# General Pharmaceutical Council

# Registered pharmacy inspection report

Pharmacy Name: Doorstep Pharmacy, 106 High Street, Harrow On

The Hill, HARROW, Middlesex, HA1 3LP

Pharmacy reference: 1114125

**Type of pharmacy:** Community

Date of inspection: 21/04/2021

## **Pharmacy context**

This is a pharmacy that is largely closed to the public and located in the centre of Harrow-on-the-Hill in Middlesex. The pharmacy 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 their medicines. It offers travel and seasonal flu vaccinations, dispenses NHS and private prescriptions as well as selling a limited range of over-the-counter medicines. In addition, it has a website (www.doorsteppharmacy.com) where pharmacy only medicines can be bought online. The pharmacy also dispenses private prescriptions for unlicensed treatments for hair loss which it prepares onsite. The pharmacy was inspected during the COVID-19 pandemic.

## **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 has satisfactory processes in place to identify and manage risks. This includes the risks associated with COVID-19. The pharmacist regularly monitors the safety of the pharmacy's services by recording mistakes and learning from them. Staff are trained to protect the welfare of vulnerable people. And, in the main, people's private information is protected. But team members are sharing their NHS smart cards to access electronic prescriptions. This makes it more difficult for them to control access to people's records and keep information safe. And the pharmacy doesn't always record all the required information in some of its records. This could mean that its team may not have enough information available if problems or queries arise in the future.

## Inspector's evidence

The pharmacy had a range of documented standard operating procedures (SOPs) that had been updated in March 2020. They provided guidance for the team to carry out its tasks correctly. The correct notice to identify the pharmacist responsible for the pharmacy's activities was on display. The pharmacy had some systems in place to identify and manage risks associated with its services. This included limiting the spread of infection from COVID-19. The premises had been modified (see Principle 3). A poster was on display asking people to wear a mask upon entering and markers were on the floor to indicate where they should wait to be served. Only one person at a time could enter the premises. The team had been provided with personal protective equipment (PPE), staff were wearing masks at the time of the inspection and had received the second dose of the COVID-19 vaccination. They were also regularly testing for COVID-19 using lateral flow tests. The pharmacy was routinely cleaned, and a rota was in place. Risk assessments for COVID-19, including occupational ones for the team had been completed. The responsible pharmacist (RP) was aware of the requirement to report any cases of staff contracting COVID-19 during work. Information about coronavirus was also on display.

The RP had been routinely recording her near miss mistakes. They were reviewed every month. Medicines that had been involved in errors, were similar in packaging or name were identified, highlighted and separated. The RP had also rearranged the dispensary and where medicines were stored. She explained that the number of mistakes being made was low because the pharmacy was closed to the public and from the way that she worked. This involved generating dispensing labels first, dispensing prescriptions one at a time and then taking a mental as a well as a physical break before conducting the final accuracy check. Dispensing activities took place in different areas of the pharmacy, this included separate workstations for dispensing and accuracy checking. The care homes had different start dates with no overlap, so it was easier for the RP to assemble the medicines for them.

The pharmacy had policies to protect people's confidential information and for safeguarding vulnerable people. Staff had read and signed them and knew who to refer to in the event of a concern. Contact details for the local safeguarding agencies were displayed in the dispensary. The RP had been trained to level two on safeguarding vulnerable people through the Centre for Pharmacy Postgraduate Education (CPPE). New members of the team were seen to have been provided with information about data protection. Confidential information was largely protected. There were no sensitive details that could be seen from the retail space. Confidential waste was shredded. Computer systems were password protected. However, the RP was not using her own NHS smart card to access electronic prescriptions. This was because it had been blocked. She had contacted the local registration authority, but they had

been unable to rectify this because of the pandemic. The RP was advised to try and unblock this as soon as possible because of the risks associated with knowing other people's passwords.

The pharmacy's records were largely compliant with statutory and best practice requirements. This included records of unlicensed medicines that had been obtained from reputable suppliers and a sample of registers seen for controlled drugs (CDs), although the occasional header for the latter had been left incomplete. On randomly selecting CDs held in the cabinet, their quantities matched the stock balances recorded in the corresponding register. Appropriate professional indemnity insurance arrangements were in place. Records verifying that fridge temperatures had remained within the required range had been completed.

