General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Green Light Pharmacy, 275 Eversholt Street, London, NW1 1BA

Pharmacy reference: 9010008

Type of pharmacy: Community

Date of inspection: 21/06/2019

Pharmacy context

This is a community pharmacy located close to the underground station for Mornington Crescent in North West London. The pharmacy dispenses NHS and private prescriptions. It supplies some people with their medicines inside multi-compartment compliance aids if they find it difficult to take their medicines on time.

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

In general, the pharmacy is managing most of the risks associated with its services appropriately. It has written instructions to help with this. But not all members of the pharmacy team have read them. This means that they could be unclear on some of the pharmacy's current processes. Pharmacy team members deal with their mistakes responsibly. But, they are not always recording them. This could mean that they may be missing opportunities to spot patterns and prevent similar mistakes happening. Team members know to protect people's private information, but they have not been trained on recent updates in the law.

Inspector's evidence

The pharmacy had very recently changed ownership (April 2019) and it was in a transitional period. The pharmacy was small with limited space for dispensing to occur (see Principle 3). The team explained that the workflow occurred in a circular motion, prescriptions were processed on one terminal, assembly occurred in one area and the final check by the responsible pharmacist (RP) occurred from a separate space.

Staff described the RP passing their mistakes back for them to identify, before they were remedied. Details about the near misses that occurred in June were seen recorded but not before this time frame. The RP explained that at the end of the month, details were collated and collectively reviewed. The RP also stated that she picked up errors that the trainee dispensing assistant had made whilst she was selecting medicines for the Monitored Dosage Systems (such as mixing up different forms and medicines), and these were not recorded as near misses.

There was no information on display at the point of inspection about the pharmacy's complaints procedure and this meant that people may not have been able to raise their concerns easily. This was subsequently implemented. The pharmacy's complaints process was seen electronically but this was dated. The RP's process to handle incidents involved checking the level of harm, informing the person's GP if anything was taken incorrectly, recording details and reporting to the superintendent pharmacist.

The company's standard operating procedures (SOPs) were held electronically. However, they were all seen to be be dated as reviewed on different dates, some were from 2009, 2015, 2016 and 2018. There was no page seen that indicated a review had occurred recently or when the last review took place. The pharmacist said that she had signed the SOPs in another branch. One member of staff had only read the SOPs about dispensing, the remaining team members had not read and signed the SOPs that were present. The superintendent pharmacist confirmed that SOPs were reviewed annually by him and this information would be clearer on the company's intranet going forward.

The trained counter assistant knew which activities were permissible in the absence of the RP and he was clear about his role and responsibilities, however the trainee dispensing assistant was unclear when questioned by the inspector, she was observed working unsupervised whilst assembling Monitored Dosage Systems (see Principle 4). The correct RP notice was on display and this provided details of the pharmacist in charge of operational activities on the day.

Team members at the inspection were not trained to identify signs of concern to safeguard vulnerable people. The pharmacist was trained to level 2 via the Centre for Pharmacy Postgraduate Education

(CPPE). Staff were unaware of relevant local contact details and there were none seen to support effective referral to the local safeguarding agencies. Evidence that staff were subsequently being trained was received.

There was no confidential material stored in areas that directly faced the public and the team segregated confidential waste before it was shredded. Dispensed prescriptions awaiting collection were stored in a way that prevented sensitive information being visible from the retail area. The staff were not trained on the EU General Data Protection Regulation (GDPR) and there was no information available to inform people about how their privacy was maintained at the point of inspection. The latter was subsequently implemented.

A sample of registers checked for Controlled Drugs (CDs) were, in the main, recorded in line with the Regulations. Some amendments were seen in the register for methadone where the full details were not recorded. Balances for CDs were checked and recorded every week and with each transaction. On randomly selecting CDs held in the cabinet (MST, Oxycontin), their quantities matched balances recorded in corresponding registers.

Records of emergency supplies were documented with the nature of the emergency, the maximum and minimum temperature of the fridge was checked and recorded daily. This verified that medicines were being stored appropriately. The pharmacist explained that a record for returned CDs brought back for destruction was not yet in place, returned CDs were appropriately segregated in the cabinet. This was subsequently implemented. There were odd entries seen within the RP record where pharmacists had not recorded the time that their responsibility ceased, and prescriber details were incomplete in the electronic private prescription register. Details for the latter were either completely missing, they were incorrect, or the prescribers address had not been recorded. This was discussed during the inspection.

There was no information present about the pharmacy's professional indemnity insurance arrangements, the RP was asked to provide evidence of this to the inspector. This was received and confirmed that the pharmacy was indemnified through the National Pharmacy Association (NPA) from the 2 April 2019, this was due for renewal after 31 October 2019.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload appropriately. It is going through a period of change and some members of the team are still learning about their roles and responsibilities. But, they are being supported by another local branch.

