General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Calea Uk Limited, Cestrian Court West, Eastgate Way, Manor Park, RUNCORN, Cheshire, WA7 1NT

Pharmacy reference: 1092153

Type of pharmacy: Closed

Date of inspection: 03/07/2024

Pharmacy context

The pharmacy provides a homecare medicines service which involves delivering ongoing medicine supplies direct to people's homes. Hospital prescribers initiate all the supplied treatments. Some aspects of the service, for example nursing care, are not GPhC regulated. Therefore, this report focusses solely on the registerable services that the pharmacy provides. The pharmacy is in a purpose-built industrial estate unit, which is not open to the public. The company that owns the pharmacy holds MHRA specials manufacturer and wholesale dealer authorisations.

This inspection is one of a series of inspections we have carried out as part of a thematic review of homecare services in pharmacy. We will also publish a thematic report of our overall findings across all of the pharmacies we inspected. Homecare pharmacies provide specialised services that differ from the typical services provided by traditional community pharmacies. Therefore, we have made our judgements by comparing performance between the homecare pharmacies we have looked at. This means that, in some instances, systems and procedures that may have been identified as good in other settings have not been identified as such because they are standard practice within the homecare sector. However, general good practice we have identified will be highlighted in our thematic report.

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 generally manages its risks well. The pharmacy team follows written instructions to help make sure it provides safe services. The team reviews its mistakes which helps it to learn from them. Pharmacy team members receive training so that they know how to protect people's information. And they have a clear understanding of their role in protecting and supporting vulnerable people.

Inspector's evidence

The pharmacy was part of a company that provided homecare services. Its main activity involved the supply of enteral and parenteral nutrition (EN and PN) feed bags and biosimilar medicines against prescriptions from NHS hospital Trusts (the Trusts) and NHS General Practitioners (GPs). And it delivered them to people across England and Wales. The pharmacy also supplied infusion devices and any ancillary equipment that the people needed.

The pharmacy team worked with other teams across the company to provide the homecare service. This included the executive leadership, quality assurance, clinical governance, medicines information, manufacturing, warehouse, distribution, nursing, pharmacovigilance, sales and marketing and business development. There was also a patient services team, most of who worked remotely, and were service user's main point of contact and co-ordinated their supplies. Nurse members of the nursing team were based locally to patients. All the other teams and the nursing team management were based on the same site as the pharmacy. The pharmacy used external national courier services to deliver people's treatments and associated products.

The pharmacy had written procedures that its management team regularly reviewed, at least every two years. The pharmacy's procedures covered safe dispensing and the responsible pharmacist (RP) regulations. Records were kept to show that team members had read and understood the procedures relevant to their roles and responsibilities.

The pharmacy regularly risk assessed its activities and maintained a risk register that the superintendent pharmacist, pharmacy manager and member of the executive leadership team updated each month. The register included a description of the risk, the possible impact on pharmacy service users, existing measures to mitigate the risk, and recommended actions to reduce the risk. Examples of activities that had been reviewed included clinical and medicine preparation checks, which documented that the pharmacy should keep records of any mistakes and use them to review the written procedures.

The quality assurance (QA) team audited the pharmacy's services annually against MHRA standards. This included how effectively the pharmacy complied with written procedures and handling concerns. These audits recommended improvements using the corrective and preventative actions (CAPA) methodology to manage and resolve quality issues. The superintendent and operations director attended an internal monthly operations quality review, which included assessing failed or late home delivery data and the recorded concerns.

The business development managers and pharmacy spoke to Trusts on a daily basis regarding operational and patient specific topics such as supply delays. These discussions became more formal if

an issue continued. The group contacted each other between these discussions to progress any outstanding matters. Sales and marketing and pharmacy representatives held quarterly performance review meetings with the Trusts. This included discussing the hospital's timeliness for sending prescriptions to the pharmacy, unsuccessful deliveries to patients and treatment they consequently missed. Meeting attendees reported relevant points to the superintendent. The company's operations director held monthly meetings with the couriers to review their delivery performance. The company worked with other homecare providers to maintain services if, for example, there was a sudden influx of many people requiring treatment.

The pharmacy had systems for identifying who was responsible for each prescription medication it had supplied, which assisted with investigating and managing mistakes. Pharmacy team members used electronic scanning equipment that recorded who had prepared each prescription item. Team members also annotated the rear of prescriptions to identify who had prepared and checked each medication.

