General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Pharmacy First, Unit 5, Crown Point South Industrial Park, King Street Denton, MANCHESTER, Lancashire, M34 6PF

Pharmacy reference: 1107410

Type of pharmacy: Internet / distance selling

Date of inspection: 07/03/2023

Pharmacy context

This is a pharmacy which offers its services to people through its website www.pharmacyfirst.co.uk. People do not visit the pharmacy in person. It mainly sells toiletries and over-the-counter (OTC) medicines, but it also has a prescribing service provided by a doctor based in the Czech Republic. The prescribing service is not registered or inspected by a UK based healthcare regulator. A wide range of prescription and OTC medicines are available via the website. The pharmacy dispenses a very small number of NHS prescriptions and some private veterinary prescriptions.

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	N/A	N/A	N/A
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 met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

Overall, the pharmacy’s working practices are suitably effective. It manages its prescribing service reasonably safely and it keeps the records required by law. The team members keep people's private information safe, and they complete training, so they know how to protect children and vulnerable adults. But the pharmacy does not always proactively identify risks associated with its online services to make sure it manages these in advance of services being introduced. And some team members have not confirmed their understanding of the pharmacy’s written procedures, so they may not always follow them, or fully understand their roles and responsibilities.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs) for the services provided. These had been reviewed by the regular pharmacist in August 2022. But some members of the pharmacy team had not indicated that they had read and accepted them, so they might not fully understand how the pharmacy operates. There were various different roles in the pharmacy team including dispensary, warehouse, accounts and IT team members. Members of the team appeared to be clear about their roles and responsibilities. The pharmacist superintendent (SI) was working as the responsible pharmacist (RP), but his name was not displayed in the pharmacy. This could cause confusion in the event of a problem or query and was not in line with RP regulations.

The pharmacy mainly supplied over the counter (OTC) medicines. These included treatments for allergies and hay fever, cough and colds, pain relief, and stomach and bowels. Medicines supplied included general sales list (GSLs) items and pharmacy (P) medicines. A number of high-risk P medicines were supplied such as pain killers containing codeine, and antihistamines used as sedatives, which are known to be overused and misused. The pharmacy had decided to stop selling codeine linctus and Phenergan elixir several months ago because of the risk of abuse; however, they still sold Phenergan tablets and tablets containing codeine which could also be abused. People wishing to purchase P medicines were required to answer some questions which the pharmacist reviewed before approving the supply. There was a risk assessment for high-risk medicines. The SI explained that risks had been identified around inappropriate sales and quantities of medicines and some maximum limits had been added to the website to prevent customers over ordering. He said the pharmacist thoroughly checked people’s previous purchasing history when they requested high-risk medication and made a judgement on a case-to-case basis. The payment process captured the IP address, so this could be crosschecked with other purchases if necessary. People were asked their age as part of the process when requesting P medicines. But the age and identity (ID) of people was not verified for any P medicines including the high-risk medicines. This could be a safeguarding risk and under-age people might be able to obtain medicines. There was a SOP for OTC analgesics containing codeine and dihydrocodeine which stated that the maximum quantity allowed was one packet per month. However, the risk assessment, that had been prepared more recently, stated that in addition to one supply per month, supplies exceeding two consecutive months would be refused and the person refunded. And the pharmacy team said they would review the procedure with regards to allowing repeated supplies, and have stricter safeguarding measures if needed. The SI said they were looking to introduce ID checks for high-risk P medicines, and following the inspection he confirmed that this was now taking place.

A wide range of prescription only medicines (POMs) were offered via the website. The most commonly prescribed medicines during the previous month were treatments for erectile dysfunction (ED), oral antibiotics, treatment for fungal nail infections, Nystatin for oral thrush and steroid skin creams. People could request a prescription by filling in an online questionnaire which was then assessed by the prescriber before the pharmacy supplied the medicine. Prescription requests were triaged by the pharmacy team. They checked for repeat orders in line with their prescribing guidelines and risks assessments, before submitting them to the overseas prescriber. The prescriber then reviewed the answers to the questionnaire and prescribed the medication if he felt it was appropriate. Electronic signatures on prescriptions were verified and were non-modifiable. The IP address of the prescriber could be checked. The pharmacy team could view the responses from the online consultations, and they were stored electronically. These could be used by the RP to help in their clinical check of the prescription. The pharmacy paid a third party to perform ID checks for the prescribing service so the prescriber and pharmacy could satisfy themselves that the person was genuine and the age they claimed to be. This was integrated into the website. If the ID check failed then the medication would not be supplied, and the person would be given a refund.

