General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Xeal Dispensary, Unit 13, Vauxhall Trading Estate, Dollman Street, Birmingham, West Midlands, B7 4RA

Pharmacy reference: 9011996

Type of pharmacy: Internet / distance selling

Date of inspection: 13/08/2024

Pharmacy context

This is a private pharmacy which is closed to members of the public and it provides its services at a distance. It is situated in an industrial estate and it dispenses specific controlled drugs for private prescriptions received from Care Quality Commission (CQC) registered clinics. The pharmacy does not have an NHS contract to supply medicines against any community-issued NHS prescriptions. The company is registered with the MHRA and holds a Wholesale Dealers Authorisation and Home Office License. This is the first inspection since the pharmacy opened.

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 demonstrate that it adequately considers and manages the risks associated with its services, in particular with respect to the invidual medicines it supplies at a distance. The pharmacy has written instructions to help deliver its services. However, not all team members have read these so they may not know the right procedure to follow. The pharmacy does not always follow its own complaint's procedure. Team members do not have adequate oversight of how the relevant clinics have dealt with complaints and the outcomes of any investigations. This means that there is a risk that opportunities to learn and make the pharmacy's services safer are missed.
		1.5	Standard not met	The pharmacy cannot demonstrate that it has appropriate professional indemnity cover for the services it provides.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy provides specialised services, but it is unable to provide sufficient assurances that its team members have received relevant training about these services. And the pharmacy does not sufficiently support its team members with ongoing learning to help keep their skills and knowledge up to date.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.4	Standard not met	The pharmacy does not make the required reports about adverse reactions under the Yellow Card Scheme.
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 identify and manage all the risks associated with its services. It does not complete the relevant risk assessments for the individual higher-risk medicines it supplies at a distance. Its team members have not all read the pharmacy's written procedures. And when it receives complaints, team members do not have the oversight of what the outcomes of the investigations were. So, they may be missing out on opportunities to learn and make the pharmacy's services safer. The pharmacy is unable to provide assurances that it has appropriate indemnity insurance to cover its services. However, the pharmacy keeps people's information securely and its team members understand how they can support and protect vulnerable people. The pharmacy has limited knowledge about the prescribing services' processes, which may make it harder for the pharmacy to make more meaningful interventions.

Inspector's evidence

This is a newly-registered private pharmacy which started operating about a year ago. Its business involved the supply of specific unlicensed controlled drugs (CDs) to people living in the UK against private prescriptions issued by UK-based prescribers. The pharmacy received approximately 95% of all its private prescriptions from one main CQC registered clinic. However, the pharmacy did not have the oversight of the relevant prescribing policies of the clinics it dispensed prescriptions for.

The pharmacy’s digital platform facilitated the clinics to securely upload scans of private prescriptions for the specific CDs ahead of providing the pharmacy with a hard copy of the prescription. The original hard copies of the prescriptions were received via post. All prescriptions dispensed by the pharmacy were written on FP10CD prescriptions. These were submitted to the appropriate authorities each month, so there was external visibility of the prescribing and dispensing activity.

The correct responsible pharmacist (RP) notice was displayed. A regular pharmacist was the RP on duty on the day of the inspection. The RP had worked for the pharmacy for about eight months. The pharmacy had a basic set of standard operating procedures (SOPs) and there was no evidence to show that all its team members had read and signed the SOPs. Team members could not confidently explain what tasks they could not undertake in the absence of a pharmacist.

At the time of the registration of the pharmacy, the director had provided an operational risk assessment which focused on supply and delivery of medicines. However, the pharmacy was unable to provide any evidence that it had conducted any risk assessments about the individual unlicensed CDs it supplied.

There was some evidence to show that the team members had made records of mistakes spotted during the dispensing process. The RP said as the pharmacy was not public facing, there were fewer distractions, and lower likelihood of mistakes occurring. And the pharmacy held very specific range and limited stock of medicines. And different types of formulations and strengths were clearly separated from each other. The RP described discussing with team members to slow down and concentrate when medicines were incorrectly selected. However, most dispensing mistakes were reviewed informally with no detailed analysis recorded to show why the mistake had occurred and learning points to mitigate similar events from happening again. This could make it harder for team members to identify and

mitigate emerging trends in the pharmacy.

