

Registered pharmacy inspection report

Pharmacy Name: Simple Online Pharmacy, 77 Dunn Street, Glasgow, G40 3PA

Pharmacy reference: 9011287

Type of pharmacy: Internet

Date of inspection: 01/10/2020

Pharmacy context

The pharmacy provides services to people through its own website. People cannot visit the pharmacy in person. The pharmacy operates an online prescribing service and supplies medicines against the prescriptions it issues. The pharmacy's website offers prescription medicines for a wide range of conditions. It mainly supplies medicines for the treatment of erectile dysfunction, contraception, weight loss and hair loss. The pharmacy also sells a range of over-the-counter medicines and dispenses some NHS prescriptions on behalf of a sister branch. This was a targeted inspection as information had been received showing the pharmacy had been obtaining an unusually large quantity of codeine linctus. The pharmacy was owned by a company. One of the directors was a pharmacist and he was present during the inspection. The inspection was undertaken during the Covid-19 pandemic.

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 does not have adequate systems to identify and manage the risks when selling codeine linctus and Phenergan which are liable to abuse, overuse or misuse.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website is arranged so that a person can choose a prescription only medicine (POM) and its quantity before there has been an appropriate consultation with a prescriber.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy sells large amounts of codeine linctus and Phenergan. It carries out checks to safeguard against misuse, but these are not always effective at restricting sales.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy has effective policies and procedures in place to help ensure the safety of most of its services. But it does not effectively control the sales of over-the-counter medicines that are often misused. The pharmacy has put restrictions in place to prevent inappropriate sales of these medicines. But the systems are not always effective. And there are no checks carried out to make sure the systems are working. This means some people may have been able to buy medicines they were not using safely.

Inspector's evidence

The pharmacy was a distance selling pharmacy and so did not provide face-to-face pharmacy services. It had implemented new safety measures since the start of the Covid-19 pandemic. An individual risk assessment had been completed for each team member and personal protective equipment (PPE) was provided. The pharmacy had up to date SOPs, and team members had read them and signed a declaration that they accepted them. The superintendent pharmacist had been in post for around four months and had reviewed and approved the existing SOPs when he started. He was in the process of developing new working instructions for a new dispensing robot. The manufacturers' operating manual was being used until they were completed. A prescribing policy was in place, but the pharmacy had no such policy for the sale of 'over-the-counter' (OTC) medicines. The pharmacy operated an online prescribing service which employed three GMC registered UK-based prescribers. Prescriptions were ordered via the pharmacy's own website (simpleonlinepharmacy.co.uk). The prescribing service was regulated by Health Improvement Scotland (HIS). A prescribing policy was in place for the online prescribing service. The director said he had reviewed inspection reports of other online prescribing services by the 'care quality commission' (CQC) to help inform some of the decisions he made about the prescribing policy. The pharmacists and prescribers attended 'quality and clinical' meetings every quarter. Minutes of these meetings were retained, but some previous action points had not been completed, for example ensuring consent was recorded on each assessment form.

The pharmacy had developed an antibiotic prescribing policy. But it did not say how prescribers should confirm someone had an infection apart from relying on the information provided on the questionnaire form. Also, it was not clear whether local antibiotic resistance was taken into consideration when antibiotics were prescribed. This meant the pharmacy's governance arrangements for its prescribing service may not always be effective. Prescribing risk assessments and protocols were informed by UK national guidance such as the British Association of Sexual health and HIV (BASHH).

The pharmacy displayed the responsible pharmacist notice. It showed the name and registration number of the pharmacist in charge. The responsible pharmacist record was up to date. Dispensing labels were initialled by the dispenser and the checker to provide an audit trail. Team members had been keeping some records of their near miss errors throughout the pandemic. They had separated some medicines to manage risks of selection errors they had identified, for example, sildenafil and sumatriptan. Team members had also used shelf-edge caution labels to highlight different pack sizes for the same product. The pharmacist used a standardised form to record dispensing incidents which included the root cause and improvement action. The pharmacy complaints procedure was explained on its website. The customer service team knew to ask for photographs of packs when people reported a dispensing error. They then referred to the pharmacist for them to investigate and correct. The

pharmacy used Trust Pilot to monitor customer service and one or two-star reviews had been investigated.

