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: 12/11/2020

Pharmacy context

The pharmacy provides services to people through its two websites. 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. This was a targeted inspection as information was received showing that the pharmacy had been obtaining unusually large quantities of codeine linctus. The pharmacy is owned by a company and one of the directors is a pharmacist. He was present during the inspection. The pharmacy also has a Wholesale Dealer Licence through the Medicines and Healthcare products Regulatory Agency (MHRA). The inspection was carried out 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 cannot show that it identifies and appropriately manages all the risks linked to the supply of medicines online.
		1.1	Standard not met	The pharmacy doesn't adequately identify and manage the risks around the sales of codeine linctus and Phenergan liquid. And, it doesn't have appropriate governance arrangements to protect potentially vulnerable people from buying them.
		1.2	Standard not met	The pharmacy does not routinely assess the safety and quality of the services it provides. With the exception of an annual review of the questions asked in the consultation, there are no clinical audits of the prescribing service provided to people. So, the pharmacy cannot assure people that all its services are safe.
		1.6	Standard not met	The pharmacy does not make adequate records about its prescribing decisions. So, important information which may impact the care a patient receives in future is not always available. And it makes it harder for the pharmacy to monitor and review the quality of its prescribing service.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	People can choose prescription-only medicines on the pharmacy's website before having a consultation with a prescriber. This increases the risks of supplying medicines to people which are not suitable.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy cannot show that its prescribing service always protects people's health and wellbeing. It doesn't routinely share information about its prescribed treatments with other healthcare professionals involved in a person's care, even where consent has been given to do so. People can change answers to the questions on the consultation questionnaire and these changes are not visible to the prescriber. So, people may be able to obtain

Principle	Principle finding	Exception standard reference	Notable practice	Why
				medication which is not appropriate for their condition. And the prescriber does not make suitable records about their prescribing decisions.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy does not identify and manage all the risks associated with the services it provides. It does not control the sales of over-the-counter medicines that are liable to abuse adequately. It has put some restrictions in place to control sales of these medicines but the volumes of these sales remains high. And there is evidence that processes to refuse some sales do not always work in practice. The pharmacy cannot show that its prescribing service is managed effectively. The pharmacy keeps some clinical records for its prescribing service, but these are very limited in scope and don't generally contain information to justify the prescribing decision. And the pharmacy doesn't have robust systems in place to monitor and review its prescribing service.

Inspector's evidence

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 pharmacist independent prescriber (PIP) who was a director of the pharmacy. 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 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 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. But some of the working practices identified in the risk assessment were not being followed.

The risk assessment for the prescribing service outlined the necessary competency criteria for prescribers. The PIP gave some examples of his clinical experience, but he wasn't keeping a record about his competency in each area of 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. Some of the documents had a brief comment from the PIP relating to his experience but there was a lack of written evidence as detailed in the competency documents.

People using the prescribing service completed an online questionnaire which formed the basis of the consultation. The questions used were specific to the medicine being requested. The clinical decision making was based on this questionnaire. If a question was answered which would indicate that a supply was inappropriate, the question turned red and the person was advised that they could not proceed and to contact the pharmacy if they had any questions. The person was able to change their answer and proceed with the questions and any such changes were not visible to the pharmacist. This increased the risk that people could manipulate the system to provide the answers needed for a supply rather than

providing accurate information to the PIP. The PIP said that he would sometimes refuse a supply if it seemed clinically inappropriate. An indicator for this was where someone did not appear to understand how to use their medication such as ordering two different treatments for chlamydia or reordering a medication before it was due. The PIP relied on people phoning the pharmacy if they wanted to discuss a decision. He said that contacting the person requesting the medicine to have a verbal consultation may be considered by the person as an unsolicited call. The inspector and PIP discussed ways to enable communication.

While 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, there was little evidence to show this was happening. 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 but there was otherwise no evidence of any regular review or clinical audit of the prescribing practices.

Review of the documents and information provided by the pharmacy identified several weaknesses in relation to clinical governance in the pharmacy. There should be robust clinical documentation so that any issues can be highlighted and followed up with people. Evidence provided did not fully demonstrate how prescribing pathways were fully integrated into practice and decision making, especially in relation to failures to respond to clinical treatment and subsequent escalation of care. The only example of this was a question to require people to contact their GP if required. Whilst there was a general reason for refusal of prescriptions (such as failed identity checks or over-ordering), these did not contain clinical reasons for the decision made.

