

Registered pharmacy inspection report

Pharmacy Name: Bin-Seena Pharmacy, 73 Edgware Road, LONDON,
W2 2HZ

Pharmacy reference: 1092477

Type of pharmacy: Community

Date of inspection: 05/09/2022

Pharmacy context

This is an independent retail pharmacy located on a busy main road in central London, close to Marble Arch. It is open extended hours seven days a week. The pharmacy serves a few local residents and workers, but most of its customer are tourists and temporary residents primarily from the Middle East and Gulf States. It dispenses a small number of private prescriptions, and it sells over the counter medicines and wellbeing products. One of the regular pharmacists is an independent prescriber and the pharmacy offers a private consultation service. The pharmacy has a 100-hour NHS contract, but it only dispenses a few NHS prescriptions.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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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 demonstrate that its pharmacist prescribing service is operating safely. It does not have a SOPs or a prescribing framework covering this activity. And it hasn't completed risk assessments for this service identifying the therapeutic areas and classes of medication included, or the key risks involved, with a plan explaining how these risks are mitigated.
		1.6	Standard not met	The consultation records for the pharmacist prescribing service do not contain enough information to support prescribing decisions.
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's prescribing service does not have sufficient safeguards in place to provide assurance that medicines are always prescribed safely. It cannot demonstrate how it verifies information about the patient and their existing health conditions or communicates with their usual doctor to ensure the continuity of their care. And it cannot show that prescribing of CDs is in line with UK guidelines.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy cannot demonstrate that its pharmacist prescribing service is operating safely, and it has not adequately identified and managed the risks associated with this service. The pharmacy generally manages the risks associated with its other pharmacy services and it has written instructions, so pharmacy team members understand their responsibilities and know how to complete daily tasks. The pharmacy team protects people's private information, and it keeps the records it needs to by law.

Inspector's evidence

The superintendent (SI) pharmacist worked as the regular responsible pharmacist (RP). A second pharmacist, who also worked as the RP regularly, was a pharmacist independent prescriber (PIP). Both had worked at the pharmacy for a number of years. The sole company director managed the business and regularly worked from an office in the basement. An RP notice was displayed which identified the pharmacist on duty. Team members did not wear uniforms or anything to indicate their role, so members of the public might not be able to easily identify them.

The pharmacy was previously registered with the Care Quality Commission (CQC) and operated a private clinic using GMC prescribers. This service was no longer offered. The CQC registration had ceased in August 2021, and the pharmacy was offering a PIP consultation service instead. People using the pharmacy's prescribing service were mainly from overseas.

The pharmacy had up-to-date standard operating procedures (SOPs) which covered its main activities. Training records indicated that the pharmacy team members had read and signed the procedures. However, there were no policies or procedures explaining how the PIP consultation service operated such as a prescribing framework indicating the scope of practice. And the pharmacy had not completed any risk assessments of the prescribing service identifying the therapeutic areas or medications that were prescribed regularly, showing how it mitigated the risks it associated with particular medicines, for example high risk medicines such as controlled drugs (CDs). The pharmacy had not completed any clinical audits, but the prescribing service was relatively new.

Professional indemnity insurance for the pharmacy was with a recognised provider. The PIP confirmed she was covered for any private prescribing under her own personal indemnity insurance as well as the pharmacy's policy. The pharmacy had procedures for recording near miss and dispensing incidents. The pharmacist who was responsible for each supply of prescription medicine usually initialled the dispensing label so they could be identified. There was a complaints procedure but information about making a complaint was not displayed or included on the pharmacy's website, so people might not be confident providing feedback or making a complaint.

The RP made an entry in a book to show when they were on duty. Private prescriptions were recorded using the facility in the patient medication record system (PMR). The pharmacy had controlled drugs (CD) registers, but it supplied very few CDs which needed to be recorded. Specials' records were not inspected.

The PIP explained how she recorded private consultations in the notes section of the PMR system.

