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: 10/08/2021

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. The pharmacy has a 100-hour NHS contract, but it only offers a limited NHS dispensing service. It sells over the counter medicines and wellbeing products, and it offers Covid PCR testing. The pharmacy dispenses private prescriptions and it works with a private doctor who offers a consultation service. The pharmacy is also registered with the Care Quality Commission (CQC) to provide private GP services. This was a targeted joint inspection with CQC during the Covid-19 pandemic.

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 does not have adequate policies and procedures in place explaining how it operates.
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	4.3	Standard not met	The pharmacy cannot clearly demonstrate that it stores cold chain medicines at the appropriate temperature, disposes of pharmaceutical and clinical waste safely, or takes appropriate action in relation to drug and device safety alerts.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy does not effectively manage all of the risks associated with its services. Its policies and procedures do not always clearly explain how the pharmacy operates, so the pharmacy team members may not always work safely and effectively. And the pharmacy cannot demonstrate that the private doctor service that it works with is meeting the regulatory requirements. Whilst the team members have an understanding of the basic principles, the pharmacy's information governance and safeguarding procedures lack formality, so they may not always know what is expected of them.

Inspector's evidence

The superintendent (SI) pharmacist worked as the regular responsible pharmacist (RP) managing the pharmacy services. She had worked at the pharmacy for a number of years. The pharmacy owner oversaw the business and regularly worked from an office in the basement. Team members did not wear badges or anything to indicate their role, so members of the public might not be able to easily identify them. The counter assistant could explain their responsibilities and they worked under the supervision of the pharmacist during the inspection. Professional indemnity insurance for the pharmacy was with the National Pharmacy Association.

The pharmacy had standard operating procedures (SOPs) which covered the main activities. Training records indicated that most of the pharmacy team members had read and signed them. However, most SOPs were overdue review so they might not always reflect current legal requirements or best practice. And SOPs were sometimes duplicated or not relevant to the pharmacy's current activities, so they were not easy to follow. This means team members might not fully understand their roles or know what action to take. And there were no policies or procedures explaining how the team worked with the private doctor or the scope of the pharmacist prescriber services.

The pharmacy was registered with CQC because it had previously operated a private clinic using GMC prescribers. A second pharmacist who provided occasional pharmacist cover had acted as the CQC registered manager, but had been absent from the business for 18 months. CQC inspectors could find no evidence of current activity in connection with the registration. The pharmacy was currently working in partnership with a private doctor, but he was was not working for the pharmacy's CQC registered service. The pharmacy team members explained how they referred people requesting prescription medicines to the private doctor. They provided the doctor's telephone number or made contact on behalf of the person concerned. The doctor did not provide consultations at the pharmacy. The SI thought consultations were usually conducted over the telephone. If the doctor issued a prescription, the pharmacy dispensed it and supplied to the patient.

The team member working on the counter wore a face mask to help prevent transmission of infection. The pharmacy did not have any other specific covid infection control measures in place, but social distancing was generally possible. The pharmacy was very quiet with a very low footfall. The SI said this had been the case throughout the pandemic because the pharmacy was largely reliant on tourists.

The pharmacy did not have any records of dispensing incidents. There was a near miss log, but the last entry was in 2018. The SI felt errors were less likely as the volume of dispensing was low, and so the team was not working under pressure. Dispensing labels were not always signed by the pharmacist

responsible for supply, so there was no clear audit trail. The pharmacy's complaints procedure was outlined in the SOPs. The SI and pharmacy owner usually dealt with any issues. The complaints procedure was not promoted in the pharmacy or on the website, so people might not know how to raise a concern. And the pharmacy did not use any other mechanisms to actively seek feedback about the pharmacy's services, so it might miss opportunities to make improvements.

The responsible pharmacist (RP) log was appropriately maintained. Pharmacists worked long days and there were very few recorded absences. A notice was displayed with the RP's details. Prescription supplies were recorded using a recognised patient medication record (PMR) and labelling system. Private prescriptions were retained and filed and stored in an orderly manner at the pharmacy. Private prescription records were captured on the PMR system. A few of those checked did not record all of the prescriber's details, including their address as required. And emergency supply records did not always include the reason for the supply. So the pharmacy may not be able to clearly demonstrate the circumstances of these supplies. The SI explained that they only supplied schedule 2 or 3 controlled drugs (CD) against NHS prescriptions. She could not recorded in the CD register. The SI explained she would usually telephone the NPA for advice if she was unsure about anything. Unlicensed medicines were sometimes supplied on prescription and the pharmacy maintained appropriate records.

