clinics, which often resulted in a new prescription being issued. However, it kept no internal records and did not carry out any investigations of its own, raising concerns about the pharmacy's level of oversight.

# **Record keeping**

Keeping accurate records of dispensed medicines is a legal requirement, and helps assure accountability, traceability, and the safe supply of CBPMs. Our inspectors mainly focused on assessing records kept by the pharmacies themselves, and not those from the prescribing clinics. We found that most pharmacies used suitable systems to manage their records. Common records checked during inspections included:

- CD registers and stock audits
- RP records
- private prescription records
- · certificates of analysis and conformity for unlicensed medicines
- relevant import/export licenses
- prescriber registration verification
- service level agreements with third-party providers

Most pharmacies we inspected used electronic systems to manage CD registers, RP records, and private prescriptions. These were generally completed accurately.

We found that the frequency of CD stock checks varied between pharmacies, ranging from daily to monthly. Our inspectors reviewed how often prescriber registration records were checked by pharmacy teams. One pharmacist who conducted regular checks, identified a prescriber who had failed to renew their registration, and alerted the prescribing clinic.

# **Areas for improvement**

### Some pharmacies had:

- incomplete RP logs, infrequently documented CD balance checks and missing or inaccurate prescriber information in private prescription records
- incomplete records for unlicensed medicines, which were missing key details such as batch numbers or expiry dates

One pharmacy that carried out infrequent CD stock checks was found to have multiple stock discrepancies, highlighting the importance of regular checks to support earlier investigation into discrepancies.

### **Our recommendations**

Pharmacies need to keep accurate and up-to-date records to support safety and meet legal obligations. This includes completing RP logs, CD stock check, and relevant details for unlicensed medicines. The *Medicines, Ethics and Practice* **produced by the Royal Pharmaceutical Society** advises organisations to check CD balances at least weekly. However, frequency may be more or less, depending on factors such as the volume of CDs dispensed and frequency of past discrepancies.

## Information governance and confidentiality

Protecting patients' privacy and confidentiality is a key part of safe and ethical pharmacy practice. Inspectors reviewed whether pharmacies had the right systems, training, and procedures in place to ensure personal data was securely managed.

Most pharmacies had documented information governance policies and provided staff with relevant training. This was often supported by signed confidentiality agreements for staff and visitors. Some pharmacies were also registered with the Information Commissioner's Office (ICO).

As expected, confidentiality was easier to maintain in pharmacies without public access. We found all pharmacies with public access had dedicated consultation rooms to protect patient privacy.

We received one concern where a patient reported feeling misled after being referred to a third-party prescriber without this being made clear. They had believed the prescriber was part of the pharmacy's legal entity and viewed the referral as a potential breach of confidentiality.

### What worked well

We saw good practice in a number of pharmacies, including:

- access controls in place to ensure staff only accessed information relevant to their role
- use of secure digital platforms for third-party prescribers to upload prescriptions and securely share patient information
- clear display of privacy policies on websites and within pharmacy premises
- clear processes to manage confidential waste
- some online pharmacies had separate rooms for carrying out consultations or private phone consultations

## **Areas for improvement**

One pharmacy placed confidential waste place with pharmaceutical waste due to time constraints.

Some pharmacies stored bagged medicines with visible patient details in public view.

Some pharmacies had consultation rooms located near the medicines counter, so prescription details were visible to people walking past.

One pharmacy left completed consultation forms unsecured in a consultation room where patients were left alone, creating a risk of unauthorised access to this information.

### **Our recommendations**

We recommend that pharmacies ensure confidential waste is securely stored and disposed of. Patient information should not be visible to the public, and all records kept secure particularly if stored in areas such as consultation rooms that are accessible to the public. Patients must be informed when services are provided by third parties and their consent obtained before sharing information. We encourage pharmacy teams to conduct information governance audits to check adherence to policies and strengthen good practice.

# Clearly defined roles and lines of accountability

Our inspectors found that most pharmacies had clearly defined staff roles, supported by a strong awareness of which tasks could or could not be carried out without a RP present.

Dispensing assistants understood their limits, such as not handing out medicines in the RP's absence and knowing when to escalate clinical queries. Most pharmacies had clear audit trails showing who had dispensed and checked each item, and many kept prescription logs to track the journey of each prescription.

### What worked well

Some pharmacies used digital systems such as the pharmacy's electronic PMR system to create a clear audit trail of who was involved at each stage of the dispensing process.

When a single pharmacist was responsible for both dispensing and checking, they separated the two stages, allowing a mental break to reduce the risk of errors.

