General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Roseway Labs, Ground Floor, Unit D, 5-25 Scrutton Street, London, EC2A 4HJ

Pharmacy reference: 9011719

Type of pharmacy: Internet / distance selling

Date of inspection: 26/02/2024

Pharmacy context

This pharmacy provides its services at a distance and it is physically not accessible to the public. It is located within a business centre and its main business is compounding unlicensed medicines under a s10 exemption which it prepares in its laboratory. It supplies these and other unlicensed medicines against private prescriptions from external prescribers. The pharmacy mainly supplies hormone replacement therapy and medication for thyroid conditions. It also supplies medicines against a relatively small number of prescriptions that are generated by its in-house Pharmacist (PIP) Independent Prescriber.

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 adequately identify and manage the risks associated with its prescribing service. Its risk assessment does not consider the individual medicines which are prescribed, and it does not have prescribing policies for these medicines. The pharmacy cannot always sufficiently demonstrate that it relies on robust clinical evidence relevant to the UK when prescribing unlicensed medicines.
		1.2	Standard not met	The pharmacy does not have a robust process to monitor or audit the safety and quality of its prescribing service, for example by doing regular clinical audits. The pharmacy does not monitor whether its own procedures are being followed, and there is evidence that they are not always complied with.
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	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 adequately identify and manage the risks associated with its prescribing service. Although it has done a risk assessment, this does not consider the individual medicines it prescribes, and it does not have prescribing policies for these medicines. The pharmacy cannot always sufficiently demonstrate that it relies on clinical evidence relevant to the UK when prescribing unlicensed medicines. And it does not always take account of relevant guidance, for example when prescribing antibiotics. The pharmacy does not have a robust process to monitor the safety and quality of the prescribing service, for example by doing regular clinical audits. So, it cannot sufficiently demonstrate that its prescribing is provided in line with appropriate guidance or that controls cited in its risk assessment are implemented effectively. People can provide feedback or make complaints about the pharmacy's services. And team members protect people's personal information. The pharmacy largely keeps the records it needs to by law.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs). But those shown during the inspection had been introduced in 2018 and were due to be reviewed in 2020. The superintendent pharmacist (SI) said that she was currently in the process of reviewing the SOPs. Since the SOPs had been introduced in 2018, the pharmacy had changed premises and had expanded its services. This may mean that the SOPs that the team referred to were not always relevant. The pharmacy had SOPs covering its prescribing service, but these were not printed out and kept in the SOP folder that the team were referring to. Following the inspection, the SI said that all SOPs had been updated and printed out for easy access. The pharmacy did not have a prescribing policy for the range of medicines the PIP prescribed.

Pharmacy team members were recording their near misses (where a dispensing mistake happened before a medicine was supplied) on each of their individual electronic records. The second pharmacist said that these were reviewed weekly with the team member involved to help identify patterns and areas for improvement. The near miss records were also reviewed monthly by the operations manager, the SI, and other pharmacists. These reviews were not documented. This may mean that any action points raised were not reviewed. The pharmacy team described some changes that had been made to reduce errors, for example, separating out batches to help ensure that the correct batch was dispensed. Dispensing mistakes which had reached a person, or dispensing errors, were documented on an electronic form. The pharmacist described a recent error where the pharmacy had misunderstood a doctor's note on the prescription and had supplied a person with the incorrect formulation. The pharmacist said that the team was now querying any ambiguous notes with the prescriber. Following the inspection, the superintendent pharmacist (SI) said "near miss reviews were done and minutes were captured via email with an action plan and discussions."

The PIP prescribed a range of medications for several conditions including Low Dose Naltrexone (LDN) for the treatment of chronic fatigue syndrome, liothyronine for the treatment of hypothyroidism and antimicrobials for conditions such as Small Intestinal Bacterial Overgrowth (SIBO) and vaginal bacterial overgrowth. The PIP also prescribed medications for weight management for a small number of people and drew on their experience in the management of diabetes within the NHS to support this

prescribing.

