General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Biscot Pharmacy, 157A Biscot Road, LUTON, Bedfordshire, LU3 1AW

Pharmacy reference: 1110108

Type of pharmacy: Community

Date of inspection: 18/11/2020

Pharmacy context

A busy community pharmacy set in a residential area of Luton. The pharmacy opens seven days a week. It stays open late every evening. And most people who use it live nearby. The pharmacy sells a range of over-the-counter (OTC) medicines. And it sells some health and beauty products too. The pharmacy dispenses people's prescriptions and substance misuse treatments. It supplies medicines in multi-compartment compliance packs (compliance packs) to help people take their medicines. And it delivers medicines to a few people who have difficulty in leaving their homes. The pharmacy offers travel and winter influenza (flu) vaccinations. This was a targeted inspection after information was received that the pharmacy had been obtaining large quantities of codeine oral solution (linctus), which is addictive and can be overused, misused and abused. This inspection took place during the coronavirus (COVID-19) pandemic. And not all aspects of the pharmacy were inspected on this occasion.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; Statutory Enforcement

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy hasn't identified or managed the risks with purchasing and selling codeine linctus. It doesn't have suitable governance arrangements to manage this situation. And there are no documented details about the action it has taken to ensure medicines, which are addictive, can be abused and misused, are sold safely. This means that there are risks that people may obtain medicines that could cause them harm.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy doesn't manage the purchases and sales of codeine linctus it makes. And it doesn't adequately monitor the movement or sales of this medicine. So, it doesn't have appropriate safeguards in place to prevent people overusing, misusing or abusing it.
		4.3	Standard not met	The pharmacy cannot demonstrate that it suitably stores and manages medicines which require refrigeration.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy doesn't identify and manage the risks with the sales and purchases of codeine linctus. It doesn't have adequate processes to make sure OTC medicines, which can be addictive, misused or abused, are sold safely. This means that there are risks that people may obtain medicines that could cause them harm. The pharmacy suitably manages the risks associated with its other services and the COVID-19 pandemic. People who work in the pharmacy can explain what they do, what they're responsible for and when they might seek help. They mostly keep people's private information safe. And they discuss the mistakes they make. So, they can learn from them.

Inspector's evidence

The pharmacy team had risk assessed the impact of COVID-19 on the pharmacy and its services. The pharmacy displayed a notice in its window stating that no more than two people were allowed into its premises at a time. And a marking on its floor was there to help people keep two metres apart. The pharmacy had put up some plastic screens on its counter to help protect its team. And it made sure its team members had the personal protective equipment they needed. The pharmacy offered to undertake an occupational risk assessment for each team member to help identify and protect those at increased risk in relation to COVID-19. The inspector reminded the responsible pharmacist (RP) of the need for community pharmacy employers to report instances of exposure to COVID-19 in the workplace.

The pharmacy displayed a notice that told people who the RP was. It had standard operating procedures (SOPs) for the services it provided. And these had been reviewed during January 2020. Members of the pharmacy team were required to read, sign and follow the SOPs relevant to their roles. And their roles and responsibilities were described in the SOPs. They knew what they could and couldn't do, what they were responsible for and when they might seek help. They explained that they wouldn't hand out prescriptions or sell medicines if a pharmacist wasn't present. And they would refer repeated requests for the same or similar products to the pharmacist. The pharmacy had a complaints procedure. It had a comments and suggestions box for people to use if they wished to provide written feedback about the pharmacy. People could also take part in a satisfaction survey once a year. And the results of some recent surveys were available online. The pharmacy team tried to keep people's preferred makes of prescription-medicines in stock when asked to do so.

The pharmacy's SOPs covered the sales of OTC medicines. And included guidance on the sales of children's cough and cold medicines, and analgesics containing codeine or dihydrocodeine. But the pharmacy didn't have any specific SOPs or policies about the OTC sales of codeine linctus. Members of the pharmacy team explained that they wouldn't recommend codeine linctus to people. And they would refer requests for it to the pharmacist. The RP agreed that this was the case. But he couldn't remember the last time he recommended or sold it. The pharmacy didn't keep records of the decisions its team made why codeine linctus was or wasn't sold. And it relied upon its team members telling each other of any concerns they may have about people trying to buy codeine linctus inappropriately or too frequently. The pharmacy didn't audit the purchases, sales and supplies of codeine linctus it made. The RP explained that codeine linctus wasn't a first line treatment that would be recommended. But it may be recommended if the person had tried another product without success. The superintendent pharmacist explained, following the inspection, that occasionally clinicians from an NHS walk-in centre

told people to purchase codeine linctus. But he hadn't knowingly sold or recommended it to someone who he suspected of overusing, misusing or abusing it. And, generally, requests made for it were declined.

Members of the pharmacy team responsible for making up people's prescriptions used baskets to separate each person's medication and to help them prioritise their workload. They referred to prescriptions when labelling and picking products. And assembled prescriptions were not handed out until they were checked by the RP. The pharmacy had systems to review dispensing errors and near misses. Members of the pharmacy team discussed the mistakes they made to learn from them and reduce the chances of them happening again. But they didn't routinely record them or the lessons they learnt from them. So, they could be missing opportunities to spot patterns or trends with the mistakes they made. The RP explained that medicines involved in incidents, or were similar in some way, such as amitriptyline and amlodipine, were generally separated from each other in the dispensary.

