General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Medicines2Home.Com, Suite 3 Railway House, Station Street, Meltham, Huddersfield, West Yorkshire, HD9 5NX

Pharmacy reference: 1109850

Type of pharmacy: Internet / distance selling

Date of inspection: 18/11/2021

Pharmacy context

The pharmacy is in a business centre in Meltham. It has a distance selling NHS contract. Pharmacy team members dispense NHS prescriptions and deliver them to people's homes. They provide medicines to people in multi-compartment compliance packs. The pharmacy sells a range of over-the-counter medicines via a website that is run and administrated by a third-party company. The inspection was completed during the COVID-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

Follow this link to find out what the inspections possible outcomes mean

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 doesn't adequately manage all the risks with its services. The pharmacy doesn't have complete and up-to-date written procedures that reflect the pharmacy's current practice. This includes the management of near miss errors and dispensing incidents. And pharmacy team members rarely use the procedures.
		1.6	Standard not met	The pharmacy does not keep all the necessary records required by law. The records it does keep are also not adequate to ensure the safety of the services it provides.
		1.8	Standard not met	The pharmacy does not have a suitable procedure to deal with safeguarding concerns. Some pharmacy team members are not appropriately trained and do not demonstrate the required knowledge to be able to suitably identify and help a vulnerable person.
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	4.3	Standard not met	The pharmacy does not have an adequately robust process for managing the storage of its medicines and for checking expiry dates. And there is evidence of out-of-date medicines. The pharmacy does not always keep its medicines in the original packs and label these properly. It doesn't store medicines requiring safe storage in accordance with the law. So, there is a risk the pharmacy may supply medicines that are not fit for purpose.
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 adequately identify and manage all the risks associated with its services. The pharmacy's processes are not always robust and written procedures are out of date and incomplete for the services provided. Pharmacy team members do not always follow the written procedures the pharmacy does have. Team members discuss errors they make in the dispensing process, but do not record or fully analyse their mistakes. So, they may miss opportunities to learn and make services safer. The pharmacy does not have a suitable procedure for safeguarding concerns. And pharmacy team members do not demonstrate the required knowledge to be able to always suitably identify and help a vulnerable person. The pharmacy does not always keep the necessary records required by law or the records for assuring the safety of its services. It keeps people's private information secure.

Inspector's evidence

The pharmacy had a set of documented standard operating procedures (SOPs) in place. It had implemented these when the pharmacy had opened in 2011. And the pharmacy had not reviewed them since. This meant that many of the documented procedures were out of date and contained information that was no longer relevant to the pharmacy. Examples included the procedure for selling medicines via the pharmacy's website, the SOP for checking the expiry dates of medicines, and the procedure for operating the pharmacy in the absence of the responsible pharmacist (RP). Some key procedures were also missing. For example, there was no documented procedure to guide pharmacy team members about what to do if they had a safeguarding concern about a vulnerable person. And there was no written procedure about how pharmacy team members should respond to or document mistakes that happened during the dispensing process. The RP during the inspection said he was a locum pharmacist that worked at the pharmacy regularly three days a week. He said he had read some of the written procedures when he had begun working at the pharmacy approximately six months ago. But he had not read them all. And he had not signed to confirm which procedures he had read and understood. The RP was aware that many of the SOPs did not reflect how the pharmacy operated. But he had not done anything to address this. Other pharmacy team members had read and signed the procedures in 2019. When the inspector arrived at the pharmacy, there was no responsible pharmacist present. The RP records showed that the pharmacist had commenced duties as RP at 09.00. But there was no absence recorded in the record. And there was no RP notice displayed in the pharmacy. The pharmacy did not have any written procedures about the arrangements which applied during the RP's absence to ensure the pharmacy was running safely. The dispenser said he had a mobile phone number for the RP if he needed anything.

The RP did not know if the pharmacy had completed a risk assessment at the beginning of the Covid-19 pandemic to help them manage the risks of infection. Pharmacy team members were not wearing face coverings while they worked. The pharmacy was large enough for them to maintain adequate social distancing in the pharmacy. The pharmacy's type of NHS contract meant that pharmacy team members did not encounter members of the public in the pharmacy. The pharmacy's delivery drivers had masks available to them.

The pharmacy had a log in place to record near miss errors. It had made five records since the beginning of 2021. And no records had been made since July 2021. The RP admitted that that not all near miss errors were recorded. A dispenser said they were told when they had made a mistake and were asked

to be more careful. The records of near miss errors available were vague or silent about what had caused the errors or what had been changed to help prevent them happening again. The pharmacy did not analyse the data collected for patterns to help aid future learning. The RP did not know how to record or report a dispensing error. And the pharmacy did not have a documented procedure to help guide him with the process. He said that he would ensure that any errors he was made aware of were corrected immediately and that peoples' safety would be his primary concern. He explained he would use the NHS National Reporting and Learning System (NRLS) to record any error. But he did not know if this was the right thing to do. The pharmacy did not have any records of any errors made after September 2020. And the RP did not know if any errors had been made since. The records available were made using a paper template. The information captured was brief and did not include details about the causes of the errors or the changes the pharmacy had made to help prevent a recurrence. Pharmacy team members could not show any examples of any changes they had made to help prevent an error happening again.

