General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Knights Chemist Ltd, 9 Palmers Road, Redditch, Worcestershire, B98 0RF

Pharmacy reference: 9011450

Type of pharmacy: Closed

Date of inspection: 16/05/2022

Pharmacy context

This is a private pharmacy which is closed to the public and located inside a warehouse unit in Redditch, Worcestershire. The pharmacy began trading during the COVID-19 pandemic. It is registered with the General Pharmaceutical Council (GPhC) to prepare and assemble multi-compartment compliance packs for some of the company's own pharmacies. It does not have an NHS contract and no sales of over-the-counter medicines take place. The pharmacy does not currently provide any other services although COVID-19 vaccinations are administered from part of the registered pharmacy premises by a different team.

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	The pharmacy's team members actively identify and manage the risks associated with the pharmacy's services. Since the last inspection, several of the pharmacy's internal processes have been modified, a robust system of checklists and audit trails have been implemented and subsequently, the potential for unidentified mistakes occurring has been minimised. This has made the pharmacy's processes safer.
		1.2	Good practice	The pharmacy regularly reviews and monitors the safety and quality of its services. Members of the pharmacy team routinely record, review and feed back near misses and incidents.
2. Staff	Standards met	2.1	Good practice	The pharmacy has enough suitably qualified and skilled staff to support the volume of work and provide a safe and effective service.
		2.2	Good practice	Members of the pharmacy team have the appropriate skills, qualifications and competence for their role and the tasks they undertake. Team members in training are appropriately supported and undertaking accredited courses.
		2.4	Good practice	The pharmacy has an embedded culture of openness, honesty, and learning. Team members are provided with training resources and given time to complete this. This helps ensure their skills and knowledge remain current. They also have opportunities for further development.
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

The pharmacy identifies and manages risks well. It has adapted several of its internal processes to make things safer. The pharmacy's team members continually monitor the safety of their services by recording mistakes and learning from them. They understand their role in protecting the welfare of vulnerable people. The pharmacy protects people's private information appropriately. And the pharmacy maintains its records as it should.

Inspector's evidence

The pharmacy acted as a hub, in a 'hub and spoke' arrangement whereby medicines for people were prepared and supplied inside multi-compartment compliance packs to each 'spoke' or individual pharmacy. The individual pharmacy then acted as a collection point for people to obtain their compliance packs from. All the pharmacies in this arrangement were owned by the same company, Knights Chemist Ltd, which is required by law for this type of arrangement. Currently, twenty-one of the company's own pharmacies were supplied with compliance packs from here. Most of them were in the Birmingham area. The superintendent pharmacist (SI) confirmed that the individual 'spoke' obtained verbal and written consent from people so that their compliance packs could be assembled from this pharmacy. This involved a twelve-week process where conversations were held with each person. This meant that people who received the packs were well informed about this situation before the hub took over the supply.

The pharmacy was clean, tidy, organised and ran an efficient operation. Since the last inspection, the superintendent pharmacist and pharmacy manager had made several changes to the pharmacy's internal processes to make things safer. This included adapting and incorporating different systems with a series of balance and checks at set stages to help identify and manage the risks associated with this service (see below and Principle 4).

A range of audit trails had been specifically created and implemented to capture, verify, and double-check that the correct details had been inputted by each individual pharmacy. These robust, in-house processes ensured the final accuracy checks and details inputted at each individual pharmacy were accurate and matched the information on the prescriptions (see Principle 4). The pharmacy was therefore not dependent on each individual pharmacy inputting the details correctly as the team made their own checks to confirm this before assembling people's medicines.

Only one pharmacy's compliance packs were dispensed and prepared at a time, from start to completion, and sent out for delivery before another pharmacy's was started. In addition, there were several other checklists and audit trails for each of the different stages in place. In a five-day week, two days were spent ensuring the files and paperwork were accurate and three days used to assemble the compliance packs for each different pharmacy. Each pharmacy's paperwork was stored in individual folders so were easy to access and locate.

