General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Day Lewis Pharmacy, The Original Pack Hub, Unit 2 Peterwood Way, Croydon, Surrey, CR0 4UQ

Pharmacy reference: 9012302

Type of pharmacy: Dispensing hub

Date of inspection: 31/07/2024

Pharmacy context

This is a hub pharmacy which assembles people's prescriptions in original manufacturers' packs for other (spoke) pharmacies owned by the same company. The pharmacy returns the assembled medicines to the spoke pharmacies for people to collect or the spoke pharmacy to deliver. The pharmacy is set in a warehouse in Croydon. And members of the public aren't allowed to visit its premises in person.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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 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 manages its risks appropriately. It has written instructions to help its team members work safely. And it monitors the service it delivers. The pharmacy keeps the records it needs to by law. And it has the insurance it needs to protect people if things do go wrong. People who work in the pharmacy know what they can and can't do, what they are responsible for and when they might seek help. And they keep people's private information safe.

Inspector's evidence

The pharmacy acted as a dispensing hub for community pharmacies under the same ownership. And its assembly process was automated to support it in supplying medicines. This meant its team was responsible for only a few manual processes. The pharmacy didn't have direct contact with the people who received the medicines it assembled. And it only dispensed whole packs of medicines which were sent to the spoke pharmacies.

The pharmacy had been operational for a few months. And it currently provided its service to a small number of spoke pharmacies. The spoke pharmacies were spread across a large geographical area and were testing the efficiency and reliability of the hub and spoke dispensing service. And each spoke pharmacy was supported by an appropriately trained team before, during and after the rollout of the service to its branch. There were clear lines of accountability between the pharmacy and the spoke pharmacies. The pharmacy was responsible for the accuracy of the medicine dispensed. The spoke pharmacies were responsible for the supplies and managing the relationship with the prescribers and each patient. The pharmacist at the spoke pharmacy retained responsibility for the clinical check of each prescription and the resolution of any clinical queries. And the spoke pharmacy assumed responsibility for the accuracy of the information or data sent to the pharmacy. But more could be done to make sure the data entered by a spoke pharmacy was screened further to highlight obvious anomalies, such as inappropriate dosage instructions, before being transmitted to the pharmacy.

The pharmacy had access to the company's core standard operating procedures (SOPs). It also had SOPs to support the specialised nature of its hub and spoke operation. And these were being reviewed as its processes were being refined. The pharmacy had processes to deal with incidents that occurred throughout the assembly process. The automated technology captured an electronic audit trail of who had completed a task. It recorded an event or an error that required a team member's intervention. And these records helped the pharmacy monitor its service and identify any learnings. The pharmacy and spoke pharmacies were required to use an electronic reporting system to record any patient safety incidents. And the spoke pharmacy was notified of any mistakes involving tasks it completed.

The pharmacy displayed a notice that told people who the responsible pharmacist (RP) was. People who worked at the pharmacy were required to read and sign the SOPs relevant to their roles to show they understood them and agreed to follow them. They knew what they could and couldn't do, what they were responsible for and when they might seek help. And, for example, the pharmacy didn't operate if it didn't have a pharmacist. The company had a complaints procedure. And concerns raised by people about the pharmacy were dealt with by the spoke pharmacy or a team at the company's head office. But the spoke pharmacies were encouraged to make suggestions on how the pharmacy could do things better.

The pharmacy had insurance arrangements in place, including professional indemnity, for the service it provided. It kept an appropriate record to show which pharmacist was the RP and when. And it didn't stock any controlled drugs (CDs) whose receipt or supply needed to be recorded in a CD register. The pharmacy didn't dispense private prescriptions or unlicensed medicinal products. And it hadn't made an emergency supply of a medicine since it opened. The company that owned the pharmacy was registered with the Information Commissioner's Office. The pharmacy had arrangements to make sure confidential information was stored and disposed of securely. Its team needed to complete training on confidentiality and data security. And third-party contractors working at the pharmacy were required to sign a confidentiality agreement. The pharmacy had a safeguarding policy. And its team was asked to complete safeguarding training to support them in their roles.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has the people it needs to deliver its services safely. And its team members do the right training for their roles. Members of the pharmacy team work well together and can make decisions to help keep people safe. They are comfortable about giving feedback to help the pharmacy do things better. And they know how to raise a concern if they have one.

Inspector's evidence

The pharmacy team consisted of a lead pharmacist, some support pharmacists, a pharmacy technician and some trainee dispensing assistants. The lead pharmacist was the RP at the time of the inspection. They supervised and oversaw the supply of medicines by the pharmacy team. And they were responsible for managing the pharmacy and its team. The pharmacy had the team members it needed to deliver its service safely. And it depended upon its team and appropriately trained team members from other branches to cover absences or provide extra support. Members of the pharmacy team worked well together. They were up to date with the workload. They didn't feel that any targets or incentives stopped them from making decisions that kept people safe. And, for example, they would refer requests to assemble an urgent medicine back to the spoke pharmacy to supply locally.

The pharmacy had an induction training programme for its team. And this included training to support its team in using the automated system and the robot. The pharmacy held regular meetings and used an encrypted messaging service to provide updates and share learning with its team. Members of the pharmacy team were required to do mandatory training during their employment. They were supported to complete accredited training relevant to their roles after a probationary period if they hadn't done so already. And they discussed their performance and development needs with their manager. The pharmacy had a whistleblowing policy. Its team knew how to raise a concern and was comfortable about making suggestions on how to improve the service. And, for example, the automated bagging process was refined following the team's feedback.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy provides a suitable environment to deliver it services from. And its premises are clean and appropriately maintained.

