Registered pharmacy inspection report

Pharmacy Name: Shivakem Pharmacy Ltd, 12a Court Parade,

WEMBLEY, Middlesex, HA0 3HU

Pharmacy reference: 1035195

Type of pharmacy: Community

Date of inspection: 27/06/2024

Pharmacy context

The pharmacy is in a parade of businesses in a residential area of northwest London. It dispenses private and NHS prescriptions and provides health advice. It supplies medicines in multi-compartment compliance packs for people who find it hard to take their medicines at the right time. Services include delivery, blood pressure case-finding, Pharmacy First, seasonal flu and travel vaccinations. The pharmacy dispenses private prescriptions for people who access healthcare services provided by Anytime Doctor at the website www.anytimedoctor.co.uk. The prescribing service is provided by doctors registered with the General Medical Council (GMC) and is regulated and inspected by the Care Quality Commission (CQC).

Overall inspection outcome

✓ Standards met

Required Action: None

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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's working practices are generally safe and effective. It has suitable written instructions for members of the team to follow. And these are being updated to help make sure the risks in providing services such as the prescribing service are managed. The pharmacy identifies prescriptions for high-risk medicines and controlled drugs to make sure people have all the information they need to use their medicines properly. It routinely works with members of the prescribing service to monitor the safety and quality of the service. The pharmacy keeps the records it needs to by law to show how it supplies its medicines and services safely. Members of the pharmacy team protect people's private information. And they understand their role in safeguarding the welfare of vulnerable people.

Inspector's evidence

The pharmacy provided a dispensing and supply function for an online third-party prescribing service. This was a remote prescribing service, led by doctors who were registered with the General Medical Council (GMC). The prescribing service was regulated and inspected by the Care Quality Commission (CQC). People were not seen face-to-face. The prescribers worked remotely from the pharmacy's premises. So people accessed this service through the prescribing service's website https://www.anytimedoctor.co.uk/ and after a consultation, a private prescription was issued and made available to the pharmacy through a specific online platform (see Principle 4). The pharmacy subsequently dispensed medicines against these private prescriptions and delivered them to people in the UK. This was via a courier which could be tracked. The service offered a limited range of medicines for selected conditions and included travel packs, antifungals for skin and nail infections, and occasionally medicines for erectile dysfunction, asthma, migraine, and weight-loss (Orlistat). See Principle 4 for further details. People could not select medicines through the online, third-party prescribing service without a consultation.

The patients were aged 18 or over and UK based. The prescribing service provided orlistat products for weight loss, rather than 'off-label' weight-loss medicines following a review of a National Patient Safety Alert that was issued last year. This was to prevent shortages of these weight-loss medicines used to treat people with diabetes. The prescribing service prescribed and the pharmacy dispensed three types of travel packs containing travel medicines, sterile dressings, sterile gauzes and sterile needles. The prescribing service did not prescribe pain-killers liable to misuse or a medicine that could lower a person's blood pressure after attempts by people to obtain and use the medicine inappropriately. Other medicines requiring refrigeration, or which were liable to misuse were not prescribed. The pharmacy rarely supplied asthma inhalers but the online doctor was emailed if they received a request for inhalers. And an anti-fungal medicine was only prescribed following the required liver function blood test and the results were sent to the pharmacy. The pharmacy team could refer to the consultation notes if they needed to and see medical records.

The pharmacy had a long-standing relationship with the third-party prescribing service and owner of this company. They routinely worked with them and the prescribers to review the safety and quality of the service. This included making interventions, and refusing to supply where this was deemed inappropriate which helped ensure supplies to people were appropriate and safe (see Principle 4). However, there was no documented service agreement in place between the pharmacy, the

prescribing service, or prescribers which could help define the relationship and terms between them. This was discussed at the time.

The pharmacy had systems to review dispensing errors and near misses. When the responsible pharmacist (RP) identified near misses, members of the pharmacy team were encouraged to discuss and correct their mistakes. They identified the types of mistakes they made and they agreed actions they could take to reduce the chances of them happening again. Members of the pharmacy team had suggested focussing on dispensing and checking one prescription at a time to minimise near misses. The pharmacy team recorded their near misses and the RP explained that medicines which were involved in incidents or were similar in some way, were generally separated from each other in the dispensary, for instance quetiapine and quetiapine XL medicines. Team members had grouped some medicines stock together such as fast-moving lines which were dispensed more frequently.

