General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Burwash Pharmacy, 9 Burwash Road, HOVE, East Sussex, BN3 8GP

Pharmacy reference: 1107887

Type of pharmacy: Community

Date of inspection: 21/08/2023

Pharmacy context

This is a community pharmacy in a largely residential area of Hove. It mainly offers NHS services such as dispensing. And it assembles medicines into multi-compartment compliance packs for some people who need this level of support. It delivers medicines to some people in their own homes. And it offers a prescribing service both onsite and via its website. It provides other services such as a travel clinic and ear wax removal. Enforcement action has been taken against this pharmacy, which remains in force at the time of this inspection, and there are restrictions on the provision of some services. The enforcement action taken allows the pharmacy to continue providing other services, which are not affected by the restrictions imposed. The inspection was undertaken over two days, on 21 and 23 August 2023.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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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 adequately identify and manage the risks associated with its services, particularly its face-to-face and online prescribing services. It does not sufficiently monitor the safety and quality of its prescribing service. And the notes it keeps for this service do not always contain the relevant information. Taken together, these increase the risks to people using this service.
		1.2	Standard not met	The pharmacy cannot sufficiently demonstrate that it monitors the safety and quality of its prescribing service, for example by undertaking and documenting regular clinical audits.
		1.6	Standard not met	The pharmacy's consultation notes for its prescribing service do not always contain the relevant information.
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 not all met**

Summary findings

The pharmacy does not adequately identify and manage the risks associated with its services, particularly its face-to-face and online prescribing services. It cannot sufficiently demonstrate that it monitors the safety and quality of its prescribing service, for example by undertaking and documenting regular clinical audits. Its consultation notes for this service do not always contain the relevant information. However, otherwise the pharmacy generally keeps the records it needs to, and largely protects people's personal information. Team members know how to safeguard the welfare of a vulnerable person. And people using the pharmacy can provide feedback and raise concerns.

Inspector's evidence

The superintendent pharmacist (SI) was a pharmacist independent prescriber (PIP), and the sole prescriber for the pharmacy. There was a range of standard operating procedures (SOPs), and team members confirmed that they were familiar with them. There were some SOPs for the online prescribing service, but these largely related to Saxenda. There were no SOPs found which directly related to the range of prescription-only treatments the pharmacy supplied via its website. However, the SI sent through a copy of an SOP for this service. The SOP was a single page, and it was dated effective from 24 August 2023 (after the inspection). It set out how team members would dispense a prescriptions issued as part of the online prescribing service. It described how dispensary staff would retrieve the prescription and dispense it. But it did not include further details, for example how a person's regular prescriber would be informed or how consent for this would be obtained. Following the inspection, the SI said that she would inform people's regular prescriber when she had consent to do so. She provided examples of emails sent to people's GPs. The examples seen included the person's name and the medicine prescribed, but not the dose of the medicine, which could make the emails less useful to people's regular prescribers.

The SI, who was also the pharmacist independent prescriber (PIP) was present on the second day of the inspection. She described how the website was still operational, but there were very few orders received in practice. The SI issued prescriptions in response to questionnaires people filled in on the website. During the inspection, she was unable to show the responses to the questionnaires people had given due to limitations with the computer system. But examples of people's responses were provided following the inspection. The responses had all the same date, and the SI indicated this is when she had printed them off. This made it harder to see when the actual supplies had been made. The website offered a limited range of topical and oral antibiotic treatments for acne. But following the inspection, the SI confirmed that the only treatments for acne the pharmacy had supplied via the website was azelaic acid, which is not an antibiotic.

The pharmacy offered a range of medicines online, including ones for erectile dysfunction, hair loss, genital warts, period delay, and migraine. The website also offered a limited range of topical and oral antibiotic treatments for acne. But following the inspection, the SI confirmed that the only treatments for acne the pharmacy had supplied via the website was azelaic acid, which is not an antibiotic. The pharmacy had not undertaken risk assessments before providing the range of medicines offered on its website. Following the inspection, the SI provided risk assessments for a range of medical conditions the pharmacy offered prescription-only and over-the-counter treatment for on its website. The documents evidenced some consideration of the risks surrounding the medicines prescribed. But there

was no consideration of the likelihood or consequences of the risks, or that the risks of providing the pharmacy's services at a distance had been sufficiently considered. And some aspects of the service did not seem to have been considered, such as access to medical history, follow-up, and communication with others involved in the care of the person.