Inspector's evidence

The pharmacy dispensed 3,000 prescription items every month with 40 people receiving their medicines inside MDS trays and five people with instalment prescriptions.

Staff present included the regular pharmacist who was a relief member of staff for the company, a pharmacist from Spain and a trainee dispensing assistant, both of whom were recently employed and had been present at the pharmacy for less than three months. There was also a trained medicines counter assistant (MCA) who delivered medicines and another delivery driver for the company seen. A permanent lead pharmacist was due to start at the pharmacy and the team, including inexperienced members of staff were being supported by staff at another close branch.

The MCA's certificates of qualifications obtained were seen, he asked a range of suitable questions to obtain relevant information before selling over-the-counter (OTC) medicines and held sufficient knowledge of these medicines. Staff were observed checking every transaction with the RP.

The MCA explained that he had received ongoing training through the previous owners and the team had not yet received any information about the resources available to them from the new owners.

In addition to the Essential Services, the pharmacy was only providing MURs and the NMS. The pharmacist explained that there were no formal or commercial targets currently set to complete services.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are adequate to ensure the effective delivery of its services. The premises are clean and secure. But, team members are storing some stock or dispensed prescription-only medicines in the consultation room. This increases the chance of them being accessed by unauthorised people.

Inspector's evidence

The premises consisted of a small sized retail area, a small dispensary and an even smaller segregated dispensary at the very rear that was being used to assemble and store MDS trays.

An unlocked, signposted consultation room was available to provide services and private conversations. There was access into the back of the dispensary and staff areas from this space. The room contained a medical fridge, this was also unlocked and meant that there was access to prescription-only medicines (POMs) that were stored here. There were POMs present in the room as part of the pharmacy's stock, returned medicines brought back for disposal as well as bulky medicines waiting to be delivered. Keeping the room and/or the fridge locked was discussed at the time, evidence was received that the former had been implemented and the returned medicines were removed from the area.

The pharmacy was suitably lit and ventilated. The retail space was clean and well presented. Pharmacy (P) medicines were stored behind the front counter and staff were always within the vicinity, this helped prevent their access by self-selection. The outside facia still had details of the old ownership present which could have been confusing for some people. Staff explained that this was due to change.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy sources its medicines from reputable suppliers and the team makes some checks to ensure that medicines are not supplied beyond their expiry date. But, the pharmacy has no up-to-date written details to demonstrate this. And, it sometimes stores medicines in poorly labelled containers. This makes it harder for the team to check the expiry date, assess the stability or take any necessary action if the medicine is recalled. The pharmacy provides some of its services appropriately. And, it has tried to ensure that these are delivered in a safer way following the inspection. But, members of the pharmacy team don't always highlight prescriptions that require extra advice or record information when people receive some medicines. This makes it difficult for them to show that appropriate advice has been provided when these medicines are supplied. And, they are not removing date-expired prescriptions in time, which means that medicines could be supplied inappropriately.

Inspector's evidence

The pharmacy's entrance was via a ramp from the street, this, along with the clear, open space inside the pharmacy's premises meant that people with wheelchairs could easily access the services. The pharmacy's opening hours were on display on the front door and there were three seats available for people waiting for prescriptions.

The pharmacy team used baskets to hold each prescription and associated medicines. This prevented any inadvertent transfer. Staff used a dispensing audit trail to verify their involvement in processes and this was through a facility on generated labels.

The pharmacy was providing a delivery service and the team was maintaining audit trails to demonstrate when and where medicines were delivered. CDs and fridge items were identified, failed deliveries were brought back to the pharmacy with notes left to inform people about the attempt made. The inspector was told that medicines were occasionally put through people’s letterbox if prior consent was obtained and relevant risks such as pets/children were checked.

The new member of staff whose employment started two months before the inspection was assembling MDS trays, unsupervised. This took place in the segregated space at the very rear of the pharmacy. She could not describe the process to the inspector and stated that a dispensing assistant from one of the company’s other branches processed prescriptions. The RP informed the inspector that this member of staff, initially selected medicines against the person’s individual record instead of the prescription, the RP then conducted accuracy-checks to ensure that the right medicines were selected. The RP stated that this situation only occurred when they were first taken over as an emergency, because prescriptions had not arrived in time, MDS trays were therefore being prepared ahead of prescriptions.

After clarifying, the RP then stated that this practice no longer occurred and the dispensing assistant selects medicines against the prescriptions, once they have been ordered by the pharmacy. The RP also stated that the prescriber informed them of changes or the person receiving the trays did. Details were not seen recorded to verify that this had occurred. One elderly person with trays was receiving valproate, that was de-blistered into the tray and four weeks at a time. The RP was unaware of stability concerns associated with this medicine.

This practice was not in line with the pharmacy's SOP, evidence was received that it was no longer occurring, the RP was instructed to ensure records were fully annotated, to complete additional training on the topic, review reference sources and complete revalidation by the inspector, on the day.

