General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Specials Pharma Ltd, TC1-32, The Cube, Londoneast-uk, Business and Technical Park, Dagenham, RM10 7FN

Pharmacy reference: 9011403

Type of pharmacy: Internet / distance selling

Date of inspection: 09/08/2023

Pharmacy context

This is a distance-selling pharmacy (www.specialspharma.com) and mainly supplies specific controlled drugs. The pharmacy dispenses private prescriptions only. People using the pharmacy are based in the UK. The pharmacy is closed to the public and situated in a business park and medicines are delivered to people via courier.

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 largely manages and identifies the risks associated with the services it provides. It protects people's personal information and people are able to provide feedback about the pharmacy's services. The pharmacy largely keeps the records it needs to by law so that medicines are supplied safely and legally.

Inspector's evidence

Standard operating procedures (SOPs) were available however, it was unclear if these had been reviewed recently, the recorded date for review on the SOPs seen during the inspection was in April 2022. The SOPs sent by the superintendent pharmacist (SI) after the inspection had been reviewed more recently. The pharmacy provided its services at a distance. Risk assessments had been carried out following the previous inspection, but these were not seen during this inspection. The responsible pharmacist (RP) confirmed that they had not seen the risk assessments. The risk assessments were forwarded to the inspector by the superintendent pharmacist following the inspection. The risk assessments looked at various aspects of the service model including staffing and identified any gaps that needed to be addressed. Following the previous inspection, the SI had also done a risk assessment covering the type of medicines dispensed by the pharmacy.

The pharmacy's business involved the supply of specific controlled drugs (CDs) to people living in the UK against private prescriptions issued by UK-based prescribers. The pharmacy worked with prescribers who were all on the specialists register and worked at specialist clinics registered with the Care Quality Commission (CQC). Agreements were in place for some prescribers who were not on the specialist register but were working under the supervision of another prescriber. The pharmacy did not supply medicines to children. Prescriptions received were generally for the treatment of chronic pain, anxiety and epilepsy although this was not in line with NICE guidance for all the conditions. The pharmacy only dispensed the specific CDs in the unlicensed form. The licensed form was not dispensed due to prescriber preference.

Clinics sent a notification when a prescription was issued and sent to the pharmacy. The original was received via post and dispensed once received. Prescriptions were annotated with a dispensing number when they were dispensed. The pharmacy monitored and reviewed mistakes made during the dispensing process. The pharmacy recorded dispensing mistakes which were identified before the medicine was supplied to a person (near misses). And those where a dispensing mistake happened, and the medicine had been supplied to a person (dispensing errors). As a result of past near misses some medicines with similar names had been separated. The RP said there had not been any reported errors whilst she had worked at the pharmacy but described the process, she would follow in the event that there was one.

The correct RP notice was displayed, initially there were two notices displayed, one was removed during the inspection. RP records and CD registers were kept electronically. There were some missing entries seen in the RP record, this could make it harder to know who was responsible on those days. The RP said she would bring this to the SI's attention. Records for unlicensed medicines dispensed were kept. Private prescription records were made on the computer system. Scanned copies of each prescription were also retained.

The pharmacy had indemnity insurance cover, and the SI confirmed that this covered all activity undertaken by it. Information about raising complaints was included in the initial email which was sent to people using the pharmacy. There was a contact number for the pharmacy on the website as well as a form through which people could contact the pharmacy. The pharmacy did not have an information governance policy, but the RP had completed some training on information governance. Team members had all signed a confidentiality agreement.

The RP had completed safeguarding training. One of the customer services assistants had completed safeguarding training as part of her previous role in a community pharmacy. Following the inspection team members had been enrolled on the safeguarding course for support staff. The NHS safeguarding application was discussed with the RP. After the inspection the SI forwarded the safeguarding SOP to the inspector. This had been read by all team members.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to manage its current workload. Team members complete relevant ongoing training to keep their knowledge and skills up to date.

Inspector's evidence

At the time of the inspection, the pharmacy team comprised of the RP, who was a locum pharmacist, two customer service assistants and the SI's wife who managed the accounts. Usually, the SI worked at the pharmacy and provided RP cover. Due to the pharmacy's volume of dispensing the RP felt that she was able to manage the workload. Since the last inspection the pharmacy's workload had increased. The SI was planning to recruit more customer service assistants and have some team members trained to help with the dispensing.

To keep up to date the RP read information online to find out information about the different types of products available on the market. She had also looked at specific websites which specialised on providing information about these specific CDs. Manufacturers also provided the team with information on new products. Following the inspection, the SI informed the inspector that although the customer services assistants were not involved in any dispensing activity, he was looking to enrol team members who had expressed interest onto the relevant course.

Team meetings were held a few times a week to discuss any issues and the plan of action for that week. The RP was able to contact the SI when she worked at the pharmacy and described how it was an open working environment where she felt comfortable to raise concerns or provide feedback and suggestions. Staff performance was managed by the SI. Team members had a 12-week probation review to discuss next steps. Team members were provided with ongoing feedback, and this was also discussed at team meetings. There were no targets in place, the RP said there was an expectation to ensure medicines were delivered in a timely manner.

