General Pharmaceutical Council

# Registered pharmacy inspection report

**Pharmacy Name:** Simply Meds Online, Unit K2, Beckingham Business Park, Beckingham Street, Tolleshunt Major, Maldon, Essex, CM9 8LZ

**Pharmacy reference:** 9010764

**Type of pharmacy:** Internet / distance selling

**Date of inspection:** 30/11/2021

## Pharmacy context

The pharmacy provides services to people through its website. People cannot visit the pharmacy in person. The pharmacy operates an online prescribing service and supplies medicines for a wide range of conditions against the prescriptions it issues. The pharmacy also sells a range of over-the-counter medicines and dispenses some NHS prescriptions. The pharmacy is owned by a company and one of the directors is a pharmacist. He was present during the inspection. The inspection was carried out during the COVID-19 pandemic. Conditions on registration are in place on this pharmacy that prevent some services being provided.

## 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 identifies and manages the risks associated with the services it provides. The pharmacy audits its prescribing service to help monitor quality and safety. It keeps appropriate clinical records and declines requests for medicines which are not clinically appropriate. And it keeps people's personal information safe.

### Inspector's evidence

Two pharmacists were present during the inspection. One was the responsible pharmacist (RP) who was also the pharmacy superintendent. The second pharmacist was the pharmacist independent prescriber (PIP). The PIP was also a director of the company. The inspection looked at the two broad areas of the pharmacy's service. It reviewed how the prescribing service was managed and provided to people and it looked at the more traditional parts of the service, including dispensing activities and how over-the-counter medicines were supplied to people. The pharmacy supplied a wide range of prescription only medicines (POMs) through a private prescribing service. Medicines were supplied against prescriptions issued by a PIP. The PIP was based at the pharmacy but could also access the prescribing system remotely if needed. Treatments offered included medicines for conditions such as erectile dysfunction, treatment for hair loss, lifestyle medicines, thrush, migraine and malaria prophylaxis. The pharmacy also supplied antibiotics for acne and chlamydia and supplied salbutamol inhalers on an emergency basis for people with asthma. It also sold a range of over-the-counter (OTC) medicines. The pharmacy only supplied medicines to people living in the United Kingdom.

The pharmacy had risk assessments to identify and manage some of the risks associated with providing online pharmacy services as well as prescribing competency documents. These were well written and provided frameworks as well as prescribing pathways for all conditions and illnesses within the scope of the pharmacy service. The documents included the decision-making process to be followed when considering if the supply of a medicine was safe. The risk assessment for the prescribing service outlined the necessary competency criteria for prescribers. The PIP gave some examples and provided evidence of his experience in clinical practice. The prescribing risk assessment indicated the competency record should include signed peer verification, individual competency documents or evidence that the prescriber works in a GP practice.

The pharmacy's risk assessment detailed the communication that the pharmacy would have with other people involved in a person's healthcare, and the pharmacy obtained consent to share information. For certain higher-risk medicines (such as antibiotics and salbutamol), the order could not proceed unless consent was given to communicate with the person's GP. For other medicines this was voluntary. The higher-risk medicines included antibiotics and inhalers for asthma. The PIP showed the letters which were sent to GPs each week detailing the medicines issued. The PIP said that he discussed prescribing as part of his annual peer review for revalidation. And the questions in the online questionnaires were reviewed annually with another prescriber.

Evidence provided demonstrated how prescribing pathways were fully integrated into practice and decision making. Repeat requests were identified and referred to the GP where appropriate. Where a decision was made to supply in the absence of consent to discuss with a GP, this was recorded in the clinical record, but generally, such refusal meant that the order was cancelled.

The pharmacy kept records about dispensing mistakes that were identified before they were handed out to a person (near misses). Team members said that they would keep records for dispensing mistakes that had reached a person (error logs). Following dispensing incidents, the mistake was discussed with the team member involved on a one-to-one basis, with any learnings shared with the dispensary team. The pharmacy had separated many of the oral contraceptives and used individual shelf labels to identify these. Prescription only toothpastes had also been separated to reduce the risk of selection errors. The pharmacy used Trustpilot reviews as a method of obtaining feedback and many of these were positive.

