General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: A.M. Clark Ltd., 1 Market Place, Penistone, SHEFFIELD, South Yorkshire, S36 6DA

Pharmacy reference: 1039344

Type of pharmacy: Community

Date of inspection: 11/07/2019

Pharmacy context

The pharmacy is in the centre of Penistone. Pharmacy team members mainly dispense NHS prescriptions and sell a range of over-the-counter medicines. They offer services including medicines use reviews (MUR) and the NHS New Medicines Service (NMS). They provide a substance misuse service, including supervised consumption and needle exchange, and provide medicines in multi-compartmental compliance packs.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
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 met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy has procedures to manage the risks to the services it provides, and pharmacy team members have read them. But, they do not regularly update their knowledge of the procedures. So, they may not be clear about the safest and most effective way to carry out their tasks. Pharmacy team members discuss and record mistakes they make. And they make changes to prevent the same or similar mistakes happening again. But, they don't always discuss enough detail about why a mistake has happened. So, they might miss opportunities to improve and make things safer. The pharmacy generally keeps the records required by law. Pharmacy team members understand their responsibility to protect people's private information. And, they know what to do if they have a concern about the welfare of a child or vulnerable adult.

Inspector's evidence

The pharmacy had a set of standard operating procedures (SOPs) in place to help manage the risks with the services it provided. The sample checked were last reviewed by the pharmacist in March 2017. And the next review was scheduled for March 2019 but had not yet been completed. Pharmacy team members had read and signed the SOPs in 2013. But they had not read them since. The pharmacy defined the roles of the pharmacy team members in some SOPs, but not all. A dispenser said her tasks and responsibilities were defined verbally and by experience of working in the pharmacy for a long time. The pharmacy employed one dispenser who was accredited as an accuracy checker (AC). And, she could perform a final accuracy check of a prescription. The dispenser was clear that she could not check her own work or any prescriptions for controlled drugs (CDs). And, she said that the pharmacist performed a clinical check of the prescription before she carried out her check. She said the pharmacist usually annotated the prescription to confirm he had performed the clinical check. But, if the prescription was not annotated, she would return it to the pharmacist before the prescription was handed out. The pharmacy did not have a system in place to revalidate the dispenser's competence to perform a final accuracy check. And, the pharmacist and dispenser were unaware of the requirement to revalidate dispensers competence every two years with the training provider. This was discussed with the pharmacist. He explained he was not aware of any mistakes that had come back to the pharmacy where the AC had missed an error. And, he gave an assurance that he would suspend the AC's checking responsibilities until a proper revalidation process was in place.

The pharmacist or accuracy checker highlighted and recorded near miss errors made by pharmacy team members when dispensing. Pharmacy team members discussed the errors made. And, they were asked to spot their own mistakes. But, they did not discuss or record much detail about why a mistake had happened. And, the pharmacist said that not all errors were recorded, despite all mistakes being discussed. They usually said rushing had caused the mistakes. And, their most common change after a mistake was to double check and slow down next time. A dispenser explained an example of separating ropinirole and risperidone on shelves in the room where multi-compartmental compliance packs were dispensed after a picking error. The pharmacy had a clear process for dealing with dispensing errors that had been given out to people. It recorded incidents using an electronic system. Pharmacy team members discussed all dispensing errors. And, the records seen were comprehensive about what had happened and why. After a recent error, pharmacy team members had changed the way the area used for compliance pack dispensing was organised. This had helped to more clearly segregate packs waiting to be checked. And, to prevent packs being mixed up and provided to the wrong patient.

The pharmacy had a procedure to deal with complaints handling and reporting. But, it did not advertise the procedure to people using the pharmacy. The pharmacist said the pharmacy was a long-standing family business and most of the local community knew him by name. So, they would always ask for him in person if they had a complaint. The pharmacy collected feedback from people by using questionnaires, Facebook and verbally. A pharmacy team member gave an example of making improvements after feedback. She said the team members would always try and obtain products they didn't stock for people when they asked for them. One recent example was a request for a specific incontinence product. This meant the patient did not have to travel further afield to get what they needed.

The pharmacy had up to date professional indemnity insurance. And, it displayed a certificate of the insurance. The pharmacy kept controlled drug (CD) registers electronically, which were complete and in order. It kept running balances in all registers. But, pharmacy team members did not frequently audit the running balances against the physical stock quantity. So, it might be difficult to deal with any discrepancies quickly. Pharmacy team members audited the running balances in the methadone register approximately once a month. It kept and maintained a register of CDs returned by people for destruction. And it was complete and up to date. The pharmacy maintained a responsible pharmacist record electronically. But, it had frequent gaps in the sign out time of the responsible pharmacist. The pharmacist displayed their responsible pharmacist notice to people. Pharmacy team members monitored and recorded fridge temperatures daily. They kept private prescription records in a paper register, which was complete and in order. And, they recorded emergency supplies of medicines in the private prescription register. They recorded any unlicensed medicines supplied, which included the necessary information in the samples seen.

