General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: LloydsDirect, 17 Wadsworth Road, Perivale, Greenford, UB6 7JD

Pharmacy reference: 9011437

Type of pharmacy: Internet / distance selling

Date of inspection: 25/04/2022

Pharmacy context

This is an internet pharmacy. Its owner is part of a group of companies which includes Lloyds pharmacy Ltd**.** It is situated in a large industrial warehouse unit and is closed to the public. And it dispenses NHS prescriptions. The pharmacy operates its services through an online 'app'. People use the app to request their prescriptions. The pharmacy then orders and dispenses them. And it sends them by registered post to people across the UK. The inspection was conducted during the COVID-19 pandemic after restrictions had lifted in the UK.

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 suitable procedures in place to ensure its services are safe and effective. And it has adequate procedures for identifying and managing the risks associated with them. The pharmacy effectively reviews and monitors the safety and quality of its services. And it keeps all the records it is required to keep. The pharmacy's team members review the dispensing mistakes they make and learn from them to try and stop them happening again. And it has insurance to protect people if things do go wrong. The pharmacy has adequate procedures for people to provide feedback to help improve its services. And it keeps people's private information safe.

Inspector's evidence

The pharmacy provided its services over the internet and so people did not usually need to visit it. The most frequent visitors to the pharmacy were delivery drivers from the pharmacy's wholesalers. And agency staff. The pharmacy had put measures in place to help reduce the risk of spreading coronavirus. It had placed hand sanitiser at different locations around the premises for the team and visitors to use. The team had a regular cleaning routine and it had access to personal protective equipment in the form of gloves and masks. Team members generally wore masks. And they sanitised their hands regularly. The pharmacy operated a large-scale dispensing service, supplying prescriptions all over the UK. Its prescription volumes had increased significantly since it began trading in 2016. The inspector and superintendent (SP) discussed the importance of having contingency plans in place to ensure that the pharmacy would be able to maintain its services in the event of systems failure or closure. The current contingency plans were under review.

The pharmacy had procedures for managing risks in the dispensing process. It had a team of pharmacists responsible for clinically checking each prescription as it came in electronically. Some of these team members worked remotely. The pharmacy had a remote workers policy as one of its terms of employment for these team members. And it had a documented induction programme for its employee pharmacists and locums. Clinical screening pharmacists were provided with a laptop which was linked to the pharmacy's automated dispensing system. The laptops were to be used solely for clinical checking. Under their terms of employment remote workers were required to work in a private space. And were required to ensure that no-one else could view people's prescriptions or any other private information. The automated system created labels from the prescription. And so at this stage those doing the clinical check made a cross check of people's details with their medication history and their prescription details. And they checked that the labels were correct according to the prescription. Pharmacists here raised queries with people's GPs when necessary. And they made notes on people's records to reflect any interventions they had made. They also made notes to communicate any relevant aspects of their interventions to the dispensing team.

The pharmacy used a highly automated barcode recognition system which team members used for checking in and picking medicines. But the pharmacy recognised that there could still be a risk of mistakes with look-alike and sound-alike (LASA) medicines. This could occur if the manufacturer had made a packing error or when a part pack was dispensed. And it had placed a reminder of the checks to make at each dispensing bench. Team members discussed every incident, including their near-miss mistakes as soon as they were discovered. And they recorded them electronically. They also discussed them within the larger team during its daily briefing meetings. The pharmacy held team briefing

meetings with every change of shift. Any errors led to an email communication to each team member and a staff forum, led by the pharmacy's clinical manager. The team discussed its mistakes to help prevent the same or similar, mistakes from happening again. The inspector, SP, senior pharmacist, professional standards pharmacist and clinical manager discussed the importance of recording what the team had learned from its near misses and any actions arising from them. They agreed that near miss mistakes should prompt staff to identify what they could do differently to help prevent similar mistakes in future. Team members reviewed and reflected on their mistakes regularly to learn and improve.