A dispensing automated system (a robot) was used for the assembly of most of the compliance packs (see Principle 4). Mistakes had occurred which involved medicines 'jumping' and being placed into the wrong slots in the packs or being damaged by the machine. As a result, the pharmacy had implemented a cell count error log to record details of these incidents. Several pages of details had been recorded

which indicated that errors were commonly seen with the system, often involved the same medicine with increased jumping between the slots being seen. The team fed these errors back to the manufacturer at the maintenance stage so that the system could be readjusted. A member of staff also physically checked the compliance packs once they came out of the robot as an additional double check.

Before medicines were replenished or loaded into the robot, additional checks were made. Two people were required to check that the correct medicine was being placed inside the robot's canisters. Once the medicine pack was scanned, the pharmacist or the manager, alongside a member of staff, confirmed that the details on the system, including the description, batch number, expiry date etc, matched the container of medicines and the relevant codes.

The pharmacy had the full range of documented standard operating procedures (SOPs). They were dated from 2020 or 2021 and included an SOP for COVID-19, the pharmacy's business continuity plan, SOPs which were specific to the nature of the business but also operational guidance for the company's other pharmacies. The SI said that he wanted the team to understand how both sides, the hub and the spoke worked. The SOPs had been amended to reflect the pharmacy's internal processes and the changes that had been incorporated. Previously, the team had been using the SOPs provided by the manufacturer of the robot. The SOPs provided guidance for the team to carry out tasks correctly. They had been read and signed by all staff. Team members knew their roles and responsibilities. They had designated tasks and were seen to work with very little direction required from the pharmacist or manager. The correct notice to identify the pharmacist responsible for the pharmacy's activities was on display. Risk assessments had also been completed. They were updated when required and included a risk assessment for the service provided but also for COVID-19, as well as individual, occupational ones for the team. The team wore personal protective equipment which included face masks and gloves.

Once the compliance packs had been assembled, the RP usually carried out the final accuracy-check but the manager, who was an accredited accuracy checking dispenser could also assist with this, if required. For the latter, the prescriptions were clinically checked by a pharmacist at the 'spoke' before it was assembled by other staff in this pharmacy. The clinical check was marked on the prescription as described in Principle 4. This helped identify that this stage had been completed. The manager was not involved in any other dispensing process other than the final check, and there was an SOP to cover this process.

Staff worked in different areas and the RP checked the multi-compartment compliance packs from a separate area. This helped minimise distractions and ensured any mistakes could be easily identified. They also routinely recorded their near miss mistakes. There were individual logs for the team to record their own details as well as a record that the responsible pharmacist (RP) used. The RP described the near miss mistakes as being situations which involved the automated dispensing system when medicines were damaged, or capsules split or broke. Details from the near miss logs and cell count records were discussed with the team and rectified where possible by changing the pipette size in the system or feeding back to the manufacturer. Regular team meetings were held, the details were formally reviewed every month and fed back to this team but also raised at an area level. Due to the pharmacy's robust in-house measures to help identify errors made by the individual pharmacies, the manager confirmed that no mistakes were now being made when details were inputted into the pharmacy system.

The RP or the pharmacy manager handled dispensing incidents or complaints. The pharmacy had the relevant policy in place. The team confirmed that no mistakes had reached patients. The individual pharmacies or 'spokes' had identified errors on occasion, and this included, for example capsules being

pierced inside the compliance pack which had not been identified or seen at the hub. Details were recorded, reviewed, and analysed to identify the root cause, the manager looked at what had gone wrong and why, before this was fed back to the team, the other pharmacies and area managers and a report was submitted to the superintendent pharmacist. The pharmacy had suitable processes in place to manage incidents but the forms being used to record these details, were labelled as ‘near misses'. Changing the title to make the distinction clearer between the two was advised at the time.