However, there were gaps within the electronic RP record where pharmacists had not always recorded the time that their responsibility ceased. There was no audit trail being kept for the receipt and destruction of CDs that had been returned to the pharmacy by members of the public. The RP said that none had been received. Ordering a register and issues with the RP record were discussed at the time. The documented records for the private prescription register were not present in the pharmacy. The RP thought that the superintendent may have taken them. Although electronic records for private prescriptions could be viewed, this meant that it was not possible to verify the records for the emergency supplies or whether the staff's usual method of documenting records for private prescriptions had been made appropriately. It was highlighted at the time that all necessary records should be readily available for inspection.

## Principle 2 - Staffing ✓ Standards met

## **Summary findings**

The pharmacy has adequate staffing levels to manage its workload. Its team members work well together. And they undertake tasks which are appropriate to their role and experience. But the pharmacy only has limited systems or resources to help keep the team's skills and knowledge up to date. This could affect how well they carry out tasks and adapt to change with new situations.

## Inspector's evidence

At the time of the inspection, the pharmacy's staff consisted of the RP, the manager who was the superintendent's daughter and the superintendent pharmacist who sometimes worked at the pharmacy. The latter was not present during the inspection, A follow up phone call took place with him after the inspection. A member of the dispensing staff had left the pharmacy's employment when the pandemic started. Two new members of staff had recently been recruited as a delivery driver and a trainee dispenser. Their first day was on the day of the inspection, the manager was responsible for their induction and they were observed being given information about data protection to read.

The manager confirmed that she did not undertake any activities which required formal pharmacy qualifications such as dispensing medicines or selling over-the-counter products. Her role involved managing the administration and paperwork. The superintendent pharmacist was responsible for preparing the unlicensed batches of minoxidil and worked as the responsible pharmacist when this took place. When asked about his skills, qualifications and ongoing training for this role, other than being a pharmacist, he said that his experience of preparing medicines spanned 60 years and the manager said that he used to own his own manufacturing business (see Principle 4).

The RP explained that she undertook all activities herself such as selling medicines, self-dispensing and accuracy-checking with the measures implemented as described in Principle 1. The RP had been able to manage the pharmacy's current volume of dispensing because it was in a closed environment, with limited distractions or interruptions. She enjoyed working at the pharmacy and felt supported by the manager and the superintendent. The pharmacy did not have a formal or ongoing training programme in place for staff although trade publications were seen to help keep people up to date with current matters.

## Principle 3 - Premises ✓ Standards met

## **Summary findings**

The pharmacy's premises provide a suitable environment to deliver healthcare services. The pharmacy has introduced appropriate measures to help reduce the spread of COVID-19 inside its premises. Its team members keep the premises clean. And it has a separate space where confidential conversations or services can take place.

#### Inspector's evidence

The pharmacy's premises consisted of two floors in a listed building. People had to ring the doorbell to come inside. Upon entering the pharmacy, there was a small retail space, an appropriately sized consultation room and an office. The dispensary was in the basement alongside a small kitchenette and two staff WCs. The retail area was professional in its appearance, well-lit and clean. The carpet in the dispensary in the basement required vacuuming but all other areas were clean, and workspaces were free of clutter. The consultation room could be locked, and it was of an appropriate size for its intended purpose. It contained suitable equipment to provide the services the pharmacy offered. And as the pharmacy was generally closed, along with the dispensary's location downstairs, this helped ensure people's confidentiality and privacy were maintained.

Due to COVID-19, the premises had been adapted to help minimise the spread of infection. One person at a time was let in after ringing the doorbell. There were markers on the floor to help people to know where to stand, the seats were positioned away from one another and a screen had been placed in front of the medicines counter as a barrier. The pharmacy was also cleaned regularly, and details were on display to provide information about coronavirus as well as wearing a mask.

## Principle 4 - Services ✓ Standards met

## **Summary findings**

The pharmacy obtains its medicines from reputable sources. It generally stores and manages its medicines appropriately. The pharmacy supplies medicines to residents in the care homes safely. And the pharmacist makes relevant checks when people receive higher-risk medicines. But the pharmacy doesn't always record any information about this. This makes it difficult for the pharmacy to show that it provides people with appropriate advice when supplying these medicines. And, the pharmacy does not always follow all the guidance set by the GPhC when it prepares unlicensed medicines. This limits its ability to show that it provides this service safely.