The private prescription register indicated that the pharmacy had dispensed eight private prescriptions written by the SI since 1 May 2023. The SI was unable to produce the associated consultation notes during the inspection and said that the records may be offsite because of the refit. Following the inspection, the SI sent consultation notes for the entries seen. The notes varied in detail but often lacked key information, such as the history of the presenting complaint, exclusion of red flags, differential diagnoses, and monitoring and follow-up. They also did not always include key information about of the prescribed medication such as the dose, quantity, or strength. And on a few, a note was made that the person's blood pressure had been taken but the reading had not been recorded. It was not clear from some of the records how the diagnosis had been reached and how other potentially more serious conditions had been excluded. In response to the draft report, the SI did provide additional information for several of the consultations including checks she had made. But these additional details had not been present in the original consultation notes.

The pharmacy had previously undertaken a clinical audit of the prescribing service but this was over a year ago. No clinical audits of the prescribing service had been done since then. And the pharmacy's SOPs indicated that a clinical audit be undertaken every three months. The SI said that this was because the pharmacy was no longer prescribing Saxenda. But it was still prescribing other medicines, and not having regular audits made it harder for the pharmacy to demonstrate that the prescribing service was safe and effective. Following the inspection, the SI confirmed that she had discussions with another prescriber roughly twice a year, and sometimes more frequently. She explained that the discussions included recent consultations she had undertaken, and said that they had reviewed her prescribing. But the SI provided no documentation or further details about this review. When asked for records of what was discussed, she explained that the records were kept on the phone and only provided an example of a phone message which appeared to relate to one person. There was no documentation provided to indicate that an overall review of the pharmacy's prescribing service took place.

At the previous inspection, the pharmacy had been using a third-party ID checking service, but this had now been stopped. The SI said it was because the pharmacy did not need it anymore. She explained how when someone requested a prescription via the questionnaire on the website, she asked them to show ID on the video calls she had with them. But notes were not made about the video calls, so the pharmacy was unable to demonstrate what had been discussed. And it meant that it was harder for the pharmacy to be able to audit the service.

Pharmacy team members recorded any mistakes that were highlighted to them during the final check process, also known as near misses. The team member that made the mistake would record it so that they can use it as a learning process. A lead dispenser was in charge of analysing the near misses to identify any common mistakes. They had created a presentation, following an audit, to support team discussion looking at the trends and ways to reduce mistakes from happening. It was recently highlighted that the quality of recording was not at the expected level, so all team members were reminded to complete the record in full. The near miss records for August 2023 showed that there was a pattern of date-expired medicines being picked during the dispensing process. And the apprentice technician explained that this had been discussed in the team.

The right RP notice was displayed on the first day of the inspection, but the wrong one was displayed on the second day. This was rectified immediately. The RP record had several entries where the RP had not

signed out, which could make it harder for the pharmacy to show who the RP had been if there was a query. Controlled drug (CD) registers seen were generally kept in accordance with requirements, and the CD running balances were checked frequently. The physical quantities of two CDs selected at random were checked and matched the recorded balances in the CD registers. CDs that people had returned were recorded and an audit trail was kept of when they had been destroyed. Records for unlicensed medicines and private prescriptions dispensed were generally maintained appropriately.

There was a complaint procedure for staff to follow, and people could provide feedback or raise concerns via several routes including in person, on the phone, or via the website. Online reviews seen were generally very positive. The pharmacy had current indemnity insurance.

No confidential information was visible from the public area, and dispensed prescriptions awaiting collection were stored in a way which protected those people's personal details. A shredder was used to dispose of confidential waste. There was some sharing of NHS smartcards and two team members had not yet received their smartcards. This was discussed with the team during the inspection. On the first day of the inspection, one of the team members (who was not a prescriber) was able to show the backend of the prescribing system on the pharmacy computer. When opened, it included a button to 'process' and from previous inspections this potentially gave the team member the ability to issue a prescription. However, there was no evidence that a non-prescribing team member had ever done this. Following the inspection, the SI provided assurances that the system would be signed out if she was not present. And provided evidence to show that non-prescribing team members did not have access to the 'process' button using their login details.

