General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Pharmadocs UK Limited, Unit 1, 223 East India Dock Road, London, E14 0ED

Pharmacy reference: 9011198

Type of pharmacy: Internet / distance selling

Date of inspection: 02/08/2022

Pharmacy context

This is a distance-selling pharmacy co-located with an optician business and on a busy main road. The pharmacy previously dispensed NHS prescriptions but now only dispenses private prescriptions and sells pharmacy-only medicines. The pharmacy has a prescribing service provided by a pharmacist independent prescriber mainly for weight loss and dermatological conditions. It also has a doctor-led prescribing service which was not registered with the CQC at the time of the inspection.

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	Risk assessments are not accessible to the pharmacy team and there is lack of evidence to show that the pharmacy is following these.
		1.2	Standard not met	The pharmacy has not carried out adequate audits of its prescribing service.
		1.6	Standard not met	The pharmacy cannot produce adequate records about private prescriptions.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy cannot show that the pharmacist independent prescriber has the necessary competence in the clinical areas they are prescribing for.
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website allows people to pre-select prescription-only medicines before they have a consultation with a prescriber. This does not meet GPhC requirements.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy cannot show that it always make sure relevant information about the medicines it supplies to people using the prescribing service is shared with people's regular prescribers. It does not have adequate systems to follow up with people about treatments that need ongoing monitoring. And prescribers that it works with do not keep adequate records about prescribing decisions.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy cannot provide assurances that its team members have access to its prescribing policies and procedures. So, they may not always work effectively or know what is expected of them. The risk assessments are not always clear about the associated hazards, cautions and contraindications, risks, patient communication guidance, and consent. The prescribers do not appear to keep records of their prescribing decisions, so are not able to show whether medicines are being prescribed appropriately. There is lack of evidence of people's GPs being notified when prescribing medicines in general, and particularly with regards to higher-risk medicines. The pharmacy doesn't undertake adequate audits of the prescribing activities to make sure these are following its own policies. This includes but is not limited to audits of weight loss treatments to check people have lost expected amounts to continue treatment; audits about consent for information to be shared with people's own GPs; and audits of adherence to prescribing frequencies. The pharmacy keeps most of the records it needs to by law, but it cannot produce adequate private prescription records. Dispensing mistakes are not always recorded, so, the team might be missing opportunities to learn and make the services safer.

Inspector's evidence

The inspection was conducted by an inspector and two clinical advisors. One of the regular pharmacists was present in the pharmacy and was acting as the responsible pharmacist (RP). This person was also registered as a medical doctor and worked elsewhere as a radiologist. They did not prescribe for the pharmacy.

The pharmacy had some standard operating procedures (SOPs). These were not annotated with the date of preparation or date of review which made it difficult to ascertain how up to date they were. Team members had signed a training log to confirm that they had read and understood the SOPs.

The trainee dispenser did not know where to record dispensing mistakes which were identified before the medicine was handed to a person (known as near misses). She was not aware of any dispensing mistakes which had reached people (known as dispensing errors). The RP said that there had not been any near misses or dispensing errors. The possibility that near misses had occurred but had not been recorded, particularly since both dispensers were trainees, and the benefits of documenting these was discussed with the RP. The trainee dispenser said that she would add a note to the person's electronic medical record if there were any issues, for example, a missed delivery.

There was a doctor-led associated prescribing service which was owned by the same company that owned the pharmacy; a GP prescribed for this service. The superintendent pharmacist (SI) was also a pharmacist independent prescriber (PIP) and issued prescriptions independently from the doctor-led prescribing service. The RP said that the pharmacy received 90% of the prescriptions from the doctor-led service and 10% from the PIP. The 10% included Saxenda, a weight loss treatment, as well as topical treatments which was predominantly done by the PIP. The GP prescribing service was not registered with the CQC at the time of inspection and the pharmacy said that an application to register would be made in October 2022.

As 90% of prescriptions were done by the GP, another person clinically checked the prescription. The RP

would clinically check the prescription when the PIP prescribed. It was noted that the majority of prescriptions were being signed late at night and in the early hours of the morning. There was no evidence seen of people being counselled before or after a prescription was issued.