People using the prescribing service or requesting codeine linctus were required to have their identity (ID) checked. The pharmacy used LexisNexis to carry out this function. It included an Equifax check and verified the person's identity by name, address and date of birth. The pharmacy term were confident this ensured tight controls to prevent misuse. Around 70% of people passed this check, others either failed outright or were asked for further evidence of ID checks, usually a passport or driving license. An example was shown where a supply was refused because of duplicate accounts. The superintendent, responsible pharmacist and director had signed-off a 'risk register' in the past year. It identified the over-ordering of P medicines subject to misuse as a high risk to public safety. The superintendent had introduced a new policy for codeine and dihydrocodeine sales. It included information about the checks that were needed to safeguard people when they made requests. This included a pharmacist check of the assessment form and the person's ordering history before preparing the products for delivery. A restriction of one bottle of codeine linctus every six months was stated. The policy also required the pharmacist to exercise their own professional judgement.

The on-line ordering system had controls and markers built into it that aimed to prevent excessive or inappropriate supplies. For some medicines there was a maximum quantity that could be ordered in a set time frame. For example only one pack of promethazine (Phenergan) each month and only one bottle of codeine linctus in a six-month period. The system did not allow codeine linctus to be purchased at the same time as Phenergan. It was also not possible to purchase more than one codeine containing product at the same time. People were not allowed to proceed to the 'checkout' if they exceeded these limits. So, the pharmacy did not know if people had attempted to purchase these medicines in excess of these limits. The superintendent estimated that they sold around one hundred bottles of codeine linctus each week. Following the inspection, the pharmacy provided details of the sales of codeine linctus and Phenergan tablets during the period 1 July 2020 to 5 October 2020. It also provided details of requests it had received for these medicines where the supply had been refused.

The information showed that the pharmacy had received 1610 requests for codeine linctus between 1 July and 5 October 2020. From these requests 1433 bottles had been supplied and 177 had been declined. The pharmacy had received 769 orders for Phenergan tablets (promethazine) from which 768 had been supplied and one declined. Further analysis of the sales information provided by the pharmacy identified a number of sales that appeared to be in conflict with the restrictions that the pharmacy had in place. These included:

1. On 27 occasions, two separate supplies of codeine linctus had been made to the same delivery address within 3 months
2. On three occasions, three separate supplies of codeine linctus had been made to the same delivery address within 3 months
3. There were 71 occasions identified in the time period where repeat supplies of Phenergan had been made to the same address, of which there were eight occasions when the supply was within one month of the previous supply
4. There was one example found where five supplies of Phenergan had been made to the same delivery address within a 12-week period.
5. There was one example found where seven supplies of Phenergan and one supply of codeine linctus had been made to the same 'parcel motel' address during the time period
6. On seven occasions codeine linctus and Phenergan had been supplied to the same delivery address in separate transactions

It was also noted that on 41 occasions people purchasing Phenergan had also purchased a product containing codeine or dihydrocodeine as part of the same transaction.

The pharmacy maintained the records it needed to by law, and public liability and professional indemnity insurances was in place for both the pharmacy service and the prescribing service. Both policies were valid until 2021. The pharmacy had policies in place to keep confidential information safe and secure. This included procedures for information governance, information technology and back-up processes. The pharmacy was registered with the 'information commissioner's office' (ICO), and it had reported a security breach to them earlier in the year. The ICO had been satisfied with the remedial action taken, which included arranging for team members to complete extra training. This included cyber security training, and handling emails with attachments and being aware of computer malware and viruses. The pharmacy had appointed an independent 'data protection officer' to ensure compliance with GDPR regulations. The computer system was password protected and access to the system was restricted according to the roles and responsibilities of each of the team members. The online prescribing service used remote prescribers. Electronic prescriptions were sent to the pharmacy from static IP addresses. The prescribers also had individual log in credentials to keep information safe and secure. Private prescription supplies were recorded electronically. A safeguarding policy was on display and accessible to team members. It included contact information for the relevant agencies across the UK to escalate safeguarding concerns should it be necessary. The prescribers had completed level four safeguarding training.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy's team members are trained for their roles and the services they provide. The pharmacy supports its trainees in developing their skills. It also provides them with some protected learning time to complete training courses. And it provides ongoing training so that team members continue to develop in their roles. Team members are enthusiastic and knowledgeable, and they suggest improvements to make services more effective.

