General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Pharmadose Limited, Unit 14, Dodson Way, PETERBOROUGH, Cambridgeshire, PE1 5XJ

Pharmacy reference: 1109048

Type of pharmacy: Closed

Date of inspection: 10/01/2020

Pharmacy context

This pharmacy is closed to the public and its main activity is supplying medicines to residents of care homes. These medicines are supplied against NHS prescriptions. And the pharmacy largely dispenses these medicines into multi-compartment compliance packs. The pharmacy's team members also provide advice to staff in the care homes about medicines management. And the pharmacy carries out checks at the homes to make sure medicines are being stored correctly. The pharmacy doesn't sell any over-the-counter medicines or offer any services online at present.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

Overall, the pharmacy identifies and manages the risks associated with its services. Its team members understand their roles and they know when to refer to the pharmacist for advice. The staff also know what they can and cannot do if there is no pharmacist present. The team learns from mistakes and introduces improvements to make the pharmacy's services safer. The pharmacy team has written procedures to refer to. However, the length of time since the last review of these procedures could increase the chances that they don't fully reflect current practice. And the pharmacy must make sure it keeps all the records required by law up-to-date.

Inspector's evidence

Pharmacy services were supported by a range of documented standard operating procedures (SOPs). Those SOPs checked had not been reviewed since 2015 though there was some evidence that staff had read the SOPs relevant to their roles since then (in 2017). Roles and responsibilities of the staff were included in the SOPs. When asked, staff could explain what they could and could not do if there was no pharmacist present at the pharmacy. The responsible pharmacist (RP) admitted he was behind schedule with his review of the procedures. He planned to work through them with the staff over the coming weeks to refresh their knowledge and to identify any changes that were needed so the SOPs reflected current practice.

The dispensing workload was planned well in advance to ensure there was sufficient time to assemble, check and supply to care homes in a safe manner. The workflow in the pharmacy was well-organised. Baskets of different colours were used to identify prescriptions destined for different care homes.

The RP was able to explain clearly the steps he took if a dispensing error happened. He said his first step was to look after the welfare of the patient and establish if medical advice was needed. If a person had taken any of the wrong medicine, their GP would be contacted. An investigation would be carried out to identify those involved, how it had happened, and any improvements to prevent the same thing happening again. Notes about any errors were added to the person's medication records for future reference. Incidents were also reported to the pharmacy superintendent and to the National Reporting and Learning System to share learnings and to help spot any patterns or trends.

There had previously been a process to record dispensing mistakes that were spotted and rectified before the medicines left the pharmacy (known as near misses). However, the RP said none had been recorded in recent months. Staff said they were asked to correct their own mistakes, for example, if they had put an extra tablet in a compliance pack. The RP explained he pointed out near misses to the staff and discussed how it had happened, on a one-to-one basis. If there were a few mistakes made by the same person, he suggested to the member of staff involved that they changed tasks for a while to try to improve their concentration. Staff explained some of the changes they had made following near misses. These included separating strengths of zopiclone tablets more clearly and keeping different formulations of mirtazapine tablets well-apart. Following the inspection, the RP provided information about how the team would start recording near misses in future so the pharmacy could make the most of learning from these events.

The pharmacy had a complaints procedure. Details about the complaints process were shared with the care homes as part of service level agreements. The pharmacy staff spoke with care homes staff on a regular basis and said they would take on board any feedback the care home staff gave about the pharmacy's services. The care homes also had contact details for the pharmacy superintendent should they need to raise any concerns. In response to a previous issue about how much warfarin a home had available to give to people, the pharmacy had provided more training to the care home staff. The pharmacy had also started to check with the home if more warfarin was needed to prevent the home from running out.

The pharmacy's services were insured appropriately. The pharmacy had not dispensed any private prescriptions or emergency supplies; the RP explained that all supplies to the care homes were supported by prescriptions due to the often complex needs of the patients involved. He said that most repeat prescriptions were planned well in advance to prevent care home residents from running out of medicines. And interims requests were always accompanied by a prescription. An RP notice was displayed in the pharmacy and this gave the correct details for the pharmacist on duty. The RP record was generally complete. Controlled drugs (CD) registers were available at the pharmacy. The RP admitted that entries had not been kept up to date during the busy period over Christmas. This meant that, at the time of the visit, entries had not been made since around 19 December 2019. The RP was advised to bring the registers up to date as soon as possible. This was completed within two working days of the inspection. Some balances were checked regularly. The pharmacy kept the notes which accompanied CDs returned by the care homes for destruction. Not all of these had been recorded in the book kept for this purpose. The RP agreed to make sure the record was updated appropriately.

