General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: County Pharmacy, 13-15 Church Road, REDDITCH, Worcestershire, B97 4AB

Pharmacy reference: 1124405

Type of pharmacy: Community

Date of inspection: 24/06/2019

Pharmacy context

This is a community pharmacy situated close to a few local GP surgeries within the centre of Redditch in Worcestershire. A range of people use the pharmacy's services. The pharmacy dispenses NHS and private prescriptions. It provides Medicines Use Reviews (MURs), the New Medicine Service (NMS) and administers travel vaccinations. It also 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 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 has not identified or managed several risks associated with its services. The team is not recording or reviewing mistakes that occur during the dispensing process, there is little evidence of remedial activity or learning occurring in response to incidents and there is no information on display about the pharmacy's complaints process. Pharmacy staff are not trained on recent developments in data protection laws and team members are not trained on safeguarding the welfare of vulnerable people. People prescribed higher risk medicines are not identified, they are not counselled, relevant parameters are not checked or details documented. The pharmacy is storing multi-compartment compliance aids unsealed overnight and on the floor, a documented owing system is not being used, queries are managed in a haphazard way and prescriptions for medicines that should be kept more secure are being taken out on delivery. The pharmacy had no valid indemnity insurance in place at the time of inspection although this has subsequently been implemented.
		1.6	Standard not met	The pharmacy's records are not always maintained in line with legal requirements and the team has been unable to demonstrate that private prescriptions are retained for the required period.
2. Staff	Standards not all met	2.2	Standard not met	Not all of the staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out. The pharmacy has not provided enough reassurance that the GPhC's minimum training requirements for the team are met and members of the pharmacy team are undertaking tasks without being enrolled on accredited training appropriate for this.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including	Standards not all	4.3	Standard not met	There is insufficient surety that stock is stored and managed appropriately. There are mixed

Principle	Principle finding	Exception standard reference	Notable practice	Why
medicines management	met			batches, loose blisters, poorly labelled containers, access to some medicines that need to be kept more secure, evidence that patient returned medicines are stored close to dispensary stock and verifiable processes to routinely identify as well as remove date-expired medicines are lacking.
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 always effectively manage risks associated with its services. It has written instructions to help with this. But members of the pharmacy team are unable to show that they have read them. This could mean that they are unclear on the pharmacy's current processes. Pharmacy team members deal with their mistakes responsibly. But, they are not always recording or formally reviewing them. This could mean that they may be missing opportunities to spot patterns and prevent similar mistakes happening in future. Team members know to protect people's private information, but they have not been trained on recent updates in the law. And, not all the pharmacy's team members understand how to protect the welfare of vulnerable people. So, they may not know how to respond to concerns appropriately. The pharmacy is not 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

The dispensary was spacious but cluttered (see Principle 4). Staff explained that one member of staff generated labels, another assembled, there were separate areas for the responsible pharmacist (RP) to carry out the final check and for staff to dispense prescriptions. The team described checking relevant details when dispensing, this included checking the expiry date on medicines.

There was no evidence at the inspection that staff were routinely recording their near misses. There was one near miss recorded in June 2019 and before then, from 2018. Staff could not locate any other details. There was also no evidence available that errors were being reviewed and no details about the action taken in response to these. Staff were unable to provide examples of trends, patterns or remedial activity taken in response to near misses to help prevent mistakes occurring.

There was no information on display about the pharmacy's complaints procedure. The pharmacist owner confirmed that this had been implemented following the inspection. Pharmacists handled incidents. The RP's process was described as checking relevant details, informing the person's GP if anything was taken incorrectly, recording details and reporting them to the superintendent pharmacist as well as to the National Reporting and Learning System (NRLS).

There were documented standard operating procedures (SOPs) present on site. They were dated from 2018, team member's roles and responsibilities were defined with them but only two members of staff (one was the superintendent, and one other, who no longer worked at the pharmacy) had signed to state that they had been read. Staff present stated that they were in the process of reading through SOPs, they could access them electronically and a sign off sheet was present. This could not be located or brought up at the inspection to verify. Electronic details of SOPs were seen.

