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: 30/06/2022

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. The pharmacy 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. A wide range of prescription and OTC medicines are available via the website. The pharmacy dispenses a very small number of NHS prescriptions and private veterinary prescriptions.

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's risk assessments do not identify all of the risks associated with the sale of high-risk pharmacy medicines or the prescribing service. And they do not clearly explain how risks are managed.
		1.2	Standard not met	The pharmacy does not effectively audit or review the prescribing service or adherence to prescribing policies, to make sure the service is safe.
		1.6	Standard not met	The pharmacy's responsible pharmacist (RP) record and private prescription records are not accurate.
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 sells medicines via its website. But it does not always provide enough information for people to be able to make sure the medicines they choose are safe and appropriate for them. And people using the pharmacy's services cannot easily contact the pharmacist for information and advice. The pharmacy is not able to demonstrate that sufficient safeguards are in place to make sure the medicines it supplies are clinically appropriate. This includes: verifying the information provided by the person completing the online questionnaire, confirming a diagnosis of an existing medical condition, sharing all relevant information with the patient's regular doctor and ensuring effective monitoring is in place. And the online questionnaires are set up so people can circumvent the system and change their responses in order to obtain a supply of medicine which may not be appropriate. This is of particular concern when supplying antimicrobials, and medicines for chronic conditions such as asthma and weight loss which require monitoring.
5. Equipment	Standards	N/A	N/A	N/A

Principle	Principle finding	Exception standard reference	Notable practice	Why
and facilities	met			

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

Summary findings

Whilst the pharmacy has made some changes and improvements, it does not consistently manage all of the associated risks with the supply of high-risk pharmacy and prescription only medicines. This means people might be able to obtain medicines which are not always appropriate for their needs and could cause them harm. The pharmacy works with a prescribing service based in Europe, so it is not registered or monitored by a UK healthcare regulator. And the pharmacy does not regularly audit or review the prescribing service to make sure it is safe and in line with UK guidelines. People can purchase high-risk pharmacy medicines without providing proof of their name, address or their age, which is a safeguarding concern. The pharmacy's records are not accurate, which could make it harder to understand what has happened if problems occur. And 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. But most 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. 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, and team members were not sure which RP was on duty. This could cause confusion in the event of a problem or query.

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 including high-risk items such as pain killers containing codeine, and sedatives, which are known to be overused and misused. People wishing to purchase P medicines were required to answer a small number of questions which the pharmacist reviewed before the supply. There were risk assessments for GSLs and P medicines. Risks were identified around inappropriate sales and quantities of medicines and some maximum limits had been added to the website to prevent customers over ordering. People requesting high-risk medication such as pain medication, sedatives and laxatives went through some additional checks. There weren't any risk assessments for individual medicines but there were procedural sheets for each of these categories, which outlined the checks, restrictions and the actions required. People were asked their age as part of the process when requesting P medicines, but it was not possible to enter an age under 18, so people under 18 might enter an incorrect age in order to proceed to the next step. The age and identity (ID) of people requesting P medicines was not verified which may be a safeguarding risk for some medicines and under-age people might be able to obtain medicines. The pharmacy had decided to stop selling codeine linctus and Phenergan elixir because of the risk of abuse; however, they still sold Phenergan tablets and tablets containing codeine.

A wide range of prescription only medicines (POMs) were offered via the website. The most commonly prescribed medicines were for erectile dysfunction (ED), oral antibiotics, antihistamines, asthma inhalers, treatments for hair loss and Nystatin for oral thrush. People could request a prescription by

filling in an online questionnaire which was then assessed by a doctor before the pharmacy supplied the medicine. The pharmacy team could view the responses from the online consultations and they were stored electronically. The doctor was based in the Czech Republic. The prescribing service was not registered or inspected by a UK based healthcare regulator as it was located in Europe. 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 not a live system, and the information was uploaded manually by the team after payment for the medicine was received. So, there was a risk that this might not happen on every occasion. If the initial ID check failed, a link was sent to the person so that they could upload additional information such as photographic ID or credit card information. If they failed these checks then the medication would not be supplied, and the person would be given a refund.

