General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Pharmaease.com, 172 Willows Lane, Bolton, Greater Manchester, BL3 4BU

Pharmacy reference: 9010200

Type of pharmacy: Internet / distance selling

Date of inspection: 16/09/2021

Pharmacy context

This pharmacy operates from a closed unit and offers its services to people through its website (www.pharmease.com). People cannot visit the pharmacy in person unless for a private service such as a vaccination. The pharmacy dispenses NHS prescriptions and it supplies a large number of medicines in multi-compartment compliance aid packs to help people take their medicines at the right time. It dispenses private prescriptions from two prescribing services accessed through a third-party website (www.apomeds.com). People can request a prescription by filling in an online questionnaire which is then assessed by a doctor. A range of prescription medicines are available through the online prescribing service, but the pharmacy mainly supplies medicines for erectile dysfunction to people living in Europe. The pharmacy sells a range of over-the-counter medicines via eBay and Amazon. The inspection was undertaken during the Covid 19 pandemic.

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 risks and it takes steps to improve patient safety. Members of the pharmacy team work to professional standards and they are clear about their roles and responsibilities. The team has written procedures on keeping people’s private information safe and protecting the welfare of vulnerable people.

Inspector's evidence

The pharmacy had up-to-date standard operating procedures (SOPs) for the services provided, including a SOP which covered dispensing private prescriptions from the third-party prescribing services accessed via the Apomeds website. The SOPs had signatures showing that members of the pharmacy team had read and accepted them. Roles and responsibilities were set out in the SOPs and the pharmacy team members were performing duties which were in line with their role. The name of the responsible pharmacist (RP) was displayed as per the RP regulations.

The risks of coronavirus to the pharmacy team and people using the pharmacy had been assessed and the pharmacy had introduced several steps to ensure social distancing and infection control. Dispensary work-stations were well spaced. Team members were carrying out twice weekly lateral flow tests. Team members were not wearing face masks during the inspection. The pharmacist superintendent (SI) said they had been strict about the wearing of face masks until a month ago when the restrictions in the UK were relaxed.

Dispensing incidents were reported on a national reporting system and learning points were included. Near misses were recorded, reviewed, and discussed with the pharmacy team. The team had been trained on look-alike and sound-alike drugs (LASAs), so knew to take extra care when dispensing these.

Risk assessments had been completed by the SI for the supply of medication through Apomeds, eBay and Amazon. The relevant SOPs were referenced in the risk assessments. The risk assessment for the supply of medication through Apomeds included: how the pharmacy communicated with the prescribers and people using the service, the security of people's information, the behaviour of people using the pharmacy services and how medicines were supplied. There was a separate risk assessment for the use of the courier service. The risk assessments for the supply of medication through eBay and Amazon considered the risk of mismanagement of therapeutic conditions and inappropriate requests, including those by people who were under age. Because of these risks the pharmacy had limited medicines sold on Amazon and eBay to general sale list (GSL) medicines. P medicines were not supplied.

A range of prescription only medicines (POMs) were offered via the Apomeds website. People could request a prescription by filling in an online questionnaire which was then assessed by a doctor before the pharmacy supplied the medicine. These included treatments for chlamydia, contraception, erectile dysfunction (ED), high blood pressure, premature ejaculation (PE) and weight loss (orlistat), although the vast majority of prescriptions issues were for ED. Following the inspection, the SI further reviewed the risks of supplying medicines via the Apomeds website and decided that the pharmacy would no longer supply any POMS, other than for the treatment of ED and PE. This was because he was not

fully satisfied with the safeguards currently in place for the other medicines.

Export laws meant that, outside of the UK, the pharmacy could only supply POMs to people in one particular European country. Currently all the prescriptions dispensed from the prescribing service were supplied to people in this one country. Private prescriptions from the prescribing service were sent electronically and contained an electronic signature. The SI said he was satisfied that the signature complied with requirements and it was under the prescriber's sole control. He confirmed that the prescription could not be altered by anyone but the prescriber.

The pharmacy worked with two prescribing services Health Finder Pro and EU doctor 24. Two of the regular prescribers worked for Health Finder Pro. This was a prescribing service based in London and it was registered with the Care Quality Commission (CQC). There was a prescribing policy for this prescribing service which included some information about clinical governance and communication, but there was no details about remote provision or the additional risks of remote prescribing and the use of online questionnaires. The SI confirmed that the prescribing service held monthly clinical governance meetings and one of the prescribers, who was General Medical Council (GMC) registered, was the clinical lead and conducted monthly prescribing audits. The SI had not yet been involved in these meetings but had requested to take a more active part in these going forward. The third regular prescriber worked for the prescribing service EU Doctor 24, which was based in Romania. The SI had checked the registration status of the three prescribers but he was unaware if they had any specialist training in the area of men's health and specifically erectile dysfunction (ED), which was the main area where they prescribed. Apomeds used an automatic identity (ID) checking feature for all people using the prescribing service. It was provided by a third-party, and there was a facility for photographic ID to be uploaded, alongside a 'selfie' style photograph when an additional ID check was required. This was used by the prescribing service to ensure the person was who they claimed to be, and this also verified their age. This was an important safeguard for people requesting contraceptives. Risk assessments and prescribing policies for individual medicines were not available in the pharmacy.