## Inspector's evidence

The pharmacy's front entrance was kept locked and people could enter the premises by steps from the street. This meant that people with wheelchairs or mobility issues could not easily enter the premises. However, a doorbell alerted staff that someone required assistance. Two seats were available for people who wanted to wait inside the retail area and a few timed, car parking spaces requiring payment were available on the street outside.

The workflow involved prescriptions being prepared in one area, the RP assembled medicines against each prescription first, then after taking a physical and mental break, the medicines were checked for accuracy by her from another section. The RP used baskets to hold prescriptions and medicines during the dispensing process. This helped prevent any inadvertent transfer of items from one place to another. Once the dispensing labels had been generated, there was a facility on them which helped identify who had been involved in the dispensing process. This had been routinely used as an audit trail. Once prescriptions had been assembled and bagged, if they were due to be collected, the prescription was attached to the bag before hand-out. However, the pharmacy had not been sending private prescriptions for CDs to the NHS Business Services Authority (NHSBSA) at the end of every month for analysis. The RP had been unaware of this requirement and was advised to ensure this was completed.

The pharmacy used licensed wholesalers such as AAH and Alliance Healthcare to obtain medicines and medical devices. Medicines had been stored in an organised manner on the shelves in the dispensary. The RP had been date-checking medicines for expiry regularly and identified short-dated medicines. However, a schedule of when this had happened had not been kept as required by the pharmacy's relevant SOP. There were no date-expired medicines seen but several loose blisters of medicines were present. This was discussed with the RP at the time. Medicines returned for disposal, were accepted by staff and stored within designated containers. Drug alerts were printed by the RP and actioned appropriately. Records had been kept verifying this.

The pharmacy provided medicines to residents inside care homes using multi-compartment compliance packs. Some of the care homes ordered repeat prescriptions for the residents themselves, for a few, the RP did this after she was provided with details of their requests. The RP monitored the requests received and followed up any queries such as missing items or changes appropriately. Notice boards and checklists assisted her in keeping track of when the prescriptions were due. The team obtained information about allergies and recorded this on the medication administration record (MAR). Detailed descriptions and images of the medicines were also provided alongside patient information leaflets (PILs) and photographs of the residents. This helped ensure that correct administration could take

place. Interim or mid-cycle items were dispensed at the pharmacy. The pharmacy also had additional audit trails in place once the medicines had been supplied. This served as an additional check to ensure the correct number of medicines were supplied.

Some people's medicines were also supplied inside compliance packs once a need had been identified for them. The pharmacy ordered prescriptions on behalf of people for this service and records were kept for this purpose. Any queries were checked with the prescriber and the records were updated accordingly. Patient information leaflets (PILs) were routinely supplied but descriptions of the medicines inside the packs were not provided. Staff were aware of the risks associated with valproates but any literature about this had already been handed out. The pharmacy had no further supplies available to provide to people at risk at the time of the inspection. The RP was advised to order some and to ensure that they were always kept in stock. People supplied higher-risk medicines were asked about blood test results, but no specific details were provided or documented.

The pharmacy usually ran a travel clinic with vaccinations offered for people travelling overseas. This included yellow fever vaccinations. The superintendent pharmacist was accredited to offer the latter and an up-to-date certificate was seen to verify this (from February 2020). The pharmacy was registered with the National Travel Health Network and Centre (NaTHNaC) to provide yellow fever vaccinations. However, a different supervising clinician was registered on their website as providing this. Other vaccinations were provided through Patient Group Directions (PGDs) and were administered on an appointment basis. Staff explained that because of the pandemic, demand for this service had significantly reduced so the pharmacy was not currently providing this. The pharmacy had been supplying lateral flow tests for people to self-test for COVID-19. People's ages were checked upon supply. The pharmacy had also supplied them to the residential care homes.