There were risk assessments for the POMs supplied, but the control measures detailed in the risk assessments and prescribing protocols to mitigate risks were not always followed in practice. For example, with antimicrobials, the risk assessments stipulated that a positive diagnosis by a GP, GUM clinic or a home test kit was required. But evidence to confirm this was not collected during the online consultation. There had been seven occasions in the last six months where patients had received more than one supply of metronidazole for bacterial vaginosis (BV), without being referred to their GP or sexual health services. One patient had been prescribed metronidazole three times in three months. Recurrence of BV is common, however the NHS page for BV recommends that patients may require longer treatment if they have had more than two occurrences in 6 months, and therefore the patient may require a referral to their GP or sexual health clinic. NICE and the British Association for Sexual Health and HIV (BASHH) guidance recommend that for recurrence diagnosis should be reconsidered and contributing factors to BV should be enquired about. However, there was no evidence of this, or of any referral, which illustrates that prescribing was not in line with best practice guidance. There had been no audits of the prescribing of oral antibiotics, which generated the second highest number of prescriptions after ED.

The operation manager explained that it was difficult to manage the risks when supplying asthma inhalers as people were reluctant for the pharmacy to share information with their own GP and accessing Summary Care Records (SCR's) was problematic. So, the team had decided to reduce the number of inhalers that were supplied to each person to one inhaler only. A letter was sent to people when they requested an inhaler for a second time explaining they must contact their own GP for any further inhalers. However, this meant that people were still prescribed an asthma inhaler without confirmation of an asthma diagnosis or any verification that the person's asthma was under control and being monitored. And without their usual GP being informed.

The pharmacy supplied a small number of prescriptions for weight loss medicines. The consultation process did not involve a physical examination or verification of the information supplied. The pharmacy only supplied oral treatments and it did not supply any injectable treatments, as it was considered too difficult to manage the risks. Questions were asked about eating disorders in the weight loss consultation but there was no way of assessing a patient's mental capacity, to determine whether a remote consultation or use of online questionnaires was appropriate.

The pharmacy was only able to demonstrate they had carried out one clinical audit in the last year, which was inadequate for the number of prescriptions and range of medicines supplied by the pharmacy. The audit was on the supply of Nystatin for oral thrush, but the time period audited was too short and so the sample size was too small for the information to be useful.

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 dispensed was relatively low. The warehouse manager explained that the team sometimes made mistakes and sent the incorrect OTC medicines to people. He said they were human errors and were logged on the computer and discussed with the warehouse team, to help avoid re-occurrences. There was a customer service section on the website with a 'contact us' tab, which led people to the Pharmacy First helpdesk, but this only contained information in a knowledgebase. It was not possible to contact the pharmacy through this link. And it did not contain the pharmacy's email address or 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 and it had a 4.7 out of 5 rating. A current certificate of professional indemnity insurance was on display in the pharmacy. The SI confirmed that this covered all the activities carried out at the pharmacy, and that the insurance provider was aware of the use of a prescriber from the EU. Following the inspection, the SI stated that he had confirmed the validity of the prescriber's identity documents and qualifications and ensured all their indemnity insurance payments were current and up to date.

Private prescriptions were recorded electronically, but the patient medication record (PMR) system defaulted to NHS prescriptions and had to be manually changed every time a private prescription was dispensed. So, there was a risk that some prescriptions might be entered incorrectly as NHS prescriptions, and therefore not be recorded in the private prescription register. Several errors were seen in the private prescription records. The EU prescriber had been incorrectly named as the prescriber on seven veterinary prescriptions in the last six months. A prescriber from a third-party prescribing service which the pharmacy had not used for around a year was incorrectly named on 56 prescriptions, five of which were veterinary prescriptions.

The SI was absent for the first half an hour of the inspection. He did not record the absence in the RP log, and he did not tell the members of the team where he had gone, or how long he would be gone for. One member of the pharmacy team said the SI often visited other branches during the day. The failure to record absences in the RP log compromised its accuracy and meant the pharmacy could not reliably demonstrate when a pharmacist was present, as required in the RP regulations. The pharmacy's operating hours shown in the practice leaflet were 9am-5.30pm Monday to Friday but on six occasions during June 2022 the RP record indicated that the RP had not commenced their duties until 10am, and on ten occasions they had ceased their duties before 5pm. This meant the pharmacy was sometimes effectively operating without an RP for periods of the days. And there was a risk that team members might carry out activities requiring an RP, when no RP was signed in.