There was no prescribing policy or drug formulary. The pharmacy had a SOP for the prescribing service but this did not outline the specific requirements relating to the medicines the service offered to prescribe. The PIP based their prescribing of LDN on guidance from the LDN Research Trust and provided a document titled 'LDN prescriber information' as evidence, which was written by a team working for a private healthcare company based in the United States. This guidance was not formalised in a policy specific to this pharmacy's prescribing service. There was no information on how the diagnosis of this condition could be differentiated between other possible conditions. And it was not clear what monitoring arrangements were required or how this medication could interact with other medicines a patient may be taking, or other medical conditions the patient may have. The evidence cited in this guidance document was published between 7 and 17 years ago, so it was not clear how the pharmacy used the most up to date evidence to support the prescribing of LDN. Prescribing for SIBO was based on a website authored by a nutritionist based overseas. It included dosing instructions for three antibiotics; metronidazole, neomycin and rifaximin but it was not clear from this guidance how the dosages were ascertained and whether they were applicable to patients based in the UK. There was no policy or protocol specific to this pharmacy's prescribing of antibiotics for SIBO. The PIP explained that the reports from laboratories which analysed the tests for SIBO were used to inform prescribing, but it was not outlined in any policy or protocol. It was not clear how antimicrobial prescribing was in line with local microbiological guidance to ensure antimicrobial stewardship. The PIP used NICE guidance to support prescribing of liothyronine for hypothyroidism but this guidance specifically stated 'do not routinely offer liothyronine for primary hypothyroidism, either alone or in combination with levothyroxine, because there is not enough evidence that it offers benefits over levothyroxine monotherapy, and its long-term adverse effects are uncertain.' Guidance produced by a CQC-registered laboratory was used to support the prescribing of antibiotics for vaginal infections. But this guidance focused on the interpretation of the vaginal swab results. It did not outline treatment options, including dosing and duration recommendations and how to ensure antimicrobial stewardship. So it was not clear what evidence or guidance the PIP based their prescribing for vaginal bacterial overgrowth on.

The two regular pharmacists were not entirely sure if the pharmacy had done any risk assessments, including for its unlicensed medicines and prescribing services. Both pharmacists were not familiar with the General Pharmaceutical Council's guidance for registered pharmacies preparing unlicensed medicines. One of the pharmacists said that calculations, use of equipment, and contamination risks were checked by the pharmacist but these checks were not documented. The SI joined the inspection later and showed a thorough risk assessment which covered procurement, packaging, deliveries, the electronic system and more, but this was not dated. Following the inspection, the SI sent a risk assessment, dated April 2023, which covered the preparation of unlicensed medicines and the prescribing service. Risks identified included faults with equipment, cross-contamination, slips, trips and falls, faulty ingredients, changes in key staff, non-medical prescribing outside of competence, risk of having multiple prescribers, lack of patient monitoring and more. The risk assessments did not cover individual risks associated with the medicines that the PIP prescribed. The pharmacy had a previous incident, involving information governance, and the SI described what changes had been made as a result, but the risk assessment had not been updated to take this into consideration. Following the inspection, the SI said "contamination risks were gathered in the batch manufacturing record".

Although the pharmacy had considered the prescribing service in its risk assessment, it did not have any formal approach to monitoring or auditing the service, so it could not demonstrate that controls were in place for each consultation, such as identity checks and access to medical information. The SI said that she regularly reviewed prescribing patterns with the prescribing pharmacist, but these reviews were not documented. As a result, the pharmacy had not identified that the prescribing SOP was not being adhered to. For example, the SOPs stated that the diagnosis and medication list must be within three months but there were examples which showed this was not the case. Following the inspection, the SI said that the diagnosis could be older than three months, but the test results had to have been done within three months. In addition, the SOPs stated that people must give consent to share information with their regular prescribers, but, in practice, the PIP decided this on a case-by-case basis. The pharmacy team was able to communicate with the pharmacist independent prescriber (PIP) to highlight any queries relating to prescribing. And the PIP worked on-site one day a week which facilitated team discussions around prescribing when needed.

