General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Apex Pharmacy, 199 Old Street, LONDON, EC1V 9NP

Pharmacy reference: 1040248

Type of pharmacy: Community

Date of inspection: 03/06/2019

Pharmacy context

This is a community pharmacy situated on a main road. It serves a diverse local community. The pharmacy dispenses NHS prescriptions. It also supplies medicines in multi-compartment compliance aids to help people to take their medicines safely. And it offers other services including a delivery service, flu vaccinations and Medicines Use Reviews.

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 generally manages the risks associated with its services. But it does not always record mistakes that occur during the dispensing process. This may mean that staff are less able to spot patterns in mistakes and they may not always understand how to prevent similar mistakes in the future. The pharmacy largely keeps the records it needs to by law. And it protects people's personal information.

Inspector's evidence

Standard operating procedures (SOPs) were in place and these had last been reviewed in 2017. Not all current members of the team had read and signed the relevant SOPs to confirm they had understood them. The pharmacist said she would ask all current members of the team to read the relevant SOPs.

Prescriptions were placed in baskets as soon as they were handed in. This helped prevent transfer between people's prescriptions. Stock levels were checked, and people were informed if their medicine was not available. The dispenser or pre-registration student then dispensed the prescription before a final check was conducted by the pharmacist. The pharmacist was verbally informed of any interactions or changes to people's medicines.

There was enough workspace in the dispensary, but some workbenches were cluttered. Medicines were stored untidily on the shelves and the shelves were very dusty. Various medicines, strengths and formulations were mixed together which may increase the chance of picking errors.

Near misses were not routinely recorded; only four near-misses had been documented in January and March 2017. The pharmacist accepted that not all near-misses were captured by said that they were discussed with the team as soon as they were identified.

Dispensing errors were documented on a Community Pharmacy Patient Safety Incident Report Form. The pharmacist said an incident had occurred in a multi-compartment compliance aid, where a tablet had moved from one time-slot to another. He described how they now took extra precautions and double-checked the compliance aids. And counted the tablets as soon as they were de-blistered from their foil pack to ensure the correct amount was available to dispense. The relevant SOP had been reviewed and the incident had been discussed with the dispenser.

In date indemnity and public liability insurance was in place. The correct responsible pharmacist (RP) sign was displayed in the retail area but it was quite high and not very visible; the pharmacist said she would move the sign so that people could see the pharmacist's details on it. Samples of the RP register examined were not all in order as the time the pharmacist ceased responsibility was not recorded the majority of the time. This could make it harder for the pharmacy to show who the responsible pharmacist was if there was a query. The medicine counter assistant (MCA) and new assistant were aware of the tasks that could and couldn't be carried out in the absence of the RP.

All necessary records, including private prescription and emergency supply records, were kept. They were mostly in order, but emergency supply records did not include the nature of the emergency for a

number of supplies made. Specials records were not available to inspect but the pharmacist said that a copy of the medicine label and bag label were attached to the certificate of conformity. This enabled the team to identify what batch was supplied to which person.

Samples of controlled drug (CD) registers examined were in order. A random stock check of a CD agreed with the recorded balance. There was a large number of expired CDs in one cabinet, taking up most of the cabinet. The pharmacist was advised to contact the CD Accountable Officer to arrange for their destruction.

The complaints procedure was displayed for people to see. The pharmacist said that Community Pharmacy Patient Questionnaires (CPPQ) had not been done for some time. She described some changes that the team had made in response to verbal feedback they had received from people.

Not all current members of the team had read the confidentiality and data protection SOP and they all could not remember completing any training on the General Data Protection Regulation. Confidential waste was normally shredded at the pharmacy, but the shredder had broken the previous week. The team was collecting confidential waste in a separate bin for now whilst a new shredder was being ordered. Computers were password protected but NHS Smart cards were shared with the locum pharmacists covering on weekends. The pharmacist said she would ask locum pharmacists to obtain Smart cards. Members of the team described signposting people to a quiet corner or to the consultation room for additional privacy.

