General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Lalys Pharmacy, 1 Guildhall Walk, PORTSMOUTH, PO1 2RY

Pharmacy reference: 1116129

Type of pharmacy: Community

Date of inspection: 14/06/2019

Pharmacy context

This pharmacy is in Portsmouth city centre and is one of several pharmacies owned by the same local company. It dispenses NHS and private prescriptions, sells a range of over-the-counter medicines and provides health advice. The pharmacy provides substance misuse services and a travel health service. It also dispenses some medicines in multi-compartment compliance aids (MDS trays or blister packs) for those who may have difficulty managing their medicines.

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	1.1	Good practice	There is evidence of learning from things that have gone wrong and that arrangements are in place to make sure that learning is shared with the whole pharmacy team. There is also evidence of shared learning from other pharmacies within their company.
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	4.2	Good practice	MDS blister packs are assembled off-site using a robot, providing photos of each item supplied. The photos help patients and/or their carers to easily identify each individual tablet or capsule in the blister packs. The pharmacy works together with the local concordance team to ensure that this service continues to meet the needs of local people.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

Members of the pharmacy team are clear about their roles and responsibilities. They work to professional standards, identifying and managing most risks effectively. The pharmacy logs the mistakes it makes during the dispensing process. The pharmacist regularly reviews them with the team so that they can all learn from them and avoid problems being repeated. The team also attends meetings with their other local pharmacy teams to share best practice and to learn from each other. The pharmacy generally keeps the records that it needs to by law, but it has missed a few details. This could make it more difficult for the team to resolve any queries which may arise in the future. The pharmacy has up-to-date written instructions which tell staff how to complete tasks safely. The pharmacy manages and protects confidential information well, and team members also understand how they can help to protect the welfare of vulnerable people. The pharmacy has adequate insurance in place to help protect people if things do go wrong.

Inspector's evidence

There were Standard Operating Procedures (SOPs) in place to underpin all professional standards, last reviewed April and May 2018, signed by all staff, and due for next review in 2020. They were all neatly stored in a well-organised file. The ACT explained how they had a lead pharmacist at one of their other branches who was responsible for reviewing their SOPs and keeping them up to date.

Near misses were recorded using a paper form, showing what the error was, the members of staff involved and the action taken. The Accuracy Checking Technician (ACT) explained how they would ask the individual involved if they could spot their error, and then discuss ways of avoiding it being repeated in future. The pharmacist would hold a meeting every couple of months to reflect upon the near misses and errors with the team. As a result of this they had identified some items that were more likely to be mis-picked, such as ‘Look Alike Sound Alike’ medicines (LASAs) which they had highlighted with a sticker on the shelf, and others such as Tegretol and Tegretol Retard tablets, which they had separated from each other on the shelf. The pharmacist also explained how they take care to follow their SOPs and check everything very carefully to minimise the risk of errors occurring. Errors which did reach patients were recorded and reflected upon in the same way as near misses, and then also recorded on the National Reporting and Learning System (NRLS) with a copy printed and filed. Staff attended meetings with all staff from their other local branches every six months to discuss current issues and to share best practice.

Roles and responsibilities of staff were documented in the SOPs, which included a pharmacy task matrix and a list of staff roles complete with named individuals. Those questioned were able to clearly explain what they do, what they were responsible for and when they might seek help. They outlined their roles within the pharmacy and where responsibility lay for different activities.

Staff were able to describe what action they would take in the absence of the responsible pharmacist, and they explained what they could and could not do. The responsible pharmacist (RP) notice was clearly displayed for patients to see and the RP log on the computer was complete.Results of the latest Community Pharmacy Patient Questionnaire (CPPQ) were displayed in a notice by the counter for people to see, showing that 99% of respondents rated the pharmacy overall as either excellent or very good. The complaints procedure was available in the pharmacy practice leaflets, which were also on display for people to see.

A certificate of professional indemnity and public liability insurance from the National Pharmacy Association (NPA) valid until Dec 2019 was on display behind the medicines counter. Private prescription records were maintained on the PMR and many were found to be missing the necessary prescriber details.

There were no separate emergency supply records as the pharmacy offers the 111 NUMSAS (National Urgent Medication and Advice Service) and the records were kept on PharmOutcomes. The record on the PMR confirmed that the entry was for a NUMSAS supply, and upon reflection the pharmacist agreed to add the NUMSAS reference number to the reason for supply. The PMR record could then be easily cross-referenced against the detailed NUMSAS record on PharmOutcomes.

The electronic controlled drug (CD) register was seen to be correctly maintained, and each entry was initialled to show who had either booked a delivery in or entered a supply out. There was a separate laptop for the Methadone CD register. Entries were printed out each day as a backup. The pharmacist explained that stock balances were checked monthly in accordance with the SOP, and that methadone was balanced much more frequently. Running balances of two randomly selected products were checked and both found to be correct. Alterations to entries in the CD register were made using a facility in the electronic record.