The pharmacy's team members had been trained to protect people’s confidential information and to safeguard vulnerable people. They could recognise signs of concern and knew who to refer to in the event of a concern. Staff, including the RP had been trained to level two through the Centre for Pharmacy Postgraduate Education (CPPE), although this needed refreshing. Details of local safeguarding agencies were on display. Confidential material was stored and disposed of appropriately. There were no sensitive details left in the premises that could be seen and unauthorised accessed was limited. Computer systems were password protected and confidential waste was shredded.

The pharmacy did not stock or supply controlled drugs (CDs), medicines that required cold storage, supply unlicensed medicines, or make supplies against private prescriptions. The team confirmed that emergency supplies were not made. Hence there were no records for these. The RP record had been kept in line with statutory requirements. The pharmacy had suitable professional indemnity insurance in place.

Due to time constraints, and the service not running fully on the day, not all aspects of the COVID-19 vaccination service were inspected and verified. This service was being provided by a different team of pharmacists, they administered the vaccine under the national protocol, risk assessments and SOPs for the service were in place. Appropriately trained volunteers were seen ushering people outside and through the building. A one-way system was in use, so people would enter this section of the registered premises from one entrance, enter gazebo-like tents to receive the vaccine before waiting on appropriately distanced chairs to be monitored if required. The tents and this section of the premises had enough space for this purpose. Fridges to hold stock and consumables were stored separately away from unauthorised access. Relatively few people were now attending this site to receive the COVID-19 vaccine, but the pharmacy was also administering vaccines to 5–11-year-olds.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has plenty of staff to manage its workload appropriately. Members of the pharmacy team work well together. They have a range of skills and experience. And the pharmacy provides additional resources to help keep their skills and knowledge up to date.

Inspector's evidence

The pharmacy team consisted of a regular pharmacist, four apprentices, three trained dispensing assistants, one of whom was the manager and a trainee dispensing assistant who was enrolled onto the appropriate, accredited training. Team members were appropriately trained for their roles or were undertaking appropriate training. Some of their certificates of qualification were seen. One of the apprentices was newly employed but she was being appropriately supported and supervised by experienced members of the team. She had also read the pharmacy's SOPs. There was enough staff to manage the pharmacy's workload and they were up to date with this.

Staff wore ID. Members of the pharmacy team knew what they could or could not do in the absence of the RP. They felt supported, liked working at the pharmacy and were kept informed through emails, noticeboards, via meetings and from management. Staff had access to various resources for ongoing training, this included completing training modules through the company's internal, on-line, learning platform. Individual training records had been maintained to verify this. Trainee staff were given time to complete course material at work. The team's performance was monitored, and they had regular meetings to discuss relevant points. The superintendent and staff explained that they also had opportunities for further development and to enrol on additional training courses.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are secure and suitable for the activities being provided. The pharmacy has enough space to deliver its services safely. And its team members keep the premises clean.

Inspector's evidence

The pharmacy premises were located on the ground floor of a warehouse unit which belonged to the company’s head office. It consisted of a large spacious area that had been divided into two sections. The larger section was currently being used to administer a COVID-19 vaccination service. The remainder of the area was used for the pharmacy operation. The pharmacy had enough space for the team to carry out dispensing tasks safely. There were different workstations where staff were situated, and various activities took place. There were also specific units and areas underneath the worktops, marked with details of the individual pharmacies. Assembled compliance packs and associated paperwork could be stored here. The pharmacy’s robot was at one end and additional storage space to one side. The pharmacy was clean, bright, and well ventilated. It was professional in its appearance. The pharmacy did not have a consultation room. It did not provide any services and was closed to the public. This was therefore not required. The pharmacy was secured appropriately. Unauthorised access was restricted, and people could not easily access the pharmacy. Staff had access to hand washing facilities, toilets and hot and cold running water at the other end of the registered premises.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy has effective working practices in place. It has several processes which can be easily checked to identify and verify the different stages of the pharmacy's workflow. The pharmacy obtains its medicines from reputable sources. And it generally manages its medicines adequately. But the pharmacy doesn't hold any information about people who receive higher-risk medicines. This makes it difficult for its team to show that it provides people with appropriate advice when supplying these medicines.

