

Registered pharmacy inspection report

Pharmacy Name: Lloyds Pharmacy Clinical Homecare Ltd, Unit 3&4
Spire Green Centre, Flex Meadow, The Pinnacles, HARLOW, Essex,
CM19 5TR

Pharmacy reference: 1117146

Type of pharmacy: Closed

Date of inspection: 16/01/2023

Pharmacy context

This pharmacy is on an industrial estate. It dispenses prescriptions which have been generated for people being treated by hospital trusts and medicines are delivered straight to peoples' homes as part of a homecare treatment. This pharmacy has an MHRA licensed manufacturing facility which manufactures the products which are then supplied from the pharmacy. The types of treatments supplied include intravenous immunoglobulins, intravenous antibiotics, treatments for cystic fibrosis and enzyme replacement treatments.

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 identifies and manages the risks associated with its services to help provide them safely. It records and regularly reviews any mistakes that happen during the dispensing process. It uses this information to help make its services safer and reduce any future risk. It protects people's personal information well and team members understand their role in protecting vulnerable people.

Inspector's evidence

The pharmacy's processes were covered by written standard operating procedures and its processes were audited at several stages.. Anything which was discovered as incorrect, in any part of the process, was reported and examined immediately and during regular audits. In the past year there had been no incidents of people receiving incorrect supplies from the pharmacy. The manufacturing and prescription teams combined were achieving fewer than 1.5 mistakes per 10,000 items per month and these had been detected before they had reached people. The superintendent pharmacist and the governance director kept the most recent data on a dashboard so that they could see on-going trends.

There was also a robust integrated business continuity plan which meant that if one part of the business had an issue, for example flood or power outage, the prescriptions could be manufactured and supplied from elsewhere. There were alternative sites in Derby and Glasgow.

The Responsible Pharmacist (RP) notice was displayed in one of the pharmacy rooms and the role of RP was undertaken by one of four senior pharmacists. The whole team was aware of who was in charge on at any time. There were three RPs during each 22-hour period which the pharmacy was operating. The dispensing and manufacturing processes were covered by appropriate indemnity insurance.

There was CCTV covering all the processes, so that if a mistake occurred during the process the CCTV could be reviewed to identify what had gone wrong.

Computer systems were bespoke and secure. The computer programmes used by the company had many built-in safety features which meant that they highlighted issues and would not let the operator continue without resolving the issue. For example, the computer system would not allow an unstable formulation to be designed without the issue being highlighted and requiring the operator to resolve it. There was an audit trail throughout the prescription assembly, product manufacturing, quality assurance (QA) and dispatch processes, so that records could show who had passed off each stage. All staff were seen to use their own log-in details and screens locked themselves after a very short period, meaning that, if left unattended, an unauthorised person would not be able to access the information. There was a safeguarding lead and all staff had undertaken appropriate safeguarding training.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough team members for the services it provides. And the pharmacy supports its team members by giving them time at work to do ongoing training to help keep their knowledge and skills up to date. They do the right training for their roles. And they work effectively together and are supportive of one another.

Inspector's evidence

The team consisted of pharmacy technicians and pharmacists, with some additional people whose main role was involved in quality assuring products but who were also trained dispensers (NVQ2) as they acted as 'checkers' for the labelling and dispatch of the medicines from the pharmacy. During the inspection there were four pharmacy technicians, and two trainee technicians present in the formulation department. There was also the senior pharmacist, and nine other pharmacists who were clinically screening prescriptions. In total the pharmacy had 23 pharmacists, and four pharmacist leads.

Staff were only put into a role when they had had adequate training. For example, the pharmacists were given an induction and were then shown how to check the prescriptions for lower-risk therapies, with the help of a mentor. Once they were considered competent in one area of expertise they were introduced to another, and the training cycle was restarted. The quality assurance team, who were all science graduates with Good Manufacturing Practice (GMP) experience were given 100 items to check to show their competence, some of which would have deliberate mistakes in.

The technicians said that they often asked the RP for advice when they were building a prescription for a stable product, and also felt able to make suggestions to improve the service. The team had split into three shifts during COVID-19 outbreaks, not mixing with the other shifts, to try to ensure that continuity could occur even if one of the other shifts had COVID-19.

Following the 2021 staff survey, the Senior Leadership Team (SLT), acted on feedback received from staff by introducing 'You Said, We Did'. As part of this the SLT delivered roadshows to explain the company's plan and increased leadership visibility across different sites. The 2022 staff survey showed that the staff understood the direction of travel for the company better.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy's premises are clean, secure and provide an appropriate environment to deliver its services.

Inspector's evidence

The pharmacy premises were situated in two warehouse units which were joined. The technicians and pharmacists were located in one building, and the QA staff in the other unit where the MHRA manufacturing took place. Both parts of the premises were clean and tidy and suitable for the processes which took place there. There were adequate handwashing facilities and hand gel was available for use as well. The premises were accessible only by security card.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy generally provides its services safely. It obtains its medicines from its own manufacturing unit, which is registered with the MHRA, and it manages them appropriately so that they are safe for people to use. It takes the right action in response to safety alerts so that people get medicines and medical devices that are safe to use.

Inspector's evidence

The pharmacy provided specialised treatments to people who received homecare. It did not dispense routine NHS prescriptions and patients did not attend the pharmacy to collect their medication. There was a customer care team based at a sister pharmacy in a near-by industrial estate who dealt with delivery issues and customer questions.

Information about a patient's needs was provided to the pharmacy by the relevant Trust and the team of technicians set about making a formulation which met the needs of the prescriber and patient and then a prescription would be issued for this formulation. The computer system they used to help with this process would not let them produce an unstable formulation. Once a suitable, stable formulation was found the details would be sent to the prescriber for a prescription to be signed. The original prescription, with wet ink signature, was then sent back to the pharmacy. This was then clinically checked by the pharmacists in the team and inputted onto the system and then sent onto the manufacturing unit for assembly.

The assembly process was done under the regulation of the MHRA and the finished product would be sent for quality assurance. If satisfied that an assembled product was of suitable quality, the Quality Assurance team will attach a confirmation of QA release to each batch. They also checked that products were labelled in accordance with the prescriptions by physically checking the labels on a sample of products. To make sure that products were kept at the right temperatures until they reached patients, deliveries were made using temperature-controlled vans. Dispensed items did not leave the premises when there was no RP present. MHRA alerts for product recalls were actioned, and the compliance with these was audited.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely. The team uses its facilities and equipment to keep people's private information safe.

Inspector's evidence

The computer systems were bespoke for the pharmacy's business. All equipment was regularly checked, and PAT testing was done regularly. Computers were password protected to prevent unauthorised access. Staff had access to relevant references online. There was a business continuity plan in place.

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.