General Pharmaceutical Council

# Registered pharmacy inspection report

**Pharmacy Name:** Pharma Aesthetics, 16 Broadway, Rainham, RM13 9YW

**Pharmacy reference:** 9011796

**Type of pharmacy:** Community

**Date of inspection:** 20/11/2024

## Pharmacy context

This pharmacy is located on a local high street in Rainham, Essex. It does not provide any NHS services but dispenses medicines against private prescriptions and offers a delivery service. The pharmacy also sells pharmacy-only and general sales list medicines through its website and over the counter. The superintendent pharmacist (SI) is an independent prescriber and provides a private prescribing service face-to-face and at a distance as part of a CQC-registered prescribing service. Separate to this CQC-registered service, the SI also issues and the pharmacy dispenses private prescriptions against requests from a third-party platform used for aesthetic treatments.

The pharmacy registered on 01 February 2022 and this was its first inspection.

## Overall inspection outcome

**Standards not all met**

**Required Action:** Improvement Action Plan; Statutory Enforcement

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 follow its own prescribing procedure when providing its remote prescribing service. Its prescribing risk assessment is not comprehensive and does not identify all the relevant risks associated with the service. |
| | | 1.1 | Standard not met | The pharmacy does not have a risk assessment in place for the sale of medicines online, so it cannot sufficiently demonstrate that it has considered the risks to people using the service. |
| | | 1.6 | Standard not met | The pharmacy does not keep all the appropriate records necessary to demonstrate that its prescribing services are provided safely and effectively. |
| **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 advertises the use of medicines outside their licensed indications. |
| **4. Services, including medicines management** | Standards not all met | 4.2 | Standard not met | The pharmacy does not always provide its prescribing service safely. It cannot demonstrate that all the medicines it prescribes are clinically appropriate. And it does not have adequate safeguards to show that it can supply them safely. |
| **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 appropriately identify and manage the risks associated with its services, particularly its remote prescribing service. Its risk assessment for the prescribing service does not identify all of the risks particularly in relation to providing services at a distance. And does not always follow its own prescribing procedure. For example, the pharmacy prescribes botulinum toxin for people without undertaking a physical examination. And as detailed under Principle 4, the pharmacy cannot demonstrate that robust checks are made to ensure that the botulinum toxin is being administered by healthcare professionals. The pharmacy does not always keep comprehensive records about its prescribing service. Taken together, these increase the risks to people using the prescribing service. However, people using the pharmacy's services can easily provide feedback. Team members protect people's information well and have the relevant training to safeguard the welfare of people using their services. When a dispensing mistake happens, team members respond adequately.

### Inspector's evidence

The responsible pharmacist (RP) record was completed in line with requirements. And a correct RP sign was visible in the main entrance area of the pharmacy. Standard operating procedures (SOPs) had been reviewed in September 2024. Team members had read them, and they were available for reference when required. On the day of the inspection the pharmacy was operating with the superintendent pharmacist (SI) and a pharmacy student. The student could explain their role and knew when to refer to the RP. When asked, they knew what activities could and could not be done in the absence of a pharmacist.

The pharmacy did not process controlled drugs (CDs) requiring safe storage, unlicenced medicines or issue emergency supplies. Private prescription records from July 2024 mostly contained the required information; however prior to this, the date of the prescription and prescribers details were not documented. This may mean that information is harder to find out if there was a query.

A prescribing procedure was available with a separate procedure for weight loss treatments. This included a list of the areas of prescribing and referred to the National Institute for Health and Care Excellence (NICE) as the guidance that should be followed when providing the service. There was evidence that the prescribing SOP was not being followed. For example, it stated 'We undertake a physical examination of patients before prescribing non-surgical cosmetic medicinal products such as Botox, Dysport or Vistabel or other injectable cosmetic medicines. We do not therefore prescribe these medicines by telephone video-link or online'. However, prescriptions were seen to have been issued for botulinum toxin via a third-party platform to a practitioner for their administration to a recipient. Most of these people were not from the surrounding area of the pharmacy and the SI confirmed in a subsequent email that a physical assessment had been performed virtually and not in-person.

