Registered pharmacy inspection report

Pharmacy Name:Healthxchange Pharmacy UK Limited, 79 Great Portland Street, LONDON, W1W 7LS

Pharmacy reference: 1097264

Type of pharmacy: Community

Date of inspection: 31/07/2023

Pharmacy context

This pharmacy is located central London close to Harley Street. The pharmacy specialises in supplying aesthetics and skincare products. It primarily dispenses private aesthetic prescriptions for people living the UK. The aesthetic service is usually accessed via the pharmacy's website <u>www.healthxchange.com</u>. Healthcare professionals can register an account and issue electronic prescriptions using the website. The pharmacy then dispenses the prescriptions and usually delivers them using courier services. The pharmacy sells a small range of over-the-counter medicines from its shop area. It does have an NHS contract, but it only offers essential services and NHS dispensing levels are very low. The pharmacy has an MHRA wholesale dealer's license enabling it supply aesthetic products as stock. This activity is regulated by the Medicines and Healthcare products Regulatory Agency and so outside the scope of this inspection.

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	1.6	Standard not met	The pharmacy does not keep appropriate records for all of its services. It cannot produce private prescriptions records for its aesthetics service. And records for supplies of unlicensed medicines do not provide a clear audit trail from source to supply.
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 not all met	4.2	Standard not met	The pharmacy does not always make sure prescriptions contain the correct details before supplying aesthetic products. And pharmacists do not have easy access to information needed to make effective clinical assessments when dispensing aesthetic prescriptions.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy does not keep appropriate records for the private prescriptions it dispenses for its aesthetic service. And it cannot not demonstrate a clear audit trail for supplies of unlicensed medicines. This means the team may not be able to explain what has happened in the event of a query. The pharmacy generally manages the risks associated with its services. It keeps people's personal information safe, and it has written procedures to make sure the team works safely. The team makes some additional checks when supplying prescriptions for aesthetic products. But the pharmacy could do more to seek assurance that the prescribers who register an account with the pharmacy have appropriate indemnity and competence to prescribe aesthetic treatments.

Inspector's evidence

The pharmacy provided few face-to-face services. It had an NHS contract but could only accept paper prescriptions as it did not have access to the NHS Digital infrastructure, so it rarely dispensed NHS prescriptions. And it did not offer any other NHS funded services. It sold a small number of over the counter medicines (OTC). The pharmacy dispensed occasional private prescriptions presented in pharmacy. These were usually issued by local private doctors and clinics.

The pharmacy's aesthetic service was well established. It was mainly provided through its website. The company that owned the pharmacy also owned two other pharmacies in Reading and Manchester. Website orders and prescriptions were dispatched from all three sites. The website offered a wide range aesthetic and skincare products, including some medicines, and associated consumables, such as syringes and gloves, for use alongside aesthetic treatments. The pharmacy supplied these products to aesthetic practitioners and clinics based in the UK. People wanting to order products or send a prescription to the pharmacy were required to register an account through the website before requesting supplies. The pharmacy did not supply aesthetics product to the general public. Only UK based healthcare professionals qualified to prescribe or employers of healthcare professionals qualified to prescribe were eligible to register for access to the aesthetics prescription service. The pharmacy permitted other healthcare professionals(non-prescribers) to register but they could only order a limited range of products such as non-prescription medical devices, skin treatments and consumables.

Individuals were required to supply proof of their identity (passport or driving licence) when registering. A customer service team in another location checked the appropriate healthcare regulator's register to confirm the applicant met the registration criteria before the account was approved and the person was authorised to use the website. The pharmacist demonstrated how she could access the account profile for a healthcare professional which showed a registration check had been completed including a check of their ID. The account identified which types of products they were able to request. The pharmacist was unsure whether people registering were required to provide any other information when registering and this was not evident from the account profile seen. The pharmacist explained how random checks of account holders' professional registration were automatically completed by the system and the date when the last check was completed was recorded on the profile. The superintendent (SI) subsequently explained that the pharmacy system was linked the healthcare regulators' registers and it automatically checked account holders' registration status each week.

Healthcare professionals qualified to prescribe were able to generate electronic prescriptions using their account details to log into the 'e-pharmacy platform' on the website. The pharmacy had a Wholesale Dealers Authorisation (WDA) but most products were supplied on prescriptions including botulinum toxins, dermal fillers and other specialist skin treatments. Prescription orders were usually delivered to the prescriber's address or the clinic where they worked.

The pharmacy team had access to standard operating procedures (SOPs) available on a shared drive. These covered the operational activities of the pharmacy and the services provided. SOPs appeared to have been periodically reviewed. Team members were required to read and agree the SOPs relevant to their role when they first started working at the pharmacy. One of the pharmacists who was relatively new to the team confirmed this had been part of their induction. The team could not locate an SOP for sales of medicines over the counter, but the team members knew what to do and that sales should be supervised.