Inspector's evidence

The pharmacy was located on the ground floor of the building. It had several parking spaces outside its premises and within the vicinity of the building. The pharmacy was closed to the public and direct access was limited. The inspectors were also challenged on trying to enter the pharmacy. The pharmacy itself did not provide any additional services. It only assembled compliance packs onsite.

This pharmacy held lists of people, who required compliance packs and the details were organised by 'spoke'. Staff at the 'spokes' were responsible for identifying who needed a pack. They ordered people's prescriptions on their behalf and once received, they were labelled through the pharmacy system, clinically checked and the details which had been inputted through the 'spoke's' system were then checked for accuracy by the 'spoke' team. A stamp was used on prescriptions as a verifiable audit trail. This helped determine who had clinically and accuracy checked the details. Once these stages had been completed, the file was available for this pharmacy, the hub to access (via a specific software). The manager or the pharmacist at this pharmacy used the prescription, backing sheet and the MAR (medication administration record) to first cross-reference and check that the details had been inputted correctly. Another specific log was used here to record any specific errors identified.

This pharmacy operated a 'three-strike' policy. If on three separate occasions, it had been identified that any of the 'spokes' had made errors or mistakes, they would no longer be able to have their compliance packs dispensed at the hub. These changes had been implemented following the previous inspection. This process meant that the hub was not dependent on the 'spoke' pharmacy inputting the correct details and had verifiable systems in place to help identify errors. The manager said that by implementing this process, this had helped reduce the number of errors being made by the 'spokes'. A branch error report was subsequently completed and sent to the area managers. The pharmacy manager also held a conference call twice a week to feedback concerns or any issues identified.

In addition to these measures, there were further audit trails completed. A medicines compliance support form was completed in-house and fed back to the person's GP if issues were seen. Each of the 'spokes' also filled out in-house audit trails and sent the hub lists of people requiring compliance packs. The manager or the RP completed another log where these details were checked, as described under Principle 1.

Once the paperwork and details had been verified, staff at the hub then scanned each person's details into the automated dispensing system (the robot) to start preparing the compliance packs. After the compliance packs had been filled with the required medicine(s), they were removed, unsealed at this point, and placed into specific slots to one side of the machine on a workbench. The compliance pack

was then checked for accuracy by dispensing staff and additional medicine(s), if required were added in by hand at this stage before the pack was sealed and passed to the RP or manager for the final check. The compliance packs were not left unsealed overnight. The team used baskets to hold each person's compliance pack once it had been prepared, checked, and sealed.

The pharmacy hub did not supply compliance packs that contained CDs, fridge items, externals or medicines required separately. This also included any, where medicines required changing mid-cycle. Compliance packs with any of these medicines or for people who were more unstable with their medicines, were prepared at the 'spokes'. Staff at the pharmacy hub were responsible for inputting descriptions of the medicines. Once staff generated the backing sheets, there was a facility on them which helped identify who had been involved in the dispensing process. Team members routinely used these as an audit trail. Staff also used various lists of patients as checklists and they had kept audit trails to identify who had helped assemble the packs, checked them for accuracy as well as when they had been delivered.

The pharmacy provided accurate images and descriptions of the medicines that were inside the compliance packs. Patient information leaflets (PILs) were supplied by the 'spoke' pharmacy and each 'spoke' had been provided with an 'A to Z' pack of PILs to provide. This was discussed at the time. The compliance packs had details of the pharmacy hub on it, but this was provided in a very small font. Making this information easier to read was advised during the inspection. All the medicines were de-blistered into the compliance packs with none supplied within their outer packaging.

