Registered pharmacy inspection report

Pharmacy Name: Midhurst Pharmacy, 92 Elthorne Park Road,

Hanwell, LONDON, W7 2JD

Pharmacy reference: 1041458

Type of pharmacy: Community

Date of inspection: 26/11/2019

Pharmacy context

This is a community pharmacy in a residential area of Ealing in West London. The pharmacy dispenses NHS and private prescriptions. It offers some services such as seasonal flu vaccinations, sells a range of over-the-counter (OTC) medicines and delivers medicines. The pharmacy also provides multi-compartment compliance aids to people if they find it difficult to manage their medicines.

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 pharmacy is not identifying and managing several risks associated with its services as failed under the relevant principles. The staff have not read and signed all of the pharmacy's standard operating procedures and they are not routinely working in line with them
		1.2	Standard not met	The pharmacy does not have a robust process in place to manage and learn from incidents. This includes complaints. The team is not always making records of incidents or investigating them appropriately and there is limited evidence of remedial activity or lessons being learnt in response
		1.6	Standard not met	The pharmacy is not maintaining records of supplies made against private prescriptions in accordance with the law. The team is using loose sheets to document records and have not maintained any records for the past month
		1.7	Standard not met	The pharmacy is not always managing and storing information appropriately to protect the privacy, dignity and confidentiality of people who receive pharmacy services. There is confidential information stored within an unlocked consultation room, a risk of access to confidential information from the way people's signatures are being obtained during the delivery service and the team is not processing confidential waste in a timely manner
2. Staff	Standards not all met	2.1	Standard not met	The pharmacy does not have enough suitably qualified and skilled staff to provide its services safely and effectively. The current staffing arrangements are insufficient to cope with the workload, routine tasks are therefore not being completed or undertaken in a timely manner
		2.4	Standard not met	The pharmacy does not have an appropriate environment for staff to learn and develop their skills. The team is not provided with or has any opportunity to complete training

Principle	Principle finding	Exception standard reference	Notable practice	Why
				resources. They do not have regular performance reviews, the pre-registration pharmacists are not being supported effectively or have set aside time to help them complete their studies
3. Premises	Standards not all met	3.5	Standard not met	The pharmacy's services are not currently being provided in an environment that is appropriate for the provision of healthcare. The dispensary is extremely cluttered, untidy and disorganized and the pharmacy's workspaces are not kept clear enough to work safely on
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy's services are not always being managed and delivered safely and effectively. The team is significantly behind with the workload, people are being left without their medicines, the pharmacy is not always maintaining effective audit trails about its services, people are reporting that medicines are being left unattended outside their home and this includes controlled drugs. There are date-expired dispensed prescriptions for controlled drugs that have not been removed and patient information leaflets are not routinely being supplied when people receive multi-compartment compliance aids
		4.4	Standard not met	The pharmacy is not making the appropriate checks in response to drug safety alerts. This means that they could supply medicines or medical devices that are not fit for purpose
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy doesn't effectively identify and manage the risks associated with its services. It's working environment is unsafe. The pharmacy has written instructions to help manage risks. But members of the pharmacy team are not always working in line with them and they haven't read or signed all of them. This means that they are unclear on the pharmacy's current processes. Pharmacy team members were previously dealing with their mistakes responsibly. But, they are not always formally reviewing them, recording all the details now or formally acknowledging complaints. This could mean that they may be missing opportunities to learn and prevent similar mistakes happening in future. The pharmacy is not adequately maintaining all of its records, in accordance with the law. This means that team members may not have all the information they need if problems or queries arise.

Inspector's evidence

This pharmacy was inspected earlier in the year. At that time, it was meeting the standards set by the General Pharmaceutical Council (GPhC) with some areas of good practice highlighted. However, on attending the pharmacy to investigate a concern that had been raised about the pharmacy's services, the pharmacy was clearly not operating safely. There was not enough staff present to manage the workload effectively (see Principle 2). The dispensary was extremely cluttered and disorganised, the workflow was chaotic, the team was behind with the workload and had been unable to complete routine tasks. Another inspection was therefore carried out.