Inspector's evidence

The pharmacy's service model had changed since it had re-located its business in December 2019. It had installed a new dispensing robot to dispense compliance pouches on behalf of its other branches. The superintendent was implementing the new policies and procedures, and was in the process of recruiting three extra dispensers and an accuracy checking technician to operate the system. At the time of the inspection the superintendent was the only team member authorised to manage the system. Dispensers had been trained and authorised to pre-pack medicines into the containers used by the robot. The robot manufacturer had provided on-site training for the superintendent and the other pharmacists. The following team members were in post; one full-time superintendent pharmacist, one full-time responsible pharmacist, one part-time dispenser, one full-time dispenser, one full-time trainee dispenser and one new part-time assistant who was about to enrol on a dispenser's training course. Three team members worked in a separate office as customer advisors; one of them had completed a dispenser's training course.

The pharmacist carried out regular individual performance reviews to be satisfied team members were competent to provide the services they offered. A dispenser who had been shielding since the start of the coronavirus pandemic had been updated about service changes. Team members had continued with training throughout the pandemic. This mostly related to new arrangements to manage the risk of coronavirus transmission. They had also recently completed training on cyber security. The dispensers had been reminded about the importance of checking prescription dates. For example, the pharmacist had recently highlighted isotretinoin prescriptions that were more than seven days old and the need for extra checks. Team members said they felt able to raise concerns and to provide suggestions for improvement. And they had been involved in planning the pharmacy's new layout when it had re-located at the end of 2019.

The superintendent said the owners had not put pressure on him to sell codeine linctus and that he felt comfortable selling it with the safeguards they had put in place. He said locum pharmacists were empowered to make professional decisions but none, that he was aware of, had refused to supply it or raised concerns about the volumes sold. There was a checklist available for locum pharmacists which was made available to all locum pharmacists working at the pharmacy. It outlined the protocols in place for codeine sales and informed them that ID checks were required for all codeine linctus. The director explained that the three prescribers were paid a set salary so there was no financial incentive which might influence their decision to prescribe or not. A whistleblowing procedure was in place and team members had been trained to follow it.

Principle 3 - Premises Standards not all met

Summary findings

The pharmacy's website enables patients using the prescribing service to select the medicine and its quantity before having a consultation with a prescriber. This means people may receive medicines which are not the most suitable for them. The pharmacy premises is clean, hygienic, properly maintained and of a high standard. It provides a professional environment for the services it provides.

Inspector's evidence

The pharmacy was situated in a large unit in a business park. It was closed to the public and there was no obvious signage that it was a pharmacy. Public health notices about Covid 19 were displayed on the door that led into the reception area of the building where the pharmacy was located. People were advised to wear a mask before entering and hand sanitizer was available at the reception desk. A Perspex screen created a barrier between the receptionist and visitors and managed the risk of virus transmission. Working areas were clean, spacious, free from obstructions and professional in appearance. Team members worked at separate workstations and they were able to maintain a two-metre distance from each other most of the time. The pharmacy premises were well maintained and in a good state of repair. It had been fitted out to a high standard and the fixtures and fittings were good. The temperature and lighting were adequately controlled. The unit contained two floors and staff facilities included offices, two kitchen areas, separate ladies, gents' and accessible WCs with wash hand basins and hand wash. Disposable gloves, hand sanitizer and face masks were available in various locations. Team members wore facemasks, used hand sanitizer and washed their hands on a regular basis. There was a 'Housekeeping, Hygiene and Pest Control procedure.