Pharmacy team members discussed any near miss mistakes they made and recorded them on an electronic system. The team reviewed these records weekly, to learn from what had happened and took action to mitigate against risks in the dispensing process that they identified. Pharmacy team members discussed their performance with the pharmacy management every six weeks, which included any near misses they were involved in. The pharmacy had an urgent issue procedure to address a serious incident or concern. This included a team meeting and escalating the issue to the executive leadership team if necessary.

The pharmacy received feedback from patients about how well it was providing its services via a private social media forum. People were able to provide general feedback or raise concerns via patient services, who forwarded pharmacy related issues to a pharmacist, who was available Monday to Friday 7am to 11pm and Saturday 8am to Monday 7am. Most people's concerns were resolved at this stage.

Patient services recorded concerns on an electronic incident reporting system. The pharmacy had written procedures for handling any concerns that people or the Trusts reported. The operations director and superintendent reviewed each concern promptly, and they recorded the potential root cause and pharmacy's actions on the reporting system. They grouped similar concerns to help identify trends. For example, the pharmacy team identified that a few patients had missed a parenteral feed dose because the pharmacy had not adhered to procedures. The pharmacy used the CAPA method to address these concerns, which led to pharmacy team members re-reading the procedures. The pharmacy also discussed complaints people raised about the delivery service with the relevant national courier, who provided documented corrective actions that addressed these concerns. For example, a courier confirmed the remedial action it had taken regarding delayed deliveries that had led to patients missing their feed. The clinical governance lead and QA director became involved with more serious concerns. These arrangements meant that concerns were usually addressed within thirty days.

The pharmacy had professional indemnity insurance for the services it provided. It maintained appropriate RP records, and the RP notice was displayed. The pharmacy kept records of people's feed formulation with each of their corresponding prescriptions.

The pharmacy initially received a scanned version of the prescription via email, and it subsequently received the original via the post. It recevied NHS prescriptions for EN feeds from the patient's GP. The pharmacy maintained a private prescription register for PN and biosimilar prescriptions from NHS Trusts. The pharmacy team had an audit trail of who had quality and date checked each product that was dispensed, and of the pharmacist who had clinically checked the prescription. The pharmacy computer system recorded the stage each prescription was at in the dispensing process, which helped the team to make sure it supplied products in good time. The pharmacy recorded the batch number

and expiry date for each medicine it had supplied.

The pharmacy maintained records of any prescription products it supplied in an emergency. The pharmacy team kept records of any discussions it had with hospitals and patients. However, the pharmacy had not been recording the reason for any delays in obtaining biosimilar prescriptions. So, the team could not demonstrate what had gone wrong or whether they had taken appropriate action to resolve the issues.

Pharmacy staff members had signed agreements about keeping people's information confidential and they had completed data protection training. They securely stored people's information and used passwords to protect access to people's electronic data.

The pharmacy had safeguarding policies and procedures. All the pharmacists had level two safeguarding accreditation and staff had also completed safeguarding training. The courier drivers had completed safeguarding training and reported concerns such as people exhibiting signs of confusion. The pharmacy team worked closely with patient services, the nursing team and hospitals to identify and support vulnerable people.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff and a clear plan to make sure it has a suitable skill mix. It effectively develops each team member. Staff members participate in regular reviews of the team's performance to help improve service quality and safety.

Inspector's evidence

Most pharmacy team members worked full-time. The team consisted of fifteen pharmacists, eighteen registered pharmacy technicians, seventeen of whom worked as accuracy checkers (ACTs) and one of whom was the pharmacy manager, and thirty-two dispensers. The pharmacy team was divided into sub-teams that were each ACT-led, except one team that a pharmacist led. The pharmacy retained a pool of locum pharmacists to cover employee pharmacist's leave. The medicines information team, which consisted of a pharmacist, a registered technician, and three staff members who had science-based degrees, reported to the superintendent pharmacist. A pharmacist, who was usually the RP, was present in the pharmacy during operating times. An on-call pharmacist was available over the weekend.

The pharmacy had enough staff to comfortably manage its workload. It consistently dispensed all the products that were scheduled to be dispatched each day. Time and motion studies were used to model the pharmacy team member numbers required each day. This modelling accounted for how long it took to complete the dispensing process for each product, vacancies, planned and unscheduled staff absence, and training and meeting times. The pharmacy planned a daily schedule, which each sub-team reviewed twice daily, to help make sure there were enough staff for each part of the dispensing process. Each sub-team reviewed outstanding orders and the manufacturing unit's production capability, which indirectly affected the pharmacy's service efficiency. At the end of each operational day each sub-team leader reassessed the staffing resources needed for anticipated prescriptions. They requested additional pharmacist support from other parts of the pharmacy team if needed.