Details of the pharmacy's complaints policy, who to complain to and the local Patient Advice and Liaison Service (PALS) were on the pharmacy's website, however some of the information was outdated. For example, the Royal Pharmaceutical Society of Great Britain (RPSGB), rather than the GPhC, was named as the professional body for pharmacists and the place to raise a concern about a professional issue.

Insurance arrangements were in place. A current certificate of professional indemnity insurance was on display in the pharmacy. The SI confirmed that he had described all the activities carried out by the pharmacy, including working with non-UK prescribers, to the insurance providers, and they had confirmed that the insurance covered all their activities. Details of the prescriber's indemnity was available in the pharmacy. The prescriber working for EU doctor 24 had a low indemnity level, compared to the UK prescribers, which might not be adequate in the event of an incident with a patient in the UK. Following the inspection, the SI stated that the pharmacy would no longer supply prescriptions issued by this prescriber due to this, and would only dispense those provided by the CQC registered prescribing service.

Private prescription and emergency supply records, the RP record, and the controlled drug (CD) register were appropriately maintained. Records of CD running balances were kept and these were regularly audited. One CD balance was checked and found to be correct. Patient returned CDs were recorded and disposed of appropriately.

There was an information governance (IG) file which included information about confidentiality. Confidential waste was collected in a designated place and shredded. A privacy and cookie policy were

available on the pharmacy’s website, and the statement that the pharmacy complied with the General Data Protection Regulation (GDPR) and the NHS Code of Confidentiality. Details of how to lodge a complaint with the Information Commissioner’s Office (ICO) was in the privacy policy.

The pharmacists had completed the Centre for Pharmacy Postgraduate Education (CPPE) level 2 training on safeguarding children and vulnerable adults, and one of the pharmacists had completed level 3. Other staff had completed training appropriate to their role, and a dispenser confirmed she would voice any concerns to the pharmacist working at the time. There was a safeguarding policy in place containing the contact numbers of who to report concerns to, including the details of where to report a concern about a person living in the country supplied in Europe.

Principle 2 - Staffing ✔ Standards met

Summary findings

Pharmacy team members work well together, and they have the right training and qualifications for the jobs they do. Team members are comfortable providing feedback to their manager and they receive informal feedback about their own performance.

Inspector's evidence

The SI was working as the RP and one of the other directors, who was a pharmacist, was also present at the inspection. There were four NVQ2 qualified dispensers (or equivalent) and a delivery driver on duty. The staffing level was adequate for the volume of work during the inspection and the team were observed working collaboratively with each other. Absences were planned to ensure there was an adequate staff level. And there was a part time dispenser, who could provide occasional cover.

Members of the pharmacy team carrying out the services had completed appropriate training. They attended training sessions provided by the pharmacy and completed training modules from an external training provider to ensure their training was up to date. Most of the training provided by the pharmacy over the last year had been related to Covid-19. Two of the dispensers were completing NVQ3 dispensing courses and attended a local college one day each week. The pharmacy team were given annual appraisals where performance and development were discussed, although these had been delayed due to the pandemic. Team members received positive and negative feedback informally from the SI and the other regular pharmacist. Weekly team meetings were held where a variety of issues were discussed, including patient safety issues. A dispenser confirmed there was an open and honest culture in the pharmacy and said she felt comfortable admitting and discussing errors with the pharmacist and would report any concerns to them. The pharmacists were empowered to exercise their professional judgement and could comply with their own professional and legal obligations. For example, they had made the decision not to sell any pharmacy (P) medicines via eBay and Amazon. Team members were not under pressure to achieve targets.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises generally provide a professional environment for people to receive healthcare.

Inspector's evidence

The pharmacy premises, including the shop front and facia, were clean and in a reasonable state of repair. The temperature and lighting were adequately controlled, although direct sunlight through the front window made the dispensary feel very warm at times. Staff facilities included a small kitchen area, and there were two WCs with wash hand basins and hot and cold running water. Hand sanitizer gel was available. There was a main dispensary and a separate room where eBay and Amazon sales were processed. There was an office which was accessed directly from a separate entrance. This was also used as a consultation room for private services, such as flu vaccinations and the processing of covid tests. It was uncluttered, clean and professional in appearance.

The pharmacy's own website (www.pharmease.com) displayed the name and address of the pharmacy, its GPhC registration number, the name and registration number of the SI and the contact details of the pharmacy. Some details were out of date, for example how to raise concerns about the pharmacy to the regulator.

