General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Osbon Pharmacy, 133 George Lane, LONDON, E18

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Pharmacy reference: 1040233

Type of pharmacy: Community

Date of inspection: 28/07/2022

Pharmacy context

The pharmacy is located in a small parade of shops on a busy main road. As well as dispensing NHS prescriptions the pharmacy supplies medicines in multi-compartment compliance packs to some people who need help managing their medicines. This was a targeted inspection as intelligence had been received that the pharmacy had been obtaining unusually large quantities of liquid codeine preparations which are addictive and can be abused.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; Statutory Enforcement

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 regularly orders unusually large volumes of codeine liquid preparations. And the pharmacy cannot properly account for these medicines. This indicates serious systemic weaknesses in the risk management and governance arrangements, which presents a serious risk to patient safety. |
| | | 1.2 | Standard not met | The pharmacy is not managing its stock of liquid codeine preparations safely. It does not have any systems in place or audit trails to identify, monitor and review orders placed for these medicines. |
| | | 1.7 | Standard not met | The pharmacy does not always manage confidential information properly. This could result in people's personal information being disclosed. |
| 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 is purchasing excessive amounts of liquid codeine preparations without the appropriate safeguards in place to prevent its diversion, misuse and abuse. |
| | | 4.3 | Standard not met | The pharmacy does not always store its medicines securely, particularly its controlled drugs. |
| | | 4.3 | Standard not met | The pharmacy cannot show that it securely stores or restricts access to its liquid codeine preparations. |
| 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 have the appropriate safeguards in place to identify, monitor and manage all the risks associated with its services, particularly with respect to liquid codeine preparations. It is regularly ordering unusually large volumes of liquid codeine preparations, but it is unclear why these medicines are needed as there is little evidence of them being sold or supplied. As liquid codeine preparations can be abused and cause harm, this risks people's safety. The pharmacy doesn't protect people's private information properly. The pharmacy's practices relating to its other services are generally safe.

Inspector's evidence

Standard operating procedures (SOPs) were available. Team members had read SOPs which were relevant to their roles. The team had been routinely ensuring infection control measures were in place.

The pharmacy's team members, including the responsible pharmacist (RP), were aware that OTC codeine-containing medicines were addictive. The trainee dispenser confirmed that there were a few regular people who purchased codeine linctus from the pharmacy regularly. The apprentice was observed to check symptoms and used an established sales-of-medicines protocol (WWHAM), she did not sell codeine linctus without referring to the pharmacist and did not recall selling any whilst working at this pharmacy. The team did not document any details of refusals. This limited the ability of the pharmacy to demonstrate that its team members had been taking appropriate steps to prevent misuse from happening. There had been no details documented of any interventions made with OTC sales of codeine linctus and there were no clear records of any sales. There was only one record found on the patient medication record of a liquid codeine preparation being dispensed between the beginning of December 2021 and the date of the inspection. Records examined during the inspection showed that the pharmacy was ordering large quantities of codeine linctus. But it was unclear why these medicines were needed as there was little evidence of them being sold or supplied. When the figures were put to the RP and the director of the company, both said that they had not realised these quantities were being purchased. The superintendent pharmacist (SI) had been away from the business for a while. The SI and director did not have oversight of what was being ordered.

The pharmacy recorded dispensing mistakes where the medicine was handed to a person (dispensing errors). Dispensing mistakes which were identified before the medicine was handed out (near misses) were recorded on a log. Team members were notified of mistakes. As a result of past mistakes different strengths of olanzapine had been separated on the shelves and team members had been advised to check the strength of medicines when dispensing. Dispensing errors were investigated and recorded on an incident report form and flagged on the person's electronic record. In the event that the person had taken the incorrect medication the responsible pharmacist (RP) would also notify the person's GP. Previously the pharmacy had completed monthly reviews of near misses and dispensing errors. As part of this a poster was generated with a 'focus of the month', this identified areas where care needed to be taken. However, this had not been done for some time.

An incorrect RP notice was initially displayed, this was changed during the inspection. Team members were not aware of the tasks that could and could not be carried out in the absence of the RP. Prior to the start of the inspection the inspector had to intervene to stop an assembled prescription from being

handed out in the RP's absence. This was discussed with the apprentice and the RP provided assurance that she would ask all team members to re-read the relevant SOPs and in future check with team members before leaving the premises. The pharmacy had current professional indemnity insurance. The pharmacy had a complaint procedure. People also left reviews online. Feedback received was usually positive.

Records for emergency supplies, unlicensed medicines dispensed, controlled drug (CD) registers and RP records were well maintained. Private prescription records were also generally well maintained but the prescriber details recorded on some of the entries were incorrect. Controlled drugs (CDs) that people had returned were said to be recorded in a register but this could not be located. A random check of a CD medicine quantity complied with the balance recorded in the register.

The RP and trainee dispenser had a smartcard to access the NHS electronic systems. An information governance policy was in place which had been discussed with team members. Confidential waste with people's private information on was shredded. The pharmacy's computers were password protected and screens faced away from people using the pharmacy. Assembled medicines which were due to be collected were stored on shelves in the dispensary. These had people's private information clearly visible to people using the consultation room. Summary care records were accessible to pharmacists. Consent to access these was gained verbally.

The RP had completed level two safeguarding training and most team members had completed level one training. A safeguarding SOP was available which team members had read. The RP was unsure if details for the local safeguarding contacts were available, but she was aware of where these could be found.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to manage its workload appropriately. Staff are given some ongoing training. But this is not very structured, which could make it harder for them to keep their knowledge and skills up to date.