The pharmacy had in-date indemnity insurance. The correct responsible pharmacist (RP) notice was displayed. Samples of the RP record were seen to be well maintained. Other records required for the safe provision of services were generally completed in line with requirements. Records about unlicensed medicines prepared by the pharmacy included most of the required information but did not include information about the formula or the source of the formula. The SI said that this information will be included in future records. The records associated with the prescribing service were reviewed by inspectors. Generally, most contained relevant information and it was clear was clear when supplies had been made, and the PIP was able to see this ordering history. Records were available to the dispensing pharmacists to compete their clinical check prior to supply. Some records seen lacked detail about clinical rationale, and this was highlighted to the SI and PIP as an area for improvement. The volume of medicines prescribed by the PIP was relatively low.

People were able to give feedback or raise concerns via several means including telephone, email, by completing an online ‘contact us’ form on the pharmacy’s website, oy by leaving an online review.

All team members had completed data protection training which covered the General Data Protection Regulation. Individual pin numbers and passwords were used to access the pharmacy’s electronic records. The pharmacy had updated its terms and conditions and external prescribers were asked to reset their passwords every 30 days. The system had additional security measures when accessing it outside the premises. The premises were not accessible to members of the public which helped in protected confidential information.

Some members of the team, including one of the regular pharmacists, had not completed safeguarding training. Both regular pharmacists were not sure how to report safeguarding concerns. The customer services team had also not been provided with some relevant training. This may mean that they are not able to identify safeguarding concerns. Following the inspection, the SI sent evidence of safeguarding training which both regular pharmacists had completed post-inspection.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to manage its workload. And team members do some ongoing training in the pharmacy to keep their knowledge and skills up to date. Team members feel comfortable about raising any concerns they have.

Inspector's evidence

The pharmacy was staffed by the SI, two regular pharmacists, three qualified dispensers, five compounders, the head of operations, three customer service assistants, two sales representatives, one marketing staff, two finance and accounting staff and four dispatch assistants. A PIP also worked one day a week in the pharmacy. Team members said there was sufficient staff cover for the services provided. All compounders involved in the preparation of unlicensed medicines had completed in-house training on compounding and were enrolled onto, or had completed, a manufacturing training module from an external training provider.

The PIP's area of expertise was diabetes, but at the pharmacy, she mainly prescribed low dose naltrexone (LDN) for chronic fatigue, liothyronine for hypothyroidism, weight loss injections, and some antibiotics. She completed ongoing training to help keep her skills up to date, including attending conferences and training by the LDN Research Trust, and completing CPPE modules such as antibiotic stewardship. She also completed continuing professional development cycles on various topics including Liothyronine prescribing and compounding.

Both regular pharmacists had completed in-house training about unlicensed medicines. One of the pharmacists had also completed training with an external provider. The SI had done a master's degree about personalised medicine with Tech University. She had specialised in compounding from Spain and had also done some compounding training in Poland and in the USA.

Formal appraisals were carried out annually with all members of the team. Team members said they worked in an open environment and were able to raise concerns to the pharmacists or head of operations. Quality management meeting were held monthly to discuss errors, complaints, any issues, and changes. Meeting minutes were retained for reference.

Team members working at the customer service departments were involved in several elements of the customer journey. They dealt with queries from both members of the public and prescribers. The customer service manager said that people were asked to verify their details before information was shared with them. She handled complaints and described how she would resolve these, including investigating the concern, contacting prescribers, or signposting people to other providers. Customer service team members had been provided with in-house training during their induction period, and this covered data protection, hygiene measures, the electronic system, fire and first aid, waste management and more. They also held regular discussions with the wider pharmacy team, to have a better understanding of compounding and types of medicines the pharmacy supplied. Team members had the option to signpost people to one of the pharmacists if they had clinical queries.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's website gives people information about the pharmacy. The premises are clean, and they are secured from unauthorised access. It provides a suitable space for its services and the premises are well laid out to clearly separate the various departments.

