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: 27/06/2019

Pharmacy context

This pharmacy is located on a busy main road in a Birmingham suburb. Although open to the public, it does not hold an NHS contract and the pharmacy's primary business is an online private prescribing service, in partnership with a Romanian-based company and prescriber. The prescribing service covers a range of lifestyle medicines including treatments for hair loss, erectile dysfunction and weight loss. The pharmacy's website is also registered for the sale of general sales list and pharmacy restricted medicines. And 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 does not effectively identify and manage risks and it cannot always demonstrate that all supplies are appropriate. SOPs do not include the prescribing service. And prescriptions issued following consultations are not always legally valid.
		1.6	Standard not met	The pharmacy's responsible pharmacist and emergency supply records are not legally compliant.
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 does not include the details of the prescriber, so people might not always be able to make an informed decision about their care. The website is arranged so that a person can choose a prescription only medicine (POM) and its quantity before there has been an appropriate consultation with a prescriber, so people may not receive the most appropriate medicine for effective treatment.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not make enough checks to make sure medicines are appropriate for the people it supplies. It does not check the identity of people requesting prescription only medicines. And the pharmacy cannot clearly demonstrate that prescription supplies are in accordance with the prescriber's direction. General sales list and pharmacy medicine supplies are not always recorded properly indicating sales have not been appropriately supervised.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy has systems in place to help to ensure people's private information is protected. But the pharmacy's prescribing procedures are unclear and it does not effectively identify and manage risks to make sure people receive appropriate care. It keeps the records required by law, but information is often missing, so team members cannot always show what has happened or that supplies are appropriate.

Inspector's evidence

People could purchase over the counter medicines or request prescription only medicines via the website. In the case of prescription only medicines, people who were in possession of a valid private prescription could send it to the pharmacy to be dispensed. Or they could select the medication they required, and complete an online consultation, which was reviewed by the prescriber, before a prescription was issued. Copies of certificates to verify the prescribers training and additional references were confirmed. The pharmacy had a set of written procedures in place. Team members had signed most of the procedures which were viewed on the day and the procedures had been recently reviewed. But they did not cover certain aspects of the service, such as the elements carried out by the prescriber, so risks may not be effectively managed.

The pharmacy had a book to record the details of near misses. A single entry had been recorded in 2016. The locum pharmacist, who worked ad hoc shifts at the pharmacy did not recall any near misses occurring when he had been present. An error report form was available for completion. The team present could not recall any previous incidents.

A complaint procedure was in place and people using the pharmacy’s services could complete an online form via a ‘contact us’ section on the website. The website also listed the direct contact telephone number for the pharmacy. A dispenser said that any concerns raised would usually be resolved by management.

An in-date certificate of insurance was displayed and confirmation of specific coverage for online pharmacy services was confirmed with the insurance provider.

A responsible pharmacist (RP) notice was displayed near to the medicine counter. An RP log was available, but entries for the period of the 10 to 21 June and the 24, 25 and 26 June had not been completed, which meant it was not legally compliant. No schedule 2 controlled drugs (CD) were supplied, so no registers were present, and the pharmacy did not source any unlicensed specials.

The pharmacy primarily dispensed prescription only medicines as emergency supplies under the direction of a prescriber. The private prescription register displayed a label with patient details, and a record of the medication supplied was then added. Upon receipt of the original signed prescription form, entries were then marked. But the date on which the prescription was received was not always explicitly recorded, meaning the record was not legally compliant. Some prescription forms were reviewed, and several were not legally compliant, as they did not specify the details of the medication prescribed. An example included a prescription supplied in May, where the private prescription register indicated that 100 colchicine 500 microgram tablets had been supplied, but the prescription recorded against the entry simply stated, ‘arthritis and gout prescription: 1’. The team said the medication would

have been supplied against the invoice, which was printed following the consultation with the doctor and would have stated which medication was prescribed. None of the prescriptions contained details of doses, but the pharmacy labelled and supplied medicines with set doses. A dispenser said that she had been informed that this was done, as the medicines being supplied were usually labelled with the standard dosage. The superintendent pharmacist confirmed that some issues surrounding the system had already been identified and the pharmacy had begun working with a new web developer and were looking to implement an electronic prescribing system to help address this.

Records on the pharmacy's software for OTC supplies were sometimes inaccurate and indicated that a different amount of medicine had been supplied.

A dispenser did not recall completing any information governance training but had a general understanding of confidentiality and data protection. The dispenser was unaware of the security protections in place for the website. The website was encrypted and verified. It displayed a privacy policy, which outlined how information was used and processed. And it also signposted to the information management policies of the webhosting company Magento. The pharmacy was registered with the Information Commissioners Office (ICO). Any confidential waste was shredded on the premises.

