General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Smile Pharma Ltd, Unit 1, Gemini 8, Apollo Park, Westbrook, Warrington, Cheshire, WA5 7AE

Pharmacy reference: 9012395

Type of pharmacy: Internet / distance selling

Date of inspection: 02/12/2024

Pharmacy context

The pharmacy is in a business park on the outskirts of Warrington. It dispenses private prescriptions mainly for aesthetic products, including botulinum toxins, and for injectable medicines for weight loss. It delivers them directly to prescribers and practitioners for treating people using their services. People receiving treatment receive little or no contact with the pharmacy and they do not directly access pharmacy services from the premises. The pharmacy has a website www.smilepharma.co.uk where prescribers and practitioners access services.

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 identify and assess all the key risks from its activities and services. It does not have a process to complete written risk assessments and audits to help it manage these risks. This includes for the treatments it supplies, unlicensed products and receiving prescriptions from a third party company. The pharmacy misses opportunities to record interventions, which could help identify unmanaged risks.
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 not all met	4.2	Standard not met	The pharmacy does not always follow its own procedures and make interventions when prescriptions contain incomplete information and directions, this includes for weight loss treatments. And it does not verify whether prescribers have face-to-face consultations with patients, when the information on prescriptions is ambiguous.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

Overall, the pharmacy does not have the documented information it needs to appropriately identify and manage key risks with its services. It does not complete risk assessments and audits to show it suitably manages and delivers its services safely and according to its own written procedures. Team members record and learn from mistakes they make whilst dispensing. And they amend the way they work to reduce the risk of similar errors happening again. They keep the records they need to by law, and they keep people's confidential information secure. Team members understand their role in helping protect vulnerable people's health.

Inspector's evidence

The pharmacy dispensed private prescriptions mainly for aesthetic products, including botulinum toxins and for licensed injectable weight loss treatments, including Wegovy and Mounjaro. Prescribers and practitioners registered either directly with the pharmacy through its website or via a third party company's website, who specialised in aesthetics. The pharmacy didn't have a process to complete written risk assessments to help identify and manage risks with providing its services. This included for any intended new services, unlicenced products and for receiving prescriptions from a third party company. It had not considered completing written risk assessments by treatment to highlight risks with individual treatments such as for weight loss and treatment with botulinum toxins. It was therefore difficult for the pharmacy to know if it had identified and managed all the key risks with providing its services. The pharmacy hadn't documented the risk with delivering cold chain medicines by courier and although they had a written procedure with deadlines around weekend posting they hadn't identified the need to check the way the pharmacy packaged medicines kept them within an acceptable temperature range during delivery. The pharmacy had identified the need for prescriptions for weight loss treatment to include details of the person's BMI, so the pharmacy team had the information to assess whether treatment was suitable. But not all prescriptions seen during the inspection contained details of the BMI and these had not been queried by the pharmacy team. The pharmacy hadn't completed any audits, using intervention records or dispensing supply data to confirm adherence to their procedures and so had not identified weight loss medicines had been supplied without checking the BMI and outside of their procedures. There were no audits completed to check adherence to the maximum supplies of treatments and frequencies of supplies, to check for clinical suitability of supplies made and whether prescriber face-to-face consultations had been conducted. The number of recorded interventions was minimal, so it was difficult for the pharmacy to identify whether standard operating procedure (SOP) guidance was being followed. The pharmacist explained how interventions were made regularly but acknowledged they could do more to record these and review them.

The pharmacy had a set of current standard operating procedures (SOP) dated June 2024 and team members had read and understood them. The SOPs were relevant to the pharmacy's business model and the services provided and included dispensing and responsible pharmacist regulations. The SOP for dispensing detailed the requirements for completing prescriber and practitioner checks, which included ID checks, checking prescribers' professional registration and professional indemnity insurance. The pharmacy received private prescriptions from a third party company specialising in aesthetics, and the company had shared two SOPs with the pharmacy detailing how the service operated. But the content did not specifically document the process for prescribers to hold face-to-face consultations with

patients before prescribing. The SI had communicated with the company to seek some reassurance of their processes, in line with the Joint Council for Cosmetic Practitioners (JCCP) guidance and the pharmacy's own policies. The pharmacy detailed in its SOP for dispensing, guidelines for the maximum number of dermal fillers and toxins to be dispensed in a six month period. The SOP detailed the clinical reasons why these quantities were appropriate, considering the amount recommended to be injected into different areas and the length of time the effects of the product lasted. The pharmacy team were all aware of the maximum quantities and frequency of supplies in the SOP and they clearly explained the checks they made on the patient medication system (PMR) history before dispensing. These checks were seen to be completed during the inspection, and of the sample of prescriptions checked the quantities and frequencies were within the guidelines in the SOP.