The pharmacy provided a complete set of risk assessments and prescribing policies for the clinical conditions it provided prescribing services for, which were underpinned by National Institute for Health and Care Excellence (NICE) guidelines. The pharmacy's prescribing policies reflected clinical risks for each condition. For example, there were clinical justifications for the request of medicines for the conditions based on the history of the presentation and relevant exclusion criteria based on precaution or red flag symptoms. Consultations could not proceed for certain higher risk conditions without consenting to access Summary Care Records (SCRs) and to notify a person's GP. For example, medication for asthma could not be processed unless a person had documentation on their SCR which demonstrated that there was an asthma plan in place, their annual review was not overdue, and they were on a regular preventer inhaler. Evidence that this was taking place was demonstrated during the inspection. A small number of asthma inhalers had been prescribed and the people receiving them had consented to allow the pharmacy to view their SCR's and to share the information about the supply with their GP. This was mandatory for asthma. And the pharmacy only allowed one asthma inhaler to be supplied to each person. A message was sent to people when they requested an inhaler for a second time explaining they must contact their own GP for any further inhalers. Access to the patient's SCRs was recorded on their patient medication record with the date of access and whether evidence of a preventer and asthma review was seen.

Prescribing policies for antibiotics prescribed for chlamydia and bacterial vaginosis (BV) required a confirmed diagnosis of genital chlamydia by GP, genitourinary medicine (GUM) clinic or by using a home test. The SI could not demonstrate evidence that this was undertaken in practice, and compliance with this had not been included in the antibiotic audit. The SI said if evidence was not provided a single one-off supply might be made. The pharmacy followed a programme of regular audits for their prescribing services and provided a number of clinical audits which the team had completed in the last few months. These covered the use of antimicrobials, medication for asthma and steroid creams for the treatment of eczema. The audits included appropriate sample sizes, and they monitored compliance against a number of clinical parameters, listed in the pharmacy's prescribing policies, including whether exclusion criteria were being adhered to, repeat requests were being monitored and reviewed, and clinical guidelines were being complied with. Following the inspection, the regular pharmacist stated that she had started an audit on the high-risk P medicines due to the volume being supplied.

There were SOPs for dealing with dispensing incidents and near miss errors. A small number of near misses which had occurred in the dispensary had been recorded on a log. The business development manager, who was a pharmacy technician (PT), explained that dispensing errors were very rare because

the volume of POMs dispensed was relatively low. One of the warehouse operators explained errors sometimes occurred when the incorrect OTC medicine was sent to a person. He said the team had a meeting following a number of mistakes when the incorrect antihistamine had been supplied to people. The issue was discussed with the warehouse team, and it was decided that the RP should check the contents of every basket of P medicines before they were sent to people to help avoid errors of this type.

There was a SOP for dealing with complaints. There was a customer service section on the website with a ‘contact us’ tab, which led people to the Pharmacy First helpdesk. This contained information in a knowledgebase, and it was possible to contact the pharmacy by submitting a support request. The customer service assistant explained that she dealt with these requests, and she would transfer any professional queries to the RP. She said she did not give any healthcare advice and any requests about medicines were forwarded to the RP. The website did not contain the pharmacy’s telephone number, so people might find it difficult to speak to a member of the pharmacy team. The pharmacy’s operating hours, telephone number and complaint procedure were included in the practice leaflet, which was available through a link on the website, but people might not know where to look for this information, and so they might not know how to raise a concern. The pharmacy used Trustpilot to monitor the customer service of its online services.

The SI confirmed that appropriate insurance was in place and the pharmacy was fully covered for the activities carried out and he stated that the insurance providers were aware that the prescriber was not in the UK. Following the inspection, the SI forwarded the prescriber’s indemnity insurance policy which was dated 2019. The SI said the insurance was automatically renewed on an annual basis. He confirmed that he had checked this with the prescriber and this year’s premium had been paid, so his indemnity insurance was current and up to date.

Private prescriptions were recorded electronically. The RP record generally appeared to be in order, but the SI had been absent for part of the morning and had not made an accurate entry in the RP record to reflect this. He completed the entry when this was pointed out. The pharmacy kept a record of all patient contact, consultations, and interventions on its own internal systems.

Confidential waste was placed in designated bins which were collected by a waste disposal company for shredding. A member of the team understood the difference between confidential and general waste. A privacy policy was available on the website, along with the details of how to contact the pharmacy’s data protection officer (DPO) and the registration details with the Information Commissioners Office (ICO). The pharmacy had a safeguarding policy. The SI, regular pharmacist and business development manager had completed level 2 training on safeguarding.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload. The team members work well together in a busy environment, and they are comfortable providing feedback to their manager. Team members have access to appropriate training courses. But the pharmacy sometimes delays providing formal training, which means team members may not have the right skills and knowledge for some the tasks they complete.