The third-party website (www.apomeds.com) allowed the selection of a POM medicine before the consultation, which might result in the person receiving a medicine which was not the most appropriate for them. The SI explained that the consultation questionnaire had been developed with limitations and blocks for each person based on the individual consultation answers. For example, on the ED questionnaire, if a person indicated that they were on haemodialysis treatment, no tadalafil related products would be allowed, regardless of what the person initially selected. If the person continued to try to choose this product the system would block them from continuing. Similarly, if a person indicated that they were using an interacting drug such as doxazosin, the prescriber would only prescribe the minimum dosage of the desired medicine to minimise the risk of side effects. Subsequent to the inspection, the SI liaised with Apomeds and the website was changed to prevent selection of a POM medicine before the consultation. They also added the details of the CQC registered prescribing service and the identity of the lead prescriber and their GMC registration number. The name, address and registration number of the pharmacy supplying the medicines was displayed so people knew where their medicines were going to be supplied from. There was a photograph of the SI on the website indicating he was part of the medical advisory board. This was misleading as he said he did not currently advise the team about medical issues, although he wanted to become more involved with this.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy offers a range of healthcare services which are generally well managed. It gets its medicines from licensed suppliers and the team carries out some checks to ensure medicines are in suitable condition to supply.

Inspector's evidence

The pharmacy was in a secure, closed unit. People could communicate with the pharmacist and staff via the telephone or by email. A list of the services provided by the pharmacy was available via the pharmacy's own website. The pharmacy team was clear what services were offered and where to signpost people to a service not offered. For example, travel vaccinations. Covid-19 PCR tests were available at the pharmacy and the tests were sent to a UKAS registered lab for processing. There was a healthy living zone with health information on the pharmacy's website.

People using the prescribing service usually contacted the Apomeds call centre rather than the pharmacy with any enquiries, and they had multilingual speaking staff at the call centre. The Apomeds website had information about the conditions listed and links to NHS information. Its website had translations in various European languages. Medicines supplied from the prescribing service were sent to people by courier, and the delivery could be tracked. The courier delivery was a next day service, which included weekends, so people requesting urgent medication such as emergency hormone contraceptives (EHC) would be supplied with their medication promptly.

The SI said before agreeing to work with Apomeds he had considered which medicines were appropriate for supply at a distance and referred to the National Institute for Health and Care Excellence (NICE) guidance as part of his decisions making. He refused to supply asthma inhalers or antibiotics for urinary tract infections (UTIs) as confirmation of diagnosis was difficult without a physical test. He was aware of the need for antimicrobial stewardship and felt that one-off antibiotics for the treatment of chlamydia was acceptable. The pharmacy did not supply any medicines liable to abuse, overuse or misuse such as medicines containing codeine. It supplied a small number of medicines that required ongoing monitoring or management. For example, medicines to treat high blood pressure and high cholesterol. The SI did not know what steps the prescribing service had in place for follow up and monitoring but stated he would meet with the clinical lead to ensure appropriate follow up procedures were in place or the pharmacy would no longer supply these medicines. The SI said the contraception questionnaire had been designed to prevent the supply of the product to anyone for whom it may not be suitable. And every supply required completion of a new consultation questionnaire, so the patient's weight and smoking status were checked every time. However, there was no specific question about blood pressure, other than checking the person did not have 'severe high blood pressure'. One question was whether the patient had seen their GP in the last 12 months, and the SI stated there was an assumption that people's weight and blood pressure would be checked as part of this. If the person had not been reviewed by their GP in the last 12 months they were unable to proceed with the questionnaire. However, this relied on the person entering the correct information.

Consent to contact the patient's usual prescriber was requested in all consultations, but the SI did not know how many people gave the required consent, and he received no verification that their own

GP had been informed. It was not clear if the prescriber made a clear record setting out their justification for prescribing if consent was not received. The SI had obtained confirmation from the prescribers that they followed UK national prescribing guidelines. He had not formally audited any prescribing himself but said he had not come across anything which he considered unusual. He raised queries directly with the prescribers if necessary and had met the clinical lead in person. The pharmacy could see some of the 'backend 'of the prescribing system, but not the full consultation questionnaire. When medicines for ED were supplied the patient was required to confirm they would not take combinations of different medicines at the same time, and this confirmation could be checked by the pharmacy. A feature was currently being developed which extracted relevant information from the questionnaire answers to the pharmacy back office. This would allow for further medication safeguarding and drug interaction checks. For example, questions about medication history, allergies, and other diseases. People in Europe, receiving their medication from the prescribing service, received a copy of the private prescription alongside their medication. It was in English with a German translation. The medication was labelled in English and the packaging leaflets were also in English, so there was a risk that the person might not understand all the information. The SI said that English was widely spoken in the country that they supplied in Europe, and packaging leaflets could be downloaded in the patient's own language via the Apomeds website if necessary.

