General Pharmaceutical Council

# Registered pharmacy inspection report

**Pharmacy Name:** Avviro Pharmacy, 108 Pentax House, South Hill Avenue, South Harrow, Harrow, HA2 0DU

**Pharmacy reference:** 9010245

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

**Date of inspection:** 25/08/2022

## Pharmacy context

This is a pharmacy that is closed to the public and provides its services at a distance. The pharmacy is in Harrow, Greater London. It dispenses NHS prescriptions, supplies medicines inside multi-compartment compliance packs to residents in care homes and to people in their own homes if they find it difficult to manage them. People can also purchase over the counter (OTC), Pharmacy-only (P) medicines, devices and some medicines for animals through the pharmacy's website www.avviropharmacy.co.uk. This is through a third-party organisation. In addition, the pharmacy supplies medicines against private prescriptions issued by a private online prescribing service.

## Overall inspection outcome

**Standards not all met**

**Required Action:** 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 is not identifying and managing all the risks associated with the third-party, private, online prescribing service as indicated under the relevant failed standards and Principles below. The pharmacy is supplying vast quantities of some medicines in conjunction with a prescribing service that is operating outside of UK regulatory control without the appropriate checks, balances and controls in place to minimise risks to people. The pharmacy does not have a service agreement or the necessary standard operating procedures (SOPs) in place to support the provision of this service. There is no evidence that the pharmacy has addressed or mitigated the risks involved with this kind of prescribing service. And there is evidence that things have gone wrong because of this. |
| | | 1.2 | Standard not met | The safety and quality of the associated, private, prescribing service is not regularly reviewed and monitored. The pharmacy has not completed any audits to provide assurances that the service is safe. |
| | | 1.5 | Standard not met | At the point of inspection, the pharmacy had not informed its indemnity insurers that it was supplying medicines for an online, third-party, private prescribing service which operated outside of UK regulatory control. This included sending medicines abroad. |
| | | 1.6 | Standard not met | The pharmacy cannot fully demonstrate that the necessary records for the supply of medicines against private prescriptions have been entirely kept and maintained in line with the law. Some of the details as required by law and within the current system used by the pharmacy are missing. |
| | | 1.8 | Standard not met | The pharmacy is not adequately safeguarding vulnerable people. The pharmacy has supplied medicines to people who may be immunocompromised and require specialist support, without making any additional checks to verify that this was safe and appropriate for them to receive in this way. |

| Principle | Principle finding | Exception standard reference | Notable practice | Why |
|---|---|---|---|---|
| **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 is not managing or delivering the third party, private prescribing service safely and effectively. It has supplied large quantities of medicines which are liable to misuse or abuse. Insufficient or minimal clinical checks and limited interventions have taken place to assess the suitability of supplying these medicines, many of which are for long-term conditions or require ongoing monitoring. The pharmacy has not identified or managed the risks associated with sending medicines abroad. And this could compromise patient safety. |
| **5. Equipment and facilities** | Standards met | N/A | N/A | N/A |

## Principle 1 - Governance **Standards not all met**

### Summary findings

The pharmacy works with a private, online prescribing service which is operating outside of the UK's regulatory control. It does not have the necessary checks, balances and controls in place to minimise risks to people when medicines are supplied against prescriptions issued by this service. The pharmacy has no specific written procedures for this service to help guide the team. It is unable to demonstrate that it regularly reviews and monitors the safety or quality of the prescribing service. The pharmacy does not effectively safeguard vulnerable people. It unlawfully supplies prescription medicines against incomplete private prescriptions. And the pharmacy has not fully maintained its records for private prescriptions, in accordance with the law.

### Inspector's evidence

This inspection was carried out in response to information received about the pharmacy's association with a private, third-party, online prescribing service (the prescribing service). People using this service have reportedly come to harm. The inspection was therefore targeted at the pharmacy's activities in relation to this service. Hence, not all the standards or Principles were inspected on this occasion.

The GPhC was aware that the prescribing service was run by a company which was not registered with a UK regulator and operated outside of UK regulatory control. This company had an online presence ( https://www.ukmeds.co.uk/). People completed questionnaires online to obtain the required medicine. Private prescriptions were then largely issued by pharmacist independent prescribers (PIPs) and a few medical doctors, who were registered with the General Medical Council (GMC). The pharmacy then supplied medicines, against the private prescriptions to people in the UK, via a courier service (see Principle 4). One of the doctors was based in Germany and medicines had been supplied to countries in the EU, through this service without all the necessary checks required (see below and Principle 4).

