General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: She Can Health Ltd, Millbank Tower 1st Floor, 21-24 Millbank, Suite 1.4, London, SW1P 4QP

Pharmacy reference: 9012166

Type of pharmacy: Internet / distance selling

Date of inspection: 23/05/2024

Pharmacy context

This pharmacy is situated in a business premises in Pimlico, London. It first registered in July 2023. It is not open to the public, and the pharmacy offers its services via its website www.shecanhealth.com. Medicines are delivered to people using a postal courier service. The pharmacy specialises in compounding and supplying unlicensed topical medicines for low libido in females.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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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 have a documented risk assessment showing how it manages the risks associated with is service on an ongoing basis.
		1.2	Standard not met	The pharmacy does not have appropriate written procedures for all of its operational activities, or documented clinical policies for its prescribing service. And it supplies medicines without having the correct legal procedures in place.
		1.6	Standard not met	The pharmacy does not maintain appropriate records as required by law. This includes responsible pharmacist logs and private prescription records.
2. Staff	Standards not all met	2.2	Standard not met	Team members do not always work under the supervision of the pharmacist when carrying out activities which require this. And they do not always have the right qualifications for their roles.
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's clinical records do not explain how prescribing decisions are made, and the prescriber does not issue legally valid prescriptions when authorising supplies. The pharmacy does not appropriately label the medicines that it supplies. And it does not provide sufficient information to make sure people understand how to use their medicine safely, or have a clear process for follow up or monitoring if people experience adverse effects.
		4.3	Standard not met	The pharmacy does not source pharmaceutical ingredients through the approved UK suppliers. It does not have appropriate systems to dispose of medicines and pharmaceuticals safely. And its records relating to the preparation of unlicensed medicines have information missing.

Principle	Principle finding	Exception standard reference	Notable practice	Why
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 effectively identify and the manage risks associated with its service. It does not have documented risk assessments, prescribing policies, or operating procedures,so it can demonstrate that it supplies medicines safely. And it does not keep appropriate records or supply medicines in accordance with the law. This could present a risk to people's health.

Inspector's evidence

The pharmacy only operated on an occasional basis once or twice a month for a few hours at a time. The business was managed by the sole director of the company which owned the pharmacy. The superintendent pharmacist (SI) worked as the responsible pharmacist (RP) and the pharmacy's prescriber. The SI had taken over the role from the previous SI in January 2024, so had only worked at the pharmacy for a few months. The pharmacy did not maintain an RP log as required by law. This meant it was not possible to identify when the pharmacy had been operational, or which pharmacist was responsible for supervising the pharmacy's activities at a given point in time.

The director confirmed that the pharmacy had professional indemnity insurance and that this covered all aspects of the service. The SI had her own personal insurance which covered her prescribing role. The pharmacy's complaints procedure was explained on its website, and the pharmacy sought feedback from people accessing the service using an online survey. The director described how they had reformulated one of the medicines following feedback from service users.

The pharmacy compounded topical unlicensed medicine intended for application to women's external genitalia. The main active ingredient was sildenafil. The preparations were all prescription only medicines. The pharmacy had developed three different formulas tailored to different needs. People accessing the pharmacy's services completed an online questionnaire to request a treatment. They were required to register an account when purchasing a medicine. This meant their ordering history was retained with their account when they made further requests. The formulations and the online questionnaire had been developed on the advice of the pharmacy's clinical lead, who was a women's sexual health expert. The director explained that the clinical lead had experience of using similar unlicensed preparations based on sildenafil whilst working in the USA.

Completed online questionnaires were reviewed by the prescriber who approved or refused to supply based on the person's responses. The SI explained circumstances when she would refuse to prescribe, for example if someone was breastfeeding or pregnant. She also described how one of the formulas was specifically indicated if people suffered from genital herpes. However, the pharmacy did not have a documented prescribing policy explaining the inclusion and exclusion criteria or treatment plans associated with each of the formulations. And it did not have a documented risk assessment as evidence that it had considered the risks prior to commencing the service or how it managed them on an ongoing basis. In addition, the pharmacy had not completed any audits to confirm prescribing was appropriate.