Records of CDs returned by patients were seen to be made upon receipt and subsequent destruction documented and witnessed. The record book was spiral bound with no numbered pages. Most of the records of unlicensed “specials” were found to be missing the prescriber details. The pharmacist agreed to ensure that these would be completed in future.

All staff were able to demonstrate an understanding of data protection and had undergone General Data Protection Regulation (GDPR) training. They were able to provide examples of how they protect patient confidentiality, for example inviting them into the consulting room when discussing sensitive information.

The driver’s delivery records were held on an electronic hand-held device, which ensured that patients could not see other people’s details when signing for receipt of their delivery. In the event of a failed delivery, the driver would leave a card, and would try again before finishing the round. Any items that could not be delivered were returned to the pharmacy and the patient contacted to arrange a new delivery time. Completed prescriptions in the prescription retrieval system were sited so that no sensitive information was visible to people waiting at the counter. Confidential waste was kept separate from general waste and shredded onsite as required, usually at the end of the day.

There were safeguarding procedures in place and contact details of local referring agencies were seen to be held on file. The pharmacist and ACT had both completed CPPE Level 2 safeguarding training, and other staff had undergone Level 1 training. Staff were able to describe some of the warning signs to look out for.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely. Pharmacy team members are well-trained and have a good understanding of their roles and responsibilities. They can make suggestions to improve safety and workflows where appropriate.

Inspector's evidence

There was one medicines counter assistant (MCA), two dispensers, one ACT and the RP on duty during the inspection. The delivery driver arrived part way through the inspection. This appeared to be appropriate for the workload and everyone was working well together. In the event of staff shortages, other team members would increase their hours or seek help from other local branches.

Paper training records and certificates were seen confirming that all staff had completed the required training, and ongoing training to keep up to date with either new products, legislative changes and quality payment requirements. Staff were able to demonstrate an awareness of potential medicines abuse and could identify patients making repeat purchases.

The dispenser or pharmacist were seen to serve customers when the MCA was busy, and all asking appropriate questions when responding to requests or selling medicines. The pharmacist and dispenser both confirmed that they were comfortable with making decisions and did not feel pressurised to compromise their professional judgement.

Team members were involved in open discussions about their mistakes and learning from them. Team meetings are held every couple of months to discuss current events, training, near misses, errors. Team members said that they could raise concerns and that there is a whistleblowing policy available for them if needed. There were no formal targets in place.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy provides a safe, secure and professional environment for people to receive its services

Inspector's evidence

The pharmacy premises were clean, tidy and in a good state of repair with step-free access and automatic opening doors. There was a compact but well laid out dispensary, with additional storage in the basement below. There was sufficient space to work safely and effectively and the layout was suitable for the activities undertaken. There was a clear workflow in the dispensary, with a checking area at the front.

There was a separate consultation room for confidential conversations, consultations and the provision of services. This room was unlocked when not in use, but the laptop was secured and logged out. There was no confidential information on display. There was a sink with hot and cold running water in the consulting room.

The dispensary sink had hot and cold running water, and handwash was available. The sinks and toilet areas were clean and well maintained.

Room temperatures were appropriately maintained by air-conditioning units to keep staff comfortable and suitable for the storage of medicines.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy delivers its services in a safe and effective manner, and people with a range of needs can access them. The pharmacy sources, stores and manages medicines safely, and so makes sure that all of the medicines it supplies are fit for purpose. Team members take steps to identify people supplied with high-risk medicines so that they can be given extra information they need to take their medicines safely. But they don't always record this, so they may be missing opportunities to follow up these checks. The pharmacy responds well to drug alerts or product recalls to make sure people only get medicines or devices which are safe. It keeps a record of the checks it makes to keep people safe.

Inspector's evidence

A list of pharmacy services was displayed in the shop window and on posters around the pharmacy area. There was also a range of health information posters and leaflets on display in the waiting area. The pharmacy provided a range of services including travel vaccinations, substance misuse services and seasonal flu vaccinations during the autumn and winter. The PGD for the Emergency Hormonal Contraception (EHC) service was seen to be valid and in date. Electronic PGDs from the National Pharmacy Association (NPA) for various travel vaccinations were seen.

Controls were seen to be in place to reduce the risk of picking errors, such as highlighting LASAs on shelf. They also held team meetings to discuss LASAs and to identify specific items relevant to their pharmacy. They used baskets to keep individual prescriptions separate, and prescription labels were initialled to show who had dispensed and checked them.

Owings tickets were in use when medicines could not be supplied in their entirety. If an item was likely to be unavailable for some time, the pharmacy staff would do their best to obtain the stock from other local branches, or the pharmacist would contact the GP to arrange an alternative. The pharmacist explained that the overriding principle was to minimise the inconvenience for the patient.

CD stickers were attached to completed prescriptions for CDs so that staff would know that they needed to look for a bag in the CD cupboard. Schedule 3 and 4 CDs were not highlighted but the Pharmacist explained that the prescription retrieval shelves were cleared every three weeks and any CDs including those in schedules 3 & 4 would be removed. Upon reflection, the pharmacist agreed to annotate all CD prescriptions with the date of expiry to further reduce the chance of them being handed out after they had expired.

