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: 18/06/2021

Pharmacy context

This is a community pharmacy in a largely residential area. It dispenses NHS prescriptions. And it dispenses medications into multi-compartment compliance packs for some people who need help managing their medicines. The inspection was undertaken during the Covid-19 pandemic. Due to the pandemic, the pharmacy is not offering its travel vaccination service. The pharmacy provides a private prescribing service both for people coming into the pharmacy and, more commonly, online. And through this service it supplies medicines to people living in the UK and other countries such as Canada, Australia, and countries in the EU.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; Statutory Enforcement

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 doesn’t adequately identify and manage the risks associated with its prescribing service, particularly the prescribing and supply of medicines online. It hasn't undertaken a robust risk assessment before providing its services at a distance. And it hasn't considered and put in place appropriate measures to manage all the risks associated with the range of medicines it provides.
		1.1	Standard not met	The pharmacy supplies weight loss products at a distance and doesn't sufficiently identify and mitigate the risks associated with this service.
		1.2	Standard not met	The pharmacy doesn't monitor the safety and quality of its prescribing service, for example by doing regular clinical audits.
		1.5	Standard not met	The pharmacy sends medicines overseas and cannot demonstrate that it has appropriate indemnity insurance to cover this activity.
		1.6	Standard not met	The pharmacy's record keeping for its prescribing service is poor; some records can be changed with no audit trail, and access to the prescribing system is not well controlled. So, the records don't provide a reliable record about the services provided to people. The pharmacy doesn't maintain a record of clinical decisions in relation to its prescribing service. The pharmacy doesn't always record private prescriptions it dispenses in line with requirements. And it doesn't ensure that private prescriptions it issues as part of its prescribing service contain all the required information.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy’s websites allow people to choose a prescription-only medicine before a consultation with a prescriber. People filling in questionnaires on the website for some medicines are prompted when an answer would result in a request being

Principle	Principle finding	Exception standard reference	Notable practice	Why
				rejected. And the pharmacy and prescriber aren't notified if people change their answers in this way. These weaknesses all increase the risk that people receive treatment which is not clinically appropriate.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy doesn’t always provide its prescribing service safely, particularly the prescribing and supply of medicines online. It doesn’t proactively inform people’s regular doctor after they receive a treatment for conditions which require ongoing monitoring. It doesn’t always make sure people understand how to use the medicines it supplies. And it doesn’t routinely check the identification of people ordering prescription-only medicines online. This increases the risks of supplying medicines to people who are underage or when not clinically appropriate.
		4.2	Standard not met	The pharmacy doesn’t provide sufficient counselling information to people obtaining Saxenda online. It doesn't proactively check that people know how to use the medicine, or what dose they are taking.
		4.3	Standard not met	The pharmacy sends out medicines which require cold storage to people living in the UK and abroad. But it cannot provide sufficient assurances that the medicines are always kept at the right temperature during transit.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy doesn't adequately identify and manage the risks associated with its prescribing service. It doesn't monitor the safety and quality of this service, for example by undertaking regular clinical audits. Its record keeping for this service is poor, and some records can be changed with no audit trail. So, the records do not provide an indelible record which can be relied upon. And the prescriber is unable to readily analyse and learn from information that is recorded to improve the service provided to people. The pharmacy sends medicines overseas and cannot demonstrate that it has appropriate indemnity insurance to cover this activity. However, the pharmacy's other services are generally provided safely. Staff know how to safeguard vulnerable people who come into the pharmacy. And team members dispose of confidential waste appropriately.