There was a page on the pharmacy's website giving people information about how to make a complaint and provide feedback. Pharmacy team members explained that people usually provided feedback verbally. They could not provide any examples of any changes they had made following feedback from people. The pharmacy had a written procedure to help pharmacy team members respond to complaints and feedback. But it was out of date. And the RP said he did not know if the procedure was still correct.

The pharmacy had up-to-date professional indemnity insurance in place. The pharmacy maintained a responsible pharmacist record electronically, which was generally complete. The pharmacist was not displaying their responsible pharmacist notice. This was discussed and the pharmacist printed a new notice during the inspection. When the inspector arrived at the pharmacy, the RP was absent. The records showed he had signed in as RP at 09.00. But there was no absence recorded. When the RP arrived later, he was absent from the pharmacy on occasions each month where he would visit a local GP surgery. But he had not recorded any previous absences in the RP records seen for the last twelve months. The pharmacy kept controlled drug (CD) registers complete. It kept running balances in all registers. But pharmacy team members did not audit the running balances regularly against the physical stock quantity kept. The last documented balance audit was in May 2021. The RP admitted that checks were not regularly completed. The pharmacy kept a register of CDs returned by people for destruction. But it was not up to date. Patient returned CDs were found in the CD cabinet that had not been documented in the register. Pharmacy team members monitored and recorded minimum and maximum fridge temperatures every day. The pharmacy kept private prescription records in a paper register and electronically. Some private prescriptions available had only been entered in one of the registers. So, neither of the registers were a complete legal record. The pharmacy recorded emergency supplies of medicines electronically. The pharmacy did not have a documented procedure instructing pharmacy team members about how to keep and maintain records of private prescriptions and emergency supplies.

The pharmacy premises could not be accessed directly by the public because of its type of NHS contract. This changes the requirements for protecting people's private information. The pharmacy had its confidential waste collected by a secure waste disposal contractor. The pharmacy had a file of information available for pharmacy team members to read about information security and confidentiality. Some pharmacy team members had signed to confirm they had read the information in 2020. The RP said he had read the information as well. But he had not signed to confirm this. Pharmacy team members gave a satisfactory explanation about how they maintained people's privacy.

The pharmacist provided evidence that he had completed distance learning on safeguarding in 2021. He gave brief examples of symptoms that would raise his concerns. And if he had a concern, he would use

the internet to find out who to contact. The pharmacy did not have a written procedure for dealing with a safeguarding concern about a vulnerable child or adult. The dispenser was unsure about how to identify a safeguarding concern in a distance selling pharmacy where they did not have regular face-to-face contact with people. Pharmacy team members had not been provided with any training about safeguarding.

Principle 2 - Staffing ✓ Standards met

Summary findings

Pharmacy team members have the necessary skills for their roles and the services they provide. They complete ad hoc training to help keep their knowledge up to date. Pharmacy team members feel comfortable discussing issues with each other. But they are unsure about who to raise concerns with about the pharmacy outside their immediate team. And they do not have easy access to their superintendent pharmacist.

Inspector's evidence

At the time of the inspection, the pharmacy team members present were a regular locum pharmacist and a full-time dispenser. The pharmacy also employed another part-time locum pharmacist, a part-time dispenser and four part-time delivery drivers. The pharmacy did not provide team members with any ongoing training. Pharmacy team members explained they read some trade press materials received in the pharmacy ad hoc. The pharmacy did not have an appraisal or performance management system for team members. Team members explained they would raise any learning needs informally with the pharmacist. And they felt comfortable doing so.

Pharmacy team members felt comfortable sharing ideas and making suggestions amongst the team members that worked at the pharmacy. They gave an example of changing the layout of the area where medicines were prepared to help improve workflow and tidiness. But pharmacy team members were not confident about easily being able to contact the superintendent pharmacist (SI) or other pharmacy owners. They explained that the SI and owners rarely visited or contacted the pharmacy. And some pharmacy team members had never met the SI. Pharmacy team members explained this was an issue when they encountered a problem that they could not resolve. This was demonstrated during the inspection when the inspector asked to see an up-to-date certificate of the pharmacy's professional indemnity insurance and evidence that the pharmacy's team members were qualified to the appropriate levels for their roles. Pharmacy team members were not sure who to contact. The pharmacy provided an up-to-date certificate of insurance after the inspection. But they were unable to provide evidence that one pharmacy team member was qualified to the appropriate level. The pharmacy did not have a whistleblowing process for team members to raise concerns about the pharmacy anonymously.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is generally clean and properly maintained. It provides a suitable space for the services provided.

