General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Dosette Pharmacy, 100 Sherbrook Road, Daybrook, Nottingham, NG5 6AT

Pharmacy reference: 9010644

Type of pharmacy: Community

Date of inspection: 02/07/2019

Pharmacy context

The pharmacy is situated in a business centre in Nottingham and has a distance-selling contract with NHS England. It supplies medicines in multi-compartment compliance packs to people in the Nottingham area. Over-the-counter medicines and other services are not currently provided. The regular responsible pharmacist was also the superintendent and owner. The pharmacy operates via the following website: http://www.dosettepharmacy.co.uk/

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 fails to identify and manage the risks associated with providing its services. It does not have adequate procedures in place for the supply of compliance packs. And it does not have adequate procedures and training for staff to protect vulnerable patients.
		1.2	Standard not met	The pharmacy fails to adequately review and monitor the safety and quality of pharmacy services. It doesn't have sufficient contingency plans to cope safely with the growth of the business.
		1.6	Standard not met	The pharmacy fails to maintain its CD registers and the responsible pharmacist log in accordance with legal requirements and best practice.
		1.8	Standard not met	The pharmacy team does not have adequate procedures to ensure that children and vulnerable adults are safeguarded.
2. Staff	Standards not all met	2.2	Standard not met	Staff do not have the appropriate skills and competencies for their roles.
		2.4	Standard not met	The pharmacy does not have a culture of openness and honesty.
		2.5	Standard not met	The pharmacy team members are not encouraged to provide feedback and raise concerns about making sure that the pharmacy is running safely.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not manage the way it prepares multi-compartment compliance packs safely.
		4.3	Standard not met	The pharmacy does not ensure that all its medicines are safe and 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 does not identify or manage risks well. It hasn't acted quickly enough to make sure its services are safe as the business has expanded. There are no written procedures for supplying multi-compartment compliance packs. And staff do not always follow the verbal guidance set out by the pharmacist. This situation brings risks for people who use the pharmacy service. The team doesn't make full use of opportunities to learn and improve from previous mistakes to stop the same errors happening again. And team members do not fully understand their role in protecting vulnerable people, so they may not know how to respond to concerns appropriately. The pharmacy does not always store its controlled drugs in accordance with legislation. And some of its records are not kept as required by law.

Inspector's evidence

The responsible pharmacist (RP) notice showing the pharmacist in charge of the pharmacy was on display. There were standard operating procedures (SOPs) in place. But they hadn’t been tailored to reflect the fact that the pharmacy was a distance selling pharmacy. For example, SOPs talked about greeting a person visiting the pharmacy. Under NHS regulations members of the public are generally not allowed to visit the pharmacy. The main activity of the pharmacy was supplying medicines in multi-compartment compliance packs to people living in the Nottingham area. There wasn’t an SOP for the assembly of compliance packs. The pharmacist said that he had trained staff in how to assemble the compliance packs safely. Other SOPs had been implemented in June 2017 and were due for review in June 2019.

The pharmacy team members had signed the SOP for recording near misses and errors but were not following it. The pharmacist said that when he found an error, if he had time, he asked the member of staff to review the near miss. But if not, he changed it himself. The last recorded near miss was from June 2018 and was not recorded on the form highlighted in the SOP.

The pharmacist said that the business had expanded rapidly over the last year. He said that he had struggled with clinical governance and to find time for his responsibilities as superintendent over this period. Professional indemnity insurance was in place.

The pharmacy had a legally compliant controlled drugs (CD) cupboard. Controlled drug records were kept and running balances were maintained though running balance checks were not done as frequently as required by SOPs. The recorded balance in the CD register and the physical balance of the stock of a CD in the CD cabinet didn’t match. The pharmacist found a prescription that had been supplied the previous Friday but not entered in the register (the inspection was the following Tuesday). This was outside of the legally required time limit for entering CDs in the CD register. There were four other prescriptions that hadn’t been entered in the CD register within the legally required timescale. A second CD balance checked matched.

There were no patient-returned CDs in the cupboard. The pharmacist couldn’t find the patient-returned CD register. The pharmacist said that the pharmacy had received patient-returned CDs but didn’t have any at the moment. The private prescriptions register was found to be kept and maintained

adequately.

