General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: PharmacyOnline.co.uk, 32 Welbeck Road, Glasgow, G53 7SD

Pharmacy reference: 9011756

Type of pharmacy: Internet / distance selling

Date of inspection: 28/11/2022

Pharmacy context

This is a distance selling pharmacy on an industrial estate in Glasgow. The pharmacy premises are closed to the public, and people access the pharmacy's services through its website, www.pharmacyonline.co.uk or by telephone. The pharmacy's private online prescribers, who are based in Scotland, prescribe for a range of treatments. These include for weight loss, erectile dysfunction, asthma and migraine. The pharmacy dispenses these private prescriptions, and it sells some over-the-counter medicines. 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.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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 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 adequately manages the risks with its online services. It has documented procedures for the prescribers and team members to follow to help make sure people receive medicines suitable for them to take. And it completes some reviews of the effectiveness of these procedures to help keep its services safe. The pharmacy keeps 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 completed risk assessments (RAs) to identify and manage safety risks. The superintendent pharmacist (SI) worked on-site at the pharmacy. And they used a template form to ensure a consistent approach to risk assessments. This included a scoring system to help show that mitigating actions were effective. Or if extra action was needed for areas that had scored highly. The RA documentation included version controls and included the implementation date and the SI's name to show they had approved them for use. The pharmacy was in the process of moving the RAs to an online platform to improve access for the 'pharmacist independent prescribers' (PIPs) and the other team members. The pharmacy employed PIPs to provide its online prescribing service. The SI had completed RAs for most of the treatments the pharmacy provided and included treatments for weight loss, urinary tract infections and erectile dysfunction. The RAs were comprehensive, for example they showed the risks of providing treatments at a distance. They also included the mitigations to help manage the risks. These included having no access to people's GP records. And so relying on people providing accurate personal information on the pharmacy's consultation assessment form. The RAs showed the follow-up action needed to manage risks. They stated maximum quantities and duration of treatment for the prescribers to adhere to and for team members to check when dispensing. For frequent treatment of gout, the RA identified the need for a previous diagnosis by a GP before prescribing any treatments. It also identified the need to monitor the number of requests. Once a maximum was reached, the PIPs signposted the person to their GP for follow-up and blood tests. The RA for the treatment Saxenda identified safety risks with the presentation of the medicine and the controls needed to manage this. It also identified the risk of relying on people to accurately record their weight on the consultation form so the pharmacist and the PIPs could assess the suitability to prescribe and to monitor weight loss. The pharmacy's monitoring arrangements had shown a significant number of people had failed to respond to a follow-up telephone consultation after 12 weeks of Saxenda treatment. As a result, the pharmacy introduced a new process to better engage people, and to help prescribers with their prescribing decisions before they provided further supplies. This ensured treatment remained appropriate or identified the need for appropriate alternatives. A pharmacy risk assessment identified the risk of relying on people to accurately input their weight onto the pharmacy's consultation form. Team members had discussed alternative options to help minimise the risk of inaccuracies at the pharmacy's regular clinical governance meeting. This included auditing a sample of people to ensure they had lost weight. And the development of video consultations as part of the pharmacy's new website design to provide a further check. These had not yet been implemented at the time of the inspection.

The pharmacy had an identity checking process in place. They used external software to confirm the identity of people. These checks included the person's name, address (billing and delivery), phone number and email when provided. If the software identified a failure in the information submitted, the

person would be required to submit further information including a photo with their ID for the pharmacy to verify. This provided assurance of people's details and identity. It also identified those entering false or fraudulent details. The pharmacy's RAs and prescribing policies both showed that they did not prescribe POMs for under 18s. The pharmacy provided prescription only medicine (POM) treatments to people over the age of eighteen. And it supplied P medicines for children when appropriate and within the licence of the product. The pharmacy trained its team members to manage safeguarding concerns. And it provided a policy for them to refer to. This included contact details for the relevant agencies. Team members knew to speak to the pharmacist if they had cause for concern. The pharmacy provided examples of interventions made by PIPs. For example, providing further information and advice for someone requesting an 'over-the counter' (OTC) supply of lactulose for a child. They kept a clear audit trail of communication including signposting to well-known national advice sites.

