General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Fox Pharma Limited, Unit 5300 Cinnabar Court, 11A and 11B, Daresbury Park, Warrington, Cheshire, WA4 4GE

Pharmacy reference: 9012072

Type of pharmacy: Aesthetic services clinic or beauty salon

Date of inspection: 21/11/2023

Pharmacy context

The pharmacy is in a large office space in a business park in Warrington. It dispenses private prescriptions specialising in supplying aesthetic products, including botulinum toxins. And it delivers them directly to aesthetics practitioners for treating people using their services. People receiving treatment have no or minimal contact with the pharmacy and they do not directly access pharmacy services from the premises. The pharmacy interacts with the prescribers and practitioners about people's care.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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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

The pharmacy has current and relevant written procedures to help the team provide services safely. And it keeps the records it must by law. It listens to people's feedback to improve services. And it has processes to learn from mistakes to help prevent similar mistakes from happening again. Team members keep people's confidential information secure, and they have some knowledge to help protect vulnerable people who access services. Overall, the pharmacy adequately manages the risks associated with its services. But as the pharmacy assesses risks informally it may miss identifying some key risks.

Inspector's evidence

The pharmacy provided a range of non-surgical cosmetic treatments. This included prescription only medicines (POMs) such as botulinum toxins and other POMs such as antibiotics, Kenalog injections and Lumigan eye drops. It dispensed prescriptions from several prescribers and supplied them directly to the aesthetics practitioner responsible for administering the treatment to the person named on the prescription. The pharmacy had a set of current standard operating procedures (SOP) due for review in November 2023 and team members had signed to confirm they had read and understood them. The SOPs were relevant to the pharmacy's business model and the services provided. The superintendent pharmacist (SI) had completed a review of the SOPs. The SI planned to introduce the updated ones to the team in line with the planned changes of using handheld barcode scanners in the dispensing process.

The SI and the resident pharmacists held regular meetings to discuss and review ways of working and to discuss any incidents. These discussions enabled them to manage risks they identified in these meetings associated with the services provided. They didn't record these discussions and the decisions made, and they didn't have formal written risk assessments for the services and treatments provided. Assessing risks in this informal way may result in key risks being missed. They demonstrated how some risks had been managed. This included stopping supplying treatment for weight loss following the release of the National Patient Safety Alert (NPSA) regarding the shortage of GLP- 1 receptor agonists. These are treatments used for both diabetes and weight loss and the SI explained the decision was made to help ensure continued stock in the market for the treatment of diabetes. The pharmacy completed checks on the prescribers' credentials to prescribe on first registration with the pharmacy. The pharmacy had reviewed the risk of missing any change in circumstance and had increased the frequency of the checks it made. The team reported that checks had identified unqualified practitioners prior to supply. Written guidance for these checks was kept at the computer terminals for team members to refer to.

The pharmacy had a dispensing policy guidance document that detailed some of the different treatments and different requirements and considerations for team members to follow when processing prescriptions. The document stated the maximum quantity allowed on a prescription and for some treatments, such as toxins, and the limit to a supply every three months. A copy of this guidance was held at the computer terminals for team members to refer to when processing prescriptions. Team members demonstrated some interventions made against this guidance and the communication with the customer care team to cancel prescriptions. This helped reduce the risk of inappropriate supplies being made to practitioners. The customer service team members held copies of the guidance. The SI described the research completed to produce the guidance document and how it had been agreed

between the SI and resident pharmacists. The guidelines did not address all the risks of inappropriate supplies, including there was no requirement for prescribers to include specific directions on the prescriptions. And it did not include checks on whether there had been a face-to-face consultation with the prescriber. Of a sample of six prescriptions for Kenalog injections all prescribers were either registered nurses or medics. One had no face-to-face consultation date on the prescription. The SI later confirmed this had been an IT error and the prescriber had confirmed a face-to-face consultation. The addresses of all patients were geographically close to the prescriber address indicating a physical face-to-face consultation would not be difficult. From other prescriptions checked during the inspection around four prescribers did not live close to the address provided for the patient. The pharmacy did not keep full records of interventions and so it was unknown if these had been checked. The pharmacy was not aware whether prescribers or practitioners informed the person's regular prescriber of medicine supplies such as Kenalog.