# **Areas for improvement**

One pharmacy pre-signed all dispensing labels before they were attached to the medicine, making it unclear who was responsible for each stage of the dispensing process.

# Staff training and development

Three pharmacies failed to meet standards under this principle, two of which supplied CBPMs as a core part of their service.

Most pharmacies had enough suitably trained staff to deliver CBPM services safely and effectively. Roles were generally well defined across dispensing, administration, and customer service functions. To support continuity, pharmacies often used locum pharmacists who were trained in the specialist service. Larger online CBPM focussed pharmacies frequently employed dedicated customer service teams to handle non-clinical queries. Administration and customer service teams were sometimes trained to cross-cover each other.

More established pharmacies which supplied CBPM as a core service, often provided specialist training alongside general mandatory training. They often built in protected learning time into staff schedules. Pharmacy teams in these settings generally showed good awareness of the legal and operational requirements for handling CDs and unlicensed products.

We found CBPM specific training was delivered through a range of platforms, including internal resources, in-house sessions led by pharmacists experienced in CBPM supply, and externally available training modules. Pharmacy teams typically relied upon various external training resources, including supplier-led sessions covering topics like product cultivation, transport, production, and dispensing guidance. However, training sources were not always clearly specified on inspection, making it difficult to assess the credibility of some learning packages. One pharmacy reported receiving cannabis-specific training from a platform which does not offer training specifically on cannabis-based products.

### What worked well

Pharmacies provided structured induction pathways for new starters, with tailored training resources for CBPM supply.

Robust onboarding processes that included cannabis-specific training for locum pharmacists.

Some pharmacies tracked progress of staff training using matrices or portfolios.

Regular formal performance reviews for all staff members.

One pharmacy used an 'end of SOP' quiz to assess understanding of the contents.

One pharmacist reported working closely with prescribing clinics and participating in multidisciplinary team meetings for pain management and psychiatry to enhance their clinical understanding of CBPM supply.

Some organisations supported learning by circulating newsletters or bulletins.

One pharmacy technician developed and shared a factsheet on different CBPM products to help improve dispensing accuracy.

# **Areas for improvement**

In pharmacies where CBPM supply was not a primary focus, the availability of cannabis-specific training was more variable or not clearly documented.

Some pharmacies were unable to provide assurance that team members had received appropriate training for their specialist services, including the handling of CDs and unlicensed CBPMs.

Two pharmacies assigned dispensing tasks to staff who were not suitably qualified. In one case, CBPM prescriptions were assembled and handed out without the presence of an RP.

# Using professional judgement

Most pharmacy teams reported feeling empowered to use their professional judgement to support the safe and appropriate supply of CBPMs. In cases where teams had access to consultation notes, prescribing policies, and National Care Records, they were able to provide clear examples of clinical interventions, such as:

- querying with the prescriber the rationale for changing from flowers to various oil formulations
- identifying potential interactions with a patient's regular medication
- clarifying appropriate doses for individual patients

Where clinical records were not available, interventions were usually limited to checking formulation changes, verifying doses, or preventing excessive supply based on dispensing history, rather than assessing the clinical suitability of the prescription.

# Areas for improvement

One pharmacist had limited ability to carry out meaningful clinical checks for potential interactions, as they had no access to the patient's medical history or consultation notes. As a result, the pharmacy functioned primarily as a 'supply-only' service.

One large online CBPM pharmacy acknowledged that it had no access to the consultation records from its partner clinic. It also faced challenges accessing National Care Records as it operated as a private provider without an NHS contract. In this case, the superintendent pharmacist relied on assurances that prescribers had carried out the necessary checks before onboarding patients.

#### Our recommendations

We recommend that pharmacies work collaboratively with third-party clinics to enable access to relevant clinical information, to enable thorough clinical checks and reviews before supplying CBPMs and promoting effective multidisciplinary working. It is essential that prescribers have adequate knowledge of the patient and the condition being treated, to enable safe and appropriate prescribing decisions.

# **Raising concerns**

Overall, we found pharmacy teams felt empowered to raise concerns and provide feedback at work. Many pharmacies had whistleblowing policies in place, and staff knew who to escalate concerns to—typically the RP or superintendent pharmacist. Some pharmacies held multidisciplinary huddles with prescriber clinics to share feedback and address operational issues collaboratively. Several also offered additional support through access to employee assistance programmes and confidential helplines.

We heard that working environments were generally described as open and supportive. Teams were encouraged to share ideas and feedback both informally and through regular meetings. Common discussion topics included patient safety, workflow challenges, and service improvements. In one case, staff feedback led to changes in the dispensary layout to improve workflow.