Inspector's evidence

The pharmacy was located within a business centre. The main doors of the business centre were fitted with intercom and kept locked throughout the day. The pharmacy unit was accessed via another door which was kept always locked. A bell was fitted at the door. The pharmacy unit was spacious and comprised of a spacious lab, a staff area, an open area for the pharmacy team, and another area for the customer service team. The dispensary and customer service areas were separated by glass partitions. The team also had access to a meeting pod. The pharmacy was secured against unauthorised access.

Access into the laboratory was via a locked double door. A sticky mat was fitted at the door and the required contamination-minimising clothing, including lab coats, hair nets, face masks and gloves, was stored nearby for easy access. There were designated areas to prepare various preparations. Compounded medicines were prepared in designated laminar flow cabinets. The ambient temperature was suitable for the storage of medicines. There was a cleaning unit inside the lab. Daily and weekly cleaning rotas were in place, and these were signed once cleaning tasks were completed.

Members of the public were not able to select or purchase medicines via the pharmacy's website (rosewaylabs.com). The pharmacy had an online platform where returning customers could order their repeat medication. People were able to book an appointment for a consultation with the PIP via the website. They were asked to complete a form prior to the consultation for the pharmacy to find out what service the person wanted to access. The website provided information about the pharmacy, including its registration number, registered address, contact details and the name of the SI.

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

Summary findings

There are risks with the pharmacy's prescribing service that need addressing, as described under Principle 1, but the pharmacy generally provides its other services safely. It gets its medicine from reputable sources and stores it appropriately. And the team has robust processes in place to check the suitability of ingredients and compounded medicines.

Inspector's evidence

Services were advertised on the pharmacy's website. People were able to contact the pharmacy via the website, by telephone or by email. The pharmacy promoted its services by visiting doctors' practices and exhibiting at trade exhibitions. The regular pharmacists said that the pharmacy supplied medication to people in the UK, parts of Europe, and other countries such as Saudi Arabia. They could not name which European countries the pharmacy supplied to but said that the people accessing the pharmacy's compounding service were required to sign a consent form informing them that the medicines they were being supplied with were unlicensed.

The pharmacy offered an in-house private prescribing service which was led by the PIP. For this service, people were able to book a virtual consultation with the PIP via the pharmacy's website. They were asked to complete a medical questionnaire and submit evidence of a diagnosis from their GP or consultant which was no older than six months. The PIP said that she verified the evidence by checking the prescriber's registration and confirming their clinic details. She said that she had contacted clinics before to confirm the validity of a prescription. Although requested, evidence of where the pharmacy had contacted other prescribers involved in the person's care was not provided during the inspection. People were asked to provide consent to share information with their regular prescriber, though they were able to withdraw consent for some services, for example, when requesting low dose naltrexone. The PIP said that she did not prescribe for people who did not provide consent when requesting weight loss and thyroid medication.

Where the medicine requested was for a medical condition which required ongoing monitoring, such as liothyronine, the PIP required up-to-date blood tests no older than three months old to be provided before they prescribed these medications. For weight management, people had to have a video consultation with the PIP where the PIP assessed suitability of treatment and considered mental health aspects including eating disorders. The lack of formal auditing meant that the pharmacy could not demonstrate that these requirements were always adhered to.

The PIP determined the most appropriate mode of consultation depending on the condition treated and the medication prescribed. For example, the PIP explained they preferred to see people visually when they prescribed medicines for weight management. Whereas they did not feel there was a need for a visual consultation when they prescribed antimicrobials for SIBO or liothyronine for hypothyroidism. These considerations were not included in the pharmacy's risk assessment so there was no formal approach to mode of consultation decisions, and instead these decisions were based on the professional judgement of the PIP. The method of communication was not documented in the person's record which may mean that it could not be audited.