The pharmacy team demonstrated individual interventions made against the guidance and there were some basic records of past interventions, but there was no formal audit process to check whether the guidance was being followed. Of the records checked, examples showed supplies followed the guidelines, including for botulinum toxins. There was one example of a cancelled order due to the prescription quantity for Kenalog being outside the dispensing guidelines. Some risks were not covered by the guidance. There was one person's patient medication record (PMR) that showed some unusual prescribing activity and there was no record of an intervention. This included intra-articular administration of Kenalog injection, two separate records of supply of different weight loss medication over time, adrenalin and Pabrinex injection. The pharmacy had not identified the need to highlight the history of supplies to pharmacists during the dispensing process to help with the clinical check. The importance of more robust risk assessments, audits, and intervention records was discussed. Following the inspection, the SI forwarded risk assessments for Kenalog treatment, with a change to maximum treatment requirements. And a risk assessment for Lumigan eye drop, with the requirement for patient-specific directions. There were documented plans for audit within these risk assessments.

The pharmacy team had a SOP to follow for the recording of near miss errors and dispensing incidents. Near miss errors were those identified before a supply was made to the practitioner and dispensing incidents were those identified after the supply had been made. The team made regular records of near miss errors each month and some records were seen for dispensing incidents. Near miss records included details of what the error was but not the action taken to prevent a similar error. The SI completed a monthly patient safety review which recorded and analysed both near miss errors and dispensing incidents. Team members discussed errors as part of the patient safety review at team meetings and dispensing incidents were recorded on this template. The SI could not demonstrate separate records of dispensing errors with patient and practitioner details, in case of queries. The patient safety review template showed evidence of learning to prevent similar errors, such as separating products on different shelves in the stockroom. Pharmacy team members understood their roles and responsibilities, this included the team member responsible for packing the dispensed prescriptions for delivery.

The pharmacy had a written complaints procedure for the team to follow. There was contact information, including an email address on the pharmacy's website homepage so people could provide feedback. The details of the complaints procedure were included in the terms and conditions on the website and not that easily accessible. Complaints and queries were received mainly from practitioners and not the people using their services. The pharmacy's customer service team managed feedback and complaints and involved the SI if needed. The customer service team sought feedback through a set of questions, for example asking about their experience with the delivery process. Records of the conversations with people, mostly practitioners, were recorded along with records of why an order had

been stopped and the reason for refunding the person. Customer service team managers reviewed the cancellation records to identify patterns such as the same practitioner not presenting evidence of appropriate training for administration of a particular product. The outcome from these reviews was shared with the pharmacy team and account managers. Following feedback, the pharmacy had worked with the IT team to increase the space on its account platform to enable prescribers and practitioners to add extra documents. Prompts had been added to each account to remind prescribers and practitioners to upload their training certificates and to send an updated insurance certificate when needed.

The pharmacy had current professional indemnity insurance, due to expire in April 2024. Its private prescription records were held electronically and contained the required details. The SI demonstrated a certificate of analysis for an unlicenced product obtained. A sample of responsible pharmacist (RP) records met requirements. The pharmacy didn't supply controlled drugs, so no records were held.

There was a privacy notice displayed on the website and it included details on the confidential data held. Team members had completed training about General Data Protection Regulations (GDPR) and were aware of their responsibilities to keep people's confidential information safe. Prescribers had a two-step authentication, which included using computers that were password protected and inputting a PIN into the IT system to access their account. They then generated an electronic prescription with a copy of their signature. The team separated confidential waste, and this was removed and shredded by a specialised third-party contractor. The pharmacy had a written procedure about safeguarding vulnerable people and team members had completed training although this was not specific to the business model of the pharmacy. Team members described how they checked the date of birth on the prescription as part of the dispensing and checking process to prevent aesthetic products and medicines being supplied for children.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has a suitably skilled and qualified team to help provide its services safely and effectively. Pharmacy team members work well together and with other staff working in different departments within the overarching organisation. They complete ongoing learning to keep their knowledge up to date. And they provide feedback to help improve the environment in which they work.