Staff were not trained to identify signs of concern to safeguard vulnerable people, this included the trained members of the team. Only one member of staff who was in the process of enrolling onto accredited training, could demonstrate understanding of this and stated that she had read the pharmacy's SOP. The locum pharmacist was trained to level 2 via the Centre for Pharmacy Postgraduate Education (CPPE). There were no local contact details for the safeguarding agencies seen or local policy information.

Sensitive details on bagged prescriptions awaiting collection could not be seen from the retail space, confidential waste was shredded and there was information on display to inform people about how their privacy was maintained. The inspector was told that staff had not received any training on the EU General Data Protection Regulation (GDPR). The RP, on previous occasions had accessed Summary Care Records for emergency supplies and verbal consent was obtained.

The superintendent pharmacist had left his NHS Smartcard in the computer terminal. As soon as this was highlighted, the RP used his own and staff maintained that they did not know the superintendent pharmacist's password. The correct RP notice was on display and this provided details of the pharmacist in charge, on the day.

Some records up until 21 June 2019 for the minimum and maximum temperature of the pharmacy fridge were seen (see principle 5). A complete record of the destruction of CDs that were received from the public was maintained.

Most records of emergency supplies were recorded with the nature of the emergency and the RP record was complete, but this consisted of loose pieces of paper. This meant that there was a risk that records could be lost or inserted inadvertently.

A sample of registers for controlled drugs (CD) were checked. There were several missed entries seen in some registers and incorrect details recorded where amendments did not include the full details. Balances for CDs were seen documented frequently for most CDs. On checking a random selection of CDs, their quantities matched balance entries in the register.

Prescriber details were missing from records of unlicensed medicines and from several electronic records of private prescriptions. The team could not locate the private prescriptions so that relevant checks could be made.

There was no evidence at the inspection that the pharmacy held appropriate professional indemnity insurance. The superintendent was asked to provide this to the inspector and details were subsequently received from one of the owners. The indemnity insurance certificate was issued from the National Pharmacy Association (NPA) and was dated for the day after the inspection, 25 June 2019.

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

Summary findings

Members of the team are carrying out tasks that they are not trained for or qualified in. This situation brings risks. It can affect how well the pharmacy cares for people and the advice that it gives. And, the team do not have regular performance reviews. This could mean that gaps in their skills and knowledge are not identified. But otherwise, the pharmacy has enough staff to manage the workload.

Inspector's evidence

The pharmacy dispensed 14,000 to 15,000 prescription items every month with around 20 people receiving their medicines through instalment prescriptions and 80 to 90 people supplied multi-compartment compliance aids.

Staff present included a locum pharmacist, two dispensing assistants who stated that they had completed accredited training with Buttercups, a trainee dispensing assistant who stated that she was enrolled onto accredited training with Buttercups but was waiting to be allocated a supervisor, a medicines counter assistant (MCA) who confirmed that she was not enrolled on any accredited training at the point of inspection and a member of staff who trained as a pharmacist in India.

The latter had been in continuous employment by the pharmacy since November 2018, although she described taking a break to return to India and had recently returned. This member of staff stated that her qualifications were the equivalent of an NVQ 7; she was not enrolled on an overseas pharmacist assessment programme and the GPhC's minimum training requirements were discussed at the time. The MCA had also been employed at the pharmacy for a year and a half, she described only undertaking training and instruction from the superintendent pharmacist.

The latter two staff members roles and tasks were not in line with the GPhC's minimum training requirements. Any assistant given delegated authority to carry out certain activities should have undertaken, or be undertaking an accredited course relevant to their duties within three months of commencing their role. Certificates for staff qualifications obtained and evidence of enrolment for the trainee dispensing assistant were not seen.

In the absence of the RP, the MCA knew which activities were permissible and knew to ask relevant questions before selling medicines over the counter (OTC). She referred to the RP when unsure or when required and demonstrated some knowledge of OTC medicines. The MCA was the longest serving member of the team as the remaining staff had commenced their employment either last year or within the last few months. She explained that no appraisal to check her progress had occurred.

In addition to the Essential Services, MURs and the NMS, the pharmacy provided vaccinations for travelling against Patient Group Directions (PGDs). The RP was not accredited to provide the latter. The pharmacist stated that there were no formal targets in place to achieve services.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are suitable to ensure the effective delivery of its services. But, the consultation room is kept in a way that detracts from the professional use of the space. And, the team is storing sharps bins here. This increases the chance of them being accessed by unauthorised people.