There was some evidence to show that the RP had made some interventions relating to the quantities prescribed exceeding 30-day supply or duplicate prescriptions issued by the clinic for the same person in error. Duplicate prescriptions were spotted by team members when the bar code on the prescription was scanned. The system flagged this and the prescription could not be dispensed. The records about interventions were very brief, which could make it harder to do any meaningful analysis.

The pharmacy had a procedure for managing feedback and complaints. It provided information on its website about how people could contact the pharmacy or raise a concern. Most complaints received by the pharmacy were about the formulation and the quality of the product supplied to people, or about people saying that they had not received the correct quantity of the prescribed medicine.

The RP dealt with all the complaints by forwarding the complaint email to the relevant clinic. And majority of times the clinic issued a new prescription for the person or refunded the fee. This appeared to the clinic's default position on these kinds of complaints. Furthermore, there were no details available about any investigations undertaken by the pharmacy to resolve the complaint. It solely relied on relevant clinics to resolve the complaint. The pharmacy was not sent any documented details about the investigations that had been undertaken by the relevant clinics. The pharmacy's complaint SOP stated that the superintendent pharmacist (SI) had the overall responsibility for dealing with complaints. But there was no evidence to show that they had the oversight of these complaints.

Records about RP, private prescriptions, and controlled drugs (CDs) were kept in line with requirements. A randomly selected medicine matched the recorded balance in the register. The pharmacy kept a separate register to record patient-returned medicines. Team members audited CD balances regularly. Records about unlicensed medicines were kept but they did not include all the legally required information. However, these details could be retrieved or obtained by cross referencing on the patient's medication record. The pharmacy did not stock any temperature-sensitive medicines and no emergency supplies had been made.

The pharmacy could not demonstrate that it had appropriate indemnity insurance arrangements for the services it provided. The insurance documents provided during the inspection related to the activities undertaken by the company and they did not cover the pharmacy's professional liability.

The company had registered with the Information Commissioner's Office (ICO). The pharmacy's computer system was password protected and team members managed confidential waste appropriately. Unauthorised staff could not access the dispensary and there was guidance about data protection which team members had read.

The RP had completed Level 2 training about safeguarding and demonstrated a good understanding about how to protect vulnerable people. They gave an example of how they had dealt with a safeguarding incident at the pharmacy. However, no records of the incident had been made.

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

Summary findings

Team members do not undertake specific training about the novel service the pharmacy provides. And they do not get relevant ongoing training to help keep their knowledge and skill up to date. However, the pharmacy has enough team members to manage its current workload safely.

Inspector's evidence

At the time of the visit, the dispensary was staffed by a regular pharmacist and they were supported by a qualified dispenser and two other recently recruited team members who were currently on a probation period. They were not yet enrolled onto an appropriate accredited training course for their roles and responsibilities. Team members appeared to work well together, and they were managing workload adequately.

There was no evidence to show that the team members had received any specific training relevant to the novel service and the unlicensed indications the pharmacy processed the prescriptions for. The RP demonstrated limited knowledge about the unlicensed medicines the pharmacy handled and supplied to people, and the novel service the pharmacy provided. They provided some examples where they would question the appropriateness of a prescription, but this was limited to dosages or quantities written on the prescription. Team members were solely reliant on the prescriber's knowledge of unlicensed medicines. And there was no evidence to show that the pharmacy supported its team members with relevant ongoing training to help keep their skills and knowledge current. There appeared to be limited involvement of the SI with regards to day-to-day operations of the pharmacy.

Team members were not given any incentives or targets to meet. The RP felt able to provide feedback or raise concerns with senior leadership about the way the pharmacy operated.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy’s premises are adequate for the services it provides. And it can be secured again unauthorised access. The pharmacy’s website includes relevant details about the pharmacy so that people can provide feedback or raise concerns about the quality of service provided. And they check where their medicines are being supplied from.

Inspector's evidence

The pharmacy was located within a manufacturing facility in an industrial estate. And it could not be accessed by members of the public. Visitors entering the site were required to sign in the visitor’s book. The pharmacy consisted of the dispensary which was located on the ground floor in a corridor with a key card entry. And it was sufficiently organised and kept clean. The ambient temperatures and lighting were adequate for the services provided.

