General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Kamsons Pharmacy, 5-8 Holbein Place, Bolton Close, Bellbrook Industrial Estate, Uckfield, East Sussex, TN22 1PH

Pharmacy reference: 9011690

Type of pharmacy: Dispensing hub

Date of inspection: 22/02/2022

Pharmacy context

This pharmacy only assembles multicompartment compliance packs for a number of other pharmacies within the Waremoss group. It is in the company's head office and main warehouse building, so is not open to the public.

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	Staff are regularly involved in reviewing and updating the SOPs as they gain experience in using the machinery, and as the scale of their operation increases. The company has taken learnings from other organisations using similar technology and has also shared what it has learned since.
2. Staff	Standards met	2.1	Good practice	Staffing levels, and skill mix, are continually reviewed to ensure that they remain appropriate for the workload which is continually growing. Staff did not appear to be under any pressure and have built in contingency so that they complete their tasks in advance of their deadlines.
		2.2	Good practice	New members of staff have a planned induction with regular performance reviews. Once they have satisfactorily completed their probationary period, they are given appropriate training which has been tailored to the specific requirements of the site. Staff have opportunities to progress their careers, as evidenced by some of those at the hub who have risen through various roles within the company.
		2.4	Good practice	Members of the team were enthusiastic about their jobs and could explain the importance of what they were doing for the company. The hub was a completely new arrangement for the company and all staff were working well as a team to make it a success.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	4.2	Good practice	The pharmacy uses an automated assembly machine and its staff are regularly reviewing its near misses, and taking the necessary action to eliminate them wherever possible. The technology also enables the pharmacy to follow up any errors, or recalls at individual patient level and prevents people being given medicines that are, or will be, out of date when they take them.

Principle	Principle finding	Exception standard reference	Notable practice	Why
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy provides its services in line with clear, up-to-date processes and procedures which are being followed by its team members. They are clear about their roles and responsibilities. And they work to professional standards, identifying and managing risks effectively. The pharmacy regularly reviews its processes and makes suitable changes as its service expands. It has also made sensible adjustments relating to the pandemic, balancing the need to minimise the spread of the coronavirus with the need to return back to normal life. The pharmacy keeps good records of the mistakes that happen during the assembly process. The pharmacist regularly reviews them with members of the team so that they can all learn from them and avoid problems being repeated. The pharmacy manages and protects confidential information well and has suitable insurance in place to help protect people if things do go wrong.

Inspector's evidence

The pharmacy's owners and senior management team had carried out a significant amount of research, including risk assessments, into the various automated dispensing systems available before selecting the SynMed system. They had identified shortcomings with various systems and used this knowledge to help inform their final choice of a system which best met their needs. The company incorporated the pharmacy into its overall warehousing Health & Safety risk assessment in order to help protect the staff working there.

The pharmacy was operating as a central assembly hub for a number of the company's other pharmacies (spokes). It undertook a fresh risk assessment each time it added a new 'spoke' pharmacy to be served by the central 'hub'. This was partly to ensure that the hub could cope with the increased workload, and partly to identify whether the machine was still loaded with the most appropriate tablets and capsules. The team carried out another review after four weeks to identify any new risks and ensure that existing risks were mitigated. The review included operating statistics such as the number of multi-compartment compliance aid packs (cards) produced per hour and the usage of individual tablets or capsules. 508 individual tablets or capsules were kept in the machine itself, and slower-moving items were kept separately for manual addition. As new spoke pharmacies were added, the hub pharmacy's review informed them whether they needed to add different medicines to the machine and remove others.

The pharmacy's team members had been wearing masks until recently but had re-assessed the risks since the government's announcement lifting all the legal requirements relating to the pandemic. They were still maintaining social distancing and using hand sanitisers, which were positioned at every workstation.

There were up-to-date standard operating procedures (SOPs), which had been signed and dated by all team members to indicate that they had read and understood them. The SOPs were shortly due for their first review and would be reviewed every three months while the pharmacy was still fine-tuning its processes. The SOPs also highlighted who could undertake each step in the process.

Near-miss incidents were recorded and there was evidence of action taken and the learnings from them. Incidents were also reviewed with team members during their regular briefing meetings. The reviews themselves were not routinely documented, but the ACT produced a review form from the company intranet ('Kamsonsnet') which they would use in future. When they identified an error in the information provided by an individual spoke pharmacy, they attached a pink 'attention' slip to the documentation and returned it, uncorrected, so that the spoke pharmacy could correct it and learn from their mistakes.