The pharmacy had a complaints procedure to report incidents to the superintendent pharmacist (SI). The team explained that mistakes sometimes occurred during the dispensing process for the third-party prescribing service when they were processing complex prescriptions with variations to some of the larger travel packs (see Principle 4) and if they were distracted in some way (for example serving people on the counter). Following this, they were no longer permitted to serve people or deal with anything else whilst they were processing and dispensing prescriptions for this service. The SI explained that dispensing incidents for this service were rare. In response however, and to prevent or minimise the risk of this happening again, certain conditions had been imposed. This included ensuring the private prescriptions for this service did not pile up, the pharmacy was kept free of clutter, no NHS workload could be nearby, and the team were instructed to focus solely on the task to hand. Distractions were not allowed but if they did occur, dispensing team members had been instructed to re-start the process, regardless of where they were before the distraction.

The team downloaded electronic prescription service (EPS) prescriptions regularly throughout the day, generated dispensing labels and ordered medicines. When the suppliers delivered the medicines, team members could complete dispensing any outstanding items on the prescriptions. If people presented a prescription at the medicines counter, a member of the team completed a legal check of prescriptions to make sure the required fields were filled in. Members of the pharmacy team responsible for making up people's prescriptions used baskets to separate each person's medicines and to help them prioritise their workload. They referred to prescriptions when labelling and picking medicines. They checked interactions between medicines prescribed for the same person with the pharmacist. If necessary, they emailed the prescriber regarding queries on prescriptions. And retained the email response in case the intervention was queried at a later date. Assembled prescriptions were not handed out until they were checked by the RP. Team members who prepared and checked prescriptions initialled the dispensing labels to create an audit trail. They highlighted prescriptions with high-risk medicines such as controlled drugs (CDs) prescriptions to make sure people had all the information they needed to use their medicines effectively. And they supplied alert cards such as for methotrexate or prednisolone. Members of the team who handed out prescriptions confirmed the person's details on the address label on the prescription bag and checked the date of birth if needed. They were aware of new rules and guidance for dispensing valproates and topiramate.

The pharmacy team considered the risks involved in dispensing prescriptions issued remotely by an online prescribing service. And this included missed deliveries, documenting interventions and monitoring therapeutic values, people granting or denying the pharmacy access to their regular doctor. People had to register, get a code for a password, complete a questionnaire for the doctor to approve. The doctor issued an encrypted prescription via the portal. The person accessing the service had patient identification and a patient prescription number. The prescription came with a fax number and electronic prescriber signature. The pharmacy received an email which it retained for their audit trail.

The pharmacy needed to verify the identity of the prescriber, consider safeguarding issues and what checks the doctors made.

At the point of inspection, the pharmacy had no SOP which was specific to this online prescribing service or risk assessments available to help provide guidance, and identify, manage, or mitigate the risks associated with this service. Nor were any audits seen to have 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. However, following the inspection, confirmation was received that the pharmacy was implementing risk assessments to enable the pharmacy team to understand and manage the risks associated with the services it provided.

The pharmacy had standard operating procedures (SOPs) which were under review to update how the team provided services where there were changes in the process. For instance, the delivery procedure had been amended to reflect a change of courier. Members of the pharmacy team were required to read and sign the SOPs relevant to their roles to show they understood them and agreed to follow them. They knew what they could and could not do, what they were responsible for and when they might seek help. A team member explained the sales protocol for over-the-counter medicines and that they could not dispatch prescriptions if a pharmacist was not present. There was a complaints procedure and people could leave feedback verbally, as well as via Trustpilot and Google review.

The pharmacy's link to the third-party prescribing service was only advertised on the latter's website. The superintendent pharmacist (SI) explained that the pharmacy obtained feedback by people who used this service through the third-party prescribing service, verbally if people contacted them by telephone and through reviews left on Trustpilot. This was monitored and relevant action taken where possible. Feedback and issues with deliveries were described. The pharmacy was currently trying to identify and review where the issues were stemming from with the previous courier as this appeared to be linked to certain depots. Following this, appropriate action had been taken as the pharmacy had changed couriers. Team members said that people phoned them about queries or if they wanted a repeat order of their medicine(s). They were signposted to the third-party prescribing service in this situation, repeat medication was rarely seen (see Principle 4).

The pharmacy had appropriate insurance arrangements in place, including professional indemnity, for the services it provided. The pharmacy displayed a notice showing who was RP at that time and kept a record to show which pharmacist was the RP and when. The pharmacy had a controlled drug (CD) register. And the stock levels recorded in the CD register were checked regularly. A random check of the actual stock of a CD did not match what was recorded in the register. The SI resolved the discrepancy and notified the inspector later. The pharmacy maintained records for the NHS Pharmacy First service on PharmOutcomes. And records of vaccinations for flu were maintained on Sonar. A member of the team described the records the pharmacy kept for the supplies of the unlicensed (special) medicines products it made. The pharmacy recorded the supplies of private prescriptions. And these generally were in order. But the name and address of the prescriber was sometimes incorrectly recorded.