Inspector's evidence

The premises consisted of a medium sized and spacious, retail area and dispensary. There was also a hallway to one side where medicines awaiting delivery were stored, staff kitchenette facilities, a room that was kept locked in the retail space, where medicines returned by the public were stored as well as two signposted consultation rooms to one side of the retail area. Both rooms were unlocked, one room was used to provide services and confidential information, however this was cluttered, looked unprofessional as there were random boxes in here and a sharps bin was present on the floor. When this was highlighted to the RP, this was sealed and placed on the table.

The retail space was very professional in appearance, fixtures and fittings were modern, the pharmacy was clean, bright and suitably ventilated. There was enough space in the dispensary for the pharmacy’s current volume of workload, but it was cluttered (see Principle 4 and the management of stock).

Most pharmacy (P) medicines were stored behind the front counter and staff were normally within the vicinity. However, at the very two ends where the counter did not extend far enough, P medicines were accessible, as there was no barrier here and staff stated that people did help themselves.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy does not always provide its services in a safe and effective way. 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. The pharmacy team sometimes fills multi-compartment compliance aids then leaves them unsealed overnight while waiting for them to be checked. This means the medicines are not very well protected and could be damaged or contaminated. It may also increase the risk of mistakes happening. The pharmacy sources its medicines from reputable suppliers. 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, some of its medicines are held 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.

Inspector's evidence

The pharmacy was open for 100 hours every week. People could enter the pharmacy by steps as well as by a ramp and the clear, open space inside the retail area helped people using wheelchairs to easily access the pharmacy’s services. There were three seats available for people waiting for prescriptions and some car parking spaces available outside the premises. Staff verbally communicated information to people who were visually impaired, they used written communication and gestures to assist people who were partially deaf or if their first language was not English.

The person’s GP and pharmacists assessed suitability for initiating multi-compartment compliance aids. Staff ordered prescriptions on behalf of people receiving compliance aids and when these were received, they checked details against records on the system and on individual records to help identify changes or missing items. Queries were checked with the prescriber and audit trails were maintained to verify this. Descriptions of medicines within compliance aids were provided. Patient information leaflets (PILs) were routinely supplied. All medicines included in compliance aids were de-blistered and removed from their outer packaging. Mid-cycle changes involved compliance aids being retrieved, amended, re-checked and re-supplied.

Compliance aids were left unsealed overnight, several were seen left from the weekend before and there were also four compliance aids, left unsealed, on the floor in a small, cluttered corridor in one section of the dispensary. The date of dispensing on these was from 12 June 2019. Staff could not explain why they were left on the floor in a corner when the rest were on one section of the dispensing bench.

Medicines were delivered. The delivery driver was briefly seen, he came in with a bundle of prescriptions in his hand which included prescriptions for CDs. These were taken out on delivery by him to obtain signatures from people. There were no records to demonstrate that he had read and signed the relevant SOP. The team explained that records were maintained to demonstrate when and where medicines were delivered. These were not seen as the driver kept this with him and staff were looking into retaining an audit trail at the pharmacy. The driver obtained signatures from people when they were in receipt of their medicines. Failed deliveries were brought back to the pharmacy and notes were left to inform people of the attempt made to deliver.

There were some random, generated labels with people's details stuck on the dispensing bench where the RP checked prescriptions, the team could not provide an appropriate explanation as to why they were present here. The RP thought that they were queries associated with the delivery of medicines for these people. This was not an appropriate method to use for queries and was discussed at the time.

The team used a dispensing audit trail through a facility on generated labels. This identified their involvement in processes. Staff used baskets to hold prescriptions and associated medicines and this helped prevent any inadvertent transfer. Baskets were colour co-ordinated to help highlight priority.

The pharmacy was not using an appropriate method to identify owed medicines at the point of inspection. Generated labels for the full item were seen stapled to prescriptions in the retrieval system. If the generated labels became detached or were lost, then there was no other record of owed medicines present.

Staff were aware of risks associated with valproate. The team at the inspection were unsure if an audit had been completed to identify patients at risk. They stated that they had not seen any prescriptions for this medicine. There was no literature seen to be able to provide to people if required.