Inspector's evidence

The pharmacy offered an NHS dispensing service. And it provided a private prescribing service which people could walk into the pharmacy for, or more commonly, access online through the pharmacy's websites. Medical conditions prescribed for included weight loss (Saxenda, orlistat), asthma (Ventolin), erectile dysfunction, and malaria prevention. The superintendent pharmacist (SI), who was a qualified pharmacist independent prescriber (PIP), was the sole prescriber for the private prescribing service. She referred to the individual questionnaires people completed on the website as 'risk assessments'. But no formalised risk assessments had been undertaken by the pharmacy for the prescribing service, or the supply of medicines overseas, or for providing its services at a distance in general. Medicines such as Saxenda required additional measures such as cold storage during transport, and there was no documentary evidence to demonstrate that the risks around this had been appropriately considered. People using the private prescribing service via the website filled in questionnaires to request a product, and there was no face-to-face interaction. This meant that for weight-loss products the PIP was unable to make a visual assessment of a person's weight to help inform their prescribing decision. Following the inspection, the SI sent a risk assessment which had been done for the 'on-line doctor service'. But this took the form of a checklist rather than fully considering the individual risks of the service. For example, under 'managing patient factors', one risk which had been identified was 'Check patient knows how to use the products?', and this had been addressed by 'Include a patient information leaflet with each product'.

People could request prescription-only medicines online by filling in a questionnaire on the website. The questionnaires were not protected. The completed questionnaires could be accessed on a computer terminal in the pharmacy to which all staff had access. The answers the person had given could be changed by staff and there was no means of detecting if this happened. The SI said that she approved or otherwise each request and would do this at the pharmacy or off-site. If the request was approved, an electronic prescription was generated on the computer system. However, these prescriptions did not contain a valid signature, and did not always include the prescriber's details. Staff had access to the prescribing system when the SI (who was the only prescriber) was not present in the pharmacy, as happened during the first part of the inspection. And there were no robust systems to stop any member of staff potentially authorising a supply of a prescription-only medicine. Following the inspection, the SI said that the answers people gave on the questionnaires were able to be changed in case a person phoned the pharmacy to say that they had made a mistake in their answers.

No regular audits were done on the prescribing service, so the pharmacy was unable to demonstrate how it monitored the safety and quality of this service. One of the computer terminals was kept signed into the pharmacy's prescribing system, and staff were able to show the records on it. The staff were not able to provide a complete audit of what had been prescribed and supplied for which people, other than the information which could be found by going into each person's individual record. Records of prescriptions dispensed from the online prescribing service were not found to be recorded in the pharmacy's main private prescription record. The SI was asked for the prescribing records for the last three months' worth of prescriptions but was unable to provide this. Although she did say that she would check with her IT provider to try and obtain it. From the limited records available, the most commonly prescribed item was Saxenda, and for one day seen there had been around 80 supplies approved for it on that day. The computer system had a facility to record 'notes' for each supply, but none of the entries seen had any notes attached. There were no records of prescribing decisions found.

In relation to other pharmacy activities, there was some evidence that risks were managed, reviewed, and monitored. The SI confirmed that a risk assessment had been done for staff in relation to Covid-19. Staff were seen wearing masks in the public area, and hand sanitising gel was available. Dispensing mistakes which were identified in the pharmacy before the medicine had reached someone (near misses) were recorded in a book in the dispensary. Most of the records of near misses seen had been completed thoroughly and included steps that would be taken to help prevent a recurrence. A near miss had occurred between sertraline and sildenafil, and as a result the two medicines had been separated on the shelves. Dispensing mistakes which had reached a person (dispensing errors) were shown to be recorded in separate documents. Staff confirmed that the SI went through and reviewed near misses and dispensing errors and provided them with feedback on an ongoing basis. But the reviews were not formally documented.

A range of standard operating procedures (SOPs) was present, but some were overdue for review. This could mean that they did not reflect current best practice or the pharmacy's current practices. Staff had generally read and signed the SOPs relevant to their roles. No SOPs were found for the supplies the pharmacy made online, for example for the supplies of Saxenda. Following the inspection, the SI said that Saxenda had been present, but that the staff initially present at the start of the inspection did not generally deal with the Saxenda service and had not been aware of them.

Staff could describe their own roles and responsibilities clearly. Of the staff present during the inspection, only the SI had significant involvement with the prescribing and online supply part of the business. Although some other staff had limited knowledge of it. The apprentice pharmacy technician was clear about what she could and couldn't do if the responsible pharmacist (RP) was not present.

The pharmacy had previously undertaken an annual patient survey, but this had paused during the pandemic. The survey for the current year had just arrived in, and the staff were intending to hand out sheets to people who used the pharmacy. Team members said that people usually provided feedback verbally. And people could leave feedback via the pharmacy's website. Staff were not aware of any recent complaints which had not been resolved quickly.