## **Incentives and targets**

Our inspections did not identify any evidence that targets or incentives were being used that compromised patient safety or wellbeing. However, we do not have evidence to suggest that targets for third party clinics were assessed on inspection.

### **Premises**

One pharmacy supplying CBPM as a core service failed to meet standards under this principle.

Most pharmacies we inspected were safe and suitable for providing CBPM services. Premises were generally well maintained, with clearly marked and organised workspaces to support safe workflow. As certain products are sensitive to environmental fluctuations (particularly heat and moisture), some pharmacies used air conditioning and temperature controls to maintain appropriate storage conditions.

Most online pharmacies used their websites to provide information about their services rather than allowing people to order medicines. The websites generally met GPhC guidance for distance selling. They clearly displayed the pharmacy's name, registration number, address, and contact details to support feedback or raising concerns. The owner's and superintendent pharmacists name and registration number were also clearly displayed.

### **Areas for improvement**

Some websites were missing registration details for the superintendent pharmacist

One website had not removed an outdated 'online shop' link. This was addressed following the inspection.

# **Security**

Given the high-risk nature and controlled status of CBPMs, robust security is critical to ensure products are safeguarded from theft, misuse, or unauthorised access. Pharmacies had strong security arrangements, including alarm systems, CCTV, coded or keycard entry, and external shutters. Some operated from industrial units with gated access and on-site security. Visitors were often required to sign in and had restricted access to specific areas. Some pharmacies added extra security by keeping dispensaries out of public view, avoiding signage that revealed the nature of the business, and installing panic buttons and separate alarms for CD rooms.

# Safe and effective delivery of pharmacy services

Six pharmacies failed to meet standards under this principle, including three where CBPM supply was a core service.

# Access to pharmacy services

Two thirds of the pharmacies we inspected offered services at a distance and were not directly accessible by members of the public. Their websites clearly showed contact details, opening hours, and outlined the services they offered. Most gave patients different options to communicate with them, including phone, email, live chat or web forms. Some also offered secure portals for patients to track their prescriptions.

Some pharmacies used dedicated customer service teams to contact new customers and explain how the service worked. They discussed details of the delivery service and estimated timeframes, payment methods, complaints procedures, and how to contact the pharmacy for further support. Clinical queries were passed to the pharmacy team, and responses either relayed via the customer service team or handled directly by the pharmacist.

### What worked well

Several pharmacies had key performance indicators in place to monitor response times for calls and emails from the public. These were reviewed monthly maintain service quality.

Some pharmacies used translation tools and large-print labels for people with visual impairment, to further support with accessibility

### Patient information and advice

Pharmacy teams have a duty to support patients in using CBPMs safely and effectively. One pharmacist described offering verbal advice on health and lifestyle topics, such as managing anxiety, fear, and panic. Others provided patient information leaflets that explained the purpose of the medicine, potential side effects, precautions, considerations around long-term use, and how to safely dispose of unused CBPMs.

The use of CBPM may impair a person's ability to drive safely, and all patients supplied CBPM should be advised of this risk. We found product labels typically included information about the risks associated with driving under the influence of the medicine, in line with MHRA guidance.

### What worked well

Some pharmacies gave patients a copy of their prescription, so they could demonstrate they had been prescribed the product and were in lawful possession of the product if needed.

Some pharmacies clearly informed patients that CBPM were unlicensed, either through website information or by providing patient information leaflets.

# **Areas for improvement**

Some pharmacies relied entirely on prescribing clinics to provide counselling and inform patients about the unlicensed nature of CBPMs.

One pharmacist had access to consultation notes but didn't routinely check what advice had been given by the clinic. They therefore couldn't confirm whether the patient had received appropriate information to use their medicine safely or knew how to check if it was no longer suitable for use.

We found that some pharmacies regularly contacted patients after supplying CBPM to offer advice, while others did not. One pharmacy considered follow-up calls or questionnaires but decided against them after clinic consultants advised this could have a negative effect on some patients.

#### **Our recommendations**

We remind pharmacies that there is no legal requirement to provide a package leaflet (or similar detailed information) with unlicensed medicines, so patients rely on the information given by the prescribers and pharmacy teams. Pharmacy teams should ensure patients receive clear and appropriate information to support the safe use of CBPMs. This includes providing verbal or written advice, medicine labels with relevant warnings, and ensuring patients know how to check whether their medicine is still suitable for use.

Pharmacy teams should provide clear contact details and work with collaboratively prescribing clinics to give consistent information. There should be clear communication pathways, so patients know who to contact with any concerns.

