

Registered pharmacy inspection report

Pharmacy Name: APC Labs, Unit 2 Hamble Court Business Park,
Hamble Lane, Southampton, Hampshire, SO31 4QL

Pharmacy reference: 9012301

Type of pharmacy: Internet / distance selling

Date of inspection: 11/09/2024

Pharmacy context

This is a closed private pharmacy located in an industrial estate in Hamble. It specialises in the supply of testosterone products against prescriptions on an individual named patient basis. The pharmacy works with various Testosterone Replacement Treatment (TRT) clinics across the country. The pharmacy compounds some testosterone products as well dispensing some licensed products and delivers them to patients.

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 suitably identifies and manages the risks associated with its services. It has up-to-date written procedures that the pharmacy team follows. It completes all the records it needs to by law, and it has suitable insurance to cover its services. The pharmacy team keeps people's private information safe. And it knows how to protect the safety of vulnerable people.

Inspector's evidence

There were a range of policies and protocols in place and held electronically, including standard operating procedures (SOPs) for the dispensing tasks and procedures for the manufacture of some products. The SOPs had recently been implemented and the staff explained that they would be changed as necessary and reviewed at least every 2 years. Pharmacy staff had read through these and confirmed they understood them and would follow them. The role of the responsible pharmacist was outlined in the SOPs, so responsibilities and lines of accountability were clear. Appropriate professional indemnity insurance from the NPA was in place and a certificate showing this was displayed in the dispensary.

The pharmacy had processes in place to identify, record and learn from mistakes. All errors would be reported on an electronic near miss log. The data from the incidents would be collated and any risks and trends would be identified regularly. The pharmacist explained that as the pharmacy was still new and doing only a few items a day, they did not have any mistakes yet. People were able to raise complaints with the pharmacy by calling them and in writing. Details of how to do this were supplied with prescriptions and were available online on the company's website.

The pharmacy used an electronic responsible pharmacist record, and a valid Responsible Pharmacist notice was on display. The maximum and minimum fridge temperatures were checked daily and recorded electronically.

Information governance training was mandatory for each member of the pharmacy team and completed annually. Passwords to access the pharmacy IT systems were only known by staff and each member of staff had their own profiles online so their work could be audited. Confidential material was suitably located, and confidential paper waste was segregated and removed for safe disposal. Safeguarding training was mandatory for all staff, and this was repeated regularly online. The pharmacists had completed level 2 safeguarding training, and the team held the details of the local safeguarding authorities electronically should they be required.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy trains its team members for the tasks they carry out, so they understand the speciality of their practice. The pharmacy team manages its workload safely and effectively. And team members support one another well. They are comfortable with assisting one another, so that they can improve the quality of the pharmacy's services.

Inspector's evidence

There were enough suitably qualified and skilled staff present to manage the workload. During the inspection, there were two pharmacists present and one member of staff who was working on marketing and not involved in the pharmacy operation. All the SOPs defined the staff roles which may work under the SOP.

The Superintendent had a Master's degree in Endocrinology and the second pharmacist had completed additional training on hormones. Both had received training from Medisca in Canada on formulations and compounding.

Staff explained that the pharmacy had an open culture, where they were able to contribute ideas or raise issues, and there was a company whistleblowing policy in place. Team members were able to work within their own professional judgement and staff explained that they were empowered to ask questions and make changes as needed for the benefit of people using their services. The pharmacists stated that there were no financial incentives in place within the pharmacy and they only had targets to ensure the products were made to specification and were sent out on time for people.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy premises are clean, organised and appropriate for the services delivered. The pharmacy has enough workspace for the team to work effectively and a suitable area for the manufacturing of some unlicensed compounded products.

Inspector's evidence

The pharmacy was located in a business park. There was free parking in front of the pharmacy and the surrounding area. People could access the pharmacy by pressing a buzzer and the staff could allow people to enter. The main pharmacy included a large bright dispensary to the right-hand side and a compounding area with fume cupboards to the left-hand side. There were bathrooms and showers downstairs. The areas were distinct from one another. Upstairs, there was a large office area and a staff kitchen.

The left hand-side used for compounding products was clean and tidy with a clear workflow which started at the fume cupboard. The area also held consumables used in the manufacturing process such as capsules shells.

The dispensary fixtures and fittings were new and suitable for use, and the pharmacy was well-presented and airy. There was plenty of space for the staff to work and lots of storage for stock and consumables. Lighting was bright throughout the pharmacy, and it was temperature controlled by an air conditioning system to ensure that medicines were kept in an appropriate environment. Air conditioning units were also available throughout the pharmacy building. Cleaning was completed daily.