There was a responsible pharmacist (RP) notice, clearly displayed on the wall by the main communications board, stating the name and registration number of RP on duty that day. The RP's details were also recorded on the pharmacy computer, as required. Each person's medicines were listed on a sheet, with spaces for three signatures against each line. This was to show who had prepared the medicine in the compliance aid, who had verified it, and the third box was for the pharmacist or accuracy checking technician (ACT) to confirm that they had completed a final accuracy check. People could only access the pharmacy's computer systems after they had confirmed their identity using a fingerprint identification. This also ensured that people could only complete those tasks they were authorised for. There were three levels of authorisation with only three people authorised as 'super users' who had access to all parts of the system. This meant that they could, for example, add new product barcodes to the system, although they still had to have their input verified by a second person.

The hub pharmacy regarded the spoke pharmacies as its customers, so they had regular reviews to ensure that they were meeting their needs and that improvements could be made if needed. There was appropriate professional indemnity insurance in place.

The pharmacy did not stock controlled drugs (CDs), temperature sensitive medicines, unlicensed medicines and nor did it dispense any private prescriptions. So it did not have records relating to those. It did have access to the necessary online systems to record them if that should change. There was an information governance (IG) policy available on 'Kamsonsnet' for staff to refer to should the need arise. This included a privacy notice. There were separate bags for confidential waste, which were sealed when full and sent down to the warehouse below. From there, they were removed by a suitably accredited company for secure disposal together with the sealed bags from the company's other pharmacies. Safeguarding procedures were in place and all registrants had been trained to level two of the Centre for Pharmacy postgraduate Education (CPPE).

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely, and they work well together. It regularly reviews the size and skills of its team, making sure it always has a good mix of trained people available at all times. The pharmacy trains its team members well so they have a clear understanding of what they can and cannot do.

Inspector's evidence

During the inspection there was one ACT, one dispensing assistant, an experienced pharmacist from the company's senior management team and the RP on duty. They appeared to be managing their workload and could call upon more pharmacists from the offices below or other trained staff from local branches if necessary. The pharmacist described how they were continually reviewing their staffing levels as the volume of work was steadily increasing. He also described the mix of qualified or experienced pharmacy staff with machine operatives, reflecting the more industrial nature of the working environment. All staff received an induction upon joining, and the newly appointed operatives would be registered on an accredited training course once they had satisfactorily completed three months employment.

There was a whistleblowing policy in place and staff could discuss any problems with their manager. The 'super users' had been trained in the use and basic maintenance of the dispensing robot by the manufacturer's technicians. They were then responsible for training the rest of the team to undertake their tasks. The training was all documented and the whole team was enthusiastic and appeared to enjoy their work.

There were no targets in place, other than ensuring that each individual spoke pharmacy received its assembled compliance packs on time. Every team member was provided with a job description and their performance would be reviewed after six weeks, twelve weeks and then annually in accordance with the company's policy. There were daily briefing meetings where the day's workload was discussed, along with any recent learnings and other items highlighted on the large communications whiteboard.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are new and provide a suitable environment for the service it provides. It has designed the premises so that its team members have more than enough space to work effectively and safely. The premises are secure so that other people can't enter them without permission.

Inspector's evidence

The pharmacy's premises were large, airy and spotlessly clean. There was plenty of space for individual workstations, enabling staff to easily maintain social distancing. The layout ensured that different tasks could be undertaken in different areas with a logical flow between them. The site was very tidy with no visible clutter.

There were no sinks or running water within the registered part of the premises as no 'wet' tasks were undertaken. There were toilet and other staff facilities elsewhere in the building for the team to use. Work surfaces were cleaned every day and the floor was mopped once a week. The floor was also vacuumed every Tuesday and Thursday.

The main entrance to the pharmacy was through a secure door, with a keypad lock, at the rear of the warehouse building. The led to a staircase with another secure door at the top of the stairs. The premises were well lit, and the temperature maintained at a level suitable for the storage of medicines and comfort of the staff.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy provides its service in a safe and effective manner. It sources, stores and manages its medicines safely, and so makes sure that all the medicines it supplies are fit for purpose. It has good processes in place to make sure it delivers the assembled compliance packs on time to the other pharmacies that are expecting them. It responds well to drug alerts or product recalls to make sure that people only get medicines or devices which are safe for them to take.