The team worked under the supervision of the responsible pharmacist (RP), with the support of the senior pharmacists and warehouse managers who managed staff working in each stage of the process. The RP's notice had been placed on display for the team to see. The pharmacy had a set of up-to-date standard operating procedures (SOPs) for team members to follow. And it was clear that they understood their job roles. The pharmacy team sought customer feedback through its website and general conversations with people. The team had responded positively to previous concerns where people using the app could not see the quantities of the medicines they had been prescribed. This had caused uncertainty for people. And an unnecessary number of queries for the team to answer. And so the senior pharmacist had engaged the pharmacy's technical team to address the problem. And this had since been resolved. Comments on 'Trust Pilot' generally demonstrated a high level of customer satisfaction overall. But the team had also received a small number of poor reviews due to delays in medicines being delivered. The team usually responded by explaining how the system worked. And explained how people could ask the pharmacy to release their prescriptions to have them dispensed elsewhere. The SP demonstrated how the team had learned from these complaints. It was reviewing its communications with people to encourage them to order their medicines with enough time for the team to order, obtain, dispense and supply their prescriptions. This included additional time often needed around public holidays. So that the team could get people's prescriptions with enough time to dispense and supply them before they ran out.

The pharmacy had a complaints procedure which corresponded with NHS guidelines. And it had a SOP for staff to refer to. But customer concerns were generally dealt with at the time by the clinical administration team, the patient care team, clinical manager or SP as appropriate. And senior team members could provide details of the local NHS complaints advocacy service and the Patient Advice and Liaison service (PALS) if necessary. But people usually raised their concerns either via the app or through the website. The pharmacy had professional indemnity and public liability arrangements so it could provide insurance protection for the pharmacy's services and its customers. Insurance arrangements were in place until 30 June 2022 when they would be renewed for the following year. The pharmacy kept its records in the way it was meant to including its CD register and its RP record. The SP and professional standards pharmacist recognised the importance of maintaining the pharmacy's essential records so that they were up to date and complete.

The pharmacy had a guidance document which advised team members on the appropriate use of the internet and the pharmacy's email system. And its team members understood the need to protect people's confidentiality. Team members involved in 'checking in' and 'picking' medicines did not have access to the pharmacy's PMR system. They did not have access to prescriptions or any patient information. This part of the process was carried out using a bar-code and QR code recognition system. Each team member who had access to prescriptions had their own USB Digital signature key with two-factor authentication for security. They used this key to access the pharmacy's computer systems so that there was a clear audit trail identifying every keystroke made by each person. Signature keys and passwords were not shared with other people. One of the pharmacists indicated that sharing of this information would be regarded as a disciplinary matter. Confidential waste was set aside for collection and subsequent disposal by a licensed waste contractor. The pharmacy stored its completed

prescriptions electronically. Team members had completed appropriate safeguarding training. The pharmacy always had a significant number of pharmacists on duty who had completed safeguarding training. This included the senior pharmacist and several pharmacists involved in both the clinical checking process and the dispensing process. 11 dispensing assistants (DAs) and four trained technicians had also completed safeguarding training. The RP could access details for the relevant safeguarding authorities online. Staff had not had any specific safeguarding concerns to report. But had consulted people's prescribers if they felt that someone was not managing their medicines well.

Principle 2 - Staffing ✔ Standards met

Summary findings

In general, the pharmacy team manages the workload safely and effectively. Team members work well together. And they have opportunities to provide feedback to one another, so that they can maintain the quality of the pharmacy's services.

Inspector's evidence

The pharmacy team was organised into several sub-teams responsible for managing the service and delivering it. The teams involved in managing the service included a clinical administration team, a patient care team, an operations team, a professional standards team, a technical team and an IQ team which was responsible for monitoring incidents to improve quality. The teams responsible for delivering the dispensing service included the clinical checking team, the dispensing teams, a team for picking products ready for assembly (pickers). And a team responsible for checking off deliveries from wholesalers. And putting the medicines into stock (goods in associates). The pharmacy had two distinct dispensing processes. Members of the clinical checking team reviewed each prescription. They had a standardised procedure to follow. And where they concluded that a prescription was straightforward and could be safely dispensed from the pharmacy's automated system, it was put through for dispensing without further input from a pharmacist. The team described these as 'clean' prescriptions. But where the prescription required a further check at labelling or dispatch the prescription was annotated accordingly and put through a separate queue. And would be subject to further input from a pharmacist, or where appropriate an accredited checking technician (ACT), or an accredited checking dispensing assistant (ACDA). The team described these as 'dirty' prescriptions. Dirty prescriptions generally involved higher risk drugs or higher risk prescriptions in general. Such as those for CDs, LASA medicines and medicines with a narrow therapeutic index, split packs and liquids. And prescriptions with several different medicines or those which required monitoring. And where people required further counselling and advice. One dispensing team dispensed the clean prescriptions and the other dispensed the dirty prescriptions. Team members responsible for assembling and labelling the medicines in the clean or dirty prescription process had completed or were in the process of completing an NVQ2 dispensing assistant's training course.

