General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Pill Time Ltd, Unit 7 & 8, Cribbs Causeway Centre, Cribbs Causeway, Bristol, Gloucestershire, BS10 7TT

Pharmacy reference: 9011779

Type of pharmacy: Internet / distance selling

Date of inspection: 29/07/2022

Pharmacy context

This is a pharmacy that offers its services to people only through its website. People cannot visit the pharmacy in person and all medicines are delivered. The pharmacy is based in two units of an industrial premises in Cribbs Causeway to the north of the city of Bristol. The pharmacy delivers medicines throughout the United Kingdom. The pharmacy only dispenses NHS prescriptions. It supplies these medicines in individual pouches to help people to remember when to take them. The pharmacy does not sell any medicines.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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 met	1.1	Good practice	The pharmacy has good written procedures in place to manage the risks associated with providing pharmacy services. It uses innovative technology which reduces the risk of mistakes.
2. Staff	Standards met	2.4	Good practice	The pharmacy team members maintain a clear and embedded culture of openness, honesty and learning. They are encouraged and well supported in their further professional development.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	5.1	Good practice	The pharmacy's equipment and technology are innovative. They help reduce the risk of dispensing mistakes and hence increase patient safety.

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy has satisfactory written procedures to help make sure the team works safely. Pharmacy team members have procedures in place to record and review mistakes when they happen. They use this information and learning to avoid future mistakes. The pharmacy uses innovative technology which reduces the risk of mistakes. Pharmacy team members are clear about their roles and responsibilities. The pharmacy asks its customers and staff for their views and uses this to help improve services. It manages and protects people's confidential information, and it tells people how their private information will be used. The pharmacy has appropriate insurance to protect people when things do go wrong.

Inspector's evidence

The pharmacy team had taken measures to mitigate the risk of transmission of COVID-19. Risk assessments had been completed assessing the impact of COVID-19 on the pharmacy premises and the individual pharmacy staff members. There was an infection control procedure in place which mandated the wearing of face masks depending on the case numbers of COVID-19. Some pharmacy team members were wearing masks during the inspection.

Processes were in place for identifying and managing risks. A new, bespoke weekly 'safer care and audit' system had been implemented by the superintendent which facilitated the pharmacy team in ensuring that they were carrying out the governance procedures relevant to the safe and effective running of the pharmacy. The pharmacy team used innovative software to record near misses. This included placing QR codes around the pharmacy which enabled the pharmacy team to quickly access an electronic system where near misses could be recorded. The near miss recording software identified trends in errors and these could show where the errors were happening, and this was used to inform changes to procedures if necessary. The software could also show which staff member was involved, allowing the pharmacy team to offer support, guidance, and re-training if necessary. Innovative bar-code technology was used so that medicines were scanned at each stage of the dispensing process by staff. This meant that near misses were kept at low levels except for stages where there would be human intervention, such as when the cannisters are refilled manually by pharmacy staff. Optical scanners were used to detect any pouching issues, such as broken tablets, which were then repaired and sent for rechecking using a further optical scanner. Dispensing incidents were recorded electronically, and this included a root cause analysis as part of the error investigation. Monthly reports were generated by the software which looked for trends as well as any changes that need to be made to reduce the risk of errors. This would then be communicated to the pharmacy staff to inform learning and mitigate the risk of future errors.

Business continuity plans were in place to help mitigate the risk of service provision issues in the event of an electrical or internet failure. Emergency generators could be obtained if necessary. The pharmacy used fourth generation (4G) data transmission and cloud-based storage of data. There were four dispensing robots so there was a back-up available if one failed.

Standard operating procedures (SOPs) were in place for the services provided and these had been recently reviewed. These were held electronically, and records were kept to verify that staff had read and signed them. There was a complaints procedure in place and staff were all clear on the processes

they should follow if they received a complaint. There was a link to the company complaints procedure on the website and this had been recently reviewed. The pharmacy team received a large amount of feedback online and recent feedback was positive. A certificate of public liability and indemnity insurance was held with the NPA and was valid and in date at the time of the inspection.

Records of controlled drugs (CD) were kept electronically. CD balances were checked weekly. A responsible pharmacist (RP) record was kept and a RP notice was displayed in the foyer of the premises. The fridge temperatures were recorded daily and were within the two to eight degrees Celsius range. Date checking was carried out regularly and records of this were seen to be completed appropriately. The private prescription records were kept but were mixed in with other records. The superintendent pharmacist agreed to address this. The specials records were retained and were in order.

Confidential information was collected for appropriate disposal. An information governance policy (IG) was in place and the healthcare team was required to complete an e-learning programme on IG. Staff had completed a training package on the General Data Protection Regulation (GDPR).