Inspector's evidence

There was a pharmacist (SI), a business development manager, two warehouse operatives, a customer service assistant, an account assistant, and an IT assistant on duty at the time of the inspection. The staffing level was adequate for the volume of work. One of the warehouse operatives was enrolled onto a medicine counter assistant (MCA) course. He explained he had nearly completed the course, although he didn't usually get protected training time. The other warehouse operative had worked at the pharmacy for more than three months, but he had not been enrolled onto an MCA course even though he was involved in the selection and packing of P medicines. He said he had done some on-the- job training and was hoping to begin an apprenticeship. Following the inspection, the SI confirmed that the unqualified warehouse operative had been provided with internal training and was being supervised, and provided evidence that he had been enrolled onto a suitable MCA course.

In addition to the SI, there was another pharmacist who regularly worked at the pharmacy but they were not present at the inspection. The SI stated that they validated the prescriber's credentials every quarter and the prescriber was fully aware of the NICE guidelines. The pharmacy audited his prescribing regularly to ensure that he was adhering to the NICE guidelines.

Individual team members discussed their performance and development informally with their line manager. Other issues were discussed within the pharmacy teams on a daily basis as they arose. Formal meetings were held when there was something significant to discuss. Team members confirmed they would feel comfortable talking to their line manager about any concerns they might have. There was a whistleblowing policy. The SI confirmed that pharmacists checked all P medicine orders and prescriptions before they were supplied. He confirmed that pharmacists had access to the person's order history for P medicines, and a copy of the patient's medication history for prescriptions and they were able to exercise their professional judgement in deciding whether to supply or not. There was evidence of the pharmacy team refusing supplies of medication and the prescriber was paid per consultation reviewed rather than for each prescription generated.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises generally provide a professional environment for the provision of healthcare services. The pharmacy's website has some useful information about the pharmacy and its prescribing service. But the design and content of the website could be improved to promote a more professional image and discourage inappropriate purchasing or use of medicines.

Inspector's evidence

The pharmacy premises were reasonably clean and in an adequate state of repair. The temperature and lighting were suitably controlled. The premises consisted of a large warehouse where P and GSL medicines were stored, picked, and packed ready for postage. There was a separate dispensary where POMs were stored and dispensed. This room had a lock on the door which could restrict access when the pharmacy was closed. Staff facilities included offices, a small kitchen area, and two WCs with wash hand basins and hand wash. There was hot and cold running water. Part of the premises were used as the company's head office and there was a stock room on the mezzanine floor which contained stock for the other pharmacy branches in the company. A buyer for the group was working in this area during the inspection.

The pharmacy's physical address and registration number was displayed on the website. There was information about the SI and how to check his registration status. There was a copy of the prescriber's qualification certificate and a link to check his registration. The website listed a range of POMs under conditions such as 'asthma' or 'erectile dysfunction'. The website showed which medicines were available for each condition. It directed people to start the online consultation for the condition they wished to treat before being able to select a medicine. The online questionnaire had been modified since the last inspection and it no longer alerted people to clinical responses which prevented them from obtaining a medication. The website sometimes used inappropriate transactional language such as 'add to bag' which gave the impression people were buying medicines rather than accessing a healthcare service. This detracted from the professional image of the website. People were also incentivised to 'bulk buy' P medicines with 'deal of the week' and 'crazy deals,' and large discounts were available, which was unprofessional and could encourage the inappropriate use of medicines.

Principle 4 - Services ✔ Standards met

Summary findings

In general, the pharmacy's dispensing and retail operation is well managed, and its services are easy for people to access. It gets its medicines from licensed suppliers and the team carries out checks to ensure medicines are in suitable condition to supply. The pharmacy has some checks and controls in place to prevent over ordering of medicines. But it supplies large amounts of over-the-counter medicines, including some high-risk items. And it could sometimes do more to check that medicines are being used correctly and make sure that they are appropriate for the people they supply.

Inspector's evidence

This was a closed pharmacy which provided its services to people at a distance. There were details about the pharmacy's services and health information on the website. Each pharmacist had their own personal log in details to access a portal where they could view the requests for P medicines and POMs. People wishing to purchase P medicines were required to answer a small number of questions. There was also a free-type box for some of the medicines. Supplies were put on hold and could not be made until a pharmacist had reviewed the answers and approved the supply. The questions were generally the same for all the P medicines although some additional information was required for some of the medicines, for example for thrush. Records of sales were recorded for each customer, so patterns could be monitored. Some blocks were built into the website to prevent over-ordering. For example, only one packet of a codeine or dihydrocodeine containing product could be sold at a time. However, people were able to purchase two packets of sedatives at a time and repeat purchases of all high-risk P medicines were allowed after an interval which the RP considered suitable. Several examples were seen when supplies had been declined and the person was refunded the price of their medicine. One example was seen when the sale of a sedative had been stopped and the person sent a message that this was because the pharmacist was concerned with the frequency of orders for medicines containing promethazine. They were signposted to their GP, but they had been given a date when they would be allowed to order it again. The pharmacy was able to block a person from the website to prevent further orders from being placed. This functionality was manual and there were no automated flags to highlight duplicate accounts or inappropriate supplies, so this relied on the vigilance of the team.

