General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Capsule Pharmacy, St Andrews Industrial Estate,

Unit 1 Devon Place, Glasgow, G41 1RD

Pharmacy reference: 9011378

Type of pharmacy: Internet / distance selling

Date of inspection: 23/11/2023

Pharmacy context

This is a distance selling pharmacy in Glasgow. The pharmacy premises are closed to the public, and people access the pharmacy's services through its website, www.rightdose.co.uk or by telephone. The pharmacy sells over-the-counter medicines via its website, and it dispenses for its private online doctor service which prescribes treatments for some conditions. These include weight loss, erectile dysfunction, hair loss and skin conditions. It also acts as a hub pharmacy, which means it dispenses medicines in compliance pouches against NHS prescriptions for one of its pharmacies. The compliance pouches help people take their medicines properly.

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

		Exception		
Principle	Principle finding	standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy does not have appropriate risk assessments to identify and manage the specific risks for the online prescribing services it provides.
		1.2	Standard not met	The pharmacy does not appropriately review its prescribing service to ensure its processes are effective at keeping people safe.
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 manages some of the risks with its online doctor service. But it does not have appropriate risk assessments to safely manage the risks associated with each condition it provides treatment for. And it does not carry out regular reviews of its prescribing service to ensure it continues to operate safely. The pharmacy has documented procedures for its dispensing services and team members follow them. The pharmacy keeps most of the records required by law and team members keep people's private information secure. It has adequate processes to help team members protect vulnerable adults and children.

Inspector's evidence

The pharmacy provided an in-house doctor prescribing service for a range of conditions which included erectile dysfunction, hair loss, hormonal contraception and skin conditions. At the time of the inspection this accounted for a small part of the pharmacy's business. The responsible pharmacist (RP), who was the chief executive officer (CEO), explained the intention to develop and promote the in-house doctor service imminently.

The pharmacy had assessed some of the risks of providing medication at a distance from an online platform. It did not offer medication that the doctor or superintendent (SI) pharmacist judged as being liable to misuse, required face-to-face assessment, or had been recently introduced and was new to the market. The doctor prescribed according to the manufacturer's license and the pharmacy's prescribing policy. The prescribing policy was primarily an operational procedure for processing orders received via the online doctor website. The policy contained only basic requirements for the prescriber to make an assessment of the consultation, understanding the limitations of an online consultation. It did not contain guidance for prescribing, reference to clinical guidelines, frequency of review or monitoring, how to provide people with information, or consideration for medicines misuse.

The pharmacy had a risk assessment (RA) for prescribing. It was not specific to each condition and did not specify the safeguards relating to the type of medicine prescribed. The RA specified the necessary information needed when people completed one of the online questionnaires. But if people changed the answers on the questionnaire this was not visible to the prescriber to help them decide whether prescribing was appropriate. And they did not routinely request people to provide proof of their medical history. The RA did not specify maximum quantities for prescribing and it did not specify limits on how often people could place orders for prescription only medication (POM). On reviewing a sample of records, if people completed the questionnaire as required, there was no follow-up by the prescriber. The pharmacy prescribed some antibiotics for conditions such as urinary tract infections. But the RA made no reference to local or national guidance for prescribing antibiotics.

The pharmacy did not demonstrate any regular monitoring of repeat orders, orders for high quantities of medication, or when it rejected orders and refused to make supplies. The pharmacy had no process to formally audit the prescribing service to ensure supplies were appropriate. So it could not provide the necessary assurances that any safeguards were effective. The pharmacy had an identity checking process for people accessing online services. It used external software to confirm the identity of people

and checks included the person's name and address. If the software identified a failure in the information submitted, the person was required to submit further information including a photo with their ID for the pharmacy to verify. But different people requesting treatment from the same address were not highlighted by this software. The pharmacy did not have a system to proactively identify and prevent people with similar names or addresses being supplied with medicines. Instead, the pharmacy expected team members to identify duplicated details at the time of dispensing. A team member had generated a one-off report to show people who had created accounts using similar names or addresses. And they had identified a number of duplicate accounts and had taken action to delete or block accounts as necessary. This showed safeguards were not robust, but there was no plan to schedule a further report in the future. So there was a risk further duplicate accounts could be created and not acted upon.