The pharmacists had completed the CPPE level 2 safeguarding package. Staff were aware of the signs to look out for that may indicate safeguarding concerns. Staff could locate local contact details to raise safeguarding concerns or ask for advice about them. The customer service staff reported that they escalated any concerns they had about vulnerable patients to a pharmacist.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy's team members have the appropriate skills, qualifications and training to deliver services safely and effectively. The pharmacy team members work well together. They are comfortable about providing feedback and raising concerns and are involved in improving pharmacy services.

Inspector's evidence

There were two pharmacists, five accuracy checking technicians (ACTs) and twelve dispensing assistants present during the inspection. A further two pharmacists provided clinical support and were working from home at the time of the inspection. The staff were observed to be working well together and providing support to one another when required.

There was a separate customer service team based in Wales and this was usually staffed by 10 to 12 people. Based on previous issues with staffing capacity relating to service provision (see principle 4), the number of customer care team staff based on-site was increased from four to six. The superintendent pharmacist had started having meetings with the head of the customer care team twice a day. This was to ensure that customer queries were responded to in a timely manner. In addition, the capacity of the phone system had been significantly increased so that people did not get disconnected when trying to phone in to raise queries about their medicines.

Staff performance was monitored and formally reviewed annually. In these reviews, a development plan would be introduced to help further develop and train the members of staff. There was also a monthly one-to-one meeting process which with each staff member and their line manager. The staff reported that they had completed training online and had regular updates to their knowledge and understanding of the services provided. A dispensing assistant explained that she was currently on an NVQL3 course and was being supported by an accuracy checking technician. She had regular, scheduled protected time to complete her training. She explained that she was progressing well with her course and could ask an experienced ACT or a pharmacist for help if necessary. The supervisory ACT explained that he had significant experience in community pharmacy and was in a good position to mentor the new trainee technicians. The superintendent pharmacist reported that staff were encouraged to develop to their full potential and that the plan was to train more ACTs.

The whole pharmacy team met monthly and to discuss any procedure changes and patient safety issues. There were regular pharmacy team social evenings and events to encourage cooperation and collaboration. The pharmacy team were encouraged to provide feedback on how procedures were working. Based on feedback from the pharmacy staff, a traying process had been reviewed for the refilling of cannisters before they were loaded into the dispensing robot. Staff explained that they felt comfortable with raising any concerns they had with the superintendent pharmacist. Staff were aware of how to raise concerns on questioning. There were no formalised targets in place at the pharmacy.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy provides a safe and appropriate environment for the services it provides. The pharmacy team protects people's private information, and the pharmacy is secure and protected from unauthorised access.

Inspector's evidence

The pharmacy based in two large units on an industrial premises which is closed to public access. These unit had two levels. The upper levels were used as office areas and the bottom levels as the dispensing areas, apart from a staff room which was also on the ground floor. The total area of the premises was approximately 26,000 feet. The two units were large and well laid out. It was organised and all areas appeared clean and were presented in a professional manner. There were specific designated areas for each stage in the dispensing and dispatching process. This included areas for prescription management, medicine processing, medicine de-blistering, medicine pouch assembly and medicine pouch checking. There were also appropriate areas for medicine storage and dispatch.

There were sinks available with hot and cold running water with hand sanitiser to allow for hand washing. The ambient temperature and lighting throughout the pharmacy was appropriate for the delivery of pharmaceutical services.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's services are accessible, effectively managed and delivered safely. The pharmacy obtains, stores and manages medicines safely and ensures that all of the medicines it supplies are fit for purpose. The pharmacy team help advise people on how to take high-risk medicines safely. The pharmacy team takes appropriate action where a medicine is not fit for purpose.

Inspector's evidence

In response to a surge in demand and a growth in their business since the start of the pandemic, the pharmacy had invested significant resources into moving into a new premises and investing in new patient medical record (PMR) software. As a result of these changes, it caused some problems with patients not getting their medication on time and delayed responses to queries about patient's medication. The pharmacy reported that they had sent emails to warn people of service provision issues. Most of these service issues occurred between the period of April and May. Since then, the pharmacy have made several improvements to the capacity of their customer care contact centre (see principle 2). They are now up to date with their dispensing and dispatching processes. In addition, they deal with most customer queries within 24 to 48 hours. The pharmacy team ordered approximately 60% to 70% of their patients. Generally, they aimed to have the medicines with the patient 5 days before they were required. This aim was now being met for the majority of people and service provision had significantly improved since May.

The pharmacy was not accessible to patients. The only advanced NHS service offered by the pharmacy was the New Medicine Service (NMS). The pharmacy only dispensed medicines from NHS prescriptions. Most of these medicines were assembled using robots which would dispense the individual medicine into pouches. Some non-pouched medicines were dispatched separately. Most people using the pharmacy had several medicines. All medicines were delivered to patients. There was a delivery policy in place and medicines were sent using tracked delivery. Signatures were obtained for controlled drugs (CDs). Fridge items were sent with cooling boxes which kept the medicines between two to eight degrees Celsius for around 80 hours. If the medicine requiring refrigeration did not get to the patient within this timeframe, medicines usually had to be re-dispensed and re-dispatched. The superintendent pharmacist confirmed that medicines were not posted through letterboxes. Patients could return unused medicines to the pharmacy via a Freepost package.

