General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Enimed Pharmacy Hub, IO Traders Centre, Deacon Way, Reading, RG30 6AZ

Pharmacy reference: 9011427

Type of pharmacy: Community

Date of inspection: 23/08/2021

Pharmacy context

This is a private pharmacy which is closed to the public and located inside a warehouse on an industrial estate in Reading, Berkshire. The pharmacy began trading during the COVID-19 pandemic in 2020. It is registered with the General Pharmaceutical Council (GPhC) to prepare and assemble multi-compartment compliance packs for some of the company's own pharmacies. It does not have an NHS contract and no sales of over-the-counter medicines take place. The pharmacy does not currently provide any other services. This inspection took place during the COVID-19 pandemic.

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 adequate processes in place to identify and manage risks. It protects people's private information appropriately. And, it generally maintains the records it should. Members of the pharmacy team deal with their mistakes responsibly. But they are not always recording all the necessary details. This could mean that they may be missing opportunities to spot patterns and prevent similar mistakes happening in future. The pharmacy has some operating instructions in place to guide its team members. But it does not have all of them. This includes safeguarding the welfare of vulnerable people. So, they may not know how to respond to concerns appropriately.

Inspector's evidence

The pharmacy was clean, tidy, and organised. It was a hub for the company's pharmacies and supplied multi-compartment compliance packs to them. The pharmacy had some systems in place to identify and manage the risks associated with its services. This included some processes to limit the spread of infection from COVID-19. A standard operating procedure to manage COVID-19 was on display. The team had been vaccinated. Staff said that they undertook lateral flow tests twice a week. They had been provided with personal protective equipment and they described being given verbal guidance on this such as regularly sanitising their hands. Hand sanitisers were present. And the pharmacy was cleaned regularly. However, at the time of the inspection, none of the staff were wearing masks. There was no business continuity plan seen and members of the pharmacy team confirmed that they had not had any individual risk assessments completed for COVID-19. This included occupational ones despite some members of the team being from the Black, Asian and ethnic minority (BAME) group. This means they could be at greater risk.

The pharmacy had some documented standard operating procedures (SOPs) to provide guidance to the team about the services it provided. They were from 2020. The staff had read and signed them, their roles had been defined, and the SOPs seen were specific to the nature of the pharmacy business. However, they did not include the full range of SOPs required such as ones to provide guidance about the pharmacy's incident management, complaints process, information governance and safeguarding. Staff said that they had read these processes when they worked at other pharmacies for the same company in the area. However, this could not be verified. There was also no notice on display to identify the pharmacist responsible for the pharmacy's activities. This is a legal requirement and should have been displayed at the start of the responsible pharmacist's shift. The inspection took place first thing in the morning and the RP was advised of this at the time.

Staff routinely recorded their near miss mistakes. There were two logs in place to record this information, one was kept by the dispensing staff and the other by the responsible pharmacist (RP). The RP described the near miss mistakes as being situations where the automated dispensing robot jammed or if tablets broke. They were discussed with the team and rectified at the time. Staff had their own tasks and responsibilities. They worked in different areas. And the RP checked the multi-compartment compliance packs from a separate area. This helped minimise distractions and ensured any mistakes could be easily found. Staff sealed those packs with fewer than six different medicines inside before the final check for accuracy was made by the RP. Any compliance packs with more than seven different medicines were left open before the final check for accuracy for easier verification.

However, there were missing details in the near miss records such as a description of the event itself or the next steps taken. There was also no evidence of a monthly or formal review taking place. The team confirmed that the pharmacy had not had any dispensing incidents or received any complaints. The RP's process to manage incidents was in line with expectations. However, there was no documented policy or procedure in place, either written or electronic, for people to learn from their mistakes. There was no complaints policy either.

The RP said that people's consent to assemble their compliance packs from this pharmacy was obtained by the individual company's pharmacies and that people who received the packs had been informed about this. However, there was no information on site to verify this. The pharmacy did not receive, undertake final accuracy-checks or download any prescriptions (see Principle 4). It was dependent on each individual pharmacy inputting the details from the prescription onto the pharmacy system for staff at this pharmacy to use.

