General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Somer Pharmacy, Unit 10, Willowbrook Technology Park, Crickhowell Road, St. Mellons, Cardiff, Caerdydd, CF3 0EF

Pharmacy reference: 9011581

Type of pharmacy: Closed

Date of inspection: 23/04/2024

Pharmacy context

This is a closed pharmacy in a business park in an eastern district of Cardiff. People can find information about the pharmacy and access its services via its websites: www.somerpharmacy.co.uk and www.somerx.co.uk. The pharmacy dispenses private prescriptions written by medical and nurse prescribers employed at various UK-regulated private clinics. The pharmacy receives these prescriptions via its own bespoke secure digital prescribing platform, Somerx. Most medicines supplied by the pharmacy are treatments for menopause symptoms or weight loss. Some of the medicines supplied are unlicensed topical treatments which the pharmacy team prepares on site. People do not visit the pharmacy in person and medicines are sent by courier.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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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	3.3	Good practice	The pharmacy is maintained to a high level of hygiene.
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 has written procedures to help make sure the team works safely. And its team members record and review their mistakes so they can learn from them. The pharmacy keeps the records it needs to by law. Its team members understand how to keep people's private information safe. And they receive training so that they know how to report concerns about vulnerable people to help keep them safe.

Inspector's evidence

The pharmacy supplied a small range of GSL (general sales list) medicines, P (pharmacy) medicines and POMs (prescription only medicines) to people aged 18 and over in the UK. All medicines were supplied against private prescriptions issued by nurse or medical prescribers employed at clinics that were based in the UK. The clinics were registered and inspected by either the Care Quality Commission (CQC), Healthcare Inspectorate Wales (HIW) or Healthcare Improvement Scotland (HIS), which are all UK health regulators.

A range of up-to-date electronic standard operating procedures (SOPs) underpinned the services provided, including the compounding service. Training records were available to indicate that the pharmacy team had read and accepted most of the SOPs. However, the dispensing assistant had not signed some of the SOPs, although he gave assurances that he had read them, and had been trained on all procedures. He agreed to re-read and sign the SOPs that had been missed. He understood the activities that could not take place in the absence of the responsible pharmacist but explained that he was not a key holder, and so could not access the pharmacy unless one of the two pharmacist owners was present.

The pharmacy had completed comprehensive risk assessments to identify and manage the risks associated with the services they provided and the products they supplied. For example, the pharmacy had a written risk assessment for the supply of weight loss medicines. It specified amongst other things that a supply would not be made unless the prescriber provided the patient's BMI as an assurance that the supply was appropriate. The pharmacists would only approve a prescription for weight loss medicines if the patient's BMI and the date of the patient consultation were provided. If this information was missing or inappropriate, the pharmacist would contact the clinic before deciding to either approve or reject the prescription. Most clinics prescribing weight loss medicines carried out face-to-face consultations with patients; one clinic conducted virtual consultations via videocalls.

To help mitigate some of the risks, the prescribing platform did not allow a non-prescriber to generate a signed prescription. However, clinics were able to register administrators on the system to enter prescription data. Prescriptions could only be approved and signed by a prescriber registered at the same clinic. An audit trail existed to show who had input the data and who had approved the prescription with an advanced electronic signature. And a process was in place to verify the electronic signature after a prescription had been issued. This reduced the risk of prescriptions being generated by unauthorised personnel.

Before a prescriber could send a prescription to the pharmacy, they were required to register on its prescribing platform and have their registration approved by one of the pharmacy owners. Registration

required a unique email address, a strong password, a contact mobile telephone number and details of the clinic where they worked. Prescribers were required to supply proof of identity using an up-to-date driving licence or passport. They were also asked to submit evidence of current professional indemnity insurance, although this could also be provided at a later stage, along with evidence of their competence to prescribe in the required clinical field, and any relevant prescribing policies. Each prescriber's registration number was checked manually on the relevant professional regulator's register. The pharmacy kept a record of each clinic's details and could add notes about clinics or prescribers for reference.

The pharmacy did not carry out any formal clinical audits. However, the superintendent pharmacist explained that he and the pharmacist co-owner reviewed all prescribing data on a month-by-month basis to understand patterns and trends and identify and address any concerns. The patient and prescription data that was captured by the pharmacy's digital prescribing platform could be exported on request. So the pharmacy team was able to provide clinics with data relating to their own prescribing information to assist them in carrying out internal audits.