One of the team members was able to describe the training they had done about safeguarding and what they would do if they had any concerns. The pharmacists seen confirmed they had undertaken safeguarding training and they could also describe what they would do if they had any concerns. Team members were aware of the 'Ask for ANI' initiative to help protect vulnerable people.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough trained team members to keep up to date with its workload. Staff do some ongoing training to help keep their knowledge and skills up to date. And they feel comfortable about raising any concerns.

Inspector's evidence

On the first day of the inspection, there was a regular pharmacist, an apprentice technician, one trained dispenser, and two foundation trainee pharmacists. On the second day there were the same staff except the SI was present instead of the regular pharmacist, and there was also a person on work experience. This person had only been at the pharmacy for a short time and was due to start an MPharm course next month. This person said she was involved in putting stock away and sometimes handing out bags of dispensed medicines. She said that she was supervised at all times, and this was observed during the inspection. Team members were up to date with their workload.

A team member described how they received training modules from a training provider around every two months, which the team then completed and had a meeting afterwards to discuss. One of the dispensers was able to show the certificate he had received after completing training about earwax removal. And he was the main person responsible for this service. Team members felt comfortable about raising any concerns, and the SI often worked at the pharmacy and was easily contactable. Staff were not set any numerical targets to achieve.

The SI said that her clinical specialisms were initially in respiratory conditions, and then she had undertaken further training about travel medications. She said that when the pharmacy's websites had been set up around three or four years ago, she felt confident to prescribe for the range of medical conditions listed on the website. This included genital herpes and erectile dysfunction. And she said she kept up to date with medicines that had moved to pharmacy-only medicines from prescription-only status and read the patient group directions for medicines that could be supplied under them to increase her knowledge.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are generally clean and tidy, and they are secure from unauthorised access when closed. People can have a conversation with a team member in a private area.

Inspector's evidence

The premises had changed since the previous inspection. Previously, the unit next door had been mainly used as a storage area, and the entrance to this unit had been sealed. This unit had now been refitted to include several consultation rooms, and the entrance to it was now unsealed. So, this had changed the address of the pharmacy. There was still an internal interconnecting door between the pharmacy and the refitted unit. The change in floorplan had not been discussed with the GPhC prior to change of use. The consultation rooms were not being used to provide registrable activities and were instead being used to provide services such as ear wax removal and laser hair removal. This was discussed with the SI, who emailed the GPhC premises team following the inspection.

The premises were generally clean and tidy, with adequate space for safe dispensing. Shelves which held medicines were organised to minimise the risk of mistakes. There was a consultation room in the pharmacy which provided an adequate level of privacy if someone wanted to talk with a team member in private. And there were several consultation rooms available in the adjacent premises. The premises were secure from unauthorised access when closed. The pharmacy had clear plastic screens protecting the counter, to help control the spread of infection. There was a sink in the dispensary area with both hot and cold-water supplies. This was suitable for preparing liquid medicines if needed. The premises maintained a suitable temperature and had adequate lighting to allow safe working.

The pharmacy had two websites. The first was burwashpharmacy.co.uk (main pharmacy website) and contained details about the services the pharmacy provided. The second was burwashpharmacymeds.co.uk website and this listed the SI's details and the details of the registered pharmacy. This second website offered prescription-only treatments for a range of medical conditions. People could click on an individual prescription-only medicine (POM), but then were taken back to the medical condition page before a consultation could be started. Both websites contained references to weight-loss medicines which the pharmacy was currently prevented from supplying due to the conditions in place on it. The first website had a link to Saxenda, which then took people through to a consultation form. The second website had links to oral weight-loss medicines. This could be misleading to people using the pharmacy's websites. However, there was no evidence found during the inspection that the pharmacy had supplied weight-loss medicines in breach of the conditions placed on it. Following the inspection, references to weight loss were removed from the main pharmacy website.

Principle 4 - Services ✔ Standards met

Summary findings

There are some issues as described under Principle 1 about the pharmacy's prescribing service, but on the whole the pharmacy provides its other services safely. People can access the pharmacy's services. Team members take the right action in response to drug alerts and recalls. The pharmacy gets its medicines from reputable sources and generally stores them properly. But it does not always remove date-expired medicines from stock in a timely way. So, this may increase the chance that people receive a medicine which is not suitable to use.