A safeguarding procedure was in place, this did not relate specifically to how online concerns may be identified. The dispenser highlighted some safeguards in place on the website to restrict the sale of some medicines such as pseudoephedrine and codeine-based medicines. The pharmacist also discussed some other types of concerning behaviours which might be identified and said that he could contact colleagues or management for further advice and to obtain safeguarding contact details, if necessary.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy team can manage the workload and they receive feedback on their development. But the pharmacist dispenses and self-checks most prescriptions, which may increase the likelihood of an error.

Inspector's evidence

On the day of the inspection, pharmacist cover was provided by a locum pharmacist, who had worked several previous shifts in the pharmacy. A qualified dispenser was also present, alongside a trainee medicine counter assistant (MCA) and a customer services assistant, who did not carry out any pharmacy related activities. Although the qualified dispenser worked full-time she carried out limited dispensing activities and was primarily responsible for managing prescription requests, medication orders and customer liaison via the pharmacy's website, which meant the pharmacist dispensed and self-checked medicines. The pharmacist said that he took a clear mental break after dispensing before medicines were checked. As the pharmacy was not processing large numbers of requests, this was possible without any workload pressure. Staff said that usually the superintendent pharmacist worked as the responsible pharmacist, and that another company director who was a pharmacist was also often present.

A small range of over-the-counter medicines were available for purchase on the premises. The MCA discussed questions that would be asked to help to ensure that any sale undertaken was safe and appropriate. Concerns were referred to the pharmacist.

The MCA was completing an accredited training programme and during quiet periods, work could be completed in the pharmacy. There was limited additional training for team members, who recalled attending previous area meetings but said no pre-planned or structured training was completed. The team were provided with feedback through appraisals, where their general development was reviewed, and any future goals were set.

Team members were comfortable to discuss issues amongst one another and were happy to approach the pharmacist and superintendent pharmacist with any concerns that they may have. A whistleblowing policy was in place, but one member of the team was unaware of how anonymous concerns could be raised as the need had never occurred. So, individuals may not necessarily know how to raise a whistleblowing concern should they need to. There were no formal targets in place.

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

Summary findings

The pharmacy is properly maintained and provides a suitable environment for its services. The website layout allows people to select a prescription only medicine before completing a consultation, which means that people may receive medicines which are not suitable for them. And the website does not provide the details of the prescriber, so people may not be able to make an informed decision about their care.

Inspector's evidence

The pharmacy was open to the public for the sale of general household goods and limited range of over-the-counter medicines. The premises were suitably maintained, with a range of healthcare promotion materials displayed. The premises appeared generally clean and there were no noticeable trip hazards in patient facing areas. The premises did not have a consultation room, which may mean that people do not always have access to a suitable area for private and confidential discussions.

The dispensary had an adequate amount of space, but the work benches were sometime cluttered with paperwork which may impact 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 patients at www.pharmacydirectgb.co.uk. The website displayed the mandatory Medicines and Healthcare products Regulatory Agency (MHRA) internet logo. And it was registered with the MHRA to enable online supplies of general sales list medicines, pharmacy medicines and prescription only medicines. 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 of the responsible pharmacist was displayed in the pharmacy but was not stated on the website. The name of the superintendent pharmacist was listed, but this did not include details of his GPhC registration number. The website stated that 'all consultations and prescribing are made by licensed and qualified EEA Doctors' but specific information such as registration number and country of registration were not made clear. Neither were the details of any indemnity arrangements which the prescriber may have in place.

The pharmacy's website enabled patients to select a prescription-only-medicine and quantity prior to completing a consultation with the online prescriber. This means that the patient may not always receive the most appropriate medicine to meet their needs. Underneath most of the prescription-only-medicines listed was a brief description of what the medication was used to treat and how many could be purchased with a single prescription. Some information was noted to contain inaccuracies. For example, the description stated under Spiriva 18 microgram inhalation powder, states that 'spiriva is used for the prevention of asthma'. This specific preparation is not licensed for use in asthma. The superintendent pharmacist confirmed that this statement, and the product had been removed from the website after the inspection took place.

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

Summary findings

The pharmacy obtains medicines from reputable sources and carries out some checks to make sure that they are suitable for supply. But it does not make enough checks to make sure medicines are appropriate for the people it supplies.

Inspector's evidence

The pharmacy was located on a busy main road and was accessible via a single-step. The pharmacy displayed a handwritten notice advising that it was unable to provide NHS services and the details of a nearby NHS contracted pharmacy were displayed. The pharmacy website had limited information on general health promotion or signposting guidance.

