General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Karepack Bucks, Unit 8, Riverside Business Centre, Victoria Street, High Wycombe, HP11 2LT

Pharmacy reference: 9011662

Type of pharmacy: Internet / distance selling

Date of inspection: 24/07/2023

Pharmacy context

This is a pharmacy which is closed to members of the public and provides its services at a distance. It is in High Wycombe, Buckinghamshire. The pharmacy has an NHS contract and an online presence https://karepack.com/. It only supplies medicines to people in residential care homes. The pharmacy does not sell medicines over-the counter. And it does not provide any other services.

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 is not identifying and managing all the risks associated with its services under the relevant failed standards and Principles below. The pharmacy's standard operating procedures (SOPs) are not fit for purpose, they are not specific to the nature of the business, some SOPs which are necessary to support the service as well as relevant details within them are missing. They do not provide sufficient guidance to the team on how to carry out tasks correctly and staff are therefore not working in line with them.
		1.2	Standard not met	The pharmacy does not have a robust process in place to manage and learn from incidents. There is no evidence that the team has been routinely recording details about incidents or near misses. There is no evidence of remedial activity taking place and no processes in place to learn, or identify trends and patterns in response to mistakes.
		1.3	Standard not met	Not all of the pharmacy's team members fully know or understand their role(s) or the activities that can take place in the absence of the responsible pharmacist (RP).
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 not all met	4.4	Standard not met	The pharmacy does not have the appropriate procedures in place to raise concerns when medicines or medical devices are not fit for purpose. The pharmacy does not receive any details about the drug alerts issued by the Medicines and Healthcare products Regulatory Agency. Team members therefore cannot fully demonstrate that they have actioned the drug alerts appropriately.
5. Equipment	Standards	N/A	N/A	N/A

Principle	Principle finding	Exception standard reference	Notable practice	Why
and facilities	met			

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy doesn't effectively identify and manage all the risks associated with its services. The pharmacy has unsatisfactory procedures in place to help guide its team members and team members are not always following them. This is because the pharmacy has not made its written procedures specific to the nature of its business. The pharmacy's team members do not fully understand some aspects of pharmacy law. The pharmacy is unable to demonstrate that its team members record all their mistakes or learn from them. But the pharmacy protects people's private information appropriately and generally maintains its records as it should.

Inspector's evidence

This is a new pharmacy which had only been operating for the past three months. Two inspectors were present. Members of the pharmacy team were up to date with the workload. The service provided to the care homes was observed to be efficiently provided and managed well. However, there were several concerns seen.

Team members knew their roles and responsibilities. They had designated tasks and the correct notice to identify the pharmacist responsible for the pharmacy's activities was on display. There were also service level agreements between the pharmacy and the care homes to define the relationship and terms between them. A set of standard operating procedures (SOPs) were available to view electronically. However, they were insufficient to support the provision of the pharmacy's services. The SOPs were not specific to the nature of the pharmacy's business. They did not match the pharmacy's internal processes. For example, the SOP to cover deliveries did not detail the pharmacy's process of handing medicines to care homes and the pharmacy's process for drug alerts stated that the NHS hospital would cascade them to relevant departments. There were also no details on them to indicate when they had been implemented, when they were due for review, who the superintendent pharmacist or person responsible for them was, and no indication that staff had read or signed them. The inspectors were told that the pharmacy team had read them, but the responses given by some members of the team did not verify or confirm that this was the case.

In addition, some relevant SOPs were missing, such as safeguarding, (see below) and the SOP to support the supply of medicines to residential care homes. Some details within the SOPs were also insufficient. This included the SOP covering the absence of the responsible pharmacist (RP). The latter did not cover what staff could or could not do in the absence of the RP and what team members should do if the RP failed to arrive first thing in the morning. Consequently, some staff stated that they would prepare, process, and dispense prescriptions if the RP failed to arrive.

The SOPs were therefore not fit to provide guidance for the team to carry out tasks correctly. The inspectors were told that the SOPs were being reviewed by an external company, however, this was unsatisfactory given that registered pharmacies are expected to meet the GPhC's standards from the first day of trading. This includes ensuring that a set of suitable SOPs are present.

In addition, the inspectors did not see any completed risk assessments to identify, manage or mitigate the risks associated with the pharmacy's services and staff were unsure if any had been done. There was therefore no evidence that the pharmacy had addressed or mitigated the risks involved when

providing services to care homes. This was therefore, not in line with the GPhC's 'Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet'.

The pharmacy had some systems in place to identify and manage risks associated with its services but some areas for improvement were also identified. The dispensary was clean, clear of clutter and had segregated areas to process prescriptions as well as for storage. Staff worked on one care home at a time and were responsible from start to finish for processing and dispensing prescriptions for their designated care home. The pharmacy's stock was also clearly highlighted. Every care home had a different start date, this, along with a noticeboard helped the team to schedule and manage the workload. In addition, the strategy and operations lead explained that he had suggested, and the pharmacy had subsequently begun to trial a new ticketing system. This was to help manage and monitor queries more effectively. A task manager platform had been implemented where during the pharmacy's checks for discrepancies, if any issues were noticed, staff could log the relevant details onto this platform. The task would then stay on the portal until the situation had been resolved which provided an additional audit trail.