The pharmacy kept records about dispensing mistakes that were identified before they were handed out to a person (near misses). They said that they would keep records for dispensing mistakes that had reached a person (error logs) but there were none recorded at the time of the inspection. 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 similarly packaged creams and gels to reduce the likelihood of mis-selection as well as introducing a third check of all dispensed medicines.

The pharmacy used Trustpilot reviews as a method of obtaining feedback and many of these were positive. There were some negative reviews where supplies of medicines had been declined.

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 activities, and dispensing incidents. There was evidence that members of staff had read and signed SOPs relevant to their roles. But there was no procedure seen in relation to the sale of medicines at risk of abuse. Some of the procedures were due for review. But on others, the date when they came into effect was not clear. There was a lack of evidence to demonstrate that SOPs and policies were regularly updated or showing how changes to policies were implemented to apply learning from practice.

The pharmacy had the correct responsible pharmacist (RP) notice on display in the premises. But the pharmacy's website had been displaying the incorrect information about who the RP was for several months because a link to the website had been disabled. The RP said that he would address this. RP records were completed using an Excel spreadsheet. This method of recording meant that entries could potentially be altered or changed at a later date, and other alternatives were discussed. 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. The pharmacist

wasn't present at the start of the inspection, but no registrable activities were carried out until he arrived.

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 more 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.

People requesting over-the-counter supplies of codeine linctus or promethazine liquid as well as those accessing the prescribing service were required to have their identity checked. The pharmacy had previously used the 'LexisNexis' system but had experienced some difficulty and changed to checking photographic ID and proof of address. 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.

Invoices provided by the pharmacy indicated that large quantities of codeine linctus had been purchased in recent months. The amount sold by the pharmacy was also large. The RP said that the demand had taken the pharmacy by surprise and that team members had not been appropriately trained on making sales of codeine linctus. He gave several examples of occasions where supplies which had gone ahead were later identified as being inappropriate. As a result of the unusual demand, the pharmacy had set a limit on the amount of codeine linctus listed on the website. Approximately three requests a day were refused. Following the inspection, the pharmacy provided information about the supplies made and sales refused of codeine linctus and promethazine liquid (Phenergan) between August and October 2020. The information showed occasions where the pharmacy had supplied more codeine linctus than the quota set by the pharmacist. And there was some evidence of supplies being made to the same or very similar locations despite refusals having been made previously. There were some systems in place to identify people trying to create multiple accounts and where identity checks were failed. This resulted in orders being cancelled, but orders were later processed for very similar locations and there was limited evidence to show that this information was used to identify further inappropriate requests.

The pharmacy maintained some of the records it needed to by law, and public liability and professional indemnity insurances were in place for both the pharmacy service and the prescribing service. But there was a lack of detail recorded in the clinical records made as part of the prescribing service. For example, the clinical records did not show a full medical history or details about other medicines a person was taking. The clinical records seen consisted solely of the questionnaire completed by the person requesting the supply and a single free-text line on the order record. There was no supporting information about how the decision to prescribe had been reached. Examples of this included supplies of salbutamol made to people who had not given their consent for the pharmacy to contact their own GP.

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. 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. One of them was the pharmacy superintendent and one was the PIP. There were two dispensers. One of these had trained to NVQ level two at a previous pharmacy and the other was registered on an NVQ level 3 course. 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. The pharmacist stated that team members had not been adequately prepared for the pharmacy to start sales of codeine linctus. He said that when inappropriate requests had been identified, he had discussed these with team members and introduced daily quotas to limit sales. He said that more robust identity checks were introduced.

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 an additional check, introducing baskets for dispensing. The pharmacy team had also started to dispense private prescriptions in batches based around the item prescribed. This meant that several prescriptions for one product would be dispensed at a time and checked before moving onto a different product. The team members found this process to be more efficient. Targets were not discussed during the inspection.

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

Summary findings

The way the pharmacy's website is arranged increases the risks that people are supplied with medicines that are not suitable for them. The website allows people to select a prescription only medicine, its strength and quantity before starting a consultation. And people can change their answers during a consultation and this information is not visible to the prescriber. However, the pharmacy team keeps the pharmacy secure, clean and tidy. And the pharmacist has an area to check prescriptions and this is kept organised to help reduce the risk of mistakes.