Prescriptions for higher risk medicines were not marked in any way to counsel or to ask people about relevant parameters. This included asking about the International Normalised Ratio (INR) level, for people prescribed warfarin. Some people's records were checked and there were no details seen documented about this. This included people receiving multi-compartment compliance aids.

Dispensed prescriptions awaiting collection were held in an alphabetical retrieval system. Fridge items and CDs (schedules 2) were stored with labels attached so that these could be assembled when people arrived to collect. Uncollected prescriptions were removed every three months and schedule 4 CDs were not routinely identified. Trained staff could not recognise some of these or their 28 day prescription expiry. Furthermore, some bulky dispensed prescriptions were stored on the floor, those that were awaiting to be delivered were stored in a hallway, some were in crates and others were stored on the floor haphazardly. They were placed into crates at the end of the inspection but this was still in a disorganised way.

The pharmacy obtained its medicines and medical devices from licensed wholesalers such as Lexon, AAH, Colorama and Alliance Healthcare. Unlicensed medicines were obtained from the latter two wholesalers.

Staff were unaware of the process involved for the European Falsified Medicines Directive (FMD). It was unclear whether the pharmacy was registered with SecurMed. This was not yet connected at the point of inspection to enable compliance with the process. There was no guidance information present for the team.

Some medicines were stored in a haphazard manner in the dispensary, this included medicines on shelves but there were also medicines and dressings stored on the floor, odd loose blisters seen on dispensary shelves, several poorly labelled containers with the expiry date of the medicine and/or the batch number missing, mixed batches seen and baskets that were piled high with random medicines and placed on top of the fridge.

There were also crates of random medicines stored on the floor in one corner behind the central unit and this contained patient returned medicines from another pharmacy. It was unclear why this was

mixed in with the pharmacy’s stock although staff were adamant that they did not re-use returned medicines and said they were always placed and processed in the separate room. Some staff stated that students on work experience were responsible for the loose blisters, another member of staff stated that the random baskets contained stock that needed putting away. These also contained split medicines.

Short-dated medicines were identified using stickers and some members of the team described date-checking some sections of medicines recently. However, there was no up-to-date schedule in place to demonstrate this. The last details seen recorded in the schedule was from 2018 but a list of medicines approaching expiry from 2019 was seen. In general, CDs were stored under safe custody. Keys to the cabinet were maintained in a manner that prevented unauthorised access during the day and overnight.

A specific locked room was used to store medicines returned by people for disposal. Most of them (except for the ones seen in the dispensary) were held within appropriate containers prior to collection. The MCA knew that cytotoxic and hazardous medicines should be placed inside a bin with a purple lid but could not identify them and did not know that a list was available to assist her with this. The list was seen in the dispensary by the sink. Sharps brought back for disposal, were accepted provided they were in sealed bins. Returned CDs were brought to the attention of the RP.

When members of the pharmacy team were first asked about drug alerts, they were unable to explain what these were, how they were received, or the action taken in response. This included trained members of the team. Upon, the inspector's return to the pharmacy to attempt to speak to the superintendent pharmacist, one trained member of staff said that she did know what these were, she was nervous when first asked, and that she had checked for affected stock in her previous employment. The RP thought that drug alerts were received by email and this was subsequently confirmed by one of the pharmacist owners. This could not be verified as other than the superintendent, no other member of staff had access to the email system and there was no audit trail seen at the inspection to verify the process.

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 and relevant equipment. This included counting triangles, a separate one for cytotoxic medicines, CD cabinets were secured in line with legal requirements and a clean sink that was used to reconstitute medicines. Hot and cold running water was available.

Computer terminals were positioned in a manner that prevented unauthorised access, a shredder was present to dispose of confidential waste and cordless phones were available to enable sensitive conversations to occur away from the retail space if needed.

There were some crown-stamped conical measures available for liquid medicines but there were also three plastic ones being used. This meant that the team could not guarantee that accurate amounts of liquids were being measured. A medical fridge was present but the function to check the minimum and maximum temperature was not working at the inspection. The RP had switched the fridge on and off in the morning but this had not resolved the situation. It was therefore not possible to determine that medicines were being stored appropriately in here on the day of the inspection.

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.