The pharmacy could not produce the risk assessment for its prescribing service as a whole during the visit, and it was sent to the inspector following the inspection. This identified some of the risks associated with prescribing and the pharmacy had taken some steps to mitigate risks it had identified. However, during the inspection the SI explained that the majority of all prescribing consultations were completed via telephone and video link, and the risk assessment did not detail any risk or mitigation

around this. Such as age and identity checking, and consent to use a particular service and consent for information to be shared with people's regular prescriber. The SI said later in the inspection, that they had not had any direct interaction with the intended recipient of the medicines being prescribed through the third-party platform. The risk assessment had not been reviewed since the first issue of the document on 26 March 2022. So, it was not clear whether the pharmacy would take appropriate steps to address emerging risks as its services developed. The pharmacy had a checklist available for botulinum toxin prescribing, which helped identify risk factors for individuals and the SI said that he utilised this when assessing a person through the third-party platform. But these were only seen for people issued prescriptions face to face, not through the third-party platform.

The SI was asked both during and after the inspection for any risk assessments for the services offered, and a risk assessment for selling medicines at a distance was not provided. And no risk assessments were in place for any of the individual pharmacy medicines sold online, although only small volumes were sold . This may mean that the risks associated with the sale of these medicines are not identified, increasing the potential harm to people using the services. However, the pharmacy student explained the process for checking people's details and addresses, demonstrating the pharmacy had considered some of the risks about selling medicines online. When asked, the SI said that people were contacted, and relevant questions were asked before pharmacy-only medicines were supplied.

On the day of inspection, the pharmacy systems were not working, and the SI was unable to produce any consultation records. The SI and pharmacy student were asked to explain the processes surrounding prescribing and supply of medicines through the third-party platform. And prescriptions were seen stored in the dispensary alongside the respective invoices for the supply of these medicines. These prescriptions did not contain any additional notes or annotations. Following the inspection, the SI was asked to provide evidence of associated consultation notes or further documentation for prescriptions issued through the third-party platform. The documentation provided was limited to the platforms standard medical form, consent form, any notes made on the prescription request by the practitioner, and written annotations on the prescriptions themselves of consultations by the SI. The records did not always include information and advice on using medicines given to people using the service, key points on which the decision to make or refuse a medicine, counselling, signposting or safety netting. Or a person's consent for their information to be shared with their regular prescriber and if they did not consent documentation of the prescriber's risk-based assessment on making a supply to the individual. Written annotations on the prescriptions did not confirm if people had been counselled around the use of medicines used for treating conditions outside their product licence. And no records were held by the pharmacy for what quantities of cosmetic medicines had been administered or to which site.

Although the pharmacy had a named doctor associated with its practice, the SI said that no clinical audit had been completed to assess the appropriateness of prescribing or to identify areas for service improvement. Audits for infection prevention and control and health and safety were seen, however these were from 2022.

The pharmacy had logs available to record dispensing mistakes that were identified before reaching a person (near misses). Informal discussions with the pharmacist were had at the time the mistake was made to address any feedback and generate ideas to prevent future mistakes. The pharmacy student explained that to prevent mistakes, the team ensured medicines were selected against the prescription rather than the labels. And that the clinic name was always checked to prevent delivering to the patient instead of practitioner, where this was appropriate. Baskets were also used to keep prescriptions for different people separate. The SI said that there had been no reported dispensing mistakes which had reached people (dispensing errors). There was an SOP available for dealing with dispensing errors for staff to refer to and the pharmacy student said they were aware to escalate any errors to the SI.

A current indemnity insurance certificate was sent to the inspector after the visit. Feedback or complaints from people using the pharmacy's services could be received in person, via telephone, email or through the pharmacy's website and online review sites. If a complaint was received, team members could escalate issues to the SI and there was a complaints procedure they could refer to.

The computers were password protected meaning confidential electronic information was stored securely. And the pharmacy student working on the day of inspection could explain ways in which the pharmacy protected people's information. Team members also understood safeguarding requirements and were able to describe some of the signs to look for and the actions they would take to safeguard a vulnerable person. They were aware they could refer onto safeguarding authorities if required.

## Principle 2 - Staffing ✔ Standards met

### Summary findings

The pharmacy has enough staff for the services it provides and manages its workload safely. Team members have the opportunity to raise concerns if needed. They complete some training as and when possible, but there is limited structure to their training. This may make it harder for them to keep their skills and knowledge up to date and relevant.

### Inspector's evidence

The pharmacy had a medicines counter assistant and dispenser who were on annual leave on the day of the visit. During the inspection, the pharmacy student was seen to be managing the day-to-day workload of the pharmacy effectively, and there was no significant backlog of work. All team members that were required to be on an accredited course were enrolled. The pharmacy student was able to demonstrate an awareness of medicines with the potential for misuse and could identify people making repeat purchases. They knew the questions to ask when selling medicines or providing advice and knew when to refer to the pharmacist. They explained that when processing orders they check when the person last had a supply on the pharmacy system and check names against card payment details.

