Registered pharmacy inspection report

Pharmacy Name: Pharmacy 2 U Ltd, Pharmacy 2U and Chemist Direct, Unit 3 Mountpark Bardon, Robson Way, Coalville, Leicestershire, LE67 1GQ

Pharmacy reference: 9011308

Type of pharmacy: Community

Date of inspection: 02/02/2023

Pharmacy context

This pharmacy's main activity is the automated dispensing of a large number of NHS prescriptions. It shares this activity with its sister pharmacy in Leeds, with most of the clinical oversight taking place at the other location. People do not visit the pharmacy; the pharmacy delivers medicines to people's homes across the UK using a UK-wide postal delivery company. And it also sells over-the-counter medicines through a separate website.

Overall inspection outcome

✔ **Standards met**

Required Action: Improvement Action Plan

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	1.2	Good practice	The pharmacy routinely records, reviews, and learns from its mistakes. It uses the information from these reviews to raise awareness with team members and to support their knowledge and understanding. Senior members of the pharmacy team proactively review all errors. And the pharmacy implements comprehensive changes to processes to support the safe delivery of pharmacy services when it identifies patterns with errors.
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

Overall, the pharmacy identifies and manages the risks associated with the provision of its services. Its innovative automated systems reduce the risk of dispensing errors. And the pharmacy routinely records, reviews, and learns from its mistakes. It uses the information from these reviews to raise awareness with team members and to support their knowledge and understanding. It implements comprehensive changes to processes to support the safe delivery of pharmacy services when it identifies patterns with errors. And senior members of the pharmacy team proactively review all errors. Its team members have defined roles and accountabilities. And the pharmacy manages people's personal information safely. However the pharmacy has not mitigated all the risks of selling certain over-the-counter medicines. So, some people may be able to get medicines which are not suitable for them.

Inspector's evidence

The pharmacy provided its services at a distance. It had two parts that were operationally separate. It mainly dispensed medicines against NHS prescriptions. And it also sold over-the-counter (OTC) medicines through a separate website. The pharmacy only dispensed medicines in original packs or full bottles of liquids. It didn't split packs or dispense medicines in multi-compartment compliance packs. And it didn't supply any Schedule 2 controlled drugs. Prescriptions with these requirements were dispensed by its sister pharmacy in Leeds.

Most of the dispensing processes at the pharmacy were automated. The pharmacy identified and managed the risks with delivering its services using risk assessments, audits, and standard operating procedures (SOPs). The pharmacy had a business continuity plan in place and had considered the risks that dispensing a large number of medicines at the site created. There was a range of up-to-date SOPs for both parts of the business. Team members recorded when they'd read the SOPs to show they had understood and would follow them. The OTC business sold a range of Pharmacy Only (P) and General Sales List (GSL) medicines, some of which were potentially abusable. There was a risk assessment which covered a wide range of the risks but hadn't fully considered issues around vulnerable people purchasing these medicines. Some SOPS, such as the SOP for the sale of medicines could be expanded to give more in-depth information which would help the team in their decision making. The superintendent said that they were currently reviewing these SOPs.

The pharmacy had processes for learning from dispensing mistakes that were identified before reaching a person (near misses) and dispensing mistakes where they had reached the person (errors). Because most of the processes were automated most mistakes that were made were linked to the automated systems. But these were rare. For example, on the day of inspection 20 boxes out of nearly 21000 had either an extra or a missing pack. These were picked up as part of the system of automated checks and changed by a member of the team. The mistake was recorded and reviewed. A bigger number of boxes that were picked up by the system when checked were accurate. The reasons for these were reviewed and assessed and action taken. The superintendent highlighted a number of changes in the processes across the automated processes which had reduced the number of near misses. A specially trained team investigated incidents and used additional information such as video from CCTV cameras to find out what had gone wrong. Team members involved in the mistake discussed the incident at the

time.

Senior team members regularly assessed all the errors and incidents. The outcomes of the assessments were discussed at clinical team meetings and shared with all team members. And they were used to identify team members who required additional training and support. The pharmacy had coaches to work closely with team members and the superintendent highlighted how this approach had reduced the number of mistakes made. The team were aware of the impact of mistakes because of the numbers of medicines dispensed at the pharmacy and had a strong emphasis on resolving problems as quickly and effectively as possible.

