General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: M.E.J. Hingley & Co Ltd., 560-562 Green Lane, Small Heath, BIRMINGHAM, West Midlands, B9 5QG

Pharmacy reference: 1038007

Type of pharmacy: Internet / distance selling

Date of inspection: 05/07/2022

Pharmacy context

This pharmacy is located on a busy main road in the Small Heath area of Birmingham. Although open to the public, it does not hold an NHS pharmacy contract and the pharmacy 's primary business is its online private prescribing service which it offers via its website www.pharmacydirectgb.co.uk, in partnership with a Romanian-based prescriber. The prescribing service covers a range of lifestyle medicines including treatments for erectile dysfunction, hair loss and asthma. In addition, general sales list and pharmacy restricted medicines are sold through the website. The pharmacy has a small range of medicines available for sale on the premises, as well as other household goods.

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's risk assessments do not adequately identify and manage all of the risks associated with its services, including the risks associated with working with an overseas prescriber. Risk assessments for the individual medicines it supplies are not regularly reviewed and updated. And the pharmacy's standard operating procedures do not always clearly explain how it operates and who is responsible for each part of the service.
		1.2	Standard not met	Proactive audits of the service are not carried out, so the pharmacy cannot demonstrate that prescribing is safe and in accordance with UK guidelines.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy team are not all appropriately qualified to carry out the tasks that they are doing on a daily basis. Regular checks to confirm the prescriber's registration and authority to prescribe are not carried out.
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website is designed so that a member of the public can select a medicine before commencing a consultation. And it contains information which is sometimes inaccurate or misleading.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy sells medicines via its website, but it does not carry out enough independent checks to provide assurance that the medicines it supplies are suitable for the person requesting them or that they are being used safely. It does not check people's identity when they purchase medicines or verify any of the information provided in the online questionnaires. And it does not share all relevant information with the person's regular doctor when it supplies medicines that require monitoring.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The risks associated with the provision of the pharmacy services are not adequately identified and managed. The pharmacy works with a prescriber who is based in Romania, and it cannot demonstrate that prescribing is following UK guidelines. The pharmacy does not carry out risk assessments or audits of the service regularly. And it does not make a reliable check of a person's identity before it supplies them with medicines. This means the pharmacy cannot show that the prescribing service is safe and vulnerable people may be able to obtain medicines that could cause them harm.

Inspector's evidence

People could purchase over the counter medicines or request prescription only medicines (POMs) through the website. In the case of POMs, people who were in possession of a valid private prescription could submit the details online and then send it to the pharmacy to be dispensed. Or they could select the medication they required from the treatment options available, and complete an online questionnaire consultation, which was reviewed by the prescriber before a prescription was issued. The prescriber was a doctor based in Romania. This meant the prescribing service was not registered with a UK healthcare regulator. And so, it was not subject to inspection by a UK regulator, such as the Care Quality Commission (CQC) in England, Healthcare Inspectorate Wales or Healthcare Improvement Scotland (HIS) to ensure the prescriber was working in accordance with the standards expected in the UK. The pharmacy had not identified this additional risk as part of their risk assessment and so it had not considered ways it could reduce or mitigate the risk of using a prescriber that was not regulated by a UK regulator. Risk assessments were required for each part of the service, to show how the pharmacy managed the risks associated with each type of medicine that was prescribed remotely. The superintendent (SI) said that risk assessments were last reviewed in mid-2019 and they had not been updated since then. This meant that the risk assessments were not reviewed regularly. In addition, the pharmacy did not carry out any planned audits of its services. This was particularly important as the pharmacy was supplying POMs prescribed by an overseas prescriber, so planned audits would provide ongoing assurance that medicines were being safely supplied to people, in accordance with UK national prescribing guidelines.

The pharmacy had a set of standard operating procedures (SOPs) in place. Team members had signed the procedures as evidence of their training and the procedures had been dated to show that they had been recently reviewed. The SOPs were based on templates from a recognised supplier, and they focused on NHS services. The pharmacists had made some minor amendments to attempt to make them more relevant to the pharmacy's private prescription service. But they did not cover certain aspects of the service, such as, the controls that were in place when selling higher-risk pharmacy medicines that contained codeine, the parts of the service that were carried out by the prescriber, or how and when to check a person's previous order history, so the additional risks might not be effectively managed.