The closed nature of the pharmacy meant that there was very limited opportunity for unauthorised access to physical records. There was however a privacy notice at the front door explaining how information was protected. Staff had received some training about the General Data Protection Regulation. Information governance arrangements were audited each year. Confidential waste was destroyed by shredding. Most staff used their own NHS smartcards to access electronic prescriptions, but one dispenser's card was not working. This meant that smartcards and passwords were sometimes shared. So, the audit trail for accessing prescriptions may not always be accurate. The RP said this would be reviewed.

The RP had completed refresher level 2 safeguarding training most recently in 2019. He had discussed safeguarding with the rest of the pharmacy team members so they understood what they should do if they was a safeguarding concern. The staff would refer safeguarding concerns to the RP in the first instance. The RP knew how to find contact information for local safeguarding agencies. He had had no safeguarding concerns to report. He knew about the possibility of covert administration of medicines and how this should be managed appropriately so that residents in care homes were protected.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy's team members have the right skills and qualifications for their roles. Pharmacy professionals can exercise their professional judgement and act in people's best interest. And the team works closely together and shares learnings from when things go wrong. This helps to make the pharmacy's services safer. The staff have opportunities to develop their pharmacy skills. But there is no formal time set aside at work for training. This makes it harder for staff to complete the training courses they are enrolled on.

Inspector's evidence

The RP at the time of the inspection provided most of pharmacist cover. The rest of the pharmacy team comprised a general manager who oversaw procurement, administration and other non-professional operations, three trained dispensers (two of whom were training to become pharmacy technicians), and two delivery drivers (one of whom also provided a lot of administrative support for the service to care homes). Staff were observed working closely together and said they would feel able to raise any concerns with the RP or the manager.

All those involved in dispensing activities had completed the required training for their roles. The RP was able to closely supervise the work of the team and staff were seen referring queries to him during the visit.

The staff said they discussed issues and improvements as a team. There was an induction process for new starters. And staff were given on-the-job coaching and feedback by the RP, but they did not have formal appraisals. Staff said they did not get formal time set aside at work to complete ongoing training. And the two dispensers training to become pharmacy technicians were a bit behind in their courses.

The RP explained that he felt able to exercise his professional judgement. He gave examples of how he had dealt with queries about crushing tablets, making sure that all the required agreements were in place with prescribers and family before providing advice. This was so covert administration of medicines was only done when appropriate and authorised. He also described providing a range of options if residents in care homes were unable to swallow tablets. These had included suggesting licensed liquid formulations if available rather than crushing tablets.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises provide a safe and clean environment for dispensing medicines. The team makes sure the premises are tidy and well-organised, and there is enough space for the volume of prescriptions it dispenses.

Inspector's evidence

Some of the information on the pharmacy's website was not up-to-date. There was a reference on one page to an online doctor service, but the pharmacy said there was no link to an online prescriber. And there was no way to access an online prescribing service on the website. No medicines were sold or supplied via the website. The manager said the website was under review and the GPhC voluntary logo was to be removed following a request from the regulator to do so.

Members of the public did not receive services at the pharmacy as all medicines were delivered to care homes. The pharmacy premises were large enough for the activities undertaken. The dispensing benches were very clean and were kept clear of clutter. There was enough space to store stock in an organised way. Parts of the dispensary were reserved for specific activities to reduce risks in the dispensing process. For example, acute prescriptions were kept on a different part of the dispensing bench so they were prioritised for delivery ahead of regular repeat prescriptions. And waste medicines were stored well away from dispensing stock.

There was adequate heating and lighting. The dispensary sink had hot and cold running water and was clean. Flooring was worn but intact and clean. There were no trip or slip hazards and fire exits were kept clear. The premises could be secured against unauthorised access and there was onsite security on the industrial estate where the pharmacy was located.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's service focusses on the supply of medicines to care homes. Overall, it does this in an effective way. And it provides additional training and support to staff looking after residents in care homes so they can manage and administer medicines safely. The pharmacy gets its medicines from appropriate sources and it generally stores them correctly. It separates out-of-date medicines from dispensing stock and disposes of waste medicines safely. It doesn't always keep a record of when it date checks its stocks so it may be harder for the pharmacy staff to be sure that all stock is checked regularly.

