Registered pharmacy inspection report

Pharmacy Name: Healthxchange Pharmacy, 45 Boulton Road,

Reading, Berkshire, RG2 ONH

Pharmacy reference: 9011125

Type of pharmacy: Internet / distance selling

Date of inspection: 15/08/2019

Pharmacy context

This is an internet pharmacy that is closed to the public and is located on an industrial estate in Reading, Berkshire. The pharmacy does not have an NHS contract. It only dispenses medicines and associated products for cosmetic procedures against private prescriptions to prescribers that are based in the UK. The pharmacy does not provide any other services.

Overall inspection outcome

✓ Standards met

Required Action: None

Follow this link to find out what the inspections possible outcomes mean

Summary of notable practice for each principle

| Principle | Principle finding | Exception standard reference | Notable practice | Why |
|---|----------------------|------------------------------|---------------------|-----|
| 1. Governance | Standards met | N/A | N/A | N/A |
| 2. Staff | Standards met | N/A | N/A | N/A |
| 3. Premises | Standards met | N/A | N/A | N/A |
| 4. Services, including medicines management | Standards met | N/A | N/A | N/A |
| 5. Equipment and facilities | Standards met | N/A | N/A | N/A |

Principle 1 - Governance Standards met

Summary findings

Overall, the pharmacy's working practices are conducted in a satisfactory manner. Members of the pharmacy team protect people's private information well and most of the pharmacy's records are kept in accordance with the law. But, team members are not trained to protect the welfare of vulnerable people and they don't record details when internal mistakes happen. This could mean that they may be missing opportunities to spot patterns and prevent similar mistakes happening in future.

Inspector's evidence

This was a newly registered pharmacy with the General Pharmaceutical Council (GPhC) and it provided its services through the pharmacy's website. Cosmetic treatments, medicines and associated products (such as syringes) for aesthetic enhancement were supplied to practitioners such as nurses, doctors and independent prescribers who were based in the UK. The practitioners registered an account through the website and prescriptions were received and processed through this before treatments were provided for use in the prescriber's clinics or practice. The responsible pharmacist (RP) explained that two sets of identification checks were required for an account to be set up, this included photographic ID and the pharmacy made necessary checks to ensure that they were registered with the appropriate regulator.

Online activity:

The pharmacy's website (https://www.healthxchange.com/) was checked prior to and during the inspection. A distance selling EU internet logo issued by the Medicines and Healthcare products Regulatory Agency (MHRA) was present on the pharmacy's website. The pharmacy's name, operating address, contact telephone number and email address were also present on the website under the 'contact us' section. However, in line with the 'GPhC's Guidance for registered pharmacies providing services at a distance including on the internet', the website did not include the pharmacy's GPhC registration number, the name of the superintendent pharmacist, information about how to check the registration status of the pharmacy and the superintendent pharmacist or details of how users of the pharmacy services can give feedback and raise concerns. The RP was advised to familiarise herself with the GPhC's guidance and to feedback to the superintendent pharmacist about the information required.

The pharmacy held a range of documented standard operating procedures (SOPs). They were specific to the nature of the business and had been implemented in April 2019. The team's roles and responsibilities were not defined within the SOPs and there was no sign-off sheet available to record and verify when staff had read them. Two out of the three staff members were very recently employed, the third member of staff had read some of the SOPs. There was comprehensive in-house training provided for the team. The RP explained that reading and signing the SOPs was work in progress and the sign-off sheets used for training the team were to be used to demonstrate that the SOPs had been read. The correct RP notice was on display and provided details of the pharmacist in charge on the day. However, there was no information present during the inspection about risk assessments or audits conducted for the online services. Evidence was subsequently received that a risk assessment about the pharmacy's wholesale operations had been recently carried out.

Dispensing services provided at the premises:

There was plenty of work space available to dispense prescriptions and separate areas for prescriptions

to be processed, labelled, assembled and accuracy-checked by the RP. The workflow and each of the different stages were laid out so that the processes flowed around the pharmacy in a circular motion with easy access to medicines. This helped to prevent errors.

