General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Oldham Late Night Pharmacy, 87-89 Lees Road, OLDHAM, Lancashire, OL4 1JW

Pharmacy reference: 1106007

Type of pharmacy: Community

Date of inspection: 12/11/2019

Pharmacy context

This is a busy community pharmacy located on a main road near the town centre. The pharmacy dispenses mainly NHS prescriptions and sells a range of over-the-counter medicines. It supplies a large number of medicines in multi-compartment compliance aid packs to patients in care homes to help them take their medicines at the right time. The pharmacy stays open for 100 hours per week, opening early in the morning and closing late in the evening.

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 standard operating procedures for the services it provides and members of the pharmacy team do not follow them.
		1.6	Standard not met	The pharmacy's responsible pharmacist (RP) record is not always available on the premises and the name of the RP on duty is not always displayed. Records of supplies of unlicensed medicines do not include the patient's details. 'Headers' are missing from the tops of most of the pages in the CD register.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.3	Standard not met	The pharmacy is not maintained to an appropriate level of hygiene.
4. Services, including medicines management	Standards not all met	4.3	Standard not met	The pharmacy does not effectively manage its stock medicines. It can not provide assurance that the temperature of the medical fridge is appropriately monitored. It does not properly restrict unauthorised access to some medicines and it stores multi-compartment compliance packs which have not been sealed for extended periods. There is no robust date checking procedure and medicines which have passed their expiry date are not always separated from current stock. Some medicines are not stored in their original packaging and have not been appropriately labelled. Some assembled prescriptions are stored on the floor.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

Members of the pharmacy team do not have up-to-date policies and procedures to follow, so may not have a clear understanding of how the pharmacy operates, their roles and responsibilities and who is accountable for what. This means there may be more risk of mistakes happening and the team might also be missing out on learning opportunities. Some of the records required by law are missing or incomplete, which could make it harder to understand what has happened if queries arise. The team has a basic understanding of how it can help to protect the welfare of vulnerable people and keep people's private information safe.

Inspector's evidence

Most of the standard operating procedures (SOPs) had been prepared in 2013, with no documented review since, so they might not be up-to-date or reflect current practice. Some of the staff had signed to indicate they had read and accepted them. But a member of the pharmacy team who had worked in the pharmacy for two years had not read or signed them, so might not be clear of the procedures to follow. He said he had not read them because they were probably out of date, and he followed the procedures from a previous pharmacy where he had worked. Pharmacy team members were performing duties which were in line with their role. But they did not wear uniforms or anything to indicate their role, so people might not be clear about this. The name of the responsible pharmacist (RP) was not displayed at the start of the inspection but was displayed when this was pointed out.

There was a SOP for dealing with near misses and dispensing errors. Some near misses had been reported on a log and the RP said he discussed them with the member of the pharmacy team who was responsible. The recorded learning points were brief such as ‘double check’ and ‘take care’. There was no documented review of near misses, so the team might be missing out on additional learning opportunities. The RP said some medicines had been separated from each other to avoid reoccurrences but he could not recall any details. The RP was not clear about the procedure for reporting dispensing errors and did not know the location of completed incident reports. He said he was not aware of any errors being made whilst he had been working.

There was a ‘dealing with complaints’ SOP and a book to record complaints but none had been documented since 2015. Nothing was on display highlighting the complaints procedure, so people might not be aware how to give feedback or raise concerns. A member of the pharmacy team said she would refer any complaints to the pharmacist. A customer satisfaction survey had been carried out in March 2018 and was available on www.NHS.uk website. Areas of strength (96-98%) from the 2018 survey were ‘how long you have to wait to be served’, ‘Having in stock the medicines/appliances you need’ and ‘providing an efficient service’. An area identified which required improvement was providing advice around stopping smoking. The published response was ‘pharmacy dispensers trained’ which did not properly demonstrate that the pharmacy had responded to the survey.

Insurance arrangements were in place. A current certificate of professional indemnity insurance was on display in the pharmacy. The RP record was not available at the pharmacy at the time of the inspection. The RP explained that one of the other owners had taken it home the night before as he wanted to check the hours he had worked. The RP had been asked to collect it from his home on the way to work

but was running late so hadn't. The RP obtained the RP record and sent photographs of it to the inspector the following day. It appeared to be fully compliant. Private prescription and emergency supply records were maintained electronically. An incorrect date had been entered on one of the samples checked, providing an inaccurate audit trail. Patient details were not always recorded when unlicensed medicines were obtained and supplied as 'Specials' in line with Medicines and Healthcare products Regulatory Agency (MHRA) requirements. The controlled drug (CD) register was generally in order but headings were missing from the tops of most pages. This increased the risk of incorrect entries and a discrepancy had occurred when an entry had been made under the wrong drug in the register. Records of CD running balances were kept and these were usually audited. Two CD balances were checked and found to be correct. Patient returned CDs were recorded and disposed of appropriately. These record keeping irregularities could cause confusion and make it harder for the team to explain what has happened in the event of a query.