Inspector's evidence

This pharmacy only provided a dispensing service to residents in care homes. It did not provide pharmacy services to other people. Most of the dispensing workload was spread across a four-week schedule to ensure medicines reached the care homes on time. Care homes generally received their repeat medicines one week in advance of starting to use them which gave them ample opportunity to check the deliveries.

Care home staff were responsible for placing orders for prescriptions for their own residents. The pharmacy always compared repeat prescriptions against existing records so the pharmacy staff could query any missing items or unexpected changes. Intervention notes were added to patients' records for future reference. An example was given where a medicine previously advised as being stopped had been requested again. This has been checked with the prescriber and it was found to have been reordered in error.

The RP explained that he asked the care homes to provide information about therapeutic monitoring for those people taking warfarin each time the medicine was ordered. This information was not routinely added to the pharmacy's medication record system. Similar checks happened for people taking lithium. The RP said that the people supplied with valproate by this pharmacy were not at risk of becoming pregnant. However, he was aware of the information that should be provided to people who might be in this group and would provide refresher training to care home staff if needed.

Medicines were largely supplied in multi-compartment compliance packs using a system called CareMeds. This had replaced Biodose which was no longer available. The switch had created some extra work for the pharmacy but this had settled. The system included a photo of the person as an additional check for care home staff when administering medicines. The pharmacy provided training to care homes about the pharmacy service and how medicines were supplied in advance of the service starting. It provided further training each year and could arrange for interim training for new starters or if there were any incidents which showed training was needed. The training included how to reorder medicines, booking-in medicines, what to do if a person's medicines changed, and the medicine administration records. Evidence of previous audits and advisory visits to care homes was kept by the pharmacy. Areas checked during the visits had included the storage of fridge lines and CDs, and the timelines for re-ordering medicines. Where issues were identified during the audits, these were highlighted to the care homes and additional training had been provided where necessary. A record was kept by the pharmacy for deliveries made to the care homes. Separate records were kept for deliveries of CDs and fridge lines.

Some medicines were de-blistered ahead of dispensing to save time. The RP explained this was done shortly before the medicines were used. And only those medicines dispensed frequently were de-blistered ahead of time. Once de-blistered, the medicines were stored in closed containers. But the labelling on the containers did not include all the information necessary to be able to identify what the brand of the medicine was or when the medicine had been removed from its original packaging. Following the inspection, the RP provided the inspector with a revised procedure for this activity and this included improved labelling of any de-blistered medicines.

Medicines were obtained from a variety of licensed wholesalers and specials suppliers. The pharmacy had the equipment and software it needed to comply with the Falsified Medicines Directive, but products were not being scanned routinely; many of the packs did not carry the correct barcode to allow this to happen. CDs were stored securely. Medicines requiring refrigeration were stored at the correct temperature. Waste medicines were separated from dispensing stock and were collected by specialist waste contractors for safe disposal. There was some medicines waste returned by care homes that needed to be sorted at the pharmacy to remove confidential information. The pharmacy also had a contract to accept sharps waste for safe disposal.

Medicines were said to be date checked regularly but no record had been made about this since September 2018. However, no out-of-date medicines were found amongst dispensing stock. Dates of opening had been added to stock containers of liquid medicines so dispensers could assess it the contents were still suitable to supply.

The pharmacy received MHRA safety alerts and recalls via email. Checks were made against stock held in the pharmacy and care homes were contacted. Evidence was retained at the pharmacy; the most recent alerts on record were for ranitidine. The records showed that stock had been checked by the pharmacy to make sure none was kept.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs for the services it provides. It makes sure its equipment is kept clean and safe to use.

Inspector's evidence

The closed nature of the pharmacy meant that all equipment and information held at the pharmacy was kept secure. Electrical equipment was regularly safety tested. Measuring equipment was of a suitable standard and was clean.

There was ample space in the pharmacy fridge for storing medicines which required refrigeration. The maximum and minimum fridge temperature ranges were checked daily and were recorded. The records seen were within the required range for storing these medicines safely. A machine was used to de-blister some medicines ahead of dispensing. Staff could explain how to clean this machine between different medicines to prevent cross-contamination. The device was not used for antibiotics or cytotoxic medications.

Vans used for delivering medicines were checked regularly; there was evidence of a recent MOT certificate.

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.