The pharmacy team had systems in place to record and review dispensing errors and near misses. Near miss rates were low, and the team had not made any dispensing errors since the pharmacy had opened. Some action had been taken to reduce risks that had been identified. For example, following a near miss, different strengths of Cyclogest pessaries had been distinctly separated on dispensary shelving to reduce the risk of selection errors. Different strengths of Wegovy injections were stored on different shelves in the medical fridge and different strengths of Evorel patches were stored in separate labelled baskets as a proactive measure to help reduce the risk of errors with these items.

The superintendent pharmacist explained that verbal feedback received from people using their services was positive and that he had received no complaints since the pharmacy had opened. Clinicians using Somerx, the pharmacy's prescribing platform, had commented that it was intuitive and easy to use. There was a formal complaints procedure in place, and information about how to make complaints was available on the pharmacy's website.

A current certificate of professional indemnity insurance was available. Insurance arrangements covered the pharmacy's compounding activities. Responsible Pharmacist (RP) records were kept and well maintained. Supplies against private prescriptions were recorded electronically. Comprehensive manufacturing records were kept for products that had been compounded on site.

The dispensing assistant was aware of the need to protect confidential information. For example, he was able to identify confidential waste and understood how to dispose of it appropriately. He had received training on information governance, including the General Data Protection Regulations (GDPR), as part of his induction programme. Each member of the pharmacy team had an individual logon. The dispensing assistant had limited access to the software system and could not register prescribers with the pharmacy's prescribing platform or approve prescriptions for dispensing.

Comprehensive information about how and when patient information was recorded and shared was included in a privacy policy that was accessible on the pharmacy website. Patient-sensitive data stored in the servers was encrypted and password-protected. Medicines were delivered in discreet packaging which did not disclose any confidential details, other than the patient's name and address. The pharmacists and dispensing assistant had undertaken formal safeguarding training. They had access to local safeguarding contact details that were displayed in the dispensary.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload. Pharmacy team members are properly trained for the jobs they do. And they feel comfortable speaking up about any concerns they have.

Inspector's evidence

The superintendent pharmacist worked at the pharmacy on most days, checking prescriptions and overseeing professional activities. He co-owned the pharmacy with his brother, who was also a pharmacist and occasionally worked at the pharmacy. They employed a member of staff to help with the workload. This team member had worked at the pharmacy for nearly a year and was enrolled on an accredited dispensing assistant (DA) training course. The DA worked under the close supervision of the pharmacists and was able to refer to them throughout the day for help and advice. The pharmacy was quiet and the team could comfortably manage the workload. The staffing level appeared adequate for the services provided.

The DA received in-house training provided by the superintendent pharmacist on clinical topics, operational procedures and services. The pharmacist explained that he took a 'knows how, shows how, does' stepped approach to training and required the trainee to successfully demonstrate each operational or service procedure to him before he could undertake the task unsupervised. There was no ongoing formal appraisal system in place, but the DA had received a performance review at the end of his three-month probation period and could discuss issues informally with the pharmacists whenever the need arose.

There were no specific targets or incentives set for the services provided. Pharmacy team members worked well together. The DA said that he was happy to make suggestions within the team and felt comfortable raising concerns with the pharmacist owners. A whistleblowing policy was available in the pharmacy's SOP file. It included details of a confidential helpline that could be contacted if team members wished to raise a concern outside the organisation.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is extremely clean and hygienic. It is tidy and secure, with enough space to allow safe working. And the pharmacy layout has been designed to provide services effectively.

Inspector's evidence

The pharmacy was very clean, tidy and well-organised. One of the pharmacist owners had a background in Good Manufacturing Practice (GMP) and had designed the pharmacy using a logical circular workflow which followed GMP principles. Potential trip hazards such as cables were securely covered with rubber strips marked with hazard tape to help prevent accidents. The sink had hot and cold running water and soap and cleaning materials were available. Hygienic cleanroom flooring had been laid throughout the pharmacy, reducing the risk of airborne particulate contamination. The pharmacy had a frosted entrance door and tinted security glass windows. These let natural light into the building and allowed the pharmacy team to see out, whilst preventing members of the public from viewing any confidential information inside. The temperature and lighting in the pharmacy were appropriate.

A section of the pharmacy had been designed as a modular 'ISO7 cleanroom' laboratory for compounding unlicensed medicines. The room was thoroughly cleaned and disinfected before compounding began. A HEPA air filtration system was activated and took about 30 minutes to clean the air to ISO7 standards. An entry room with a foot-operated sink allowed pharmacy team members to wash their hands and put on protective clothing and footwear before they entered the compounding area.