The pharmacy team had no current vacancies and usually had a minimal vacancy rate. Each pharmacy sub-team had an allocated number of staff at a specific role and qualification. Every quarter each sub-team leader reported any training needs or vacancies to the pharmacy management team to maintain the required number of staff at each grade. Sometimes team members moved internally to other teams. The pharmacy then had the option to recall them temporarily if needed. But it rarely had to use this contingency. The pharmacy team met every Monday and Friday to review staffing and any outstanding training.

The pharmacy used a competency-based framework, mapped against its procedures, to design the staff training required to provide its services. Team members rotated across the different tasks fulfilled to provide each service, including dispensing EN and PN feeds. Staff had protected study time for any training that they needed to complete. Pharmacists completed specialist training over three years that Leeds University provided on prescribing, formulating and dispensing feeds, and aseptic preparation. They also completed training on PN and EN nutrition. These arrangements helped to maintain each team member's skills.

The sub-team leaders focussed on managing and developing their team members. They closely supervised new team members training, who started on dispensing basics before moving onto more complex tasks. These arrangements helped to make sure that new staff members had opportunities to

develop their skills by working alongside other more experienced team members who had higher qualifications.

The pharmacy agreed locums' schedule several months ahead, and at a maximum of three months between individual locum's bookings. This helped to make sure the pharmacy stayed fully staffed and the locums retained their skills. The locum pharmacists had read the pharmacy's procedures and completed the training to provide its service, and their role was limited to tasks that required minimal training and supervision.

Pharmacy sub-team leaders held regular reviews with new and existing team members. These reviews included assessing compliance with written procedures, identifying remedial training, discussing process changes, and learning from mistakes. Each sub-team held monthly meetings to discuss operational matters and team members were encouraged to make suggestions to improve ways of working.

Team members participated in an annual staff survey, the results of which led to an action plan for each sub-team. The feedback was mostly regarding team members requesting to work in other teams such as nursing or patient services.

The pharmacy team had incentives to improve service quality in relation to supplying products correctly, on time and to reduce the number of complaints that people made.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are clean, secure and spacious enough for the pharmacy’s services. It provides a professional environment for healthcare services and keeps people's information secure.

Inspector's evidence

The pharmacy, manufacturing and warehouse units were located on the same site. The level of cleanliness was appropriate for the services provided. The pharmacy premises had the space and lighting that the team needed to dispense prescription products safely. An air conditioning system was installed, which helped to maintain suitable temperature conditions for treatments, and the premises were tidy and organised. The premises were access controlled, which meant unauthorised people could not enter or view confidential information. The company’s website and social media page included contact information for the service as a whole. There pharmacy's website caleapharmacy.co.uk included information about how to contact the pharmacy. The sales and marketing team forwarded any relevant queries it received to the pharmacy.

Principle 4 - Services ✔ Standards met

Summary findings

Overall, the pharmacy's working practices are effective, which helps make sure people receive safe services. It gets its medicines from licensed manufacturers and suppliers and manages them effectively to make sure they are in good condition and suitable to supply.

Inspector's evidence

The pharmacy operated from early morning to late night Monday to Friday, and over the weekend. People ordered and arranged standard delivery of their products up to 11pm during the week. On weekdays between 11pm and 7am people had access to a nursing telephone advice line, which forwarded urgent queries to the superintendent pharmacist. The on-call pharmacist was available on-site via telephone during the weekend. The pharmacy could arrange early next day delivery for treatment requests it received late during an operational day.

Teams at the Trusts initially assessed each patient's suitability for the homecare service. The Trusts completed a registration form for each new patient that it sent to the pharmacy along with the proposed prescription. The pharmacy team entered the received information on its systems, and patient services explained to the patient how the service worked and arrange a delivery date.

The patient services team provided a multi-lingual information booklet to new patients which covered all aspects of the service provided, contact details, and frequently asked questions. The team also contacted new patients to make sure they knew how to use their treatment. And it involved the nursing team if anyone needed additional assistance. The nursing team trained all new PN patients and signposted them to online instructional videos on how to self-administer their treatment.