Confidentiality and information governance (IG) documents were available but these had not been updated since around 2013. Some members of the team had signed a confidentiality agreement around this time. The RP said he had discussed confidentiality with all the team and some members of the team had training on General Data Protection (GDPR) and confidentiality as part of their dispensing training course or before they started working at the pharmacy. A member of the team correctly described the difference between confidential and general waste. Confidential waste was collected in a designated place and then taken away by a waste disposal company. The delivery driver had an understanding about patient confidentiality. Assembled prescriptions awaiting collection were not visible from the medicines counter. Consent was received when Summary Care Records (SCR) were accessed.

The pharmacist and one of the pharmacy technicians (PT) had completed the Centre for Pharmacy Postgraduate Education (CPPE) level 2 training on safeguarding. The delivery driver said he would voice any concerns regarding vulnerable people to the pharmacist working at the time. There was a brief document showing the key issues for child protection and the pharmacist's duty in regard to this. The contact numbers of who to report safeguarding concerns to in the local area were not readily available. The RP said he had not had cause to report any concerns but would look up the details on the internet if necessary. There was nothing on display highlighting that patients could request a chaperone to accompany them in private consultations with the pharmacist, so people might not realise this was an option.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy team members are qualified for the jobs they do. They are comfortable providing feedback to their manager and receive informal feedback about their own performance. They get some ongoing training to help them keep up to date. But this is not structured, and they do not record it, so they might not always identify gaps in their knowledge.

Inspector's evidence

There was a pharmacist, two pharmacy technicians (PT), a medicines counter assistant (MCA) and a delivery driver on duty at the time of the inspection. The staffing level was adequate for the volume of work during the inspection and the team were observed working collaboratively with each other and the patients. Absences were covered by re-arranging the staff rota and there was flexibility in the team. One of the team members said he often worked extra hours when required. There were four directors who all worked shifts as the responsible pharmacist to cover the 100 hours that the pharmacy was open.

There was no regular ongoing training other than for those on accredited courses. The pharmacy team did not have regular protected training time but carried out training when the pharmacy was quiet. There was no record of completed training in the pharmacy. One member of the pharmacy team explained that he had completed training in his own time on mental health and Viagra Connect and used these to complete GPhC revalidation.

The pharmacy team had informal discussions about performance and development, but this was not documented. A member of the team felt there was an open and honest culture in the pharmacy and would feel comfortable talking to either of the owners or pharmacist superintendent (SI) about any concerns he might have. He said the staff could make suggestions or criticisms informally and he had introduced improved recording for multi-compartmental compliance packs and the delivery service since he started.

The RP felt empowered to exercise his professional judgement and could comply with his own professional and legal obligations. For example, refusing to sell a codeine containing pharmacy medicine because he felt it was inappropriate. He said no targets were set for Medicines Use Review (MUR) or the New Medicine Service (NMS), and none had been carried out over the last year or so.

Principle 3 - Premises **Standards not all met**

Summary findings

The premises are generally safe but the lack of cleanliness and inadequate hygiene present a risk of infection or contamination. And the generally poor state of repair detracts from the professional image.

Inspector's evidence

The pharmacy premises were not clean and they were not in a good state of repair. The front door, windows and flooring were damaged in places. A member of the team said the floor was swept daily and mopped every weekend, but it looked dirty. There were boxes and bags of rubbish outside the back door of the pharmacy. The retail area had a waiting area with four chairs. The temperature and lighting were adequately controlled. Maintenance problems were reported to one of the four pharmacy owners who owned the building. The owners were considering renovating the shop front.

There were two separate rooms where compliance packs were assembled and stored. These were cleaner and better organised than the main dispensary. There was a sink in one of these rooms. It was not used but contained confidential waste. There was a kitchen area and a WC with a wash hand basin and hand wash. Neither the WC nor the wash hand basin were very clean. There was a separate dispensary sink for medicines preparation with hot and cold running water. The sink itself was clean but the area around the sink was badly discoloured with what appeared to be mould. Hand washing notices were displayed above the sinks and hand sanitizer gel was available.

The consultation room was equipped with a sink but it had stock in it. The room was untidy and cluttered and did not present a professional image. The availability of the room was highlighted by a sign on the door. The pharmacy team used the room when carrying out the services including meningitis vaccinations and when customers needed a private area to talk.

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

Summary findings

The pharmacy offers services over extended hours and these are suitably managed. It gets its medicines from licensed suppliers, but it does not always store and manage them effectively. The fridge temperature is not regularly monitored so the pharmacy cannot show that it always stores medicines requiring refrigeration at the correct temperature.

Inspector's evidence

There was a slight step up to the front door and the door was quite narrow. The pharmacy team did not know if wheelchair users were able to access the pharmacy but confirmed it was possible for customers to enter with prams. Services provided by the pharmacy were not clearly advertised, so people might not know what was offered. There was a small amount of health promotion information on display. The pharmacy team were multilingual, speaking Urdu, Gujarati and Bengali which helped the non-English speaking members of the community.

