General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Tabi Health, 126 Queen Street, Hitchin, Hertfordshire, SG4 9TH

Pharmacy reference: 9012163

Type of pharmacy: Community

Date of inspection: 14/10/2024

Pharmacy context

This is a private pharmacy near a town centre in a largely residential area. The pharmacy dispenses medicines against private prescriptions. And it dispenses some unlicensed topical medicines which it prepares on site for various skin conditions. The pharmacy uses patient group directions for a variety of services, including COVID vaccinations, flu vaccinations and travel vaccinations. And it sells some pharmacy-only and general sales list medicines from its online shop. This is the pharmacy's first inspection since it opened in September 2023.

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	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy identifies and manages the risks associated with its services to help provide them safely. It keeps its records up to date and accurate. And it protects people's personal information well. People can provide feedback about the pharmacy's services. And the pharmacy knows how to protect vulnerable people.

Inspector's evidence

The pharmacy had up-to-date standard operating procedures (SOPs). And the pharmacist had signed to show that she had read, understood, and agreed to follow them. The pharmacist was aware of the General Pharmaceutical Council's (GPhC) guidance for registered pharmacies preparing unlicensed medicines. The pharmacy had undertaken several risk assessments for its services, including compounding of unlicensed medicines, blood testing services and pharmacy services at a distance including on the internet.

The pharmacy compounded and supplied a range of topical medicines mainly for the treatment of hyperpigmentation and hyperkeratosis. The medicines contained combinations of ingredients some of which were prescription only medicines (POMs) such as tretinoin and tacrolimus. The medicines were prepared under section 10 of the Medicines Act 1968 which meant the medicines did not hold a UK marketing authorisation or registration and were unlicensed. Therefore, the medicines had not been formally assessed through the licensing process for safety, quality, and efficacy. The pharmacist said that the unlicensed nature of medications was explained to the patient by the prescriber at the time of the consultation. Medicines were supplied against private prescriptions written by consultant dermatologists.

The pharmacist stated that there had only been one near miss since the pharmacy opened. A near miss is where a dispensing mistake was identified before the medicine had reached a person. That near miss had been recorded, and the pharmacist said that if further incidents occurred, she planned to review the near miss record regularly for any patterns in future. The pharmacist was not aware of any dispensing errors, where a dispensing mistake had happened, and the medicine had been supplied to a person. She explained that she would record dispensing errors on a designated form and undertake a root cause analysis.

There was an organised workflow which helped the pharmacist organise the workload. Workspace was free from clutter and baskets were used to minimise the risk of medicines being transferred to a different prescription. The pharmacist initialled dispensing labels when she dispensed and checked each item to show that she had completed these tasks.

The pharmacy had current professional indemnity insurance. The correct responsible pharmacist (RP) notice was clearly displayed, and the RP record was completed correctly. Controlled drug (CD) registers examined were filled in correctly, and the CD running balances were checked at regular intervals. And the private prescription records were completed correctly. Records of unlicensed medicines prepared by the pharmacy had the required information, including information about the formula.

Confidential waste was shredded, computers were password protected and people using the pharmacy

could not see information on the computer screens. People's personal information on bagged items waiting collection could not be viewed by people using the pharmacy. The pharmacist had completed training about protecting people's personal information.

The complaints procedure was available for team members to follow if needed and details about it were available on the pharmacy's website. The pharmacist said that there had not been any complaints. She explained that she would deal with any complaints herself.

The pharmacy had contact details available for agencies who dealt with safeguarding vulnerable people. The pharmacist had completed the Centre for Pharmacy Postgraduate Education training about protecting vulnerable people. She described potential signs that might indicate a safeguarding concern and explained that she would refer any concerns to the relevant authority if needed. She that there had not been any safeguarding concerns at the pharmacy.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacist normally works alone but it able to comfortably manage the workload. The pharmacist keeps their knowledge and skills up to date. They can raise any concerns with the relevant people and can make professional decisions.

Inspector's evidence

The pharmacist normally worked alone. The pharmacy would not open if the pharmacist had not turned up and it would close if the pharmacist had to leave the pharmacy during the day. The pharmacist said that she planned her leave and gave notice to the healthcare providers who used the pharmacy. The pharmacy was up to date with its dispensing.

