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: 15/10/2021

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. The inspection was undertaken during the Covid-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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 not all met	1.1	Standard not met	The pharmacy does not carry out risk assessments for the service and medicines it supplies at a distance. It has some written procedures, but it does not always follow them.
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 not all met**

Summary findings

The pharmacy does not manage and identify all the risks associated with the services it provides. It has not gathered evidence about the risks for each individual medicine it provides at a distance and has not completed any risk assessments or audits. And does not always follow its own written procedures. However, the pharmacy largely 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 and in date. The pharmacy provided its services at a distance. No risk assessments had been carried out for the services provided or for the types of products dispensed. The superintendent pharmacist (SI) gave an assurance that he would work on completing these. The pharmacy did not have an SOP to deal with returned medicines or missed deliveries. And it did not always follow its own SOPs. For example, the delivery SOP said that people's identification should be checked by the courier when the medicines were delivered, but this was not happening.

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 five prescribers who were all on the specialists register and worked at specialist clinics registered with the Care Quality Commission (CQC). The pharmacy did not supply medicines to children. Prescriptions received were generally for the treatment of chronic pain although this was not in line with NICE guidance. The pharmacy only dispensed the specific CDs in the unlicensed form. The licensed form was not dispensed due to prescriber preference.

People were referred by the SI to a patient advocacy group. The group triaged people and needed access to their Summary Care Records (SCR), medical history and confirmation of diagnosis. The person was then referred to a relevant prescriber. The SI at times directly referred people to a clinic, but explained that this was rare. Clinics sent a notification when a prescription was issued and sent. The original was received via post and dispensed once received. Prescriptions were annotated with a dispensing number when they were dispensed.

The pharmacy had systems in place to monitor and review 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). The SI described one dispensing error that had occurred in which the correct item had been labelled with an incorrect patient name. This had been recorded on an incident report form but was not reported to the local CD Accountable Officer (CDAO).

The correct Responsible Pharmacist (RP) notice was displayed. RP records and CD registers were generally well maintained, although some CD registers were loose sheets of paper. The SI gave an assurance that these would be attached to the registers. Records for unlicensed medicines dispensed were also kept. Private prescription records were made on the computer system. These did not include

information relating to the date the prescription had been issued and details of the prescriber were incomplete. So, it could be harder for the pharmacy to find out these details if there was a future query.

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 leaflet 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, the SI had completed some training on information governance. Only the SI had access into the pharmacy.

There was no safeguarding policy, although the SI had completed safeguarding training. The SI gave an assurance that he would put a safeguarding policy in place and look into the NHS safeguarding application.

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

The pharmacy team comprised of the SI who was also the regular RP. Due to the pharmacy's volume of dispensing the SI felt that he was able to manage the workload. The SI was looking to recruit an administrative assistant to help with customer services, the paperwork and record keeping. The SI explained that as the pharmacy's workload increased and with the start of compounding, he planned to recruit a second pharmacist and another assistant. The pharmacy had no contingency plan in place for the SI's absence. The SI had a friend who could come and help if needed but he had not been trained on the systems or services. The SI gave an assurance that he would look into this.

To keep up to date the SI read and watched blogs and videos produced by a relevant organisation. He also read information provided by the MHRA as well as product information from manufacturers and other organisations. He had attended an expo where he had heard a few talks on the specific CDs the pharmacy dispensed. The SI had not been aware of the relevant e-learning on the NHS Health Education England e-LfH website. He gave an assurance that he would look into this.

The pharmacy received prescriptions from five prescribers. All were on the specialist register. Four were anaesthesiologists and one a psychiatrist. The SI was in close contact with the prescribers and had regular meetings with the clinic that he worked with.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are clean and they are secured from unauthorised access. The pharmacy’s website gives people information about the details of the superintendent pharmacist and pharmacy registration information. 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. 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 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 where medicines were supplied from 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. The SI checked with people about any other health conditions or medicines they were taking. The SI gave an assurance that he would speak to prescribers about any contraindications.

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. The SI was unsure if the clinics conducted ID checks and gave an assurance that he would check with them. 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. As the SI worked on his own, he used different coloured baskets for different stages of the dispensed process as well as using a separate area to check. Two weeks after the initial supply the SI had a telephone consultation to check if everything was going fine and if the person knew how to take the medication. People were also informed that they could contact the pharmacy if they had any additional questions. This was not documented. All further checks and monitoring were then done by the clinics. Clinics generally held three and then six-monthly reviews. The pharmacy was not involved with these reviews and no checks were carried out on the outcome. The clinics sent information to people's regular GPs.

People were provided with a leaflet on the use of inhaler devices. This was also discussed during the call. The SI checked if the person was ok and if they knew how to use the vapes. Storage instructions were found on the product label. People were not counselled on storage or how to spot if the medicines were not suitable to use. Information on dealing with unwanted medicines was also not provided. The SI gave an assurance that he would consider adding additional information to the leaflet which was sent out initially. The SI checked if the person had used the product before and during the consultation explained that they should stop using any previous supplies, records of this was not made.

During the phone call the SI spent time with people discussing titration, counselling on side-effects, reducing the dose if needed as well as finding out if the medication was working. The majority of the reported side-effect was drowsiness. The importance of applying for a specific card, which is a piece of documentation that people carried and confirmed that the medicine was for medicinal purposes was sent in the introduction email. People were advised on when best to take their medication but no advice was provided on diet.

The pharmacy used a tracked courier service to deliver medicines. Medicines were packed in dispensing bags and then in outer containers. An SOP was available for the delivery service which required medicines to be delivered to the named patient and a signed ID to be checked by the courier. The SI

explained that the courier company did not do this. In the event that there was no one there to receive the delivery it was returned to the depot. There was no SOP for dealing with returned medicines or missed deliveries.

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 SI 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 SI spoke to both the prescriber and person and requested for an alternative item to be prescribed. In the past the pharmacy had taken on the extra cost with someone's prescription if their normal formulation was not available and the pharmacy had to order another at a higher cost. CDs were stored securely.

Date checking was done by the SI, the pharmacy held a very limited amount of stock. An SOP was available for CD destruction but this did not cover all the formulations which were dispensed by the pharmacy. 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. There had been one complaint from a person relating to a product issue, where there had been a report that the product was brown. This had been classed as a minor issue as the pharmacy could not compare it to other batches and the person had not used that particular brand before. This had not been reported to the manufacturer, NRLS or MHRA.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for 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. The SI 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.