The pharmacy offered a repeat prescription ordering service. Some of the local GP surgeries allowed the pharmacy to order patients' repeat medication on their behalf. The patients were required to contact the pharmacy to confirm their requirements or order their own 'extra' medication such as inhalers and creams. But the pharmacy automatically ordered some regular repeat medicines without contacting the patient. This risked leading to stockpiling and medicine wastage. Patients could be sent a text to let them know their prescription was ready to collect and patients who were required to order their prescriptions themselves were sent a text each time to remind them to order. There was a delivery service with associated audit trail. Each delivery was recorded, and a signature was obtained from the recipient. A note was left if nobody was available to receive the delivery and the medicine was returned to the pharmacy.

Space was limited in the main dispensary and the dispensary shelves were very full, untidy and dusty. Dispensed by and checked by boxes were not always initialled on the medication labels to provide an audit trail, so it might not be clear who had been involved in the event of an error and this might make it harder to work out what had gone wrong. Different coloured baskets were used to prevent prescriptions becoming mixed up. But the baskets were stacked to make more bench space available. Some assembled prescriptions were stored on the floor which risked physical damage of the medicines and contamination.

Stickers were put on assembled prescription bags to indicate when a fridge line or CD was prescribed. The RP said notes were added to assembled prescriptions if counselling was required. He said INR levels were requested but not recorded when dispensing warfarin prescriptions. The team had an understanding of the valproate pregnancy prevention programme but did not know if an audit had been carried out to identify patients in the at-risk group. The valproate information pack and care cards were not available, but the RP confirmed he would obtain some to ensure people in the at-risk group were given the appropriate information and counselling.

One of the pharmacists carried out meningitis vaccinations. The patient group directive (PGD) for this service could not be located in the pharmacy. Subsequent to the inspection, the pharmacist forwarded a copy and confirmed that he had completed the appropriate training. This included practical injection

technique and resuscitation.

Multi-compartment compliance aid packs were reasonably well managed. The care homes were split into four groups and each had a designated pharmacist who was responsible for checking the prescriptions. There was a partial audit trail for changes to medication in the packs, but it was not always clear who had confirmed the changes and the date the changes had been made which could cause confusion in the event of a query. A dispensing audit trail was completed. Medicine descriptions were included on the labels to enable identification of the individual medicines. Packaging leaflets were included. Disposable equipment was used. Some packs were left unsealed until they were checked by the pharmacist and members of the pharmacy team said this could be for up to a week, which increased the risk of error and contamination.

The MCA knew what questions to ask when making a medicine sale and when to refer the patient to a pharmacist. She was clear which medicines could be sold in the presence and absence of a pharmacist and understood what action to take if she suspected a customer might be abusing medicines such as a codeine containing product.

CDs were stored in a CD cabinet which was securely fixed to the wall. Date expired, and patient returned CDs were segregated and stored securely. Patient returned CDs were destroyed using denaturing kits. Pharmacy medicines were stored behind the medicine counter so that sales could be controlled.

Recognised licensed wholesalers were used to obtain medicines. No extemporaneous dispensing was carried out. The pharmacy was not compliant with the Falsified Medicines Directive (FMD). They were not registered with SecurMed and did not have the software or hardware needed, so were not currently scanning to verify or decommission medicines. They were still taking advice about which system to use.

Around thirty pots of loose tablets were seen on the shelves without appropriate labelling, so it was not clear what their batch number was or their expiry date. The RP removed them from the dispensary shelves when they were pointed out and said they should not be there and would not be used. A member of the team explained the medicines had been popped out of their original container for use in the compliance packs. But they had not been used, either because they were not correct, or the medication had been changed and so they had been removed from the compliance pack. Date checking was carried out twice yearly but records to verify this could not be found and several date expired medicines were found on the dispensary shelves. Some had expired in August 2019 and September 2019. They contained stickers which the pharmacy used to highlight ‘short-dated’ stock when they date-checked, but one packet of medicine had not been highlighted as short-dated and expired in June 2018. Dates had been added to opened liquids with limited stability. The minimum and maximum temperatures for the medical fridge had only been recorded on three days since 30 September 2019. The thermometer used to record the fridge temperature was not working at the start of the inspection. The RP re-positioned the batteries and it started to work. He reset the temperature and the fridge remained within range during the inspection.

Alerts and recalls were received via e-mail messages from the gov.com website. These were read and acted on by a member of the pharmacy team and then filed if relevant.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely.

Inspector's evidence

Recent copies of the British National Formulary (BNF) and BNF for children were available and the pharmacist could access the internet for the most up-to-date information. There was a large medical fridge and all electrical equipment appeared to be in good working order. There was a selection of glass liquid measures with British standard and crown marks. A separate measure was marked and used for methadone solution. The pharmacy had a range of equipment for counting loose tablets and capsules, with a separately marked tablet triangle that was used for cytotoxic drugs. Medicine containers were appropriately capped to prevent contamination.

Computer screens were positioned so that they weren't visible from the public areas of the pharmacy. Patient medication records (PMRs) were password protected. Cordless phones were available in the pharmacy, so staff could move to a private area if the phone call warranted privacy.

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.