The pharmacy had a range of standard operating procedures (SOPs) which covered the more traditional aspects of the pharmacy's services. These included dispensing processes, information governance (IG), controlled drugs (CDs), responsible pharmacist (RP) activities, and dispensing Incidents. There was evidence that members of staff had read and signed SOPs relevant to their roles. The SOPS had recently been reviewed.

The pharmacy had the correct RP notice on display in the premises and the website displayed the details of the current RP. This was linked to the electronic RP log to ensure the correct information was displayed. Roles and responsibilities were identified in the SOPs. When asked, members of the pharmacy team clearly understood what they could and couldn't do when the pharmacist was not present

People requesting over-the-counter and pharmacy medicines were also required to answer an online questionnaire which was then reviewed by the pharmacist and pharmacy team. The questions used for this aspect of the service were largely open ended and allowed people to describe their symptoms. This meant that the pharmacy team could see the full information provided to make a decision about whether or not to supply a medicine.

The records the pharmacy needed to keep by law, and public liability and professional indemnity insurances were in place for both the pharmacy service and the prescribing service. Clinical records showed any previous medicine requests, any declined requests with reasons, as well as any information provided by people about their medical history. There was space in the records where the PIP could make notes about prescribing decisions.

The RP confirmed that he had completed the level 3 safeguarding training course and could describe what he would do if he had a concern about a vulnerable person. Other team members said that they would refer any concerns to the pharmacist. Contact details for local safeguarding agencies were available on a noticeboard in the pharmacy. The RP said that nobody under 18 years of age was allowed to set up an account with the pharmacy. This was verified during the ID checks. And that the pharmacy did not let people to set up accounts on behalf of another person. He said that if the team members or himself suspected someone was doing this, he made additional checks to help prevent it.

## Principle 2 - Staffing ✔ Standards met

### Summary findings

The pharmacy has enough team members to manage its workload safely. They are appropriately trained and have a good understanding about their roles and responsibilities. They can make suggestions to improve safety and workflows where appropriate.

### Inspector's evidence

The pharmacy had three regular pharmacists who covered the opening hours between them. Two pharmacists were present during the inspection. One of them was the RP and one was the PIP. There were four dispensers. All had trained to NVQ level two and one had registered on an NVQ level 3 course but had not managed to pursue the training due to lack of time. The PIP talked about some of the experience he had to support his prescribing practice. This included training in anticoagulation and cardiovascular medicine. He had also been involved in running an asthma clinic and was involved in providing an erectile dysfunction service in association with a GP. He said that he had worked in a GP practice and spent some time visiting a dermatology clinic.

Team members were trained using accredited courses and discussed their roles and responsibilities in the pharmacy. They gave some examples of ongoing learning to keep their knowledge and skills up to date. This included reviewing articles in pharmacy magazines and completing relevant training modules. Some team members had recently completed a level 2 dispensary stock management course. The pharmacy was up to date with dispensing and routine housekeeping activities such as date checking. Staffing levels were enough for the volume of work and the size of the pharmacy. One of the dispensers demonstrated a good working knowledge of the ordering and dispensing system and talked through the prescription journey in the pharmacy. The pharmacy would be able to source locum cover if members of the team had to self-isolate.

Communication was largely verbal as the pharmacy's team was small. There was a noticeboard on the wall to share relevant information. Team members had reviewed the dispensing process and made changes including the introduction of a process to prioritise dispensing based on the selected delivery method and how urgently the medication was required. The pharmacy team had introduced coloured baskets to distinguish between NHS and private prescriptions as well as medicines for same day delivery. The team members found this process to be more efficient. Targets were not discussed during the inspection.

## Principle 3 - Premises ✔ Standards met

### Summary findings

The pharmacy team keeps the pharmacy secure, clean and tidy. The website has been updated to prevent medicines being selected before starting a consultation and the questionnaires provide the PIP with the information required to decide about prescribing. The premises is kept secure. Whilst the current location is not ideal due to height restrictions, a move to a more appropriate area of the building is planned.

