Registered pharmacy inspection report

Pharmacy Name: Smartway Pharma, 10 Lyon Road, London, SW19 2RL

Pharmacy reference: 9010774

Type of pharmacy: Closed

Date of inspection: 28/02/2024

Pharmacy context

This is an online pharmacy based on an industrial estate between Wimbledon and Colliers Wood in South London. The pharmacy dispenses prescriptions that it receives online, either through its own website or directly from a number of clinics. People can't visit the pharmacy in person so it delivers medicines all over the country.

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 thoroughly assesses the risks involved in providing its services and takes appropriate action to keep those risks to a minimum. It has detailed written instructions for its team members to follow when carrying out their tasks. It regularly reviews them and makes sure its team members read and follow them. It records any mistakes its team members may make and regularly reviews them with the team to help reduce the chance of the same mistakes happening again. The pharmacy keeps all the records it should and makes them easily accessible. Team members clearly understand how to protect people's private information and have a satisfactory understanding of their role in helping to protect vulnerable people.

Inspector's evidence

The pharmacy had online standard operating procedures (SOPs) which all team members could access. The pharmacy used a quality management system (QMS) which it had tailored to meet its needs. This, together with the SOPs helped ensure its team members carried out their tasks in a consistent, safe and effective manner. They were reviewed every two years and their next review was imminent. The system included a version control facility so that it was clear each time a document was updated. The Responsible Pharmacist (RP), who was also the company's superintendent pharmacist (SI), explained that they were considering moving back to paper-based SOPs or having a paper-based signature sheet as they recognised that the current system didn't allow each individual SOP to be signed by their team members. The system did however show who had read them, so they could demonstrate that all team members had done so. The pharmacy had a business continuity plan in place so that the pharmacy could carry on providing its services in the event of some unforeseen emergency. This was part of the overall business continuity plan for the whole warehouse in which the pharmacy was located. Staff Roles and responsibilities were set out in the pharmacy's management folder.

Near misses and errors were recorded on paper and then transferred to the 'issue manager' part of the QMS. This was also used for recording complaints. The company's regulatory team monitored all entries on the QMS, analysing them so that the SI could then make any necessary changes and brief the team accordingly. The paper records were also reviewed between two pharmacists who also carried out an audit every three months. Any errors that left the pharmacy were reported to the NHS learning from patient safety events (LFPSE) service, formerly known as NRLS.

There were over 30 separate risk assessments on the QMS, including verification of EU doctors, dispensing unlicensed medicines and monitoring the supplies of medicines prescribed by online doctors. Each risk assessment included a description of the risk, an assessment of likelihood and severity to produce an overall risk rating, mitigations either implemented or to be implemented, again with an assessment of likelihood and severity to produce a revised risk rating. There were also risk assessments relating to each of the clinics the pharmacy received prescriptions from. They carried out a risk assessment on every new clinic, and then audited them every three months. The SI explained how they continually added new risk assessments to the system as new situations arose. They held a quarterly management team meeting and carried out an audit of their own internal procedures every six months.

The pharmacy had a valid certificate of professional indemnity and public liability Insurance on display.

Private prescription records were maintained on the pharmacy's patient medication record (PMR) computer system, and those records examined were all in order. The SI explained that they never needed to order specially manufactured unlicensed medicines ('specials'), but they did order medicines that were licensed elsewhere in the world, known as 'special obtains'. They obtained these through the wholesaling part of their company and those records seen were all in order. The controlled drugs (CD) records were complete and up to date. CD stock balances were checked every month. Any alterations were made using an asterisk and a signed and dated footnote. There were no patient-returned CDs. Private CD prescriptions were sent off at the end of each month as required to the NHS Business Service Authority.

Those team members questioned understood how they could protect people's confidential information, describing for example, how they would check people's details carefully before discussing their medicines over the phone. The pharmacy was registered with the Information Commissioner's Office (ICO) and had an information governance (IG) policy. There was a privacy notice on their website. Confidential waste was kept in boxes, separate from other waste, and shredded onsite.