These contained some details about the patient's medical history, red flags, safety netting and recorded advice. But the records did not capture details of identity checks, consent, or indicate whether evidence of an existing diagnosis, ongoing monitoring or confirmation that the patient was on regular medication had been requested. This was particularly relevant given the PIP was prescribing CDs and medicines for chronic conditions that required ongoing monitoring. And there was no evidence of the pharmacy communicating with the person's usual doctor or informing them if medication was prescribed.

The pharmacy team members signed confidentiality agreements. Confidential material was stored and disposed of safely. A privacy notice was not displayed in the pharmacy or on the associated website, so people using the pharmacy may not have known how their information was handled

The pharmacist had completed safeguarding training so she knew how handle matters relating to vulnerable people sensitively and could signpost them or escalate a concern if needed. Safeguarding information was included in the SOP folder.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to provide its services. The team members work under the supervision of a pharmacist and have completed the right training for their roles.

Inspector's evidence

At the time of the inspection the PIP working with a single team member on the counter, and this was the usual staff profile. The company director was working in the office in the basement. Pharmacists worked 16-hour shifts, but the pharmacist felt this was not an issue as the pharmacy was not very busy and she had opportunities to rest. The footfall was very low, and the workload was easily manageable.

The team member working on the counter was a qualified dispensing assistant. Two other team members worked regularly at the pharmacy to cover the extended opening hours; one was a qualified dispensing assistant and the other was a medicines counter assistant. Training certificates were available. Several team members had worked at the pharmacy for a number of years, so they were experienced. The dispensing assistant understood what activities required the supervision of the pharmacist.

The PIP had qualified specialising in diabetes and hyperlipidaemia and she said that she also worked as a GP surgery pharmacist. She explained that she had also completed various courses and was qualified to administer aesthetics.

The team members worked flexibly to cover absences and holidays. Team members could speak to the company director or the SI if they had a concern or query. There was a whistleblowing policy. The team could seek advice from the NPA for advice if needed. Pharmacy team members were not directly incentivised to provide specific services.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy provides a suitable environment for healthcare services. It has facilities that allow people to have a conversation in private. The website associated with the pharmacy does not contain accurate and up to date information about the pharmacy and its services, so people using the website may not fully understand how the pharmacy operates.

Inspector's evidence

The pharmacy was situated in a standard retail unit. There was a retail area, a medicines counter and a small open plan dispensary to the rear. The dispensary had around two metres of bench space and open shelving. The size and layout were suitable for the volume of dispensing and the amount of stock. Fixtures and fittings were basic but suitably maintained.

Lighting was adequate and air conditioning regulated the room temperature. The pharmacy was reasonably clean and tidy. The retail area at the entrance was leased to a mobile phone retailer which only operated when the pharmacy was open. There was a small staff kitchen, a stock room, toilet and a cubicle-style consultation room behind the dispensary. The room was small and being used for storage, so it was not suitable for conducting consultations. There were two suitably equipped consultation rooms in the basement which was accessed via stairs from the retail areas. These were previously used by the CQC registered service and they were no longer in use. The RP indicated she would use a quiet part of the retail area for consultations if needed, but the lack of a consultation room on the ground floor could be restrictive, particularly when offering the prescribing service. The basement also contained an office and a small stock room.

There was a website associated with the pharmacy www.bin-seena-health-clinic.business.site. It contained basic information about the pharmacy's location and opening hours. But it did not include the pharmacy's GPhC registration number or the superintendent's details. The website promoted a 'health clinic' but it contained inaccurate information as it indicated this service was provided by GMC doctors.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy's services are easy to access. It obtains, stores and manages medicines appropriately, so they are suitable to supply. However, the pharmacy's prescribing service does not have sufficient safeguards in place to provide assurance that medicines are always prescribed safely.

Inspector's evidence

The pharmacy was usually open from 10am until 1am seven days a week. The pharmacy had a single non automated door and step free access from the street. Some team members were able to converse in Arabic which was helpful given that many of the people visiting the pharmacy were Arabic speaking. The pharmacist consultation service was not promoted in the pharmacy but the 'health clinic' was advertised on the website and people could request a quote. There were some promotional signs in the pharmacy advertising aesthetic services. The PIP said she was intending providing these but there had been little interest, so the pharmacy was not actively offering aesthetic services at the moment.