The pharmacy had appropriate insurance arrangements in place, including professional indemnity, for the services it provided. The pharmacy team generally kept the controlled drug (CD) register in order. But the address from whom a CD was received from wasn't always recorded. And the CD running balance wasn't checked regularly. So, opportunities to spot mistakes or discrepancies could be missed. The pharmacy kept a record to show which pharmacist was the RP and when. It also kept records for the supplies of the unlicensed medicinal products it made. The pharmacy recorded the emergency supplies it made and the private prescriptions it dispensed electronically. And while these records were mostly in order, the name and address of the prescriber were sometimes missing.

The pharmacy was registered with the Information Commissioner's Office. It also displayed a privacy notice. And this told people how their personal information was gathered, used and shared by the pharmacy and its team. The pharmacy team tried to store prescriptions so people's names and addresses couldn't be seen by someone who shouldn't see them. The pharmacy team used an NHS smartcard for a team member who wasn't present during the inspection. But this was promptly removed by the RP when the matter was brought to his attention. So, it could be returned to the team member it belonged to. Members of the pharmacy team generally knew what to do or who they would make aware if they had concerns about the safety of a child or a vulnerable person.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough people in its team. Members of the pharmacy team undergo training for the jobs they do. This means they can deliver safe and effective care. They work well together and make decisions about what is right for the people they care for. They're comfortable about giving feedback on how to improve the pharmacy and its services. And they know how to raise a concern if they have one.

Inspector's evidence

The pharmacy team consisted of two full-time pharmacists (including the superintendent pharmacist), two part-time pharmacists (including the RP), two full-time dispensing assistants, a full-time pharmacy apprentice, a full-time trainee dispensing assistant, a part-time trainee dispensing assistant, a part time medicines counter assistant (MCA) and two part-time MCAs. The RP and the superintendent pharmacist were directors of the company that owned the pharmacy. The RP, a dispensing assistant, the trainee dispensing assistant and the pharmacy apprentice were working at the time of the inspection. The pharmacy relied upon its team to cover absences.

Members of the pharmacy team worked well together. So, people were served promptly, and their prescriptions were processed safely. The RP supervised and oversaw the supply of medicines and advice given by the team. One of the team members described the questions they would ask when making OTC recommendations. They referred requests for treatments for babies and young children, people with long-term health conditions and people who were pregnant or breastfeeding to a pharmacist. Members of the pharmacy team needed to undertake accredited training relevant to their roles. Team members could talk to the RP or the superintendent pharmacist about their development needs. They could ask questions and familiarise themselves with new products. The pharmacy held informal team meetings or one-to-one discussions to update its team and to share learning. The pharmacy team didn't feel under pressure to complete the tasks it was expected to do. Members of the pharmacy team felt comfortable about making suggestions on how to improve the pharmacy and its services. They knew who they should raise a concern with if they had one.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy provides an adequate and secure environment for people to receive healthcare. It has a room where people can have private conversations with members of the pharmacy team.

Inspector's evidence

The pharmacy had a retail area, a counter, a dispensary, a small consulting room, a toilet and an area it used as a kitchenette and stockroom. The pharmacy's premises were air-conditioned, bright, secure and adequately presented. The pharmacy's flooring was worn in places. And some of its fixtures were dated too. The dispensary had limited workspace and storage available. The dispensing worksurfaces could become cluttered when the pharmacy was busy. But the pharmacy team tried to keep the pharmacist's checking workstation clear of clutter. People tried to socially distance themselves from one another when inside the pharmacy. And appropriate face masks were available for team members to use if they chose to. Members of the pharmacy team could use the consulting room if people needed to speak to them in private. But the consulting room couldn't be locked when it wasn't being used. The pharmacy had some sinks. And it had a supply of hot and cold water. The pharmacy's team members were responsible for keeping the pharmacy's premises clean and tidy. And they could wash or sanitise their hands regularly too.

Principle 4 - Services **Standards not all met**

Summary findings

The pharmacy doesn't always provide its services safely. It doesn't have suitable safeguards in place to manage the purchases and sales of codeine linctus. It cannot account for, or adequately monitor the movement or sales of, this medicine. Otherwise, the pharmacy's working practices are generally safe and effective. This includes the dispensing of people's medicines. The pharmacy generally sources and manages its other medicines appropriately. But it cannot show that all medicines, such as those that need to be kept in a refrigerator, are suitably stored.

Inspector's evidence

The pharmacy had some off-street parking in front of its entrance. It had step-free access. But it didn't have an automated door. So, a pharmacy team member opened the door when needed. This meant that people with mobility difficulties, such as wheelchair users, could enter the building. The pharmacy listed the services it could provide in-store and online. Members of the pharmacy team were helpful. They spoke different languages reflective of the local community. They took the time to listen to people. So, they could advise and help them. And they signposted people to another provider if a service wasn't available at the pharmacy.