The pharmacy was registered with the Information Commissioner's Office. The pharmacy team members were aware of general data protection regulation (GDPR). They needed to reprint and display a notice that told people how their personal information was gathered, used and shared by the pharmacy. The SI was completing the Data Security and Protection Toolkit. Team members were using their own NHS cards. The RP had completed a level 3 safeguarding training course. A member of the pharmacy team described a scenario where a customer who kept trying to purchase codeine-containing medicines was referred to the pharmacist. Team members knew what to do or who they would make aware if they had concerns about the safety of a child or a vulnerable person. The RP was

signposted to the NHS safeguarding App.

The third-party prescribing service only prescribed medicines for people over the age of eighteen. People's age and date of birth were checked via the third-party service. The upper age-limit for people was dependant on the treatment or medicine(s) required. There were also maximum supplies of certain medicines permitted, for example if terbinafine was prescribed, people were only prescribed and supplied forty-two tablets at a time. The third-party prescribing service had a mandatory policy to inform people's GPs about medicines which were prescribed and supplied through this service. Consent to share people's treatment information with their GP was therefore routinely obtained and if people refused, the service was declined. The pharmacy also had appropriate systems in place to refuse excessive, inappropriate, or unsafe quantities. The SI described being vigilant about this, and when supplies had been refused, details were documented to verify.

Principle 2 - Staffing ✓ Standards met

Summary findings

Members of the pharmacy team work well together to manage the workload. They are suitably trained or being appropriately supervised. Trained team members understand their roles and responsibilities well. They are supported in their roles. But the pharmacy does not provide them with enough resources to complete their ongoing training in a structured way. This could affect how well they can keep their skills and knowledge up to date.

Inspector's evidence

The pharmacy team consisted of a regular full-time pharmacist and three part-time pharmacists, one full-time NVQ2 qualified dispenser and one newly recruited team member who would be enrolled on accredited training on completion of the probationary period, and one full-time accredited medicines counter assistant. Another part-time member of the team cleaned the premises. Members of the team covered each other's absences. Two of the pharmacists provided the Pharmacy First Service. And the vaccination services.

One dispensing assistant was newly employed and had not yet read any SOPs but was being appropriately supervised and directed by the RP as well as trained team members. This team member knew which activities could or could not take place in the absence of the RP. There was also an apprentice and two other regular pharmacists, one of whom was the superintendent pharmacist (SI). The pharmacy had enough staff to support the workload and the team was up to date with this.

Members of the team wore uniforms and name badges. Their certificates to verify qualifications obtained were seen and on display. Trained team members were observed to work well and efficiently, they described being supported by the RP and owners and said that they enjoyed working at the pharmacy because it was stress free, and they appreciated the family-run environment. The MCA asked people relevant questions before over-the-counter (OTC) medicines were sold and referred to the pharmacist appropriately. Medicines which could be abused were monitored and awareness raised. As they were a small team, verbal discussions took place when needed. Staff performance was managed by one of the regular pharmacists and was said to be a formal process. Team members described receiving regular updates and in-house training or updates from the pharmacists in an ad-hoc way. But they were not provided with many training materials for ongoing training. There were no targets in place to achieve services.

Principle 3 - Premises Standards met

Summary findings

The pharmacy's premises are bright, clean, secure and suitable for the provision of healthcare services. The pharmacy prevents people accessing its premises when it is closed to protect people's private information and to keep its medicines stock safe. The consultation room is signposted and used regularly by people who want a private conversation with the pharmacist.

Inspector's evidence

The pharmacy premises were light, bright and clean and presented a professional image. The pharmacy was spacious. There was seating available for people who were waiting for prescriptions or to speak to the pharmacist. The pharmacy provided hand sanitiser for people to apply. There were two consultation rooms where people could have a private word with a member of the team. The dispensary was a step up from the public area of the premises. It had workbench space and storage space to manage the current workload. The pharmacist and dispensers had an overview of the activities in the public area of the pharmacy was cleaned regularly. The pharmacy team had access to appropriate handwashing facilities.