The pharmacy had up-to-date indemnity insurance. The pharmacy displayed the responsible pharmacist (RP) notice. The pharmacy used an electronic spreadsheet as the RP record, but it was not protected so entries could be amended or removed. This had been highlighted at a previous inspection for another of the company's pharmacies in Leeds. A sample of RP records found the entries met legal requirements. The RP SOP required any amendments to clearly identify when they occurred and who was involved.

The pharmacy's websites displayed details about the confidential data kept and how the pharmacy kept people's personal information safe. The pharmacy's websites provided people with details about how to raise a concern or make a complaint. The pharmacy checked feedback from people using online and social media platforms. It used feedback received to inform discussions amongst team members and senior management to identify patterns and to take action to address key findings.

The pharmacy provided training and guidance to the teams on confidentiality and data protection. Confidential waste was destroyed securely. The pharmacy team had completed safeguarding training. The pharmacist understood safeguarding requirements and could explain the actions he had taken recently to safeguard a potentially vulnerable person.

Principle 2 - Staffing ✔ **Standards met**

Summary findings

The pharmacy's team members manage the day-to-day workload within the pharmacy effectively. They are mainly suitably trained for the roles they undertake. And team members can raise concerns if needed.

Inspector's evidence

The RP at the time of the inspection was a regular, full-time pharmacist. He worked onsite for part of the week as the RP and remotely for the rest of the week. Another pharmacist then took on the RP role when this pharmacist was working remotely. There were an additional 17 pharmacists working across the two sites. There were 145 people in the rest of the team.

The pharmacy team members understood their roles and managed the pharmacy's workload effectively. They had a clear management and coaching structure. They worked systematically and efficiently at their allocated stations and within their teams. The pharmacy provided a structured training and induction programme for new team members. Team members were mainly appropriately trained for their roles. But there were some team members involved in checking medicines that the automated systems had highlighted as potentially having a mistake. This involved tasks such as checking the dispensing labels and opening the packs to check the medicine inside was correct. The team had received internal training but had not completed any externally validated training required for people carrying out a dispensing function. The superintendent had thought that these activities were not a dispensing function and that the internal training was sufficient. But he subsequently indicated that the team members involved had been registered on a training course with an appropriate provider.

The pharmacy had considered the risks of working across various sites and of staff working remotely. The pharmacist explained that there was a range of communication channels to contact other members of the team including the other pharmacists and customer services. For example, the pharmacists had a generic email box for all teams to use which was regularly checked. They used remote meeting technology for their meetings so colleagues working from home could attend. There were also monthly team meetings and learning events. And these systems enabled all team members to keep in touch outside of the meetings by sending messages, sharing learning, and asking questions. All team members had access to ongoing e-learning training, and they had protected time at work to do the training.

Senior team managers frequently visited the site to provide regular contact and support. The RP said that he felt supported by his manager and had regular one-to ones and a performance development review. He was given opportunities to develop his role. And was currently leading a project developing a new service. The pharmacy had a whistleblowing procedure and team members received whistleblowing training. Team members were comfortable raising concerns with their line manager and the superintendent when necessary. They were invited to provide feedback using annual surveys which they had protected time to complete. The outcome from the surveys was presented to all team members. And used by the senior management to team make appropriate changes.

Principle 3 - Premises ✔ **Standards met**

Summary findings

The pharmacy keeps its premises safe, secure, and appropriately maintained. The pharmacy's websites are clearly laid out with appropriate information available.

Inspector's evidence

There was no physical access by members of the public to the pharmacy. The pharmacy was in a large warehouse facility that provided plenty of space for storing stock, the automated assembly processes the team's activities. There were separate areas for each part of the processes which the team kept clean and tidy. The pharmacy was a reasonable temperature for storing medicines. The pharmacy had separate office space, including for the RP, to ensure privacy and an appropriate environment for the work completed. There were appropriate health and safety processes for the size and type of premises. The pharmacy had sufficient staff facilities for the number of team members.