The PIP sometimes prescribed GLP-1 agonists off-label for the management of weight loss, for example Ozempic. And other times they prescribed licenced GLP-1 agonists for weight management, such as Wegovy. Their decision on which medication to prescribe was mainly based on what was available on the market at any given time. There was no consistent approach to this, which made it harder for the pharmacy to show how it was working towards complying with the National Patient Safety Alert issued by the Department of Health and Social Care regarding the off-label use of GLP-1 agonists for weight management. The inspection took place before the deadline of 28 March 2024 stated on the National Patient Safety Alert. Following the inspection, the SI said that the pharmacy tried to switch people to medicines that were licensed for weight loss but the pharmacy still had a small number of people who were still requesting the medicine which was not licensed for weight loss. These people had started their weight loss journey prior to the patient safety alert being issued. The pharmacy was not initiating people on the version which was not licensed for weight loss and the SI said that they were trying to move people on to the licensed versions of the medicine.

Once the pharmacy received a prescription from either an external prescriber or the PIP, the pharmacists conducted a legal and clinical check. Additional checks were carried out, for example, when antibiotics were prescribed, and the pharmacists would check the reason for prescribing and if the person had taken the antibiotic before for a similar concern. The pharmacists said that antibiotics were not supplied to people living outside the UK.

Colour-coded baskets were used throughout the dispensing process to differentiate between the types of prescriptions, for example, urgent orders and compounded preparations. Patient information leaflets were supplied with all medicines, including compounded medicines. These included information on the active and inactive ingredients, how to take the medicine, potential side effects, and how to report side effects. The pharmacists said that they would contact the prescriber if they had any queries about a prescription. Interventions were documented on the person's electronic record.

Following the inspection, the pharmacy sent an example of a quality control check it had conducted on one of its preparations. These involved several checks and tests, for example, checking the appearance of the preparation and testing the weight of a random sample of the product.

When preparing compounded products, the dispensers in the lab were provided with a label containing a batch number. When entered onto the electronic system, the batch number directed the dispensers to the formula. Master formulas were created by the SI, and these could be modified by the regular pharmacists up to a degree (no more than a 1% deviation of the active ingredients) when needed for a prescription for a slightly different strength. When complete, the preparations were stored on designated shelves for the pharmacists to check. They were then sent to the dispatch team who packaged the items and arranged for their delivery.

Medicines were packed in tamper-evident cardboard boxes. Medicines requiring cold storage were packed with ice packs. The SI said that only medicines which did not require cold storage after first use were supplied, such as Ozempic, which could be stored at room temperature for up to six weeks. The pharmacy used the Royal Mail signed-for service when delivering within the UK an DHL when delivering abroad. The pharmacy used an external company to carry out checks on custom requirements when sending medicines outside the UK. If a package was returned, the pharmacy contacted both the person and their prescriber to inform them. The medicine would be disposed of. Missing deliveries were dealt with by the customer service team who recorded the relevant details in a complaints log. These were

reviewed during the monthly management meetings.

The pharmacy used reputable wholesalers to source their medicines and ingredients. It had a validation process in place to ensure that the wholesalers it used were appropriate. This included checking Good Manufacturing Practice certificates, certificates of analysis, and safety data sheets. The pharmacy also checked commercial agreements between wholesalers and delivery companies to ensure that wholesalers could maintain the supply chain. The pharmacy stored its compounding ingredients in a separate storage room in the laboratory. It kept its active, inactive, corrosive, and flammable ingredients separate, and ensured that all were retained in their original packaging. All medicines were marked with their batch number and expiry date. Expiry date checks were carried out weekly and documented. No out of dates were found during the inspection. MHRA alerts and recalls were seen to be received and actioned in a timely manner. Fridge temperatures were checked and recorded daily.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the appropriate equipment to provide its services safely. And it protects people's privacy when using its equipment.

Inspector's evidence

The pharmacy used a range of equipment to prepare its unlicensed medicines, these included: laminar flow cabinets, high and low precision scales, manual and electronic pestle and mortars, encapsulaters, planetary mixers, a conventional oven, a pharmaceutical fridge, and several glass measures. Equipment was serviced and PAT-tested annually. Balances and cabinet hoods were serviced every six months. Computers were password protected.

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.