The pharmacy had a range of documented standard operating procedures (SOPs) that were dated from 2018 or 2022. They were in the process of being updated and provided guidance for the team to carry out tasks correctly. New members of staff were in the process of reading and signing them. The correct notice to identify the pharmacist responsible for the pharmacy's activities was on display.

However, there were no specific SOPs to support the provision or provide guidance on the prescribing service. The superintendent pharmacist (SI) who was also the responsible pharmacist (RP) said that he had asked the 'facilitating service' or provider for this. In response, he was given an SOP for Saxenda (liraglutide) only. The latter however, focused on the delivery of cold-chain products, there was no mention of Saxenda, or the process required before dispensing this medicine and it hadn't been signed by anyone, including the SI. There was no documented service agreement between the pharmacy and the prescribing service provider to define the relationship and terms between them. The pharmacy had not completed any risk assessments to identify, manage or mitigate the risks associated with this service. Nor had any audits been completed to verify the safety and quality of the service being provided. Consequently, this meant that there was no effective oversight, analysis of the prescribing habits taking place, or analysis of the medicines being supplied for this service. This was therefore, not in line with the GPhC's 'Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet'.

The RP was trained to level two to safeguard the welfare of vulnerable people through the Centre for

Pharmacy Postgraduate Education (CPPE). The pharmacy had a policy in place to guide the team on the process to take in the event of a concern and contact details for the local safeguarding agencies were available. However, the team had provided medicines to people throughout the UK and abroad. But there were no details of local contact numbers for the areas covered. At the point of inspection, and over the previous nine months, the pharmacy had dispensed over 58,000 medicines against prescriptions provided by the prescribing service. This included more than a thousand supplies of some medicines which were liable to overuse, abuse, misuse, or which required additional monitoring or safeguards.

The pharmacy had also supplied certain medicines, on several occasions for potentially vulnerable, immunocompromised individuals, which were usually provided in specialist settings. Although the RP had looked up what these medicines were for, he had not made any additional checks to determine the suitability of supplying them. There were also no recorded details seen on the prescribing service's system about any blood test results, additional monitoring, checks or contact made with these people's specialists that could help justify the supply of these medicines. In summary, the RP was unable to justify those supplies from this pharmacy.

The RP had been told that people using this service were given the option to notify their GP and that this was also possible through the website mentioned above. He said that he had not seen many GP notes on the prescribing service's system and had been informed beforehand about how the prescribing service verified people's identities. The inspector noted that whether people 'passed' the ID check was noted on the prescribing service's system but with no further information recorded about this. There were no GP notes or details about whether the person's GP had been contacted, seen during the inspection. One documented prescribing justification was seen when the RP had asked about prescribing two different medicines (tadalafil with sildenafil) for erectile dysfunction at the same time. The prescriber had also provided advice within this note. Compared to the vast quantities of prescriptions as well as the wide range of medicines being supplied, there had only been limited, minimal or superficial clinical checks carried out when medicines had been dispensed (see Principle 4).

The pharmacy's professional indemnity insurance arrangements were through Numark and due for renewal after January 2023. The SI explained that before he had enlisted the prescribing service, he had arranged for the indemnity insurance to cover his own personal prescribing activity (see Principle 2). This was still active. However, he had not informed them about his association with or the supply of medicines from the unregulated prescribing service at the point of inspection.

The pharmacy received private prescriptions from this prescribing service through a communications application before they were processed through a different system (see Principle 4). Both systems had been provided by the prescribing service provider and remained under this company's control. There was a risk that if the third-party provider decided to shut this system down, the pharmacy could lose all the associated dispensing data and medication records. However, the SI had backed all the relevant information on a separate device.

The inspector noted and highlighted during the inspection that the private prescriptions issued by some of the PIPs were not legally valid. The prescriber's address was missing. However, these prescriptions had still been processed and medicines had been dispensed, checked against them and supplied by the pharmacy. This was unlawful. The SI had amalgamated the details from the prescriptions that had been processed through the third-party provider's system into an Excel Spreadsheet, and when asked about the private prescription records, he referenced this document. However, as most of the prescriber addresses were missing from the prescriptions, the data captured for the private prescription records was incomplete. Hence the pharmacy had not been keeping records of these supplies fully in line with the law.