Staff explained that when orders were received through the website, relevant details were checked such as the delivery address, the prescriber's details and the quantity before this was passed to the next section to be labelled. The pharmacy team was not currently recording details about near misses. The RP explained that it was rare for an internal mistake to happen and no dispensing incidents had been seen since the pharmacy began trading (since April 2019). There was a documented complaints process available. However, as mentioned above, there were no details available about the pharmacy's complaints process on the website. Ensuring the pharmacy incorporated procedures to identify, record and review near misses and mistakes was discussed during the inspection.

Confidential waste was segregated before it was disposed of through an authorised carrier. Confidential information was contained within the pharmacy and staff were trained on data protection. The RP was trained to level 2 via the Centre for Pharmacy Postgraduate Education (CPPE) to safeguard vulnerable people, staff were not yet trained on safeguarding and there were no local contact details or guidance information present to support the team.

The pharmacy's professional indemnity insurance arrangements were through the National Pharmacy Association (NPA) and due for renewal after 30 June 2020. Emergency supplies and controlled drugs (Schedules 2-3) were not provided. Records for unlicensed medicines were maintained in line with the legal requirements. As the pharmacy held a Wholesale Distribution Authorisation (WDA), the RP described retaining copies of the private prescriptions as the pharmacy's record of this. The pharmacy was advised that if the supply to practitioners was being made against private prescriptions as opposed to wholesale dealing, then the appropriate records (as written or computerised records) in accordance with the law were required to be kept.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely. It now ensures that all of its team members are undertaking appropriate training for their roles. And, the company provides them with resources to help improve their skills and knowledge about the pharmacy's processes.

Inspector's evidence

The pharmacy dispensed approximately 50 to 60 private prescriptions and supplied around 300 items every month. The pharmacy held a WDA but did not sell medicines to members of the public. There were no other services provided.

Staff present during the inspection included the RP, who was also the pharmacy manager and three members of staff. One had been employed in the last few days and was labelling prescriptions, the second had been employed for a week and was assembling medicines and the third was processing prescriptions from the website in addition to dispensing prescriptions. The latter had been employed since the end of April 2019. This member of staff was not enrolled onto any accredited training course that would support their activity in line with the GPhC's minimum training requirements. This was discussed with the RP at the time. Evidence was received following the inspection that all three members of the team had been subsequently enrolled onto the relevant training courses with Buttercups.

Training for the team consisted of a comprehensive set of in-house resources, staff explained that they took instruction from the RP, they were reading the SOPs and were being trained on the importance of good distribution practice (GDP). Two members of the team were signed off as trained on GDP. Protected time to complete training was provided every week although this was described as taking place when it was possible. They were a small team and details about processes or updates were provided and discussed verbally with them or by email.

Principle 3 - Premises Standards met

Summary findings

The pharmacy premises are clean, secure and provide a professional environment to deliver pharmacy services.

Inspector's evidence

The pharmacy premises were located on the ground floor of the building, the site was newly constructed, and this was reflected in the modern fixtures and fittings. The front section contained telephones, desks and several PC's where prescriptions could be processed from the website. There was a designated PC to label prescriptions to one side and the dispensary was large and spacious. The latter consisted of long workbenches. Staff worked on one side of the dispensary when packing and assembling prescriptions and the RP worked on the other side. There was plenty of space to store stock. This was in an organised manner. There were also staff areas available. All areas were clean. The pharmacy was suitably bright and well ventilated. There were temperature control systems in place to monitor the ambient temperature and the pharmacy was professional in its appearance.

As the pharmacy was closed to the public and did not provide additional or private services, there was no consultation room on site. The company's second registered pharmacy was also located in the same building on the ground floor and was adjacent to this pharmacy but separated through key coded access. The first floor of the building was used for training purposes and holding seminars. The RP explained that practitioners who were trained in the field of aesthetics were asked by the company to lead training courses for prescribers.

