General Pharmaceutical Council

# Registered pharmacy inspection report

**Pharmacy Name:** Elite Direct Pharma, Unit 8, Guardian Point, Guardian Street, Warrington, WA5 1SJ

**Pharmacy reference:** 9011655

**Type of pharmacy:** Internet / distance selling

**Date of inspection:** 15/06/2022

## Pharmacy context

The pharmacy is located in a small business park. It mainly specialises in the supply of aesthetic products, including botulinum toxins. It also supplies some medicines for weight loss. It makes supplies against private prescriptions and delivers them directly to prescribers and to aesthetics practitioners for people using their services. The premises has a small reception area, but people do not directly access pharmacy services from the premises, instead the pharmacy uses couriers to deliver its medicines.

## 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

The pharmacy generally identifies the risks associated with the services it provides and it takes some action to help manage them. But it doesn't always undertake audits or monitoring to make sure it is providing its services safely. Pharmacy team members protect people's private information, and they mostly keep the records they need to by law. They record mistakes they make so they can learn from them, to reduce the risks of similar mistakes in the future.

### Inspector's evidence

The pharmacy had a set of up-to-date standard operating procedures (SOPs), prepared in July 2021, detailing team members roles and responsibilities. They related to the services provided and included responsible pharmacist SOPs. Most team members had signed to confirm they had read and understood the SOPs. But the newest team member, who had been working in the pharmacy for a few months had not yet read them. The pharmacy had adapted to working during the COVID-19 pandemic and it had completed a risk assessment (RA) to assess the risks to team members and help keep them safe.

The pharmacy had completed a number of risk assessments (RAs) to help identify and manage the risks with its services. The number of different RAs made it difficult to clearly identify what risks had been identified and what actions taken. The pharmacy had completed a business risk assessment that included documented risks associated with the aesthetics private prescription dispensing and supply of dermal fillers. It also included documented risks regarding the supply of antibiotics and recognised the potential abuse of some prescription only medicines (POMs). This RA included an action that prescribers must assess a patient face to face before issuing a prescription for a POM and those patients were to be given no more medicine than needed. This included not supplying more than six vials of Azzulure or Botox for a six-month prescription duration. Some examples of written interventions were seen where unusual quantities had been queried by the pharmacy before supply. At the time of the inspection, the pharmacy didn't demonstrate any audits to confirm that the policies identified in the RA, including prescriber face-to-face assessments with patients were being followed. Following the inspection, the pharmacy reported that it had completed a telephone audit with eight people to check whether they had received a consultation and what treatment they received. Six people had received a face-to-face consultation, one had a virtual consultation and one had received no consultation. The pharmacy was making three-monthly checks on prescribers' authorities to prescribe. There was an example where the pharmacy had identified that a prescriber was no longer authorised to prescribe, and had refused the supply. A recent RA had identified a need to introduce checks on prescribers' training, but no action had been taken to address this. Some prescriptions that had been received had been issued by prescribers who would not necessarily be associated with aesthetics, for example a radiographer and a paramedic. But the pharmacy had not taken steps to seek assurance that the prescribers were operating within their sphere of competence. The prescription template used, included a disclaimer stating that the prescriber accepted clinical responsibility for prescribed items, for taking a suitable medical history and completing an appropriate clinical assessment. The prescriber also confirmed by signing that they followed the RPS competency framework for prescribers. The pharmacy didn't complete checks on this information and relied on people using its service following the terms and conditions.

The dispensed medicines were delivered to aesthetic practitioners and prescribers, and not directly to patients. The pharmacy held some training certificates for practitioners, but it didn't document checks of their training against the types of products supplied to them to ensure they had the necessary skills to administer treatment. A further RA highlighted risks associated with transport conditions when delivering cold-chain medicines. To address this the team used of a polystyrene box with ice packs and further insulating materials. The RA detailed the requirement to audit the delivery process to ensure this packaging was sufficient, but to date, although the pharmacy had an audit template, this had not been completed. But the SI explained when he started, he had made a simple check of the temperature of a product after 72 hours and had no concerns. The pharmacy dispensed POMs used for weight loss, including for Saxenda and Ozempic and supplied them to practitioners. The RA indicated the need for regular monitoring, to avoid potential harm to the patient and it also highlighted that the pharmacy's procedures to check this were limited. There was an outstanding action point to update prescriptions to include the person's BMI and details of ongoing monitoring. The pharmacy had not completed an audit on prescribing for weight loss medication and so didn't have the assurance that it was supplying these products appropriately or within licence. A review of the private prescription records showed that the pharmacy had supplied these products to people from a wide age range of between 20-70 years. The supplies were normally limited to one of two pens in one transaction, although there were two transactions for five pens of Saxenda and one transaction for 10 pens.