## Principle 2 - Staffing ✔ Standards met

### Summary findings

The pharmacy has enough staff to manage its workload appropriately. And its team members are enrolled onto the appropriate accredited training in line with their role.

### Inspector's evidence

Not all aspects of this Principle were inspected.

At the time of the inspection, the pharmacy team consisted of the RP, who was also the superintendent pharmacist (SI) and a full-time, trainee dispensing assistant. The latter was enrolled onto appropriate, accredited training for his role. This member of staff was appropriately supervised, felt supported by the RP and was given time to complete his training at work. There was also a part-time driver and locum pharmacists sometimes worked alongside the RP. The pharmacy had enough staff to manage the workload and the team was up to date with this. The SI was also an independent prescriber. He had completed his training in medicines for diabetes, with additional training completed on weight loss and Saxenda. However, he had not used his prescribing qualification to prescribe medicines for people from the pharmacy. The SI was noted to be open and honest with the inspector.

## Principle 3 - Premises ✔ Standards met

### Summary findings

The pharmacy's premises are suitable for the provision and delivery of its services. The premises are maintained appropriately. Access into the pharmacy is controlled and the pharmacy is secure when closed.

### Inspector's evidence

The pharmacy's premises consisted of a room, on the first floor inside an office block. People had to ring the intercom for the pharmacy and wait for staff to allow them entry. The building was also manned by a receptionist which further assisted with security. The room itself was small but adequate, with an adequate amount of space to safely dispense and store medicines. The pharmacy was suitably lit and ventilated. The air temperature was monitored and controlled appropriately. It could have been less cluttered, but this was largely observed to be work in progress. The pharmacy had no consultation room or facilities for this purpose, but this was not required. Members of the public could not enter the pharmacy and the lack of patient access enabled activities within the pharmacy to remain private and confidential.

The pharmacy had its own online website (www.avviropharmacy.co.uk). This website gave clear information. It displayed the SI's details, information about the pharmacy's opening times, how people could complain, the pharmacy's contact details and GPhC registration information. The website had no direct reference to the prescribing service or any prescription-only medicines (POMs) but there were options to purchase General Sales List (GSL), P medicines, devices or some medicines for animals once people registered. This was through another third party, Medicines Chest ( https://www.medicinechest.co.uk/). The SI explained that sales of the medicines on the website were separate to his activities in the pharmacy.

As stated above, there is no direct or indirect reference to the prescribing service through the pharmacy’s website. The SI confirmed that he had done this purposefully as he was not advertising this service.

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

### Summary findings

The pharmacy is not operating its associated, online prescribing service safely. It has supplied vast quantities of medicines within a short period of time which are liable to abuse or misuse. This includes medicines for long-term conditions that require ongoing monitoring. The pharmacy team carries out insufficient and unsatisfactory clinical checks to make sure that prescriptions are appropriate and safe for people. The pharmacy is not adequately assessing the risks involved when supplying some medicines outside the UK. But it sends medicines to people in the UK, using a suitable and tracked service.

### Inspector's evidence

Not all aspects of this Principle were inspected.

The pharmacy received private prescriptions from the prescribing service electronically. This was through a specific communications application. An order was raised through the prescribing service when people purchased medicines. Each order in the communications App included the generated prescription as a PDF file, the order number within the prescription and an Excel file which contained a summary of the prescription details. The RP, however, could not confirm that the systems and applications being used were secure and encrypted. Nor did he know what the advanced electronic signature consisted of, or the requirements associated with electronic prescriptions. Hence, the pharmacy could not demonstrate or verify that it was receiving electronic prescriptions that complied with the law.

The workflow with this service involved the RP accessing and printing off the prescription, which had a barcode, the associated label for the delivery and dispensing labels for the medicines. The medicines were then dispensed and accuracy-checked before being packaged for delivery. To complete the process, the RP was required to log into the third party's 'dashboard', scan the prescription's barcode and complete the order. This 'dashboard' was a separate system that had been installed on the pharmacy's PC. All the order details were on here and listed by order number (not by patient details). The order number was referenced on the prescription but unless this number was known, specific prescriptions were not easy to locate. Each order on the 'dashboard' gave details of the patients (name and address, contact number, date of birth), whether they had 'passed' the ID checks, their height, weight and BMI but no other parameters (such as details of blood tests etc.), and notes or queries when they had been raised.