### Inspector's evidence

All the services provided to people were accessed via the pharmacy's website. This displayed the address of the pharmacy, the voluntary GPhC logo and the MHRA medicines seller's logo. The registration details of the superintendent pharmacist, RP and pharmacist independent prescriber were displayed. Payment was through a separate payment gateway rather than the pharmacy website. At the time of the inspection the website allowed a person to select a prescription only medicine (POM) and quantity before starting the consultation. This had previously been addressed by the pharmacy but reverted during an update to the website. The pharmacy promptly changed the website so that prior to being able to select any medication, the person had to start the consultation. And they were asked a series of questions to identify whether a supply would be suitable. Some of the answers would prevent certain medicines being displayed (such as nitrofurantoin for cystitis). The responses to these were saved so that people could not then go back and change their answers to manipulate the system.

The website stated that decisions about treatment would be jointly considered and that the final decision would rest with the prescriber. The pharmacy was a distance-selling pharmacy and therefore did not provide face-to-face pharmacy services. It had implemented some new safety measures since the start of the COVID-19 pandemic and had personal protective equipment (PPE) available including face shields and masks. But these were not being worn during the inspection. Hand gel was available but not seen to be routinely used.

The pharmacy was located upstairs in a building shared with a wholesaler and had a locked door to prevent unauthorised access. As the premises was essentially in the roof of the building, it was spanned by steel beams around shoulder height. These were padded with foam to reduce the risk of people hitting their head on them but required staff to duck under the beam when moving around the premises. There were several areas of the pharmacy where it was not possible for taller people to fully stand up. This included part of the area used for dispensing NHS prescriptions and part of the room used for OTC medicines. The RP said that the wholesaler was going to be moving to a new location which would allow the pharmacy to relocate to the main area downstairs in the near future. This would provide a much more comfortable and appropriate working environment. The pharmacy premises were kept secure from unauthorised access.

## Principle 4 - Services ✔ Standards met

### Summary findings

The pharmacy gets its medicines from reputable suppliers and it stores them properly. It takes the right action if any medicines or devices need to be returned to the suppliers. This means that people get medicines and devices that are safe to use.  Information about prescribed treatments are shared with other healthcare professionals involved in a persons care, where appropriate. Prescribing decisions  are documented  The pharmacy identifies and gives advice to people taking high-risk medicines to make sure that they are taken safely.

### Inspector's evidence

The pharmacy was closed to the public, but people could contact it via phone, email, or via the pharmacy's website. The RP explained how the pharmacy had recently started a same-day delivery service for Essex and London, to help improve people's access to urgent medicines. The website suggested that people could collect medicines from the pharmacy by prior arrangement, but the RP said that no medicines were collected in person. If necessary, private prescriptions could be collected as it was only the collection of NHS prescriptions that was not allowed.

The pharmacy had appropriate safeguards in place to make sure that all the medicines it supplied online to people were clinically appropriate. For antibiotics and management of sexually transmitted infections, a previous diagnosis was required by the pharmacy. Requests for supplies of these required the person to give consent for the supply to be notified to the persons GP. Failure to give consent meant that the order was cancelled. Antibiotics were chosen based on the guidelines in place in a geographical area. The NHS Summary Care Record (SCR) was also used with consent to verify any previous treatment.

People using the prescribing service completed an online questionnaire which formed the basis of the consultation.  The clinical decision making was based on this questionnaire. Since the previous inspection, the form had been changed so that people were able to provide more information about their condition. The form no longer indicated to the person requesting the supply if an answer had been given which would prevent a supply. Once the form had been submitted, the answers were analysed and send to the PIP. If an answer had been given that contraindicated a supply, the person would receive a message at the end of the questionnaire referring them to their GP. But it did not indicate which question triggered the refusal. The questionnaires were stored on the person's pharmacy record and any changes in a future questionnaire were noted. If there were any queries or concerns about the answers given, the PIP would contact the person by phone or email to discuss. If the person failed to respond, the order was cancelled. The PIP said that he would sometimes refuse a supply if it seemed clinically inappropriate. Reasons for declining a supply were recorded and regularly audited. Some of the reasons seen included a female requesting medication for erectile dysfunction, a male requesting medication for cystitis and a person requesting antibiotics in case they experienced food poisoning.