MDS trays were dispensed at another local branch with a robotic blister pack dispensing machine. Those prescriptions were clinically checked in this pharmacy, the printed MAR charts and tokens were then sent to the dispensing robot for assembly. They were then checked before sealing and returning to the pharmacy where they would be checked again, and any additional non-blistered items added. There were individual files containing records of each person's medication, when they were to be taken and any known allergies. Hospital discharge information was kept in a separate file. Changes were recorded in the file and any discrepancies were followed up before dispensing.

Blisters were seen to include product descriptions and photos but patient information leaflets (PILs) were not always supplied unless there was a newly prescribed item. Upon reflection the pharmacist agreed that they should always be supplied. Patients were referred to the pharmacy for this service by

the local concordance team, and the pharmacy was kept up to date with regular communications from them. The pharmacy also worked closely with the local hospitals and surgeries to ensure that they were always up to date with any changes to people's medication. They ensured that patients and/or their carers understood how the service worked and how to use the blister packs and charts. The concordance team and the pharmacy worked together to ensure that the service continued to meet the needs of local people.

Staff were aware of the risks involved in dispensing valproates to women who may become pregnant, and all such people would be counselled and provided with leaflets and cards highlighting the importance of having effective contraception. The leaflets and cards were seen to be stored together with the valproate products themselves. The valproate audit did not identify any patients in the at-risk group.

Patients on warfarin were asked if they knew their current dosage, whether they had their yellow book and whether their INR levels had been recently checked. Patients were also asked about their diet and when they took their medication. These interventions were not routinely recorded. Prescriptions for large quantities were generally checked with the GP. Patients taking methotrexate and lithium were also asked about blood tests and the pharmacy held spare record cards and books in stock.

Substance misuse key workers at “the hub” were contacted when people using the service failed to turn up for three consecutive days. They had recently been audited by the “the hub” and the audit was described as having gone very well. A local GP rented a room at the rear of the pharmacy for providing health monitoring services, mainly for HGV driving licence applications. No prescribing was offered.

Medicines were obtained from licensed wholesalers including AAH, Alliance, Colorama, Sigma and. Unlicensed “specials” were obtained from Sigma specials or Ascot laboratories. The pharmacy had the scanners and software necessary to comply with the Falsified Medicines Directive (FMD), but they were waiting for training before starting to decommission products.

Routine date checks were seen to be in place, and record sheets were seen to have been completed. The pharmacist explained how they would usually do it on a Sunday when it was quiet. There was a separate page for noting products approaching 6 months of expiry (coloured dots) and then the date when they were removed from stock. There were separate sheets for over-the-counter products.

The majority of opened bottles of liquid medicines were not annotated with the date of opening. The pharmacist explained that they only marked those that stated a specific expiry once opened. But upon reflection the pharmacist said that they would start recording all of the dates as they opened them. There were no plain cartons of stock seen on the shelves, and no boxes of tablets or capsules were found to contain mixed batches.

There were three fridges and the temperatures were recorded daily and all seen to be within the correct temperature range. Staff explained how they would note any variation from this and check the temperature again until it was back within the required range. They pointed out the relevant SOPs, fridge instruction manuals and audit records. Pharmacy medicines were displayed behind the medicines counter, preventing unauthorised access or self-selection of those medicines.

Patient-returned medicines were screened to ensure that any CDs were appropriately recorded, and that there were no sharps present. People with sharps for disposal were signposted to the local council, unless they were using the needle exchange service. There was a purple-lidded bin for hazardous waste and a separate list of hazardous medicines was available. DOOP containers for the safe disposal of CDs were also seen.

The pharmacy received drug alerts and recalls from the MHRA, copies of which were seen to be kept in a file. Each alert was annotated with any actions taken, the date and initials of those involved. There was also a log at the front of the file summarizing each recall. The team knew what to do if they received damaged or faulty stock and they explained how they would return them to the wholesalers.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the right equipment for the range of services it provides, and it makes sure that it is properly maintained. The pharmacy keeps people’s private information safe.

Inspector's evidence

The pharmacy has the necessary resources required for the services provided, including a range of crown stamped measuring equipment, counting triangles (including a separate one for cytotoxics), reference sources including the BNF and BNF for children. The pharmacy also had internet access and used this as an additional reference source.

An external company comes in annually to calibrate the BP monitor and the glucose monitor is calibrated with control solution monthly. Access to PMRs was controlled through individual passwords, which had been changed from the original default password. Computer screens are positioned so they are not visible to the public

Staff were seen to take precautions such as moving to the rear of the dispensary when making telephone calls so as not to be overheard. NHS smartcards were seen to be used appropriately and with no sharing of passwords. They were not left on the premises overnight. Confidential information was kept secure and items awaiting collection were not visible from retail area

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.