The pharmacy had standard operating procedures which had been developed by the previous SI. The SOPs covered some of the pharmacy's operational activities, such as the RP regulations and basic

manufacturing procedures. But they did not cover all aspects of the service, such as the prescribing function, pharmaceutical stock management, or the dispatch and delivery processes.

The pharmacy used a bespoke software system and records were integral to the pharmacy's website. Records of supplies contained the person's details (name, address, email, telephone number and date of birth), the completed questionnaire, details of any previous supplies and any feedback survey responses. This meant the SI could review this information when considering whether to authorise a supply. The records included a prescribing notes section, but this was not routinely completed to show what additional checks the prescriber had completed or how they had made their decision whether to prescribe or not. The records did not identify the prescriber or the date they had authorised the supply. This meant the pharmacy could not produce a appropriate private prescription record of the supplies it had made. In addition, the prescriber did not produce a legally valid prescription when authorising a supply, so supplies were not made lawfully.

The pharmacy was registered with the Information Commissioner's Office. Its privacy policy was displayed on the website. Confidential material was stored securely, and the computer system was password protected.

The pharmacy used an age checking service to ensure the pharmacy only supplied people over the age of 18. It mostly supplied people living in the UK but occasionally supplied to people living in certain countries of the EU subject to customs requirements. The SI had completed level 3 safeguarding training. The pharmacy did not have a formal safeguarding policy explaining how potential concerns were managed. It did not seek to verify people's healthcare information, and the pharmacy had not considered providing people with additional information about the unlicensed medicines they had been prescribed so they could inform their usual doctor if needed.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy has enough staff to manage the workload. But some of its team members are not suitably qualified for their roles, and they do not always work under the supervision of a pharmacist. In addition, the pharmacy does not effectively support team members to communicate easily with each other, which makes it harder from them to discuss concerns or help the pharmacy make improvements.

Inspector's evidence

The pharmacy's workload was very low, and it could be easily managed by the team, who all worked on an ad hoc basis. The team consisted of the director, the SI and an overseas qualified pharmacist. The SI worked as both the RP and the prescriber. The overseas qualified pharmacist compounded the medicines as she had experience in this. She had not completed any accredited pharmacy training in the UK and she did not work under the supervision of the RP when preparing batches of medicines, which was unlawful.

The director coordinated the team and administrated the business. She had not completed any clinical or pharmacy related training. She handled queries and sometimes helped to dispatch prescriptions. The clinical lead was not employed by the pharmacy, but they provided occasional advice and support to the director.

The SI had completed her training in dermatology. She also worked regularly in a private community pharmacy and a GP practice. She had not had any contact with the clinical lead or had any direct guidance from them. She was not able to provide evidence of any training or experience that would demonstrate her competence to prescribe treatments for low libido.

Team members appeared to work in isolation with the director as their main point of contact. This meant they couldn't easily discuss issues and concerns as a team.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is basic in design, but it is generally suitable for the service it provides. Its website provides useful information about the pharmacy and the service it offers.

Inspector's evidence

The pharmacy consisted of a single room in a business premises. The other business units were mostly offices.
The pharmacy was basically fitted with a work bench for compounding, a desk with seating and storage shelves. The room was small, but there was sufficient space given the low volume of dispensing.

The pharmacy was secured when not in use. Lighting was adequate and fixtures were suitably maintained. The room could not easily be ventilated although there was a portable air purifier which was used when compounding. The building had air conditioning, but the pharmacy team had no control over this. The director said the room temperature could get quite warm and agreed to monitor it moving forward to makes sure it remained below 25 degrees and suitable for the preparation and storage of medicines.

The pharmacy's website contained information about service, including frequently asked questions. It provided information about the company, the superintendent, and the prescriber, as well as contact details.