The pharmacy had two websites for the separate services that it provided. The websites provided people with information about the services offered, contact details for the pharmacy and details of the Superintendent Pharmacist (SI). The websites had appropriate security and both the public facing and back-office sites had back-up facilities in case there was a problem.

Team members who worked from home accessed the pharmacy's IT system which held people's confidential information. They used work-issued laptops and access was through a virtual private network. There was a risk assessment to identify and address the risks of team members working in this environment. And a working from home policy was in place that team members had read and understood to ensure people's confidential information was protected.

The pharmacy had clearly marked fire exits. Unauthorised access to the pharmacy was prevented during working hours and when closed.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's healthcare services are suitably managed and are accessible to people. The pharmacy uses advanced robotic systems to reduce the risks of dispensing errors occurring and actively reviews processes to drive improvement. The pharmacy gets its medicines and medical devices from reputable sources. It stores them safely and it knows the right actions to take if medicines or devices are not safe to use to protect people's health and wellbeing.

Inspector's evidence

This was a closed pharmacy so there was no physical public access. People accessed the pharmacy's services through the pharmacy's websites. The first part of the persons journey through the pharmacy's dispensing service was managed by teams who were based at and managed through the company's other pharmacy located in Leeds. The RP was part of a team of pharmacists who clinically assessed the prescriptions. The other pharmacists worked at the pharmacy in Leeds or remotely. This team was managed by a pharmacist who was based in Leeds. The creation of the dispensing label and accuracy check were also completed remotely by a team of dispensers and accuracy checking technicians or dispensers, none of whom were based at the pharmacy. These processes created a digital audit trail which would show who had carried out which activity should something go wrong. These processes were managed, audited, and reviewed through the Leeds pharmacy. After these processes were completed prescriptions could be dispensed at either of the company's two pharmacies depending on the type of medicine and the requirements of the person.

The pharmacists had a rota to ensure the timely completion of tasks such as the clinical checks. The RP could explain his role including the clinical assessment. Prescriptions were accessed through a computer. There was a clinical assessment screen which showed the prescriptions waiting to be assessed. There was an automated system for highlighting time-critical medicines such as antibiotics or emergency contraception which the pharmacist checked first and were then given priority through the dispensing process. The pharmacist could also access the person's medicine history and individual information that the person had given. When a person requested a medicine that required ongoing monitoring such as warfarin, lithium or methotrexate they had to enter appropriate details such as their INR levels when ordering the medicine. This information was available to the pharmacist when clinically checking the prescription. If there was a query a pharmacist would contact the person's prescriber or asked the customer contact team to contact the person. A specific pharmacist would be on the rota to follow-up these queries. The RP knew the advice about pregnancy prevention that should be given to people in the at-risk group who took sodium valproate. He explained the ways that people could contact the pharmacy if they had a query about their prescription. There was also a range of information about medicines on the website. But it was less clear how often the pharmacist gave advice on a one-to-one basis to people.

Once these processes had been completed the information from the electronic prescription was sent to the pharmacy for the medicines on the prescription to be assembled. A bar code unique for each prescription was generated and this was used through a number of automated processes from picking an individual medicine, combining the medicines for a prescription into one container and packing with

address details to be sent for delivery. Some medicines used a pick-by-light system where the bar code was automatically scanned, indicating by a light the section holding the product that was then picked by a person. The medicine then continued through the automated system.

Where an original pack contained 30 capsules or tablets these were cut by a machine into blisters of 28 which were then put in a standard white box with a bar code. These boxes were then randomly checked by team members to make sure they were correct. They then went through the same automated processes as standard original packs. Because there were now more packs than the original number some of these packs didn't include a patient information leaflet (PIL). The superintendent said that people were directed to a webpage with the PIL. The inspector recommended that the superintendent checked whether this met legal requirements.

A member of the team picked (using a bar code scanning system to ensure accuracy) any item requiring cold storage. The medicine was packed in a storage bag for holding fridge lines to make sure that it remained at the correct temperature from the point it was removed from the fridge. Specialised packaging was used for delivering fridge lines to people to make sure the medicine remained at the correct temperature. The viability of the packaging was checked to make sure it maintained the correct temperatures.

