General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Derix Healthcare Pharmacy, 1065 London Road, LEIGH-ON-SEA, Essex, SS9 3JP

Pharmacy reference: 1092675

Type of pharmacy: Community

Date of inspection: 14/11/2023

Pharmacy context

The pharmacy is located on a parade of shop on a busy main road in a largely residential area. It provides NHS dispensing services, the New Medicine Service, flu vaccinations and COVID vaccinations. It also provides a private prescribing service, an ear irrigation service, blood pressure checks and vitamin B12 injections. It provides medicines as part of the Community Pharmacist Consultation Service. The pharmacy supplies medicines in multi-compartment compliance packs to a small number of people who live in their own homes and need this support. And it supplies medicines to some care homes. The pharmacy provides substance misuse medications to a small number of people.

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 cannot show that it identifies and manages the risks associated with its prescribing service adequately. It does not carry out adequate risk assessments for this service. And it cannot demonstrate that it shares information about the treatment it supplies with people's usual prescriber.
		1.2	Standard not met	The pharmacy does not sufficiently monitor the safety and quality of the various elements of its prescribing service. For example, by undertaking regular clinical audits.
		1.6	Standard not met	The pharmacy does not keep adequate consultation records for its private prescribing service to show that this service is safe.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy cannot sufficiently demonstrate that all its prescribers have the appropriate training and competence for the services they provide.
3. Premises	Standards not all met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy cannot demonstrate that its prescribing service is safe. For example, the pharmacy's prescriber does not make the appropriate records to show that medicines are only supplied when clinically appropriate. The pharmacy doesn't routinely seek consent to share information with other healthcare providers or share details about what has been prescribed with people's regular prescribers when it has consent to do so. It does not monitor the safety and quality of its prescribing service. The pharmacy cannot sufficiently demonstrate that it provides its vitamin B12 injection service in accordance with legal requirements.
		4.3	Standard not met	The pharmacy does not always manage its medicines properly or store them securely.
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

The pharmacy cannot show that it adequately identifies and manages the risks associated with all its services, particularly its prescribing service. It does not undertake risk assessments before implementing a new service. And it does not monitor the safety and quality of its prescribing service, for example by conducting regular clinical audits. The pharmacy does not share information about the treatment it provides through its private prescribing service with people's usual prescribers. And it doesn't keep consistent records about its consultations to show that its prescribing service is safe. The pharmacy doesn't always record mistakes that happen during the dispensing process. And this could mean that team members are missing out on opportunities to learn and improve the pharmacy's services. However, it protects people's personal information well. And team members understand their role in protecting vulnerable people. People can provide feedback about the pharmacy's services.

Inspector's evidence

The pharmacy had some generic standard operating procedures (SOPs), but they had not been tailored to the pharmacy. And the staff roles and responsibilities matrix had not been completed. The SOPs were not always being followed, for example, prescriptions were routinely processed for payment before medicines were collected. The superintendent pharmacist (SI) said that team members had signed to show that they had read, understood, and agreed to follow them. But he could not find the signature sheets during the inspection. The pharmacy issued private prescriptions for conditions such as respiratory tract infections and urinary tract infections. And the pharmacy's website advertised that the pharmacy also issued prescriptions for inhalers, antibiotics, creams, ointments and emergency contraception. But when asked, the SI was unable to produce evidence of any risk assessments for the clinical prescribing services the pharmacy provided.

We were told the pharmacy's prescribing service was provided by an external pharmacist independent prescriber (PIP) who periodically came into the pharmacy to provide the service. The SI was also a PIP but he said that he had not issued any prescriptions as part of this clinical service. However, during the inspection a number of prescriptions were identified that had been written by him in March 2023. His name was also in the private prescription register as having written a prescription recently for a medicine for a urinary tract infection. He could not find a copy of this prescription during the inspection. The SI said that he prescribed under the National Institute of Clinical Excellence (NICE) guidance and the British National Formulary (BNF). When asked, the SI seemed to be unaware of any local urinary tract infection prescribing guidance.

The pharmacy also provided an ear irrigation service. When asked, the SI stated that this service relied on a verbal consultation and verbal consent. The pharmacy did not keep any records about people's ear irrigation consultation or ongoing treatment as part of this service, and patient outcomes were not monitored.

Records about the vitamin B12 service were only documented on paper and not electronically. This increased the risk of duplicate vitamin B12 injections being administered to the same person and interactions being missed.