Team members involved with the goods in process or picking process had either completed or were in the midst of completing a stock management course. Goods in associates, pickers and dispatchers had had been fully trained in the use of the automation system. But had not completed a dispensing assistant's course. These team members handled complete packs only. The pharmacy often used un-skilled agency staff for the stock management process. But all team members including agency staff had an induction briefing before beginning their first shift. The induction was a slide-show presentation. It included an introduction to the regulatory framework governing pharmacy premises, an overview of the pharmacy's operation and business model, team members' roles and responsibilities, health and safety, confidentiality and safeguarding responsibilities.

The pharmacy operated two shifts with a 30-minute gap between the end of the first shift and the start of the second shift to avoid cross-contamination between shifts. The shifts ran from 6am until 2pm and from 2.30pm until 10.30pm. senior pharmacists began their shifts half an hour before the start of the morning shift. And they finished their shifts half an hour after the end of the afternoon/evening shift. When the morning shift ended a full, new team of staff came in to work the afternoon. On the morning

of the inspection the pharmacy had the following staff in the dispensing team. It had a responsible pharmacist. And 10 pharmacists involved in the 'dirty' dispensing process. It also had two ACTs 47 dispensing assistants (DAs), seven of which were ACDAs. It had 25 staff responsible for checking goods in and 37 'pickers' many of which were agency staff. And it had 26 'dispatchers'. Senior management staff on duty included the SP and a senior pharmacist. And the professional standards pharmacist, the clinical manager who was also a pharmacist. And the product manager. The clinical manager had an operational role. And she managed the staff rotas. This included pharmacist cover. The product manager was a pharmacist. And he was responsible for managing the pharmacy's automation system. Senior pharmacists oversaw the dispensing process in the warehouse. The pharmacy's clinical check team had five pharmacists working alongside each other on the premises and 14 pharmacists working remotely.

The clean and dirty dispensing teams on duty on each shift were subdivided into a number of smaller teams, working at their own area of dispensing bench. Pharmacists generally worked with one smaller team but also moved around between teams when needed to accuracy check prescriptions when ready. The RP worked separately. He dealt with any additional queries produced from either the clean or the dirty dispensing process. In general staff were able to raise queries and concerns. And they were invited to contribute to team briefings to express any concerns or contribute any ideas they may have. The SP explained that they did not have numerical targets for team members to achieve. Instead, they encouraged them to undertake additional projects and other pieces of work to keep them motivated. However, they did monitor people's work rate and if it appeared to be unduly low then they adopted a supportive approach to see if they needed any help or additional training.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises provide a suitable environment for people to receive its services. They are tidy and organised. And they are sufficiently clean and secure. The layout of the pharmacy's premises allows the team to effectively manage and monitor the different aspects of its services. The pharmacy's premises are suitable for the type of work it does. The pharmacy has taken appropriate precautions to prevent people from entering the building when they shouldn't. And it is secure when closed.

Inspector's evidence

The pharmacy was in a large warehouse-style building on an industrial estate, with car parking for some staff and visitors. People could only enter the building if they had an access card or if they were admitted by the receptionist. There was a digital visitor log to record all visitors. All doors within the building were secured and could only be opened with an access card so that the pharmacy's managers or owners would have a record of who opened each door and when.