### Assurance of safe prescribing

Pharmacies working with third party prescribing services should communicate clearly with prescribers and ensure that prescribing is safe and appropriate. This includes ensuring that relevant information is shared with patients' GPs and that appropriate follow-up arrangements are in place.

### **Inappropriate prescribing and adverse events**

We received several serious concerns that highlighted potential gaps in clinical oversight and safeguarding related to the prescribing and supply of CBPMs.

In one case, a patient with a significant cardiac history developed chest pain after taking a single dose of CBPM. The patient reported that the Pharmacist Independent Prescriber failed to consider their medical history before supplying the product. After experiencing the adverse effect, they struggled to get support and had to contact the pharmacy multiple times before receiving a response.

Two relatives raised concerns about vulnerable patients being inappropriately supplied CBPMs:

 one patient with Parkinson's disease experienced adverse effects from a product provided by an online pharmacy without any prior consultation with their GP or specialist Parkinson's team and had not tried any conventional treatments first  one patient had a history of cannabis misuse, raising concerns about whether appropriate clinical and safeguarding checks had been completed by the Pharmacist Independent Prescriber prior to prescribing

A healthcare professional raised a concern questioning the appropriateness of prescribing CBPMs to a patient with a history of mental health issues.

# **Duplication of prescriptions**

A duplicate prescription was dispensed and delivered to a patient one week after the original supply. The prescriber submitted the request in error which was not picked up by the dispensing pharmacy.

One pharmacy delivered a prescription that had been voided due to miscommunication with the prescribing clinic.

One patient reported receiving a duplicate supply, with no support from the pharmacy to retrieve the unwanted medication, causing them further distress.

A concern was reported from a CBPM supplier regarding a request using details from a previously dispensed prescription. Their internal checking process flagged the issue and successfully prevented unlawful distribution. The MHRA was also notified of this incident.

The CQC update on the safer management of controlled drugs in 2024 highlighted key themes from the Prevention of Future Deaths reports. These included cases of medicine oversupply and poor communication between healthcare providers. The report called for improved and more timely communication between services, especially when managing CDs. It also raised concerns about deaths linked to polypharmacy and the failure to identify or share information about potential drug interactions.

### What worked well

One pharmacy held monthly meetings with the director of its associated prescribing clinic. This helped the pharmacist develop a strong understanding of prescribing practices and risk management processes.

Several pharmacies had visibility of clinic appointments, consultation notes, and prescribing records through a shared system, allowing them to review relevant information before dispensing.

We saw good practice from a RP who followed a structured process for each CBPM prescription. They confirmed if the patient was new to treatment, asked about other medicines and allergies, reviewed the date of the last supply, and ensured the prescribed amount matched the treatment period. They also used clinical records to clinically screen and check for potential drug interactions.

Some pharmacies would not supply CBPMs to individuals who withheld consent for their GP or other healthcare providers to be informed about their treatment. Several confirmed the prescribing clinics they worked with followed a similar policy.

Some pharmacy teams verified prescriber identification and registration prior to dispensing each CBPM prescription.

# **Areas for improvement**

In pharmacies without access to patient records, pharmacists relied on self-reported information from patients about their previous use of CBPMs, allergies, and other medicines. GPhC guidance for pharmacies providing services at a distance recommends independently verifying this information to support the safe and appropriate care of medicines liable to abuse.

Some pharmacies had limited oversight of whether a patient's GP had been informed about their CBPM treatment. They assumed this responsibility rested with the prescribing clinic and did not follow up to confirm communication had taken place. In some cases, the RP was unaware of the clinic's process for managing situations where patients withheld consent to share information with their GP. This posed a risk to patient safety, particularly when the pharmacy was not involved in clinical decision-making or follow-up. Our inspectors have advised pharmacies to strengthen systems to ensure information was appropriately shared with patients' GPs.

One pharmacist acknowledged they received prescriptions from a group of known prescribers, and therefore did not repeat identity checks. This pharmacy relied on all further clinical checks and monitoring to be carried out by the prescribing clinic, but did not look for assurances that these were routinely being done.

### **Our recommendations**

#### We recommend that:

- pharmacies maintain clear communication with any third-party prescribing clinics to ensure that changes in medication are shared promptly and to avoid unintentional supply
- anyone involved in prescribing or supplying CBPMs checks the patient's medical history and current medication list. A thorough medication review should be conducted both before supply, and at regular intervals during treatment

The MHRA requires all suspected adverse drug reactions (ADRs) to CBPMs (whether serious, non-serious or related to lack of efficacy) are reported through the MHRA Yellow Card reporting scheme. All those involved with the sale or supply of CBPMs have a responsibility to report ADRs<sup>6</sup>.