Once this process was complete, medicines were delivered to people in the UK by Royal Mail. This service could be tracked. The RP informed the prescribing service provider when deliveries had failed. This had occurred two or three times, Royal Mail contacted the pharmacy, the packages were returned to them, and the returned medicines were then disposed of in the pharmacy.

However, there were concerns noted with the pharmacy's process when medicines were sent to Germany or abroad. One of the prescribers associated with the prescribing service was a German doctor. A different communications application was used to receive the prescriptions from Germany. The RP said that he had checked that the prescriber was registered with the GMC, he thought that the medicines were only sent to Germany, this constituted a small percentage of the dispensed items and had been sent to different addresses. Once the RP had packed the medicines for each person

individually, they were then packed into another box before being couriered to a third-party in Northern Ireland. The RP did not know what happened to them once they reached the third-party. Although he had ensured that he could accept prescriptions from prescribers in the EU after Brexit, the RP had not made any checks about customs regulations. The RP had not informed the pharmacy's indemnity insurer about medicines being supplied abroad under this prescribing service. And was unsure of the process or what happened to failed deliveries once they reached the third-party. This had not been checked.

The RP knew that the PIPs and doctors prescribing for this service were registered with the GPhC or the GMC. These prescribers had, over a nine-month period, prescribed vast quantities of medicines for a wide array of conditions. This ranged from inhalers for asthma or chronic obstructive pulmonary disease (COPD), medicines for blood pressure or cardiac conditions, diabetes, high cholesterol, hypothyroidism, narcolepsy, gout, weight loss and painkillers as well as antibiotics and numerous other conditions. Many of these medicines were also for long-term conditions which required ongoing monitoring for certain parameters, such as blood tests, kidney and liver function tests, blood pressure, glucose and lipid profile measurements, peak flow meter readings and counselling on inhaler techniques. There were no documented or recorded details seen on the 'dashboard' to justify the ongoing prescribing of these medicines. And the RP did not know and had not queried, checked or seen any information which would help reassure and determine whether the PIPs were competent to prescribe in these areas.

As mentioned under Principle 1, very few clinical checks had taken place before medicines were supplied against the private prescriptions. The RP stated that he had questioned the dose of azithromycin once and was sent a link about the treatment range for Chlamydia. This was through the prescribing service's system portal or 'dashboard'. He had asked if it was okay to prescribe tadalafil with sildenafil (as described in Principle 1). The RP had refused to stock certain items such as fertility tests, COVID-19 face masks and hand sanitisers when requested by the prescribing service. These were items that people could buy through the associated, third-party's website. And he had refused to supply prescriptions where both creams and ointments had been prescribed for the same drug. Details about this had been documented on the prescribing service's system. But he had not refused to supply anything else. The RP described seeing some messages about cancelling prescriptions, this included where the prescriber had issued a prescription for a salbutamol inhaler accidentally when they should have been referred. He also said that he looked up unfamiliar medicines such as modafinil where he had checked the indication and the dose. In addition, the RP stated that he checked the prescribing service's website to see the treatments and what they were being prescribed for, even though this was not an authoritative, reliable source or a national guidance.

Limited interventions had been made to determine the suitability of the prescribing. For example, within the previous nine months, over 6,000 salbutamol inhalers had been prescribed, whereas the numbers of corticosteroid inhalers prescribed, ranged in the hundreds. This brings into question the management of these patients' asthma or COPD. The pharmacy had not routinely queried this through the system or documented any details about this situation. The RP said that he had asked one of the PIPs informally about why three Ventolin (salbutamol) inhalers were prescribed at a time and why it was just the Ventolin being prescribed. He was told that it was fine, they were for asthmatics, the GP had been notified and he assumed they were urgent requests.

The RP explained that he always checked the history before supplies were made, when the medicine was last dispensed and prescribing intervals when repeat requests were seen for any of the medicines prescribed. However, there were only a few details recorded about this (four to five notes on the system) and they were all about Ventolin inhalers. The RP also had access to the prescribers and to patients' contact details, but very limited checks had been made with the former and no checks with

the latter (for example to check any interactions or provide counselling). The pharmacy appeared to rely mostly on the PIPs or prescriber's ability to prescribe appropriately.

Following the inspection, the SI informed the inspector that he has ceased to work with, or operate the private, third-party, online prescribing service from this pharmacy.

## Principle 5 - Equipment and facilities ✔ Standards met

### Summary findings

This Principle was not inspected on this occasion.

### Inspector's evidence

## 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. |