There was no formal mechanism for communicating with the person's usual GP or any other healthcare

professionals. When asked, the SI said that the pharmacy did not contact or communicate with people's regular prescriber or other healthcare professionals involved in a person's care about medicines the pharmacy had prescribed. When asked the SI stated that the pharmacy had not conducted any audits of the prescribing service.

Near misses, where a dispensing mistake was identified before the medicine had reached a person, were highlighted with the team member involved at the time of the incident. And once the mistake was highlighted, team members were responsible for identifying and rectifying them. Dispensary team members said that there had been several near misses recently, but none had been recorded since May 2023. A separate near miss record was kept for the care home service. Team members said that the record was reviewed regularly, but there was no documentary evidence to show that this had been done. And there was no record of any action taken as a result of the reviews. Dispensing errors, where a dispensing mistake had reached a person, were recorded on a designated form. The SI said that there had been a recent error where the directions on the label were confusing, so he had spoken with the team to remind them how to make the directions clearer.

Workspace in the dispensary was limited and there was little clear space for dispensing and checking medicines. Baskets were used to minimise the risk of medicines being transferred to a different prescription. The team members initialled the dispensing label when they dispensed and checked each item to show who had completed these tasks.

Team members said that the pharmacy would not open if the pharmacist had not turned up. And they knew that they should not sell any pharmacy-only medicines or hand out dispensed items if the pharmacist was not in the pharmacy.

The pharmacy had current professional indemnity insurance. The electronic private prescription records were mostly completed correctly, but the correct prescriber details were not always recorded. This could make it harder for the pharmacy to find these details if there was a future query. There was a document from a hospital for a person, but it was not a valid prescription as it was not signed by a prescriber. And a supply appeared to have been made. The SI said that he had written a prescription for the medicines listed on the document, but he was not able to locate this prescription during the inspection. The SI said that the pharmacy did not make supplies of medicines in an emergency without a prescription and said that all people were referred to use the NHS 111 system. Controlled drug (CD) registers examined were largely filled in correctly, but the address of the supplier was not routinely recorded. The CD running balances were checked at regular intervals and any liquid overage was recorded in the registers. The recorded quantity of one CD item checked at random was the same as the physical amount of stock available. The responsible pharmacist (RP) record was completed correctly. But the wrong RP notice was being displayed at the start of the inspection, and the SI then put up the correct notice.

Consultation records about the private prescribing service were seen for prescriptions that the SI and PIP had written. The records were not recorded in a consistent manner and at times did not contain sufficient detail. A selection of paper private prescriptions was reviewed during the inspection. Some of the prescriptions were seen to have consultation notes written on the pack of the prescription. A number of these records seen included a single diagnosis but had little record of the person's signs or symptoms or any clinical examination information such as temperature, respiratory rate, pulse, urine colour, pain scores, or gum and tooth colour. The SI explained that in other instances there were electronic records made on the pharmacy's patient medication record (PMR) about the consultation. When asked, he was only able to show one consultation record that had been recorded on the PMR which was for a urinary tract infection. It was noted that the record lacked sufficient detail and consisted of only four words (burning pain frequent urination). The record did not include any medical

history, allergy status, drug history or previous medications the patient had received before accessing the pharmacy's prescribing service. There was no evidence of 'safety netting' where people were told when to seek further medical assistance if their symptoms did not get better or worsened. This lack of consistency about consultation notes could impact on patient safety and create additional risks particularly as the pharmacy employed two PIPs. The SI said that he accessed people's Summary Care Records if they could not remember the name of their medication.

Confidential waste was removed by a specialist waste contractor. Computers were password protected and the people using the pharmacy could not see information on the computer screens. The SI used his own smartcard to access the NHS electronic services. And team members said that they took their smartcards home when they finished work. People's personal information on bagged items waiting collection could not be viewed by people using the pharmacy.

The complaints procedure was available for team members to follow if needed. There was a notice at the medicines counter asking for feedback from people if they had been satisfied with the service they had received. But there was nothing to inform people about how they could complain. The SI said that there had not been any recent complaints.

Team members had completed the Centre for Pharmacy Postgraduate Education training about protecting vulnerable people. One of the dispensers described potential signs that might indicate a safeguarding concern and would refer any concerns to the pharmacist. The pharmacy had contact details available for agencies who dealt with safeguarding vulnerable people. And the SI said that there had not been any safeguarding concerns at the pharmacy. The SI said that he asked people their name, address, and date of birth to check against their NHS number before issuing a prescription.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy cannot sufficiently demonstrate that its prescribers have the right knowledge and skills for the services they provide. However, there are enough team members to adequately manage the pharmacy's workload and they can raise concerns. Team members are not provided with regular ongoing training, which could make it harder for them to keep their knowledge and skills up to date.

