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: Closed

Date of inspection: 25/02/2020

Pharmacy context

This is a pharmacy located in the centre of Harrow-on-the-Hill. It has an NHS distance selling contract for supplying medicines to care homes and provides NHS flu vaccinations. The pharmacy also operates a private travel clinic providing a full range of vaccinations. The pharmacy has a small retail area and sells a limited range of over-the-counter medicines. Public access to the pharmacy is restricted to the vaccination services, travel clinic and sales of medicines. The pharmacy has a relationship with two private providers offering treatments for hair loss; they prepare unlicensed external preparations which are prescribed for patients for use on an on-going basis. The pharmacy website www.doorsteppharmacy.com offers pharmacy-only medicines for sale.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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 risks associated with the preparation of unlicensed products are not appropriately managed.
		1.2	Standard not met	The quality of the unlicensed products made by the pharmacy is not assessed.
		1.3	Standard not met	Staff complete tasks in the absence of the responsible pharmacist which they should not be doing.
		1.6	Standard not met	Records in the pharmacy are not complete and do not accurately reflect the activity of the pharmacy.
2. Staff	Standards not all met	2.2	Standard not met	There is a lack of supervisory control in the pharmacy as the trainee dispenser is allowed to carry out tasks alone in the pharmacy.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	Unlicensed products are not prepared in accordance with GPhC guidance.
		4.3	Standard not met	Raw materials for the preparation of unlicensed medicines are not stored appropriately or managed well.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy is failing to adequately manage all of its risks. Team members sometimes record some of their mistakes, but they do not do this regularly and so may miss out on learning from all their mistakes. It keeps most of its records complete, but some of the legally required records are not accurate. This means that the pharmacy may not be able to easily identify or correct its mistakes. Team members understand their role in protecting vulnerable people. But they are not aware of the tasks they can complete in the absence of the pharmacist

Inspector's evidence

The trainee dispenser explained that the team kept a near miss log to record any incidents the pharmacist identifies. However, there were very few entries in the log, and they did not include much detail. There was a workflow in the dispensary where labelling, dispensing and checking were all carried out at different areas of the work benches. Standard Operating Procedures (SOPs) were in place for the dispensary tasks. The team had signed the SOPs to say they had read and understood them. Staff roles and responsibilities were described in the SOPs and they had been last reviewed on the 1st February 2018. The next review was due on the 14th February 2020, but it had not been completed yet. A certificate of public liability and professional indemnity insurance from the NPA was on display in the dispensary and was valid until the 18th December 2020.

There was a complaints procedure in place within the SOPs and the dispenser was clear on the processes she should follow if the pharmacy received a complaint. The website for the pharmacy also had a section for comments and complaints and included information about the NHS complaints procedure, Patient Advice and Liaison Service (PALS) and Independent Complaints Advocacy Service (ICAS). The pharmacy's website also included a section about the Community Pharmacy Patient Questionnaire. However, the results displayed on the website were from 2017/2018 and had not been updated.

Records of controlled drugs were available in the pharmacy. A sample of MST 15mg tablets was checked for accuracy and was correct, but there was no evidence to show the running balance was checked regularly in accordance with the SOP. The CD cabinet was very small and could not hold a lot of CDs. The pharmacy did not have a register for patient-returned controlled drugs. The pharmacist explained that they have never had any patient-returned CDs. The responsible pharmacist record was held electronically, and the correct responsible pharmacist notice was displayed in the pharmacy where patients could see it. However, on entry to the pharmacy, the pharmacist was not present, only the trainee dispenser. The entries in the RP log did not accurately reflect the pharmacist's absence. When the doorbell of the pharmacy rang, the dispenser went to answer it and then came back down to the dispensary, picked up a bagged prescription and took it back upstairs. When asked if she had handed out a prescription, she explained that she had. However, the responsible pharmacist was not on site. The private prescription records were completed electronically. The specials records were not complete, and the certificates of conformity did not include the required information. Extemporaneous preparations in the pharmacy had been recorded appropriately and the manager explained how they could trace batches if there was a recall.

The computers were all password protected, confidential information in the consultation room was

stored away from the public and conversations inside the consultation room could not be overheard clearly. Confidential waste was collected in baskets on the workbenches to be shredded. The pharmacist explained that he had completed the CPPE Level 2 training programme on safeguarding vulnerable adults and children, and team members explained that they were aware of things to look out for which may suggest a safeguarding issue. The team explained that they were happy to refer to the pharmacist if they suspected a safeguarding incident. The contact details for the local safeguarding authorities were displayed in the dispensary above the pharmacist's desk.