The pharmacy received prescriptions from a number of clinics. The SI carried out checks on the prescriber to ensure they were on the specialist register. Service level agreements were available where the prescriber was not on the specialist register but was working under the supervision of a prescriber. The SI was in close contact with the prescribers and had regular meetings with the clinics that he worked with; he provided the RP with feedback when needed.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are clean and secure. The pharmacy’s website gives people information about the details about the pharmacy and superintendent pharmacist, so that people can check where their medicines are supplied from.

Inspector's evidence

The pharmacy premises were clean and organised. There was sufficient work and storage space. Workbenches were kept clutter free. Cleaning was done by team members. There were adequate hygiene and handwashing facilities for staff. The pharmacy was closed and could not be accessed by the public. Contact with people was generally via telephone or email. The pharmacy was secure from unauthorised access. The room temperature and lighting were adequate for the provision of pharmacy services.

The pharmacy's website could not be used to access services. The website displayed the name of the superintendent pharmacist and the pharmacy's registration details.

Principle 4 - Services ✔ Standards met

Summary findings

People can access the pharmacy's services easily. The pharmacy gets its medicines from reputable suppliers and generally stores them properly. It responds appropriately to drug alerts and product recalls. This helps make sure that its medicines and devices are safe for people to use.

Inspector's evidence

The pharmacy's services were accessed at a distance. The website was not used for the provision of any services but was there for information. The website showed the location of the pharmacy on a map, it also gave details of the SI, his registration number and the pharmacy's registration number. People could communicate with the pharmacy via telephone or email.

Customer service assistants made a courtesy call to all new customers. As part of this the person's personal details and contact details were confirmed. Team members confirmed the item the person had been prescribed and explained how the service worked including estimated times of delivery, information about the delivery service, payment procedure and complaint procedure. This was followed up with an email which contained all the relevant information.

Prescriptions were sent to the pharmacy directly by a group of prescribers, who were known to the pharmacy. For this reason, the SI did not carry out identity checks. People were required to sign an agreement at the clinic to give permission for the pharmacy to contact them. The pharmacy was sent a notification before the prescription was sent. Once received prescriptions were scanned into the system and a copy of this was retained. Pharmacists generally self-checked their work and the RP described taking a mental break in between dispensing and checking. Coloured baskets were used to separate prescriptions. People were also informed that they could contact the pharmacy if they had any additional questions. However, this contact was not documented. All further checks and monitoring were then done by the clinics. The pharmacy was not involved with these reviews and no checks were carried out on the outcome. The RP thought clinics sent information to people's regular GPs.

People were provided with a generic information leaflet which had information on the uses of the medicines, common side-effects, long term use, precautions and how to dispose of unused medicines. Leaflets on the use of inhaler devices were also sent. Storage instructions were found on the product label. People were not counselled about how to spot if the medicines were not suitable to use. However, the pharmacy had been contacted previously by people if they had felt that there was an issue with their medicine. Information on dealing with unwanted medicines was provided on the generic information leaflet that was sent out. People were only individually counselled on side-effects and use if they contacted the pharmacy. Counselling instructions were recorded on the dispensing labels and when oils were dispensed people were supplied with two syringes to ensure they could administer the correct quantity.

The pharmacy used a tracked next-day courier service to deliver medicines. Medicines were only delivered to the person and a signature was obtained by the courier service. Medicines were packed in dispensing bags and then in outer containers. An SOP was available for the delivery service. In the event that there was no one there to receive the delivery it was returned to the depot. Delivery was

attempted on three occasions before the item was returned. Team members said they had not received anything back which hadn't been delivered. Following the last inspection an SOP for dealing with returned medicines or missed deliveries was introduced.

Medicines were obtained from four wholesalers. The SI had carried out checks to ensure that the wholesalers had the correct certificates, authorisations, and licenses. In the event that there were delays in receiving medicines from the wholesalers due to quality control, the team contacted the person and provided them with a new timescale of estimated delivery times. If there was going to be a long-term delay, the pharmacists spoke to both the prescriber and person and requested for an alternative item to be prescribed.

Date checking was done when stock was received and dispensed. An SOP was available for CD destruction. The pharmacy did not dispense any fridge lines. Drug recalls were received from the MHRA, the pharmacy had not had relevant stock for any recent alerts. The pharmacy had quality control forms, patient complaint forms, product report, service report and adverse event report forms. Complaints from people relating to a product issue, were referred back to the manufacturer.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services. It uses its equipment to help protect people's personal information.

Inspector's evidence

Reference sources were available including access to the internet. Computer systems were password protected. Confidential waste was shredded. As the pharmacy was closed to the public this helped to protect people's confidentiality. Team members said that the systems used were secure.

What do the summary findings for each principle mean?

Finding	Meaning
✔ Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✔ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✔ Standards met	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.