Team members had been briefed on the principles of data protection and confidentiality. Team members were not required to sign a confidentiality agreement and there were no formal information governance policies, so there was a risk that team members may not fully understand their responsibilities. The PMR system was password protected and it was accessible to most of the pharmacy team. Confidential material was stored appropriately out of public view and paper waste was shredded. The pharmacy was registered with the Information Commissioner's Office. A privacy notice was not displayed in the pharmacy or on the website. So people using the pharmacy may not know how their information is handled.

The SI stated she had completed safeguarding training some years ago but did not provide evidence of this. Other pharmacy team members had not completed any formal safeguarding training. There was some guidance in a governance folder, along with details of local safeguarding contacts. But team members were not familiar with these and they did not know whether the information was current. This meant that if a safeguarding issue arose, staff may not know how to deal with it.

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 they receive the right training for their roles. But the pharmacy does not have formal reviews or a structured training programme, so team members may have gaps in their skills and knowledge. And the pharmacy could do more to support a culture of openness and learning.

Inspector's evidence

At the time of the inspection the SI working with a dispensing assistant and this was the usual staff profile. The pharmacy owner arrived at the pharmacy during the inspection. A work experience student was working for a short period in the retail area.

The SI was employed as a locum and she worked 16 hour shifts several days a week without a scheduled break. She felt this was not an issue as the pharmacy was not very busy and she had ample opportunity to rest. The second pharmacist had recently returned to work at the pharmacy and had covered a few shifts.

The assistant worked mainly on the counter as the volume of dispensing was low. Two other assistants worked regularly to cover the extended opening hours; one was a qualified dispensing assistant and the other a medicines counter assistant. Training certificates were available.

The footfall was very low and the workload was easily manageable. Support staff worked different shifts and could provide extra cover if needed. Team members completed occasional additional ad-hoc training as needed. For example, if a new product was launched. But they did not have formal reviews or access to structured ongoing training programmes to make sure they kept their knowledge up to date. And team members did not have formal contracts of employment or access to a staff handbook.

Team members could speak to the pharmacy owner or the SI if they had a concern or query. They were not aware of a whistleblowing policy. The SI said she would seek advice from the NPA if she was concerned about the practice at the pharmacy. Pharmacy team members were not directly incentivised to provide services.

The GMC registered doctor did not work specific hours at the pharmacy. Team members confirmed that he visited occasionally to drop prescriptions off, and he was contactable by telephone.

Principle 3 - Premises Standards met

Summary findings

The pharmacy provides a safe, secure and professional environment for the provision of healthcare services. It has suitable facilities, so people are able to have a conversation in private. But the pharmacy's website does not provide much information about the pharmacy and its services. So people using the website may not fully understand how the services are provided.

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 held. 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 to the left of the entrance was leased to a mobile phone retailer which sometime 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 consultation room was cramped and did not permit social distancing; the SI said they rarely used it. The toilet was currently not in use.

Stairs from the retail area led to a basement which was where the CQC service was based. There was an office and two suitably equipped consultation rooms. A walk-in cupboard between the two rooms was used to store pharmacy stock.

The pharmacy's website https://bin-seena-health-clinic.business.site/ 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 clinic with GMC doctors, but it did not provide any details. The absence of information did not support people to make informed decisions when opting to access the pharmacy's services.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy's services are easily accessible, and it generally supplies medicines safely. But the pharmacist knows little about the practice of the private doctor they work with. So the pharmacy cannot provide assurance that the prescriptions are always clinically appropriate, or that people receive the most appropriate level of care. And the pharmacy cannot always demonstrate it has suitable systems in place to make sure it stores and manages medicines safely.

Inspector's evidence

The pharmacy was usually open from 9am until 1am Monday to Sunday. There was step free access from the street. The main consultation rooms were not accessible to people with mobility difficulties or wheelchair users but the area to the rear of the store could be used for confidential conversations if needed. Some team members were able to converse in Arabic which was helpful given that many of the people visiting the pharmacy were from the Gulf states.