Inspector's evidence

The SI worked full-time at the pharmacy along with three full-time resident pharmacists. The pharmacy team consisted of a full-time accuracy checking pharmacy technician (ACPT), a full-time pharmacy technician and five full-time dispensers. The ACPT checked prescriptions usually twice a week and when a pharmacist was on leave to help maintain their skills. Several team members had no previous experience of aesthetics and their induction programme had focused on providing knowledge and skills in this area. This was achieved by shadowing experienced team members and attending training sessions led by a nurse practitioner from the training academy linked to the company. All pharmacy team members were trained on how to complete key tasks, which helped during periods of absence. Team members worked well together and were seen supporting each other. The workload appeared manageable, and the team worked in a calm and organised way. Other non-qualified team members worked alongside the dispensers and pharmacists packing the dispensed prescriptions ready for delivery. They were suitably trained in their roles. There was also a customer care team, account managers, a purchasing team, a marketing team, and an associated training academy.

Pharmacy team members completed ongoing learning, for example when new products were launched, they were given protected time to attend training sessions at the academy. The customer service team worked closely with the pharmacy team contacting prescribers with queries about prescriptions and asking practitioners to send training certificates. New customer service team members learnt how to check different healthcare professionals' registration. They knew what to look for when checking a registered healthcare professional's fitness to practice status and if they had authority to prescribe. They also received training on the products supplied and when new ones were introduced so they could ask for relevant documentation and check practitioners' training was appropriate.

The SI held performance reviews with team members, where they received individual feedback and had the option to discuss their development needs. An example of this included when a pharmacy technician had used the opportunity to ask about ACPT training, which was agreed, and an initial training plan was in place. There was an employee forum and one of the dispensers represented the pharmacy team at these meetings. Issues raised at these forums had introduced changes such as providing jumpers for team members to keep them warm. A cleaning rota had been introduced for the communal kitchen. There were weekly staff briefings and every three months a longer more formal meeting took place. Team members not able to attend were advised of key pieces of information. Team members used an online communication platform to keep each other up to date.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are large, clean, and secure. They provide a suitable and professional environment to provide the pharmacy's services.

Inspector's evidence

Prescribers and practitioners accessed the pharmacy's services through its website, by email and by telephone. Members of the pharmacy rarely contacted patients directly and consulted with practitioners. The registered pharmacy premises were within a modern office block and in a good state of repair and kept secure. Temperature on the premises was controlled with air conditioning units and additional heaters were used in areas where team members were more sedentary and felt cold. Lighting was bright throughout the premises with plenty of natural light.

The dispensing area was large, bright, and airy with plenty of bench space for the team to work from. Team members kept the pharmacy clean and tidy. And they kept floor spaces clear to reduce the risk of trip hazards. The separate storeroom was and tidy and helped keep the dispensary area free from clutter. The pharmacy had separate sinks for professional use and hand washing, with hot and cold water available. The pharmacy provided the team with facilities in a separate area of the premises to have uninterrupted lunch breaks.

The pharmacy's website was professional in appearance and was used by prescribers and healthcare professionals to access services. There was general information on the website informing people about aesthetics, about the products supplied and the use of the various fillers, botulinum toxins and other products. The SI's name and registration number was displayed as were the registration details of the pharmacy premises. The website was aimed at prescribers and practitioners, and they were required to set up an account to access services. Members of the public couldn't order any products displayed on the website.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy makes its services accessible to the right people. And it stores, manages, and delivers its medicines and devices appropriately. The pharmacy has some suitable procedures to help it manage and deliver its services safely and effectively. But the prescriptions it receives lack directions and information. So, it may be difficult to know if they are suitable for people's needs.

Inspector's evidence

Prescribers and practitioners accessed the pharmacy's services via its website. They contacted the customer service team by telephone and email, the details of which were published on the website. There were several telephone lines, which meant team members could answer the telephone quickly. Pharmacy team members, particularly the pharmacists, supported the customer service team with queries and on occasion contacted prescribers directly to resolve clinical queries. The products stocked by the pharmacy were clearly laid out on its website. They were supplied only with a valid private prescription from a prescriber, who was registered with the pharmacy and held an online account. The pharmacy did not supply products directly to members of the public. As part of the pharmacy's procedures a series of checks were completed prior to registering a prescriber and a practitioner. The pharmacy checked the prescriber's registration status and their registration number. For both prescribers and practitioners, the pharmacy obtained photographic identification and details of their professional indemnity insurance. The system identified when insurance was six weeks from expiring. Copies of the practitioners' training certificates were stored on the system for team members to refer to. However, there were no checks done on the prescriber's competency to prescribe these aesthetic products.