The pharmacy had its own website, <https://www.webrx.co.uk/> which displayed the GPhC logo. The superintendent pharmacist's (SI) details were present, the pharmacy's terms and conditions, including how people could complain, and the pharmacy's contact details. The address provided was where the medicines were supplied from. This website had no reference to any medicines, including prescription-only medicines (POMs). There was no option to choose a medicine, strength or quantity.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy provides a range of specialist services to support the requirements of some people using specialist TRT clinics. The team makes suitable checks to ensure prescriptions are appropriate and they provide some suitable counselling. Team members store and manage medicines appropriately and manufacture some medicines safely. They take the right action in response to safety alerts and medicines shortages, so people get medicines and medical devices that are safe to use.

Inspector's evidence

The pharmacy is registered as an internet pharmacy (<https://www.apclabs.co.uk>). The pharmacist explained that the pharmacy works with clinics focussing on testosterone replacement therapy. The clinics would sign up with the pharmacy and submit documentation showing they were registered with CQC, the prescribers had all the relevant qualifications and were GMC registered. The clinics also signed an agreement that stated all patients were reviewed appropriately, appropriate blood tests were carried out and all treatments prescribed were for the treatment of age-related low testosterone levels.

The pharmacy had a website which the clinics could log onto and submit prescriptions to the pharmacy. The prescribers had their own access to these and once the prescription had been created, it remained under the sole control of the prescriber. The pharmacy was alerted through its system workflow and after receiving it electronically, it was synced to the patient medication records (PMR).

The RP stated that the systems and applications being used were secure and encrypted. There were also audit trails in place. The pharmacist could easily trace who had created the prescription, when it had been locked by the prescriber and when it had been opened. In addition, after approval, the prescription was synced to the pharmacy so that it could be pulled off the pharmacy's system manually, if required.

The RP explained that the prescribers used the European and British guidelines on sexual health for men and stated that they had specialised in testosterone replacement therapy. In addition to licensed products, some unlicensed medicines were also prescribed and dispensed, and some special medicines could be manufactured in the pharmacy if a licensed or unlicensed product was not suitable. The RP said that side effects and sperm counts were routinely checked. The pharmacist stated that they were familiar with the guidelines, doses and medicines being prescribed and would often see repeated doses. The RP stated that he did query unusual doses, or when on occasion, larger quantities had been prescribed and had made interventions.

For medicines which were manufactured in the pharmacy, the pharmacy team used the Medisca compounding formulas and kept the manufacturer's formulation records (MFR) in the pharmacy. Each MFR included a batch number, and a full audit trail was included to trace each formulation back to its original ingredients. Items were manufactured on a named patient basis. A copy of the dispensing labels was also attached to the MFR.

The pharmacy was not readily open to members of the public and due to the nature of its business, it

did not advertise its services. People were supplied with the pharmacy's contact details. If required, the team could generate labels with a larger sized font for people who were partially sighted and could use a translation service for people whose first language was not English.

The pharmacy's stock was stored in an organised way and the pharmacy only kept a limited number of medicines and associated products for testosterone replacement. The pharmacy used licensed wholesalers such as Alliance Healthcare to obtain medicines and medical devices. Other licensed suppliers were also used to obtain ingredients for compounding of some testosterone products.

The team date-checked medicines for expiry regularly and kept records of when this had happened. Stock was rotated and short-dated medicines were identified. Medicines returned for disposal that had been dispensed by the pharmacy, were accepted by staff, and stored within designated containers before being collected. The pharmacy had an arrangement with a waste disposal company for this. The team did not accept sharps, people were referred appropriately. Drug alerts were received by email, checked, and actioned appropriately. Records had been kept verifying this.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the appropriate equipment it needs to provide its services safely. And its equipment is kept clean.

Inspector's evidence

There were crown-stamped measures available for use and amber medicine bottles were seen to be capped when stored. There were also clean counting triangles available as well as capsule counters. Up-to-date reference sources were available such as a BNF and other reputable information sources and texts. Internet access was also available should the staff require further information sources.

There were suitable pharmacy facilities including a fridge. There were maintenance contracts for the refrigerator and the air conditioning system. Designated bins for the disposal of waste medicines were available for use and the team also had separate bins for the disposal of hazardous waste.

Members of the team all had their own login details to ensure access was appropriate and audit trails could be maintained. Electrical equipment appeared to be in good working order. All computer screens were suitably located and access to computers containing patient data was protected using individual passwords which were changed regularly. All data was saved on secure servers.

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.