The pharmacy had plenty of space for staff to work safely and effectively. It had separate areas for different activities. This included a separate room on the first floor with several workstations where the clinical checking team worked. This provided a quiet environment in which the team could concentrate without being disturbed. The remainder of the first floor was occupied by office space and meeting rooms. The main area of dispensing activity was on the ground floor. It was filled with storage racking arranged in lanes based around workstations for assembling, packing and despatching prescription medicines. It had 17 'dirty' lanes for assembling prescriptions requiring additional checks, and 17 'clean' lanes for those with no outstanding queries. It had also begun work to add another nine lanes to accommodate the increased volume of work seen during the pandemic. And it had a sink for washing equipment and making up liquid preparations.

The pharmacy had two separate sets of doors for deliveries of stock. It had designed its layout so that stock deliveries were located close to stock storage areas. The pharmacy had a large loading bay at the rear of the premises which could be accessed by smaller commercial vehicles. And next to the loading bay it had a large metal refrigerated room with an electric roller shutter. It had placed a barrier across the access route via the side of the building to make it safer for people to use. The pharmacy also had a separate loading bay at the front. This was for when bulk deliveries arrived. This area also led to the staff exit and the car park. And so the floor had been marked with safety lines to help ensure that people stayed away from moving forklift trucks. The premises were clean, tidy and in a good state of repair. There was some electrical work underway at the time of the inspection as the pharmacy was having a lift installed. The pharmacy employed a facilities manager whose role included ensuring that any repairs needed were undertaken in a timely and safe manner.

The pharmacy's website displayed its address and registration number as well as the name and registration number of its SP. It also had details of the company that owned the pharmacy. The premises had a staff rest area which staff were encouraged to use when they needed a break. Staff toilets were not inspected. Work areas were cleaned in between shifts to reduce the risk of spreading the coronavirus during the COVID-19 pandemic. There was a 30-minute gap between shift to allow for this. The premises were well lit, and the temperature was controlled by combined heating and air conditioning units throughout. At the time of the inspection room temperatures were appropriate to

keep staff comfortable and were suitable for the storage of medicines. And the pharmacy had a security policy for staff to follow.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy provides services that people can easily access. It gets its medicines and medical devices from appropriate sources. And it stores them appropriately and securely. Members of the pharmacy team carry out the checks they need to. So, they can make sure the pharmacy's medicines and devices are safe and fit for purpose. The pharmacy has sufficient procedures to ensure that its dispensing service is safe.

Inspector's evidence

The pharmacy's services focused on ordering people's repeat NHS prescriptions, dispensing them and posting them using the royal mail track and trace service. And it aimed to deliver people's medicines within 24 hours or 48 hours. If they preferred, people could also have their prescriptions redirected through the pharmacy's secure internal electronic mail transfer system to be dispensed and collected from their local branch of Lloyds pharmacy. The pharmacy promoted its services on its website and through its app. The app provided a facility for people to track their prescriptions, raise queries and chat to staff. And it also prompted people to re-order their prescriptions when they were due, to help prevent them from running out. The pharmacy obtained all of its prescriptions electronically. Prescriptions could be viewed from any of the pharmacy's computer terminals and so did not need to be printed. The pharmacy had a web-based patient medication record system (PMR). The system also had a facility for pharmacists to communicate with one another. Those performing the clinical check provided the checking pharmacists with information about their decision making on an individual PMR. And the checking pharmacist could ask questions in return. Communications between teams appeared as easy to see speech bubbles on the PMR.

Pharmacists used the app to provide people with advice about their medicines and answer any queries they may have. This also allowed pharmacists to provide people on high-risk medicines with additional advice. The team could also use the app to identify when people may be over or under ordering their medicines. And to see when people's medicines may be getting out of sync. with each other. The pharmacy had SOPs for staff to follow. SOPs were under continual review as the business expanded and the size of the team grew. Agency staff had been briefed on their tasks. And they had been trained on how to use the pharmacy's automation system for checking off, storing and picking medicines. The dispensing system was highly automated. It checked stock in and out on hand-held devices using a sophisticated bar-code checking system. Every time a team member handled an item of stock, they scanned its bar-code. These team members did not have sight of any prescriptions. The QR on each dispensing basket were matched to an individual prescription. And team members matched the bar-code on each dispensing basket with the items picked. Selection of the wrong item would generate an alert. The alert could not be over-ridden until the correct item was selected.