Patient medication records (PMR) were checked when prescriptions from the prescribing service were dispensed which helped to identify inappropriate requests. The SOP relating to prescriptions dispensed from the online prescribing services included the requirement for a member of the pharmacy team to check the number of times the person had ordered the medicine in the last six months, and they could refer to the pharmacist for a clinical review if necessary. Pharmacists were required to contact the prescriber via phone or email and refer to NICE guidelines when necessary to determine whether it was appropriate to dispense. The option to refuse the supply was used if the pharmacist felt the prescription was clinically unsuitable. For example, a male who had requested a contraceptive, which might be a safeguarding issue. The SI confirmed that other checks to identify multiple orders to same address or same payment details were carried out by Apomeds.

Over the counter (OTC) medicines sold on eBay or Amazon were sent on a next day Royal Mail service which could be tracked by the pharmacy. A signed for service was used for expensive medicines. There were two dispensers responsible for the supply of medicines via eBay and Amazon. They were clear which medicines were P medicines and which were GSL medicines, and knew that the pharmacy did not supply any P medicines via these platforms. Most of the products typically consisted of non-regulated counter lines such as hands warmers, non-medicated heat pads, vitamin supplements, fisherman's friends, Jakemans pastilles and plasters. People's purchasing history was checked by one of the dispensers and he reported any concerns to the pharmacist before agreeing the supply. Maximum quantities were set for certain lines such as paracetamol containing medicines. However, some large quantities of GSL medicines were being sold on Amazon, such as 4 packs of 30 cetirizine tablets. The SI felt this was acceptable as some people needed to take antihistamines every day, however they did not ask any questions to verify the reason for the large volume, and had not considered the risk of a more serious condition going undetected, or the risk of overdose. Follow up calls were sometimes made to confirm the sale was appropriate, for example a person who was purchasing a large quantity of vitamin B. A record was made of this call. Another sale was declined as the person did not reply to messages from the pharmacy. Medicines returned due to failed deliveries were not re-used.

There was a home delivery service for NHS prescriptions with associated audit trail. The service had been adapted to minimise contact with recipients, in light of the pandemic. The delivery driver stayed a safe distance away whilst the prescription was retrieved from the door-step, and then confirmed the safe receipt in their records. There was separate sheet completed for the delivery of CDs.

Space was adequate in the dispensary and the workflow was organised into separate areas with a designated checking area. The dispensary shelves were well organised, neat, and tidy. Dispensed by and checked by boxes were generally initialled on the medication labels to provide an audit trail, although a sample of compliance aid packs had not been initialled by the dispenser, so this might limit learning if an error occurred. Different coloured baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. The baskets were stacked to make more bench space available.

The team were aware of the valproate pregnancy prevention programme. The SI didn't think that any of the regular patients were in the at-risk group. He confirmed valproate care cards were available to ensure people in the at-risk group were given the appropriate information. Records of referrals to GPs, counselling and interventions were maintained and recorded on the patient's medication record (PMR)

A large number of people with NHS prescriptions received their medication in multi-compartment compliance aid packs. These were well managed with an audit trail for communications with GPs and changes to medication. Medicine descriptions were included on the labels to enable identification of the individual medicines and packaging leaflets were included. Disposable equipment was used.

CDs were stored in a CD cabinet which was securely fixed to the wall. The keys were under the control of the responsible pharmacist during the day and stored securely overnight. Date expired, and patient returned CDs were segregated and stored securely. Patient returned CDs were destroyed using denaturing kits. Medicines were stored in their original containers at an appropriate temperature. Dates had been added to opened liquids with limited stability. Alerts and recalls were received via email messages from the NHS area team and the Medicines & Healthcare products Regulatory Agency (MHRA). These were read and acted on by a member of the pharmacy team and then filed. A copy was retained in the pharmacy with a record of the action taken so the team were able to respond to queries and provide assurance that the appropriate action had been taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

Pharmacy team members have access to the equipment and facilities they need for the services they provide.

Inspector's evidence

The pharmacists were able to access the internet for the most up-to-date information including the electronic British National Formulary (BNF). There was a clean medical fridge. The minimum and maximum temperatures were being recorded regularly and had been within range throughout the month. The fridge thermometer was recording a maximum temperature of 9 degrees Celsius, which was outside the required range at the start of the inspection, however once it had been reset, it remained within range throughout the inspection. All electrical equipment appeared to be in good working order. The pharmacy had clean equipment for counting loose tablets and capsules. Medicine containers were appropriately capped to prevent contamination. PMRs were password protected. Cordless phones were available in the pharmacy, so staff could move to a private area if the phone call warranted privacy.

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.