Dispensing was undertaken on the premises and baskets were used to keep medicines separate and reduce the risk of them being mixed up. The pharmacist on the day signed the 'checked by' box on the dispensing label as an audit trail.

Requests for general sales list and pharmacy medicines were authorised by the responsible pharmacist present on the premises. Patients selected the medication required and payment was processed through the website. Once an order was received the pharmacist was informed and reviewed the request. The pharmacy sold some medications which were susceptible to abuse, such as codeine-based pain relief and pseudoephedrine containing medicines. On the website there were statements which read that only one box of such a medication could be supplied at a time. Despite this, patients were able to request and pay for more than one pack. In instances where this occurred the dispenser said that people were contacted via email and the statement on the website was reinforced to them. They were then refunded any relevant monies that had been paid and only one box was supplied. Records on the pharmacy's software for OTC supplies were sometimes inaccurate and indicated that a different amount of medicine had been supplied. The dispenser said that it had not previously been possible to update the website with the details of refunded items but showed the inspector evidence of monies being refunded via the Sage Pay payment provider and correspondence which had been sent to the patient.

Patients purchasing pharmacy only medicines were asked to complete a 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. A range of prescription only medicines were available through the pharmacy website. Treatments were available for a limited range of conditions including asthma, contraception (including the emergency hormonal contraceptive), weight loss, hair loss and erectile dysfunction. 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 checked, before a supply was then made. People requesting medications available on the website, completed payment and were then required to complete a health questionnaire, which was reviewed by the prescriber. Information captured included date of birth, weight, height, smoking status, medical history and blood pressure. There was no requirement for the patient to provide confirmation of identification, which could mean that medicines could be being purchased by other individuals, and it could make it difficult to check the safety of some medicines such as Propecia, which is only for use in males. The team

present on the day said that they did not have access to the information provided to the prescriber, but they were able to contact the prescriber via email. The prescriber placed a record on the system when an approval of a prescription had been granted. The relevant invoice was then printed and used to dispense from and the prescriber sent prescriptions to the pharmacy through the post. This means that the pharmacy is not always able to show that they have supplied medicine in accordance with the prescriber's directions. Medicines were supplied with labels which stated a usual standard dose of medication, such as colchicine 500 microgram tablets, one tablet 2-4 times a day; maximum 12 per course and Propecia 1mg tablets, take one daily.

An order history was in place to view any previous purchases made by a patient. The dispenser also believed that the email address could be used to recognise people who were potentially trying to obtain further supplies under a different name. Additional fraud measures were in place through the Sage Pay payment provider, who flagged potentially fraudulent transactions for investigation. A company director confirmed that photographic ID had previously been obtained to verify requests, but this was not done for each purchase. PMR systems and the website administration system were used to monitor the frequency of ordering and concerns were reported to and discussed with the prescriber. A company director said that explanations were requested where excessive quantities were requested and where an explanation had not been forthcoming, supplies were declined, and refunds provided. This was said to be an infrequent occurrence.

Deliveries were sent as standard via a 48-hour tracked service which required a signature upon receipt. At an additional charge a special delivery service could be provided to ensure medicines would be received before 1pm the next day. Return address labels were used and the pharmacy kept audit trails of medications which had been supplied. Returns were also tracked. Overseas deliveries were sent via Royal Mail international track and send. Supplies were not sent to countries which did not recognise online pharmacy, such as the Republic of Ireland.

Stock medicines were sourced from several reputable 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 frequently and that date checks were carried out by the regular pharmacist, 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. A cytotoxic waste bin for hazardous waste could not be located. The pharmacy was not currently compliant with requirements as part of the European Falsified Medicine Directive (FMD) and the locum pharmacist was unaware as to the progress of implementation. The superintendent pharmacist subsequently confirmed that the pharmacy had registered with SecurMed. Drug alerts were received through an email system and via wholesalers and were actioned as appropriate.

The pharmacy had a fridge available for medicines storage. It was fitted with a maximum and minimum thermometer and the temperature was checked and recorded. There were several gaps in records, which means that pharmacy may not always be able to show that medicines with cold chain storage requirements are stored appropriately. No CDs which were subject to safe custody requirements were stored on the premises.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has adequate equipment and facilities for the services it provides

Inspector's evidence

The pharmacy had access to pharmaceutical reference materials and the internet for up-to-date information.

The web facilities were password protected and electrical equipment appeared generally in working order, although the PMR system in use appeared dated. A quarterly back-up of data was carried out. The locum said he had previously experienced a problem with getting the system to turn on, but a member of management had resolved the issue at the time. No further problems had been experienced.

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.