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 are comfortable providing feedback to their manager. Some members of the team are on appropriate training courses, but others are doing tasks that they aren't trained or qualified to do, sometimes without appropriate supervision, which increases the chance of mistakes happening.

Inspector's evidence

There was a pharmacist (SI), an operation manager, a business development manager, a warehouse manager, a warehouse operative, two account staff and an IT assistant on duty at the time of the inspection. The staffing level was adequate for the volume of work. The operation manager had a background in IT and dealt with website issues. He was enrolled onto a dispensing assistant course. The warehouse manager was enrolled onto a medicine counter assistant course. They both confirmed that they had made some progress on these courses, which they commenced around a year ago, but they had not yet completed them. The warehouse operative was completing a warehousing apprenticeship, but they had not been enrolled onto a medicine counter assistant course even though they were involved in the selection and packing of P medicines. The SI agreed to enrol them onto an appropriate course and provided confirmation that this had happened the same day. In addition to the SI, there was another pharmacist who regularly worked at the pharmacy. They were not present at the inspection. The SI confirmed that the prescriber was a registered medical practitioner in their home country, but information on their specific expertise was limited. Following the inspection, the SI confirmed they had spoken to the EU doctor and had reaffirmed with him that he was up to date with his knowledge of current UK NICE guidelines.

Individual team member's performance and development was discussed informally, apart from the apprentices, who were on a structured training programme with formal assessments and appraisals. Tutors from their college visited the apprentices at the pharmacy. Most issues were discussed within the pharmacy teams on a daily basis as they arose. A formal meeting had been held in the pharmacy which had been attended by pharmacists and management when the updated GPhC guidance for registered pharmacies providing services at a distance was issued. A record of this meeting was made. Team members confirmed they would feel comfortable talking to the SI 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 they had access to the person's order history for P meds 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. The prescriber was paid per consultation reviewed rather than each prescription generated.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises generally provide a professional environment for the provision of healthcare services. But the pharmacy's website frequently incentivises sales which could encourage the inappropriate use of medicines. And information about the pharmacy and the prescriber is difficult to find on the pharmacy's website, so people may not have enough information to make an informed decision about their care.

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.

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 and the prices. It directed people to start the online consultation for the condition they wished to treat before being able to select a medicine. The website sometimes used inappropriate transactional language such as, ‘add to bag’ or ‘shopping cart’ which gave the impression people were purchasing 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 discounts were available for both P and POMs, which was unprofessional and could encourage the inappropriate use of medicines.

The pharmacy’s registration number was on the website, but it did not prominently display the name of the owner and SI, information about how to check the registration status of the SI or the physical address and contact details of the pharmacy. The website did not prominently display the name and address of the prescribing service, the prescriber’s registration number and how to check their registration status.

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

Summary findings

The pharmacy's working practices are not suitably safe and effective. Its website does not always provide enough information about the medicines it sells or explain how to use them safely. This means people may not make the most suitable choice when selecting medicines. And people cannot easily contact the pharmacy for information and advice. The pharmacy does not always make enough checks to ensure medicines obtained through the prescribing service are appropriate for the people they supply. It supplies some medicines which may not be appropriate for supply via a remote consultation using online questionnaires because they require confirmation of diagnosis, physical examination, blood tests or monitoring. The pharmacy routinely supplies medicines without informing the patient's regular doctor. This means their condition might not be properly monitored, and their use of medication may not be adequately controlled. The pharmacy obtains medicines from recognised suppliers, and it generally stores and delivers them safely.

Inspector's evidence

This was a closed pharmacy which provided its services to people at a distance. Some information about the pharmacy's services were available on its website. There was a small amount of health information on the website and blogs on topics such as hay fever and pain, but information about each medicine was very limited. Website listings for P medicines including co-codamol tablets, Paramol, kaolin and morphine mixture and Phenergan tablets contained only one or two lines of information without any safety advice or informing the person of the risk of addiction. This means people may purchase medicines without fully understanding what they are used to treat, and the risks involved.