People wanting to purchase over-the-counter (OTC) medicines accessed a separate website. There was an identity check before a purchase could take place. The person could see the medicine they were purchasing and a range of information such as the active ingredient, what the medicine was for, side effects and instructions for use. The pharmacy had limitations on the number and how often medicines could be sold. If the person was looking to buy a pharmacy only (P) medicine they had to complete a questionnaire with appropriate questions before making the purchase. The purchase request was reviewed by a dispenser who worked remotely. If necessary, further information could be sought from the person and advice sought from the pharmacist. An example of this was seen where the dispenser had sought advice on an interaction between a prescription medicine and the P medicine. The pharmacist as RP had responsibility for the sale of medicines. But wasn't sure if he could access the system to review the information on it. But another pharmacist did have oversight of the system and there were regular team meetings and reviews of medicines sold.

The assembly of OTC medicines and other items usually sold from pharmacies took place on a separate floor of the pharmacy. A picking list of products was generated which were then picked by hand by a member of the team. This was taken to a separate station where the items were barcode scanned against an order and packed.

The pharmacy had procedures and systems to safely store and manage its medicines and medical devices to ensure they were fit for purpose. The automated picking systems captured the expiry dates of products to reduce the risk of short-dated stock being selected.

The pharmacy delivered medicines using a UK-wide postal delivery company. The pharmacy upgraded deliveries from a 48-hour delivery to 24-hour delivery if an urgent supply was needed such as for an antibiotic or emergency contraception. The pharmacy reviewed and monitored delivery performance to ensure it met the service levels agreed. And it had worked closely with the postal delivery company to understand when industrial action was planned, to minimise the risk of delays to deliveries. The pharmacy's website provided people with information about how their medication would be delivered and how to track their delivery. Some people had given consent for their medication to be put through their letterbox or to be stored in a safe place. The pharmacy asked the person specific questions such as whether there were children or pets at home before this was agreed. But the details of what was asked

were not captured on the system; it only showed a yes or no response to whether consent had been obtained. The person was asked to update the pharmacy if their circumstances changed so this delivery option could be reviewed. But the pharmacy didn't have a process to repeat these questions after a certain timescale to confirm this delivery arrangement remained safe. The pharmacy offered people a safe place option for certain medicines which was recorded on the person's account. The pharmacy relied on the person's assessment of whether the designated place was safe. The pharmacy usually contacted the person when there was a failed delivery, and the medicines were returned to the pharmacy and investigated why the medication was returned. This was used to analyse any trends and for the teams to refer to when handling people's queries.

The pharmacy obtained its medicinal stock from a range of reputable sources. The pharmacy's purchasing team managed any problems with stock shortages and generated a daily report to share with other teams so they were aware and could take appropriate action. The pharmacy had procedures and systems to safely store and manage its medicines and medical devices to ensure they were fit for purpose. The automated picking systems captured the expiry dates of products to reduce the risk of short-dated stock being selected. The pharmacy had a process for managing alerts about medicines and medical devices which included a record of the action taken. The systems in place meant that the pharmacy could contact individual people to recall a medicine supplied if required.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has a range of equipment that is well maintained to help ensure it supplies medicines safely and effectively. And its systems suitably protect people's private information.

Inspector's evidence

The pharmacy had access to a range of up-to-date reference sources. The pharmacy used a range of complicated automated machinery to dispense medicines. There were a team of engineers onsite to resolve any problems with the equipment. There was back-up systems and IT support available should any of these systems break down. Large open-fronted fridges were connected to an alarm that was triggered by temperatures outside the accepted range. Team members on call were alerted to the alarm when it was triggered outside of the normal operating hours. A back-up generator provided 24 hours of electricity in the event of a power shortage and was regularly tested to ensure it would operate when called upon. When checked the current fridge temperature for medicines that required cold storage for Chemist Direct was within the required range of 2 and 8 degrees Celsius. It also had an alarm that was triggered by temperatures outside the required range. But the team only checked the current temperature and were not making any records of the temperatures they found. The superintendent said he would make sure that appropriate checking and records were implemented. The pharmacy's portable electronic appliances had been tested recently to make sure they were safe.

The pharmacy had systems in place to support team members health and safety at work including a policy and information for team members to refer to. There were clearly marked first aid points that included a defibrillator.

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.