There was a page on the website which gave contact details for external organisations that complaints could be made to, the practice leaflet outlined the complaints and feedback process and this was available on the pharmacy website. Other information on the website included the MHRA logo, the name of the superintendent and the GPhC premises number.

The pharmacy had local contact details for reporting safeguarding concerns available. But there was no SOP. A staff member had some understanding of when and how to report a concern. But the driver who had most contact with patients had not been trained. The pharmacist had some understanding of safeguarding but hadn't considered his safeguarding responsibilities in the context of how the pharmacy had contact with the patients. Confidential waste was bagged and taken away for destruction. There was an information governance policy in place.

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

Summary findings

The pharmacy has enough staff to cope with the workload. But some staff members are not properly trained in how to assemble multi-compartment compliance packs safely and do not do much ongoing training. So their knowledge may not always be up to date. There isn't a work culture of openness, honesty and learning. Staff know that some activities in the pharmacy do not comply with best practice but they have not raised their concerns with the pharmacist.

Inspector's evidence

The pharmacy had an RP log which showed who the RP was. The RP signed in on a Monday and out on a Friday. The pharmacist said that sometimes he came in at the week-end to complete an accuracy check of dispensed medicines but didn't sign in the register. This was an activity that required a pharmacist to sign in as the responsible pharmacist in the RP register.

The staffing level at the time of the inspection was adequate to manage the workload. There were two qualified dispensers, a trainee dispenser who was studying an apprenticeship course, and a pharmacy undergraduate working there for the summer.

Staff said they didn't have formal appraisals but they had informal discussions about how things were going. The dispenser said that she felt comfortable to make suggestions or provide feedback about the services that were offered. The trainee dispenser said that she was studying an apprenticeship with a local college. She said that she had regular protected training time at work. The dispenser said that she had discussed starting the pharmacy technician course with the pharmacist. She said that there was informal training from the pharmacist but there was no other training in place.

There was a whistleblowing SOP. But one of the members of staff said that she was aware that not all of the procedures in the pharmacy followed best practice but had 'gone with the flow'.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are secure from unauthorised access. But they are not big enough for the pharmacy's current workload. However, there are firm plans to address this.

Inspector's evidence

The pharmacy was too small for the current number of items dispensed but the pharmacist had made arrangements to expand into the unit next door. There was limited workbench and storage space with some stock medicines kept on the floor.

The pharmacy was clean but was untidy. There was adequate heating and lighting throughout the pharmacy. There was hot and cold running water in the premises.The pharmacy was in a business centre. The pharmacy could only be accessed by pharmacy staff. The room was lockable.

Principle 4 - Services **Standards not all met**

Summary findings

The pharmacy does not manage its multi-compartment compliance pack service safely. The staff don't always refer to the prescription when assembling a pack. So any changes in a person's medicines may be missed. And they sometimes leave tablets in unsealed trays for extended periods of time. This could increase the chances of mistakes being made and could affect the quality of the medicine.The pharmacy does not record its fridge temperatures. And it doesn't consider how storing medicines other than in their original containers may affect their shelf-life. This makes it harder for the pharmacy to be sure that its medicines are safe to supply. It doesn't always identify people who receive higher-risk medicines. So, it may miss opportunities to provide people with the information they need to take their medicines safely. And the pharmacy doesn't keep records about how it reacts to medicine safety recalls. So, it may not always be able to show that it has taken the right steps to keep people safe.

Inspector's evidence

The main business of the pharmacy was supplying medicines in multi-dose compliance packs to around 400 people. This work was divided into four weeks to allow time for prescriptions to be ordered and delivered and so that the workload was evenly shared. Compliance packs were supplied on a weekly or monthly basis; the frequency of supply was indicated by the prescriber. Each person who received their medicine in a compliance pack had an individual chart which listed their medicines and when they should be taken. Some of the charts seen had medicines crossed through or covered with correction fluid with no date or indication of why a change was made. Staff said that any changes in or missing medicines were checked with the surgery before being dispensed.