The pharmacy dispensed less than 200 NHS items each month. Some prescriptions were received electronically, and most were for local residents or workers. The SI had an NHS smartcard and was able to access Summary Care Records. The pharmacy did not offer any other NHS services.

The pharmacy supplied around 150 private prescriptions each month. A few were walk-ins from doctors working in local clinics, but the vast majority were issued by the private doctor as a result of referrals made by the pharmacy team. Records relating to the private doctor consultations were not available in the pharmacy, and the pharmacist did not have access to these. It was unclear how the patient's consent was obtained or what identity checks were completed by the doctor. Most people accessing the prescribing service were overseas visitors with hotel addresses. The SI explained they were usually under the care of a doctor in their own country but seeking to obtain their regular medication in the UK. Prescriptions were for medicines used to treat a range of conditions, both chronic and acute, including occasional antibiotics and some high-risk medicines. Prescribed medicines included schedule 4 and 5 CDs which are known to misused and abused and can cause addiction. The pharmacy did not supply any schedule 2 or 3 CDs against private prescriptions (FP10PCD). People presenting these would be signposted to other pharmacies. Prescriptions supplies were often for multiple packs and the SI explained this was because people needed several months' supply to last them whilst they were out of the country. The doctor occasionally prescribed unlicensed medicines or medicines for off license use. And prescribing was sometimes potentially outside of the scope of GMC prescribing guidance. Some prescriptions were issued for people diagnosed with long term conditions such as blood pressure or diabetes which require ongoing monitoring. But here was no evidence of the pharmacist having made any interventions or liaising with the doctor, to make sure they were clinically appropriate.

The pharmacist usually assembled and checked all prescription medicines. Dispensed medicines were appropriately labelled, and patient leaflets were supplied. Some cold chain medicines were supplied such as Ozempic and the pharmacy supplied cold pack and bags as most people needed to transport these overseas. The pharmacist understood the risks of taking valproate during pregnancy and that people should be counselled accordingly.

The second pharmacist was qualified as a pharmacist independent prescriber (PIP) and had occasionally issued prescriptions whilst working at the pharmacy. These were mostly for antibiotics. The SI was unsure of the scope of the PIP's practice and no prescribing notes were available.

The pharmacy provided a covid- PCR testing service and the SI explained this was also managed by the doctor. The SI was unclear if is this service was UKAS accredited. The pharmacy staff were trained to facilitate completion of the relevant forms and self-sampling. Tests were conducted in the consultation rooms. The covid-19 PCR testing service was operated in partnership with an accredited laboratory who collected tests and issued results usually on the same day.

Pharmacy (P) medicines were stored behind the counter and the dispensing assistant understood that P medicine sales should be supervised by the pharmacist. When asked about high-risk medicines, the assistant explained she referred all requests for medicines containing codeine such as Nurofen Plus to the pharmacist. The SI stated that the pharmacy did not sell codeine linctus as she knew it could be misused.

Medicines were sourced from licensed wholesalers and a sample of invoices were viewed. The pharmacy's stock holding was fairly low, and medicines were stored in an orderly manner. The pharmacy did not have a stock control system and stock audits were not routinely undertaken. A random check of the shelves found no expired items. There was a date checking system and short dated items were highlighted using stickers. Cold chain medicines were stored appropriately, and the fridge temperature was monitored by the pharmacist to make sure it was within the required range, but this was not recorded. Obsolete medicines were segregated in designated bins. These were stored in the ground floor stock room. Clinical waste was disposed of in a yellow bin. The yellow bin in the upstairs consultation room was full and had not been removed. The SI could not remember when the last collection by a pharmaceutical or clinical waste contractor had been or produce any examples of recent consignment notes.

The pharmacy did not have a system in place to make sure MHRA medicine and device recall and alerts were received and actioned. The SI subscribed the pharmacy to receive MHRA email alerts during the inspection.

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 used in a way that protects privacy.

Inspector's evidence

The pharmacy team could access the internet and suitable reference sources such as the British National Formularies. The pharmacy computer terminal 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 medical fridge was used for storing medicines. There was a sink in the staff kitchen and a glass measure was available for preparing medicines. Cartons and counting equipment were available. The team had access to personal protective equipment including face masks, hand sanitiser and gloves.

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.	