Auditing and monitoring provided a systematic approach to help improve the safety and effectiveness of services. Pharmacy team members and the PIPs provided regular feedback to improve safety arrangements. And the SI reviewed the RAs at least annually. They also reviewed them following a change in service, such as the introduction of a new medicine and when there had been non-compliance with the pharmacy's prescribing policies. The pharmacy had not completed a RA for supplying medication out-with licensed indications (or off-label). The pharmacy's website listed acetazolamide, but it was currently marked as out of stock. Acetazolamide license allows treatment of pressure in the eye, but it can be used off-label to treat altitude sickness. The SI had made the decision not to make this an available treatment. The website therefore was confusing for people as it appeared as a treatment offered but out of stock. The pharmacy only supplied medicines licensed for their use. The SI had recently undertaken an audit of the PIP's consultations. This involved reviewing a sample of people's records and the consultation outcomes. PIPs were expected to keep prescribing notes and signposting information when appropriate. And the audit identified they sometimes used abbreviations that were not always understood by the other pharmacy team members. As a result, the pharmacy had developed its systems to improve understanding and consistency of record keeping. The SI had identified an increase in nitrofurantoin requests which was used to treat urinary tract infections (UTIs). This had prompted an audit of UTI supplies over a three-month period which the SI was in the process of analysing. The audit evaluated each consultation against five key standards that needed to be met. The SI explained that on completion they would use the findings to identify areas for improvement and re-audit after an appropriate time.

Pharmacy support staff were working in the pharmacy at the start of the inspection, and they knew not to commence dispensing tasks or any other regulated activities until the RP signed in. The pharmacy used 'standard operating procedures' (SOPs) to define the dispensing processes and governance arrangements. And team members annotated records when they had read and understood them. This included a new dispenser who had recently taken up post. A 'roles and responsibilities' matrix listed the key tasks that the SI had authorised team members to carry out. For example, only the pharmacists could carry out clinical and accuracy checks. Team members signed dispensing labels to show who had 'dispensed' and who had 'checked' prescriptions. This meant there was an audit trail of who was involved in dispensing. It also helped the pharmacist to support individuals learn from their mistakes. The RP kept records of near miss errors which they displayed above the dispensary bench. And they monitored them and discussed any patterns and trends they had identified. This helped to identify risks and implement improvements to manage dispensing risks. The dispenser provided examples of improvements they had introduced to help avoid errors, such as highlighting the different formulations of Solpadeine to manage selection errors. And agreeing to take regular pauses to re-focus on dispensing tasks and to reduce pressure in the workplace. The pharmacy used a template report to record dispensing errors. This included a section to record information about the root cause and any mitigations to improve safety arrangements. Previous errors had included wrong quantities due to

labelling errors, and the RP had discussed the need for improved accuracy with the team members.

The PIPs and the pharmacy team members attended the SI's six weekly clinical governance meeting. This was a formal meeting with all team members in attendance. The SI delivered a presentation which included information about dispensing errors, dispensary interventions, clinical audits, and complaints. The presentation was uploaded to the pharmacy's system along with the minutes of the meeting for those team members who had been unable to attend and for future reference. The minutes from the November 2022 meeting showed the team had discussed the implications of prescribing diclofenac for people with hypertension. It was agreed that such people would be assessed on an individual basis provided treatment was for short term use. One of the pharmacists had suggested placing a block on orders received from males for norethisterone. They had also suggested highlighting specific contraindications in red on assessment forms. And there was evidence to show the pharmacy had introduced a red flag system following the discussion. A team member had suggested using 'look alike and sound alike' (LASA) labels on shelves to highlight similar medication to manage the risk of selection errors. And they had added a label to highlight the different formulations of Solpadeine tablets. The pharmacy had arranged for an inspection of ways of working to be carried out by an external consultant. The findings were shared with the team members, such as improving some of the audit trails the pharmacy kept and introducing a dedicated phone to be used to communicate with the PIP.