Principle 2 - Staffing **Standards not all met**

Summary findings

Although the pharmacy has enough staff to provide its services safely, it does not properly supervise its trainees. And its team members are not aware of the tasks they can complete in the absence of the pharmacist. This could affect how well they care for people and the advice they give.

Inspector's evidence

On entry to the pharmacy, there was one member of staff who explained that she was a trainee dispenser and on the NPA's NVQ Level 2 course. There was no other member of staff present on entry and the trainee dispenser was observed completing paperwork and orders. The superintendent pharmacist and the pharmacy manager, who was the superintendent's daughter, came into the pharmacy at about 11am, an hour after the inspection had started.

There was no formal on-going training programme for the staff. The team received training material from Training Matters, and they also had reps who visited the pharmacy to train them on new products.

The dispenser explained that team members were open to raising anything with one another whether it was something which caused concern or anything they believed would improve service provision. There were no targets in place and the team explained that they would never compromise their professional judgement for business gain.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are generally suitable for the provision of its services. The pharmacy keeps its premises maintained fairly well. And it keeps them secure when closed. Pharmacy team members use a private room for sensitive conversations with people to protect their privacy.

Inspector's evidence

The pharmacy was located across two floors in a listed building. On the ground floor there was a retail area, consultation room and office. In the basement there was a dispensary, small staff kitchen and staff bathroom. The waiting area of the pharmacy on the ground floor was presented professionally and was clean and tidy. However, the dispensary in the basement was cluttered, untidy and disorganised. The carpet by the specials preparation area was very sticky and dirty. The team explained that they had a cleaner who cleaned the pharmacy once a week and a window cleaner cleaned the front windows every fortnight.

Medicines were stored on the shelves in a suitable manner and the lack of patient access allowed for privacy and confidentiality in the dispensary. The consultation room was adequately sound proofed and could be locked. The consultation room included seating, a computer with the PMR system, a sink for the provision of services and storage.

Lighting throughout the pharmacy was appropriate for the delivery of pharmacy services. The pharmacy shared the hall and stairways with a first-floor office suite for use by a separate business. The different areas of the pharmacy could be closed off from the shared space.

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

Summary findings

The pharmacy does not adequately manage the preparation of its hair loss treatments. It is not following guidance from the GPhC on preparing unlicensed medicines. This means that products made in the pharmacy may not safe to supply. But it does make its services accessible to the public. And it manages its travel services adequately

Inspector's evidence

Pharmacy services were displayed in the window of the pharmacy and on the website. There was a range of leaflets available to the public about services on offer in the pharmacy and general health promotion in the retail area of the pharmacy near the waiting area. The main entrance of the pharmacy was kept locked and the pharmacy could be accessed by steps from street level. There was a buzzer in place to alert staff to enable access through the front door. The steps meant that those with mobility difficulties could not easily gain access to the pharmacy.

The pharmacy team prepared multi-compartment compliance aids for domiciliary patients and those in care homes. The trainee dispenser explained how they used the CareMeds and MultiMeds systems to ensure patient were provided with accurate MAR charts which included descriptions of the medicines inside as well as images of the medicines. Labelling also included a picture of the nursing home resident to aid correct administration. The dispenser explained that patient information leaflets (PILs) would always be provided.

Travel and vaccination services were provided under private PGDs with Pharmadoctor and NaTHNaC. The superintendent was able to provide these services and certificates of appropriate training were displayed in the pharmacy. Appointments were usually made online through the pharmacy website or by phone. The pharmacy had an arrangement to provide travel services for the pupils of Harrow School which was nearby, and boys under 16 would attend with their matron. Records of supplies were kept on paper and the pharmacy provided vaccination certificates where necessary.

The pharmacy's website offered a range of pharmacy-only (P) medicines for sale to the public. The SOPs included a risk assessment of the problems which may arise from the sale of P-medicines without face to face consultations. The SOP listed the controls in place to mitigate these risks. For example, a software update had been implemented to ensure that purchases of P-medicines promted the purchaser to upload proof of identity to ensure medicines are only supplied according to the relevant age restrictions. The website had authentication by card payment gateway and sales were restricted to the cardholders address which had 3D authentication. No POM medicines were available on the website or opioid P-medicines such as co-codamol.