People wishing to purchase P medicines via the internet were required to answer a small number of questions. There was also a free-type box for some of the medicines. Each pharmacist had their own personal log in details and the requests were placed on hold 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 medicines for thrush and EHC. 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, they could be purchased again after an interval of one month. Additional checks were made by the IT team when people requested opioid containing medicines, sedatives or laxatives. Names, addresses and IP addresses were checked for multiple accounts and the date of the last supply was noted. Some sales were 'stopped' because they didn't pass these checks and the person could be blocked on the website to prevent further orders from being placed. This functionality was all manual and there were no automated flags to highlight any duplicate accounts or inappropriate supplies, so this relied on the vigilance of the team. During the previous month 79 pharmacy medicines supplies had been stopped including Phenergan tablets, Nurofen plus, Solpadeine and kaolin and morphine mixture. Some of these were because they were repeated orders within one month. This indicated the person ordering might have a problem with addiction, yet they had not been signposted for support. Examples were found which would indicate that a person might be overusing codeine containing medicines. One person had received ibuprofen and codeine on 28/3/22, 29/4/22. 26/5/22 and 27/6/22. This was not in line with the current guidance which specifies that medication containing codeine is for short-term use only and for a maximum of 3 days. The person

had not been signposted to their GP for a review of their condition, or for further support. Another patient made two orders on the same day for Phenergan. This was identified and the second order stopped, but one of the supplies was still permitted, and no support was offered.

The warehouse manager and operative were packing up large quantities of antihistamines. Each person was receiving 12 packs of 30 cetirizine tablets, which was a year's supply. The orders had been approved by a pharmacist. The pharmacy's procedure was that the assembly of P medicines orders should be checked by a pharmacist or PT before being supplied, however this was not being followed. 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 as people with recurring thrush should be referred to their GP for further investigation. People requiring a POM, completed an online consultation, however most of the questions were set up so that it was clear which answer would prevent the supply of the medicine. The person was then allowed to change their answer without any record of the change being made. So, neither the pharmacy team nor the prescriber knew that the incorrect responses had previously been entered. And no evidence was required 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 prescription request was first triaged by the pharmacy team who checked for repeat orders in line with their prescribing guidelines and risks assessments before being submitted for the EU prescriber to review. The EU prescriber then reviewed the answers in the questionnaire and prescribed the medication. The operation manager confirmed the electronic signature complied with requirements. He said it was checked on each occasion and was non-modifiable. The IP address of the prescriber was reviewed as part of this process.

A free-type box had been added to the asthma consultation which appeared after the initial questionnaire had been submitted. A question about consent for the prescriber to contact their GP was asked at this point but it came with the warning that a positive response might delay the person receiving their medication. This would probably deter most people from choosing this option. The operation manager said very few people consented to share information with their usual prescriber and he estimated around 5%. The pharmacy team could not demonstrate evidence of any GP notification. There was no proof required that a person was asthmatic or any questions about the use of a preventer inhaler during the asthma consultation. Consent to view the person's SCR was not part of the online consultation. The RP could access the consultation completed by people for supplies of POM medication, to assist with their clinical check. There were a couple of occasions where inhalers were dispensed more than once contrary to the pharmacy's prescribing guidelines, but the SI said these were probably errors which should have been deleted.

All medicines were packaged appropriately and posted by a Royal Mail service which could be tracked by the pharmacy. A very small number of NHS prescriptions were dispensed. The SI said they offered this service, but it was not promoted. The business development manager said she could not recall when the last NHS prescription had been dispensed, it was so long ago. These were usually for members of staff and their friends and family, so they did not require delivery or postage. 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. Dispensed by and checked by boxes were initialled on the medication labels of POMs. 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 a plastic tote tray containing returned medicines. The warehouse manager said he dealt with the OTC medicines, including P medicines which had been returned. He said they would be examined and if the packaging was in good condition, they would be returned to stock to be re-used. However, the storage conditions of these medicines whilst they had been away from the pharmacy was unknown, so they might not be fit for use.

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, but the action taken was not recorded so they would not easily be able to respond to queries and provide assurance that the appropriate action had been taken.

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). 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.