Team members maintained the records they needed to by law. And the pharmacy had appropriate public liability and professional indemnity insurance policies in place which were valid until 21 April 2023. The PIPs had also arranged their own professional indemnity insurance cover. The pharmacy displayed a 'responsible pharmacist' (RP) notice, and the RP record showed the time the pharmacist took charge of the pharmacy and the time they finished. Team members retained prescription forms electronically so they could easily retrieve them if needed. The PIPs maintained records of their prescribing decisions. All the PIPs could access the records to inform their decisions in the future. For example, information about signposting people to other agencies. The pharmacy kept electronic records of supplies of private prescriptions for (POM) treatments and pharmacy only medicines (P). It also kept records to show requests for medication that the pharmacy had refused. A question on the consultation assessment form asked people to provide consent. This provided the necessary authorisation for the pharmacy to notify their GP of any treatments supplied as part of the consultation. Consent was mandatory for some treatments such as asthma. And the SI explained they would not provide treatments if people did not provide consent when they were required to. This managed the risk of GPs not being aware of people receiving long term treatment from the pharmacy. The pharmacy had a subscription that provided access to GP practice contact details including their postal addresses. And the pharmacy notified people's GPs of supplies of medication by post. It did not maintain an audit trail to confirm the letters had been received by the GP practice. And the pharmacy had not received any confirmation from GPs following notification. The pharmacy was closed to the public and only authorised persons were granted access. A data protection policy was available for team members to refer to. Team members understood data protection requirements and how to protect people's privacy. And they used a cross-cutting shredder to safely dispose of confidential information. Access to people's personal information was password protected. And each team member had their own personal log on credentials which was dependant on their roles and responsibilities. This ensured they only accessed relevant information to carry out the tasks they had been authorised to. For example, the RP accessed and approved requests for P medicines. But they were unable to access any requests for POM treatments which was restricted to PIPs.

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 is good at supporting its team members' ongoing learning and development needs. The pharmacy reviews its staffing levels in line with changing workload. And it has reliable plans in place to cover team members' absence. The pharmacy provides team members with the opportunity to provide regular feedback. And they are proactive and suggest improvements to keep pharmacy services safe and effective.

Inspector's evidence

There had been significant changes at the pharmacy since its last inspection in 2020. The new owners had moved the pharmacy to a new premises due to an increase in workload. And a new superintendent pharmacist (SI) worked onsite at the pharmacy. The responsible pharmacist (RP) had worked at the pharmacy since it started operating and supported the SI in their role. The new SI was the lead for clinical governance. And they held formal meetings on a regular basis to share information about auditing and monitoring results. They encouraged team members to participate and contribute to discussions at the meeting. And this helped to improve safety at the pharmacy. This included highlighting the different Solpadeine formulations which helped to reduce dispensing mistakes.

The pharmacy had appointed new team members to help manage the extra workload. And the well-established operations manager, who was a qualified dispenser, supported the new team members in their roles. They had arranged for the newly appointed qualified dispenser to read and sign the relevant SOPs to confirm their understanding of the pharmacy’s working practices. Also, as part of their induction, they had learned about the pharmacy's arrangements for providing people with extra information due to the lack of face-to-face consultations. Such as for codeine containing medications. A newly appointed customer service advisor with many years experience had been in post since July 2022. They dealt with service queries, refunds when requests had been refused and increased complaints about deliveries due to the recent industrial action by Royal Mail. They knew when to refer to the RP or the operations manager when queries were out with their level of competence. The SI had enrolled the customer service advisor on the NVQ pharmacy services level two qualification to help them develop the knowledge and skills required for working in a pharmacy and to support them in their role. The customer service advisor participated in discussions involving pharmacy operations and attended the SI’s clinical governance meeting. The pharmacy provided protected time in the workplace, and this supported team members to complete qualification training coursework. Regular locum pharmacists worked at the pharmacy, and they had developed the necessary knowledge of online pharmacy operations to safely work there. The SI was in the process of developing a locum guide for team members to refer to.

The pharmacy employed a part-time ‘pharmacist independent prescriber’ (PIP) who prescribed most of the treatments supplied by the pharmacy. The PIP was supported by the SI who was also an accredited PIP. The prescribers were able to manage the number of requests for the treatments that the pharmacy offered. And they provided backfill for each other when needed. The RP and the other pharmacy team members had access to the PIPs should they need to discuss prescription queries. And the pharmacy arranged for a second pharmacist to carry out separate clinical and accuracy checks of prescriptions.