People could order Pharmacy (P) medicines from the pharmacy's website (www.doorsteppharmacy.com). No prescription-only medicines (POMs) were advertised or available through here. The process involved people completing questions relating to them or the product before being assessed by the team. The pharmacy had an SOP in place to guide the team about this. This included a risk assessment about the potential issues when people ordered medicines online as well as the measures that the pharmacy had in place to minimise them. This included only allowing a repeat purchase of a product that could be misused (such as codeine) every three months. If people tried to purchase P medicines more frequently the request was put on hold until the RP had assessed the situation. The person was contacted, and the relevant details checked. Documented details of the refusals had been kept as an audit trail by the team. Medicines were delivered using a courier and service that could be easily tracked.

The pharmacy also extemporaneously prepared six different formulations of minoxidil for people against prescriptions received from 'The Hair Growth Clinic'. This is a private centre with clinics across the UK, although the pharmacy received prescriptions from the centre in West London. The prescribers are doctors registered with the General Medical Council. However, on inspecting the prescriptions, it was evident that they had been faxed to the pharmacy, and the team had no verifiable system in place to ensure that the original had been received. The manager confirmed that since the pandemic started, they had not always received the original prescription. This had not been taken up with the clinic at the time of the inspection. This was discussed at the time.

The superintendent pharmacist prepared the formulations on one side of the dispensary. This area had been kept clean and tidy. Hazardous materials were kept inside a safe, designated and purpose built for flammables. Other excipients were stored inside a cupboard. The excipients or raw materials had certificates of conformity or analysis available and although their expiry dates were listed on the

paperwork, the products themselves only had batch numbers present. There was therefore a risk that the excipients could continue to be used after they had expired. The team was subsequently advised to include this information on the containers. Photographic evidence was received after the inspection that this had been complied with.

This had the calculated amounts of the excipients to be used but there were no details present, at the time of the inspection, of the formula or where this had come from (such as an approved source like the British Pharmacopeia). Subsequently, it was not possible to determine or verify the calculated quantities. Records of the batches that had been prepared had been kept but some details (such as the date of the preparation or the supply) were incomplete. The pharmacy had however, completed a batch recall exercise in 2018. This could help trace who had received a certain batch if any of the excipients were recalled, but no audits or a regular review of this situation had been carried out.

The inspector spoke to the superintendent pharmacist by telephone after the inspection. He explained that when the pharmacy received the prescriptions from the clinic, he prepared different strengths of the minoxidil preparation in line with the prescriber's instructions, in 3kg batches with packs of 12 prepared. The superintendent said that the original formula came from the doctors at the hair clinic who had completed their own research. The preparations being made were not a product from the British Pharmacopoeia. When the doctors had sent him the basic formula, the calculations had been made in response and the superintendent said that a specific consultation firm (M & T Associates Ltd) had validated the formula and verified the calculations.

The manager also said that the pharmacy had completed a risk assessment about this activity. However, this could also not be located at the time of the inspection. She was asked to submit this along with further evidence that the pharmacy had been complying with the guidance set by the GPhC to the inspector. The superintendent was also asked to submit further details regarding the origin of the formulas being used and details of when and who validated the calculations. This information was subsequently received. A qualified scientist from this firm had verified the calculations and acted as an external assessor for the superintendent. A training record for the latter was also submitted along with a letter from the clinic outlining their instructions. However, aside from the SOP for the preparation of these products, the previous batch recall exercise and the risk assessment, the other documents were dated for after the inspection.

## Principle 5 - Equipment and facilities ✓ Standards met

## **Summary findings**

The pharmacy overall, has the necessary equipment and facilities it needs to provide its services safely. And its equipment is clean.

#### Inspector's evidence

The pharmacy generally had an appropriate range of equipment and facilities. This included current versions of reference sources, two clean, standardised conical measures for liquid medicines, counting triangles, a legally compliant CD cabinet and appropriately operating pharmacy fridges. The weighing scale had been calibrated recently. It was due for a portable appliance test in January 2022. The pharmacy had a spill kit, mortar and pestle and an appropriate unit to store flammable liquids. However, there were a few plastic conical measures present. The RP said that they were not used and was advised to remove and replace them with standardised ones if needed. The dispensary sink for reconstituting medicines was clean. Computer terminals were positioned in a manner that prevented unauthorised access. The pharmacy's telephones were situated in the basement along with a cordless telephone so that private conversations could take place if required. There was also a shredder to dispose of confidential waste. The superintendent however, had left his NHS smart card inside a computer terminal and he was not present during the inspection. Storing NHS smart cards appropriately was discussed at the time.

## 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.	