The pharmacy kept sensitive information and materials in restricted areas. And, it collected confidential waste in dedicated bins. The bins were closed when full and taken for incineration. Pharmacy team members had been trained to protect privacy and confidentiality. The pharmacist had delivered the training verbally. Pharmacy team members were clear about how important it was to protect confidentiality. And there was a procedure in place detailing requirements under the General Data Protection Regulations (GDPR).

When asked about safeguarding, a dispenser gave some examples of symptoms that would raise their concerns in both children and vulnerable adults. They explained how they would refer to the pharmacist. The pharmacist said they would assess the concern. And would refer to local safeguarding contacts for advice. The pharmacy had contact details available for the local safeguarding service. Pharmacy team members had attended a training event provided by the Local Pharmaceutical Committee (LPC) in 2018. And, there was a procedure to instruct pharmacy team members about what to do in the event of a concern.

Principle 2 - Staffing ✔ Standards met

Summary findings

Pharmacy team members have the right qualifications and skills for their roles and the services they provide. They complete training ad-hoc. And, pharmacy team members talk together openly to manage the workload and improve ways of working.

Inspector's evidence

At the time of the inspection, the pharmacy team members present were a pharmacist, two qualified dispensers, two trainee dispensers, three medicines counter assistants and a delivery driver. Pharmacy team members completed training ad-hoc by reading various trade press materials about seasonal conditions and new medicines. And, they attended some local training events and regularly discussed topics with the pharmacist and colleagues. The pharmacy did not have an appraisal or performance review process. Pharmacy team members said they discussed any learning needs informally with the pharmacist. And, he would support them to address any learning needs.

A pharmacy team member explained that she would raise professional concerns with the pharmacist or superintendent pharmacist (SI). She said she felt comfortable raising a concern. And confident that her concerns would be considered, and changes would be made where they were needed. The pharmacy did not have a whistleblowing policy. And, the pharmacy team member was unsure about how they would raise a concern anonymously.

The pharmacy team communicated with an open working dialogue during the inspection. A dispenser explained she was told by the pharmacist when she had made a mistake. The discussion that followed did not fully explore why she had made the mistake. But, she said she would always try and change something to prevent the mistake happening again, even if certain details were not recorded.

Pharmacy team members explained a change they had made after they had identified areas for improvement. A medicines counter assistant explained changes they had made to the prescription retrieval area. Prescriptions had previously been stored on shelves, which had led to untidiness and being unable to easily find a prescription bag. They had reorganised the area so that prescriptions waiting to be collected were stored in totes alphabetically by surname. The area had also been moved out of the consultation room. She explained that prescriptions were now easier and quicker to find for people. And, they could still be retrieved if someone was using the consultation room for a private conversation. The pharmacy owners and SI did not ask the team to achieve any targets.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and properly maintained. It provides a suitable space for the health services provided. And the pharmacy has a suitable room where people can speak to pharmacy team members privately.

Inspector's evidence

The pharmacy had a large retail area. And, a much smaller dispensary at the back of the premises where medicines were prepared. The pharmacy was clean and well maintained. All areas of the pharmacy were tidy and well organised. And the floors and passage ways were generally free from clutter and obstruction. The pharmacy had a limited amount of bench space available for the volume of dispensing being carried out. But, there was a larger room on the first floor used to dispense multi compartmental compliance packs. And, there was a safe and effective workflow in operation. And clearly defined dispensing and checking areas. It kept equipment and stock on shelves throughout the premises. The rest of the first floor was used for storage. The pharmacy had a private consultation room available. The pharmacy team used the room to have private conversations with people. The room was signposted from the retail area.

There was a clean, well maintained sink in the dispensary used for medicines preparation. There was a toilet, with a sink which provided hot and cold running water and other facilities for hand washing. Heat and light in the pharmacy was maintained to acceptable levels. The overall appearance of the premises was professional, including the exterior which portrayed a professional healthcare setting. The professional areas of the premises were well defined by the layout and well signposted from the retail area.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy is generally accessible to people. It stores, sources and manages its medicines safely. Pharmacy team members identify people on high-risk medicines and give them some advice. And they help people to remember to take their medicines by dispensing in to multi-compartmental compliance packs. But they don't always provide these people with all the information they may need to take their medicines safely. Pharmacy team members deliver medicines to people. But, they don't keep an audit trail of the deliveries they make. So, it might be difficult to resolve any queries.

Inspector's evidence

The pharmacy was accessed by steps from the street. There was no bell or signage to help people get the staff attention if they needed help accessing the pharmacy. And there was no ramp available. The pharmacist explained they had recently come to the end of a planning application process to install a ramp. But, the planning application had been rejected because the pharmacy was in a conservation area. He said he was now assessing alternative options, which included considering temporary ramp facilities. Pharmacy team members demonstrated how they could provide large print labels to people with visual impairment. And, they said they would use written communication for someone with a hearing impairment.

