General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Excelsior Pharmacy Services, Unit 4, 40-40 Link, 30-34 Mill End Road, High Wycombe, HP12 4AX

Pharmacy reference: 9011805

Type of pharmacy: Internet / distance selling

Date of inspection: 28/02/2023

Pharmacy context

This is a pharmacy which is closed to the public and provides its services at a distance. The pharmacy is in a warehouse unit in High Wycombe, Buckinghamshire. It has an NHS contract but mostly dispenses medicines against private prescriptions. The pharmacy also has an online presence (https://pharmazonhomecare.com/).

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 is not identifying and managing several risks associated with its services. The pharmacy's standard operating procedures (SOPs) are not specific to the nature of the business, and there is no evidence that they have been read by all the team, including the regular, responsible pharmacist. There is no evidence that the pharmacy has addressed or mitigated the risks involved with the pharmacy's business model. And there are indications that things have gone wrong because of this.
		1.2	Standard not met	The safety and quality of the pharmacy's service provided at a distance is not regularly reviewed and monitored. The pharmacy has been unable to verify that it has completed any audits to provide assurances that the service is safe. The pharmacy has no SOPs in place to provide guidance about dispensing incidents. And the pharmacy is not managing mistakes made with controlled drugs (CD) appropriately. Details are not always documented nor reported to the CD accountable officer.
		1.3	Standard not met	The regular pharmacist routinely, and a regular locum pharmacist on occasion, have been acting as the responsible pharmacist (RP) for two pharmacies on the same day. This is not in line with legal requirements.
		1.6	Standard not met	The pharmacy is unable to demonstrate that it has been keeping all the necessary records to verify that its services are provided safely. The records should also be readily available for inspection, some of the pharmacy's records for assuring the safety of its services were not available at the point of inspection, or are incomplete. This includes the RP record, and records about supplies made against private prescriptions.
		1.8	Standard not met	The pharmacy does not have adequate processes in place to safeguard vulnerable

Principle	Principle finding	Exception standard reference	Notable practice	Why
				people. It does not adequately address the safeguarding risks that some vulnerable people who use its services may face. And the regular pharmacist has not completed any recent training to a level appropriate to their role. This puts vulnerable people at risk.
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	4.4	Standard not met	The pharmacy cannot show that it has the appropriate procedures in place to raise concerns when medicines or medical devices are not fit for purpose. The pharmacy team does not know how to access details about the drug alerts issued by the Medicines and Healthcare products Regulatory Agency. And they cannot demonstrate that the drug alerts are actioned appropriately.
5. Equipment and facilities	Standards not all met	5.2	Standard not met	None of the CD cabinets are secured in line with legal requirements. This is unlawful and compromises the security of these medicines.

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

Summary findings

The pharmacy does not fully identify and manage the risks associated with its services. It does not have the specific procedures in place to help guide its team on all the pharmacy's activities. Pharmacists are not working in accordance with certain aspects of pharmacy law. The pharmacy has not always been maintaining its records as it should. And the pharmacy does not adequately address the safeguarding risks that some vulnerable people who use its services may face.

Inspector's evidence

This is a newly registered pharmacy. The pharmacy was inspected due to this, and because of a complaint made to the GPhC. This involved a concern associated with the management of controlled drugs (CDs) as well as the pharmacy's internal processes. On 28.02.23, the inspector attended the pharmacy around 10am and found no pharmacist initially present. The regular responsible pharmacist (RP) was on leave and staff stated that the locum pharmacist that had apparently been booked for the morning, had failed to arrive. A different locum pharmacist arrived shortly before 1pm. A re-visit to the pharmacy also took place on 10 March 2023 to gain further details whilst the regular pharmacist was present. This was in conjunction with the CD accountable officer (CDAO) and local police CD liaison officer (CDLO). The pharmacy predominantly supplied CDs against private prescriptions for people with attention deficit hyperactivity disorder (ADHD).