Medicines were stored haphazardly in the dispensary and every workspace was taken up with stacked baskets of prescriptions that had either been labelled and required dispensing or paperwork, prescriptions and multi-compartment compliance aids that required stock or a final accuracy-check. Consequently, there was no free space available to dispense prescriptions. During the inspection staff were having to look in several different areas to locate people's prescriptions. People's prescriptions were not ready on time for them to collect. This included compliance aids and some people were asked to come back to allow the responsible pharmacist (RP) enough time to accuracy-check them. The inspector was told that the team was a week behind with the workload. However, there were prescriptions dated from the start of the month that had been processed, left in baskets and may have been awaiting stock but had not been assembled. There was no indication that any checks had been made about the availability of the stock.

A few near misses had been recorded in the last few months. The RP stated that they were discussed at the time. However, there was no evidence that they had been formally reviewed, any trends or patterns identified, or that any remedial activity had taken place in response. The RP admitted that the review process had not been taking place because the team was so behind with the workload.

There was information on display about the pharmacy's complaints procedure and the pharmacy did have a documented complaints procedure. However, a recent complaint made to the GPhC had not been handled in line with this. The RP handled incidents and her process usually involved apologising and responding to the person. According to the RP, the owner was informed about serious complaints or incidents. However, the owner who was also the superintendent had not been informed by the RP about the recent complaint made to the GPhC and there had been no formal acknowledgement or a response to the incident that had taken place in line with the pharmacy's standard operating procedure (SOP). The RP had spoken to them but had not had the time to formally respond. There was also no incident report completed about this situation. Previous reports seen were from August 2019. The inspector was told that the pharmacy had been receiving a high number of complaints about people's prescriptions not being ready on time and about the stock issues. There was no evidence that this had been documented, reviewed and remedial activity undertaken. There was no sign or details in the retail area to inform people about the delays.

There were two folders present that contained a range of documented SOPs to support the services provided. They were prepared in April 2019 but not all the staff had signed them to indicate that they had read them and only some of the SOPs had been signed by the pre-registration pharmacists. One folder and SOPs stored here had not been signed by any of the team members. The trained counter assistant understood her role and responsibilities relating to this role, she was still in the early stages of learning about the dispensary's processes. She knew when to refer to the RP and which activities were permissible in the absence of the RP. The correct RP notice was on display and this provided people with details of the pharmacist in charge of operational activities on the day.

Dispensed prescriptions awaiting collection were stored in a location that prevented sensitive information being visible from the retail area. There was information on display to inform people about how their privacy was maintained, and a shredder was present to dispose of confidential waste. However, there was a mound of confidential waste accumulating in the dispensary that had not been disposed of. This was knocked over during the inspection and staff explained that they had not had the time to process this. There was also sensitive information present in the consultation room (see Principle 3).

Some of the pharmacy's records relating to its services were seen but only a few were fully compliant with statutory requirements. This included a sample of registers seen for controlled drugs (CDs) and a section of the RP record. On randomly selecting CDs held in the cabinet, their quantities matched the balances that were recorded in the corresponding registers. Staff kept a complete record of CDs that had been returned by people and destroyed at the pharmacy. The pharmacy's professional indemnity insurance arrangements were through the National Pharmacy Association and due for renewal after 31 January 2020.

However, there were details seen to be missing from the records of unlicensed medicines and issues with the way in which records of private prescriptions were being maintained. The RP stated that she had been told by the pharmacy's head office to record details about private prescriptions on a proforma that was sent by them and printed off at the pharmacy, but this consisted of loose pieces of paper that were then stapled together. The documented records were therefore not being held within a bound register and there was a risk that the loose sheets could become lost or records inadvertently inserted. This method also made it impossible to verify whether the records were being made on the day that the supply took place or the following day, in line with the law. Furthermore, no records for private prescriptions had been made in the month of November. This was again described as due to staff being behind with the workload. After discussing this with the superintendent pharmacist following the inspection, he stated that this was not the company's policy and no such advice would have been given to the pharmacy.