The pharmacy offered a delivery service to people who couldn't attend its premises in person. It kept some records to show it had delivered medicines to the right person. And it had adapted its delivery process because of the pandemic. So, the team member making the delivery and the person they were delivering to could socially distance from each other. The pharmacy had appropriate resources in place for its vaccination services. And people needed to book a vaccination appointment. So, the pharmacy team could continue to safely manage its workload. And to make sure an appropriately trained pharmacist was available. The pharmacy had almost run out of flu vaccines. And the demand for travel vaccinations was low due to the pandemic. The pharmacy used a disposable and tamper-evident system for people who received their medicines in compliance packs. The pharmacy team generally checked whether a medicine was suitable to be re-packaged. It provided a brief description of each medicine contained within the compliance packs. But it didn't always keep an audit trail of the person who had assembled and checked each prescription. And patient information leaflets weren't always supplied. Prescriptions were highlighted to alert the team member when CDs or refrigerated lines needed to be added or if extra counselling was required. Members of the pharmacy team were generally aware of the valproate pregnancy prevention programme. And the RP knew that people in the at-risk group who were prescribed valproate needed to be counselled on its contraindications. The pharmacy had some valproate educational materials available. The pharmacy allowed people to access a paid-for GP video consultation service (Medicspot) from its consulting room. This was an online service regulated by the Care Quality Commission. People could book a Medicspot appointment online or when they were in the pharmacy. They would have a video consultation with a GP through a dedicated computer terminal. And their details would be verified by Medicspot. The GP could ask the person accessing the service to use the equipment, such as a stethoscope, blood pressure monitor, thermometer and a fingertip pulse oximeter, connected to the computer terminal to help with their diagnosis. And if the GP decided to prescribe a medicine for the person then they could choose to have their prescription dispensed at the pharmacy. People were left unattended in the consulting room when accessing this service. But the pharmacy used the consulting room to store some of its excess OTC stock. And the pharmacy team needed to make sure that the sharps bin used in the pharmacy's

vaccination services and any confidential information were removed before people were left alone in the room.

The pharmacy used recognised wholesalers, such as AAH, Alliance Healthcare, B&S, DE South, Phoenix and Trident, to obtain its pharmaceutical stock. It kept invoices from these wholesalers untidily in the dispensary. And some crates and boxes of invoices were found in an outbuilding. The superintendent pharmacist identified that six bottles of codeine linctus had been broken in the past year. But he was unaware of any losses due to expiry or theft. He confirmed that the pharmacy didn't wholesale medicines as it didn't have a licence to do so. And it didn't sell OTC medicines online or at a distance. The RP explained that OTC products, including codeine linctus, tended to be ordered manually by one team member. But this team member wasn't present at the time of the inspection. The RP, the pharmacy team and the superintendent pharmacist, couldn't account for the apparent large discrepancy in the amount of codeine linctus purchased by the pharmacy and the amount in stock, and how much had been sold and dispensed.

The pharmacy kept most of its medicines and medical devices within their original manufacturer's packaging. But the dispensary wasn't as tidy as it could have been. The pharmacy team checked the expiry dates of medicines when it dispensed them and at regular intervals. But it hadn't recorded when it had done these checks since June 2019. This increased the possibility of it giving people out-of-date medicines by mistake. The pharmacy stored its CDs, which weren't exempt from safe custody requirements, securely in its CD cabinets. The pharmacy kept a record of the destruction of patient-returned CDs. The pharmacy team needed to keep patient-returned and out-of-date CDs separate from in-date stock. But these had been allowed to build up and needed to be destroyed. The pharmacy was required to store its stock, which needed to be refrigerated, between two and eight degrees Celsius. And it was using three domestic refrigerators to do so. But the pharmacy team hadn't been monitoring or recording two of the pharmacy's refrigerators maximum and minimum temperatures for about a week as the thermometers' batteries were flat. And it hadn't be monitoring the temperature at all for the other refrigerator, which was used to store some vaccines, as this didn't have a thermometer. The RP was unsure how long stock had been stored in this refrigerator.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and the facilities it needs to provide its services safely. It uses its equipment to make sure people's data is kept secure. And its team makes sure the equipment it uses is clean.

Inspector's evidence

The pharmacy had equipment for counting loose tablets and capsules. And it had some glass and plastic measures. The importance of using standardised measures for accurate results was discussed with the RP. And he agreed to discontinue the use of plastic measures. Members of the pharmacy team made sure the equipment they used to measure, or count, medicines was clean before they used it. The pharmacy team had access to up-to-date reference sources. And it could contact Numark to ask for information and guidance. The pharmacy restricted access to its computers and patient medication record system. And only authorised team members could use them when they put in their password. The pharmacy positioned its computer screens so they could only be seen by a member of the pharmacy team. The pharmacy had a cordless telephone system. So, its team could have confidential conversations with people when necessary.

What do the summary findings for each principle mean?

Finding	Meaning
✔ Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✔ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✔ Standards met	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.