The pharmacy had documented standard operating procedures (SOPs) in place to provide guidance to the team about the services it provided. The only team member present was relatively new and was in the process of reading and signing them. Following the inspection, confirmation was received that she had completed reading the SOPs. This member of staff was also clear about her role, the activities that could take place when a pharmacist was not present and the pharmacy's internal procedures. However, the SOPs had not been signed by the regular pharmacist who had been involved with the pharmacy's conception from the very beginning. The SOPs seen were standard templates which were not specific to the nature of the pharmacy's business, and included details of three people who had no links, nor association with the pharmacy business and did not work at the pharmacy. In addition, there were no details in the SOPs to define the team's roles or accountabilities. So, it was unclear which members of the team the procedures were meant for.

Only a few of the different clinics had documented service agreements in place with the pharmacy to define the relationship and terms between them. The pharmacy had no risk assessments available at the point of inspection to identify, manage or mitigate the risks associated with the service they provided. Nor were any audits seen to have been completed to verify the safety and quality of the service being provided. Consequently, this meant that there was no effective oversight, analysis of the prescribing habits taking place, or analysis of the medicines being supplied for this service. This was therefore, not in line with the GPhC's 'Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet'.

Staff had their own set tasks and responsibilities. They worked in different areas, the different workstations and sections in the dispensary were clearly labelled and the responsible pharmacist (RP) checked medicines from a separate area. This helped minimise distractions and errors. As the pharmacy was closed to the public, there were fewer distractions, and a lower likelihood of mistakes occurring

because the team could effectively concentrate more easily. There was some evidence that near miss mistakes were recorded but there was no evidence of a monthly or formal review taking place. The inspector saw evidence of a dispensing error involving a controlled drug that had not been managed appropriately, no details were recorded either on a specific form used for this purpose or in the patient's medication record. The CDAO had also not been informed by the pharmacy. The pharmacy did not have a specific SOP in place to provide guidance about managing dispensing incidents or complaints. The inspector saw evidence of complaints being raised by email regarding deliveries and data protection breaches, but no details were seen to corroborate the pharmacy's response or how to help prevent this from recurring.

The pharmacy had some processes in place to protect people's confidential information. Unauthorised staff could not access the dispensary, computer systems were password protected, sensitive information was stored within a cloud system and confidential waste was shredded. The dispensing assistant had been trained on data protection. However, documented procedures were seen to help provide guidance to the team on protecting people's private details, but the relevant details within them had not been completed. The regular pharmacist's NHS smart card to access electronic prescriptions had also been left within a computer terminal and not stored securely. This was not being accessed by other staff.

A documented safeguarding policy was seen to guide the team on the process to take in the event of a concern for vulnerable people. However, this contained minimal generic details and did not specifically address any potential risks associated with regularly dispensing CDs against private prescriptions, for people with ADHD. At the point of inspection, staff had not been trained to safeguard the welfare of vulnerable people. This was discussed at the time with the dispenser and the inspector provided details about how this could be completed. Following the inspection, confirmation that this member of staff had completed training to level one through the Centre for Pharmacy Postgraduate Education (CPPE) was received. However, the regular pharmacist confirmed that he had not completed any recent training for some years about this. The pharmacy also had no details about relevant local or national safeguarding agencies or for the areas that the pharmacy supplied medicines to. This could lead to delays in reporting or dealing with concerns effectively.

The inspector was told that the pharmacy had not dispensed any unlicensed medicines or made any emergency supplies. There were some concerns noted with a sample of registers seen for CDs. Footnotes regarding mistakes were inadequate, appropriate explanations had not been documented and crossed out pages were seen. Records about supplies made against private prescriptions were held electronically but lacked some relevant details about prescribers.

At the initial inspection, there were no details present about the pharmacy's indemnity insurance. The regular pharmacist stated that this was through Numark, confirmation from the superintendent pharmacist was received following a conversation with the inspector. There were also no complete records about who the RP had been since the pharmacy started trading. A bound register to hold details about the RP was present but this had pages that had been ripped out at the front and only contained details for five pharmacists recorded, two of which had no dates recorded. The dates listed in this were 1 February 2023, 24 February 2023 and 27 February 2023. The locum pharmacist signed herself in this when she arrived before 1pm on the day of the inspection. At the second visit, there were further entries made by locum pharmacists who had been the RP from 1 March until 8 March 2023. The inspector was told that the pharmacy had started trading in August 2022. When this was put to the regular pharmacist, he said that the key-fob or code entry into the pharmacy and CCTV electronically recorded the details of his arrival as well as when he left the premises. Details of this, however, were not readily available for inspection, and a physical or electronic copy was not kept at the pharmacy. In

addition, when the regular pharmacist left the premises, taking advantage of the two-hour absence period, these details were not recorded (see below). This is not in accordance with The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008.