The pharmacy had a SOP about recording near miss errors and dispensing incidents. Near miss errors were those identified before a supply was made and dispensing incidents were those identified after the supply had been made. From the records seen, the team regularly recorded near miss errors each month and the SI documented a monthly patient safety review of errors recorded to look for trends. Although the SI had not yet completed the paperwork for the reviews for the last couple of months team members discussed errors at team meetings, and they described some changes made to reduce the risk of errors occurring again. This included using clear bags and highlighting strengths of Mounjaro on prescriptions following an error.

Pharmacy team members understood their roles and responsibilities, this included the trainee dispenser who knew when to refer queries to the pharmacist and when to highlight potential issues on prescriptions to the pharmacist. The correct RP notice was displayed. The team knew how to deal with complaints, which they received by email and telephone. They explained these were usually queries about missing deliveries and resolved easily by accessing the courier's tracking system. The dispenser explained the steps they would take to resolve a missing delivery to ensure people's expectations were met. They also knew when to escalate concerns, particularly clinical concerns, to the pharmacist.

The pharmacy had current professional indemnity insurance, due to expire in May 2025. Its private prescription records were held electronically and contained the required details. A sample of responsible pharmacist (RP) records met requirements. The pharmacy didn't supply controlled drugs, so no records were held. The pharmacy had a privacy notice on the website, and it included details on confidential data held. Team members had completed training about General Data Protection Regulations (GDPR) and signed confidentiality forms. They were aware of their responsibilities to keep people's confidential information safe. The team separated confidential waste, and stored it separate from general waste until a specialised third-party contractor removed it monthly. Prescribers registered with the pharmacy had a two-step authentication to access the system to prescribe. This included using computers which were password protected and inputting a PIN into the IT system to access their account. They then generated an electronic prescription, which included a copy of their signature. The pharmacy held copies of prescribers' signatures to refer to when dispensing.

The pharmacy had a written procedure about safeguarding vulnerable people. The SI had completed safeguarding training and the operations manager, who was also a dispenser, had completed level 3 training. The team were aware of the importance of not dispensing aesthetic products to people under 18 years, and the PMR system converted the date of birth to the age, which the team explained helped to prevent mistakes. They recognised the importance of only supplying weight loss medicines to people with a high BMI as part of weight management treatment.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has a small and dedicated team, who have the necessary skills and experience to provide services safely. And they manage the workload well. Team members make professional decisions based on the wellbeing of people using pharmacy services and they feel comfortable raising professional concerns if needed.

Inspector's evidence

Two pharmacists covered the opening hours of the pharmacy. The RP during the inspection was the superintendent pharmacist (SI) and worked at the pharmacy four days a week. They were supported by the operations manager, who was a dispenser, and a trainee dispenser. The team worked well together to manage the workload and resolve queries. They came across as enthusiastic and knowledgeable in their roles. The SI was involved in decisions about products stocked and advertising of medicines on the website and social media. They gave an example of how they had used their professional judgement in a decision about a product to stock. A member of the marketing team asked for the pharmacy team's advice on marketing a product during the inspection.

The trainee dispenser felt supported in their accredited training and had time at work to learn. As part of their induction, they had produced a product information sheet listing information about different toxins, dermal fillers, and other aesthetic products to help with their learning and to use as a reference guide. They had completed product knowledge questions as part of their induction to support their learning. The SI had previous experience of working in a pharmacy supplying similar products and they had peer review and support to help them in their role. Team members completed ongoing learning for example when new products were launched. The trainee dispenser felt comfortable to suggest ideas to improve services and knew how to raise professional concerns within the company and externally if needed. The team had regular team meetings and there was a staff briefing notice board, highlighting the date of the next planned meeting. They explained how they informally discussed matters as they worked, which included being open and honest about any mistakes made so they could learn together as a team. The pharmacy team didn't have targets to meet.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are clean, tidy, and well maintained. They provide a suitable and professional environment for pharmacy services.

Inspector's evidence

Prescribers and practitioners accessed the pharmacy's services through its website, by email and by telephone. Members of the pharmacy rarely contacted patients directly and consulted with prescribers and practitioners. The registered pharmacy premises were within a self-contained unit on a business park. There was a reception area for visitors, with a window through to the dispensary so the pharmacy team could see people waiting to be attended to. The premises were well-maintained, well-lit and the temperature was controlled with heaters providing a pleasant working environment. The dispensing area was spacious enough for the workload, with separate areas for processing prescriptions and labelling, checking, and packing ready for delivery. The pharmacy was clean, tidy, and hygienic. Floor spaces kept clear to reduce the risk of trip hazards and there were separate staff facilities to have breaks un-interrupted.

The pharmacy's website was for professional use only, and prescribers and practitioners were required to set up an account to access services. The SI's name and registration number were displayed as were the registration details of the pharmacy premises. Members of the public couldn't order any products displayed on the website.