The pharmacy extemporaneously prepared six different formulations of minoxidil for the 'The Hair Growth Clinic'. The trainee dispenser demonstrated the SOP for preparing these formulae and the batch production cards which had a unique batch number which linked to the patients they were supplied to. The superintendent explained that only he prepared these formulations. The team had completed a recall exercise to demonstrate how they could trace which patient had which batch if a product was recalled. Raw materials and excipients for the formulations were not all stored appropriately; an open bag of minoxidil powder and a progesterone powder jar had been left on the

bench. The alcohol used for the preparations was stored in a metal flammable liquids safe. Raw materials were sourced from various UK suppliers, and certificates of conformity or analysis were available. However, the certificates of conformity showed that a few of the raw materials had expired, but the products they corresponded to were out on the dispensing benches and appeared to be in use but the pharmacist explained that they were not being used. The pharmacist was advised to to segregate out of date ingredients to avoid them being used inadvertently.

The special preparations were made on a hot plate at the back of the pharmacy and equipment was kept close by and was generally seen to be clean. The batch numbers were included on the records and the dispensing labels. A nominal one year expiry was applied to the final product. However, assays or stability tests were not undertaken to ensure the quality of the product or the manufacturing process as per the GPhC's Guidance for registered pharmacies preparing unlicensed medicines. Around 25 to 30 patients at the Hair Growth Centre were supplied every month and supplies were labelled for individual patients and sent to the clinic to be handed out by staff on-site. The pharmacy also received prescriptions for minoxidil from a remote prescriber, but prescriptions detailed the prescriber's address as the pharmacy. The trainee dispenser explained that the prescriber was not an employee of the pharmacy. The prescriber worked remotely and would write the prescriptions and post them to the pharmacy. The team were advised that the prescriptions should record the prescribers own address. Medications were extemporaneously prepared on an individual basis and posted to the patient via a courier service or through Royal Mail Special Delivery so it can be tracked. Extemporaneous records of these supplies were available on paper and electronically.

The team explained that they were all aware of the requirements for patients in the at-risk group to be on a pregnancy prevention programme if they were on valproates and they had checked the PMR to see if they had any patients affected by this. The pharmacist explained that he would ask the delivery patients who were taking warfarin if they were having regular blood tests, but information about these blood tests was not stored on the PMR. Examined dispensing labels were not signed so it was not possible to identify who had dispensed and who had checked a prescription.

The team were aware of the EU Falsified Medicines Directive (FMD). They had signed up with an FMD programme provider and had a scanner in place, but they had not started using it. The pharmacy obtained medicinal stock from Alliance, AAH or Sanofi directly for vaccinations. Invoices were seen to verify this. The pharmacy had two fridges, one was used for regular pharmacy stock and the other was used for wholesale stock and for storing vaccinations. The records for the wholesale fridge were kept on paper and the records for the other fridge were kept electronically.

Date checking was carried out regularly and the team highlighted items due to expire with coloured stickers. Designated bins for the disposal of waste medicines were available and seen being used for the disposal of medicines. The team also had a bin for the disposal of hazardous waste. The CD cabinet was appropriate for use and properly secured. The trainee dispenser explained that MHRA alerts came to the team via email and they would check for any affected stock, but they did not routinely print off the recalls or keep an audit trail of them.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the appropriate equipment and the facilities it needs to provide its services safely. Its equipment is clean and well maintained.

Inspector's evidence

There were several crown-stamped measures available for use, including 100ml, 50ml, 25ml and 10ml measures. Some were marked to show they should only be used with oral preparations. The team prepared the minoxidil preparations on hot plates in the pharmacy and used metal pots to make the preparations. The equipment used for the preparations was seen to be generally clean. Scales were used to weigh raw materials for the preparation of minoxidil products and the pharmacist explained that the scales were calibrated annually, but records of this could not be found.

Amber medicine bottles were capped when stored and there were counting triangles available as well as capsule counters. Up-to-date reference sources were available such as a BNF and a BNF for Children as well as other pharmacy text. Internet access was also available should the staff require further information sources and the team could also access the NPA Information Service.

The maximum and minimum temperatures of the fridges were recorded irregularly but were seen to always be within the correct range. The computers were all password protected and conversations going on inside the consultation could not be overheard.

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.