Inspector's evidence

All the services provided to people were accessed via the pharmacy's two websites. These displayed the address of the pharmacy, the voluntary GPhC logo and the MHRA medicines seller's logo. The registration details of the superintendent pharmacist and pharmacist independent prescriber were displayed. But the responsible pharmacist details had not been updated since April 2020. Payment was through a separate payment gateway rather than the pharmacy website.

The way the pharmacy's website was arranged increased the chances that people could obtain medicines that were not suitable for them. People using the website could choose a medical condition and were then presented with a list of POMs for that condition. People then selected a medicine from the list, a strength and quantity, and were shown a price before starting the consultation. This opened a specific questionnaire for the product. However, people could change their responses to the questions during the consultation. And any changes made in this way were not visible to the PIP authorising the prescription. If the PIP felt that a supply was inappropriate, the order would be cancelled, the payment refunded, and the person invited to contact the pharmacy. There was a not a mechanism in place for the PIP to contact the person requesting the medication as the PIP believed that this would be classed as an unsolicited contact. People could also search for a particular POM using the website search function.

The website stated that the information supplied in the questionnaire would be used by the prescriber to issue a prescription. This did not follow the guidance in that it did not make clear 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. The pharmacy had moved to this location after the previous inspection but had not submitted an updated floor plan to the GPhC. This was provided shortly after the inspection and updated on the pharmacy record. 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 to fully stand up. This included part of the area used for dispensing NHS prescriptions and part of the room

used for OTC medicines. Team members said that the pharmacy could become very warm in the summer but there was a powerful air-conditioner to reduce the risk of medicines being stored at inappropriate temperatures. The pharmacy premises were kept secure from unauthorised access.

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

Summary findings

The pharmacy cannot show that its prescribing service always protects people's health and wellbeing. It doesn't routinely share information about its prescribed treatments with other healthcare professionals involved in a person's care, even where consent has been given to do so. People can change answers to the questions on the consultation questionnaire and these changes are not visible to the prescriber. So, people may be able to obtain medication which is not appropriate for their condition. And the prescriber does not make suitable records about their prescribing decisions. This includes medicines requiring additional monitoring such as asthma inhalers and antibiotics. The pharmacy's processes for managing the supplies of some over-the-counter medicines pharmacy do not always ensure that these medicines are supplied 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. And he had undertaken an audit on how people paid for the pharmacy's services. As a result, the pharmacy had started an arrangement with a new payment processing organisation which the RP said would make it easier for people to pay. And he said it would reduce unnecessary phone calls to the people using the service. 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.

The pharmacy did not have all the appropriate safeguards in place to make sure that all of 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, but no documented evidence was obtained to verify this. The website allowed people to select the second line treatment for chlamydia provided that they acknowledged that they were aware that the medicine was not the first line treatment. The definition of first line and second line treatment was not made clear to members of the public. The pharmacy also supplied salbutamol inhalers for people with asthma, a condition that requires ongoing monitoring. The consultation for people requesting an inhaler asked if they had been diagnosed and whether they were being monitored by their GP. It asked if they had received an asthma review within the last 12 months. And the pharmacy provided some limited documentary evidence of 'review due' dates such as repeat prescription slips and a screenshot of a summary care record. If the person was taking any other medication (including for their asthma), the questionnaire turned red and indicated a supply could not be made. People could then change their answer to allow the consultation to proceed and the change was not visible to the PIP. 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. He said that it was very rare for him to contact a GP and that he did not document his reasons for deciding to make a supply where such consent was declined. This could affect the care provided to the patient and makes it harder for the pharmacy to monitor and review the quality of its prescribing service. However, the PIP gave an example of referring to a GP where a person was ordering large quantities of doxycycline and of refusing a sale of Ella-One because it had been ordered more than once in a month. This was the limit set by the pharmacy, but the record did not show whether any further enquiries had been made or what advice had been given to the

person. 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 pharmacist gave an example where the pharmacy stopped the prescribing service for gonorrhoea due to a change in first line treatment to an injectable medicine. The gonorrhoea treatment area was removed from the website.

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. 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. 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. A record of this action was not made, which could make it harder for the pharmacy to show what it had done in response if there was a future query.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs for its services and largely maintains it well. The pharmacy 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. 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.