### **Safeguarding**

Pharmacies, particularly those providing services at a distance, must have appropriate safeguards in place to identify inappropriate requests and prevent misuse of CBPMs. Some pharmacies had robust systems in place for this.

### What worked well

One pharmacy used audits to record and review interventions related to excessive quantities for each clinic it worked with.

Some pharmacies set a maximum order limit on the patient's medication record. If the limit was exceeded, it triggered a pharmacist review who contacted the prescribing clinic if needed.

Some pharmacies used their systems to check whether customers were using multiple addresses to order medicines.

### What could be improved

One pharmacy's system flagged if the same medicine was requested within seven days. However, prescriptions requested slightly further apart such as every 10 to 14 days could bypass this alert, risking excessive supply going unnoticed.

One pharmacy did not carry out the appropriate validity checks of its customers. Consequently several patients received CBPMs from two different prescribing services, with some prescriptions being issued to the same person 1-2 weeks apart.

### **Our recommendations**

Given the risks of misuse, diversion, and patient vulnerability associated with CBPMs, robust safeguarding measures are essential. Pharmacies should have clear checks and processes to flag requests for excessive quantities. They should have clear communication channels with prescribers to share relevant concerns.

# **Supplying extended quantities of CBPMs**

It is best practice that the maximum quantity of Schedule 2, 3 or 4 CDs prescribed should not exceed 30 days, so prescribers should be able to justify the quantity requested on a clinical basis if more than this is prescribed.

We found that some pharmacies routinely supplied more than a month's worth of CBPM at a time. One pharmacy explained this was common practice, often due to supply chain concerns or specific patient needs such as travel abroad. Prescriptions typically covered 35–40 days, with one case reaching 70 days to accommodate a patient visiting relatives overseas.

Some pharmacies queried and recorded all supply requests over 30 days. Others routinely accepted extended supplies from known prescribers, only querying or recording them when a new prescriber was involved or there was a significant change in supply.

### **Identity checks**

As outlined in the GPhC's <u>guidance for registered pharmacies providing pharmacy services at a</u> <u>distance</u>, pharmacy staff should ensure the person receiving pharmacy services is who they claim to be by carrying out an identity check appropriate to the medicine being supplied.

Where pharmacies carried out identity checks themselves, they followed clear procedures to ensure CBPMs were supplied to the correct person. Common methods included requesting photo ID (such as a passport or driving licence) and recent proof of address (such as a utility bill). Some pharmacies verified identity before each prescription, while others used customer service teams to complete checks during the registration process.

We also found that some pharmacies relied entirely on their partner prescribing clinics to verify identity and confirm patient details.

### **Our recommendations**

We recommend that pharmacies ensure robust identity checks are in place before supplying CBPMs. Where identity checks are conducted by third-party clinics, pharmacies should have regular checks in place to ensure these are robust, effective and consistently applied.

### **Dispensing**

We found that most pharmacies followed structured processes when dispensing CBPMs to ensure accuracy. Some services used digital platforms to submit prescription information in advance, helping pharmacies plan stock and manage workload before receiving the original paper prescription. We heard that no medicines were prepared or dispatched medicines until the physical prescription was received.

We received 44 concerns relating to the dispensing of CBPMs. Around 60% were due to delays in receiving prescriptions. These delays, often due to stock supply issues, resulted in patients running out of medication or having to switch treatment. Other reasons for delays included:

- unresolved payment issues
- miscommunication between prescribers and pharmacies
- outstanding prescription queries between the pharmacy and prescribing clinic

Some patients reported being left without medicines for weeks, leading to severe pain, distress and anxiety.

One case involved a hospital admission following a disease flare-up caused by treatment delay.

One patient resorted to using an unregulated cannabis source, after miscommunication between the prescribing clinic and pharmacy left them without treatment.

Delays in prescribing appointments left some patients without enough time to arrange a timely resupply.

We also received reports of incorrect strengths and quantities of CBPM being received by patients, including:

- a case where a patient was supplied MedCan Isondots at 19% THC instead of the prescribed 24%. This was due to a 'LASA' (look-alike, sound-alike) error during dispensing.
- one patient who reported receiving less than the prescribed quantity of CBPM, and felt the pharmacy dismissed their concern without proper investigation or support

### Our recommendations

Medicines shortages and manufacturing issues that lead to stock disruptions can cause significant distress for both pharmacy professionals and patients. To minimise the impact, we recommend providing clear and timely communication wherever possible. Pharmacies should support patients in identifying and accessing suitable alternative treatment options when necessary. This can include:

- checking with the manufacturer for updates on when the medicine will be available
- contacting the patient's prescriber to jointly consider if other suitable treatment options are available
- checking if the medicine is available at another pharmacy

We discuss how pharmacists can support patients with medicines shortages in more detail in our related Regulate article, *The struggle around medicines shortages*.

