General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: MedExpress Pharmacy, Unit 7B, Datapoint, Cody Road, London, E16 4TL

Pharmacy reference: 9011509

Type of pharmacy: Internet / distance selling

Date of inspection: 16/08/2022

Pharmacy context

This is a distance-selling pharmacy (www.MedExpress.co.uk) linked to an online prescribing service. The pharmacy dispenses private prescriptions only, generated by a team of pharmacist independent prescribers. Medicines are delivered via courier to people living in the UK and EU. The types of medicines mainly dispensed are for conditions such as erectile dysfunction, weight management, hay fever, migraine, situational anxiety and asthma. The pharmacy is closed to the public and situated in a serviced warehouse.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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 follow its own risk assessments designed to protect people's wellbeing. It does not adequately manage all the risks of people obtaining medicines which are not clinically appropriate. This includes treatments for weight loss, asthma and situational anxiety. And it has not fully considered and addressed the risks of bulk prescribing medicines largely by relying solely on an online questionnaire without getting further information from people.
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 allows people to start a consultation from the page of an individual prescription-only medicine. This does not meet GPhC requirements.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy cannot demonstrate that it seeks sufficient assurances from people requesting higher-risk medicines, including weight-loss treatments, and asthma treatments to make sure the medicines are clinically appropriate. Its bulk prescribing process means there is limited individual input into a person's care by prescribers.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

Overall, the pharmacy has made significant improvements since its last inspection. It identifies and adequately manages most risks associated with the provision of its pharmacy services. But some weaknesses remain. It has not adequately considered and mitigated all the risks of more vulnerable people obtaining medicines which are not clinically appropriate. This includes treatments for weight loss and situational anxiety. And medicines are generally prescribed by relying solely on an online questionnaire without getting further information from people. This increases the risk of supplying medicines to people on the basis of inaccurate or incomplete information. However, it keeps the records it needs to by law. And the pharmacy manages people's personal information safely. The pharmacy has suitable procedures to learn from its mistakes.

Inspector's evidence

The pharmacy's business involved the supply of prescription-only medicines (POMs) to people mainly based in the UK and EU. The medicines were supplied against private prescriptions issued by one of the Pharmacist Independent Prescribers (PIPs) employed by the pharmacy. The pharmacy's website had treatments available for a wide range of conditions such as erectile dysfunction, hair loss, asthma, and weight loss.

Standard operating procedures (SOPs) were available. They had been prepared recently and were due for a review in 2023. Individual signature sheets were signed by team members to confirm that they had read and understood the relevant SOPs. Two new SOPs had been introduced and these covered returned medicines and obtaining consent from people accessing the pharmacy's services to share information about their treatment with their own GPs.

The pharmacy had risk assessments for all the various conditions it prescribed for. These included treatments for erectile dysfunction, cystitis, situational anxiety, weight loss, Ventolin for asthma, herpes, period delay, cystitis, chlamydia and thrush. The pharmacy was currently only providing orlistat for weight loss and planned to start providing Saxenda in the future. The pharmacy's risk assessments took into consideration hazards identified and controls and safeguards in place, clear inclusion and exclusion criteria, and clear actions of what to do if consent to share information with their GP was not provided. They also had clear instructions on how the prescribers and pharmacy team would communicate with the person if there were any concerns. The pharmacy had a medical advisor who advised on the risk assessments. The team held regular meetings to discuss prescribing decisions. There was a clear audit trail of who wrote the prescription and evidence of any documentation that took place. People were made aware of risks through information provided on the website or by the pharmacy team, for example via patient information leaflets.

The risk assessments had 'stop gaps' which were interventions which would prevent inappropriate quantities being supplied to the person and ensure that people were not over ordering over a defined period. For example, the pharmacy limited the supply of Ventolin to two inhalers every 180 days. This was checked and was seen to be followed the majority of the time.

The pharmacy had stricter criteria for higher-risk medications, such as Ventolin, propranolol and

Saxenda, with regards to a patient not consenting to share information with their GP If a person did not provide consent, the prescriber may refuse a supply and carry out an individual assessment. For example, if a person requested Ventolin and consent to share information with their GP was not provided, the RP would use an Asthma Control Test which is a validated tool to help determine if a person asthma is controlled or not. Based on the score of the test, the pharmacy would make a decision whether to tosupply Ventolin to the person.. However, some Ventolin supplies were seen where consent to share with the person's GP was not provided and an asthma control test had not been carried out. The pharmacist explained that the requirement for an asthma control test had only recently been implemented. Asthma reviews were conducted at the person's fourth order. If a person's asthma management score was low, they were advised to contact their GP. The contact details of a person's GP were requested at that point, if they had not been provided initially. The pharmacist said that a supply was not made if the person did not provide their GP's details and if their asthma score was low. Letters to people's GPs were seen to be sent and copies were retained at the pharmacy.