The pharmacy had previously supplied prescription-only medicines (usually Saxenda) to the USA. But the SI said that this had stopped around the middle of May 2021 and this had been due to a business decision. She said that the pharmacy still supplied medicines to English-speaking countries such as Canada and Australia, and to countries in Europe. The pharmacy had indemnity insurance but the certificate on display had expired. Following the inspection, the pharmacy's indemnity insurer confirmed that the pharmacy had current insurance. However, the indemnity insurer confirmed that

the policy did not cover any indemnity claims which were made in the USA or Canada. The SI explained that the pharmacy had only used the same indemnity insurance provider in the past.

The right RP notice was displayed. The RP record had mostly been filled in correctly, but on some days the SI came in before the pharmacy opened to dispense medicines for the online service. And usually did not sign into the record. So, this could make it harder for the pharmacy to show who had been responsible for the activity if there were any future queries. The SI said that she would sign into the RP record in the future if this situation occurred. Records about private prescriptions from external prescribers that the pharmacy had dispensed complied with requirements. Some records about emergency supplies did not contain a clear reason as to the nature of the emergency. So, it could be harder for the pharmacy to show why the prescription-only medicine had been supplied. Entries in controlled drug (CD) registers seen had been made correctly. CD running balances were checked regularly. And a random check of a CD medicine showed that the amount of physical stock matched the recorded balance.

No confidential information could be seen from the public area. Confidential waste was destroyed in a shredder. The SI's NHS smartcard was found in a computer terminal which other staff were using. The RP had his own smartcard, but other staff did not. Following the inspection, the SI confirmed that she was in the process of ensuring the other staff obtained their own smartcards.

The RP confirmed he had completed level 2 safeguarding training. And staff could describe what they would do if they had a concern about the welfare of a vulnerable person who came into the pharmacy. The apprentice technician had previously worked in a role in social care and was clear about how the pharmacy could help safeguard people. She gave an example of a vulnerable person who the pharmacy had helped.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough trained staff to provide its services. Staff do ongoing training to help keep their knowledge and skills up to date. And they feel comfortable about raising any concerns or making suggestions.

Inspector's evidence

At the time of the inspection there was one pharmacist (who worked there one day a week), one trainee pharmacist, and an apprentice pharmacy technician. And another member of staff who had started work in the pharmacy the previous day and was looking to start as a trainee pharmacist. Later in the inspection, a trained dispenser and then the SI arrived into the pharmacy. The team was up to date with its workload.

The online side of the business was run from a large room adjacent to the main pharmacy. The SI and two other members of staff (who were not present) managed and ran the online medicine supply service. The SI confirmed that one of these was a trained dispenser, and the other team member was untrained but only did logistics and did not undertake any dispensing activity. Other staff working in the main pharmacy had little involvement with the online prescribing service. The RP was not generally involved in the online service. But said that couriers sometimes came to collect packages for delivery to people who had ordered medicines online. This sometimes happened when the SI was not present. The RP knew they were packages of Saxenda but otherwise had little awareness of what was inside them. This was discussed with the RP during the inspection.

Staff received ongoing training, and they had recently completed a package about suicide prevention. Some records were made of the ongoing training staff had done, and the staff said that the SI also regularly gave them information, such as new products and changes in services. The SI said that she had initially trained in respiratory conditions and had then undertaken further training on other areas such as Saxenda for weight loss.

Staff were comfortable about raising any concerns and felt able to make suggestions. They said that if any dispensing mistakes occurred, they openly discussed this in the team. There were no targets in place for team members.

Principle 3 - Premises **Standards not all met**

Summary findings

The pharmacy's websites allow people to choose a prescription-only medicine before a consultation with a prescriber. People filling in questionnaires on the website for some medicines are prompted when an answer would result in a request being rejected. And the pharmacy and prescriber are not notified if people change their answers in this way. These weaknesses all increase the risk that people receive treatment which is not clinically appropriate. The pharmacy's website is not always accurate. However, the pharmacy's premises are secure and largely suitable for the pharmacy's services. People can have a conversation with a team member in a private area.