Manufacturers should clearly communicate the expected duration of stock shortages to enable healthcare teams and patients to plan appropriately or seek alternative treatments if needed.

# Sourcing CBPM products from reputable suppliers

Overall, pharmacies demonstrated good practice in sourcing CBPMs from reputable suppliers. CBPMs were obtained through licensed manufacturers, specialist importers with the appropriate Home Office licence, and wholesale dealers holding the necessary authorisations. Some pharmacies sourced medicines through their own company's wholesaler. Further Information regarding the specific licenses and authorisations required by suppliers can be found from the MHRA guidance, <u>The supply</u>, <u>manufacture</u>, <u>importation and distribution of CBPM</u>.

### What worked well

We saw that pharmacies carried out the necessary checks before sourcing CBPMs, including requesting relevant licences and certificates from suppliers. One pharmacy demonstrated how it uploaded these records into its system for each supplier. Others conducted additional in-house checks to validate their wholesalers.

There was evidence of pharmacies checking Certificates of Conformity (CoC) or Certificates of Analysis (CoA) for unlicensed CBPMs. We saw evidence of pharmacy teams matching these certificates to individual dispensing records to include key details such as batch number and expiry date. This helped create a clear audit trail and supported traceability in the event of recalls or quality concerns.

Some pharmacies regularly obtained stock updates from their suppliers and shared this information with prescribing clinics. They told us they contacted patients if delays occurred, such as those caused by quality control checks, to provide revised delivery times. For longer delays, pharmacists consulted both the prescriber and the patient to agree on a suitable alternative treatment.

### **Areas for improvement**

One pharmacy stocked CBD products classified as food supplements that were not listed on the Food Standards Agency's (FSA) approved list for novel food applications. Inspectors reminded the pharmacy of the importance of checking products against the FSA's list to ensure compliance.

#### Our recommendations

We remind pharmacies that CBD products not marketed as medicines are classified as 'novel food' products. The Food Standards Agency (FSA) requires all CBD food products in England and Wales to have a credible authorisation application submitted. Pharmacies in England and Wales should check the FSA's list of CBD products to ensure the products they supply are included. Food Standards Scotland (FSS) also requires CBD products to be authorised. Further information can be found on the Food Standards Scotland website. The GPhC's Regulate article on selling cannabidiol (CBD) 'novel food' products provides more information on this topic.

### Safe handling and storage of CBPMs

Unlicensed CBPMs are classified as Schedule 2 CDs and must meet safe custody requirements under the Misuse of Drugs (Safe Custody) Regulations 1973. Pharmacies implemented a range of measures to ensure the secure storage, monitoring, and handling of these medicines.

We found that most pharmacies stored CBPMs in secure CD cabinets. Larger companies often used locked cages or multiple CD storage rooms.

Where rooms or cages were used to store CDs, most pharmacies had obtained the required police exemption certificate or Home Office licence.

Pharmacies stored CD keys securely and appropriately. Keys were typically held by RP during the day and locked in a safe overnight. Safe access was often restricted to designated staff, such as the RP, superintendent pharmacist or a regular pharmacy technician.

### What worked well

One pharmacy used separate CD rooms to distinguish between wholesale stock and dispensing stock.

Some pharmacies implemented additional security measures, such as double-lock systems and reinforced brick structures to further reduce the risk of unauthorised access to CD storage facilities, including:

- one pharmacy which maintained daily logs of who accessed CD keys.
- one pharmacy which used colour-coded CD keys that were not visibly labelled, adding an extra layer of security.
- one pharmacy which changed safe codes after a locum pharmacists' shifts to maintain security.

# Areas for improvement

One pharmacy used a cage to store CDs without the required exemption certificate. This was addressed following the inspection.

One pharmacy obtained approval by the local police Controlled Drug Liaison Officer (CDLO) to allow CD stock cabinets to remain open during the working day, to support dispensing efficiency. We would advise vigilance to make sure this practice doesn't compromise the security of CD stock.

In one pharmacy, the majority of the pharmacy team took their lunch break at the same time during an inspection, leaving many dispensed and assembled CBPM prescriptions unsupervised in the main dispensary.