The pharmacy had a basic website which described its private prescription fulfilment and compounding services. The website also displayed a short list of conditions that could be treated by the superintendent pharmacist using his independent prescribing qualification. These included acid reflux, acne, allergy relief, erectile dysfunction, hair loss and thrush. If a person selected a condition, they were asked to complete an online consultation questionnaire to provide information about their symptoms and medical history. This allowed the pharmacist to make a professional decision about whether to prescribe a treatment from a limited range of low-risk licensed P or POM medicines. However, he explained that he had never been required to assess a consultation questionnaire or write a prescription as the website had never been used in this way. The pharmacy's GPhC registration number, and the name and GPhC registration number of the superintendent pharmacist were prominently displayed on its website.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's working practices are safe and effective. The pharmacy gets its medicines from licensed suppliers and its team members carry out checks to make sure they are in an appropriate condition to supply.

Inspector's evidence

The pharmacy premises was not open to the public. But people were able to contact the pharmacy team directly. Details of the pharmacy's name, address and website were printed on dispensing labels for reference. The pharmacy's telephone number and email address were not printed on the labels, but these were easy to find on the pharmacy's website. The pharmacy received about two or three telephone calls daily from people who had queries about their medicines, and these were always dealt with directly by a pharmacist. When the pharmacy was closed, its telephone number diverted to the pharmacy owners' mobile phones so that people could be assisted out of hours. The pharmacy had a signposting SOP and the team signposted people requesting services they could not provide to nearby pharmacies or other local healthcare services.

The pharmacist owners had developed their own bespoke secure digital prescribing platform called Somerx, which had launched in March 2023. They explained that they did not market the prescribing platform, but approached private clinics registered with UK healthcare regulators. The pharmacists would usually meet with members of the clinic teams to demonstrate the prescribing system before the working relationship began. In this way they built good relationships with clinics and prescribers and had effective channels of communication that allowed them to address queries or problems quickly and effectively.

To send a prescription to the pharmacy, a registered prescriber logged into the prescribing platform and provided details which generally mirrored those that would legally be required when writing a paper prescription. These included the patient's personal details, including a contact number or email address, and details of the medicine prescribed: name, form, strength, quantity and directions. The pharmacist said that they did not accept 'as directed' as a direction as they felt that this was too ambiguous. The pharmacy had a formulary of medicines that had been risk-assessed: a prescriber could choose to prescribe anything from the formulary, with some exceptions. For example, the system would not allow prescribers to select an unlicensed compounded medicine unless it had been agreed during the registration process that they would prescribe these products. Formulary medicines could also be 'activated' or 'deactivated' by the pharmacy team as necessary: for instance, if an MHRA alert directed that a medicine should not be prescribed or supplied. Any quantity of medicine could be prescribed: the formulary displayed pack sizes that could be obtained for the medicine selected so that the prescriber could make an informed choice about an appropriate quantity. If a prescriber wished to write a prescription for a medicine that was not included in the formulary, they could contact the pharmacy and request this. The pharmacists would risk-assess the medicine before adding it to the formulary if they felt that this was appropriate. The prescribing platform also allowed the prescriber to add the diagnosis, as well as other notes such as drug allergies, preferred delivery dates or any other extra information for the pharmacy team. Finally, the prescriber had to acknowledge that they had read and accepted the pharmacy's terms and conditions.

Prescribers had the ability to recall a prescription if it needed to be amended or was no longer required by the intended person. The pharmacy was alerted when this happened. Prescribers were required to contact the pharmacy directly if a prescription had already been dispensed but needed to be amended or cancelled. An audit trail was available to show when prescriptions were recalled or cancelled. This was reviewed by the pharmacy team to identify any prescribing anomalies. For instance, they were able to see if people had moved to another clinic, or if they were receiving prescriptions from more than one clinic, and could investigate this if necessary.

The pharmacy's patient medication record (PMR) system was linked to the prescribing platform and could only be accessed by the pharmacy team. Each patient record had a unique identifying code as an audit trail. The pharmacy team logged into the PMR system throughout the day to see if any new prescriptions were waiting to be dispensed. These were clinically checked and approved or rejected for dispensing by a pharmacist. Approved prescriptions were downloaded to a designated folder and printed. Each prescription was marked with a unique reference number. If a prescription was reprinted, the software system automatically marked it with the message: 'Copy – Not for Dispensing'.