A recent PN manufacturing capacity review concluded not to increase the total number of PN patients. Due to the manufacturing element of the PN and biosimilar services, the clinical governance team checked the available capacity each time it received a new PN or biosimilar treatment request.

The pharmacy was contracted to supply new PN patients within five days of agreeing to provide them the service, which it usually achieved. The delays in supplying PN products to new patients were usually beyond the pharmacy's control. For example, the Trusts may not have provided enough product specification information to register patients, or where there was a lack of nursing availability. Occasionally, the Trusts issued a PN formulation that did not have satisfactory stability. This sometimes led to delays in the Trust agreeing to the reformulation. The pharmacy queried any outstanding reformulations every week day, and the Trusts did not discharge new PN patients until these issues had been resolved. The pharmacy had asked the Trusts to mark their emails 'urgent' for any pressing changes to people's PN formulations.

The pharmacy had written procedures and checklists for formulating and prescribing PN and biosimilar products. A pharmacy technician checked the Trust's proposed formulation against previous prescriptions to confirm product viability. The pharmacy subsequently used specialist software to generate a product formulation for the hospital to agree. A pharmacist and the medical information team assessed the formulation's stability to calculate its shelf-life. The pharmacy completed three final formulation and stability checks before it provided a prescription for the Trust's prescriber to sign. It then compared the signed and unsigned prescriptions for any discrepancies. Any changes to the signed

prescription meant the formulation process started from the beginning, but this was rare. The time taken for a Trust to supply the signed prescription ranged between a few days and up to four weeks.

Pharmacists clinically checked each prescription before sending the formulation to the manufacturing team. The finished products were then released to the pharmacy team for dispensing and supply. ACTs and dispensers referred to people's files and their prescriptions when they checked their prepared feeds and products.

The pharmacy was contracted to supply new biosimilar and EN patients one day after it received the prescription. The pharmacy operated until the late evening to make sure dispensed products would be available for next day delivery.

The Trusts normally issued PN prescriptions that covered six to twelve months' supply, which the pharmacy then supplied against in instalments to the patients when needed. Most EN prescriptions covered twenty-eight day's supply, and some were for six months. The pharmacy used an automated electronic system to request repeat prescriptions and tracked the status of each request.

The pharmacy asked the Trusts to issue repeat PN prescriptions four weeks before the current prescription ended, and it sent weekly reminders for outstanding prescriptions. The pharmacy had processes to make sure people did not miss their feed when a Trust delayed issuing the prescription. For example, if the pharmacy was able to confirm that the formulation remained unchanged, it would supply using the previous formulation or prescription. If that prescription had expired, the pharmacy checked how much residual stock the patient had and, if necessary, would supply their treatment under emergency supply regulations.

The GP continued EN prescribing to the patient after their discharge from hospital. The pharmacy requested repeat EN prescriptions from the GP two weeks before the current supply ended, and it sent daily reminders for outstanding prescriptions. Arranging EN supplies was usually uncomplicated, so there were no obvious systemic issues of patients missing treatment. On the rare occasion when the patient might finish their EN stock before they received their next delivery, the pharmacy would supply their treatment without a prescription because EN feeds were not prescription only products.

The pharmacy requested repeat biosimilar prescriptions from hospitals six weeks before the current prescription ended, and it sent weekly reminders for outstanding prescriptions. Delays to the hospital issuing a prescription were typically due to the patient having an overdue routine blood test. But the superintendent pharmacist confirmed that patients had rarely missed a medication dose, because the pharmacy encouraged them to contact the hospital. Biosimilar supplies covered a two-week period beyond when the next prescription was due and the pharmacy usually received the new prescription before the patient exhausted their supply. The pharmacy also used a same-day courier service, if necessary, to urgently fulfil supplies.

The pharmacy had identified that some biosimilar medication patients, whose prescription the Trust had delayed issuing, had not received a supply for several months. These cases were raised with the Trust, and there was normally an explanation that the patient had an infection which prevented treatment or they needed a blood test to continue treatment. Patient services subsequently reminded the patient of this.

The Trusts sometimes insisted that the pharmacy not supply a biosimilar treatment to the patient without a prescription when they were at risk of missing their treatment. The superintendent explained that the pharmacy had frequently attempted to discuss these delayed prescriptions with the Trusts without resolution. So, it was unclear why these delays happened, and the matter had not been raised

with NHS England. The frequency of these situations was low, but the company planned to significantly expand its biosimilar supply service, which may increase the risk of a patient missing a dose.