Principle 2 - Staffing Standards not all met

Summary findings

The pharmacy does not have enough staff to manage the workload safely. Its current staffing levels means that the team is struggling with the workload. As a result, members of the pharmacy team are under considerable pressure and are unable to keep up to date with routine tasks. This situation is unsafe. The pharmacy does not provide an effective learning environment for the team. Once team members have completed basic training, the pharmacy does not provide them with any resources to help keep their knowledge and skills up to date. And, they do not always have regular performance reviews. This could mean that gaps in their skills and knowledge are not identified and supported.

Inspector's evidence

The inspection took place at lunchtime and the only staff present to manage the workload were the regular locum pharmacist and a trained medicines counter assistant (MCA). A pre-registration pharmacist arrived about an hour into the inspection. There was one other pre-registration pharmacist who worked alternate shifts at the pharmacy alongside the former. Both pre-registration pharmacists spent half their time at a GP practice and worked half days at the pharmacy.

The MCA stated that as of this week, she was due to start training for dispensing activities and had been asked to increase her hours. The regular dispenser had recently left, and the inspector was told that over the years, dispensing staff had left and had not been replaced and that the pharmacy was currently advertising for a part-time MCA but had not had many enquiries. There were no contingency arrangements in place for staff absence. The RP stated that when the dispensing assistant had resigned, she had called the pharmacy's head office to ask if they were going to replace them with a full-time dispenser. She was told that they would and that she should start advertising for the position. The RP did not however, get around to doing this although when the owner and area manager arrived the week before the inspection, the RP was then advised that they would only be recruiting for someone to cover the counter part-time.

There was little evidence that the pre-registration pharmacists were being supported effectively by the pharmacy. The inspector was told that from the start of their employment, the pharmacy had been behind with the workload, the pre-registration pharmacist stated that she had not been provided with a formal training plan, there was no set-aside time for study and she had not had the opportunity to learn or study because of the pharmacy's workload. The pre-registration pharmacist's tutor at the pharmacy was the locum pharmacist who was present at the time, but she stated that she was going to resign. They also had another tutor based at the surgery who conducted their 13-week review. According to the pre-registration pharmacist, this was a collaboration between both tutors, but the inspector was told that there had not been much feedback or effective learning delivered from the pharmacy's side.

The team was clearly struggling to effectively manage the workload. There were large queues seen during the inspection because people's prescriptions could not be easily located as they either hadn't been ordered, received or assembled in time. When the MCA was on her break, people in the queue were not being acknowledged or served quickly as the RP and pre-registration pharmacist were both spending a considerable amount of time trying to look for prescriptions or deal with queries for the people at the front of the queue or on the telephone. There were people observed asking for their prescriptions that had been ordered ten days before.

Staff stated that they usually liked working at the pharmacy because it was convenient for them. However, it had now become stressful for the team and it had been this way for the past few months. Staff explained that the pharmacy's situation had begun to deteriorate from the end of August 2019 onwards and had steadily become worse.

The MCA was knowledgeable about over-the-counter (OTC) medicines and knew when to refer appropriately. She had worked at the pharmacy for the past three years, but once the accredited training for this role had been completed, the MCA described only undertaken some training at the pharmacy's head office about selling Viagra OTC and completed online training about oral health. Team members had not been provided with any ongoing training materials or resources to help keep their knowledge up to date. The MCA's progress had been checked recently with regards to the change in her role, however, other than this, the inspector was told that staff had not had any other performance reviews.

Both the superintendent pharmacist and area manager were called when the inspector first arrived to inform them of the unacceptable situation and that they needed more staff to effectively run the pharmacy. However, neither one returned the telephone call or provided an update before the inspection report was compiled. The inspector was told by the team that it was normal for them not to be able to speak to either one easily, staff did not feel supported by them or by the pharmacy's head office. The RP stated that the area manager had been informed verbally that the pharmacy was struggling without enough staff and the owner had seen the situation the week before.

The inspector spoke to the superintendent pharmacist and area manager after the draft report had been released. They both stated that the pharmacy had been appropriately staffed by a pharmacist, an MCA and a dispensing assistant up until very recently. They had been advertising for a dispensing assistant since August 2019. Neither one picked up voicemail messages, there were training plans in place for the pre-registration pharmacists and the latter had not raised any concerns with them directly about the situation. Evidence was seen about the training plans and the advertsiement for a dispenser.