The questions included in the online consultation had evolved and changed over the time that the service had been in operation. There was no formal process for reviewing and updating the questions,

and the questionnaires had been created using the SI's experience, together with input from the prescriber. There was an option on the website for people to give consent for their usual GP to be contacted to inform them that a supply had been made. The pharmacy team members did not contact the GP when consent was given, and they were unsure whether the prescriber did this. The pharmacy supplied prescriptions for asthma inhalers. These medicines require ongoing monitoring or management, so, it was important that the persons usual GP was pro-actively informed of the supply so that their ongoing condition could be effectively monitored.

The pharmacy's telephone number was clearly published on the website and the 'contact us' section had the telephone number, email address, physical address and an online messaging form. The invoice that was sent with the order, and the dispensing label for prescriptions also contained the pharmacy's contact details. The SI explained that she was unaware of any errors or concerns in recent years and explained the process that was followed if the pharmacy was to be contacted about an error or complaint. People also left feedback about the pharmacy on Trustpilot, and this was generally positive.

The pharmacy had up-to-date professional indemnity insurance which covered online activity and prescribing services. The Responsible Pharmacist (RP) notice was clearly displayed in the shop area and the RP log met requirements. Private prescription records were maintained in a record book and appeared to be in order: each had a reference number which allowed the team to quickly cross-reference to a printed copy of the prescription form that they had dispensed against. Additional records, such as delivery tracking, back up paper records for deliveries, failed/returned deliveries, and rejected orders were also kept.

The website had been created by a specialist developer and the SI had enquired during the tendering process about website security so that people's information was kept safe. The SI had been given specific details at the time to assure her that the website was safe and had 'banking grade' security and encryption. She had also been assured that the prescriber had password protected access to the prescribing part of the system and she was the only person that could approve and issue the prescriptions that were authorised by the prescriber. The privacy policy was displayed on the website and the company was registered with the Information Commissioners Office (ICO). Confidential waste was separated and was disposed of securely.

The pharmacy team members were aware that codeine-based medicines could be abused, misused or overused. They checked the information that the person had supplied when they had placed the order and then cross-referenced their details to the date that they had last placed an order and how often they were ordering, before deciding whether to approve or reject the order. People were sent an email to warn them of the risk of addiction with codeine containing products as part of this process. The dispenser and SI had an agreed policy between themselves on when to approve or reject, however, this was not documented for reference. The SI was aware of general safeguarding procedures and explained an example of when she had intervened when a request for antibiotics had been made and the different steps she had taken to safeguard the person involved.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy has enough staff to provide its services. The team members work well together in a supportive environment, and they can raise concerns and make suggestions. But pharmacy team members do not always complete the training they need to do their jobs, so they might not have the right skills and knowledge. And the pharmacy does not regularly check the prescriber's registration status to confirm they have the authority to prescribe.

Inspector's evidence

The pharmacy team comprised of the SI (RP at the time of the inspection), a dispensing assistant and a trainee medicines counter assistant. The trainee medicines counter assistant had been enrolled on an accredited training course several years ago but had not managed to complete it before it had expired, therefore she was not appropriately qualified for the tasks she was doing. Holidays were requested in advance and cover was provided by other staff members as required. Two other pharmacists were available to work at the pharmacy when the SI had other duties to carry out and they always worked with the dispenser as she understood the systems that the pharmacy used.

Members of the team were knowledgeable about their roles and discussed these during the inspection. They correctly answered hypothetical questions related to high-risk medicine sales, both for online sales and in person requests. Ongoing training was undertaken by reading pharmacy magazines and literature that was sent to the pharmacy.

The prescriber had provided Diploma certificates and a reference of good standing from an employer. She had previously been registered with the General Medical Council (GMC), but this registration had lapsed in January 2018. The SI had copies of these certificates, but she had not regularly checked the prescriber's registration with the relevant regulator in Romania, to make sure she was still authorised to prescribe.