The website was facilitated by the prescribing service and provided the information about the prescribers and how to register and complete a questionnaire. A person could see a list of medicines and read about a prescription-only medicine before starting an online consultation. The product information explained that people could not just buy prescription only medicines. The website also told people about the prescribers the company used. The website was maintained by the prescribing service and included information about this pharmacy to which it sent all the prescriptions. The GPhC registration details, pharmacy name, address and SI information were set out on the website.

The pharmacy's own website was not currently in operation. The pharmacy's involvement in dispensing and supplying medicines for the third-party prescribing service was clearly set out on this organisation's website (https://www.anytimedoctor.co.uk/). This provided the pharmacy's name and address, GPhC registration number and SI details.

Principle 4 - Services Standards met

Summary findings

The pharmacy and its services are easily accessible to people with a variety of needs. And its working practices are generally safe and effective. The pharmacy obtains its medicines from reputable sources to help make sure they are fit for purpose and safe to use. It maintains clear audit trails with details of the medicines it supplies and these are updated daily in the event of a query. The pharmacy team provides people with the information they need to help them use their medicines effectively. The pharmacy team members carry out suitable checks when they receive medicine alerts and recalls to help make sure people get medicines and medical devices that are safe to use.

Inspector's evidence

People accessed the pharmacy through a wide automatic door. There was a step as the pharmacy floor was not level with the pavement. And they could contact the pharmacy by telephone during business hours.

The online prescribing service was provided to people aged 18 or over. People needed to complete an online questionnaire when requesting a treatment. The responses submitted were reviewed by one of the prescribers, who if satisfied, then approved and generated a prescription, which was sent to the pharmacy electronically. But a patient could be contacted if further information was needed or when they needed to be signposted to another clinician or provider. Private prescriptions from the third-party prescribing service were issued by doctors who were registered with the GMC. The SI knew and had made necessary checks to ensure that the service and prescribers were registered with the appropriate regulator.

People were required to set up an account for the third-party prescribing service through their website. Once private prescriptions were generated, the pharmacy was alerted by email. The pharmacy received private prescriptions from the prescribing service electronically. This was through a specific application or online platform which the pharmacy and prescribing service could both access. This held all the relevant details such as consultation notes, allergies and sensitivities, interventions, documented discussions, additional monitoring including blood test results and the generated private prescriptions. The SI confirmed that the system being used was secure and encrypted.

Dispensing staff explained that after downloading and printing the private prescriptions, they processed them in batches through the pharmacy's patient medication record (PMR) system which generated the dispensing labels. There was a facility on the labels which helped identify who had been involved in the dispensing process. Team members routinely used this as an audit trail. The pharmacy had also maintained an additional audit trail for this service which effectively identified the order and dispatch date, which medicines had been supplied, to whom (including people's names and date of birth), who the prescriber was, the RP at the time of supply and the tracking details for the courier. This was through an Excel spreadsheet which was updated daily, this was a useful way to quickly check necessary information in the event of queries.

One dispenser was responsible for processing prescriptions for this service, she, along with the records seen, verified that the private prescriptions were predominantly for new people. Repeat requests for

antifungal medication (Trosyl Nail solution or terbinafine tablets) did occur, but this was appropriate (see below for additional safeguards) and in line with the requirements of the person's condition. Staff described seeing repeat requests for Ventolin inhalers rarely. The records confirmed that there had been no repeat prescriptions issued for this medicine in the last two years. The SI confirmed that where repeat prescriptions for people with asthma, had occurred, the pharmacy checked and queried this with the prescribing doctors. A reason for the supply was provided (for example as an emergency), but this situation, the SI said, had not occurred for the past three to four years.

The pharmacy could access people's consultation notes and medical records if this was required, and details could be queried with both people using this service and with the prescribers. There had been no requirement for the former. A sample of consultation records were viewed during the inspection. Relevant details were visible on each person's record with visible audit trails of who made comments or changes to the record. Interventions had been made by the pharmacy as well as the prescribers. Details of any refusals were documented. Examples of this included people requesting more amoxicillin capsules after they had initially received this in a travel pack. The third-party prescribing service clearly highlighted on a specific section of their website that the medicines prescribed, including antibiotics were for standby future use and the dangers of antibiotic resistance caused by overuse, or inappropriate misuse was emphasised. When people received medicine(s) through this service, they were provided with additional documented information about the prescribed medicine at the point of supply. This included relevant information on how to take their medication which helped reinforce the details.