The warehouse operatives were packing up large quantities of antihistamines to post out to people. Some people were receiving 12 packs of 30 cetirizine tablets, which was a year's supply. The orders had been approved by a pharmacist. Some orders were for large quantities of treatments for vaginal thrush. For example, three fluconazole 150mg capsules and two or three tubes of clotrimazole cream for the same person, which does not promote good antimicrobial stewardship and people with recurring thrush should be referred to their GP for further investigation.

People requiring a POM, completed an online consultation, however, other than treatments for asthma, there were few checks made to verify that the information they had entered was correct. This was a risk because people might accidently or deliberately enter incorrect information in order to receive a supply. And some higher risk medication, such as antibiotics, could be ordered for indications other than those listed by circumnavigating responses on the online questionnaire. The SI said only one supply of antibiotics, asthma inhalers and steroid creams were allowed. When people requested a

further supply, they were referred to their GP. A search of the private prescription register in the six-month period September 2022 to March 2023 showed very few repeat supplies. There were two repeat orders for steroid creams and they were for the same person, who received two supplies of Betnovate and two supplies of Eumovate within three months. There were three occasions when people had received two supplies of Nystan oral suspension, one occasion when a person received two supplies of metronidazole tablets and another person received two supplies of Macrobid. This was contrary to the pharmacy's prescribing guidelines. Following the inspection, the SI confirmed that in all these cases the patients were contacted before further supplies were given, and the need assessed on a case-by-case basis. He said these contacts were recorded, and in general if a suitable period of time had not elapsed, then the person would be refused treatment and referred to their GP.

The RP could access the consultation completed by people for supplies of POM medication, to assist with their clinical check. The pharmacy team demonstrated evidence that people's GPs had been notified when they had consented to this. One example was seen when a request for an asthma inhaler was declined because the person's SCR did not show an asthma diagnosis. A message was sent to the person asking for them to send a repeat prescription slip to show they had previously been prescribed an asthma inhaler from their usual prescriber.

All medicines were packaged appropriately and posted by a Royal Mail service which could be tracked by the pharmacy. Space was adequate and the workflow was organised into separate areas. The warehouse and dispensary shelves were reasonably neat and tidy. High- risk P medicines were stocked on separate shelves. Recognised licensed wholesalers were used to obtain medicines. Medicines were stored in their original containers. There was a controlled drug (CD) safe in the pharmacy, but schedule 2 and 3 CDs were not usually stocked or supplied by the pharmacy. There was an area containing returned medicines. One of the warehouse operators said he dealt with the OTC medicines, including P medicines which had been returned. He said they were not re-used.

Alerts and recalls were received via email messages direct from the Medicines & Healthcare products Regulatory Agency (MHRA). These were read and acted on by a member of the pharmacy team and filed.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

Members of the pharmacy team have the equipment and facilities they need for the services they provide.

Inspector's evidence

The pharmacist could access the internet for the most up-to-date information. For example, the electronic versions of the British National formulary (BNF) and medicines compendium (eMC). There was a clean medical fridge in the dispensary which was suitable for storing medicines. The minimum and maximum temperatures were being recorded regularly and appeared to have been within range throughout the previous month. But the temperature was 1.4 degree Celsius at the time of the inspection and the minimum temperature was showing as minus 4 degrees Celsius, which was outside of the required range. The pharmacy did not normally supply any medicines requiring refrigeration and the SI explained that the medicines which were stored in the fridge were obsolete and would be destroyed. The thermometer was reset, and the SI adjusted the positioning of the thermometer probe and asked a member of the pharmacy team to monitor the temperature. All electrical equipment appeared to be in good working order. There was a small selection of equipment for measuring liquids and counting loose tablets and capsules, but this was very rarely used, as medicines were usually supplied in their original container. Secure Sockets Layer (SSL) was installed on the webserver for website and data security. This was a computing protocol that ensured the security of data sent via the internet by using encryption. PMRs were password protected. Cordless phones were available in the pharmacy, so staff could move to a private area if the phone call warranted privacy.

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.