If acute prescriptions were received for patients, there was a team of clinical pharmacists who would check whether the medicine was urgently required and could return to the spine if necessary, allowing it to be collected from another pharmacy. This may include medicines such as antibiotics and inhalers. The pharmacy used artificial intelligence dispensing software which would learn and automate dispensing processes for people who had been on repeat medicines for some time. The software could also generate directions on labels depending on what it had detected before. The superintendent pharmacist explained that this approach had worked well so far and reported very few mistakes. Most mistakes happened when a pharmacy staff member manually intervened in a process. All new medicines, CDs and high-risk medicines would be referred to a pharmacist for checking. The pharmacist gave an example of the artificial intelligence system highlighting a prescription for naproxen 500mg tablets. This is because it had directions that were unusual for naproxen, and this was passed to a pharmacist who would query it with the GP surgery.

The pharmacy was using bar-coding software which kept robust electronic audit trails of the entire dispensing and checking process. Those medicines assembled by the robot were checked by an optical checker. Most common medicines were de-blistered into canisters that were then placed into the dispensing robots. The pharmacy team used published data on the stability of medicines to ensure that they were suitable for pouching. This included the timescale of their stability outside of their original packaging. Staff gave examples of some medicines that were not suitable for pouching, such as ramipril tablets.

The pharmacy team had an awareness of the strengthened warnings and measures to prevent valproate exposure during pregnancy. Valproate patient cards were available for use during valproate dispensing to female patients. An e-mail would be sent to make patients aware of the risks around valproate medicines in pregnancy and to ensure that they had effective contraception in place. But it was not clear whether this email was being always received by patients. The superintendent pharmacist was in the process of writing up a new valproate medicines policy which address this issue. Patients taking other high-risk medicines such as lithium and methotrexate were sent appropriate guidance cards and counselled by the pharmacists.

The pharmacy used recognised wholesalers such as AAH, Alliance Healthcare and Phoenix to obtain medicines and medical devices. Specials were ordered from suppliers such as Alliance specials and Quantum Pharmaceutical. Destruction kits for the destruction of controlled drugs were available. Designated waste bins were available and being used for out-of-date medicines. A bin for the disposal of hazardous waste was also available for use. Waste was collected regularly and the pharmacy team explained they would contact the contractors if they required more frequent waste collection.

Medicines and medical devices were stored in an organised fashion. Where they were dispensed into cannisters, these contained labels and bar-codes which identified the medicine, the medicine’s form, strength, batch number and expiry date. Pharmaceutical stock was subject to date checks which were documented and up to date. Short-dated products were appropriately marked. The fridges were in good working order and the stock inside was stored in an orderly manner. MHRA alerts came to the pharmacy electronically and the pharmacist explained that these were actioned appropriately. Records were kept to verify this.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has access to the appropriate equipment and facilities needed to provide the services it offers. These are used in a way that helps protect patient confidentiality and dignity. The pharmacy uses innovative equipment and technology to reduce the risk of mistakes.

Inspector's evidence

The pharmacy was equipped with four large robots which were fitted with cannisters that enabled the dispensing of medicines into individual pouches. There were also three large optical checking machines that used light and near infrared image analysis technology to examine the content of each dispensed pouch. There was also a smaller version of one of these optical checking machines. This was used to scan pouches that had to be re-checked if a manual modification, such as a repair, had been made to one of the pouches. The pharmacy robots had regular maintenance and engineers could called out the same day to resolve any issues if necessary. Contingency measures were in place if any of these robots failed. The pharmacy used a barcode-based system which was used throughout the dispensing process. The superintendent pharmacist explained that this innovative technology used alongside the robot dispensing process reduced the risk of medicine selection errors and hence improved patient safety (see principle 1).

There was a satisfactory range of crown stamped measures available for use, although very few liquid medicines were dispensed. Electrical equipment appeared to be in good working order and was PAT tested annually. Pharmacy equipment was seen to be stored securely from public access. Up-to-date reference sources were available including a BNF and a BNF for Children. Internet access was also available should the staff require further information sources. There was a cloud based 4g internet connection backup if necessary.

There were two large fridges and one smaller fridge in use which were in good working order. The maximum and minimum temperatures were recorded manually daily and were seen to be within the correct range. These were also fitted with a probe that gave a 15-minute reading of the temperature and this could be connected to an application on a pharmacy team member’s phone. Designated bins for storing waste medicines were available for use and there was enough space to store medicines. The computers were all password protected and patient information was safeguarded.

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.