Once prescribers submitted prescriptions a team member checked the details and whether the prescription was suitable to be dispensed. Prescribers completed a generic electronic prescription template when prescribing. This ensured consistency across prescribers and meant the prescriber was required to confirm a physical face-to-face consultation had taken place with the patient. Prescribers completed the date of the consultation to confirm it had happened. But on a few occasions where the addresses of prescriber and patient were geographically far apart there was no record that the team had queried this with the prescriber. And prescriptions seen had 'as directed' as the dose instructions. This made the clinical check of prescriptions more difficult and increased the likelihood of an inappropriate supply. On these occasions, the pharmacy team didn't check with the prescriber whether the practitioner was given clear instructions on where, how much to administer and for how long. A prescription seen stated Kenalog intra-articular and on the same prescription intra-muscular but there were no further directions on the prescription. Some medicines were prescribed outside of the licensed use, for example Lumigan eye drops. Limited information was provided about how to use these medicines.

As part of the dispensing process the prescription was printed together with an order sheet detailing the name and address of the practitioner the supply was to be made to. The initial check of the prescription checked the practitioner named had the relevant training for the product prescribed. And the team checked whether practitioners held appropriate insurance to cover the aesthetic procedures. Progress of dispensing was tracked on the system so team members had information available when queries arose. Any change in prescriber from the last dispensing meant the prescription was put on

hold to complete further checks for suitability of supply. There were several examples of interventions seen, including a prescription was put on hold during the inspection when the person receiving treatment was also named as the practitioner.

There were separate areas for labelling, dispensing, and checking of prescriptions. Baskets were used to keep people's prescriptions and products separate from others, to minimise the risk of mistakes. Team members used dedicated baskets for items requiring storage in a fridge. This meant these were prioritised for delivery. Team members initialled dispensed by and checked by boxes on dispensing labels, to record their actions in the dispensing process. Supplies were made as a next day tracked delivery service via a recognised courier. The pharmacy used discreet, sturdy cardboard boxes of varying sizes to package the items for delivery. The pharmacy had completed an audit testing cold storage deliveries using different packaging materials. A team member was seen to be following the documented procedure for packing these items as identified in the audit. They used cool packs and insulating materials. The packaging was clearly marked to alert the practitioner on receipt that the contents required storage in a fridge. The pharmacy tracked the delivery and received confirmation of successful deliveries and had a process for managing failed deliveries. The courier met with the pharmacy to discuss any changes in service and resolve any issues. They advised of changes to procedures which may alter the delivery time. This was shared with the customer service team to inform the person expecting the delivery.

A large stock room off from the dispensary held medicines, fillers, toxins, and other items. CE marks were checked for fillers, to ensure they were licensed. Shelves were kept neat and tidy. There were seven medical grade fridges, all seen to be within the correct temperature range. Team members kept an electronic record and a sample of records seen were within the required range. Team members checked the expiry dates of products and recorded when these checks had been completed. They marked medicines with a short expiry date and kept a list of short-dated stock. Storage boxes holding medicines had the expiry date and batch number recorded on them to assist the team with stock management. The pharmacy received medicine recalls and safety alerts by email and kept a record of the actions taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services. And the equipment and facilities suitably protect people's confidential information.

Inspector's evidence

The pharmacy team had access to the internet for up-to-date information, including for aesthetic products. And it had the facilities of a training academy on site. There was equipment available for the services provided, including enough computer terminals for the team positioned at the different workstations in the dispensary. The pharmacy had its electronic equipment tested regularly. The pharmacy computers were password protected and data was encrypted to ensure people's confidential information was protected. An IT team based in the same building supported the pharmacy team with IT issues. The system had recently been upgraded which the team reported helped reduce the time it took to dispense prescriptions.

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.