The team worked well together during the inspection and were observed helping each other and moving onto the healthcare counter when needed. The team discussed pharmacy matters on an ongoing basis, rather than waiting for a formal meeting. The pharmacy staff said that they could raise any concerns or suggestions with the SI or one of the other regular pharmacists and felt that they were responsive to feedback. Team members said that they would contact the GPhC if they ever felt unable to raise the issue internally. No targets were set in relation to the prescribing service.

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

Summary findings

The pharmacy is clean, properly maintained and it provides a suitable environment for the services carried out. The pharmacy uses a website that allows people to select the prescription only medicines they want before they have a consultation with a prescriber. This means people may receive medicines that are not always suitable for them. The website contains out of date information about the service, which could be confusing and means people may not be able to make a fully informed choice when deciding to use the pharmacy's services.

Inspector's evidence

The pharmacy was open to the public for the sale of general household goods and over-the-counter medicines. The premises were suitably maintained. A range of healthcare promotion materials was displayed. The premises appeared clean and there were no noticeable trip hazards in patient facing areas. The dispensary had an adequate amount of space, but the work benches were sometimes cluttered with paperwork which impacted on the space available for prescription assembly. There was adequate lighting throughout the premises and the ambient temperature was appropriate for the storage of medicines.

The majority of the pharmacy's business was provided through their website, which was accessible to people at www.pharmacydirectgb.co.uk. The pharmacy address, telephone number and GPhC registration number were also displayed on the home page, along with additional company information on an 'about us' tab. The name and registration number of a pharmacist was displayed as SI; however, these details were of the previous SI who had not held this role since March 2020. The website stated that 'all consultations and prescribing are made by licensed and qualified EEA Doctors' and listed the prescriber's name, registration number and address. But there was no information explaining how to check their registration. And the details of any indemnity arrangements were not displayed. The shipping and returns page of the website incorrectly stated that the services used a GMC registered doctor to review and approve prescription requests.

The pharmacy's website enabled people to select a prescription only medicine prior to completing a consultation with the prescriber. This means that they may not always receive the most appropriate medicine to meet their needs. Underneath most of the prescription only medicines there was a brief description explaining what the medication was used to treat and how many could be requested at one time. But the pharmacy's website content could be improved to provide people with more information about the medicines it supplies. Especially for pharmacy medicines, where there was only basic information provided for many of the products available.

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

Summary findings

The pharmacy does not make enough checks to ensure that medicines are safe and appropriate for the people it supplies, and its online consultation questionnaires are not as effective as they could be. The pharmacy does not proactively share information with other health professionals involved in the person's care when supplying prescription medicines for ongoing conditions, such as asthma. The pharmacy gets its medicines from licensed suppliers, and it stores them securely and at the correct temperature, so they are safe to use.

Inspector's evidence

The pharmacy was located on a busy main road and was accessible via a small step. The pharmacy did not hold an NHS contract and the pharmacy team referred people requesting NHS pharmacy services to nearby pharmacies. The pharmacy website had limited information on general health promotion or signposting guidance. It contained a blog section with articles relevant to the medicines supplied by the pharmacy, such as erectile dysfunction, weight loss, back pain and incontinence.

Dispensing was undertaken on the premises and baskets were used to keep medicines separate and reduce the risk of them being mixed up. The pharmacists signed the 'checked by' box on the dispensing label as an audit trail. And the dispensing assistant undertook an accuracy check as she was packing the medicines for delivery.

Patients already in possession of a valid prescription proceeded to payment and were then sent an email informing them of the pharmacy address to send the prescription to. Orders remained on the system until the prescription was received and were not dispensed or dispatched in advance of the prescription physically arriving at the pharmacy.

A range of OTC and prescription only medicines were available through the pharmacy's website. Prescribing service treatments were available for a limited range of conditions including asthma, oral contraception, weight loss, hair loss and erectile dysfunction.

Requests for general sales list and pharmacy medicines were checked before being approved for supply. Patients selected the medication required and payment was processed through the website. Once an order was received the dispenser or pharmacist reviewed the request and either approved or rejected the order. The pharmacy sold some medications which could be abused, misused or overused, such as codeine-based pain relief. On the website there were statements which explained that only one box of such a medication could be supplied at a time and the ordering history was checked before the supply was approved, this included orders that had been cancelled. If an order was refused the person was sent an email to explain why, and a refund was processed.