The pharmacy protected people's confidential information appropriately. There were no sensitive details left in the premises that could be seen from the warehouse. Computer systems were password protected and confidential waste was shredded. However, as described above there were no documented or electronic processes in place to provide guidance to the team. Although the team required some prompting, they were able to describe some details about safeguarding the welfare of vulnerable people. They said that they would speak to the person's GP or the RP in the event of a concern. However, there was no SOP about this, no contact details available for the local safeguarding agencies or for the areas that the pharmacy provided compliance packs to. And the RP had not been trained on this either.

The pharmacy did not stock or supply controlled drugs (CDs), medicines that required cold storage or supply unlicensed medicines or make supplies against private prescriptions and it had not made any emergency supplies. Hence there were no records of this. The RP record had been kept in line with statutory requirements. The pharmacy had suitable professional indemnity insurance in place.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload. Its team members work well together. But, the pharmacy does not provide many resources to help keep the team's 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 regular pharmacist, and three full-time dispensing assistants. One member of staff had been enrolled onto an accuracy checking course but stated that this was when she worked at another branch. This had been put on hold since she had transferred to this site. There was enough staff to manage the pharmacy's workload and the team was up to date with this. Members of the pharmacy team covered each other as contingency. There was also a warehouse manager and two drivers seen. They were all employed by the company. The drivers were responsible for delivering the compliance packs to the company's pharmacies.

They were a small team and said that they liked working at the pharmacy. They regularly discussed things with each other and had links with the other pharmacies in the company. Staff stated that they felt confident with raising concerns. They could raise issues with the RP, the operations manager or the area manager if required although they were unaware on whether a formal whistleblowing process was in place. The team said that the operations manager was seen regularly at the pharmacy. The staff felt supported by him. Some of the training that members of the pharmacy team had completed could be verified. This was from some of the certificates that were on display. However, staff confirmed that this was for mandatory training that required refreshing every year. The pharmacy did not have a formal or ongoing training programme to keep the team informed about new developments once the mandatory training had been completed.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are secure and suitable for the activities being provided. The pharmacy has enough space to deliver its services safely. And its team members keep the premises clean.

Inspector's evidence

The pharmacy premises were located inside a warehouse unit which belonged to the company and consisted of a relatively spacious room. It had an automated dispensing system (a robot). The pharmacy was clean, bright, and well ventilated. It was professional in its appearance. The dispensary had enough space for the team to carry out dispensing tasks safely with different workstations for various activities to take place. The pharmacy did not have a consultation room. It did not provide any services and was closed to the public. This was therefore not required. The pharmacy was secured appropriately. Unauthorised access was restricted, and warehouse staff could not access the pharmacy without team members being present.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy obtains its medicines from reputable sources. It generally manages its medicines appropriately. And it has auditable processes in place to verify the different stages of the pharmacy's workflow. But the pharmacy doesn't hold any information about people who receive higher-risk medicines. This makes it difficult for it to show that it provides people with appropriate advice when supplying these medicines. And it doesn't have the full records to show that it has been taking the appropriate action in response to safety alerts. This risks people receiving medicines and devices that are not safe to use.

Inspector's evidence

The pharmacy was located on the ground floor of the warehouse. It had some reserved parking spaces outside the warehouse, but the pharmacy was closed to the public, so access was limited. Staff could make the necessary adjustments for people with different needs if required. This included speaking clearly and using a translation line for people whose first language was not English. However, the pharmacy did not have any information present to easily signpost people to other services.

The pharmacy did not provide any additional services. It only assembled compliance packs onsite. It acted as a hub, in a 'hub and spoke' arrangement whereby it supplied the compliance packs to each 'spoke' or individual pharmacy. The individual pharmacy then acted as a collection point for people to obtain their medicines or compliance packs from. All the pharmacies in this arrangement were owned by the same company, Enimed Ltd, which is required by law for this type of arrangement. Staff said that most of the company's pharmacies were in Reading, but they also supplied compliance packs to one in Leeds.