Inspector's evidence

There was one pharmacist, one trained dispenser and two trainee dispensers working on the day of the inspection. The SI said that there were two team members on unplanned absence. Some team members had completed an accredited course for their role and the rest were undertaking training. The pharmacy was largely up to date with its dispensing. The SI said that the PIP worked at the pharmacy on an ad hoc basis, but this was not made clear on the pharmacy's website. The SI said that he did not usually prescribe as part of the pharmacy's prescribing service. And would ask people to return to the pharmacy another day. Or he would signpost them to their GP or to the NHS 111 service if the PIP was not available. The SI was not able to contact the PIP throughout the inspection.

The SI said that he prescribed for minor ailments and pain. But he had not undertaken any specific training in managing pain and had only undertaken some minor ailment training during his independent prescriber course. And he had previously prescribed co-codamol 30/500mg to treat pain. Both prescribers had diagnosed and prescribed medicines for respiratory infections and urinary tract infections. The SI was unaware of the training the PIP had undertaken to prescribe these medicines. When asked during the inspection the SI was unable to provide specific training records linked to the UTI and respiratory tract infection prescribing records that were seen for himself and the PIP he employed. The SI subsequently provided copies of his own training records and certificates linked to his scope of prescribing practice. Some of the courses had been completed after the inspection date. There was evidence that the current PIP the pharmacy employed was diagnosing dental abscesses, but the SI was unsure of the PIPs clinical training in diagnosing dental infections. There were no training records, continuing professional development (CPD) or prescribing qualifications available at the pharmacy for either the SI or the PIP. The PIP's training records and CPD certificates were requested by email after the inspection, but the PIP did not respond to the email request for information. The SI was not sure what guidance the PIP followed when prescribing medicines for infections. The SI said that he would clinically check prescriptions written by a different PIP. But if he had written the prescription and it was dispensed at the pharmacy, there was no second check. He said that a dispenser would dispense the medication before he carried out the final accuracy check. The SI was unable to show any examples of clinical interventions or refusals to authorise a prescription.

Team members appeared confident when speaking with people. They were aware of the restrictions on sales of medicines containing pseudoephedrine. And they said that they would refer to the pharmacist if a person regularly requested to purchase medicines which could be abused or may require additional care. They knew which questions to ask people to establish whether the medicines were suitable for the person they were intended for.

During the inspection the SI was asked if he had received training to perform ear irrigation and if he was able to provide any evidence of certification of training. The SI was unable to provide a certification of

training during the inspection. Following the inspection, the SI provided evidence that he had completed training about ear irrigation on 10 December 2023.

Team members involved with administering vaccinations had valid vaccination certificates to show that they had completed training. But they had not completed any additional more recent training updates relating to vaccination services. The trained dispenser said that he did not undertake any regular ongoing training but said that he had recently completed the NVQ level two dispenser course and wanted to be enrolled on the NVQ level three course.

Team members said that there were informal huddles each morning to discuss any issues and allocate tasks. And they felt comfortable about discussing any issues with the pharmacist. They said that they had yearly performance reviews. Targets were not set for team members.

Principle 3 - Premises **Standards not all met**

Summary findings

The pharmacy's premises are generally adequate for the pharmacy's services and are kept secure. And people can have a conversation with a team member in a private area.

Inspector's evidence

The pharmacy was secured from unauthorised access and it was generally clean and tidy. Pharmacy-only medicines were kept behind the counter and there was a clear view of the medicines counter from the dispensary. Air conditioning was available, and the room temperatures were suitable for storing medicines.

There was limited workspace in the dispensary for dispensing and checking medicines. And the workspace was cluttered. The area where dispensed medicines were usually checked was being used to check deliveries during the inspection. The room upstairs was used to assemble multi-compartment compliance packs and this area was well-organised with clear workspace for dispensing.

There were several baskets and boxes on the floor in the dispensary and on the stairs. These presented tripping hazards for staff. The decking to the rear of the pharmacy was very slippery. Staff needed to walk on this to gain access to the outside storage. The SI said that the decking had been painted with an anti-slip paint. But this had not solved the issue. The SI said that he would find another way to address the issue. Following the inspection, the SI sent photos to show that the decking had been covered with anti-slip matting.