The SI explained that their area of prescribing competence was in diabetes and minor ailments. And they said that they had previously worked in a GP surgery prescribing for these conditions. When asked, the SI was able to produce certificates for a large number of different training courses they had completed. They said that they followed NICE guidance when prescribing for these conditions. No audits were seen for the conditions the SI was prescribing for. However, some feedback from the doctor associated with the pharmacy was provided, demonstrating some evidence of peer review.

Informal feedback was provided to team members, and they were given the opportunity to raise ideas and concerns. The pharmacy student said that they felt comfortable raising issues with the SI and gave an example where they had recently discussed the pharmacy's website and problems with functionality. The SI sought external help with web design following this feedback. The student said that they usually kept up to date with new information by looking through online resources or through various newsletters from professional bodies. But there was no formal structured process for ongoing development of the team. There was not regular designated training time, however team members could complete learning in work hours if necessary.

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

### Summary findings

The pharmacy's website advertises medicines for unlicensed indications. The pharmacy's premises, however, provide an appropriate environment from which to deliver its services. And its premises are generally clean and secure. People using the pharmacy can have conversations with team members in a private area.

### Inspector's evidence

The pharmacy entrance had a door just large enough for people with wheelchairs and pushchairs and there was a small area for the public between the entrance and the medicines counter. The pharmacy stocked a small range of pharmacy-only medicines and most of them were kept in a locked display cabinet. The dispensary was of adequate size for the services provided. Workbenches were a little cluttered, but medicines were observed to be dispensed in the dispensary and handed to the SI for checking in his office. A clean sink was available for preparing medicines. There was also an area in the pharmacy where the SI conducted phlebotomy training sessions. There were chairs available for people wanting to wait for a service or waiting whilst their medicines were being assembled.

The pharmacy had three treatment rooms, which were largely clean. Two of the treatment rooms were in a private area that allowed a conversation at a normal level of volume to take place inside and not be overheard. One of the treatment rooms was also used as the SI's office and was slightly cluttered. The room temperature was adequate for providing pharmacy services and storing medicines. The premises were generally secure from unauthorised access and fire exits were not obstructed. The premises were maintained in an adequate state of repair. The pharmacy team had use of a staff area and toilets with hand wash basins and antibacterial hand wash.

The pharmacy website contained details about the superintendent pharmacist and the pharmacy's location and contact details. The website also included details of the doctor who oversees the clinic. Information about how to check the registration status of the pharmacist was displayed and the website had a 'feedback and complaints procedure page' and a 'contact us' page.

Some prescription-only medicines (POMs) including Ozempic and Kenalog were advertised for off-label use (outside the scope of its product licence) through the pharmacy's website. The homepage did not promote POMs and people could commence a consultation or questionnaire from a conditions page. Some of the consultations started with a treatment choice that led to a questionnaire and many POMs were listed on the website with prices and the option to add to the cart. This meant that a person could select a preferred POM before there had been an appropriate consultation with a prescriber. And several links on the website were not fully functioning. The pharmacy also had a storefront on the third-party platform where people could purchase POMs after logging in and submitting a prescription. These included higher-risk and medicines liable to misuse such as weight loss products, codeine-based, and testosterone-based products. From the private prescription register provided by the SI, only two prescriptions for weight loss had been issued in the last six months, and no records were found about supplies of codeine-based products or testosterone products.

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

### Summary findings

The pharmacy does not always provide its services safely. As described under Principle 1, there are risks with the pharmacy's prescribing service which are not being appropriately managed. And the pharmacy cannot demonstrate that it makes clear records setting out the justification for prescribing. However, the pharmacy obtains its medicines from reputable suppliers, and stores them securely. People with a range of needs can access the pharmacy's services.

### Inspector's evidence

The pharmacy had step-free access which made it accessible to a wide range of people. Large-print labels were available on request. Some team members were multi-lingual.