Principle 4 - Services **Standards not all met**

Summary findings

The pharmacy has some suitable procedures to help it manage and deliver its services safely. But prescriptions do not always contain the necessary information for the pharmacy to have confidence it can supply products safely. And the team does not always make interventions to obtain further information. So, it is difficult for the pharmacy to know if these products are appropriate for people's needs. The pharmacy makes its services accessible to the right people. And it stores and manages the products it supplies appropriately.

Inspector's evidence

Prescribers and practitioners registered with the pharmacy via its website and set up an online account to access services. The products stocked by the pharmacy were clearly laid out on its website. They were supplied against valid electronic private prescriptions, which the prescriber sent electronically by accessing the pharmacy's system. The pharmacy did not supply products directly to members of the public. The pharmacy also received electronic prescriptions from a third party company, which the team processed separately. The pharmacy team were contactable by telephone and email, the details of which were published on the website. A small number of practitioners attended the pharmacy in person but mostly products were delivered to the practitioner for use in a clinic setting. Team members completed a series of checks prior to registering a prescriber or practitioner. They obtained photographic identification, such as a passport and obtained details of their professional indemnity insurance. They checked the prescriber's registration status online at the time of registration and on an adhoc basis but there was not a clear process of how often these follow up checks were made. The pharmacy reported no problems with the registration status of prescribers. Copies of the practitioners' training certificates were stored on the system for team members to refer to.

The prescription templates had a section where prescribers confirmed a physical face-to-face consultation had taken place with the patient as per the pharmacy's policies. But of twenty prescriptions checked from the company's system there were eight occasions where the prescriber's address was geographically far from the patient's address. And for the twelve prescriptions checked from the third party company, there were eight occasions where the prescriber's address was geographically far from the patient's address for example Belfast and the Midlands and London and Newport. There had been no intervention checks by the pharmacy that there had been face to face consultations before prescribing. The prescriptions were for botulinum toxins and/or injectable weight loss medicines. Of the twelve prescriptions checked for injectable weight loss medicines eight had a BMI suitable for treatment but four had no BMI recorded on the prescription and this had not been queried before supply. Four prescriptions for a skin booster and botulinum toxins were seen without specific directions for administration, which made it more difficult to clinically assess as suitable to supply and was not in line with the pharmacy's SOP. On these occasions, the pharmacy team didn't check with the prescriber whether the practitioner was given clear instructions on where, how much to administer and for how long. The pharmacy explained how they contacted prescribers with queries on prescriptions, but only had three recorded interventions to show since June 2024. The pharmacy team acknowledged recording interventions would allow them to identify trends in prescribing both with prescriptions received via their website and from the third party company and show any prescriptions not dispensed and why.

There were separate areas for labelling, dispensing, checking of prescriptions, and packaging for delivery. Baskets were used to keep people's prescriptions and products separate from others, to minimise the risk of mistakes. Team members initialled dispensed by and checked by boxes on dispensing labels, to record their actions in the dispensing process. Supplies were made using tracked delivery service via a recognised courier, and packages were signed for on receipt. No deliveries of products requiring cold storage were made on a Friday to help ensure the cold chain was maintained. The pharmacy used insulating materials to package these products and had a technical data sheet from the company of the packaging used, but this was not specific to the process in the pharmacy. And the pharmacy could not confirm that it had completed audit testing the cold storage deliveries. The SI confirmed this had been set up to do following the inspection. The pharmacy used discreet cardboard boxes to package the items for delivery, which were appropriately sealed. Packaging was clearly marked to alert the practitioner on receipt when the contents required storage in a fridge. The pharmacy tracked deliveries and had a suitable process for managing failed deliveries.

The pharmacy purchased products, medical devices and medicines from recognised wholesalers, and some aesthetic products directly from manufacturers. It stored medicines, fillers, toxins, and other items neatly on shelves. There were two medical grade fridges, with records confirming them to be operating within the correct temperature range. The temperatures were within the correct range during the inspection. Team members checked the expiry dates of products and recorded these checks electronically. No out of date products were identified from a sample checked. The pharmacy received medicine recalls and safety alerts by email, to date none had needed to be actioned.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services. And the equipment and facilities suitably protect people’s confidential information.

Inspector's evidence

The pharmacy team had access to internal reference resources and the internet for up-to-date information, including for aesthetic products. There was equipment available for the services provided, including enough computer terminals for the team positioned at the different workstations in the dispensary. The pharmacy computers were password protected and it used a recognised PMR supplier for dispensing. There was IT support for its systems and the electrical equipment appeared free from wear and tear. The pharmacy sourced discreet carboard packaging for deliveries. There was a cordless telephone so conversations could be held in private if needed.

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.