The pharmacy highlighted prescriptions containing high-risk medicines which required the pharmacist to provide counselling. It had warning cards for medicines such as steroids or methotrexate. The RP explained guidance given to people taking warfarin about food and medicines that may affect their INR. The team were aware of current rules for dispensing valproates and topiramates. The pharmacy prepared multi-compartment compliance packs for people who found it difficult to take their medicines at the correct time. The pharmacy team managed re-ordering of the prescriptions and checked them for changes before dispensing. Its team checked whether a medicine was suitable to be re-packaged. It provided patient information leaflets and a brief description of each medicine contained within the compliance packs. So, people had the information they needed to make sure they took their medicines safely.

Members of the pharmacy team could identify which of them prepared a prescription because they initialled the dispensing labels. And they marked some prescriptions to highlight when a pharmacist needed to speak to the person about the medication they were collecting or if other items needed to be added. They were aware of the new rules for dispensing valproate and of the pregnancy prevention programme. They knew that girls or women in the at-risk group who were prescribed valproate needed to be counselled on its contraindications. The pharmacy had the valproate educational materials it needed. The third-party prescribing service routinely obtained details about relevant blood tests before initiating certain treatments. This was through a specific company which offered private blood tests and at home health checks. People were supplied with test kits appropriate to their therapy, for example, before initiating or issuing a prescription for terbinafine, and before repeat prescriptions were issued, people were required to undertake a liver function home finger prick blood test. The results were analysed by the third-party prescribing service, but the pharmacy also had access to this information. In addition, the pharmacy could request the results from the company or labs direct if needed. This meant that suitable monitoring, tailored to the person's therapy routinely occurred. This, in turn, ensured any adverse effects from ongoing treatment could be easily checked, verified and treatment stopped or changed if needed.

Whilst the third-party prescribing service advertised prescribing for specific conditions on their

website, private prescriptions had only been raised and medicines supplied for a limited range of conditions. Medicines for certain conditions were rarely prescribed (for example Imigran for migraine) or never prescribed and supplied (such as medication for high blood pressure). The records seen confirmed that no CDs or opiate based medicines, temperature sensitive fridge-lines, or medicines that could potentially be abused had been prescribed or supplied.

Most medicines supplied under this service were for travel packs. People could receive different types of travel packs, with variations given depending on the person's requirements or allergies for example. One pack was for sailors which included scopoderm (hyoscine) patches for the prevention of travel sickness symptoms, one was a long-term remote travel pack for travelling for extended periods or to remote areas and the most comprehensive pack contained nine items such as dispersible aspirin, cetirizine, and amoxicillin. The pharmacy pre-packed commonly prescribed tablets such as forty-two terbinafine tablets and had created their own bespoke packs to contain the prescribed items for the travel packs. Medicines stored outside of their original containers were clearly highlighted with batch numbers and expiry dates.

Once dispensed, medicines were delivered to people in the UK by courier in unmarked, opaque packaging. This service was a next day 24-hour service which could be tracked. There had been no failed deliveries, but this process involved attempting to deliver twice before referring to the prescribing service. There had been no medicines returned to the pharmacy by people using this service for disposal.

The pharmacy used recognised wholesalers to obtain its pharmaceutical stock. And it kept its medicines tidy on the shelves in their original manufacturer's packaging. Members of the pharmacy team checked the expiry dates of medicines at regular intervals which they recorded. And they marked medicines which were shortdated. This helped reduce the chances of them giving people out-of-date medicines by mistake. The pharmacy stored its stock, which needed to be refrigerated, at an appropriate temperature between two and eight degrees Celsius. CDs were stored securely in line with safe-custody requirements. The pharmacy had a process for dealing with the alerts and recalls about medicines issued by the Medicines and Healthcare products Regulatory Agency (MHRA). And it had a process for notifying the MHRA if it had concerns about the medicines it supplied. The pharmacy had procedures for handling waste medicines which were kept separate from stock or were placed in one of its pharmaceutical waste bins. And the RP described the actions they took and demonstrated what records they kept when the pharmacy received a concern about a product.

Principle 5 - Equipment and facilities Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for the services it offers. The pharmacy uses its equipment appropriately and keeps people's private information safe.

Inspector's evidence

The pharmacy team had access to up-to-date and online reference sources. It had clean measures to measure liquid medicines stored near the dispensary sink. And a separate triangle to count methotrexate tablets. The pharmacy stored its pharmaceutical stock requiring refrigeration between two and eight Celsius which its team regularly checked and recorded. The CD cabinet was fixed securely. The pharmacy team collected confidential wastepaper to be disposed of securely. The pharmacy restricted access to its computers and PMR system. And only authorised team members could use them when they put in their password. The pharmacy positioned its computer screens so they could only be seen by a member of the pharmacy team. And its team members made sure they used their own NHS smartcards.

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.	

What do the summary findings for each principle mean?