CDs were delivered to the reception of the business park where a pharmacy was located, and left unattended until collected by pharmacy staff.

One pharmacy did not have a CD cupboard within the main pharmacy, and kept dispensed CDs with them until delivered.

### Our recommendations

Most pharmacies had suitable storage for CDs but we remind them to check with local police Controlled Drug Liaison Officer (CDLO) about any necessary exemptions when using larger storage units like vaults or cages. Pharmacies should also have clear processes for managing CDs during receipt, dispensing, and dispatch to ensure they are not left unattended and are securely handed over when using third-party couriers.

### **CBPM** returns and destruction

Overall, we found that pharmacies had clear procedures in place for managing the return and destruction of CDs. Most kept patient returns separate from current and expired CD stock and used appropriate CD destruction kits for safe disposal. Where required, CDs were destroyed in the presence of an authorised witness.

### **CBPM** shelf life

Pharmacies and patients reported that many CBPM products had short expiry dates. During inspections we reviewed how pharmacies managed the shelf life of their stock and found a range of approaches. Expiry dates were checked at various points—on arrival, during dispensing, and through routine stock checks.

We received six concerns related to patients being supplied with short-dated or expired medicines.

In some cases, patients on variable doses had to renew prescriptions earlier than expected, leading to increased costs.

A product was supplied with an expiry date that did not cover the full prescribed treatment period.

One product was supplied with an expired date on the packaging. This was later justified by a manufacturer's leaflet explaining the expiry had been extended. However, the pharmacy had not informed the patient of this at the time of supply which caused confusion.

### What worked well

Some pharmacies used date-checking matrices or logs to record and track checks.

Pharmacy teams told us they clearly marked short-dated products to ensure these were used first.

One pharmacy reported not supplying medicines with less than 30 days of shelf life remaining. Another pharmacy team explained their digital dispensing system blocked selection of products with 30 days shelf life or less remaining. If manufacturers extended expiry dates, staff manually updated the digital system with the new dates for the relevant batches.

Pharmacies told us that patients received letters directly from the manufacturer if the expiry dates of their products were extended.

### **Our recommendations**

We recommend that pharmacies carefully check CBPM expiry dates and avoid supplying products that do not cover the full treatment period. Patients on variable doses should be offered products with suitable shelf life to prevent early re-prescribing and added costs. Pharmacies should also clearly communicate any manufacturer-issued expiry date extensions at the time of supply.

### **Delivery services**

The Home Office advises that postal or courier services with processes for full tracking (i.e. from collection through to delivery) are likely suitable for transporting CDs. They advise providers to keep a complete audit trail and put in security measures to minimise the risk of theft or loss.

We received several concerns regarding suspected contaminated or poor-quality CBPM products, highlighting the following issues:

- overall poor condition of the product
- · mouldy medication
- unusual taste or smell
- broken packaging seals

We heard that some pharmacies did not request faulty medicines to be returned to them for investigation and did not offer support or refunds to affected patients.

### What worked well

Most pharmacies used third-party couriers such as Royal Mail, DPD, or DHL to deliver CBPMs, typically via tracked or special delivery services.

Many services confirmed receipt with a signature or PIN, and some captured delivery photos to support the audit trail.

One pharmacy reported that a security guard supervised the loading of CDs onto the courier van, with each parcel scanned individually during loading.

Some pharmacies used tamper-evident seals to further enhance delivery security.

Pharmacies told us they supplied all CBPMs in their original, sealed containers. Many used robust unmarked packaging, such as jiffy bags or boxes to prevent damage and reduce the risk of identification during transit.

Some pharmacies told us they added gel packs to absorb odour which reduced the risk of diversion of the medicine. Others used tamper-evident seals.

Some pharmacies used couriers to return unused CBPMs for destruction; one reduced diversion risk by avoiding use of the pharmacy's name on the returns label.

The Home Office expects suppliers to report any loss of CDs in transit immediately to its drug licensing unit. Some pharmacies told us they required both the courier and the customer to immediately report any missing packages to them. Another reported it had had switched courier companies after experiencing several lost deliveries.

### **Areas for improvement**

One pharmacy delivered dispensed CDs on foot to a postal sorting office over a mile away, posing a security risk.

One pharmacy described its service level agreement with the courier company, which included two delivery attempts before returning undelivered items to the pharmacy. The courier was aware of the nature of the medication and reported storing packages securely at its depot if re-delivery was needed. In line with Home Office guidance, if CDs are transferred to a storage facility overnight, the premises may require a Home Office licence.