Inspector's evidence

The pharmacy offered a prescribing service for Saxenda from its main website (www.burwashpharmacy.co.uk) and from another website (burwashmedsdirect.co.uk) for a range of conditions such as erectile dysfunction, weight loss, asthma, genital herpes, and hair loss. The consultation was primarily based on a person completing an online questionnaire. The websites allowed a person to choose a prescription-only medicine (POM) before a consultation. For example, people could choose and go to the page for 'Ventolin Asthma Inhaler' before a consultation with a prescriber.

For some medicines, the questionnaire people filled in highlighted in red answers that would result in a supply not being made. And people could change these answers to a different one without the pharmacy or prescriber being made aware. This meant that people could potentially change their answers in order to obtain a supply of a POM which was not clinically appropriate. The website was potentially misleading in parts. In the process of a sample order that was submitted, the website asked people to confirm their details and 'to submit your consultation to our Doctors'. The prescribing service was run by a PIP without doctor involvement.

The premises were generally clean and tidy, and there was a sufficient amount of clear workspace for dispensing. There was a consultation room which allowed a conversation at a normal level of volume to take place inside and not be overheard. A doorway had been knocked through to the shop next door, and this had created a large room. The online supplies were prepared from this room. The pharmacy had not informed the GPhC of the change in floorplan and following the inspection the SI contacted the GPhC with an update. The doorway between the main pharmacy and the large room was unfinished, and the floor in the doorway was uneven. The SI gave assurances that this would be addressed.

Due to the pandemic, the pharmacy had installed clear plastic screens on the front counter to help prevent the spread of infection. The pharmacy was secure from unauthorised access.

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

Summary findings

The pharmacy doesn't always provide its prescribing service safely, particularly the prescribing and supply of medicines online. It doesn't proactively inform people's regular doctor when it supplies a treatment to people for conditions which require ongoing monitoring. And it doesn't provide sufficient counselling information to people obtaining Saxenda online. The pharmacy doesn't routinely check the identification of people ordering prescription-only medicines online. Meaning that the pharmacy cannot assure itself about the person's age of that they are who they say they are. The pharmacy sends out medicines which require cold storage to people living in the UK and abroad, but it cannot always provide sufficient assurances that the medicines are kept in the right conditions to be fit for purpose. However, the pharmacy generally provides its other services safely. It gets its medicines from reputable sources and largely stores them in the pharmacy properly. It takes the right action in response to safety alerts so that people get medicines and medical devices that are safe to use.

Inspector's evidence

There was a ramp into the pharmacy from the street. Staff said that people with wheelchairs or pushchairs were able to easily navigate it. And although the space in the public area was limited, people with wheelchairs or pushchairs would be able to manoeuvre. There were some signs in the front window to inform people what services the pharmacy provided. And there was a small selection of leaflets in the public area. People could access some services online through the pharmacy's websites.

As described under Principle 1, the pharmacy prescribed and supplied a range of POMs, including for conditions such as weight loss, erectile dysfunction, hair loss, asthma, and malaria. The most commonly prescribed item was Saxenda for weight loss, and the SI said she had prescribed around three Ventolin inhalers for asthma in the last three months. The RP confirmed after the inspection that no supplies of Saxenda had been made under a patient group direction.

People could request POMs online for conditions which required ongoing monitoring such as inhalers for asthma, or Saxenda for weight loss. It was unclear if people were asked for the details of their regular doctor and consent for the pharmacy to contact them as part of the questionnaire. The SI explained that it was not mandatory for people to give their regular doctor's details or consent to contact them. She said that some people had provided this information, but she had not contacted someone's regular doctor as she said she had not had a need to before. So, the pharmacy was unable to demonstrate that it contacted the person's regular doctor to update them about the care episode that the person had received to ensure continuity of care.

The SI explained that if Saxenda was prescribed, it would be dispensed for the person and a dose of 'as directed' would usually be put on the label. The person was then expected to read the patient information leaflet and check the dose in there themselves. The SI did not proactively check what dose people were taking. The SI said that after a supply, some people did contact the pharmacy by phone to seek advice, but there was no record made of this if it happened. And people were not proactively counselled on how to use their Saxenda. Saxenda is a medicine which requires injection, which brings additional risks if a person started using it without knowing the right injection technique.