The pharmacy had procedures for recording dispensing incidents and near misses. The near miss log had very few recent entries. The records identified why the error occurred but there was no evidence of documented reviews identifying patterns or trends. The pharmacist said the team often discussed common issues such as packaging similarities as they arose, so everyone was aware. And they sometimes shared learning from incidents with the pharmacy teams in the other sites. The SI confirmed dispensing incidents were tracked and discussed each week and consolidated at monthly meetings. There was a 'contact us' section on the website. People could submit an online query or make contact using a centralised customer service telephone number. The pharmacy had an SOP explaining how to manage complaints. But there wasn't any information displayed in the pharmacy or on the website informing people how complaints were managed.

The pharmacy team did not have a documented risk assessment for the aesthetic service. The pharmacist described how the pharmacy mitigated some of the risks associated with the aesthetic service. For example, there were maximum order limits for some products. And the pharmacist described an occasion where she had refused to supply a healthcare professional who had prescribed for themselves. Another pharmacist explained how she had recently contacted a prescriber who had ordered unusually large amounts on a single prescription. The prescription order was hold pending a response. The pharmacist said the team sometimes discussed issues they had identified but there was no evidence of recent changes being made to procedures in response incidents or concerns that the team had identified.

The SI confirmed the pharmacy's regulatory team completed random audits of accounts to monitor unusual prescribing. The pharmacy had an aesthetics formulary which limited the range and volume of products which could be prescribed using the e-pharmacy platform. The SI explained that prescribers were required to confirm they had completed a face-to-face consultation with the person receiving the treatment with each prescription they issued. And the pharmacy's terms and conditions which prescribers agreed to, meant they were not permitted to prescribe for themselves or close associates. The pharmacy did not undertaken any additional checks to confirm people registering an account to prescribe aesthetic products had completed any relevant training in aesthetics or had indemnity cover. The SI said that the pharmacy intentionally only supplied healthcare professionals as it was expected that would act responsibly and were obliged to follow any regulatory standards and guidance.

The pharmacy had up-to-date professional indemnity insurance and a copy of the current certificate was available. The responsible pharmacist (RP) notice was clearly displayed, and the RP log complied

with requirements. The pharmacy used a recognised patient medication record system for its face-toface services and private prescriptions were recorded in a book. The pharmacy used bespoke electronic systems for its aesthetics service. The pharmacy team could not produce a private prescription register relating to aesthetic supplies. The pharmacist showed an order history, but it did not include the prescription details, and it did not comply with legal requirements. Record of supplies of unlicensed medicines were kept but they did not include enough information to provide a clear audit trail from source to supply.

There was a privacy policy on the pharmacy's website which contained information about website security, and this was also included on the 'frequently asked question' (FAQ) page. Confidential waste was stored separately and disposed of securely. The pharmacists had completed level two safeguarding training and staff had received informal guidance on how to protect vulnerable people.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough team members to manage the current workload and the services that it provides. The pharmacy's team members have the right qualifications for their roles, and they receive some ongoing training to keep their knowledge up to date. Team members feel well supported by their colleagues and managers, and they feel comfortable raising concerns.

Inspector's evidence

The pharmacy team consisted of two regular full-time pharmacists, two qualified dispensers and three dispatchers. Holidays were planned to make sure there was enough staff cover. One of the dispensers and one to the dispatchers were on leave at the time of the inspection. The workload appeared to be manageable. Orders were generally dispatched the same day they were received. If there was a backlog or a team member was unexpectedly absent, the pharmacy could divert some of the workload to the other pharmacy sites.

Pharmacy team members completed role specific tasks. They had completed some in-house training tailored to the aesthetics service and the pharmacy occasionally provided the team members with opportunities to attend some of the company wide training events. The pharmacist demonstrated how team members had individual folders which contained certificates and documents showing what training they had completed.

Dispatchers completed administrative duties and packed orders ready for collection by couriers. They had completed or were in the process of completing medicines counter assistant training. The dispensers had completed NVQ2 pharmacy training and were involved in the assembly of prescriptions. One of the pharmacists was relatively new to the business and was positive about her induction process. She felt well supported working at the pharmacy. Pharmacy team members communicated openly and felt able to raise concerns with the pharmacists. They could contact a member of the management team or superintendent if they wanted to discuss anything with them directly. The pharmacy had a whistleblowing policy. The team did not have specific targets related to financial rewards and pharmacists felt able to exercise their professional judgement when working.

Principle 3 - Premises Standards met

Summary findings

The pharmacy provides a safe, secure and professional environment for the provision of its services. The website contains useful information about the aesthetic service and the pharmacy.

Inspector's evidence

The pharmacy occupied a retail unit. It was well presented. There was a small retail area, pharmacy counter and larger dispensary to the rear. There was limited additional storage. There was staff toilet with hand washing facilities, but no dedicated staff rest area. The dispensary had defined work areas for administration, assembly and checking. Work benches were clear, and the dispensary was reasonably well organised.