The pharmacist had completed a safeguarding module from the Centre for Pharmacy Postgraduate Education (CPPE). The pre-registration student had completed training on the subject with an external provider, but other support staff had not received any training. They could not describe signs of neglect but said they would raise concerns with the pharmacist. The pharmacist said that she would be providing training to all members of the team.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy team are under some pressure to manage their workload, but new members have been employed to help relieve some of the pressure. And they are generally managing their workload well. Team members do not always get time set aside for training or receive feedback about their performance. This may make it harder for them to keep their knowledge and skills up to date.

Inspector's evidence

There was a regular pharmacist, a dispenser, a pre-registration student, an MCA and a newly employed assistant during the inspection. Another newly employed part-time assistant also worked at the pharmacy.

Members of the team said they were able to cope with the workload but there was some pressure to complete some tasks in a timely manner, such as date checking and housekeeping. The dispenser said that she was often distracted when assembling multi-compartment compliance aids as she had to deal with walk-in prescriptions. Two new assistants had recently been employed to cover the medicines counter and staff said they would help manage the queues and deal with queries once they were sufficiently trained.

The newly employed assistant present during the inspection had been working at the pharmacy for just under one month. She had been told by one of the owners that she would be enrolled onto the medicine counter assistant course soon. She was about to sell hydrocortisone cream for a person requesting it for on their eyelids. The pharmacist had not overheard the conversation and was prompted to intervene by the inspector. She prevented the sale of the cream and recommended an alternative product to the person. The assistant had received some in-house training from the MCA. She said she would use the WWHAM questioning technique before selling pharmacy-only medicines and normally checked with the pharmacist or MCA before selling a product.

The MCA described asking the WWHAM questions and said she referred some people to the pharmacist, for example those with other medical conditions. She could name products which were liable to abuse and said she had refused to sell these to people who requested them on a regular basis.

Set study time was not provided. The dispenser said she read pharmacy magazines in her own time. The MCA said she had not completed much ongoing training since finishing the medicine counter assistant course several years ago. She said she rarely read additional material, such as leaflets or booklets.

Performance reviews were not conducted. The MCA and dispenser said that they had not discussed their performance for several years or since they started working at the pharmacy. The new assistant said that the pharmacist and MCA provided her with feedback verbally. Members of the team were happy to raise concerns with the regular pharmacist or one of the owners. The dispenser had reviewed the repeat prescription service with the previous pharmacist and had implemented changes to the system. Targets were not set for the team.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are generally suitable for the pharmacy's services.

Inspector's evidence

This was a large pharmacy. The dispensary was located at the back of the shop and was relatively small compared to the retail area. The pharmacy's fittings had not been updated for some time and some workbenches were cluttered with stock and paperwork. The cushioned bench available in the retail area was ripped.

Some shelves and products in the retail area were very dusty. This detracted somewhat from the overall appearance of the premises There was some building work being done outside the pharmacy and scaffolding had been fitted. All shop fronts in the building were being moved slightly forward.

A large consultation room was available for private conversations and services. The room was located behind the dispensary and was generally tidy. A sink, with hot and cold running water, was used for the preparation of medicines. But it was not clean. The room temperature and lighting were suitable for the provision of pharmacy services.

A storage room, office, staff room and WC were located behind the dispensary. Another room was fitted with cupboards and a workbench and was used to store assembled multi-compartment compliance aids. The premises were secure.

Principle 4 - Services ✔ Standards met

Summary findings

People with a range of needs can access the pharmacy's services. The pharmacy generally provides its services safely. But it does not always highlight prescriptions for people taking some higher risk medicines. This could mean that they might not get all the information they need to take their medicines safely. The pharmacy generally manages its medicines adequately

Inspector's evidence

Access into the pharmacy was step-free and aisles were wide enough for people with wheelchairs. Members of the team said they helped older people into the premises. Some team members were multilingual and translated for people when possible. A range of information leaflets was displayed for people. Services were listed on a poster which was displayed in the waiting area.