Inspector's evidence

The pharmacy was located at the company’s head office and was within the same warehouse as a wholesaler business. It was separated from other businesses operating within the building. And individual key cards provided assurance that only approved team members and other key personnel had access to the warehouse and the pharmacy.

The pharmacy was subject to the same temperature controls as the wholesaler. It was air-conditioned, bright, clean and appropriately maintained. And a cleaning contractor was responsible for keeping its premises tidy. The registered pharmacy premises were set over two floors. The first floor consisted of a large open plan room fitted with some automated assembly lines as well as a robot which was used to store and pick medicines that weren’t available from its main wholesaler. And it had some work bench space for completing administrative tasks. There was an automated secure tote storage unit which was integrated vertically across both floors. And totes were sealed, labelled and dispatched from the ground floor.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy has working practices that are safe and effective. And it uses automation and technology to help other pharmacies support people in receiving the right medicine at the right time. The pharmacy gets its medicines from reputable sources. It stores them appropriately. And its team carries out checks to make sure its medicines are safe and fit for purpose.

Inspector's evidence

The pharmacy wasn't open to the public. It only assembled people's repeat prescriptions. And it didn't provide any other services. The spoke pharmacy told people that their medicines would be made up by the hub pharmacy, but it would supply them their medicines. And it was responsible for making sure people received the right medicine and information. So, people could take their medicines safely.

Members of the pharmacy team were aware of the valproate pregnancy prevention programme. The pharmacy only assembled whole packs of valproates. So, all the information people needed about taking this medicine was provided. The spoke pharmacies were responsible for making sure women and girls able to have children who were prescribed a valproate were appropriately counselled on its contraindications. But the company was considering whether the pharmacy should continue to assemble valproates for its spoke pharmacies. This was due to a risk that important patient safety information on the packaging could be obscured by the label which was applied during the automated dispensing process. It was assumed that spoke pharmacies chose to assemble medicines locally for people who used braille. But the pharmacy could do more to make sure the dispensing labels it applied to the packaging didn't cover up any braille or written information about the assembled medicine.

The company maintained an electronic audit trail for each step of its hub and spoke operation from data entry to the receipt of the assembled medicines at the spoke pharmacy. The pharmacy received data from each spoke pharmacy via software that was integrated with the spoke pharmacy's patient medication record. The spoke pharmacies could retrieve a submitted prescription and dispense it locally if required to make sure people received their medicines when they needed them. And there was a cut-off time for the spoke pharmacy to submit its data to the pharmacy for the medicines to be assembled and returned by the next working day. The assembly process relied on automation and two-dimensional barcode technology to track each step. The pharmacy received the stock it needed from the adjoining wholesaler. This was ordered using a picking list generated on the information provided by the spoke pharmacies. And these medicines were delivered in a tote. But medicines that weren't available from the adjoining wholesaler were picked from the robot and added to the relevant tote. Team members then placed each medicine onto the conveyer belt at one of the work stations. The automated system then scanned the barcodes on the stock for recognition. This provided information unique to that medicine including its batch number and expiry date. And this information linked to a person's prescribed medicine and allowed the system to produce and apply a dispensing label to the box, which was also barcoded. The dispensing label included the address of the spoke pharmacy and the address of the hub pharmacy as it had assembled the medicine. The automated assembly line sorted the assembled medicines and sealed them in compostable and recyclable bags for each person. And these bags were labelled and deposited into a tote assigned to a particular spoke pharmacy. The bags and the totes were barcoded too. If the system was unable to apply a label or identify a medicine then this triggered an intervention which required a response from an appropriately trained team

member. And the team member then manually intervened and resolved the issue. This included highlighting with the spoke pharmacy when it needed to add a medicine that couldn't be assembled, such as a medicine that required refrigeration, or was out of stock at the pharmacy. Completed totes were sealed and were dispatched and delivered to the spoke pharmacy by a third-party wholesaler.

The pharmacy used recognised wholesalers to obtain its pharmaceutical stock. And the original packs of medicines it kept on its premises were stored securely within the robot. The pharmacy used the adjoining wholesaler's date checking process to help support the safe supply of medicines. It also had an automated process to check and record a medicine's batch number and expiry. And systems were in place to remove products nearing their expiry too. The pharmacy quarantined stock it received from the wholesaler that was short-dated, picked incorrectly or was damaged in some way. And its team checked that a medicine had an appropriate expiry date when it manually checked the accuracy of an assembled prescription. The pharmacy didn't receive any patient-returned medicines. It didn't have any CDs which needed to be stored in a CD cabinet. It didn't keep any medicines that required refrigeration. And it had a process for the disposal of its expired or unwanted medicines. The pharmacy had a process for dealing with the alerts and recalls about medicines and medical devices issued by the Medicines and Healthcare products Regulatory Agency (MHRA). And a team member described the actions they took and what records they made when the pharmacy received an MHRA medicines recall.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has access to the equipment and facilities it needs to provide its services safely. It appropriately maintains its equipment and it has suitable arrangements to support it in ensuring its equipment remains fit for purpose and keeps people's data safe.

Inspector's evidence

The pharmacy had the personal protective equipment its team needed. Its automated system and robot were serviced and maintained by the system's manufacturer, which also conducted routine servicing of the equipment on a regular basis. And on-site engineers were available to support the pharmacy and to resolve technical difficulties promptly. The warehouse had back-up generators to mitigate the impact of any local power cuts on the wholesaler, the pharmacy and the company's head office operations.

The pharmacy restricted access to its computers. And only authorised personnel could use them when they put in their password. But it didn't use a patient medication record system. The data transmitted between the spoke pharmacies and the pharmacy was encrypted. And patient-identifiable information was decrypted at the pharmacy to generate dispensing labels. This meant that people's data was kept secure.

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.