This independent check helped ensure that treatments were safe and appropriate for people to use. The PIPs worked part-time in other healthcare settings which provided them with further clinical learning opportunities. The SI audited the part-time PIP's prescribing activities. And this provided them with the opportunity for reflection on practice and to identify areas for learning and improvement. The pharmacy did not keep records of the training and development that the PIPs completed. But the PIPs kept their own records to evidence their ongoing learning and professional development. And the SI had recently undertaken a training needs review for PIPs and had identified key areas for development. They had arranged accredited training for skin care and weight loss due to an increase in the number of requests for treatments. The pharmacy did not provide any incentives to reward prescribing activity. Team members were aware of products liable to overuse or misuse. The pharmacy had set limits for certain medicines such as codeine-containing medicines, to limit the ordering of these items. And the pharmacy's ordering system was designed to identify and reject orders that exceeded the set limit. But the pharmacy did not regularly review or monitor orders to identify non-compliance with its arrangements, and it could not confirm if all inappropriate orders were identified.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises 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. It is well-maintained and up to date and suitable for the services it provides.

Inspector's evidence

People accessed treatments online from the pharmacy's website. The website displayed the voluntary GPhC logo. And it provided details about the owners, its physical location and contact details. It also provided the names and the registration details of the SI, PIPs and the RP. Prescribing consultations were undertaken via the company's website. The consultation was questionnaire based and generally avoided providing a negative answer to a question. This helped to avoid leading people through the questionnaire. The website was laid out in such a way that a POM could not be selected before completing a consultation. The pharmacy had a service level agreement contract with its website provider. This included twice weekly maintenance checks to ensure the system was operating effectively.

The pharmacy had relocated to new premises in 2022 due to an increased workload. It was in large, modern purpose-built premises which provided ample space for its services. The dispensary was located at the rear of the premises. It was well-organised and provided a series of shelves and bench space for dispensing. Team members kept the areas neat and tidy and free from congestion. A large storage area was next to the dispensary. All areas were organised and free from slips, trips and falls hazards. A reception area and well-equipped offices were at front of the premises. And these provided suitable areas for activities that required extra safeguards to manage confidentiality. Team members used the dispensary sink for hand washing. And they cleaned and sanitised the pharmacy on a regular basis. Hand washing arrangements were also available in the toilet. Lighting provided good visibility throughout, and the ambient temperature provided a suitable environment from which to provide services.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy has adequate safeguards in place to help ensure people receive medicines that are suitable for them to take. And it makes its services accessible to people. The pharmacy orders its medicines from reputable suppliers and stores them properly. Team members carry out checks to make sure medicines are in good condition and suitable to supply. And it has arrangements to identify and remove medicines that are no longer fit for purpose.

Inspector's evidence

People accessed the pharmacy's services via its website, and it provided information about its online prescribing service and how to use it. The website included a link to an NHS website which provided information about conditions, symptoms and treatments, and what to do and when to get help. It also provided a link to a recognised pharmacy reference resource, the BNF, which included details about many medicines available in the UK. People communicated with the pharmacy via the telephone or e-mail and contact details were provided. A banner along the top of the website showed the pharmacy's Christmas and New Year opening arrangements. This ensured people knew when they would be unable to access services and to make alternative arrangements. The RP was available for people to ask questions about their medication by phone or email. And examples were provided during the inspection.

People registered with the pharmacy and provided their personal details on the website before they could access the online consultation questionnaire for treatments. Once registered they accessed services for repeat consultations using the same registration details. The SI explained the pharmacy's system highlighted any P or POM medications that had been issued to the person in the past. This meant the pharmacist was able to easily assess if further supplies were appropriate. The pharmacy regularly reviewed the content of the website and the medical questionnaires that people completed.

When people completed a medical questionnaire to obtain treatments, their answers appeared on the system that the PIPs used for their prescribing decisions. The pharmacy used proprietary software for managing the prescribing process. PIPs used a secure online portal to access the platform with a unique individual username and password. And they reviewed the information people had submitted online before prescribing. When a prescription was generated, the system recorded the name of the PIP, and the date and time to provide an audit trail. The PIP recorded any information about signposting to other agencies and advice they provided on a consultation notes section on the platform. The SI demonstrated how a prescriber would review a consultation on the prescribing platform. Evidence showed that prescribers changed records to pending whilst they contacted the person for further information and when they were waiting for communication from the person's GP before prescribing.

