General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Innovation Pharmacy, Unit 8B Carrmere Road, Leechmere Industrial Estate, Sunderland, Tyne and Wear, SR2 9TW

Pharmacy reference: 9011372

Type of pharmacy: Internet / distance selling

Date of inspection: 20/07/2023

Pharmacy context

The pharmacy is in an industrial unit in the suburbs of Sunderland city centre. It has a distance selling NHS contract. Pharmacy team members mainly dispense NHS prescriptions for people living in care homes and nursing homes, and they provide the majority of these medicines in multi-compartment 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 adequately identifies and manages risks associated with its services. And it has most of the documented procedures it needs to help team members provide services effectively. Pharmacy team members understand their role in helping to protect vulnerable people. They suitably protect people's private information. And they generally keep accurate records. Team members record and discuss the mistakes they make so that they can learn from them. But they don't always document why mistakes happen and so they may miss opportunities to make improvements to the pharmacy's services.

Inspector's evidence

The pharmacy had been taken over by the current owners in November 2022. It had a set of standard operating procedures (SOP) in place to help pharmacy team members manage risks. The pharmacy's owner was currently reviewing the SOPs to make them specific to the way team members worked. And they were migrating the SOPs to an electronic platform to make them easier for team members to access and review. The pharmacist manager showed a newly developed SOP for dispensing. They explained how they had sought input and feedback from various team members about the contents to make sure it incorporated all the necessary steps of preparing medicines. This included detailed instructions for preparing medicines in the various types of multi-compartment compliance packs provided by the pharmacy. And for preparing prescriptions that were dispensed in the manufacturer's original packs. The SOP also provided team members with a list of "Do's and Don'ts", which highlighted and reinforced learning from common mistakes and processing errors. The pharmacy owner explained how they assessed various risks, such as the suitability of the pharmacy premises to deliver services, the layout of the areas where prescriptions were prepared, and ensuring that people had completed the necessary training. But these assessments had not been written down to help team members manage emerging risks on an ongoing basis.

Pharmacy team members highlighted and recorded near miss errors and dispensing errors, which were errors identified after the person had received their medicines. But there were no documented procedures to help team members do this effectively. This was discussed with the pharmacy owner, who agreed to implement an SOP immediately. Pharmacy team members discussed their errors and why they might have happened. And they used this information to make some changes to help prevent the same or similar mistakes from happening again. For example, team members described how they had separated different strengths of epixaban on the shelves, which had very similar packaging, to help prevent the wrong strength being selected. But during the inspection, these medicines were found together on the shelves. This was discussed, and team members agreed they needed to do more to make sure any changes were clear to everyone so they could be easily sustained. Pharmacy team members did not always capture enough information about why the mistakes happened or the changes they had made to prevent a recurrence to help aid future learning. But they gave their assurance that these details were always discussed. The pharmacy manager explained how they analysed the data collected every month to look for patterns and discussed their findings at a monthly patient safety meeting with the team. But they did not record their analysis to help them reflect on any changes made to improve safety. Team members explained how they had recently identified and discussed several errors that had been caused by them being distracted by the telephone while they were dispensing medicines. In response, they were trailing a system where the telephone ringing was placed at

someone’s workstation for 30 to 60 minutes, and during which time, the team members was responsible for answering the phone. Then the phone was passed on to the next workstation. They explained this helped the person responsible for the phone to plan to perform less high-risk activities. And it helped to prevent other team members making mistakes by reducing distractions while they were dispensing prescriptions.

The pharmacy had a documented procedure in place for handling complaints or feedback from people. Pharmacy team members explained people usually provided verbal feedback. And any complaints were referred to the pharmacist manager to handle. There was information available for people on the pharmacy’s website about how to provide the pharmacy with feedback.

The pharmacy had up-to-date professional indemnity insurance in place. It kept accurate controlled drug (CD) registers. And it maintained running balances in all registers, which pharmacy team members audited against the physical stock quantity each week. Checks of the running balances against the physical stock for three products were found to be correct. The pharmacy maintained a responsible pharmacist (RP) record electronically. The record had several gaps in the sign-out time of the RP. The pharmacist displayed their RP notice. Pharmacy team members monitored and recorded fridge temperatures.