The pharmacy had two toilets for staff to use and these were upstairs. And there were hand washing facilities available. There were several unsealed pharmaceutical waste bins stored in one of the toilet areas. This made it harder for the pharmacy to show that these medicines were being kept securely.

A consultation room was available and conversations at a normal level of volume could not be heard from the shop area. The room was accessible to wheelchair users, and it was suitably equipped and well-screened. The room was not kept locked when not in use and there were some in-use sharps containers on the floor in the room. This was discussed with the SI during the inspection, and he said that these would be removed from the room if the door could not be locked. Team members said that they cleaned the consultation room between each patient consultation, but team members were unable to find the cleaning materials during the inspection.

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

Summary findings

The pharmacy does not manage all its medicines safely or store them securely. As described under Principle 1, there are issues with how the pharmacy manages some of its services. And it cannot sufficiently demonstrate that it provides its vitamin B12 injection service in accordance with legal requirements. But on the whole, it generally manages its other services appropriately. People with a range of needs can access the pharmacy's services. And the pharmacy gets its medicines from reputable suppliers. People who get their medicines in multi-compartment compliance packs receive the information they need to take their medicines safely.

Inspector's evidence

There was step-free access to the pharmacy through a wide entrance. Team members had a clear view of the main entrance from the medicines counter and could help people into the premises where needed. A bell sounded when the door to the pharmacy was opened, and this alerted team members. Services and opening times were clearly advertised and a variety of health information leaflets was available at the pharmacy. But not all the services listed on the pharmacy's website were provided by the pharmacy, for example, the travel vaccination service. The PIP did not work at the pharmacy on a regular basis which meant that people were not able to access the prescribing service when he was not on site. During the inspection the SI said that if the PIP was not present, he would signpost people to the NHS 111 system or to their GP if the PIP was not available. There were no set days on which the PIP came to the pharmacy, so this could make it harder for people to know when the service was available.

Prescriptions for higher-risk medicines were not routinely highlighted. So, opportunities to speak with these people when they collected their medicines might be missed. The SI said that he checked monitoring record books for people taking higher-risk medicines such as methotrexate and warfarin. But a record of blood test results was not kept. And this could make it harder for the pharmacy to check that the person was having the relevant tests done at appropriate intervals. Prescriptions for Schedule 3 and 4 CDs were not highlighted. This could increase the chance of these medicines being supplied when the prescription is no longer valid. The SI said that the pharmacy supplied valproate medicines to a few people. But there were currently no people in the at-risk group who needed to be on the Pregnancy Prevention Programme (PPP). The SI said that he would refer people to their GP if they needed to be on the PPP and weren't on one. Team members were not aware that the warning card attached to the medicine packaging could be removed to allow space for the dispensing label to be attached. They had been placing the labels on the box but in a place that was sometimes covering up important information.

During the inspection, the SI was unable to show that there were signed in-date patient group directions (PGDs) or National Protocols available for the relevant services offered. The SI was not sure if the pharmacy had valid PGDs or was working under a National Protocol for administering flu and COVID vaccinations. Team members said that they used 'PharmOutcomes' to check a person's eligibility for a vaccination. And the SI said that this was also used to record the consultation. Following the inspection, the SI provided signed copies of flu and COVID vaccination National Protocols.

The SI said that one of the pharmacy team administered the vitamin B12 injections, but that team member was not working on the day of the inspection. There were some completed vitamin B12

consultation forms at the pharmacy. Following the inspection, the SI provided evidence that a team member had completed theory and practical training in administering vitamin B12 intramuscular injections. And he provided one consultation form for the vitamin B12 service. He also stated that the vitamin B12 service used PGDs as the legal mechanism for the administration of the injections. When asked for evidence of this, he provided two documents that he said were PGDs for the vitamin B12 and ear irrigation services. However, on examination they were not valid PGDs. It was not clear why the ear irrigation service would require a PGD given that it did not involve the supply of medicines. Only certain qualified healthcare professionals can supply or administer medicines under PGDs. The SI was then asked for the qualifications of the team member administering the vitamin B12 injections, but he did not provide this information. So, it was not clear if the person administering the vitamin B12 under a PGD was legally allowed to do so.