Staff could identify higher-risk medicines from a list that was on display. They ensured gloves were worn when certain medicines such as finasteride were handled. Compliance packs which required higher-risk medicines like warfarin were provided separately and therefore prepared at the 'spokes'. The inspector was told that each 'spoke', or pharmacy was responsible for counselling people, asking about relevant parameters, and obtaining this information. The SI described implementing 'pharmacist checking forms' at the screening stages in the 'spoke' pharmacies to help staff to identify when pharmacist intervention or counselling was required. The manager was asked to test this, he was able to download reports of people who had received higher-risk medicines such as lithium inside compliance packs that had been prepared at the hub and sent to individual pharmacies to be collected. On accessing people's records, no specific counselling details had been recorded. The RP said that she called pharmacies sometimes about any relevant points that required checking or counselling. However, there were no documented details seen about this, the RP did not attach any additional notes about any relevant points that may have needed checking and the pharmacy itself, did not hold information about any parameters obtained such as blood tests results.

Once the compliance packs had been assembled and checked, internal checklists were used to confirm details before the compliance packs were placed inside designated containers, sealed with zip ties (so they were tamper evident) and delivered via Lexon to each individual 'spoke' pharmacy. The pharmacy had been keeping verifiable audit trails about this process. There had been no failed deliveries but on one occasion, the wrong pharmacy had received the compliance packs. This was rectified and the root cause identified as the two pharmacies having similar codes.

The pharmacy's stock was stored in an organised way. The pharmacy used licensed wholesalers such as Lexon, Alliance Healthcare and AAH to obtain medicines and medical devices. The team date-checked medicines for expiry regularly and kept records of when this had happened. Short-dated medicines were routinely identified. Medicines requiring disposal were not accepted by staff. Drug alerts were received by email and actioned appropriately. Records were kept verifying this.

However, there were numerous containers present which contained medicines that had been de-blistered into them. Most of them were labelled with the appropriate details such as the batch number, name of the product, the expiry date, manufacturer, and the date they had been de-blistered. The superintendent pharmacist explained that the manufacturer of the robot expected stock to be ready before the medicines went into the machine. Staff used de-blistering machines to remove medicines from the blisters or the original packaging and placed them into individual containers. The pharmacy had, in response to the last inspection, moved away from the manufacturer's suggestion and moved to on-demand dispensing. The inspector was told that medicines de-blistered in this way were used within a two-week period. However, there were containers present indicating that some medicines had been present since February or April this year. They were removed at the time and the manager confirmed that they would not have been used, staff would have identified this before the medicines had been placed into the robot. He was advised to ensure the stock was regularly and visually spot-checked. The pharmacy's high use of this practice was also discouraged. De-blistering medicines in this manner meant that the pharmacy was no longer storing the medicines inside its original packaging and under the optimal conditions. This could impact the medicine's overall stability and efficacy. A discussion was held about obtaining stability data, as far as possible and marking this information, directly onto the containers.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment and facilities it needs to provide its services safely. Its equipment is kept clean, serviced appropriately, and used in a way which protects people's private information.

Inspector's evidence

The pharmacy had a suitable range of equipment and facilities. This included reference sources, machines to de-blister the medicines, scales, an automated dispensing robot, a shredder which was located upstairs and a fridge. The latter was not used to store anything as the pharmacy did not stock or supply any medicines that required cold storage. The equipment looked new and was kept clean. Portable appliance testing (PAT) had been carried out in September 2020. The robot was serviced every month, the pharmacy's cell count log was checked at this point and the system adjusted accordingly. The team also had access to local technical support. The pharmacy had a back-up generator which assisted in the event of power failures. The manager explained that the robot had never broken down, but on one occasion, the team had seen it operate on low power, before the pharmacy's generator kicked in. The pharmacy did not supply any reconstituted medicines so there was no dispensary sink but hand washing facilities were available. Computer terminals were positioned in a manner that prevented unauthorised access. They also had fingerprint access to help maintain access control.

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.