The pharmacy recorded near miss errors that team members made during the dispensing process. And the SI completed analysis of these errors to look for trends each month and produced reports including graphs to share with the team for learning. The SI demonstrated actions taken following these errors including additional training on different botulinum toxin products after selection errors. Different strength lidocaine products were stored on different shelves to minimise the risk of error. Team members recorded some interventions made and these were mainly due to the quantity prescribed. This included for Kenalog injections, where one person usually required one to two doses per year, but the quantity prescribed was for five vials. There was no record of the outcome of these interventions but the SI confirmed the increased quantities had not been supplied.

Pharmacy team members understood their roles and responsibilities and were seen referring queries to the RP throughout the inspection. The RP displayed his RP notice in the reception area. The pharmacy had a complaints SOP for the team to follow and it advertised on its website how to provide feedback and raise concerns. The SI described the escalation process and how he managed to address concerns without the need for escalation.

The pharmacy was not able to provide evidence of professional indemnity arrangements to cover its services. The SI believed indemnity was covered and by the parent company but was not able to confirm this. Following the inspection a certificate was provided showing a new professional indemnity insurance policy had been obtained. The pharmacy kept electronic private prescription records, which met requirements. The RP records were mostly in order. The pharmacy did not stock or supply controlled drugs and unlicenced specials.

The team separated confidential waste, using locked bins designed specifically for the purpose. The website displayed a privacy notice, and the team had a SOP to follow relating to confidentiality. The pharmacy had an information governance mapping document that assessed the overall probability of something going wrong, so it could be managed.

The SI had completed level 2 and one of the directors had level 3 safeguarding training. The dispensers hadn't completed any formal safeguarding training. The pharmacy didn't provide services for children and the RP described how the team checked people's date of birth when they entered the prescription details on to the patient medication records (PMR). He demonstrated a recent intervention when a

prescription for a 17-year-old person had been queried. The pharmacy's safeguarding information only detailed local safeguarding contacts even though it supplied products to people across the UK.

## Principle 2 - Staffing ✔ Standards met

### Summary findings

Pharmacy team members have the appropriate qualifications and skills to provide the pharmacy's services. They work well together and keep their knowledge up to date. The pharmacy supports ongoing training, and it listens to team members ideas to improve its services.

### Inspector's evidence

There were three dispensers, two of whom were appropriately trained and one of whom was in-training. They supported the RP, who was also the SI. The SI worked full time in the pharmacy and regular locum pharmacists covered his absences. There was another full-time dispenser employed by the pharmacy but not present. Two company directors, who were aesthetic prescribers/practitioners, were also present for some of the inspection. Team members were seen working well together, managing the workload, and answering telephone queries in a timely manner. They asked the pharmacist for advice when they needed to.

The trainee dispenser, who had started working in the pharmacy a few months previously described the support she received to understand her role and the tasks she was required to complete. The pharmacy had enrolled her on a recognised training course, and she felt her induction had gone well. Team members fed back any ideas they had to improve the way they worked. They described the directors and SI as approachable, and willing to listen to concerns raised with them. The pharmacy had a whistleblowing SOP.

The SI had trained to be an aesthetic practitioner and showed a good understanding of aesthetic procedures and products. This helped him have the knowledge and skills to clinically check prescriptions. The directors also ran an aesthetic training academy and the SI described how he approached them with any queries he had. This helped him improve his knowledge and keep it up to date. It also meant the team kept up to date with any changes and new products. The team members did not have formal appraisals but did have some team meetings, where they discussed near miss errors and identified trends.

## Principle 3 - Premises ✔ Standards met

### Summary findings

The pharmacy premises are clean, secure and of a suitable size for the services provided. The pharmacy's website clearly explains how it provides its services directly to healthcare professionals and this helps avoid confusion for the general public.

### Inspector's evidence

The pharmacy premises were clean, bright, airy, and appropriate for the workload and services provided. It had air-conditioning to ensure people worked in a suitable environment and medicines were stored correctly. There was a small reception area which it shared with the wholesale business, and it had a dedicated receptionist working there. This prevented unauthorised access into the pharmacy. The pharmacy stored and dispensed its medicines, including POMs, in a separate dispensary room. Other tasks such as packaging medicines for delivery were completed on clear benches in a larger adjoining room. The team had enough bench space to be able to dispense and check in separate areas. The pharmacy had recently completed some building work to increase the dispensary area. This provided ample space for the storage of medicines. The pharmacy had an office area on a mezzanine floor, situated above the packaging area. Some meetings were held there, but no confidential information was on show and the computers were password protected.

The pharmacy's website highlighted its aesthetic services were for healthcare professionals and not the general public. It provided the details of the pharmacy including the GPhC registration number for the pharmacy, which included a link to the GPhC website. It detailed the name and registration number for the SI.