The volume of dispensing was low. The pharmacy dispensed fewer than 200 NHS prescriptions each month and fewer than 20 private prescriptions each day. Most of the private prescriptions dispensed by the pharmacy were issued by either the PIP or one of two GMC doctors. The pharmacy also dispensed occasional walk-in prescriptions issued by other local private clinics or hospitals.

The PIP usually offered the consultation service on the days she was working as the RP. She confirmed all consultations were held face-to-face at the pharmacy. People accessing the prescribing service were mostly overseas visitors from the Middle East region including, Saudi Arabia, Qatar UAE and they often had hotel addresses on their prescriptions. This meant they were usually under the main care of a doctor in their own country. Most prescriptions were one-off supplies which meant the prescriber did not have the opportunity to follow up or monitor the patient herself. And as they were based overseas the PIP did not have routine access to people's medical records to verify information and make sure their request for medicines was legitimate.

Most of the recent prescriptions issued by the PIP were for z drugs (zimidone or zolpidem), benzodiazepines or Ozempic. According to the private prescription records the PIP had issued four prescriptions for a 'z' drug, two for clonazepam, and eight for Ozempic on 2 and 3 September. No other medicines had been prescribed. Benzodiazepines and z drugs are schedule 4 CDs and considered high risk medicines because they can cause addiction and be misused. Ozempic is licensed to treat diabetes which requires ongoing monitoring.

The PIP explained she was not usually initiating treatment but prescribing medication that the person was already taking. She said she asked for confirmation of the patient's identity, and she sometimes requested confirmation that they were already taking the medicine, such as copies of healthcare documents or records. She showed some examples of documents she had seen which she'd captured as screenshots on her personal mobile phone, but she had not indicated this in the consultation notes to confirm when she had done this. And she did not seek any confirmation or communicate with the person's usual doctor to inform them when she prescribed medicines to ensure continuity of their care.

The pharmacy did not have any specific safeguards in place to make sure prescribing of CDs was in line with UK prescribing guidelines as she did not usually have access to the person's medical records or confirm that a supply was needed with their usual doctor. And there was a possibility that people could also be obtaining these medicines from several other sources. The pharmacy could not provide clear evidence showing how they confirmed that people diagnosed with long term conditions such as diabetes were being monitored. The PIP said she advised people to tell their usual doctor about any medicines they had been supplied with by the pharmacy, but there was no obligation for them to pass this information on.

The PIP usually assembled and checked all prescriptions she had issued which introduced an element of risk. Dispensed medicines were appropriately labelled, and patient leaflets were supplied. Pharmacy (P) medicines were stored behind the counter. The dispensing assistant understood that P medicine sales should be supervised by the pharmacist. When asked about high-risk medicines, she knew about the risk of addiction with codeine containing medicines. The pharmacist said the pharmacy did not sell codeine linctus and the team were aware it could be abused. The team were also alerted to the risks associated with Phenergan Elixir and sedative antihistamines.

The pharmacy sourced medicines from licensed wholesalers and examples of invoices were provided. The pharmacy had a small stock holding and medicines were stored in an orderly manner. A random check of the shelves found no expired items. Short-dated items were highlighted using stickers and the team completed regular checks. Obsolete medicines were segregated in designated bins and a waste contract was held with an authorised provider. The last collection note was dated September 2021. The pharmacy received MHRA medicine and device alerts by email these were actioned and filed for reference, and the pharmacy had received the most recent alerts.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment that it needs to provide its services safely. Equipment is appropriately maintained so that it is safe to use, and it is used in a way that protects privacy.

Inspector's evidence

The team could access the internet and suitable reference sources such as the British National Formularies. The computer terminal used to access the PMR was suitably located so it was not visible to the public. Telephone calls could be taken out of earshot of the counter if needed. A small medical fridge was used for storing medicines and the temperature was monitored to check it was suitable for the storage of medicines. The pharmacy team had access to a sink if needed preparing medicines.

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.