The pharmacy used an electronic stock control system that automatically ordered and planned the production of treatments and ancillary products six weeks before the scheduled patient delivery date. The pharmacy team used a manual override to obtain any products that the patient needed sooner. The manufacturing and warehouse teams provided all the requested feeds and ancillary products respectively to the pharmacy. The pharmacy also obtained medicines from MHRA licensed wholesalers. The pharmacy team informed patient services of any temporarily unavailable or part-supplied products, so they could liaise with the patient to make sure they had enough treatment in the interim. The pharmacy discussed alternative options with the hospital if a product was unobtainable.

When prescription products had been dispensed and checked, the pharmacy team packaged treatments and then transferred them to a dispatch area for the external couriers to collect. Patient services communicated with patients and external couriers to co-ordinate deliveries. PN feeds and biosimilar medicines were scheduled for delivery every two weeks, and the team contacted PN patients every week to check whether they needed any ancillary products. Patient services arranged EN feed delivery dates four weeks in advance. It informed the Trust or NHS Integrated Care Board if the patient was not contactable. The couriers operated a next-day delivery service for biosimilar medicines, if needed, and they returned products to the pharmacy after three attempted deliveries.

PN and biosimilar medicines needed to be delivered within a strict timeframe to ensure continuity of care. The pharmacy dispatched products up to 9pm that the couriers delivered the next day as standard. The couriers also delivered on Saturday and could deliver on the same day if necessary. Deliveries to remote post codes were available on specific days.

At 5pm each weekday the pharmacy reviewed the list of outstanding priority prescriptions. The manufacturing team had until 10.30pm to supply urgent products to the pharmacy for them to be delivered the next day. The pharmacy also had access to a twenty-four-hour delivery service for urgently requested products.

The pharmacy provided people with a 'buffer reserve' of their treatments to keep in case of delayed deliveries, supply-chain issues or faulty items. Patient services checked how much extra stock people had each time they arranged a delivery, and reminded people to report any occasions when they used their reserves so that the pharmacy could replenish their surplus.

The pharmacy kept a patient priority list that included infants and children, whose feeds had a limited shelf-life of eight days, those who were receiving palliative care, and people with diabetes or who had a stoma. These patients had more complex feed formulations, so the pharmacy had reserved extra stock to make sure it avoided running out of their feeds.

The pharmacy team supplied feeds shortly after they had been manufactured. So, a stock expiry date check programme was unnecessary. The pharmacy monitored the storage temperatures of its refrigerated products. Most feeds had a thirty-day shelf life, which helped to reduce the number of times people had to order them. The team checked biosimilar medicine expiry dates during the accuracy check stage of the dispensing process.

The pharmacy used a specialist cold-chain courier for PN feeds using vehicles that had ambient and cold chain temperature monitoring. The courier notified the pharmacy pre-delivery of any cold-chain temperature excursions during transit. The delivery driver quarantined the affected packages until the pharmacy team had reviewed the vehicle refrigerator temperature data. The pharmacy either agreed to

supply the products in transit or re-supplied products the same or next day depending on the patient's reserve feed stock.

Most unsuccessful deliveries were due to no person being available at the delivery address at the scheduled time and date. Patient services contacted the patient to re-arrange delivery up to three times, after which the treatments were returned to the pharmacy. The pharmacy investigated and notified the Trusts of unsuccessful deliveries that led to the patient missing their treatment, or if they had a safeguarding issue.

All delivery drivers had completed training that covered good distribution practice and maintaining the cold chain. The pharmacy had access to the courier's services electronic delivery records when needed. Delivery drivers completed a checklist at the destination address to make sure the assigned number of feeds and any associated products had been delivered and all the patient's feeds had a suitable shelf-life. They rotated the patient's stock and checked their refrigerator storage temperature.

The pharmacy used a quality management system for all the products it supplied to record people's reports about any product quality issues. The pharmacovigilance team reviewed these records to identify anything that required addressing such as side-effects, and onward reporting.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment that it needs to provide its services effectively. It properly maintains its equipment and it has the facilities to secure people's information.

Inspector's evidence

The team had the facilities it needed to dispense feeds. Staff could report equipment issues to the contracted maintenance company, which helped to sustain service continuity.

The pharmacy had the facilities needed to secure people’s written and electronic information. It regularly backed up its people’s data on its patient medication record (PMR) system, so it secured patients’ electronic information and could retrieve their data if the PMR system failed.

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.