Inspector's evidence

The pharmacy had step-free access from the street. And there was just enough space for people with wheelchairs or pushchairs to manoeuvre. There was a small selection of leaflets in the public area, and there were some signs in the front window to inform people about the services the pharmacy provided. People could also access some services online through the pharmacy's websites.

The pharmacy assembled medicines into multi-compartment compliance packs for some people. The packs were labelled with a description of the medicines inside, but this was not always accurate. This was discussed with team members , and they said that they would ensure the correct descriptions were on the packs in future. Staff initialled the labels to provide an audit trail. Patient information leaflets were usually supplied with the packs, but this was not always the case. This could mean that people might not have all the information they need to be able to take their medicines safely.

The pharmacy delivered medicines to some people's homes and kept an audit trail to show what had been delivered. Signatures were not obtained from recipients to help with infection control. And if a person was not at home, the medicines were returned to the pharmacy.

Team members were aware of the additional guidance about pregnancy prevention for some people taking valproate medicines. They were not aware of any people who were currently in the at-risk group, and they could show where they would put the dispensing labels on the original packs. They could not locate any spare stickers for use with split packs, and the apprentice technician said that she would order more in from the manufacturer. Prescriptions for Schedule 3 and 4 CDs were not always highlighted, which could make it harder for the team member to know if the prescription was still valid when handing out. The apprentice technician explained how prescriptions for other higher-risk medicines were highlighted. There were no examples found in the current medicines awaiting collection.

The pharmacy obtained its medicines from licensed wholesale dealers and specials suppliers and stored them in a largely organised way. The dispenser gave an example of a medicine which had been sent incorrectly by the wholesaler and explained how he would return it. Medicines people had returned, and date-expired medicines were appropriately separated from stock before they were sent offsite for disposal.

The pharmacy team had a process to check the dates of its medicines on a regular basis though there was some evidence that medicines were not always removed from dispensing stock in a timely way. Sections were created in the dispensary, and these were usually checked weekly on a rolling basis.

Records of date checking, and who checked the medicines, were kept. The team member carrying out the checks would highlight the expiry date on the box and record any short-dated medicines in the date checking folder under the month that it was due to expire. They would then remove these medicines off the shelf each month. A random spot check of stock was carried out and a few expired medicines were identified, this was brought to the attention of one of the dispensers who then quarantined the items.

The pharmacy had three pharmaceutical fridges for storing medication that required cold storage. Temperature records for all three fridges were being made daily. The temperatures of all three fridges were found to be in range. There was a record made where the temperature of one of the fridges had exceeded the upper limit and no additional information was noted to explain the reason why. One of the team members explained that the door had been replaced and therefore the temperature was higher than it should be. The team were advised to make a note of any deviations from the normal temperature range as an audit trail. CD stock was held securely and stored in an orderly way. Medicines used for substance misuse were kept in separate baskets for each patient, together with the prescription to help prevent any mistakes.

The SI described how the regular pharmacist administered vaccinations under patient group directions (PGDs). And following the inspection, sent through a range of in-date and signed PGDs and patient specific directions along with evidence that the regular pharmacist had undertaken relevant training. The SI said that she did not use the PGDs as she was a prescriber, and showed the notes she kept whenever she administered a vaccination. These notes included details about the patient, where they were travelling, relevant medical history, and the batch number and name of the vaccination given.

Team members could describe what action they took in response to any drug alerts or recalls. But they did not keep a record of the action taken, which could make it harder for the pharmacy to show what it had done in response.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs for its services. And it uses its equipment in a way which helps protect people's personal information.

Inspector's evidence

Calibrated glass measures for measuring liquids were available and were appropriately calibrated. Tablet and capsule counting equipment was clean, and a separate counting triangle was used to count cytotoxic medicines to help avoid cross-contamination. Staff had access to up-to-date reference sources in both paper and digital formats. The phones were cordless and could be moved somewhere more private to help protect people's personal information. There was sanitising hand gel available for the staff to use. There was a suitable staff room area with toilet and hand washing facilities. Following the inspection, the SI confirmed that anaphylaxis kits were available in the consultation room for use with vaccinations.

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.