The pharmacy's name, address, e-mail address and phone number were displayed on the pharmacy's website. There was a link from the pharmacy's website to the GPhC register. The voluntary GPhC logo showed the incorrect GPhC registration number but the link took the person to the correct registration details of the pharmacy. The name and details of the superintendent was displayed on the pharmacy's website. The Medicines and Healthcare products Regulatory Agency (MHRA) EU distance selling logo was also displayed. The website stated that medicines were sent to certain countries in Europe, however the director said they had decided against this and now only supplied people in the UK. The name and GMC registration numbers of the prescribers were available on the pharmacy's website and there was a link to check registration details of these prescribers. However, this information was not very easy to find. The pharmacy's website was arranged so that the person using the service chose the prescription only medicine (POM) and the quantity before filling in the consultation questionnaire. This meant that people may not always receive the most suitable medicines for their needs. It was also not in line with the GPhC guidance published in April 2019.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy offers a range of services that can be accessed via the internet. The pharmacy team members mostly work to the policies and procedures to provide safe and effective services. And people are required to complete a questionnaire when they want to buy over-the-counter medicines. This allows the pharmacy team to check whether the medicine is appropriate. But these arrangements are not always effective at preventing people from obtaining medicines that are not suitable for them. And people who buy medicines that can be addictive may not always get the counselling they need.

Inspector's evidence

People accessed the pharmacy's services via the associated website, and people could communicate with the pharmacy via the telephone or e-mail. The website had a chat facility, and this provided the opportunity for instant messaging. The pharmacy had introduced a dispensing robot which produced compliance packs in a pouch. It did not have an NHS contract, and intended to operate a hub and spoke model for two of its branches in NHS Scotland and one in NHS England. At the time of the inspection it had started dispensing pouches for a sister branch in Aberdeen. The pharmacy website offered treatments for a range of medical conditions. A sample of 72 prescriptions from the previous day was examined. The largest treatment areas were erectile dysfunction (ED) 26%, contraception (including EHC) 20%, hair loss 12.5%, weight loss 12.5%, antibiotics 8%, smoking cessation 6% and migraine 4%. Others included topical treatments for acne and asthma inhalers. Prescribing was audited and included external and peer review. Anyone requesting a prescription medicine was required to complete an assessment questionnaire, which was then reviewed by a prescriber before the prescription was issued. The answers to the questionnaire could also be seen by the pharmacist when the prescription was dispensed.

The patient's previous order history was checked by the prescriber and the pharmacist during clinical screening, and the prescribers and pharmacists could contact patients if additional information was needed. A business communication platform was used to communicate messages between the pharmacy and prescribers. Prescriptions were generated once the consultation was approved by the prescriber and sent electronically to the pharmacy in PDF format, which could not be altered. Records of rejections were maintained with the reasons why. Any answers changed during the consultation were not auditable, but most questions did not alert the patient to a response which would lead to a refusal. When completing the consultation questionnaire for propranolol a pop up appeared if the person said they had asthma; "Bronchoconstriction can occur, especially when non-selective beta-blockers such as Propranolol are administered to asthmatic patients, this medication is also contraindicated for patients with atrioventricular (AV) block, intermittent claudication and psychosis."

This prevented the person from continuing but allowed them to change their answer and provide false information without the prescriber being aware.

A sample of refusals were viewed from the previous few days. Two prescriptions for Orlistat were refused because 'BMI was too low'. Orlistat and Saxenda were refused because 'these should not both be used together'. Trimethoprim was refused with the message 'please see your own GP for review. Male UTIs usually require a 7-day course of antibiotics and further investigation.' Ella one was refused for 'outside therapeutic window'. There was some monitoring and follow up activity when certain medicines were prescribed. Follow up emails were sent after a person was prescribed medicine for erectile dysfunction to check if they were having any side effects and asking if they would like to speak to a pharmacist or prescriber. A follow up email was sent to people prescribed Champix for smoking cessation. Patients details including their customer's body mass index (BMI) and progress to reduce weight were recorded on their individual records. Health information was sent out with some prescription only medicines such as an information leaflet on chlamydia. Leaflets were sent out when any unlicensed medicines were supplied, which explained what a medicines license was and the implications of taking a medicine which was 'used out with its license'.