A consultation room was available although rarely needed and it was being used to store packaging materials. The pharmacist explained that she would check of the person was comfortable before using the room and as the shop was quiet, it was often possible to have a conversation at the counter without being overheard.

The pharmacy's website had information about the pharmacy and its aesthetic service. It had links to the GPhC registers so both he pharmacy and the SI's details could be checked.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy does not always make sure prescriptions contain the correct details before supplying aesthetic treatments. And pharmacists do not have easy access to information needed to make effective clinical assessments when supplying aesthetic prescriptions. This means prescription supplies may not always be appropriate. The pharmacy manages its face-to-face services safely. And it gets its medicines from licensed suppliers. The team members store medicines securely and at the right temperature, to make sure they are safe to use. And the pharmacy makes regular checks to ensure that medicines are kept at the right temperature whilst they are being transported.

Inspector's evidence

The pharmacy provided its services Monday to Friday 9am- 6pm. Physical access to the premises was reasonably unrestricted. People could contact the pharmacy by telephone or email. The pharmacy stocked a small range of OTC medicines. Pharmacy medicines were store behind the counter. The team knew which OTC medicines could be abused or misused and pharmacists supervised any sales. The pharmacist was aware of the risks of taking valproate and isotretinoin and the need for a Pregnancy Prevention Programme for people who were at risk. The pharmacy supplied isotretinoin for some patients through its aesthetic service. Prescribers confirmed when prescribing that a pregnancy test had been completed if relevant and patients had signed a consent form when commencing treatment. The pharmacy did not often dispense schedule 2 or 3 CDs. It occasionally supplied CDs against written requisitions.

The pharmacy's computer system was integrated with the electronic prescription ordering system. Most aesthetic prescriptions were generated using the electronic prescribing function of the pharmacy's website. The system could restrict which products each person could order depending on their registration profile. Generated prescriptions were allocated to the pharmacy by the customer service team. Prescriptions and invoices and labels were printed so the pharmacy team could refer to these when dispensing. Dispensers selected and labelled the products, and they were passed on to the pharmacists who completed clinical and accuracy checks. Team members signed the paperwork when dispensing and checking so there was an audit trail of the team members involved.

Prescriptions did not always include the patient's address and the date of birth was sometimes missing. Prescriptions generally did not include instructions for use, so it was unclear what area was being treated or how often treatments were being administered. And pharmacists did not have access to the patient's ordering history to be able to check this if needed. This meant that pharmacists may not have all the information they need to complete an effective clinical check and make sure the prescription was appropriate for the person receiving the treatment. If the pharmacist had a prescription query, they would usually contact the prescriber by email and request a direct response. The pharmacists could recollect occasions when they had queried unusual prescribing. The pharmacy did not usually have any direct contact with people prescribed aesthetic treatments and resolved issues with the clinic or prescriber involved in their care. Prescribers could issue prescriptions for adjunct treatments on prescription such as creams and antibiotics. Occasionally other prescription medicines such as benzodiazepines were requested but the pharmacists said this was rare and they would query any unusual prescribing. Schedule 2 and 3 CDs could not be prescribed using the e-pharmacy platform. Prescriptions were sometimes delivered to the patient's home. For example, topical creams for self-administration.

Once prescriptions had been checked and approved by the pharmacists, they were passed on to the dispatch team. Orders were photographed before they were sealed ready for dispatch. This meant the team could refer to the photographs if there were queries about order quantities or products. Prescriptions were delivered using a tracked 24-hour courier service. Fridge items were packed in specially designed boxes with ice packs to ensure the contents were kept at the required temperature. The pharmacist explained the delivery packaging was validated monthly to check the temperature was maintained over various journey distances and fluctuations in outside temperature.

The pharmacy sourced its medicines from a range of licensed suppliers. Medicines were stored in an orderly manner on shelves. The pharmacy had a stock control system and monthly stock checks were completed. No out-of-date medicines were found during a random check of the shelves. A pharmaceutical waste contract was in place. The pharmacy did not have any CDs requiring safe custody. The pharmacy received email alerts from the MHRA, and these were actioned by the team. The SI said the team had completed mock recalls to make sure the pharmacy's procedures could trace any stocks or supplies of affected products. Service users who were encouraged to report adverse events through the pharmacovigilance section on the website.

Principle 5 - Equipment and facilities Standards met

Summary findings

The pharmacy has the correct equipment that it needs to provide its services. And it stores its equipment securely.

Inspector's evidence

The team could access the internet and appropriate reference sources. There were medical fridges for storing medicines and freezers for storing cold packs. Fridge temperatures were monitored constantly to make sure they were in range and there was an alert system if one of the fridges failed to maintain the correct temperature. Air conditioning controlled the ambient room temperature. The pharmacy had a suitably secured CD cabinet.

There were packaging materials for dispatching medicines, including cold packs and insulated materials for refrigerated items. All electrical equipment appeared to be in working order. Computer systems were password protected and each team members had their own log-in to the IT systems. Terminals were not visible from the public area.

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.	

What do the summary findings for each principle mean?