The pharmacy could not provide evidence to show which people had consented to sharing prescribing information with their GP and those who had refused to. This meant the pharmacy missed opportunities to identify trends and potential misuse and to introduce changes and improvements. For selling pharmacy-only (P) medicines online, the pharmacy had implemented automated restrictions on how often medicines prone to overuse could be ordered. And records showed the restrictions were effective at preventing supplies beyond these limits on individual records. But the pharmacy did not carry out regular audits to review these restrictions and provide assurance that the supplies it made were appropriate.

The pharmacy used standard operating procedures (SOPs) to define its dispensing processes and associated governance activities which included the dispensing of medicines into compliance pouches. And team members had signed a record to show they were competent to follow them. But they had not signed to confirm they had read and understood individual SOPs. This would provide further assurance they complied with the requirements of their roles and responsibilities. The pharmacy had been dispensing a significant number of compliance pouches and it used SOPs to define its operating procedures. A short time before the inspection, the pharmacy had significantly reduced the number of pouches it dispensed due to available resources. It had carried out a risk assessment to identify the people that would be affected. And it had written to them in advance so they could make alternative arrangements to receive their next supply in good time.

Documentation showed that team members had recorded some near miss errors at the time of dispensing and assembling medicines. The pharmacy used bar-code technology to carry out accuracy checks for compliance pouch dispensing and the technology used to dispense them recorded a photograph of each individual dose and highlighted any anomalies. These were checked by the accuracy checking dispenser (ACD) and included damaged items or those that were not visible to the technology. The pharmacy manually dispensed private prescriptions and the pharmacist reviewed the near miss records to identify any patterns and trends and discussed them with the team members. They had identified a significant number of expired items in May 2023, and had instructed team members to take greater care when carrying out checks of their own dispensing before passing to the RP or ACD for a final check. A stock check in August 2023 had ensured that any expired stock was identified and removed. The pharmacist also had added a date checking task to the monthly task list that was displayed on a large white board on the pharmacy wall as a reminder. Shelf edge caution labels were also seen on a few shelves to help manage the risk of dispensing the incorrect quantity. The pharmacy used a template report to record dispensing mistakes that people reported after people received their items. This included a section to record information about the root cause and any necessary mitigations to improve safety arrangements. People contacted the pharmacy using an online form and by telephone when they were dissatisfied or had concerns. The pharmacy had received a significant number of complaints in the past about its compliance pouch service. But complaints had reduced since the pharmacy had made changes to it's service model.

Team members demonstrated the system for dispensing authorised private prescriptions from its online doctor service and how they generated medication labels. They also printed a prescription form for the final check by the RP. The RP could view peoples completed online questionnaires, and any consultation notes made by the prescriber. On reviewing a sample of consultations, notes were observed on rejected orders. Examples included people requiring further checks by their GP, and the prescriber requesting further information on the duration of a trip for anti-malarial treatment. The electronic private prescription was date and time stamped with the prescriber's details. But prescriptions did not include the dose which was to be added to the label. The RP explained they would add directions when producing the label using information from the product's license. But this process was not documented. And it did not allow the prescriber to add patient-specific directions.

The pharmacy had appropriate public liability and professional indemnity insurance policies in place which were valid until 11 August 2024. And the prescribing doctor was in possession of their own professional indemnity insurance. The pharmacy was not displaying an RP notice at the time of the inspection. And the RP record did not always show the time the pharmacist finished their duties for the day. The pharmacy kept electronic records of supplies of private prescriptions for prescription only medicine (POM) treatments and pharmacy only medicines (P). Team members maintained controlled drug (CD) registers and kept them up to date. And evidence showed they had checked and verified the balances in August and November 2023 to confirm the accuracy of stock.