It was mandatory for patients to provide consent to inform their GP about asthma treatment, however it was decided that a one-off supply would be allowed if consent was not obtained. The superintendent explained that asthma treatments via their prescribing service were usually only for people in an emergency, if they had lost their inhaler or required an extra one for some reasons. Consent to inform the patient's GP should have been requested in all consultations. However, a sample of consultations were viewed, and consent was not requested on the consultation for Seretide inhaler. The director said this was an oversight and it would be corrected. Less than 2% of people who received 'prescriptions-only-medicines' in September had provided consent for their GP to be informed. When consent was provided GPs were informed in retrospect of the supply, so this meant that a supply could be made which the patient's own GP did not agree to. However, the operator responsible for this task said he had never seen any adverse feedback from a patient's GP. A list of emails was seen which were being sent to patients GPs, for prescriptions that had been dispensed that day. The pharmacy did not access the patient's Summary Care Records (SCR) or use any other way of verifying the information provided on the questionnaire so there was a risk that the person using the service may enter incorrect information either accidentally or deliberately and therefore receive a medicine which may be inappropriate.

The pharmacy also offered a wide range of over-the-counter medicines, including Promethazine tablets and codeine linctus. People wanting to purchase medicines had to complete an assessment questionnaire which was reviewed by a pharmacist before supply. A sample of refusals were viewed from the previous few days. Several codeine linctus transactions had been refused for 'failed ID check' and one for use of 'same card'. Night nurse had been refused for 'frequent night nurse orders. No additional information, was sent with pharmacy medicines other than the packaging leaflet. Records of sales were recorded for each customer, but these had been inadequately monitored to identify inappropriate sales.

Recognised licensed wholesalers were used to obtain stock medicines. The pharmacy was registered with Securemed and it was compliant with the Falsified Medicines Directive (FMD). Team members carried out regular stock checks every three months. They highlighted short-dated stock and attached coloured stickers to packs to show products with a short-expiry date. The superintendent had programmed the robot to apply a six-month expiry date for all stock, and they instructed the robot to

remove short-dated stock. each month. Team members checked the fridge temperature every day. Records showed that the temperature had remained in the safe range of between 2 and 8 degrees Celsius. Team members acted on drug alerts and recalls. They recorded the date they checked for affected stock and what the outcome had been. All medicines were posted to the patient by Royal Mail, via a tracked service which required a signature on receipt. Any returned medicines were destroyed, and none were re-used. If the medicine was returned to the pharmacy because it was faulty or damaged, then it would be replaced. Fridge lines were sent in special insulated boxes with disposable ice packs, to ensure the medicine was maintained at the correct temperature during delivery. The pharmacy was spacious with ample work benches and storage areas.

The workflow was organised into three separate areas with designated areas for P medicines, POMs and the NHS business. This meant that team members were able to socially distance from each other. The dispensary shelves were well organised and neat and tidy. Medicines were stored in their original containers, apart from those to be used in the dispensing robot. There was restricted access to the robot with fingerprint and bar-code technology used to operate the system. The robot had an accuracy checking function. But this had not been activated, and the pharmacist continued to carry out the final accuracy check for all prescriptions. The superintendent had authorised dispensers to pre-pack the containers that were needed for robotic dispensing. The activity was carried out in a separate part of the dispensary. And the pre-packs were checked by a pharmacist before the bar-coded labels were scanned and accepted and placed in a unique position inside the robot for dispensing.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

Members of the pharmacy team have the equipment and the facilities they need for the services they provide. They maintain the equipment so that it is safe to use and use it in a way that protects privacy.

Inspector's evidence

The pharmacy team were able to use the internet to access websites for up to date information, such as the electronic BNF. The RP explained that all medicines were supplied in original containers so there was no need for counting and measuring equipment. The pharmacy used a robot to dispense compliance pouches. A service contract was in place, and there was good access to the engineer for who was based in Edinburgh.

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.