All staff had completed safeguarding training to the equivalent of level one. The pharmacists had completed level two training. Safeguarding procedures were in place and the SI explained how they were further developing their safeguarding policy to reflect their nationwide coverage. Staff knew some of the signs to look out for which may indicate a safeguarding concern, and knew when to refer to the pharmacist.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough suitably trained team members to safely manage the workload. They appear well motivated and work well together. The pharmacy gives them suitable training, tailored to the specific services on offer. And they understand their roles and responsibilities.

Inspector's evidence

There were two dispensing assistants and the RP on duty during the inspection. They were working well together, supporting each other with their tasks if required. They covered for each other in the event of unexpected absence or holidays. There was a whistleblowing policy in place and team members felt able to make suggestions to help improve their service. There appeared to be an open culture and team members could easily speak to the SI if they had any queries.

There was a training folder containing certificates for the training courses that each member of the team had completed. There was evidence of online training undertaken by the pharmacists, including NHS pathways, CPPE Menopause training and training modules provided by the Gender Identity Research and Education Society aimed at primary care teams. There were also training factsheets available for reference by all team members. There were no formal targets in place and the SI was able to freely exercise her own professional judgement.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are clean, tidy and very well organised. They have plenty of room for people to work in without any distractions. The premises are secure from unauthorised access. Its website is suitably laid out and carries the necessary information about the pharmacy.

Inspector's evidence

The pharmacy premises were inside a large wholesale warehouse on an industrial estate. They were not open to the public, and access could only be gained by ringing the bell on the entry intercom. The premises were completely enclosed and secure within the building. There were workbenches along the walls and also several bays of shelving with more workbenches across the centre of the room. There was no external signage to indicate the presence of a pharmacy.

The premises were clean, tidy and in a good state of repair. There was plenty of space for the team to work safely and effectively. There were several computer workstations, with trays of stock below each workbench. The floors, work surfaces and shelves were regularly cleaned.

Staff toilets and other facilities were shared with the warehouse. The premises were well lit, and the temperatures were comfortable for people to work in and suitable for the storage of medicines. There were heaters for use when it was cold and fans to cool it down in the summer.

The pharmacy had its own website, https://smartwaypharmacy.co.uk/, which it was using to highlight its services. The RP explained that they didn't sell any products through their website. People were able to use the website to transmit their private prescriptions to the pharmacy, and it also had a separate section for prescribers to use. The website was clearly laid out and displayed the required information in accordance with the GPhC guidance for registered pharmacies providing pharmacy services at a distance, including on the internet. The pharmacy's computers were able to identify repeat purchase attempts, and the suitability of every prescription was assessed by the pharmacist during the clinical check. The pharmacist contacted the prescriber and the person concerned to verify that the prescription was appropriate, documenting the reasoning provided.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy sources, stores and manages its medicines safely, and so makes sure that all the medicines it supplies are fit for purpose. It responds well to drug alerts or product recalls to make sure that people only get medicines or devices which are safe for them to take. The pharmacy makes detailed checks before dispensing any of its prescriptions, making sure that each supply is safe.

Inspector's evidence

The pharmacy's website was the main way in which it highlighted its services. The website included the pharmacy's contact details so that people could email or speak to them if required.

There were controls in place to help minimise errors, such as allocating a single bench for all prescriptions from each individual clinic, and then keeping each prescription from that clinic separate from the next one. Each bench was tidy and well organised, with the most commonly prescribed items from that clinic kept in storage bins beneath the workbench, easily to hand. Dispensing labels included 'dispensed by' and 'checked by' boxes to indicate who had carried out those tasks. There was a complete audit trail, showing who had carried out the clinical check on each prescription, and details of what had been checked. The SI explained how they checked the prescriber's registration with the relevant regulatory bodies before making any supplies. They also checked the prescriber's professional indemnity cover, their specialism and that there were no restrictions on their practice, or any professional disciplinary action was pending. The SI described one instance where they identified that a prescriber's indemnity cover had expired the previous December so contacted the clinic to obtain a copy of a new valid certificate before dispensing the prescription. The pharmacy rarely made part supplies of prescriptions, but there was a process for managing owings for those situations when prescriptions couldn't be supplied in full.