## Principle 4 - Services ✔ Standards met

### Summary findings

The pharmacy offers a limited range of services, supplying aesthetic products for individual patients. And it makes supplies to the practitioners who are going to administer them. The pharmacy team makes some checks to help make sure people receive suitable treatment. But it doesn't make thorough checks on the medicines it supplies for weight loss. So, it may not have the assurance that they are being used properly.

### Inspector's evidence

Aesthetic practitioners and prescribers accessed the pharmacy's services through its website and through a third-party website, Faces Consent. People receiving services from the aesthetic practitioners didn't access the pharmacy directly. But their prescriptions were dispensed by the pharmacy and delivered by recognised couriers directly to the practitioner. The pharmacy and an associated wholesale business shared a staffed reception. The SI confirmed practitioners rarely picked up prescriptions from the pharmacy. The pharmacy team was contactable by telephone, email and on a recognised encrypted social media chat group. The pharmacy advertised its services via a closed social media group. But it had stopped advertising prescription only medicines (POMs) in this way after a concern had been raised.

Prescribers and practitioners wanting to use the pharmacy's services first had to register an account. As part of registration the pharmacy team checked ID, the prescribers' professional registration status and indemnity insurance details. They also checked people's indemnity insurance had been renewed and had started rechecking prescribing status at regular three-monthly intervals. They had intervened when a nurse prescriber's status had changed and so they were no longer eligible to prescribe. Prescriptions from this prescriber had been received through the third-party website. The pharmacy had put the prescriptions on hold and had informed the relevant practitioners. It was noted that this prescriber had been prescribing for several people in various locations in the UK. So it was unlikely that the prescriber had assessed individual patients face to face. The SI admitted that the location details of prescribers, practitioners and patients was not part of the checks made.

Once an account had been registered the prescriber submitted electronic prescriptions to the pharmacy, these included name and address details for the patient and the practitioner. The SI described the process whereby the prescriber had a unique log on known only to them and a unique PIN code. Team members processed the prescriptions, printing a copy along with a courier postage label. When the team member labelled the prescription on the patient medication record (PMR) they entered the date of birth and checked the age to make sure they were not under 18 years old. The pharmacy used dispensing baskets to keep people's prescriptions separate to help reduce the risk of errors. The team created an audit trail by initialling the dispensed by and checked by boxes of the dispensing labels. The SI demonstrated how he completed the clinical check for prescriptions and highlighted occasions when quantities or combination of products resulted in contacting the prescriber. The pharmacy kept a record of such interventions, but the outcome was not recorded so it was not clear if the intervention had resulted in any action such as supplying a reduced quantity or refusing the supply completely. The pharmacy had not completed any audits on these interventions or on the number and types of refusals to supply. Some practitioners prescribed vitamin B12 injections. The SI didn't have information about the clinical checks the prescribers made or any ongoing monitoring done

for repeat supplies. He demonstrated how he would make interventions on the quantities prescribed if needed. For prescriptions received via the third-party company website full administration details were not always included for botulinum products, which meant the RP didn't have full details to complete the clinical check and the practitioner didn't have administration details on the pharmacy label.

The pharmacy completed some small volume retail sale orders for some products and equipment. POMs were only supplied on prescription. The pharmacy didn't have a wholesale dealers' licence (WDL). It obtained POMs and sundries from some recognised wholesalers and also from some aesthetic pharmacies with a WDL. The SI said the pharmacy had recently received some stock that was not licenced in the UK. This was destroyed when the pharmacy was informed. Medicines requiring cold storage were kept in three large medical fridges and the temperatures were in the required range during the inspection. But the last recorded fridge temperature record available was from 24 April 2022, which appeared to be an issue with the electronic record. The pharmacy had freezers, holding the gel packs used for the delivery of fridge lines. It held medical waste bins for disposal of unwanted medicines. Stock medicines were stored tidily on shelves, with different strengths and medicines clearly separated. A sample of medicines checked were in date, however the pharmacy didn't have a date checking record so it was not clear how often the stock was checked. The pharmacy kept records of actions taken following medicine recalls and safety alerts, including a recent product recall for water for injection. The records included recording quantity in stock, a checked by signature and a date.

## Principle 5 - Equipment and facilities ✔ Standards met

### Summary findings

The pharmacy has the equipment and facilities it needs to provide its services. It uses its equipment appropriately to protect people's private information.

### Inspector's evidence

The pharmacy had access to the internet and access to up-to-date training resources for aesthetic services. The team had other resources such as the electronic British National Formulary (BNF). The pharmacy had a SOP relating to the secure transfer of digital information and its computers were password protected. The pharmacy had maintenance contracts for its computers and patient medication record (PMR) system. The pharmacy used discreet packaging for delivery.

## 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. |