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

Summary findings

The pharmacy does not manage its service safely. It doesn’t source its pharmaceutical ingredients through approved UK suppliers, or have a safe system to dispose of pharmaceutical waste. The pharmacy doesn't follow robust procedures when compounding unlicensed medicines to make sure these are safe to use. It does not provide people with enough information about their medicines to make sure they understand the risks. or have a process for follow up and monitoring if people experience adverse effects.

Inspector's evidence

People could contact the pharmacy by email, telephone or using an online form. The director managed most communications and was usually contactable when the pharmacy was closed.

The pharmacy did not stock or supply any conventional medicines. It sourced most of the raw ingredients for compounding from an overseas based supplier based in the USA. However, the pharmacy was not registered with the MHRA to permit it to do this. One formulation was compounded using aminophylline tablets produced in India. These were obtained directly from India rather than through a licensed importer in the UK, which was not in line with requirements.

Pharmaceutical ingredients were mostly stored in original containers in the pharmacy with batch number and expiry dates, although a couple of containers did not have batch details. Certificates of conformity were available for some of the pharmaceutical ingredients.

Unlicensed medicines were prepared in small batches. A formulation sheet was used to record the preparation. Each batch was allocated a number and the date, the person preparing the batch, and the percentage of each pharmaceutical ingredient used was recorded. But the batch number and expiry date of ingredients was not recorded on the formulation sheet, and the key steps of preparation were not documented. Some notes were kept about the resultant batch quality and formulations had been adjusted based on this information. Each batch was given an arbitrary two-month expiry date. The pharmacy had not conducted any external assays to assure itself of the quality or stability of the unlicensed medicines to inform its compounding techniques.

The SI did not contact people requesting medicines by telephone or make further enquiries about their clinical need. She based her prescribing decisions solely on the questionnaire and the purchasing history available on the system. The SI could not recollect refusing to make a supply since she started working at the pharmacy. The pharmacy didn’t have a clear process for follow up and monitoring which was relevant given the medicine was unlicensed, and the efficacy and side effects were largely unknown.

Compounded medicines were dispensed into containers with a pump to control the dosage amount. When a prescription was dispensed the container was placed inside a box and a dispensing label was applied. Medicines were then placed in discreet protective packaging and dispatched using a tracked 24-hour delivery service. The medicine container itself had a small label with ingredient details, but it did not have any warning labels such as ‘keep out of reach of children’. This was a risk as the box could be easily discarded, and it was not obvious from the information on the container that it was a

medicine. The website contained information about the medicines which indicated they were unlicensed, but this may not be obvious to people. The pharmacy did not provide people with any other written information, such as possible side effects and precautions, to support them to use the medicine safely or remind them to report any issues to the pharmacy. There was a QR code on the dispensing label on the box linking to 'frequently asked questions' but this did not appear to work. The batch details of the medicines supplied were documented on the person's record. The director demonstrated how they could search the system for people who had received a specific batch if one was found to be defective.

The director reported that one person had reported a mild adverse reaction after using a medicine. This appeared to be a one-off reaction as no one else receiving the same batch had reported any issues. The director had advised the person to stop using the medicine and contact their doctor if they were concerned, but she had not reported this to the SI or queried this with the clinical lead to determine if follow up was needed. People were advised to return unwanted medicines to their local pharmacy for disposal. The pharmacy did not have a pharmaceutical waste contract as yet. The director said they had thrown some substandard or expired batches in the bin, which presented a safety risk.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for the services it provides. The team maintains and monitors the equipment so that it is accurate and safe to use.

Inspector's evidence

Team had access to the internet and reference sources. Equipment included scales, mixing utensils and a homogeniser used for compounding. Equipment was kept clean and cleaning materials were available. Scales were calibrated every time they were used and had been calibrated recently by an external company. Hair nets, aprons and gloves were worn when medicines were prepared. Container and packing materials were available for dispensing and dispatch purposes.

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.