No records were made about when requests for prescription-only medicines were declined by the

prescriber, or why the request had been declined. The SI said that the computer system rejected requests automatically if the criteria in the questionnaire had not been met. The SI said that the system was set up for a maximum of five Saxenda a month at once. But this could not be assessed due to the limitations of the audit facility on the pharmacy's computer system. People requesting prescription-only medicines did not have their identification (ID) checked. So, the pharmacy could not demonstrate that people requesting the medicines were who they said they were. Or if they were underage. The SI said that she was planning to implement a system for ID checking in the near future.

Saxenda was delivered to people in the UK and around the world. It is a medicine which needs to be kept cold during transport once it leaves the pharmacy. 'Chill packs' and ice packs were seen in the pharmacy, but packs containing dispensed medicines had already been sealed. Following the inspection the SI explained that the pharmacy used either 24-hour or 48 or 72-hour chill packs. And that these packs were used for deliveries in the UK and to other countries. The couriers the pharmacy used could take up to four days to Canada and up to five days to Australia. The SI said that if the transit time was exceptionally long (for example to Australia), she emailed the person and offered a full refund. But said that if the person accepted the pharmacy's disclaimer and gave approval to ship then the pharmacy proceeded with the order.

The pharmacy delivered some medicines dispensed against NHS prescriptions to people in their own homes. Due to the pandemic, the delivery driver was not obtaining signatures from recipients to help reduce the spread of infection. An audit trail was maintained in the pharmacy to show what deliveries had gone out on a particular day.

Dispensed multi-compartment compliance packs were labelled with a description of the medicines inside, to help people and their carers identify the medication. The packs had an audit trail to show who had dispensed and checked the pack. Patient information leaflets were not always supplied, and the staff said that this would be done in the future. People were assessed to see if they needed the packs by their GPs.

Dispensed prescriptions for higher-risk medicines were not routinely highlighted. So, it may be harder for staff handing them out to identify people who could benefit from additional advice. Staff showed that they had stamps which they would use in future to highlight prescriptions for these medicines. No CDs were found in with the dispensed medicines. Staff were aware of the additional guidance about pregnancy prevention to be given to people in the at-risk group who were taking valproate. The relevant cards were available, but there were no leaflets and staff said that they would order more in.

Medicines were obtained from licensed wholesale dealers and specials suppliers and were stored in the pharmacy in an orderly manner. Staff described how they regularly date-checked the stock, but this activity was not recorded. No date-expired medicines were found in with stock on the shelves sampled. Liquids with a limited shelf life when opened were not always marked with the date of opening. This could make it harder for the staff to know if they were still suitable to use. A small number of medicines in stock were not appropriately labelled, for example the batch number was not present. So, this could make date checks or acting on safety recalls less effective. These items were removed, and this was discussed with the team members present. CDs were stored securely.

Two fridges in the dispensary were available for medicines which required cold storage. The temperatures were monitored and recorded daily, and records seen indicated that they had been kept within the required range. In the adjacent room there was a fridge which was used to store Saxenda. A team member described how they checked that the current temperature was within range each day, but the minimum and maximum temperatures for this fridge were not monitored, and they were not

recorded. The current temperature on this fridge on the day of inspection was within range, but the maximum temperature showed as 11.5 degrees Celsius. Staff explained the temperature may have risen if the door had been opened to load or retrieve stock. But due to the lack of records, it was not possible to see when this maximum temperature had been reached. Following the inspection, the SI confirmed that the Saxenda fridge temperatures were being recorded daily on the computer system, and action would be taken if it went out of the appropriate temperature range.

The apprentice technician understood what records were needed and was observed taking the appropriate action when a drug alert or recall was received. Medicines for destruction were separated from stock into designated bins and sacks.

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

There were two calibrated glass measures, which were clean. There was also a plastic measure, which was not calibrated, and this was disposed of during the inspection. 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 including the internet. The phone was cordless and could be moved somewhere more private to help protect people's personal information.

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.