The pharmacist appeared confident when speaking with people. She was aware of the restrictions on sales of pseudoephedrine-containing products. She explained that she would speak with a person if they regularly requested to purchase medicines which could be misused or may require additional care. And she asked people relevant questions to establish whether the medicines were suitable for the person they were intended for.

The pharmacist was aware of the continuing professional development requirement for professional revalidation. She had recently completed training about flu, COVID training and yellow fever vaccinations. And had undertaken the necessary training for the phlebotomy service. She had completed declarations of competence and consultation skills for the services offered and had done the associated training.

The pharmacist had completed a manufacturing and a compounding course, and training about formulations. And she had worked as a formulator for an unlicensed medicines manufacturer. She kept her knowledge up to date by reading compounding journals, the MHRA orange guide and the handbook of pharmaceutical excipients. And she had completed training in quality assurance procedures.

The pharmacist said that she had peer discussions about new services before providing them. And she could discuss any issues with other pharmacists. She said she could exercise her professional judgement and could comply with her own professional and legal obligations. And she could raise any clinical issues with the prescribers and could refuse to supply a medicine if she felt it was inappropriate. The pharmacy did set any performance targets.

Principle 3 - Premises ✔ Standards met

Summary findings

People can have a conversation with a team member in a private area. The premises provide a safe, secure, and clean environment for the pharmacy's services.

Inspector's evidence

The pharmacy was secured against unauthorised access. It was bright, clean, and tidy throughout which presented a professional image. And pharmacy-only medicines were kept behind the counter. Air conditioning was available, and the room temperature was suitable for storing medicines. Toilet facilities were clean and not used for storing pharmacy items. And there were separate hand washing facilities available. The unlicensed medicines were prepared in a room separate to the dispensary. There was a kitchen area and a dishwasher available to clean equipment. The pharmacy was regularly cleaned, and records were kept.

There was seating in the shop area for people waiting for services. The consultation room was accessible to wheelchair users and was in the shop area. It was suitably equipped but the window was see-through. The pharmacist explained that she had arranged for this to be covered. But she currently asked people to sit out of view to protect their privacy if needed. Conversations at a normal level of volume in the consultation room could not be heard from the shop area. And the room was kept locked when not in use. The pharmacist explained that a bell sounded when the door to the pharmacy was opened. And this made her aware that there was a person in the shop area when she was in the consultation room.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy provides its services safely and manages them well. The pharmacy gets its medicines from accredited suppliers and stores them properly. It responds appropriately to drug alerts and product recalls. This helps make sure that its medicines and devices are safe for people to use. People with a range of needs can access the pharmacy's services.

Inspector's evidence

There was step-free access into the pharmacy through a wide entrance and an alarm sounded when the door was opened. Services and opening times were clearly advertised on the pharmacy's website and at the pharmacy. And a variety of health information was available. The pharmacy's website showed the details of the pharmacist and the pharmacy's GPhC registration number. The pharmacy's contact details were available on the pharmacy's website.

The pharmacist had undertaken the necessary training for the phlebotomy service. Samples were sent to the laboratory via a courier using a same day delivery service. People were sent their results and could contact the pharmacy if needed.

The pharmacy offered for sale some pharmacy-only and general sales list medicines for sale via its website. The pharmacy only supplied these medicines to UK addresses. The pharmacist explained that she reviewed each consultation before supplying pharmacy-only medicines. She had recently quarantined an order where the person had requested two packs of a medicine which had potential for misuse. The pharmacist said that she would contact the person to ensure that it was suitable before making the supply. But only one pack would be supplied, and a refund would be given for the second pack. The pharmacy kept records of any communication and refused sales. People could not add a pharmacy-only medicine to their basket without completing consultation form first. The pharmacy used an external software provider to detect multiple purchases from the same address, similar spelling of names and where a person had used the same bank card for different addresses. ID checks were undertaken to prove a person's age and address. And the pharmacy checked a person's purchasing history before making supplies.

There were signed in-date patient group directions available for the relevant services offered. The pharmacist explained that she spoke with people about their medicines if they collected them from the pharmacy in person. She said that the pharmacy had not dispensed any higher-risk medicines such as warfarin or lithium. But she would check monitoring record books for people taking these medicines and keep a record of blood test results. The pharmacy had not supplied valproate medicines since opening. The pharmacist said that she would refer people to their GP if they needed to be on the Pregnancy Prevention Programme and weren't on one. And these medicines would be supplied in their original packaging.