The pharmacy worked with a third-party platform by providing prescribing and dispensing services for consultations started through this website. For this prescribing service, the SI understood that face-to-face consultations had been carried out by the practitioners who were registered with the platform, with the people that medications were being requested for. And these people completed a standard medical form and consent form which was countersigned by the practitioner. The SI said the information provided on the forms was used to prescribe for the person. The SI had made refusals to prescribe through this platform in the past due to incomplete medical history or consent forms, and there was some documentation to support this. The medical forms completed were not treatment specific and the same form was used for different conditions such as non-surgical liquid buttock augmentation and botulinum toxin. An example of the medical and consent form for one person was sent to the inspector after the inspection, however this did not contain documentation to confirm that face-to-face consultations had taken place between practitioner and recipient prior to the medication being prescribed. During the inspection, when discussing the prescriptions remotely issued through the third-party platform, the SI said that they had not had any direct interaction with the intended recipient of the medicines being prescribed. However, following the inspection the SI then said that they performed visual assessments via remote consultations with people who receive the prescribed aesthetics medicines.

Prescriptions written by the SI through the third-party platform were mostly for botulinum toxin products but included some weight loss and medicines used off-label for hayfever. On the day of inspection, there was no evidence that identification checks were routinely obtained from people using the service or the practitioners. The SI said they believed the platform were making these checks to make sure that people were who they were claiming to be and the practitioners were qualified to administer the products sold through their website. Following the inspection, the SI indicated that remote checks had been made to confirm the qualification and experience of the practitioner, however they provided no documentation to support this. There were also no verification checks in place to ensure that these practitioners were healthcare professionals as per GPhC guidance.

Anticipatory prescribing of an antibiotic medication had been issued to a practitioner to provide if a patient reported symptoms of an infection following a cosmetic procedure. There was no indication from the associated notes that the person receiving the treatment had been seen by the prescriber . And considerable quantities of two different codeine-based medicines had been issued to another patient . This indicated weaknesses in the clinical appropriateness checks for the prescriptions issued

by the pharmacy.

Medicines were sourced from licensed suppliers. The pharmacy team members said that they checked the expiry dates of medicines at regular intervals and a date checking matrix was in place. A random spot check was performed and no expired medicines were found on the dispensary shelves. Temperature records for the pharmaceutical fridge were completed daily and showed no deviations in temperature outside of the required range of between 2 and 8 degrees Celsius. At the time of inspection, the current temperature was in range. However, the maximum and minimum temperatures were out of range and the pharmacy student said that the fridge had not been reset for some time. The pharmacy student gave assurances that they would ensure the fridge was reset. Waste medicines were stored in appropriate containers and collected by a licensed waste carrier. Drug alerts and recalls were received electronically but the pharmacy did not maintain records of action taken in response to them. So, this could make it harder for the pharmacy to show what it had done in response.

An emergency kit was stored in the treatment room and included several emergency medicines, expired Adrenaline ampoules and an adrenaline auto-injector pen (AAI) were amongst the kit. The AAI had a blank pharmacy label covering another dispensing label which had been partially removed. When this was questioned with the SI, they said that it had come from outside the pharmacy. They were reminded that returned medications from the public cannot be used as stock, and they were asked to dispose of the AAI and expired adrenaline. Following this a new AAI was taken from dispensary stock to replace the expired ampoules and returned AAI.

The pharmacy operated a delivery service using Royal Mail services. The pharmacy student explained that a tracked service was used. Fridge items were sent using cold packs via special delivery for arrival by 1pm to ensure the cold chain was maintained. They said that when people purchased through the third-party platform they were able to choose their own delivery service. This meant that although medicines were tracked, people could choose for them to be left in a safe space or with a neighbour. Some deliveries were seen to have been returned to the pharmacy which had been refused due to incorrect delivery addresses. These were medications including POMs which had been sent to other European countries. The pharmacy student confirmed that supplies had been made to customers in countries such as Spain, Portugal, Romania, and Ireland, and these were mostly for steroid creams or Norethisterone. When asked, the SI said that they had not assessed whether the pharmacy abides by overseas regulation before supplying these medicines and has since stopped supplying outside the UK after having a large number of rejected parcels.

## Principle 5 - Equipment and facilities ✔ Standards met

### Summary findings

The pharmacy has the appropriate equipment to provide its services safely. And it protects people's privacy when using its equipment.

### Inspector's evidence

The pharmacy used a range of equipment to deliver its services, these included: a centrifuge machine, a blood pressure machine, a radiofrequency machine, ear micro suction and irrigation machines, a weighing scale, height measure, treatment beds and a shockwave machine. There was also a range of disposable apparatus, which included tips for irrigation, suction cannulas, wipes, gloves, tongue depressors, bed sheets, needles, syringes, and dressing packs. Appropriate glass measures and tablet counters were available in the dispensary. And a sharps bin was available for the correct disposal of vaccinations and injectables.

Confidential waste was shredded on site. And up to date references sources including BNF, medical dictionary and access to the internet were available.

## 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. |