The pharmacy had some safeguards in place that required people to have been first seen by their own GP or to have had a face-to-face consultation with a healthcare professional, before the pharmacy provided ongoing supplies of some treatments. For example, those requesting contraceptive medication or hormone replacement therapy were asked to provide their last review date and most recent blood pressure to help the pharmacy ensure that people were being monitored appropriately. This relied on people inputting the information accurately. People were asked to self-declare they had taken a urine test and obtained a positive result for the treatment of chlamydia. But the pharmacy

didn’t check this and make sure people had completed the test appropriately. So, there was a risk people were prescribed antibiotics when they were not suitable for them leading to an increased risk of antibiotic resistance developing. The RP explained that the pharmacy was in the process of updating their website design and functionality. And as part of the process, they had considered requesting photographic evidence for information in some instances to improve prescribing and dispensing safety.

Team members managed dispensing tasks well. They used dispensing baskets during the assembly and labelling process to keep items safely contained and to avoid the risk of items becoming mixed up. The pharmacy retained private prescriptions electronically and this meant they did not need hard copies for their records. A second pharmacist who was usually the RP clinically checked the prescriptions that the PIPs generated. This separated the prescribing and checking process and provided an extra check of clinical appropriateness. The RP had access to the prescribing consultation and the PIP's notes which they could refer to during checks. And this was observed during the inspection. The RP kept records of any discussions they had about prescribing decisions with the PIPs in the dispensary intervention log. Interventions records showed the RP had queried a prescription for antibiotics following a review of the person’s answers on their consultation form. Following the discussion, the PIP had reviewed their decision and noted that the supply would not have been appropriate. The PIP communicated their decision to the person and offered self-care advice. Another example was seen with the potential for interaction between a medicine prescribed by the PIP and a medication listed by the person on their consultation form. The SI discussed the incident with the PIP, and evidence of safety in short term use was discussed. The supply was made with a record of the discussion made on the person’s notes.

Team members kept stock neat and tidy on a series of shelves. And they used a large glass-fronted fridge to keep medicines at the manufacturers' recommended temperature. Team members monitored and recorded the temperature every day. This provided assurance that the fridge was operating within the accepted range of two and eight degrees Celsius. A large freezer cabinet kept the thermal foil packs and ice packs that were used to keep Saxenda at the correct temperature during transportation to people’s delivery address. Team members followed the pharmacy’s SOP for dispensing and packaging Saxenda. And they supplied an information pack, a box of needles and a sharps bin. They knew to assemble and dispense Saxenda in the afternoon. And they placed the labelled packages for posting in a dedicated container to maintain the cold chain. The pharmacy had carried out a risk assessment before selecting the most appropriate delivery option. And it posted sample packs to the pharmacy using the various delivery options. This showed that the next day delivery option was the most suitable to maintain the cold chain and managed the risk of temperature increases. The pharmacy used the postal service and a recognised courier for deliveries. And it was able to track supplies during the delivery process. The pharmacy had added information to a banner at the top of its website to advise people of delays due to industrial action. And it provided information about an alternative courier service as an option for people to consider. The pharmacy purchased medicines and medical devices from recognised suppliers. Team members carried out regular expiry date checks. They updated records to keep track of when checks were next due and when short-dated items were due to expire, so they could remove them in advance. A random sample was checked, and all the items were found to be within their expiry dates. 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 received a drug alert notification concerning Saxenda in July 2022. And team members had carried out checks. But they did not document their findings and could not show who had carried out the checks and when. The pharmacy had medical waste bins. And this supported the pharmacy team to manage pharmaceutical waste. The pharmacy did not supply valproate medication. But pharmacy team members were aware of the risks to the unborn child.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs for its services. And it uses its equipment appropriately to protect people's confidentiality.

Inspector's evidence

The pharmacy had access to a range of up-to-date reference sources which included the electronic BNF. The pharmacy had password-protected computers. And separate office areas could be used to hold confidential discussions with people that contacted the pharmacy. The pharmacy provided most of its medicines in original containers. And it had counting triangles in case it needed to split packs and provide a specified number of doses. The pharmacy used discreet packaging for deliveries. This meant that people were unable to identity the medicines that were contained within. The pharmacy used cleaning materials for hard surface and equipment cleaning. And team members had access to personal protective equipment including face masks.

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.