Overall, the pharmacy is significantly behind with its workload. At the point of inspection, there was not enough staff present to manage or cope with the workload and the pharmacy did not have any contingency arrangements in place. This had already had an impact on the safety of people using the pharmacy's services. People had been left without their medicines for days which has resulted in a complaint made to the GPhC. People's confidence in the pharmacy's ability to safely provide its services has been affected and in order for the pharmacy to continue to operate, this requires addressing.

Principle 3 - Premises Standards not all met

Summary findings

In general, the pharmacy's premises are appropriate to deliver healthcare services. But, the premises are not being maintained in a safe manner. The pharmacy's workspaces are extremely untidy. This increases the risk of mistakes happening. And, people's private information is not kept as secure as it should be.

Inspector's evidence

The pharmacy premises consisted of a small to medium sized retail space, a similar sized dispensary was behind this with a small area at the very rear that was used to store compliance aids. The latter was also the staff kitchenette. Staff WC facilities were clean. The pharmacy was bright with plenty of natural light in the retail space, it was appropriately ventilated and generally clean overall. The retail area was professional in appearance, the floor needed cleaning, but it had been raining. Pharmacy (P) medicines were stored behind the front pharmacy counter. The pharmacy had a plastic chain that could be pulled across the entrance into the dispensary. This acted act as a barrier and restricted unauthorised access into this area. However, the dispensary was disorganised, and every workspace was extremely cluttered as described under Principle 1.

A signposted consultation room for private conversations and services was present on one side of the counter. The room was of an adequate size for its intended purpose. The entrance consisted of a sliding door and although it was usually kept closed, it was unlocked. The room contained several folders with the pharmacy's paperwork such as its SOPs. However, there was also confidential information present. This included people's details, risk assessments and consent forms when they had been administered with an influenza vaccine from the pharmacy. In addition, a member of staff's password for their NHS smart card was written in bold and highlighted on an A4 piece of paper in a folder that was stored here. This information should not have been shared as per the terms of agreement for use of their smart cards. This was brought to the attention of the RP at the time.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy obtains its medicines from reputable sources. But, it doesn't always provide its services, prepare or store its medicines in a safe and effective way. The pharmacy delivers prescription medicines to people's homes. But it keeps only limited records of its deliveries and those are disorganised. This means that team members may not have all the information they need in the event of future queries. And, people can see other people's private information when they sign to receive their medicines. The pharmacy is not always taking the appropriate action in response to safety alerts. This means that people could receive medicines and devices that are not safe to use.

Inspector's evidence

Entry into the pharmacy was through an automatic door with a ramp from the street. There were some leaflets on display and two seats available for people waiting for prescriptions. The pharmacy supplied compliance aids to approximately 70 people in their own homes. They were initiated once the GP authorised this. The MCA had started to assemble them but was still learning about the process. Prescriptions were ordered by the pharmacy and when received, staff stated that details were cross-referenced against people's records on the system to help identify any changes or missing items. Queries were checked with the prescriber. However, the current staff members were not making any records about this as they were unaware that they should be. There were several incomplete compliance aids stored in the back section awaiting stock. They had been sealed. Staff ensured that all medicines were de-blistered into the compliance aids with none left within their outer packaging. Descriptions of the medicines inside the compliance aids were provided but patient information leaflets (PILs) were not routinely supplied. This is a legal requirement and means that people may not have all the information they need to take their medicines safely. Mid-cycle changes involved either compliance aids being retrieved, amended, re-checked and re-supplied or new compliance aids were provided.