Inspector's evidence

The pharmacy only provided its services to other pharmacies within the company, and did not actively promote its services directly to members of the public. Its main purpose was to assemble multi-compartment compliance aids for its spoke pharmacies. The RP explained that the prescriptions themselves were clinically assessed by the pharmacists in the spoke pharmacies, who then sent an electronic file containing the details of each medicine, the dosage specified on the prescription, and instructions on which pocket(s) of the compliance aid should be used. Each of the individual spoke pharmacies had a deadline for this to be sent so that the hub would have sufficient time to assemble the compliance packs and deliver them back to the original spoke pharmacy. This electronic file was checked to ensure that the specified pockets were consistent with the dose required. If any anomalies were identified, then a printed copy of the file was returned to the spoke with a pink 'attention' slip attached. The spoke pharmacy would either correct the anomaly, in which case it was recorded as a near miss or confirm that it was in fact correct. The manufacturers specification for the robot indicated a potential error rate of two per 1000 tablets dispensed, usually having jumped from one pocket to another. The ACT described how they monitored this and the adjustments she made to the machine to account for the varying sizes and weights of the various tablets and capsules. Error rates were reviewed internally every two weeks, and with the manufacturer every three months to ensure that the compliance packs were correctly assembled by the robot.

The ACT demonstrated how the files were transferred from the patient medication record system (PMR) in the spoke pharmacy to the software which operated the robot. The ACT identified any items which needed to be added manually to the compliance packs and these were highlighted in the robot's software. Tablets such as Adcal-D3 were added manually as they were too large for the robot to be able to add safely. Other examples might be less frequently used medicines which weren't kept inside the robot's storage bins. The ACT also demonstrated how new items were added to the software, usually because they had a new or different barcode. This task could only be carried out by three people within the team, and it also had to be verified by someone else as an additional safety precaution. New batches were also added to the system so that the team could track the location of any individual batch of tablets.

Once the tablets had been manually added, the paper copy of the file referred to earlier was signed by the assistant adding the tablets, and then counter-signed by another team member to verify it. The tray containing four separate compliance aids was then placed in the robot for it to add the remaining medicines. When the robot had finished filling the trays, they were then checked for accuracy by either the pharmacist or the ACT who signed the final box on the paper record.

The assembled compliance packs were packed into totes, which were sealed and then sent down to the

warehouse for onward delivery to the spoke pharmacies. The paper record sheets were annotated to indicate the delivery details which could then be cross-referenced against the individual driver's drop sheet.

The pharmacy obtained most of its medicines from its own warehouse, and the remainder from recognised pharmaceutical wholesalers. The batch numbers and expiry dates of all medicines were recorded on the robot's software. This prevented the robot from including any medicines in a compliance pack that might expire before all of the medicines were due to be taken.

There was a file of alerts received from the Medicines and Healthcare Products Regulatory Agency (MHRA) indicating if any action had been taken, and if so by whom and when. The pharmacy could identify exactly who had received any given batch of tablets or capsules so that individual people could be contacted in the event of a medicines recall. Unwanted medicines were placed in designated waste containers to keep them separated from those held in stock. The designated bins were sealed when full and removed by approved waste contractors for safe disposal.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has suitable facilities for the service it provides. It makes sure that its equipment is regularly cleaned and maintained by suitably trained and qualified people. It regularly reviews the performance of its equipment so that adjustments or improvements can be made quickly. It also ensures that people's private information is kept safe and secure.

Inspector's evidence

There was one automated dispensing robot in place, and space for a second to be installed in the future. The ACT demonstrated the routine maintenance tasks she undertook on a weekly basis to ensure that the machine continued to work properly. This included cleaning the small filters which prevented tablet dust and debris from going into the assembled compliance packs. Stray tablets and capsules that may have bounced out of a compliance pack were removed and disposed of safely. Pipettes and tubes were also inspected and cleaned at the same time. These routine tasks were usually carried out every Friday afternoon, which was kept clear to allow for any catching up that may be required. This weekly maintenance was not routinely documented but upon reflection the ACT and RP agreed that a record to show who had carried out the task would be useful. The manufacturer sent a technician to carry out routine maintenance every three months, and this was documented. They also held regular review meetings between the senior management teams of both companies, so that any issues could be discussed and solutions agreed upon.

The company built enough spare time into the process to allow for any unforeseen delays so that the 'spoke' pharmacies would always receive their assembled compliance packs on time. The second machine, once installed, would also provide a backup in case of any problems. The pharmacy had a service level agreement (SLA) in place with the manufacturer to have a technician onsite within 24 hours in the event of a problem arising that couldn't be fixed remotely.

There was also a deblistering machine for removing tablets and capsules from their foil blisters. The machine was only used by trained operatives, who cleaned the machine in between different tablets or capsules. Gloves were worn at all times when handling medicines.

Access to all computers was controlled by fingerprint detectors, so that only those authorised to use them could do so. This also ensured that each person using the computers could only carry out those tasks they had been trained and authorised to do.

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.