Dispensing assistants at the dispensing workstations were observed attaching prescription labels to the appropriate medicine after it had been picked and placed in a dispensing basket by a 'picker'. They were seen to cross check the item with the prescription and the label with the prescription. They scanned the product bar-code against the prescription bar-code. An error warning would be displayed if the wrong product was being dispensed. For clean prescriptions, the assembled medicines would then be passed to the team member responsible for packing the item ready for dispatch. The 'packer' carried out a further crosscheck by scanning the packs, and labels with the prescription. If the dispensing

assistant had placed the wrong label on the pack, it would be picked up by this second scan. Packed items were placed in large royal mail sacks or boxes for dispatch. The assembly process was the same for 'dirty' prescriptions. But after assembly the dispensing assistant placed the basket on the pharmacist's checking area for a further check. The items were then re-scanned and packed by a packer as before. The logins and digital signature keys ensured there were clear audit trails in place so that managers could identify who was involved at each stage of the prescription journey.

The pharmacy obtained its medicines and medical devices from suppliers holding the appropriate licences. The team stored its medicines, appropriately and in their original containers. And stock on the shelves was tidy and organised to assist selection of the correct item. The pharmacy team date-checked the pharmacy's stocks regularly, checking a different section each time. And it identified and highlighted any short-dated stock. A random sample of stock checked by the inspector was in date. Team members kept records to help them manage the process and to show what had been checked, when and by whom. The pharmacy did not put split packs back into stock, considering this to be high risk. So it discarded all remaining tablets from split-packs. Team members put any out-of-date, split packs and patient-returned medicines into dedicated waste containers.

Medicines that needed to be kept refrigerated were left inside the fridge room until they were ready to be dispatched. The pharmacy also had a separate freezer outside for keeping cool packs frozen. It kept them here until team members needed them in the fridge room for packaging the medicines prior to dispatch. The team had organised the workflow by having two to three key time slots during each day when these 'fridge lines' were given priority over other medicines. So that the 'cold chain' could be preserved. There was also a cut off at 5pm on Fridays for packaging fridge lines to ensure they were all ready for the last post collection before the weekend. The temperature in the fridge room was continuously monitored and recorded with several sensors at different heights around the room. The temperature records were stored in 'the cloud' so were not immediately available for examination. The pharmacy received email notifications about drug recalls and safety alerts from the MHRA. And it monitored its emails daily. The team responded promptly to any drug recalls and safety alerts and it kept appropriate records.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs in order to provide its services safely and effectively. It has appropriate arrangements in place for its team members and suppliers to keep its equipment working as it should. Its team members understand the need for confidentiality, and they can only see the information they need to complete their tasks.

Inspector's evidence

The pharmacy used crown marked measures for measuring liquids. It had equipment for counting tablets and capsules. Team members had access to a range of up-to-date reference sources. And they had access to PPE, in the form of face masks and gloves, which were appropriate for use in pharmacies. Team members washed or sanitised their hands at regular intervals throughout the day and on entering and leaving different areas of the building.

The pharmacy's computers were located at different workstations the dispensary, in a way that meant that staff members using them were not close to one another. Computers were password protected and members of the public didn't access the building. Team members generally used their own smart cards when working on PMRs, so that they could maintain an accurate audit trail and ensure that access to patient records was appropriate and secure. The pharmacy ether owned or leased all of its computer hardware and peripherals and kept spares in case of any breakdowns. The pharmacy had its own internal IT team to manage the computer systems, and they were able to replace parts as required. There was a service level agreement (SLA) in place with the computer software supplier which incentivised them to keep the pharmacy's systems online with a maximum of 40 minutes downtime. As everything was cloud based, the software supplier could assist with any problems remotely. The pharmacy had two separate broadband connections and two separate mains electricity supplies to minimise the risk of being cut off. There was also a backup generator as an additional precaution.

Access to PMR was controlled using the USB digital signature keys referred to earlier, and also through individual NHS smart cards. No patient-sensitive information was visible to members of the public as they could not enter the building. Members of staff gathering items of stock ready for prescription assembly didn't have access to personal information as they could only see a picking list with barcodes or QR codes for them to scan.

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.