Inspector's evidence

On the day of the inspection the pharmacy team comprised of the RP, a locum pharmacist, a trainee dispenser and an apprentice who was covering the trainee medicine counter assistant who was on leave. Team members were all trained or undergoing training. Team members were able to manage their workload during the inspection. The superintendent pharmacist (SI) who also worked at the pharmacy regularly had been on extended leave. The pharmacy had since been covered by locum pharmacists. Since April 2022 one of the locum pharmacists had started working at the pharmacy two to three days a week regularly.

Due to there not being a regular pharmacist there was no formal process for managing staff performance. Pharmacists provided team members with verbal feedback. There was no structured ongoing training and team members were updated on relevant information by pharmacists during quieter times. Both regular team members who were on formal accredited training courses had stopped their training as the SI had been on leave. They had restarted their training since one of the locum pharmacists had started working regular shifts.

Issues were discussed as they arose. The owner visited the pharmacy from time to time and team members were able to contact him by telephone if needed, he also called and spoke to the pharmacists when needed.

Principle 3 - Premises ✓ Standards met

Summary findings

The premises are generally suitable for the services offered and they are kept secure. There is a room where people can have private conversations with a team member. But the pharmacy could do more to keep its consultation room clean and tidy at all times.

Inspector's evidence

The pharmacy was bright and the retail area was clean in organised. Although the dispensary was generally clean some workbenches were disorganised and there were a number of wholesaler boxes on the floor. There was ample workspace available for dispensing and checking. A clean sink was available for the preparation of medicines. Cleaning was carried out by team members at regular intervals.

The pharmacy had a consultation room which was easily accessible from behind the medicines counter. The room allowed a conversation at a normal level of volume to take place inside and not be overheard. The room was disorganised and untidy. There was no confidential information held within the room. But due to the location of where assembled prescriptions were kept people accessing the room were able to see other people's private information. The room temperature and lighting were adequate for the provision of pharmacy services and the safe storage of medicines. The premises were secure from unauthorised access.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy does not provide all of its services safely. It has limited systems to ensure that supplies of medicines liable to abuse are made safely. It is unable to satisfactorily account for the large quantities of liquid codeine products that it orders. And it does not always store its medicines securely, particularly its controlled drugs. The pharmacy obtains its medicines from reputable sources. And it provides most of its other services in an appropriate way.

Inspector's evidence

The range of services offered by the pharmacy was adequately promoted. Access into the premises was via a flat entrance from the street, team members would go and help people who required assistance. Aisles were also wide and clear with easy access to the counter. The local population predominantly were English speaking and the pharmacy had not had issues with languages in the past. Team members were aware that signposting may be necessary where people required an additional or alternative service. The pharmacy had the ability to produce large print labels when needed.

Prescriptions were received electronically, then printed out and labels were processed. These were dispensed by a dispenser and left for the RP to check. On occasions where the RP dispensed, she obtained a second check. Dispensed and checked-by boxes were available and were routinely used. Baskets were used to separate prescriptions, preventing transfer of items between people.

The RP was aware of the guidance for dispensing sodium valproate and the associated Pregnancy Prevention Programme. In most cases sodium valproate was dispensed in its original pack. The need to use warning labels when sodium valproate was not dispensed in its original pack was discussed. The team were also made aware of space for placing dispensing labels on the pack. Additional checks were carried out when people collected medicines which required ongoing monitoring.

Some people's medicines were supplied in multi-compartment compliance packs. The pharmacy ordered prescriptions on behalf of people for this service. The pharmacy worked one week in advance to ensure people's medicines were ready for when they were needed. Prescriptions were compared against the person's electronic record and any changes were queried with the surgery. Packs were prepared by a dispenser and checked by the RP. Assembled packs included product descriptions, however, mandatory warnings were missing and patient information leaflets (PILs) were not routinely supplied. The RP gave an assurance that they would ensure mandatory warnings were recorded on all packs and PILs were routinely supplied.

Deliveries were carried out by a designated driver who was shared with other branches. Team members were unsure if the driver obtained signatures when delivering medicines. The pharmacy team prepared an audit sheet of deliveries for the driver and marked any fridge lines or CDs. In the event that someone was not available a note was left for them and medicines were returned to the pharmacy.

The pharmacy used licensed wholesalers such as AAH, Alliance Healthcare, Sigma, and Phoenix to obtain medicines and medical devices. The team date-checked medicines for expiry regularly and kept records of when this had happened. Short-dated medicines were identified. There were no date-expired medicines found on the shelves checked.

Fridge temperatures were checked daily and recorded. These were observed to be within the required range for the storage of medicines. Out-of-date and other waste medicines were disposed of in the appropriate containers which were kept separate from stock and collected by a licensed waste carrier. CDs not always held securely, and access to them was not always appropriately restricted. Drug recalls were received via email and these could be accessed by all team members.

Pharmacy stock was manually ordered by the trainee dispenser and pharmacists. This included liquid codeine preparations. Invoices detailing the purchase of codeine linctus that were present on the premises were obtained. The pharmacy group had an online presence but all activity for this was processed from another branch. The director also confirmed the pharmacy was not supplying any other organisation or pharmacy with this medicine. The pharmacy did not have a wholesale distribution authorisation (WDA).

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide services safely. And it keeps them clean. The team uses its facilities and equipment to keep people's private information safe.

Inspector's evidence

Equipment was clean and ready for use. The pharmacy had glass measures and tablet counting equipment. A fridge of adequate size was available in the dispensary. Up-to-date reference sources were available including access to the internet. The pharmacy's computers were password protected and screens faced away from people using the pharmacy.

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. | |