The RP said that risk assessments and audits for the prescribing service had been conducted but could not provide these during the inspection. He said that these were not held at the pharmacy. The pharmacy's risk assessments were sent to the inspector following the inspection. The prescribing included treatments for asthma, erectile dysfunction, weight loss, sexual health, migraine, hypothyroidism, dermatological conditions such as eczema, jet lag, cystitis, and contraception. The risk assessments were lacking in some detail with the exception of a few which were more comprehensive such as Saxenda and salbutamol where the risk assessments set out very clear inclusion and exclusion criteria. However, there was no evidence to indicate the pharmacy had considered fully the possibility of people with an eating disorder attempting to obtain weight loss treatments.

The risk assessments did not include what questions were asked during the consultation. The maximum number of orders a person could place for prescribed medication was outlined in the risk assessments. However, the pharmacy team did not have ready access to these risk assessments in the pharmacy to ensure these limits were being followed. The RP explained that if they had any concerns, they would communicate these back to the prescriber. There was no policy for these types of interventions nor evidence to demonstrate this was happening. It was noted as part of the risk assessment that, for people who were prescribed Saxenda, if there was no consent to share information with their GPs then the pharmacy would not prescribe this medicine. However, it was found that people were still being prescribed the medication despite not consenting to share information with their GP.

The RP said that prescribing was in line with national guidelines and evidence-based prescribing. However, there was no consideration about local prescribing guidance in relation to antibiotics. There was no documentary evidence that any counselling before or after a supply took place from the prescriber or the pharmacy especially in relation to higher-risk medication such as weight loss treatments. The RP said that people were advised to read the patient information leaflet.

The pharmacy was asked for any prescribing audits that had been undertaken but was unable to produce any during the inspection. Following the inspection, the pharmacy provided evidence of one audit that it had undertaken, dated May 2022; this related to the doctor-led prescribing service rather than the prescribing by the PIP. As part of the audit, the pharmacy had sampled 20 prescriptions from April 2022 to assess if the prescriber was adhering to the prescribing policy. The pharmacy had identified that in 100% of cases, these were in accordance with their prescribing policy The pharmacy did not produce any audits about the prescribing of the PIP.

The trainee dispenser thought that the technician was a pharmacist. They also said that the SI only worked on Friday and the other pharmacist worked two to three days a week. She said that the doctors or pharmacist shifts changed, and team members did not necessarily know who would show up on the day. The RP then said that there was a pharmacist on site every day. The RP record could not be accessed to confirm this.

Details about the pharmacy's indemnity insurance cover as well as the prescribers' indemnity cover, were sent to the inspector following the inspection. An RP notice was not displayed. The RP said this would be displayed in the future. There was some uncertainty about how the RP record was kept. The RP could not access the RP record during the inspection and said that it was held electronically on a new system, but he could not remember his log-in details, although he was the RP for the day. Following the inspection, the pharmacy sent a document stating that the pharmacy had lost its RP records following a restructure in April 2022, and that since then, the RP record was maintained on a spreadsheet. If using a spreadsheet, the pharmacy should make sure any future changes made are auditable so the record can be relied upon.

The private prescription record could not be accessed during the inspection. The RP was asked to produce a sample of this following the inspection but produced copies of delivery notes instead. Controlled drug (CD) registers were seen to be filled in correctly.

The pharmacy's patient medication records were not accessible during the inspection. There was no evidence available of any consultation notes being made by the prescribers. The pharmacy showed evidence of letters sent to GPs only for the month of April 2022 when prescribing Saxenda. No other evidence was seen of letters being sent prior to or after this month.

A complaints procedure was in place and people were able to contact the pharmacy by telephone, email or via the website.

The trainee dispenser said that she had been briefed about protecting people's confidentiality and was provided with a leaflet to read at home. Confidential waste was shredded on site. Computers were password-protected. But some passwords were seen to be written on a whiteboard in the pharmacy. These were removed during the inspection.

The trainee dispenser said that she had been provided with a booklet on safeguarding vulnerable groups. She had also read and signed the SOP covering this and said she had access to the relevant contact details should the need to raise a concern arise. The pharmacy only prescribed for people over 18 years old. It relied on the questionnaire model for higher-risk medicines such as Saxenda and there was limited contact with the person to further clarify their weight or check if they were losing weight. The pharmacy had no process for video consultations.

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

Summary findings

The pharmacy has enough staff to manage its workload. But the pharmacy does not have access to all the information it needs for pharmacy professionals to have adequate oversight to intervene and prevent inappropriate supplies. And the pharmacy cannot show that pharmacist prescribers have the necessary competence in the areas they are prescribing for.

Inspector's evidence

During the inspection there was a trainee dispenser and the RP, who arrived after the inspection had started. The superintendent pharmacist (SI), another trainee dispenser, a technician and another doctor also worked at the pharmacy.