The pharmacy was closed to the public and only authorised persons were granted access. Team members knew to safeguard sensitive information. They used designated containers to safely dispose of confidential information. And approved providers collected the bags for off-site destruction. Risk assessments were carried out before authorization was granted to team members to allow them to access information on the pharmacy's systems. The scope of access and the location in which access was required was checked with line managers. Once confirmed strong passwords were created by the team members. For example, the dispensers had been authorised to access the PMR system and only the pharmacists and the prescribers had access to the information supplied by the patient via the questionnaires. The pharmacy only supplied medication to adults, and it used software to provide robust identity checks which included age-verification. These checks included the person's name and address.

Principle 2 - Staffing ✓ Standards met

Summary findings

Pharmacy team members have the necessary qualifications and skills for their roles and the services they provide. And the pharmacy supports its team members ongoing learning and development needs. The pharmacy reviews its staffing levels in line with changing workload. And it has reliable plans to cover team members absence.

Inspector's evidence

There had been a significant reduction in the pharmacy's dispensing activity over the past few months. And the pharmacy had subsequently reduced the number of team members it employed. Two regular pharmacists worked at the pharmacy and included one of the owners who was the CEO. The regular pharmacists were responsible for carrying out risk assessments and implementing new services. The superintendent pharmacist (SI) did not usually work at the pharmacy but had oversight of the pharmacy's safety arrangements and operations. The pharmacists were able to cover for each other's absence and mostly did not need to rely on locum pharmacists. When they did they ensured they provided them with information about the requirements of online pharmacy and prescribing services. Team members were mostly long-serving and experienced in their roles and responsibilities. This included five full-time dispensers and one full-time accuracy checking dispenser (ACD). One of the dispensers had been trained to operate the automated dispensing machine which the pharmacy used to dispense compliance pouches for two of its branches. And the other dispensers had been trained to provide cover when necessary, such as for annual leave. Another dispenser responded to customer service requests and queries and knew to refer to the RP when necessary. Minimum staffing levels across the dispensing team meant that only one dispenser could be off at the one time to ensure service continuity.

The online doctor service was provided by two GMC-registered doctors. They worked mainly in general practice and provided prescribing cover when needed due to the low volume of prescription requests. The CEO and SI worked with the operations pharmacist manager and the doctor to review the online prescribing service regularly. They did not document the outcomes of these reviews. The doctors were contactable should the RP or wider pharmacy team need to contact them. The pharmacist said they felt able to challenge prescribing decisions freely with the prescriber if they felt a prescription was not appropriate.

The pharmacy acted as a hub pharmacy for two of its pharmacies which held NHS contracts. The hub pharmacy did not possess an NHS contract but it legally dispensed prescriptions on behalf of its branches. This helped the branches with their dispensing workload and freed up staff to perform other tasks. The RPs at the pharmacy branches were responsible for carrying out clinical checks and approving the prescriptions before they transmitted them electronically for dispensing. Team members had been trained to retrieve, reconcile, and print copies of the prescriptions and to send them to the automated dispensing machine for dispensing into pouches.

The RP supported team members to keep up to date with the requirements of their roles and responsibilities. The ACD maintained a portfolio of evidence to show they had acted on near misses and dispensing mistakes to keep dispensing safe. This included providing feedback to dispensers so they could learn and improve their accuracy in dispensing. The ACD had also learned to use the electronic

medicines compendium (EMC) when carrying out final accuracy checks to identify tablets and capsules in the compliance pouches. The RP discussed topics for team members to learn more about. And they had recently discussed medication to treat menopausal symptoms and attention deficit hyperactivity disorder (ADHD) due to national shortages.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy premises are large and are suitable for the services provided. They are clean, hygienic, and secure. The pharmacy's website looks professional and provides ease of access for people to use.

Inspector's evidence

dispensing machine.

Online consultations were undertaken via the company's website which was well laid out and displayed the voluntary GPhC logo. It provided information on treatments, and consultations were started from the conditions page. It provided details about the owners, its physical location and contact details. It also provided the names and the registration details of the SI and the prescribing doctors. Consultations were questionnaire based and started from the page for the condition being treated. This helped to manage the risk of people receiving a medication that was not suitable for them.