Descriptions of medicines within trays were provided and Patient Information Leaflets (PILs) were routinely supplied. Trays were not left unsealed overnight and all medicines included in trays were de-blistered and removed from their outer packaging. Some people with trays received warfarin separately but there were no relevant checks being made about their International Normalised Ratio (INR) level or details seen documented about this. Mid-cycle changes had not yet occurred, and the RP explained that the trays would be retrieved and a discussion with the prescriber would occur about how to implement the change.

The pharmacist was aware of risks associated with females prescribed valproate, there was no literature seen to provide to people if needed but the RP stated that she could print these if required and that no prescriptions for females at risk had been received. Prescriptions for people prescribed higher risk medicines were not seen to be identified to enable pharmacist intervention, counselling or to check relevant parameters. The inspector observed the RP hand out a prescription for warfarin and relevant information such as the INR level was not asked about, the RP stated that this was asked when the person handed their prescription in. There were no details documented to demonstrate this.

Dispensed prescriptions requiring collection were held within an alphabetical retrieval system. However, there was a high volume of photocopied prescriptions present, when questioned, the RP admitted that they had been sent to the prescription pricing bureau for payment before they had been collected. Fridge items and CDs (Schedules 2-3) were identified with stickers. Schedule 4 CDs were not highlighted, and staff could not recognise all of these. Uncollected medicines had not been checked or removed since the change of ownership.

Date expired prescriptions were present. This included expired prescriptions for gabapentin and diazepam from April 2019 that had not been removed from the retrieval system. Staff could not identify some of these as CDs and did not know how that they were only valid for 28 days. They did however, run all dispensed prescriptions past the RP, before they were handed out.

There was also a basket present that contained prescriptions for the MDS trays once they were assembled and bagged, the prescriptions were not left attached to the dispensed bags and no details were matched or checked against the prescription when the trays were handed out. Evidence was received that the prescriptions were now filed with the rest of the prescriptions and the process occurred in line with the pharmacy's SOP.

Licensed wholesalers were used to obtain medicines and medical devices. This included AAH, Alliance Healthcare, OTC Direct, DE South and Bestway. Unlicensed medicines were obtained through AAH specials. Only the RP was aware of the processes involved to comply with the European Falsified Medicines Directive (FMD). The inspector was told that the pharmacy was not yet compliant with the legislation, another one of their branches were trialling this currently and the process would be rolled out when this had been tested. This was also confirmed by the superintendent pharmacist. There was no guidance information seen for the team, to help support the process at the point of inspection.

Medicines were generally stored in an organised manner in the dispensary. CDs were stored under safe custody and the keys to the cabinet were maintained in a manner that prevented unauthorised access during the day as well as overnight.

The RP admitted that systematic date-checking of medicines had not occurred since the change of ownership, she thought that a full check of the pharmacy may have occurred at the initial change-over and this was confirmed by the superintendent pharmacist. There was no schedule being used to demonstrate when the last date-checks for POMs occurred. A matrix was being used for OTC stock and stickers were used to identify short-dated medicines here. No date-expired medicines were seen.

There were several concerns seen with the way medicines were being stored. This included loose blisters of medicines on shelves (co-trimoxazole, varenicline), mixed batches (venlafaxine) and several poorly labelled containers, with no details about the expiry date or batch number were present, there were also medicines that were de-blistered and removed from their original container (propranolol, Sulpride, bisoprolol, allopurinol, ferrous sulphate, co-codamol, gabapentin).

There were appropriate receptacles available to store medicines returned by the public for destruction, but these were initially being stored in the consultation room, this detracted from the professional use of the room and presented a risk of diversion as the room was left unlocked. People bringing back sharps for disposal were referred to the GP surgery and returned CDs were brought to the attention of the RP.

Drug alerts were received by email according to the RP, she described the process involving checking for stock and acting as necessary, however, when the email system was brought up, only alerts from the NHS Central Alerting System were present. There was no evidence that recent safety alerts from the Medicines and Healthcare products Regulatory Agency (MHRA) had been received or suitable action taken. Evidence was received that the pharmacy was now subscribed to receiving alerts from the MHRA.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely.

Inspector's evidence

The pharmacy was equipped with current versions of reference sources, it also had crown-stamped conical measures present but some of these were grimy with black mould/residue around the top half where a label was present. This was discussed at the time and the RP stated that they were not being used. The sink used to reconstitute medicines in the staff area was relatively clean, there was hot and cold running water available as well as hand wash present. Counting triangles required cleaning as there was tablet residue present. This meant that cross-contamination was possible. They were subsequently cleaned.

Computer terminals were positioned in a way that prevented unauthorised access. The RP was the only person with an NHS smart card to access electronic prescriptions and this was taken home overnight. An operating shredder was available to dispose of confidential waste. The medical fridge was packed with stock but seen to be operating at the appropriate temperature. There was also milk stored in here. The CD cabinets were secured in line with legal requirements. The blood pressure machine was replaced recently according to staff.

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.