The regular pharmacist confirmed that he had signed on as the RP and taken responsibility for another pharmacy (Pharmazon GPhC premises number 9011189) whilst he was also the responsible pharmacist at this pharmacy, on the same day. This had been taking place since August 2022. The inspector also saw records to verify that a locum pharmacist had also done this. This is unlawful and not in line with section 72A of the Medicines Act.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload effectively and its team members work well together. The dispensing assistant is a capable member of the team. But the pharmacy does not provide any resources to help keep its team members' skills and knowledge up to date. This could affect how well they carry out tasks and adapt to change with new situations.

Inspector's evidence

The pharmacy's team members consisted of a dispensing assistant who had worked at this pharmacy for the past two months and a regular, full-time pharmacist. The latter was on leave during the inspection and the pharmacy was said to be locum-run during this period. The dispenser had worked in a pharmacy previously, she was a qualified pharmacist from overseas but had not completed any formal qualifications in dispensing. In line with the pharmacy's volume of dispensing, there was enough staff to manage the workload and the pharmacy was up to date with this.

As they were a small team, they communicated verbally and regularly discussed things with one another. The dispenser liked working at this pharmacy. Her progress was monitored informally by the regular pharmacist. She stated that she had subscribed to relevant journals, checked queries in the British National Formulary (BNF), the regular pharmacist highlighted the legalities around CDs, provided further information and reinforced her knowledge here. However, the pharmacy did not provide any resources, have any formal or ongoing training programme in place to improve staff knowledge or keep the team informed about new developments. Advice about this was provided at the time and relevant resources suggested. The inspector noted that the dispenser was competent in her role, any improvements required were immediately acted upon and relevant training was completed shortly after the inspection.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are secure and suitable for the activities it undertakes. The pharmacy has enough space to deliver its services safely. And the premises are sufficiently clean. But the pharmacy doesn’t do enough to keep some of the details on its website complete and accurate.

Inspector's evidence

The pharmacy premises were located inside a warehouse unit and over two floors although only the top floor was used to provide this pharmacy’s services from. The bottom floor was used to export goods, activity here is regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA). The dispensary on the top floor consisted of a spacious room with a section at the front that had two PCs and was used for admin work and the back section was used for preparation and assembly of prescriptions. The pharmacy was clean, ventilated appropriately and bright. It was clear of clutter and there was enough space in the dispensary to prepare medicines. The pharmacy did not have a consultation room, the inspector was told that other than dispensing and providing services at a distance, no other services were provided, and it was closed to the public. This was therefore not required. The pharmacy was secured appropriately. Unauthorised access was restricted, and people could not access the pharmacy without team members being present.

The pharmacy also had its own online website (https://pharmazonhomecare.com/). The GPhC’s voluntary internet pharmacy logo was present at the bottom, along with the pharmacy’s registered address, email details and telephone number. The GPhC’s internet logo provided reassurance to the public that this was a registered pharmacy. The website had no direct reference to the pharmacy’s association with controlled drugs or any prescription-only medicines (POMs) although it did mention prescription services, private clinics and the process involved. However, there were no details listed about the pharmacy’s GPhC registration number, the name as the owner of the registered pharmacy, the name of the superintendent pharmacist, the name of the registered pharmacy, or details of how users of the pharmacy services could give feedback and raise concerns. This was therefore, not in line with the GPhC's 'Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet'.

In addition, the website was not as clear as it could be and potentially some inaccurate information was seen. The website detailed that the pharmacy had “developed robust software systems to manage the entire homecare delivery process from obtaining your prescriptions to dispensing and delivering your medicines reporting and accounting”. However, as detailed under Principle 4, the pharmacy received prescriptions by email to verify the details and post before dispensing which were then delivered through Royal Mail. This did not match what was described. The website mentioned tracking for people from initial prescribing to delivery, but this was also not in operation.