The pharmacy used licensed wholesalers to obtain medical devices and licensed medicines. Drug alerts and recalls were received from the MHRA. The pharmacist explained the action the pharmacy took in response to any alerts or recalls. But the pharmacy did not keep a record of any action taken, which could make it harder for the pharmacy to show what it had done in response. The pharmacist said that she would keep a record of any action taken in future.

Stock was stored in an organised manner in the dispensary. Expiry dates were checked regularly and this activity was recorded. Stock medicines due to expire within the next three months were highlighted. A random sample of stock medicines were checked and no date-expired items were found. All stock medicines were kept in their original packaging.

The pharmacy had a few uncollected prescriptions. The pharmacist explained that she regularly attempted to contact people before the prescription expired. Any items remaining uncollected after a prescription expired would be returned to dispensing stock where possible and the prescription was retained at the pharmacy. The pharmacy did not have any part-dispensed prescriptions due to the pharmacy only ordering stock when a prescription was received.

CDs were stored in a CD cabinet and denaturing kits were available for their safe destruction. The pharmacist explained that the pharmacy did not keep stock of CDs and ordered these when a person presented a prescription. The pharmacy had not received any returned CDs since it opened. The pharmacist said that if any were received, they would be recorded and destroyed with a witness. Fridge temperatures were checked daily, and maximum and minimum temperatures were recorded. Records indicated that the temperatures were consistently within the recommended range. The fridge was suitable for storing medicines and was not overstocked.

Ingredients were purchased from authorised suppliers. Certificates of Analysis (CoA) and transmissible spongiform encephalopathy (TSE) records were received for every batch ordered. Medicines were prepared for each prescription and not in batches. Worksheets were prepared by the pharmacist before compounding a product. The required ingredients were collected for each production and the products were checked against the CoA. A dispensing label was created by the pharmacy and contained the name of medicine, directions for use, batch number, expiry date and the pharmacy's details.

The ingredients were weighed by the pharmacist, and she carried out a second check before compounding the medicines. Ingredients were added according to the formula and mixed using the relevant equipment such as ointment slab, pestle and mortar or electric mixer. The pharmacist took a break between compounding the medicine dispensing it. And she carried out quality and texture checks, including colour and odour throughout the manufacturing process and at the end. Duplicate medicine labels were attached to batch sheets so that people could be contacted if there was an issue with a particular batch. The pharmacist said that there had not been any issues with the compounding process, but she would keep records of these if needed. The pharmacist referred to information from various sources and used her professional judgement when applying expiry dates to unlicensed medicines prepared at the pharmacy.

When dispensing the preparations, the pharmacist added the dispensing label to the filled container and checked the label and medicine against the worksheet. She then took a break before carrying out a final accuracy check. The worksheet and medication labels were used to dispense and check against during the dispensing process. And the prescriptions were routinely used as reference during the dispensing and checking processed. The dispensing label was not generated directly from the prescription. The pharmacy's computer auto populated the dispensing label with the product name and quantity selected from a drop-down menu. The pharmacist added the patient's name, batch number and expiry date manually. .

Medicines were sent using a courier using next day delivery and signed for. And the medicines would not be posted through people's letter boxes. People were notified once their treatment was dispatched. The pharmacist said that there had not been any medicines returned to the pharmacy. And

explained that these would be treated as waste medicines and would not be re-used.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely. It uses its equipment to help protect people’s personal information.

Inspector's evidence

Up-to-date reference sources were available online. Suitable equipment for measuring liquids was available. The pharmacy did not have a triangle tablet counter available. The pharmacist said that the pharmacy had not yet needed to count loose tablets, but she would ensure one was ordered. The blood pressure monitor, patient weighing scales and shredder appeared to be in good working order. The phone in the dispensary was portable so it could be taken to a more private area where needed.

The pharmacist wore a laboratory coat, disposable mask, gloves, and hair covering while compounding medicines. She said that these were disposed of after each production. Scoops, spoons, spatulas, and electric mixer were cleaned with soap and water, and alcohol after each use. And the work surfaces in the compounding room were cleaned regularly. The digital weighing scales were calibrated every three months using calibrated weights. Records were kept for cleaning and calibration of equipment.

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.