Inspector's evidence

The pharmacy was in a business unit and the premises were not accessed directly by the public due to the NHS contract it held. The pharmacy had a large room used for dispensing and storage. The pharmacy was generally tidy. It had defined areas for dispensing and checking. The floors and passageways were free from clutter and obstruction. There was a defined workflow in operation. There was a clean, well-maintained sink used for medicines preparation. There was a toilet, a sink with hot and cold running water and other facilities for hand washing. Heat and light in the pharmacy was maintained to acceptable levels. The overall appearance of the premises was adequate for the services being provided.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy does not always manage its medicines appropriately. Pharmacy team members do not follow the pharmacy's documented process for checking the expiry date on medicines. And they do not always keep medicines in the original packs or store all medicines appropriately. The pharmacy sources its medicines from reputable suppliers. It has some processes to manage the risks and provide advice for people taking high-risk medicines.

Inspector's evidence

Because of its type of NHS contract, the pharmacy was not physically accessible to people. People communicated with the pharmacy by telephone, email and by using the pharmacy's online prescription ordering system. The system enabled people to tell the pharmacy which medicines they needed. And the pharmacy ordered prescriptions on their behalf. The pharmacy had a website where it provided its contact details. Pharmacy team members could provide large print labels for people with visual impairment. They said they would communicate in writing with people with a hearing impairment.

The pharmacy had a documented procedure for checking stock for short-dated and expired medicines. But this did not match the process being carried out by pharmacy team members. Pharmacy team members explained they currently checked medicines expiries ad hoc. But they had not recorded their checks in the available log since May 2021. They highlighted medicines expiring within three months of the check. But there was no process in place to remove these medicines from the shelves if they expired before the next scheduled date check. After a search of the shelves, the inspector did not find any items that were out of date. But out-of-date controlled drugs (CDs) were found in the CD cabinet that had not been segregated from in-date stock. This increased the risk of out-of-date medicines being provided to people. The inspector found several amber bottles on shelves containing medicines that had been removed from their original packaging. These bottles were labelled with the name of the medicine. And some also included the expiry date. But they did not include other required information, such as the quantity or the batch number of the medicine so the medicines could be removed if it was subject to a manufacturer's recall. One of the bottles contained a large quantity of loose Epilim tablets that had been removed from their original foil packaging. These medicines are sensitive to moisture in the atmosphere. And there was no information provided about when they had been removed from their original packaging.

The pharmacy delivered medicines to people. The delivery drivers recorded the deliveries they made. Under normal circumstances, people signed to confirm receipt of their deliveries. But this was not currently happening to help protect people from transmission of coronavirus. The delivery driver left a card through the letterbox if someone was not at home when they delivered. The card asked people to contact the pharmacy. Pharmacy team members signed the 'dispensed by' and 'checked by' boxes on dispensing labels during dispensing. This was to maintain an audit trail of the people involved in the dispensing process. They used dispensing baskets during the dispensing process to help prevent prescriptions being mixed up. The pharmacy supplied medicines in multi-compartment compliance packs when requested. Pharmacy team members attached labels to the packs, so people had written instructions of how to take their medicines. And these included descriptions of what the medicines looked like, so they could be identified in the pack. They routinely provided people with information leaflets about their medicines. Pharmacy team members documented changes to medicines provided in

packs on the patient's electronic record and on their master record sheet. This master record sheet detailed the person's current medicines and the times of administration. Pharmacy team members stored completed packs waiting to be checked by a pharmacist on a bench. These packs had not been sealed or closed. This increased the risk of medicines falling out or moving to the wrong compartment because there were several packs stored together like this. And they were stored for some time before the pharmacist was able to check them. The pharmacist counselled people receiving prescriptions for valproate if appropriate. And he checked if the person was aware of the risks if they became pregnant while taking the medicine. He advised he would also check if they were on a pregnancy prevention programme. And he was aware that local GP surgeries were good at communicating these risks to people when they prescribed valproate. Pharmacy team members were aware of the importance of carefully placing dispensing labels on packs of valproate, so they didn't obscure the safety information on the packaging.

The pharmacy obtained medicines from six licensed wholesalers. It stored medicines on shelves. And it kept all stock in restricted areas of the premises where necessary. It had adequate disposal facilities available for unwanted medicines, including CDs. Pharmacy team members kept the CD cabinet tidy. The pharmacy kept the contents of the pharmacy fridge tidy and well organised. Pharmacy team members monitored minimum and maximum temperatures in the fridge each day. And they recorded her findings electronically.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the necessary equipment available, which it properly maintains. And it manages and uses the equipment in ways that protect people's confidentiality.

Inspector's evidence

The pharmacy had the equipment it needed to provide the services offered. The resources it had available included the British National Formulary (BNF), the BNF for Children, various pharmacy reference texts and use of the internet. The pharmacy had equipment available to help prevent the transmission of Covid-19. These included gloves, hand sanitiser and face masks. The pharmacy had a set of clean, well maintained measures available for medicines preparation. It kept its computer terminals in the secure pharmacy premises. And these were password protected. The pharmacy fridge was in good working order. The pharmacy restricted access to all equipment and it stored all items securely.

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.