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

Summary findings

Members of the pharmacy team do not know how to, and cannot demonstrate that they have been, taking the appropriate action in response to safety alerts. This risks people receiving medicines and devices that are not safe to use. But the pharmacy uses suitably licensed suppliers to obtain its stock and medicines are generally managed appropriately.

Inspector's evidence

The pharmacy had built links with a few private clinics across the UK and received private prescriptions from doctors and independent prescribers such as nurses. Staff described, and provided evidence of them making relevant checks to ensure appropriate registration and qualifications. The private prescriptions were predominantly for CDs but also for other medicines. The pharmacy had not dispensed any prescriptions for sodium valproate or other common higher-risk medicines. The pharmacy did not provide people's GPs with details about the supplies made, this was described as the responsibility of the prescribing service.

The inspector was told that ADHD specialist nurses scanned prescriptions onto a phone before sending the details via email to the pharmacy. The details were printed, cost calculated, and this information was sent via a specific payment processing company to people prescribed the medicines. Patients then made the payment through this same company, after which the team placed the relevant details into individual baskets. Staff stated that they waited for and did not prepare medicines until the original prescription arrived in the post, and attached this to the printed details before they dispensed and dispatched the medicine(s).

The workflow involved the administration side taking place first before prescriptions were prepared in one area and the RP checked medicines for accuracy from another section. The team used baskets to hold prescriptions and medicines during the dispensing process. This helped prevent any inadvertent transfer between them. They were also colour-coded to indicate if people had paid, or if the original prescription had been received. After the staff had generated the dispensing labels, the regular pharmacist stated that they placed their initials on them which helped identify who had been involved in the dispensing process. This was used as an audit trail. Interventions were recorded via the pharmacy's email system, but no details were recorded on people's medication record (PMR). This risked concerns with repeat or future supplies not being highlighted or addressed appropriately.

Once these processes were complete, medicines were delivered to people in the UK by Royal Mail. This service could be tracked. Staff stated that no medicines that required refrigeration had been supplied. Failed deliveries were returned to the pharmacy. The pharmacy was not recording failed deliveries involving CDs appropriately. Advice was provided about this by the CDAO at the second visit.

The pharmacy's stock was stored in an organised way. The pharmacy used licensed wholesalers such as Alliance Healthcare and Phoenix to obtain medicines and medical devices. Staff described date-checking medicines for expiry regularly and short-dated medicines were identified. There were no date-expired medicines or mixed batches seen. Although the team described date-checking medicines for expiry regularly, at the point of inspection, there were no records to verify how often this took place. At the second visit, records for January and February 2023 were present but no records had been located prior

to this. Staff stated that there had been no medicines returned that required disposal. A designated container was available for this if needed. There were no medicines stored in the pharmacy fridge.

CDs were not stored under safe custody (see Principle 5). There were also several CDs seen that had been stored outside of their original containers. Staff stated that this was because the pharmacy had a policy in place to supply people with original packs and where quantities differed from this, they stored the remainder in other containers. This was stated as required to assist people with ADHD. However, storing medicines in this manner meant that the pharmacy was no longer storing them inside their original packaging and under the optimal conditions. This could impact the medicine's overall stability and efficacy. Pharmacy staff were unaware about drug alerts or the process to take involving this. The pharmacy's email system was checked, and no recalls had been received via this method. An up-to-date audit trail was not present which could verify that the appropriate checks had taken place. The pharmacy could not therefore show that it was routinely taking the appropriate action in response to affected batches of medicines.

Principle 5 - Equipment and facilities **Standards not all met**

Summary findings

Some of the pharmacy's equipment is not secure enough to store medicines which require additional controls. But the pharmacy has an appropriate range of equipment available to provide its services. It keeps its equipment sufficiently clean and uses them to help protect people's private information in a suitable way.

Inspector's evidence

The pharmacy team had access to reference sources and relevant equipment. This included counting triangles, capsule counters and a pharmacy fridge. The dispensary did not have a sink to reconstitute medicines, but staff could access hot and cold running water via the staff areas and kitchenette if needed. Computer terminals were positioned in a way and location that prevented unauthorised access. However, the three CD cabinets were free-standing. They had not been secured to the floor or wall using any means. This was not in line with legal requirements.

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.