The pharmacy used licensed wholesalers to obtain medicines and medical devices. The SI explained the action the pharmacy took in response to any alerts or recalls. He said that a copy of relevant ones was kept at the pharmacy for future reference, but there was only one recent alert found in the folder and the one before was from 2016. Not keeping a record of any action taken could make it harder for the pharmacy to show what it had done in response. The SI said that he would review this process and keep a record in future.

Stock was stored in an organised manner in the dispensary. Expiry dates were checked regularly, and this activity was recorded. Items with a short shelf life were marked. There were no date-expired items found in with dispensing stock during a spot check. But there were several boxes which contained mixed batches found with dispensing stock. Not keeping the medicines in appropriately labelled containers could make it harder for the pharmacy to date-check the stock properly or respond to safety alerts appropriately. The SI said that he would remind team members to not do this in future.

The pharmacy did not always store its CDs securely and some were found in an insecure location. These were moved to a secure location when it was highlighted with the SI. Denaturing kits were available for the safe destruction of CDs. Returned CDs were recorded in a register and destroyed with a witness, and two signatures were recorded.

The SI said that the fridge temperatures were checked daily, and maximum and minimum temperatures were recorded. But the records had not always been completed daily. There was no record to show that the temperatures had been checked since 11 November 2023, which was a few days prior to the inspection. During the inspection thermometers were showing that the maximum and minimum temperatures for one fridge were outside the appropriate ranges. And the maximum temperature for the second fridge was outside the appropriate maximum range. However, the previous records seen indicated that the temperatures were consistently within the recommended range. The current temperatures showing on the thermometers were within the appropriate range.

Part-dispensed prescriptions were checked regularly, ‘Owings’ notes were provided when prescriptions could not be dispensed in full, and people were kept informed about supply issues. Prescriptions for alternate medicines were requested from prescribers where needed. Prescriptions were kept at the pharmacy until the remainder was dispensed and collected. The SI said that uncollected prescriptions were checked regularly. And if a person had not collected their items after around one month these were returned to dispensing stock where possible. Team members confirmed that they did not routinely check the validity of a prescription before items were handed out.

The SI said that people had assessments to show that they needed their medicines in multi-compartment compliance packs to show that they needed them. Prescriptions for people receiving their medicines in the packs were ordered in advance so that any issues could be addressed before

people needed their medicines. Prescriptions for ‘when required’ medicines were not routinely requested. The dispenser said that people requested these if they needed them when their packs were due. The pharmacy kept a record for each person which included any changes to their medication, and it also kept any hospital discharge letters for future reference. Packs were suitably labelled, but there was no audit trail to show who had checked each tray. This could make it harder for the pharmacy to identify who had done this task and limit the opportunities to learn from any mistakes. Medication descriptions were not put on the packs to help people and their carers identify the medicines. And patient information leaflets were not routinely supplied, which could make it harder for people to have up-to-date information about how to take their medicines safely. Prescriptions for care homes were largely ordered and managed by the care homes. A dispenser said that prescriptions were checked when they were received to ensure that all items that had been requested had been prescribed. There were several team members who could assemble the packs, to provide cover when needed.

Deliveries were made by a delivery driver. The pharmacy obtained people’s signatures for deliveries where possible. There were multiple people’s details on each sheet so the layout might make it harder to ensure that people’s details were protected when signatures were recorded. The SI said that he would ensure that other people’s personal information was protected when signatures were recorded. When the person was not at home, the delivery was returned to the pharmacy before the end of the working day. And a card was left at the address asking the person to contact the pharmacy to rearrange delivery.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy uses its equipment to help protect people's personal information. And it generally has the equipment it needs to provide its services safely. But it could do more to ensure that its equipment is maintained properly.

Inspector's evidence

Some calibrated glass measures for measuring liquids were available but the pharmacy was also using some plastic ones which are not suitable. The SI said that he would order suitable replacements for these. To prevent cross-contamination, a separate measure was used for certain medicines only. Triangle tablet counters were available, and a separate counter was marked for cytotoxic use only to help avoid cross-contamination.

There was no servicing contract for the ear irrigation machine and there was some water on the tray that the irrigation machine was sitting on. The SI said that he would enquire about calibration and servicing for this machine and the blood pressure machine.

Up-to-date reference sources were available in the pharmacy and online. The SI said that the carbon monoxide testing machine had been received around two weeks ago. He confirmed that it would be calibrated in line with the manufacturer's instructions. The phone in the dispensary was portable so it could be taken to a more private area where needed.

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.