The pharmacy hub held lists of people who required compliance packs. Staff at the 'spokes' were responsible for identifying who needed a pack. They ordered their own prescriptions and once received, staff described them undertaking a clinical check first, checking for any changes or errors against the individual records that the pharmacy held, before labelling their own pharmacy system with the details from the prescription. The pharmacy systems of the 'spokes' were linked with the pharmacy system at the hub. This meant that once prescriptions had been inputted into the system, the hub could access the details through the backing sheets. The pharmacy hub used an automated dispensing system – a robot. This was linked to the hub's pharmacy system. Staff at the hub, then selected medicines using the automated system, the compliance pack was prepared and checked for accuracy.

This system meant that the pharmacy did not receive or accuracy-check details of the medicines against prescriptions. This meant that they were dependent on the 'spoke' pharmacy inputting the correct details. The pharmacy hub did not supply compliance packs with medicines that contained CDs, fridge items or any where medicines required changing mid-cycle. These were prepared at the 'spokes'. Staff at the pharmacy hub were responsible for inputting descriptions of the medicines. Once staff generated the backing sheets, there was a facility on them which helped identify who had been involved in the dispensing process. Team members routinely used these as an audit trail. Staff also used various lists of patients as checklists and they had also kept audit trails to identify who had helped assemble the packs, checked them for accuracy as well as when they had been delivered and by whom.

The pharmacy provided descriptions of the medicines that were inside the compliance packs and they were seen to be accurate. However, staff said that Patient information leaflets (PILs) were supplied by the 'spoke' pharmacy. The compliance packs had details of the pharmacy hub on it but this was provided in a very small font. The team stated that people could contact them if required through this information. This was discussed at the time.

Staff stated that any compliance packs which required higher-risk medicines such as warfarin were provided separately, except for methotrexate. The RP described implementing additional care for this medicine. Each 'spoke', or pharmacy was responsible for counselling people, asking about relevant parameters, and obtaining this information. The RP said that she attached notes about any relevant points that required checking or counselling. However, there were no documented details seen about this and pharmacy did not hold information about any parameters obtained such as blood tests results. After some prompting, staff were able to describe the risks associated with valproates. However, there was no literature available to provide to people at risk. Staff said that the individual pharmacy was responsible for counselling people about this and for providing this information. This was discussed at the time.

Once the compliance packs had been assembled, checked, and packed, the company's drivers delivered them back to the original 'spoke' pharmacies. They used in-house checking processes to ensure they had the required packs and number before delivering. Signatures from the pharmacies were obtained. The pharmacy had been keeping verifiable audit trails about this process. The team said that there had been no failed deliveries and the pharmacy would be notified beforehand if there was a problem.

The pharmacy's stock was stored in an organised way. The pharmacy used licensed wholesalers such as AAH, Sigma and Alliance Healthcare 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. Any medicines with less than six-month expiry were transferred internally to one of the company's other pharmacies. Medicines requiring disposal were not accepted by staff. People were signposted accordingly. However, there were several containers present which had medicines that had been de-blistered into them. Most of them were labelled with the correct details such as the batch number, name of the product and the expiry but some had details missing. This was discussed at the time. The pharmacy's high use of this practice was also discouraged. De-blistering medicines in this manner meant that the pharmacy was no longer storing the medicines inside its original packaging and under the optimal conditions. This could impact the medicine's overall stability and efficacy.

There were also some issues seen with the pharmacy's process for drug alerts. Staff said that they received this information through the company network, they described checking the details but only one recall could be located. This was dated from October 2020. The pharmacy therefore did not have enough records to be able to verify this process fully.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment and facilities it needs to provide its services safely. And they are used appropriately to protect people's private information.

Inspector's evidence

The pharmacy had a suitable range of equipment and facilities. This included machines to de-blister medicines, scales, an automated dispensing robot, a shredder and a legally compliant CD cabinet. The equipment was new and kept clean. The robot was serviced every month, and at three months as well as annually. The pharmacy did not stock or supply any medicines that required cold storage. Hence, it did not require a fridge. The dispensary sink could have been cleaner. There was hot and cold running water available. Computer terminals were positioned in a manner that prevented unauthorised access. They also had fingerprint access. The pharmacy had cordless telephones so that private conversations could take place if required.

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.