There was limited consideration given to contacting people particularly those requesting higher-risk medication such as propranolol. This was prescribed only to treat situational anxiety. For example, as long as the person filled out the questionnaire correctly, there was no contact made by the prescriber. There was no additional reassurance to confirm if the person had been prescribed the medication before by their GP.

The pharmacy was, in the majority of cases, prescribing in line with national guidelines and evidence-based prescribing. But there were examples seen where people were still supplied with orlistat despite no weight loss reported. The pharmacy relied solely on its online questionnaires to verify the person's weight when prescribing orlistat. Although the pharmacy was not prescribing Saxenda yet, it said that it would be adopting a similar principle. There was limited contact with the person to further clarify if the person was losing weight. There was no process for face-to-face contact with people ordering weight-loss medicines, for example video consultations, and the prescribers generally relied on the answers people gave in the questionnaires. The pharmacy had stop gaps in place to prevent over ordering of weight loss medication. But the absence of any visual contact during a consultation increased the risk that people with eating disorders were able to obtain medicines which were not clinically appropriate.

The pharmacy undertook several audits to review various aspects of the prescribing service. It completed a pre and post audit when a product was launched to ensure the consultation questions were accurate and up to date, and that it was prescribing in line with the latest guidelines. Furthermore, regular audits were conducted to ensure that the stop gaps in place were effective. The pharmacy had undertaken an audit for higher-risk medication to identify the prescribing patterns and found that for propranolol and Ventolin a minorty of people ordered more than once. For those people who did order more than the allowance as per the stop gap policy there were system-led interventions to prevent further prescriptions being issued. These interventions did not involve prescribers. There were limited audits to review prescribers' consultation notes.

Near misses, where a dispensing mistake was identified before the medicine had reached a person, were documented by the person involved in a near-miss register. Team members had written "double check" as the learning point for most entries. A patient safety report was completed by the pharmacist who collated information on the type of error and any contributing factors. Dispensing mistakes, complaints and any issues were also reviewed as part of the process. The same two action points were repeated in the last 11 patient safety reviews, and these were "slow down" and "stock review". This was discussed with the pharmacist who agreed that action could be more robust. The pharmacist described changes that had been implemented as a result of these reviews, for example, the pharmacy

no longer supplied split packs of propranolol tablets and only provided original packs. Dispensing mistakes which reached people, called dispensing errors, were also documented. The pharmacist described a recent dispensing mistake where a person claimed that they had received the incorrect quantity. The pharmacist said that medicines underwent two or three checks before they were packed. People were asked to send photographs of the medicine to clarify the mistake and help in the investigation process.

An interventions log was in place to record any delivery issues, adverse effects and side effects. The log was reviewed during the clinical governance meetings which were held monthly. An audit of the log had been carried out and presented to the pharmacists, clinical lead, and customer service team.

The pharmacy had current indemnity insurance cover and confirmed that the PIPs were covered under the pharmacy policy for prescribing activity. A responsible pharmacist (RP) sign was displayed. Samples of the RP record were generally well maintained. Other records required for the safe provision of pharmacy services were generally completed in line with legal requirements, including those for private prescriptions. The pharmacy did not dispense controlled drugs or provide emergency supplies.

A complaints procedure was in place and available on the pharmacy's website. People were able to give feedback or raise concerns online, by live chat or by contacting the customer service team. They were also able to review and rate the pharmacy on various platforms, such as Trustpilot. Complaints were documented in an interventions log and a pharmacist was asked to contact the person if necessary.

Team members were provided with training on protecting people's confidentiality and were asked to sign confidentiality agreements at the start of their employment. An information governance policy was in place and accessible to team members. Confidential waste was shredded at the pharmacy and computers were accessed via individual usernames and passwords.

Team members, including the customer service team, were provided with training on safeguarding vulnerable groups by the medical lead and had the opportunity to ask questions during the session. They also completed online training on capacity and coercion. The contact details of local safeguarding teams were displayed in the pharmacy. The pharmacy did not prescribe for anyone under the age of 18 and in the individual risk assessments had a clear outline of this.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to manage its workload. Team members have clearly defined responsibilities, and they do the right training for their roles. And they complete some ongoing training to help keep their knowledge up to date.