Pharmacy team members signed the dispensed by and checked by boxes on dispensing labels. This was to maintain an audit trail of staff involved in the dispensing process. They did not routinely use baskets to help prevent prescriptions being mixed up. The pharmacist said they had a system to visually separate prescriptions neatly on the bench. But, he said it was rare for them to have more than one dispensed prescription on the bench at a time. This was discussed, and the pharmacist agreed to use baskets on the occasions where there was more than one dispensed prescription waiting to be checked.

The pharmacy supplied medicines in multi-compartmental compliance packs when requested. It attached labels to the pack, so people had written instructions of how to take the medicines. But, it did not provide descriptions of what the medicines looked like, so they could be identified in the pack. And, the sheet the labels were attached to were not fixed to the pack. So, there was a risk that the labels and information could become separated from the pack. And, this does not meet labelling requirements. Pharmacy team members provided people with patient information leaflets about their medicines each month. They documented any changes to medicines provided in packs on the patient's electronic medication record. And, they ordered prescriptions weekly and prepared packs a week in advance of them being supplied. The pharmacist carried out an assessment for each patient who had their medicines dispensed in a pack and had them administered with help from a carer. The assessment was used to establish the most appropriate form and level of adjustment needed to help the patient take their medicines safely. People were referred to the pharmacist for an assessment by another healthcare professional, such as a GP, nurse, social services or occupational health. The pharmacist explained that he then made his recommendation and communicated this to the referring healthcare professional. He said the system had helped to resolve issues and clarify needs between all the professionals involved in a person's care. And, to streamline the decisions about the most appropriate adjustments.

Pharmacy team members checked medicine expiry dates ad-hoc, usually on a Saturday when the

pharmacy was quiet. Pharmacy team members said they also checked medicines expiry dates during the dispensing process. There were no records kept of any date checking. And there was no system in place to highlight short dated medicines. The pharmacist said he was always aware of the stock and said he continually looked for medicines that he thought had been in stock for a long time. The inspector checked the dispensary shelves and did not find any out-of-date medicines. The pharmacy responded to drug alerts and recalls. And, any affected stock found was quarantined for destruction or return to the wholesaler. It recorded any action taken. And, records included details of any affected products removed.

The pharmacy obtained medicines from ten licensed wholesalers. It stored medicines tidily on shelves. And all stock was kept in restricted areas of the premises where necessary. It had adequate disposal facilities available for unwanted medicines, including controlled drugs (CDs). Pharmacy team members kept the CD cabinet(s) tidy and well organised. And, out of date and patient returned CDs were segregated. The inspector checked the physical stock against the register running balance for three products. And they were found to be correct. The pharmacy team kept the contents of the pharmacy fridge tidy and well organised. They monitored minimum and maximum temperatures in the fridge every day. And they recorded their findings. The temperature records seen were within acceptable limits.

The pharmacist said that he would provide the necessary information to someone presenting a prescription for valproate who may become pregnant. But, he said he did not routinely check whether they were taking steps for adequate pregnancy prevention. The pharmacy did not have a supply of information material to provide to people or the necessary warning labels to attach to valproate dispensed outside its original container. But, the pharmacist said he would order the necessary resources. Pharmacy team members were aware of the requirements of the Falsified Medicines Directive (FMD). But, there was no equipment or software available. Pharmacy team members had not been trained about the new requirements and there was no updated procedure available to incorporate checks for falsified medicines. The pharmacist said staff were checking packs for tamper evident seals. And, he was currently discussing installation of the necessary equipment with his system supplier.

The pharmacy delivered medicines to people. But, it did not keep any records of deliveries made. And, it did not ask people to sign to confirm receipt of their deliveries, including deliveries for CDs. So, the pharmacy didn't have an audit trail for deliveries. But, they kept a record of the people who had asked for their medicines to be delivered. And, they could use this information and electronic dispensing records to reconcile who had received a deliver if necessary.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment available, which it properly maintains. And it manages and uses the equipment in ways that protect people's confidentiality.

Inspector's evidence

The pharmacy had the equipment it needed to provide the services offered. The resources available included the British National Formulary (BNF), the BNF for Children, various pharmacy reference texts and use of the internet. Pharmacy team members obtained equipment from the licensed wholesalers used. And they had a set of clean, well maintained measures available for medicines preparation. They used a separate set of measures to dispense methadone. The pharmacy had a dispensary fridge that was in good working order. And, pharmacy team members used it to store medicines only. They restricted access to all equipment and they stored all items were securely.

The pharmacy positioned computer terminals away from public view. And they were password protected. It stored medicines waiting to be collected in the dispensary, also away from public view.

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.