The trainee dispenser was enrolled onto a suitable course and said she completed her course modules at home. She described her role which included arranging deliveries, putting stock away, dispensing during busy periods and housekeeping. She said that she only completed administrative work if the RP was not present and did not dispense or send out dispensed medicines. She had been briefed about processes but did not complete other ongoing training. She explained that performance reviews were conducted at the end of the year and said that the managers regularly asked her for feedback and if she had any concerns.

A medical doctor and the PIP who was also the SI prescribed for the pharmacy. The RP said that the SI, who was a pharmacist independent prescriber (PIP), had specialised in weight loss and was the main prescriber for Saxenda. The PIP had attended training courses though certificates were not available on site. A copy of the PIP's certificate showing that he had completed CPPE modules on sexual health and weight management in adults were sent following the inspection. Some other training certificates were seen for the SI, including for adult basic life support, safeguarding, non-medical prescribing, and sepsis. There was no evidence of any dermatological training done. Furthermore, for a specialised service such as weight loss, there were no testimonials or evidence to show that the PIP was competent in this area.

The prescribers did not have a contract with the pharmacy and were paid a flat fee for three or six months of work. Therefore, there was no financial incentive for a prescriber to provide a prescription. The GP had worked for NHS111 for five years and had experience in working at other online pharmacies. The RP said that prescribers were normally interviewed by the pharmacy owners, but their performance or training was not regularly reviewed. There was no evidence of any shared learning taking place between the prescribers.

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

Summary findings

The pharmacy’s website allows people to start a consultation from the page of an individual prescription-only medicine (POM). But the pharmacy's premises are generally well maintained and fit for purpose. Some aspects of access to the premises could be tightened to improve security .

Inspector's evidence

The pharmacy was in the basement of an optician. The door to the pharmacy was seen to be kept open which meant that access by unauthorised people to the pharmacy was not sufficiently restricted. There were two rooms at the pharmacy, one was used to store pharmacy items and the other was kept locked. The trainee dispenser said that this was the optician’s office. And the office was accessible to the optician manager even when the pharmacy was not operating,. This was discussed with the RP who said that this arrangement would be stopped.

The pharmacy was fitted with a long workbench and some shelves. The trainee dispenser said that the pharmacy was cleaned every week, but the carpet was in need of vacuuming. The sink was rusty in some areas. The ambient temperature and lighting were adequate for the provision of pharmacy services.

The pharmacy’s website allowed people to start a consultation from the page of an individual prescription-only medicine (POM). This was contrary to GPhC guidance. The pharmacy’s website displayed most of the required information, but it did not identify the owner’s name and who the prescribers were, including their registration details.

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

Summary findings

The pharmacy can’t show that it always supplies medicines safely. The pharmacy does not have access to records about people’s care to help it undertake appropriate checks about the medicines it supplies. It cannot show that that relevant information about the medicines its associated prescribing services prescribe is shared with people’s regular prescriber. And it doesn’t always follow up with people who receive treatments that need ongoing monitoring. However, the pharmacy's services are accessible to people, and it orders its medicines from reputable suppliers and generally stores them properly.

Inspector's evidence

The pharmacy was not open to the public and provided its services at a distance. Its services were advertised on its website. Medicines could be delivered anywhere in the UK and were not posted outside the UK.

The pharmacy was in the process of changing its patient medication record (PMR) system. The previous PMR system could not be accessed, and the RP said that the new system was not necessarily accurate as it was still being tested. The RP said that people could communicate with the prescriber directly but was unable to provide any evidence for this as the systems could not be accessed. He said that people could also contact the pharmacy which in turn would pass any messages on to the prescriber. This could be via email or telephone. However, there was no documentary evidence to show this was happening.

People were able to select POMs on the website and then start a questionnaire. People were not informed if there were any responses to the consultation which would result in a supply not being approved. The completed questionnaire was sent to the GP or PIP for approval. Once approved, an electronic prescription was sent to the pharmacy. This was printed out and dispensed by the pharmacy team.

The RP said that the person's regular GP was informed when a weight-loss medicine or a medicine used for long-term conditions were prescribed. The most recent letters sent to GPs were seen to be from April 2022. And these types of medicines had been prescribed since then. People ticked a box to provide consent to share information with their regular prescriber. The RP said that weight-loss medicines were not supplied if consent was not provided. A supply of Saxenda was seen to have been made although the person had not provided consent to share information with their GP. The RP said that the prescriber would have contacted the person and their GP, however, there were no records to confirm this. The RP said that the PIP contacted people before prescribing the weight-loss medicine Saxenda. The RP was unable to produce any evidence to show this was happening. There was no evidence that people's weight loss was reviewed and whether any action was taken if the target weight loss was not achieved.