The pharmacy was not accessible to the public. It kept all sensitive information and materials in the secure pharmacy. It collected confidential waste in dedicated bags, which were collected for destruction by a secure waste disposal contractor. The pharmacy did not have a documented procedure in place about handling sensitive information for pharmacy team members to refer to. But team members explained how important it was to protect people's privacy and how they would protect confidentiality. Team members gave some sound examples of signs that would raise their concerns about vulnerable children and adults. And how they would discuss their concerns to the pharmacist and other professionals engaged in the person’s care. The pharmacy had written procedures for dealing with concerns about children and vulnerable adults. Registered pharmacy team members had completed formal safeguarding training in 2022. But the pharmacy had not provided other team members with any formal safeguarding training.

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 some ad hoc training to help keep their knowledge and skills up to date. Pharmacy team members feel comfortable raising concerns and discussing ways to improve services.

Inspector's evidence

At the time of the inspection, the pharmacy team members present were the pharmacist owner, three pharmacists, two pharmacy technicians, six qualified dispensers, one overseas pharmacist, four trainee dispensers, and two administrators. The owner explained they had experienced significant staff turnover since then but had managed to recruit successfully to replace the team members that had left. Pharmacy team members completed training ad-hoc by reading various materials. And by completing training modules provided by the NHS e-Learning for Healthcare platform when available. The pharmacy did not have a formal appraisal or performance review process for pharmacy team members. A team member explained they would raise any learning needs verbally with the responsible pharmacist (RP), the pharmacy manager, supervisor or the pharmacy owner who worked at the pharmacy regularly. And they were supported by being signposted to relevant reference sources or by discussion to help address their learning needs.

A pharmacy team member explained how they would raise professional concerns with the RP or the pharmacy owner. They felt comfortable raising concerns, confident that their concerns would be considered, and that changes would be made where they were needed. The pharmacy did not have a formal whistleblowing policy. Pharmacy team members were aware of organisations outside the pharmacy where they could raise professional concerns, such as the NHS or GPhC. Pharmacy team members communicated with an open working dialogue during the inspection. They felt comfortable making suggestions to improve their ways of working, either informally or at regular team huddles. One recent example of an issue they had raised was the need to write the date opened on bottles of liquid medicines after some had been found on the shelves without dates. This helped team members to remove these medicines when they expired. The pharmacy owners did not ask pharmacy team members to meet any performance related targets.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and properly maintained. It provides a suitable space for the services it provides. And pharmacy team members manage the space well to help provide services safely.

Inspector's evidence

The pharmacy was in a large industrial unit that could not be accessed by the public. Team members kept the benches well organised to help maximise the space they had available. The pharmacy's floors and passageways were generally free from clutter and obstruction and team members kept equipment and stock on shelves throughout the premises where possible. This was sometimes difficult during the pharmacy's busiest times of the month. The pharmacy had a clean, well-maintained sink in the dispensary used for medicines preparation. There was a staff toilet, with a sink with hot and cold running water and other hand washing facilities. The pharmacy kept its heating and lighting to acceptable levels. Its overall appearance was professional and suitable for the services it provided.

Principle 4 - Services ✔ Standards met

Summary findings

Pharmacy team members manage and provide the pharmacy's services safely and effectively. The pharmacy suitably sources its medicines. It generally stores and manages its medicines appropriately. And it has processes in place to help people understand and manage the risks of taking some medicines.

Inspector's evidence

The pharmacy had a distance selling NHS contract, so the premises could not be accessed by the public. It had a website that displayed the pharmacy's telephone and email contact information and provided people with information about how to make a complaint.

The pharmacy mostly supplied medicines to people in various types of multi-compartment compliance packs. And most of these people lived in care homes or nursing homes, although a small proportion of people who used the pharmacy's services lived in their own homes. Pharmacy team members explained how they organised their work to make sure the right people's medicines were prepared each week. Team members usually organised the workload according to the care or nursing home where people lived. And the work for each home was usually assigned to one team member to complete, although larger homes were assigned to several team members to help manage the workload. Homes usually ordered prescriptions for people, and pharmacy team members were responsible for reconciling prescriptions when they were received, including managing any missing prescriptions or discrepancies. All queries about prescriptions were recorded so they could be tracked at each stage to make sure they were fully resolved before the medicines were due to be supplied. The pharmacy attached backing sheets to the packs, so people had written instructions about how to take their medicines. Pharmacy team members included descriptions and photos of what the medicines looked like, so they could be easily identified in the pack. The also provided packs with accompanying medicines administration record (MAR) when requested. They provided people with patient information leaflets about their medicines each month. Changes made to people's prescribed medicines were provided to the pharmacy in writing. These records were stored with the person's master record sheet, which was a record of all their medicines and when they should be taken. Team members also recorded changes on people's electronic patient medication record (PMR).