Principle 4 - Services Standards met

Summary findings

In general, the pharmacy provides its services safely and effectively. The pharmacy sources its medicines from reputable suppliers. It stores and generally manages its medicines appropriately. The team are making some checks to ensure that medicines are not supplied beyond their expiry date. But, the pharmacy has no up-to-date written details to demonstrate this. So, the team may not always be able to show that all stock is safe to supply.

Inspector's evidence

The pharmacy's services were advertised through a website and their customer services team handled payments and general queries. Clinical queries or issues that required a pharmacist's intervention were brought to the attention of the RP at the premises by them. There were three dispensing audit trails being used to identify the staff involved in each of the different processes. This included details of the person who processed the initial prescription from the website, when the prescription was labelled, when the medicines were assembled and once they were accuracy-checked by the RP. Staff at the assembly stage also took photographs of the dispensed items and picking lists before the medicines were dispatched. This meant that the pharmacy held an additional record of the supply.

Once medicines or associated products were assembled, details about the batch number and expiry date were incorporated onto the picking lists and records were maintained. The pharmacist explained that the practitioners were responsible for carrying out face to face consultations before they generated prescriptions and uploaded them through the website. If over-prescribing was noticed or was taking place with frequent requests seen or unusually large quantities, this would be checked with the prescriber and the RP would intervene. During the RP's accuracy-checking stage, she also verified the type of prescriber and made relevant checks on which prescribers were ordering stock. If self-dispensing was observed, medicines would not be supplied, interactions and records were also checked with each supply.

After the medicines were packaged they were sent direct to the practitioners and the pharmacy used courier services with tracking facilities for this. This was with APC and Royal Mail. Signatures were obtained from people when they were in receipt of their medicines and records were kept showing each of the different stages that the package went through in transit. The RP explained that the courier made two attempts during the day to deliver the medicines, after this, they were brought back to the courier's hub and refrigerated before a third attempt was made the following day. If no-one was available to receive the package on the third attempt, the medicines were brought back to the pharmacy. The pharmacy did not deliver Schedule 2 or 3 CDs.

Licensed wholesalers such as Alliance Healthcare, AAH and Colorama were used to obtain medicines and medical devices. The pharmacy obtained unlicensed medicines direct from the manufacturer, from Baxter, Durbin or from Alliance Specials. Staff were aware of the process involved for the European Falsified Medicines Directive (FMD), relevant equipment and guidance information for the team was present and the pharmacy was complying with the decommissioning process.

Medicines were stored in an organised manner. This included appropriate storage of medicines in the cold chain stores (see Principle 5) and the keys to the CD cabinet were maintained in a manner that

prevented unauthorised access during the day as well as overnight. Drug alerts were received through the superintendent, the process involved checking for stock, acting as necessary and maintaining an audit trail to verify this. However, only the superintendent was signed up to receive emails from the MHRA. This meant that in his absence, the team may not have known about or have been able to take the right action with recalls for medicines. Staff checked expiry dates of stock whilst they were assembling prescriptions and marked details of this, onto the picking list but there was no datechecking schedule to demonstrate when medicines were date-checked for expiry. There were no dateexpired medicines or mixed batches of medicines seen.

Designated containers were used to contain and dispose of medicines when they were no longer required by practitioners. There were separate containers for hazardous or cytotoxic medicines, but no list seen to assist the team to identify these medicines. Once stored, the unwanted medicines were then removed and disposed of by an authorised contractor. The pharmacy provided practitioners with generated returns labels for them to use for this purpose.

Principle 5 - Equipment and facilities Standards met

Summary findings

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

Inspector's evidence

The pharmacy had access to the necessary equipment and resources in line with its dispensing activity. This included online access to resources, a clean dispensary sink, with hot and cold running water and hand wash as well as two cold chain stores. The latter were linked to a wireless and digital temperature monitoring system (Kelsius). Deviations outside of the recommended temperature range fed details to the control box in the dispensary and an alarm would be triggered to help alert staff to this. There was also a freezer to store cold or ice packs that were required to help keep the integrity of thermolabile medicines during transportation. A legally compliant CD cabinet was also present. The pharmacy's computer terminals were password protected and records were backed-up every evening.

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. | |