The pharmacy’s website displayed the name of the superintendent pharmacist and the pharmacy’s registration details. It could not be used to order any on-line medicines or access services on-line.

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

Summary findings

The pharmacy supplies unlicensed medicines, but it does not make the required reports about adverse reactions under the Yellow Card Scheme. However, it obtains its medicines from licensed wholesalers and it stores its medicines safely and securely. Its services are accessible to people. The pharmacy has limited opportunities to check for interactions with the prescribed medicines and existing medicines people are taking. So, this could limit the effectiveness of any interventions.

Inspector's evidence

The pharmacy's main activity was to dispense private prescriptions it received from various CQC registered clinics. People accessing the service from these clinics were required to complete an online questionnaire. the vast majority of private prescriptions were issued by medical doctors, who were registered with the General Medical Council (GMC) and they were on the specialist register. The RP said that checks about the prescriber's validity to prescribe such medicines had been made but there were no recorded details to verify this. There were a very small number of prescriptions issued by pharmacist independent prescribers working at CQC-registered clinics under shared care agreement. In these cases, the clinics were contacted to confirm that the prescribing took place under the supervision of a specialist and also checked the independent prescriber's status.

The pharmacy dispensed and supplied medicines against these private prescriptions to people in the UK, via a courier service. The pharmacy had limited ability to conduct any meaningful clinical checks for potential interactions. It provided a 'supply only function.' The RP had no access to the person's medical history or consultation notes, albeit the condition the medicine was prescribed for was noted. This may mean that the RP is unable to check whether there may be a risk of interaction with the unlicensed medication leading to a risk of toxicity or sub therapeutic treatment with other meds.

The pharmacy did not have any information about whether the person had consented for their regular GP to be informed about the medicine being prescribed by the clinic. Furthermore, the RP was not aware of the clinic's process if the person did not consent for their GP to be informed. This was not in accordance with the GPhC's 'Guidance for registered pharmacies providing pharmacy at a distance, including on the internet.' The RP had not yet had the opportunity to read the above guidance.

The workflow in the dispensary was organised. Team members used baskets during the dispensing process to minimise the chances of prescriptions getting mixed up. Team members checked people's identity by obtaining a nationally recognised form of ID such as a passport or driving license. The person was also required to provide a proof of delivery address by providing a current utility bill.

People's medicines were delivered via Royal Mail or a third-party courier service. The delivery service was trackable and team members kept records to provide a robust audit trail. Team members packaged the medicines securely with a clear address label and tracking information. The pharmacy used suitable packaging to ensure the contents of the medicines could not be identified and protected from any environmental factors during the transit. The RP said that it was a requirement for any failed deliveries to be returned to the pharmacy. But there had been no failed deliveries since the pharmacy began operating.

The pharmacy obtained its stock medicines from licensed suppliers and it stored these in an organised fashion. CDs were stored in line with requirements. Obsolete stock and patient-returned CDs were separated. The pharmacy had denaturing kits to destroy waste CDs safely. People returned unwanted medicines to the pharmacy by post. Team members said that medicines were date-checked at regular intervals but no records when these were undertaken had been made. No date expired medicines were found amongst in-date stock when checked during the inspection. Short-dated medicines were marked so that they could be removed from in-date stock at an appropriate time.

Team members could explain the process they would follow when dealing with alerts and recalls. The pharmacy received Information about drug recalls and alerts via email. The pharmacy had not had any relevant stock for any recent alerts. When people who used the pharmacy's services informed team members of adverse reactions, the team members did not report this through the Yellow Card Scheme. It is a requirement for the pharmacy supplying specific CDs to report to the MHRA of all suspected adverse reactions (serious and non-serious, whether the product is licensed or unlicensed), including reports of failure of efficacy. Given the limited safety data that is currently available of these products, an enhanced vigilance is required to support their safe use.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment and adequate facilities it needs to provide its services. It maintains its equipment appropriately. And its team members use the equipment in a way that protects people's confidentiality and dignity.

Inspector's evidence

Team members had access to current reference sources. And they could access the internet to help resolve queries and to obtain current information. The pharmacy had a range of clean equipment available to support the delivery of its services. And its computers were password protected and people's confidential information was stored securely. All electrical equipment was in good working order.

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.