Baskets were used during the dispensing process to hold prescriptions and medicines. This helped to prevent the inadvertent transfer of items. A dispensing audit trail was used to identify the staff involved. This was through a facility on generated labels. Dispensed prescriptions awaiting collection were stored within an alphabetical retrieval system. However, several prescriptions for CDs (Schedules 2 to 4) were seen that had not been identified, staff could not recognise them or did not know that they held a 28-day prescription expiry. The inspector was told by staff that all prescriptions were valid for six months. The team had not removed uncollected prescriptions for some time and dispensed prescriptions were present here from June 2019. In addition, there were date-expired prescriptions for CDs present (for example, gabapentin, dated 10 October 2019 and diazepam dated 28 June 2019) that had not been removed, staff were unaware that they could no longer be handed out until the inspector pointed this out to them. Prescriptions for higher-risk medicines were also not being routinely identified. On checking the pharmacy's records, there was no indication that relevant checks were being made with people about blood test results or details seen recorded to help verify that this was happening.

The pharmacy delivered medicines via a designated and employed driver. The pharmacy had been keeping some records to verify this although the records were stored and maintained in a haphazard manner. Most of the records seen had no date on them to indicate when medicines had been delivered. The inspector was also unable to verify when deliveries had been made previously for some people as

these records could not be located. The pharmacy's audit trail for this service held a facility to obtain people's signatures once they were in receipt. However, people's signatures were not routinely being obtained as the driver often wrote 'delivered' when this had taken place. There was also a risk of unauthorised access to confidential information when people signed to receive their medicines. This was from the way people's details were laid out. The RP stated that failed deliveries were brought back to the pharmacy with notes left to inform people about the attempt made unless permission had been obtained previously to leave them in a safe place (such as a key safe). However, the GPhC had received a concern that medicines, including a CD had been left unattended outside someone's front door. There was a risk that the medicines could have been diverted or picked up by children who lived in the same area. The RP was unaware of this situation.

The pharmacy ordered people's repeat prescriptions from people's GP surgeries on their behalf. There were audit trails in place for when orders had been placed for most of the surgeries although one required an email about the request. This served as the pharmacy's audit trail. However, there had been an incident where staff had forgotten to order repeat medicines, this led to a delay in receiving the prescription and supply which had left them without their medicine. The RP stated that when it had been brought to her attention, she had only identified the error when the email system was checked.

The pharmacy used licensed wholesalers such as Phoenix, Colorama, Alliance Healthcare, Sigma and AAH to obtain medicines and medical devices. Staff were unaware of and held no knowledge about the European Falsified Medicines Directive (FMD). The pharmacy was not set up to comply with the decommissioning process, according to the team, it was not registered with SecurMed, there was no equipment present to help comply with this process and no guidance information available for the team. Staff described medicines being date-checked for expiry every month and some records were seen to verify that this process had been carried out. There were warning cards available to supply to people if they had been prescribed valproates. Some loose blisters were seen on shelves and stockholding was disorganised. 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.

Medicines returned for disposal, were accepted by staff and stored within designated containers. Although there was a list available for the team to identify hazardous and cytotoxic medicines requiring disposal, there were no designated containers to store them. There was also a large amount of returned medicines stored in the back section that had not been processed or stored appropriately because of the lack of staff available to complete this task.

The RP explained that her usual process for dealing with drug alerts was to print them once they had been received by email, stock was checked, and action taken as necessary. However, the RP admitted that this process had not been taking place. There were several unopened emails seen on the pharmacy system from the Medicines and Healthcare products Regulatory Agency (MHRA) about recalled medicines. They had not been checked or processed. Staff had little knowledge about this process and described seeing and reading one recall over the past few months. The last printed drug alert seen with information recorded about any action taken was from the 5 November 2019.

Principle 5 - Equipment and facilities Standards met

Summary findings

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

Inspector's evidence

The pharmacy held the necessary equipment for it to operate appropriately. This included current versions of reference sources, a range of standardised conical measure for liquid medicines and the dispensary sink that was used to reconstitute medicines. There was hot and cold running water with hand wash available. The equipment and facilities seen were relatively clean. The fridge used for medicines requiring cold storage appeared to be operating at appropriate temperatures although it was packed with stock. The computer terminal was positioned in a manner that prevented unauthorised access. Cordless phones were available to maintain people's privacy. The RP was using her own NHS smart card to access electronic prescriptions and a shredder was available to dispose of confidential waste.

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.