The pharmacy received private prescriptions from a number of aesthetic clinics through an online portal. Using this portal ensured that the digital signature was legally valid and that unauthorised repeat supplies couldn't be made. Each prescription was given an 'Admin ID' and the signature itself had its own 'e-sign ID' which were both validated before proceeding. Once they had carried out the checks referred to above, the SI also clinically checked each prescription for clinical appropriateness, including a check on the length of time since the previous supply. If the pharmacist had any concerns, they would contact the prescriber or the patient directly to clarify any issues. Prescriptions received from another online prescribing service were also subject to similar checks, including verifying that the patient was over 18 years old. Additional checks, as referred to above, included checking that the prescriber was appropriately registered to practise in the country where they were based, their clinical specialism, that there were no restrictions in place or pending upon their practice and checking for any disciplinary action. Prescriptions would only be dispensed once these checks had been made. If the pharmacy had any queries, they would first contact the service's UK administrator before contacting the prescriber or the patient as appropriate. They checked people's photo ID to verify their identity before discussing anything with them. They carried out a random audit every three months to confirm details of blood tests, and any queries were flagged to the UK administrator who managed the clinics and tests.

Deliveries were made using a recognised courier company, with all deliveries being tracked. Items requiring refrigeration were packed in 'Icertech' boxes with cold packs to maintain the low temperature

for up to 72 hours. People were called before despatch if they were to receive a CD. Delivery was confirmed by the courier company and then followed up by a call to the recipient to make sure they had received them. The pharmacy had online access to all tracking information for each delivery.

The SI was aware of the risks involved when supplying valproates to people who could become pregnant. But the pharmacy didn't currently supply any valproates so there were no examples to see. The SI knew to check whether people had long-term contraception in place as part of the pregnancy prevention programme (PPP), and to record any interventions on their PMR system. The same applied to other high-risk medicines such as lithium, warfarin or methotrexate and the regular blood tests that people should have.

The pharmacy obtained its stock from recognised pharmaceutical wholesalers, including the wholesaling part of its own company. It stored its stock in the manufacturers' original containers. There was a date checking matrix and fridge temperature records. Those examined were all in order.

There was a CD cabinet which was securely bolted to the wall in accordance with the regulations. There hadn't been any unwanted CDs returned to the pharmacy so there were no records to check. The CD cabinets were well organised and contained minimal stock. The SI explained that they generally only ordered what they needed once they were in receipt of the necessary prescription. If any of the pharmacy's stock went out of date, then it would be safely disposed of through its wholesaler.

The pharmacy received drug alerts and recalls from the Medicines and Healthcare Products Regulatory Authority (MHRA) through the 'Issue Manager' part of the QMS referred to under Principle one. The company's regulatory affairs team monitored the alerts and maintained a complete audit trail to show what, if any, action had been taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has suitable facilities for the services it provides, and it makes sure that they are properly maintained. It also ensures that people's private information is kept safe and secure.

Inspector's evidence

The pharmacy had access to up-to-date online reference sources. Its computer systems were regularly backed up and kept up to date. Team members knew who to contact in the event of any problems with their computers. All the computers were password protected with no sharing of passwords. No computer screens, or other sources of confidential information, were accessible or visible to people outside the pharmacy. There was a set of appropriately calibrated glass measures.

The pharmacy had a medical grade fridge, and a freezer for storing the coldpacks it used when sending medicines that needed to be kept cool. The SI explained that they used their knowledge of wholesaling to ensure they used the most appropriate coldpacks, maintaining the cold chain for up to 72 hours. All the equipment appeared to be well maintained, with contact details available for servicing when required.

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.