'Dispensed by' and 'checked by' boxes were at the bottom of the backing sheet below where the individual medicine labels had been attached to the sheet. When the assembly process was examined during the inspection, staff were seen to have signed the 'dispensed by' box at the bottom of the sheet before the assembly had been completed. Staff understood that by signing the box they were indicating that all the medicines recorded on the labels on the sheet had been put correctly in the compliance pack. They realised that signing the box before this had been completed was not best practice but said that this was what usually happened. Staff were also aware that the compliance pack should be assembled from the information on a prescription not the patient chart. But a member of staff was seen dispensing from the patient chart. She didn't have the prescription in front of her. She said that she assumed that the sheet was correct but that it was checked against the prescription before it was supplied. Staff said that backing sheets recorded the shape and colour of medicines to allow easy identification but most of the compliance packs seen didn't carry this information. This could mean patients and carers are not able to easily identify which medicines are which.

On the shelving for dispensed compliance packs waiting checking there was an open compliance pack from the previous day. The stock had not come in that day and the dispenser said it would stay open, on the shelf, until the medicine arrived. The dispenser said that it was usual practice to dispense a compliance pack and then leave it on the shelf unsealed until the missing stock came in. The pharmacist said that it would be safer to wait until all the stock was available before starting the assembly process.

On another shelf there were two compliance packs containing medicines for a care home which hadn't been sealed. The pharmacist said these had been dispensed the previous Friday and were also waiting for stock to come in.

There was another assembled compliance pack on the shelf. This one didn't have a backing sheet with any medicine labels attached to it to identify the medicines. In the basket there was a roll of medicine labels and the prescription. The pharmacist explained that the compliance pack had been dispensed without the prescription because the patient ordered the prescription themselves. The prescription had been received on the day of inspection.

A further compliance pack was checked that was waiting to be delivered. The person's record showed that they had three medicines. The record was confusing because it said '½ at night' for one of the tablets, but the correct dose was one tablet at night. The incorrect dosage instruction related to a previous supply when a tablet of double the strength had been used. The compliance pack contained three medicines which matched the information on the chart. When the prescription was checked it had four medicines. The pharmacist said that the fourth medicine was a new item that had been missed. He said that it was possible the compliance pack had been dispensed and checked against the patient's record not the prescription. One of the medicines in the compliance pack was Temazepam. Temazepam requires storage in the CD cupboard but the tray was on the standard shelf. The compliance packs checked waiting delivery didn't have patient information leaflets included. The pharmacist said they were only supplied with new medicines or when a leaflet was requested.

A record of invoices showed that medication was obtained from licensed wholesalers. Stock requiring cold storage was stored in the fridge. The current temperature was within the required range of between 2 and 8 degrees Celsius. The thermometer showed a minimum of 3 degrees Celsius, but the maximum was 11 degrees Celsius. The last recorded fridge temperature was in October 2018. CD stock requiring safe custody was stored in a controlled drugs cupboard.

Staff said that medicines were date checked every month but that no records were kept. No out-of-date stock was seen. Medicines that had been transferred into brown bottles from their original containers were labelled with the name, batch number and expiry date but not the date of assembly. The pharmacist said that the aim was to use the medicine the following month but that he would use the medicine up to the original manufacturer's expiry date. The manufacturer's expiry date is for when the medicine is stored in the original container and cannot be relied upon once the medicine has been removed.

Opened bottles of liquid medications were marked with the date of opening. Out-of-date and patient-returned medications were segregated and disposed of appropriately in pharmaceutical waste bins.

The pharmacy delivered medications to people using a delivery driver. The pharmacist said that signatures were obtained from the recipient on delivery but that the records were shredded the same day. This meant that there was no audit trail should a query arise later.

The pharmacist said that people knew that they could ring the pharmacy if they wanted advice or help. He said that he had a good relationship with the carers. He said that when people started a higher-risk medicine he would phone them but there was no routine contact after that. The pharmacist knew that he didn't have any people taking sodium valproate to whom the pregnancy prevention programme was applicable. He knew the advice that should be given but didn't have the information leaflets. He said that he would obtain them. There was access to a range of health advice on the pharmacy's website.

The pharmacy had registered with Secure Med but had not yet got scanners to implement the Falsified

Medicines Directive. The pharmacist received medicine safety alerts to his email. There was no record made to provide an audit trail to show what action had been taken in response to these alerts.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for the services it offers.

Inspector's evidence

The equipment held by the pharmacy was suitable for the services it offered. The pharmacy used crown stamped measures for measuring liquids. Equipment was in good working order and was maintained adequately.

The pharmacy website was provided by an external provider who had given assurance that website security complied with current best practice. The computers were new and other electrical equipment was under two years.

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.