Some patients requested deliveries to alternate addresses, like workplaces. One pharmacy verified this via written confirmation from a verified email, but did not complete additional checks to verify the new address was linked to the patient.

### **Our recommendations**

We recommend that pharmacies have robust processes to verify patients' identities and addresses, and continue to apply these checks whenever any information changes. We also remind pharmacies to ensure that any storage arrangements for CDs made by third-party providers meet appropriate security standards.

# Managing concerns about product quality

We found that most pharmacies received relevant medicines alerts, typically by email from the MHRA or directly from manufacturers. Pharmacies that sourced products from its own CBPM manufacturer reported having direct communication with them, so they could easily receive alerts and raise concerns about product quality. Most pharmacies kept records when alerts were reviewed and actioned.

### What worked well

Some pharmacies documented specific actions taken in response to medicines alerts, such as completing product recall forms and contacting affected patients.

Several pharmacies told us they referred patient complaints about medicines quality directly to the manufacturer. One pharmacist described how they that followed up with the manufacturer after receiving concerns, and then updated the patient with the outcome of the investigation.

As CBPMs are unlicensed products, any adverse effects or suspected defective medicines must be reported via the MHRA's Yellow Card reporting scheme. One pharmacy demonstrated good practice by using access to the prescribing clinic's records to actively identify and report adverse reactions, leading to a significant increase in reports since the previous inspection. Reported issues included lack of efficacy, cough, and headache.

### **Areas for improvement**

Some pharmacies did not receive relevant alerts or failed to consistently record what actions they took after reviewing them.

Some pharmacy teams did not report adverse reactions appropriately to the MHRA.

### **Our recommendations**

We recommend that pharmacies:

- promptly review and act on all relevant medicine alerts, and keep a clear audit trail of their actions
- have processes in place to support the safe return of faulty CBPMs for investigation
- follow up complaints about product quality with manufacturers and keep patients informed of outcomes.

Pharmacy teams are reminded of their responsibility to report all suspected adverse reactions or product defects related to CBPMs via the MHRA Yellow Card scheme and to keep clear documentation of these incidents. This is especially important given the unlicensed status of CBPM products.

# **Conclusion**

The findings from this themed review provide assurance that most pharmacies met the required standards for the safe procurement, storage, and dispensing of CBPMs.

Where pharmacies did not meet standards, our inspectors supported them in making the necessary improvements, and where appropriate put further measures in place to protect the public. At the time this review was written, three of the eight pharmacies that didn't meet standards were awaiting reinspection. The remaining five had already taken effective action to address the issues raised.

However, there remains a need for clearer messaging around the risks associated with the prescribing and supply of CBPMs, particularly for online models where the process is often more complex and carries greater risk. Pharmacies must identify and manage risks throughout the entire process to ensure they are providing safe and effective care.

A key theme in our findings was the importance of clear communication and timely information sharing between pharmacies and third-party providers. While we couldn't always assess the strength of these relationships, examples in this review showed that those with open, regular communication and clear systems for collaborative working delivered better care. Pharmacy teams should be recognised as an integral part of the wider multidisciplinary team. Strong partnerships and open dialogue help better manage risks, safeguard patients, and ensure appropriate prescribing practice.

We highlighted the importance of pharmacy teams having access to relevant clinical records to support effective clinical screening of CBPM prescriptions before supply. We saw examples of meaningful clinical interventions by pharmacy teams who had access to the necessary patient information.

We understand that pharmacies continue to face challenges accessing GP care records. We welcome plans to extend access to patient records to all pharmacies, including those providing private services.

### Limitations

The significant rise in private CBPM prescriptions has raised concerns amongst organisations about the level of oversight clinicians have over their patients. While CBPMs must be initiated by a doctor on the GMC Specialist Register, ongoing prescriptions can be issued by other registered professionals, such as GPs, Pharmacist Independent Prescribers, and Nurse Independent Prescribers.

This report summarises our findings from inspections of registered pharmacy premises, including concerns we received about CBPM supply from these pharmacies. We recognise limitations in this review around pharmacist prescribing activity as we received only three related concerns: the majority of prescribing likely occurs in services that are regulated by others (e.g. CQC), which sits outside the scope of our direct inspection work.

We recognise that the prescribing and supply of CBPMs is complex, and closer working between prescribing clinics and pharmacies is essential. In the same way, strong collaboration between regulators and other organisations is key to improving and maintaining high standards of care. We see this as an important area for further exploration and will continue to work collaboratively with other regulators, relevant government departments, professional leadership bodies and representative organisations to strengthen oversight and understanding.

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