The RP said that limits were set for some medicines, such as inhalers. Only two inhalers were provided up to a maximum of four times per year. But the pharmacy team did not have easy access to the pharmacy's prescribing guidance or risk assessments so it could make it harder for them to be aware of the limits. The RP accepted the potential weakness during the inspection. The person's regular prescriber was not routinely informed when an inhaler was prescribed. The RP said that there was an assumption that people were using other inhalers, such as steroid inhalers, and that it was 'unrealistic'

to discuss everything with the prescriber. He added that asthma guidance was in place but was not available for the pharmacy team. This was discussed with the RP.

The RP said that levothyroxine was only provided as a one-off supply. The PMR system could not be accessed during the inspection so this could not be verified. The risk assessment for levothyroxine had a list of reasons to supply, contraindications and safety netting. The risk assessment said that the pharmacy would request blood levels and check with the person's GP. But there was no evidence produced to show that this was happening. Furthermore, the risk assessment mentioned a "letter should be written to all levothyroxine patients" but it was not clear what this letter detailed, and the pharmacy was unable to produce any examples during the inspection. Following the inspection the pharmacy sent a draft letter, but no evidence that the letter had been sent to people's GPs. There was not enough consideration about how the pharmacy obtained access to blood test results and how this information was documented onto the patient record. The RP showed some rejected levothyroxine requests for example, where the person had not ticked that the medicine had been initiated by their GP.

There was a risk assessment in place for Saxenda, but there was no evidence of any consultations taking place nor any extra safeguards considered to determine if the weight the person provided on the questionnaire was accurate. This was also the case for orlistat.

The RP said that the prescriber almost always contacted the person before prescribing antibiotics. But there was no documentary evidence produced to support this. The RP said that the pharmacy had an SOP which covered urinary tract infections (UTIs). However, the RP could not produce this SOP during the inspection. The RP said that this had been modified from the West Sussex Clinical Commissioning Group local guidance. People requesting antibiotics did not necessarily live in West Sussex, but the RP said that the guidance was clear and understandable. A request was seen for trimethoprim and metronidazole from a person who had noted that they had suffered from two UTIs previously. The patient was only prescribed trimethoprim but there were no records as to why this had been prescribed, what checks had been made and if the prescriber had in fact contacted the person. The person's regular prescriber was not informed if an antibiotic was supplied. The risk assessment stated that if a person was requesting an antibiotic for prophylaxis treatment, the pharmacy would request proof, but it was not clear what proof was requested and how this would be obtained. Furthermore, there was no documentation on the consultation notes to determine whether a supply was appropriate, or any contact made by the pharmacy to counsel the person.

A third-party system was used to verify a person's age as soon as they registered on the pharmacy's website. A person was asked to submit formal documentation if they did not pass the verification process. The RP said that the prescriber would only receive age-verified requests.

Medicines were delivered by the Royal Mail. The trainee dispensers generated delivery labels and packed the medicines in boxes and then in a sealable plastic bag. Fridge lines were sent by special delivery to arrive by 1pm the following day. An ice pack was placed with the medicine. The trainee dispenser said that packages could be tracked, and the person was contacted if there was an issue with the delivery. People were asked to wait five days if their medicine did not arrive on time, before another supply was made. Any delivery issues were noted on the person's record, but these issues were not regularly reviewed.

The trainee dispenser said that expiry-date checks were conducted every two to three months. The date-checking record which was displayed in the dispensary had not been updated since January 2022. Three date-expired medicines were found in with stock. Some tablets which had been removed from

their original pack and placed in amber medicine bottles were not annotated with their batch number.

Some drug alerts and recalls were found printed out and stored in a folder, but these were not up to date. The pharmacy was not aware of the recent recall for Saxenda. Waste medicine was placed in suitable bins. The fridge temperature record only had five readings recorded in July 2022. The RP said that another system was previously used but this could not be accessed during the inspection. The fridge temperature was within the recommended range during the inspection.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely.

Inspector's evidence

There were two tablet counters and several glass measuring cylinders. A fridge was fitted in the dispensary for medicines requiring cold storage and a freezer was available to store cool packs. A shredder was available to destroy confidential waste.

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.