The pharmacy was in large, modern purpose-built premises which provided ample space for its services. Team members kept the areas neat and tidy and free from congestion. And they were organised and free from slips, trips and falls hazards. Team members carried out their tasks for each of the services in well-segregated areas. A series of benches provided for dispensing with a separate area used for compliance pouches. The shelves were well-organised with areas for the assembly of pharmacy only (P) medicines and the dispensing of private prescriptions. A separate area was used for de-blistering

The pharmacy was in a good state of repair. Lighting provided good visibility throughout, and the ambient temperature provided a suitable environment from which to provide services. Team members cleaned the pharmacy on a regular basis and staff rooms and toilet facilities were available for them to use. Large office spaces were available in an upstairs area and used for the various meetings that took place. A separate sound-proofed area ensured that telephone conversations were carried out in private.

medications and storing them in containers to be used to replenish the canisters in the automated

Principle 4 - Services ✓ Standards met

Summary findings

Overall, the pharmacy has safeguards in place to help it manage and deliver its services safely. And it uses automation to help manage the delivery of its dispensing services effectively. The pharmacy manages its medicines appropriately and stores them properly. Team members carry out checks to make sure medicines are in good condition and suitable to supply. The pharmacy makes its services accessible to people through its website.

Inspector's evidence

The pharmacy's services could be accessed through its website www.rightdose.co.uk. People could also contact the pharmacy by phone, or email. The pharmacy operated five days per week, with its opening times displayed on its website. The pharmacy provided information about the conditions it provided treatment for, including hair loss, treatment of urinary tract infections, malaria prevention and erectile dysfunction. It provided an overview of common causes of the condition, the treatments available and any relevant lifestyle advice. The pharmacy's website also encouraged people to "ask the pharmacist "using an online form. And provided written and video blogs about different health topics.

To obtain a treatment for prescription only medicines (POMs), people started a questionnaire-style consultation before selecting a medicine. Questions were specific to the condition being treated and were designed to inform the prescriber about the person's past medical history. Most of the question options were simple yes or no answers. When an answer was given that required additional information for the prescriber to determine the suitability of treatment, people were prompted to give more information using a free text box. Access to the pharmacy consultation software was restricted and role dependent. This meant only those with prescriber access rights were able to issue a prescription. The prescriber reviewed each consultation before deciding whether a treatment was suitable and they either authorised a prescription, rejected the request, or requested further information.

Members of the team demonstrated how a consultation was reviewed and documented on the pharmacy's own consultation platform. The prescriber used unique log in details to access the prescribing platform and review the consultation forms. They authorised medication treatments once they were satisfied that supplies were appropriate, and they produced a prescription that the pharmacy dispensed. The system kept a record of who prescribed each medication, and it was date and time stamped to provide a complete audit trail. Consultation notes or advice given to people about their medicines was also recorded and could be seen by other users that had been authorised to access the system. The pharmacy team commenced dispensing on receipt of the prescription. The system did not permit dispensing before prescriptions had been authorised by a prescriber. Once a prescription was issued by the prescriber, it was filed into a workflow for the pharmacy to action. This included automated identity checks, which relied on established identity checking software for all requests received through the pharmacy's website. If the software identified a failure in the information submitted, the order was rejected, and the person refunded.

To obtain a treatment for pharmacy only medicines (Ps), people started a questionnaire-style consultation after selecting a medicine and the RP was responsible for approving medication supplies. The pharmacy had limits on some P medicines sold on its website. It had maximum frequencies on

some medicines that were prone to overuse. And pharmacy team members were able to demonstrate where supplies had been refused for being ordered too frequently.

The pharmacy operated as a dispensing hub and team members reconciled and checked the prescriptions from two of its branches against patient records to confirm doses. This helped them to identify any changes so they could query them with the pharmacies. The pharmacy used automation for the dispensing of the compliance pouches. Team members transferred medicines from original manufacturer's packaging into containers. They labelled the containers with details that included the manufacturer, the batch number, the expiry date, and the bar code of the medicines. And they transferred the stock in the containers to the canisters in the automated dispensing machine when they were depleted. They used bar-code scanning technology to scan the unique bar-code on the canisters and the labels on the containers. This ensured the canisters were refilled with the correct medication. The base of the canister was a unique shape, and this meant it could only be placed in the machine in one location.