Each printed prescription was put into a separate basket for dispensing. Prescription details were transcribed into the pharmacy's labelling system. Dispensing labels and a courier label were printed and placed into the basket with the corresponding prescription. The pharmacy's labelling software system was not a pharmacy system and did not have pharmacy functionality, such as automatic safety warnings or drug interaction alerts. The pharmacy team explained that when a new medicine was prescribed, it was added to the labelling system database with the required safety warnings. The pharmacists used the BNF to check any interactions that might occur with previously prescribed or co-prescribed medicines. Dispensing labels were marked with the patient's unique identifying code which linked it to the PMR system as an audit trail.

The DA assembled each prescription on a dedicated bench. He explained that he had been trained to ensure he had a clear bench before starting to dispense each prescription, and always used the original prescription for reference. He assembled each prescription individually before starting the next, and used colour-coded baskets to ensure that medicines and associated paperwork did not get mixed up during the dispensing process. Once dispensing was complete, the DA checked the delivery address and patient name on the courier label against the prescription. He then moved the dispensed prescription onto a storage shelf underneath the bench, where it was retrieved and checked by the pharmacist. The pharmacist explained that he used a three-point check for accuracy, checking the product against the prescription, the label against the prescription and finally the label against the product. The dispenser and checker both initialled dispensing labels to provide an audit trail.

Most medicines were dispensed as original packs, but some prescriptions called for the pharmacy team to split these to supply the exact quantity prescribed. The loose medicines were repackaged into a white box. The quantity supplied was written on the inside flap of the box and initialled by the dispenser to show that it had been double checked. The expiry date and batch number of the medicine was added to the dispensing label for reference. The relevant patient information leaflet was printed from the Electronic Medicines Compendium website and added to the box before supply.

Weight loss clinics often prescribed metoclopramide or cyclizine as an adjunct to the weight loss medicine. These were anti-sickness treatments which were sometimes necessary as people often suffered from nausea as an initial side-effect. The pharmacists explained that a small quantity of the medicine was prescribed for short-term use until the nausea had resolved. They understood that there was a possibility that long-term use of anti-sickness medicines combined with weight loss treatment might mask symptoms of a more sinister condition and explained that they were vigilant to repeated

supplies, querying these directly with the prescriber. People prescribed medicines for weight loss were supplied with needles (if these were not included with the product), alcohol wipes and sharps bins at regular intervals. The customer care team signposted people to regional sharps collection services for disposal of waste or unwanted sharps. Prescriptions for temperature-sensitive weight loss medicines were dispensed and checked between 2 and 3.30pm each day. They were then packaged appropriately for despatch and collected by a courier soon afterwards. This reduced any risks associated with moving the medicines away from their temperature-controlled environment for prolonged periods.

The pharmacy received some prescriptions for testosterone replacement therapy from a local clinic registered with HIW. The pharmacist said that he kept a visual check on the amount of testosterone items in stock each day and was able to create a usage report from the pharmacy labelling system if required. The pharmacy also supplied Botox 100-unit vials to aesthetics clinics. These were supplied directly to the clinics for administration to the patient by the prescriber. The pharmacy had written risk assessments for these supplies.

One clinic wrote prescriptions for an unlicensed alcohol-free, polyethylene-glycol free topical minoxidil 5% spray for hair loss. The pharmacy team compounded this item on site under the Section 10 exemption of the Medicines Act 1968, which allowed them to prepare unlicensed medicinal products under the supervision of a pharmacist. A template 'batch sheet' was completed each time the unlicensed medicine was compounded against a prescription. The batch sheet recorded details of the raw materials, the equipment and method used and the final product. It included a quality assurance checklist. Initials of the person compounding the product and the person checking it were recorded as an audit trail. Plasticised dispensing labels were used for labelling the compounded topical solution to ensure that their integrity would be maintained if they got wet. Compounded items were labelled with patient and medication details, relevant warnings, such as 'For External Use Only', and an appropriate expiry date. The pharmacists explained that the expiry date could be no longer than 90 days from the date of compounding, as the pharmacy had no quality control function for stability testing. The pharmacy team did not conduct any random sample testing or audit the ongoing quality of the compounded products, but a retention sample was kept in the dispensary. This was a sample of a batch of finished product stored for identification purposes, which could be tested in the event of a query or incident. The pharmacists explained that they sought feedback from prescribers about patients' experiences of the compounded product.