Inspector's evidence

The pharmacy was staffed by two pharmacists, four dispensing assistants and five trainee dispensing assistants. The trainee dispensing assistants were all enrolled onto a suitable course. Members of the customer service team worked from home and were not involved in dispensing. Three PIPs prescribed for this pharmacy and a sister company. The RP undertook the clinical checks of the prescriptions at the pharmacy. If a prescriber was unwell, then the other prescribers stepped in. The PIPs worked remotely.

Team members had a good understanding of their roles and responsibilities and said that they had been provided with an introduction of processes at the pharmacy. They were assigned tasks on a daily basis. The dispensary team was provided with ongoing training, for example, on new products and changes in procedures. They completed online training at the start of employment, and this covered topics such as information governance and manual handling. They had completed training on Saxenda (a weight-loss medicine) which the pharmacy was planning on providing in the future. They had also completed other modules such as hay fever, antifungal products and over-the-counter emergency hormonal contraception. The pharmacy maintained a spreadsheet of training modules completed by members of the team to help keep track. There was clear evidence that the pharmacy team shared learning. For example, the RP discussed and implemented the 'stop gap' policy to avoid repeated medicines being prescribed.

The curriculum vitae of the three PIPs was reviewed and these showed experience of working in GP and hospital settings. They had undertaken an independent prescribing course and all three were annotated on the GPhC register as PIPs. Prescriber induction training was provided by MedExpress on all the medications prescribed, patient questionnaires and consultation information. The PIPs also have access to a medical doctor for medical related queries who also supported the pharmacy if they needed advice with regards to the provision of clinical services. PIPs were emailed information which related to new products due to be introduced to the service. This information included the risk assessments, and the PIPs were requested to book training on conducting the corresponding consultations and the new medications. PIPs had to be approved on all the consultations before they were able to prescribe during their induction training. All the prescribers had signed to confirm that they had understood the risk assessments. The pharmacy also held records of the prescribers' declarations of competence in the areas they were prescribing for. There was limited evidence of appraisals of the prescribers or review of the prescribers' consultation notes. There was limited evidence of how they carried out continual learning and development. Prescribers had access to a channel where they could communicate with each other.

Performance reviews for other pharmacy staff were conducted every six months. Team members had the opportunity to discuss any challenges, development needs, support needs, and successes. Targets

were not set for dispensing staff or the PIPs. Team members said they felt comfortable about discussing any issues with the team lead or pharmacists.

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

Summary findings

The pharmacy's website does not meet GPhC guidance about online consultations and how people access prescription-only medicines. It allows people to start a consultation from the page of an individual prescription-only medicine. However, the pharmacy's premises are well maintained and fit for purpose.

Inspector's evidence

The pharmacy was not accessible to members of the public. It was located within a large warehouse which was split into two units, housing two pharmacies. This pharmacy was located on the first floor. A reception area was located on the ground floor. The pharmacy was well organised. There were separate stations for processing and labelling prescriptions, packing and assembling medicines, checking, and dispatch.

The pharmacy's website displayed the General Pharmaceutical Council (GPhC) voluntary logo. The website displayed the required information, including names of prescribers, the superintendent pharmacist and the responsible pharmacist. But the website did not make it clear that the UK-registered prescribers were pharmacist independent prescribers.

The pharmacy's website allowed people to select a prescription-only medicine (POM) before starting an appropriate consultation by clicking on a 'continue visit' button located on the individual medicine's page. This button directed people to a conditions page where they could start a consultation.
The pharmacy premises were clean and organised. Cleaning was carried out by external cleaners. There was sufficient work and storage space. Workbenches were generally kept clutter free. There were adequate hygiene and handwashing facilities for staff. The room temperature and lighting were adequate for the provision of pharmacy services The pharmacy was secure from unauthorised access.

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

Summary findings

The pharmacy's services are accessible to people and it orders its medicines from reputable suppliers and stores them properly. But it cannot demonstrate that it seeks sufficient assurances from people requesting medicines including higher-risk medicines such as asthma and weight-loss treatments. Some people have been able to obtain prescriptions for Ventolin without definitive confirmation they have been prescribed this previously for asthma. And its bulk prescribing process may also increase the risk of inappropriate supplies of medicines as this may mean there is limited individual input into a person's care by prescribers.