The system manufacturer provided information about medicines that had been removed from the manufacturer's original packaging. And this helped the team identify medicines that were not suitable to be dispensed in this way. Access to the system was restricted to authorised and trained members using unique passwords and fingerprint scanning. This helped to keep an audit trail of who had accessed the system and who had filled each individual canister. Not all medicines were dispensed from the canisters. Pharmacy team members manually added some higher risk medicines to the system's removable tray to be dispensed into pouches from there. A pharmacist carried out an accuracy check of each medicine after a dispenser added them to the tray. After the medicines were dispensed into pouches, the pharmacy used photographic identification technology to scan the medicines in each pouch. The ACD completed a visual check of pouches that the system highlighted as having a potential inaccuracy or anomaly. Once completed, team members transferred a person's pouches into a box and attached dispensing labels so people had written instructions of how to take their medicines. They included descriptions of what the medicines looked like, so they could be identified in the pack. And they provided people with patient information leaflets about their medicines each month. Each pouch also displayed printed information about its contents, including the name and quantity of each medicine, the day, date, and time the medicines should be taken and the person's details. Team members responded to prescription changes. They followed a documented procedure which involved removing and adding pouches as required. They also arranged delivery of new pouches and collections of the old pouches.

The pharmacy used Royal Mail and a national courier service for delivery of P and POM medicine treatments. It used the courier service to deliver compliance pouches to the two pharmacies for onward distribution. The pharmacy used wool cool bags with ice packs for refrigerated items for delivery. And packages were clearly labelled as cold-chain items. They were dispatched using a tracked service. The pharmacy regularly monitored the integrity of cold-chain packaging by dispatching a package containing a monitoring device to a pre-determined address. The monitoring device transmitted temperature information to the pharmacy so they could confirm the package contents had been maintained at the expected temperature. The pharmacy monitored items for delivery via Royal Mail and relevant courier service website to identify failed deliveries.

The RP had discussed the Pregnancy Prevention Programme for people in the at-risk group who were prescribed valproate, and of the associated risks. They were aware of the recent legislative changes of supplying valproate in the original container and not to spilt packs. The pharmacy provided valproate supplies in compliance pouches for around five or six people. And it had conducted risk assessments to assess suitability of supplies before continuing to dispense them into pouches.

Team members kept stock neat and tidy on a series of shelves. And they used four large fridges to keep medicines at the manufacturers' recommended temperature. One of the fridges was used for items that had been dispensed and were ready for delivery. Team members monitored and recorded the temperature every day. This provided assurance that the fridges were operating within the accepted range of two and eight degrees Celsius. A freezer kept the cold packs that the pharmacy used to keep refrigerated items at the correct temperature during transportation to people's delivery address. Team members carried out monthly expiry date checks of all medicines, including medicines dispensed from the automated dispensing robot. They kept track of when checks were next due on a large whiteboard in the main area. The pharmacy used four large cabinets for some of its items. And team members recorded any items they removed for dispensing on a clipboard next to them. This helped the RP keep accurate records in the necessary registers. The pharmacy received notifications of drug alerts and recalls. And team members carried out the necessary checks and knew to remove and quarantine affected stock. The pharmacy had medical waste bins. And this supported the pharmacy team to manage pharmaceutical waste. The pharmacy used a large whiteboard to help team members carry out the various governance checks. This included fridge temperature checks, CD balance checks and date checking.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has a range of equipment, including automated technology, available to help provide its services effectively. And its team members know how to clean and maintain it.

Inspector's evidence

The pharmacy had access to a range of up-to-date reference sources. And separate private offices could be used to hold confidential discussions with people that contacted the pharmacy. Team members used cleaning materials for hard surface and equipment cleaning. And they cleaned the pharmacy on a regular basis. They also followed procedures to clean the automated dispensing system it used to dispense some medicines into pouches. A service contract was in place to mitigate the risk of breakdowns.

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.	