Dispensing audit trails were generally not maintained to help identify team members involved in dispensing and checking prescriptions, including for assembled CD instalments.

The pharmacist and pre-registration student had read the valproate guidance, but the dispenser had not been provided with any information. The pre-registration student described checks she would make with patients in the 'at-risk' group. She said she would give the information card, but this, as well as additional warning stickers, were not available to hand. The pharmacist said she would order additional supplies of these.

Members of the team said they checked INR levels of people taking warfarin but there was no system in place to flag up prescriptions for higher-risk medicines once they were dispensed. The pharmacist said she checked if a person taking lithium was being monitored but she did not routinely provide additional counselling or advice, for example, on the possible side effects and signs of toxicity.

Repeat prescriptions for multi-compartment compliance aids were requested by the pharmacist. Records of repeat requests were maintained on the PMR system. Prescriptions were screened by the pharmacist first before she generated the labels. These labels were handed over to the dispenser, alongside the individual record cards which had been set up for each person receiving compliance aids. The dispenser picked stock against the record sheets and the labels and assembled the compliance aids, without seeing the prescriptions. The pharmacist said she would review this process and provide prescriptions to the dispenser to allow for a double-check and to help reduce the chance of errors. Drug descriptions were provided, and patient information leaflets (PILs) were routinely supplied. The pharmacy had not contacted the prescriber to discuss the inclusion of valproate in the tcompiance aids for a person. One part-dispensed, unsealed compliance aid was found. The pharmacist said that a CD had been dispensed in the compliance aids but the prescriptions for this were normally received a week later as they were post-dated. She said she would review the process so that compliance aids were not left unsealed for prolonged periods of time.

There was no system in place to highlight prescriptions for schedule 3 and 4 CDs. Prescriptions for

gabapentin and zopiclone, both dated December 2018, were found still in the retrieval system.

The pharmacy did not have the system or equipment required to meet the Falsified Medicines Directive. Members of the team had not received any information as to when the pharmacy would be compliant.

Expiry date checks were conducted at irregular intervals; some sections had not been checked for one year according to the date checking record. Several packs of expired medicines were found still on the shelves and medicines with a short expiry date were not always marked. This means that it could be more likely that people were given medicines which were past their ‘use-by’ date. Some medicines removed from their foil blister were not always stored in amber medicines bottle but were sometimes put back loose in their outer carton. Medicines removed from their original pack and stored in amber medicine bottles were not always labelled with batch number and expiry date. This could make it harder for the team members to undertake date checks and respond to safety alerts. The bottles were disposed of during the inspection.

Fridge temperatures were not always checked and recorded daily and there were one week gaps between some checks. Those recorded were within the recommended range of 2 to 8 degrees Celsius, but the minimum temperature was 1.2 degrees Celsius and the maximum was 12.8 degrees Celsius at the time of inspection. The last reading recorded was on 20 May 2019 and was within the recommended range. The pharmacist said she would contact the relevant manufacturers to check if the medicines inside the fridge were still safe to supply and she would check the fridge temperature daily.

The pharmacist said that drug alerts and recalls were received via email. Audit trails of action taken in response to these alerts were not maintained. This may make it harder for the pharmacy to show that the stock is safe and fit for purpose. The pharmacist was not aware of the recent alert for co-amoxiclav powder and said she would check the MHRA's website for recent alerts.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy generally has the equipment and facilities it needs to provide its services safely. But it does not always keep its equipment as clean as it could.

Inspector's evidence

There was one glass measure and two plastic measures available. The plastic measures were used for CDs, but they had some residue inside and one was mouldy. The pharmacist said that she would order additional glass measures and dispose of the plastic ones.

The fridge was clean and suitable for the storage of medicines. Clean counting triangles were also available, including a separate one for cytotoxic medicine. This helped avoid cross-contamination. Waste medicine bins and destruction kits were used to dispose of waste medicines and CDs respectively. Members of the team had access to the internet and several reference sources.

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.