People requesting prescription only medicines were required to complete an online questionnaire. This included providing information such as who the medicine was for, the type of symptoms being experienced and the details of any other medications or health issues. In addition, people provided

information such as their weight, height, smoking status, medical history and blood pressure. There were some 'pop-ups' during the online questionnaires which prevented the person from continuing unless the response was changed. The pop-ups were only used to prevent the person continuing with the questionnaire when medication requested was specifically for men, such as erectile dysfunction treatments or treatment for male pattern baldness. Some responses to 'yes or no' questions resulted in a free text box opening. The free type boxes were used for the person to add in extra information about their response for the prescriber. It was unclear whether the prescriber requested additional information from the person to confirm that their responses to the online questionnaire were true and reliable. For example, the pharmacy team did not know whether the prescriber confirmed that a person had a formal asthma diagnosis or made additional enquiries when a person requested weight loss medication. The pharmacy team did not have access to the prescribers' notes or the online responses, so they were unable to make additional checks without asking the prescriber directly.

Despite the pharmacy operating the website that people used to access the prescribing service, the pharmacy team did not have access to the information provided by the person during the online questionnaire, so they were unable to carry out their own clinical check using this information or undertake any prescribing audits. People had the option of requesting a video consultation with the prescriber. But the SI was not aware of anyone selecting this option. There were some questions asked during the online questionnaire that were different, dependent on the medication requested. They were not always sufficiently tailored to the medicine requested, for example, the consultation questions for emergency hormonal contraception (EHC) appeared to the same as contraceptive pills and did not explore the usual questions that are included in a consultation for EHC. The pharmacy team explained that whilst they did not have access to the information provided to the prescriber, they were able to contact the prescriber via email or telephone and she usually replied promptly.

An additional dispensing label was added to Ventolin inhalers for asthma to remind people that they should seek a review with their usual GP if they were using more than one inhaler per month. The online questionnaire for Ventolin did not contain sufficient questions to ensure a supply was appropriate as outlined in the NICE Asthma: diagnosis, monitoring and chronic asthma management guidance document. For example, the questions about occupational asthma were not asked. In addition, the questionnaire did not include questions about how often the person was using their Ventolin inhaler which would indicate whether their asthma was suitably controlled. If a person was needing a new Ventolin inhaler every month it could suggest that their asthma was uncontrolled, and they would benefit from a review with their usual GP or asthma nurse. This meant the pharmacy supplied people with inhalers without necessarily confirming an existing diagnosis or making sure their asthma was suitably managed or monitored.

There was no requirement for the people to provide confirmation of their identification when purchasing or requesting medicines, which could mean that medicines could be being purchased by individuals using someone else's credit card. And it could make it difficult to check if it was safe to supply some medicines; for example, Propecia, which is only for use in males, or for contraceptive pills, which is only for use in females. The SI explained that she used the Sage Pay system to identify when people attempted to place an order using fake details. It was unclear whether this met the requirements of the Identity Verification and Authentication Standard for Digital Health and Care Services.

Deliveries were sent as standard via a 48-hour tracked service which required a signature upon receipt. At an additional charge, people could request a special next day delivery service. Return address labels were used and the pharmacy kept audit trails of medications which had been supplied. Returns were also tracked and there were special bins for returned medication.

Stock medicines were sourced from several licensed wholesalers. The stock was reasonably organised and remained within the original packaging. Date checking records could not be located on the day, but team members reported that stock was usually used up quickly, and date checks were carried out by the pharmacy team, and by any responsible pharmacist at the point of final accuracy check. No out-of-date medicines were identified from random checks. A medicine waste bin was available for the disposal of pharmaceutical waste. No CDs which were subject to safe custody requirements were stored on the premises and medicines that required cold-chain storage were not supplied. Drug alerts were received through an email system and via wholesalers, and these were actioned as appropriate.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely. And the team uses equipment in a way that keeps people’s information safe.

Inspector's evidence

The pharmacy had access to a range of up-to-date reference sources. Internet access was available. Patient records were stored electronically and there were enough terminals for the workload currently undertaken. Computer screens were not visible to the public as members of the public could not access the dispensary. The pharmacy team were observed taking phone calls in the back part of the dispensary to prevent people using the pharmacy from overhearing.

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.