The definition of first-line and second-line treatments on the website was not made clear to members of the public but the pharmacist said that he would review the wording of this. The pharmacy also supplied salbutamol inhalers on an emergency basis for people with asthma, a condition that requires ongoing monitoring. Orders were not progressed unless consent was given to notify the person's GP of the supply. If the person was taking any other medication (including for their asthma), they could enter

this information in the questionnaire, and this was flagged to the PIP. Examples seen included an antidepressant and a preventer medication for asthma. This allowed the PIP to assess the clinical appropriateness of the supply. People were reminded to contact their GP if they had any difficulties or side effects. The PIP said that the final part of the ordering process included a section where the person was required to give consent for the prescriber to contact the person's GP. The pharmacy printed and sent these notifications in the form of letters on a weekly basis. The PIP said that since moving to a written notification rather than an email, they had stopped receiving complaints from GPs. The PIP said that they had not received any recent feedback from GPs, either positive or negative. There was not any evidence of recent feedback from GPs, either positive or negative.

Supplies of combination trial packs of medicines for erectile dysfunction were only made when the person confirmed they would not take more than one of the medicines at a time. The pharmacy obtained its medicines from licensed wholesale suppliers and stored them in an orderly manner in the dispensary. Stock was regularly date checked, and this activity was recorded. On the shelves looked at during the inspection, no date-expired medicines were found in with stock. Stock in the pharmacy was arranged in three distinct areas to reflect each of the services, namely: OTC sales, NHS prescriptions and private prescriptions. Medicines requiring cold storage were stored in a suitable fridge and the temperatures were monitored and recorded daily. Records examined showed that the temperatures had remained within the appropriate range. The pharmacy did not usually need to split bulk liquids, but the RP said that if they needed to, then the bottle would be marked with the date of opening.

The pharmacy used the 'LexisNexis' system to verify identity as well as checking photographic ID and proof of address for some medicines. The RP explained that he also used the NHS Summary Care Record (SCR) system to verify whether a person with that name was registered at the address provided. But he said that he did not go into the person's SCR without their consent.

Medicines for destruction were separated from stock and stored in designated bins for secure offsite disposal. The pharmacy sometimes supplied valproate medicines against NHS prescriptions. The RP was aware of the guidance about pregnancy prevention with these medicines. The pharmacy had one person it supplied valproate to who was in the at-risk group. The RP said that the person's carers were aware of the need for pregnancy prevention. The pharmacy occasionally dispensed higher-risk medicines such as lithium and methotrexate against NHS prescriptions. The lithium had been marked on the shelf as 'high risk'. The RP explained that when the pharmacy first dispensed a higher-risk medicine for a person he contacted them and went through the relevant counselling information. He said that if a person received further supplies of these medicines, they were not routinely contacted, but the patient information leaflets were always supplied. The pharmacy did not have any Steroid Emergency Cards but said that they would obtain some and supply them where appropriate.

Supplies of liquid antibiotics against prescriptions were only made where the person receiving the medicine had confirmed that they were able to accurately reconstitute the medicine. The RP described the cold-storage packaging they used to delivery temperature-sensitive medicines. He said that the pharmacy had chosen a system which guaranteed the medicines would be kept within the appropriate range for 48 hours. He said that he had undertaken a test run through the courier and found that the appropriate temperatures had been maintained for just under the 48 hours. The RP said that this would allow ample time, as deliveries were generally made the same day or the next day. The RP showed how the pharmacy received drug alerts and recalls via email and explained the action that was taken in response. This was recorded electronically.

## Principle 5 - Equipment and facilities ✔ Standards met

### Summary findings

The pharmacy has the equipment it needs for its services and largely maintains it well. It uses its equipment to help protect people's personal information.

### Inspector's evidence

Tablet and capsule counting devices were clean, and a separate marked triangle was used for cytotoxic medicines. Although not routinely used, the pharmacy had appropriate equipment to accurately dispense liquids. Computer terminals were password protected, and confidential waste was disposed of with a shredder. The pharmacy was closed to the public, and there was a separate room which was used to store over-the-counter medicines. The phone was cordless and could be moved into this room to help protect people's personal information.

The patient medication record was password protected. The pharmacy had spare computer and printer equipment which could be used in the event of a computer fault. There were no fire extinguishers on the premises and the pharmacy was in the upstairs of the building with only a single route of access, which could make it difficult for people to escape in the event of a fire. The RP said that he would source a fire extinguisher for the pharmacy. And that he would carry out a full fire safety risk assessment There were fire extinguishers in the downstairs area of the building and the proposed relocation would address this risk. All electrical equipment appeared to be in good working order and there were plans to have it safety tested.

## 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. |