If the pharmacy team supplied an unlicensed or 'off-label' medicine, including a medicine compounded on the premises, they provided a letter to the patient which explained that their medicine was being used in a manner or for a condition not specified in its original license. The letter reassured the patient that their prescriber had assessed their individual needs and had determined that the medicine was safe and suitable for them. It signposted them back to their clinic to discuss any concerns or questions about this.

Dispensed and checked items in baskets were moved to a designated 'release area' of the dispensary where they could be packed for delivery. Pharmacy team members processed one basket at a time to avoid the risk of transposition of medicines. If the medicines were to be delivered directly to a clinic, all medicines for that clinic were packed into one parcel with one courier label. Dispensed medicines were put into cardboard boxes that were packed with foam padding for protection and sealed securely. A courier label was attached, and the parcel was put into either a Royal Mail or a courier sack for despatch. Fridge items were protected by sealing them in a pre-cut card sleeve and putting this into an insulated cool bag which contained frozen gel packs. The pharmacy team had validated this method of temperature control by packaging a temperature sensor in this way on a warm day and sending it via Royal Mail. The temperature had remained within the required range for 48 hours. If a fridge line took longer than 48 hours to reach the recipient, the pharmacy contacted the patient and arranged to collect

and replace the item. If collection was not possible, the pharmacy team instructed the patient to take the item to any pharmacy for disposal. There had been very few failed deliveries, and these had been returned to the pharmacy and dealt with appropriately.

Medicines were only delivered within the UK. The delivery service was managed using Royal Mail's Special Delivery or Tracked 24 services and a next-day courier service. Both Royal Mail and the courier made a collection from the pharmacy each day between 4pm and 5pm. The Royal Mail and courier depots were close to the pharmacy and the superintendent pharmacist explained that it was possible to take parcels there if necessary. Each parcel was scanned to create a tracking number and could be tracked from the pharmacy to its destination. When the medicines had left the pharmacy, the team marked the corresponding prescriptions as 'collected' on the pharmacy software system and this sent the patient an automated text message to inform them that their medicines had been despatched. The prescriber also received a notification of despatch via the prescribing platform.

Medicines and raw materials were obtained from licensed wholesalers or MHRA-approved suppliers and were stored appropriately. Some medicines supplied for weight loss required cold storage. These were stored in a large, well-organised medical fridge that was kept digitally locked. Maximum and minimum temperatures were recorded daily and were consistently within the required range. The pharmacy team explained that they had ordered a second identical fridge to provide more storage space. This was delivered during the inspection.

Stock was subject to regular documented expiry date checks. The pharmacist explained that an expiry date check was an integral part of the goods in, dispensing and accuracy checking procedures. Date-expired medicines and patient returns were disposed of appropriately and pharmaceutical waste was collected regularly by an external company. The pharmacy received safety alerts and recalls via emails from manufacturers and the MHRA (Medicines and Healthcare products Regulatory Agency). The pharmacists gave an appropriate description of the way in which they would deal with medicines or raw materials that had been recalled as unfit for purpose. This included identifying people who had been supplied medicine from an affected batch, contacting them where necessary and returning quarantined stock to the relevant supplier. The pharmacy had recently received a communication from a manufacturing company that had been granted an extension to the printed expiry date on one of their weight loss products. The pharmacist had created a note informing patients of the new expiry date for their medicine and this was currently being included with every supply of the affected product.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide the services that it offers. And these are safe and generally properly maintained.

Inspector's evidence

The pharmacy used a range of validated measures to measure liquids for compounding purposes. However, some glass measures were not validated. The superintendent pharmacist removed these from use as soon as this was pointed out. Triangles and a capsule counter were available to count loose tablets and capsules, although the pharmacy team said that these were rarely needed. A separate triangle was available for use with cytotoxics to prevent cross-contamination. Masks, gowns and overshoes were available in the dispensary for use in the pharmacy's cleanroom. The pharmacy had access to a range of up-to-date reference sources, including compounding reference sources.

All equipment was clean and in good working order. The pharmacists gave assurances that electrical equipment was routinely tested. They also confirmed that weighing scales used for compounding medicines were regularly calibrated. But calibration records were not kept, so it was not clear how often these checks were made. A back-up internet connection was available for use if the main connection failed. The pharmacist explained that this switched over automatically, so there was negligible downtime on the rare occasions that it needed to be used. The pharmacy software systems were protected with passwords

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.