Inspector's evidence

The pharmacy's services were accessed via its website. People were required to create an account after completing the questionnaire to checkout their basket. Patient information leaflets were available in different languages for medicines sent abroad. The pharmacy had recently implemented this. The pharmacy was looking at obtaining an NHS license to be able to access peoples' Summary Care Records.

Dispensing audit trails to help identify who dispensed and checked medicines were completed. Baskets were used throughout the dispensing process to separate prescriptions and prevent transfer between people.

Once prescriptions were received, labels were generated automatically by the system. Stock was then picked by a dispensing assistant, but they were only provided with the labels and postage stamp. The risks of dispensing against labels and not the prescriptions were discussed with the pharmacist. The dispensers were aware of some quantity limits which had been set by the pharmacy, for example, a maximum of 64 sildenafil tablets could be supplied at any one time. A prescription for a person who had requested 24 sildenafil tablets and 16 tadalafil tablets was seen to be dispensed. The dispenser said that the person would be sent a letter in the package advising them not to take both medicines at the same time.

Identification (ID) checks were carried out by a third-party organisation. The pharmacy's customer service team contacted the person directly and requested ID if the third-party check failed. The ID, which had to be formal documentation such as passport or driving license, was uploaded on the pharmacy's platform. The pharmacist said that prescriptions were not processed if ID was not provided. Examples of cancelled orders were seen on the pharmacy's system. The pharmacy's system did not allow a new account to be created with the same name, address, and date of birth as an existing one.

Once a person had filled in the online questionnaire it was submitted. A payment was needed to be made before the order could be processed. At this point the prescriber checked the consultation and provided a prescription. The questionnaire allowed the person to see if an answer which would result in a supply not being approved was selected. PIPs were able to identify if answers had been changed. And if the answers had been changed, this directed the prescriber to a separate screen so they could further clarify the answers. There was evidence seen where this was taking place and documented on the system and there was evidence where the prescriber would not supply medication if they were not satisfied with the information provided. The questionnaire form could not be submitted with answers which would result in a supply not being made or without agreeing to the terms and conditions. For

weight loss medicine, the request was flagged up on the system if a person changed their answer to whether they suffered from bulimia or anorexia. The pharmacist said that the pharmacy team members or the PIP would be involved in contacting the person to confirm they had answered correctly, however, this was done over the telephone; there was no visual contact with the patient. The pharmacy said they checked if people taking orlistat were losing at least 5% of their body weight and maintained records of these checks. But there were examples seen where orlistat had been prescribed and where people had no reported weight loss.

Prescribers could choose to pre-approve some 'consultation formats' and bulk prescribe some consultations using one of the 'prescribe all' buttons. The SOP stated that the company 'guaranteed' that all consultations conformed to the pre-approved consultation formats allowing the prescriber to prescribe in confidence. PIPs were not able to bulk prescribe if the person had changed their answers during the consultation, or if additional notes had been added to the person's record. But there was limited evidence that the pharmacy had considered all the risks associated with their 'blanket-prescribing' process. If there was no issue identified in the questionnaire such as changed answers, or patients who had been delisted previously, the majority of requests were bulk prescribed even for treatments for involving higher-risk medicines such as propranolol. The pharmacy and prescribers didn't take into consideration what they would do to review those patients that sat in the bulk prescribing inbox, even if prescribing the medicine for the first time. By allowing the prescribers to issue multiple prescriptions without needing to see the individual details of people increased the risk that people were prescribed medicines that were not suitable for them.

Dispensed medicines were packed in boxes and plastic envelopes. The dispensing assistants said they checked the name on the medicine label and postage stamp. Medicines were delivered by Royal Mail tracked or special deliveries. Returned medicines were kept in a designated area and a member was assigned to process these and update a spreadsheet. The medicines were disposed of in waste medicine bins which were collected by an approved contractor.

Medicines removed from their original packs were labelled with their batch number and expiry date. Members of the team were assigned a section to carry out expiry date checks. These were done every three months and a record was maintained to keep track. The fridge temperatures were checked and recorded daily. Drug alerts and recalls were received electronically, actioned and filed for reference.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely.

Inspector's evidence

The fridge was clean and suitable for the storage of medicines. The pharmacy was only providing original packs or tablets in blister packs and did not require tablet counting equipment or equipment to measure liquids.

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.