Pharmacy team members signed the 'dispensed by' and 'checked by' boxes on dispensing labels during dispensing. This was to maintain an audit trail of the people involved in the dispensing process. The pharmacist clinically checked each prescription, ready for the pharmacy technician to perform the final accuracy check once the prescriptions had been dispensed. The technician gave clear examples of the types of prescriptions they were permitted to check and were clear about the limitations of their role and competence. Pharmacy team members used dispensing baskets throughout the dispensing process to help prevent prescriptions being mixed up. Team members also used Individual notebooks to record information such as tasks, phone calls and personal to-do lists to help them track key tasks they needed to complete. They also explained how the notebooks helped them to manage distractions by keeping track of their tasks and to help prevent work being missed, especially during busy times.

The pharmacist counselled people receiving prescriptions for valproate if they were at risk, where possible. They checked if the person was aware of the risks if they became pregnant while taking the

medicine. And whether they were on a pregnancy prevention programme and using effective contraception. The pharmacy did not have stock of information materials to give to people to help them manage the risks of taking valproate. This was discussed and they agreed to obtain a stock of materials as soon as possible. The pharmacy had not carried out an audit of people who received valproate from the pharmacy, to help to ensure that the right people had received the appropriate information and counselling. And the pharmacist was not aware of the need to counsel men on the risks of valproate in pregnancy. They gave their assurance that they would revisit the guidance and update their knowledge.

The pharmacy obtained medicines from licensed wholesalers. It had disposal facilities available for unwanted medicines, including CDs. The pharmacy had a system in place to monitor the minimum and maximum temperatures in the pharmacy's fridge each day. But there were significant gaps in the pharmacy's temperature records. The temperature records available were within acceptable limits. But team members had only recorded temperatures twice in July 2023. The fridge's temperature during the inspection was within acceptable limits. This was discussed with the pharmacy owner, who gave their assurance that daily temperatures would be recorded daily going forward. Team members recorded checks of medicine expiry dates approximately every three months. They completed checks in various areas of the pharmacy on a rolling cycle. Pharmacy team members highlighted and recorded any short-dated items up to six months before their expiry, and they recorded these items on monthly stock expiry sheets. This meant team members could easily identify and remove expiring medicines at the beginning of their month of expiry. Pharmacy team members responded to any alerts or recalls they received about medicines from manufacturers and other agencies. They removed any affected medicines from the shelves, and they recorded the actions they had taken. Several amber bottles were found on the shelves in the dispensary containing medicines that had been removed from their original packaging. Some of these bottles had labels attached giving information about the medicine, its strength, batch number and expiry date. But some of the labels attached did not show a batch number or expiry date of the medicines in the bottles. This meant that there was a risk of these medicines not being removed from stock and supplied to people after they had expired or after they had been recalled by the manufacturer. The owner gave their assurance that these medicines would be removed from stock immediately.

Because the pharmacy was not open to the public, it delivered all the medicines it prepared and dispensed. It recorded the deliveries it made, including the need for all medicines for each person to be checked and signed for when delivering to care and nursing homes. This helped provide the pharmacy with closure of the audit trail for medicines they had prepared and dispensed. For people living in their own home, the delivery driver left a card through the letterbox if someone was not at home when they delivered. The card asked people to contact the pharmacy.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment available for the services it provides. It manages and uses its 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 it had available included the British National Formulary (BNF), the BNF for Children, various pharmacy reference texts and use of the internet. The pharmacy had a set of clean, well-maintained measures available for medicines preparation. It had suitable containers available to collect and segregate its confidential waste. It kept its password-protected computer terminals and bags of medicines waiting to be collected in the secure 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.