There had been no dispensing incidents or complaints at the point of inspection. The responsible pharmacist's (RP) process to manage incidents however, lacked some key actions. For example, if a person had inadvertently taken an incorrectly dispensed medicine, even after some prompting by the inspectors, the RP did not know, or realise that the person's GP would need informing. The manager said that staff normally recorded their near miss mistakes. However, team members stated that the pharmacist recorded them and informed them when they occurred. They described separating tablets and capsules including ensuring effervescent formulations were clearly segregated from other forms. On checking the near miss records, no details had been recorded. The RP confirmed that she hadn't been recording them but said that she informed the team when they took place. There were also no details seen to verify that mistakes had been reviewed, whether contributory factors had been identified, or the learning and action taken. This meant that there was no evidence that the near misses had been formally identified, reviewed, any trends or patterns identified, or that any remedial action had been taken in response. There was therefore no evidence that the pharmacy was currently and routinely identifying its mistakes or learning from them. In addition, as per above, the pharmacy's SOP also stated that staff had weekly and monthly meetings about this which had not been taking place.

Team members were trained to protect people's confidential information. Confidential material was stored and disposed of appropriately. The pharmacy's computer systems were password protected and staff used their own NHS smart cards to access electronic prescriptions. Some documented details about data protection were available to provide guidance to the team. There were, however, some concerns noted with the pharmacy's ability to safeguard vulnerable people. The RP was trained to level 2 through the Centre for Pharmacy Postgraduate Education (CPPE). One team member from the company's other pharmacy knew what this term meant and described attending an in-house meeting where they were provided with relevant details. Other staff initially were unable to inform the inspectors about this and described health and safety concerns or injuries, but later said that they remembered and described being vigilant for signs of domestic abuse. There were, however, no contact details present for the relevant agencies if concerns required escalating and no SOP to provide guidance to the team about this.

The pharmacy's professional indemnity insurance arrangements were valid until 13 December 2023. Some of the pharmacy's records were compliant with statutory and best practice requirements, others required improvement. A sample of registers were inspected for controlled drugs (CDs). On randomly selecting CDs held in the cabinet, their quantities matched the stock balances recorded in the corresponding registers. Records verifying that fridge temperatures had remained within the required

range and records of unlicensed medicines had been completed appropriately. However, the RP record kept electronically had some details missing where pharmacists had not recorded the time that their responsibility ceased.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely. Members of the pharmacy team are trained through accredited routes. But they have gaps in their knowledge. And the pharmacy only has limited resources to help keep the team's skills and knowledge up to date. This could affect how well they carry out tasks and adapt to change with new situations.

Inspector's evidence

Staff at the inspection included a locum pharmacist, the strategy and operations lead who was also a trained dispenser, four trained dispensing staff, one of whom was the manager and another who usually worked at the company's other pharmacy, as well as admin staff who dealt with queries. There was also a delivery driver. The locum pharmacist and superintendent pharmacist usually provided pharmacist cover and there was also an apprentice. The pharmacy had enough staff to support the workload and the team was up to date with this. The manager as knowledgeable about the pharmacy's internal processes and the staff were seen to work independently of the pharmacist.

Members of the pharmacy team were fully trained through accredited routes for the role(s) they carried out. However, there were gaps in their knowledge as described under Principle 1. Some team members described meetings being held when they worked at the company's other pharmacy where training was delivered. However, this had not yet been implemented here and there was no structured framework or formal resources provided for ongoing training. This could make it harder for the team members to keep their knowledge and skills up to date.

The superintendent pharmacist was described as open and approachable. Staff communicated verbally or via email with the company's other pharmacy, they also had team meetings and were able to feedback suggestions as per the ticketing system described under Principle 1.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are generally suitable for the provision and delivery of its services. The pharmacy has enough space to manage its workload. And it is secure against unauthorised access. But parts of the premises are cluttered.

Inspector's evidence

The pharmacy premises consisted of a large dispensary, an office, a meeting room, staff areas at the very rear and one room which was completely filled with miscellaneous items such as large vases and carpets. The same vases were also stored in other rooms on the pharmacy premises which detracted from the overall professional look and feel of the pharmacy. Staff stated that this was the pharmacy owner’s personal property. The dispensary was large and had enough space to prepare and process prescriptions as well as to store medicines. The pharmacy was clean. Some of the fixtures and fittings in the premises were dated, but the pharmacy was suitably bright, appropriately ventilated, and clean. It was also secured against unauthorised access.

The pharmacy had its own online website (https://karepack.com/). This website gave clear information. It displayed information about the pharmacy’s opening times, the pharmacy's contact details, specific information about the SI and GPhC registration information. At the point of inspection, details about the pharmacy’s complaints procedure were missing.

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

Summary findings

The pharmacy cannot show that it routinely deals with safety alerts appropriately. And the pharmacy's team members are not identifying people who receive higher-risk medicines or making the relevant checks. But the pharmacy obtains its medicines from reputable sources, it stores and manages them appropriately. And it has efficient processes in place to ensure medicines are suitably dispensed and delivered to the residential care homes.

Inspector's evidence

Team members spoke several languages such as Arabic, Gujarati, Punjabi, Cantonese, and Portuguese. This meant that they could assist people whose first language was not English. Staff described liaising with next of kin or representatives if needed and dispensing labels could also be printed with a larger font size if needed to assist people who were partially sighted.

The team used baskets to hold prescriptions and medicines during the dispensing process. This helped prevent any inadvertent transfer between them. Once staff generated the dispensing labels, there was no facility on them to help identify who had been involved in the dispensing process. However, the pharmacy's internal dispensing system recorded who had processed each prescription, each staff member was responsible for processing and dispensing medicines for the same care home. This system was therefore used as an audit trail.

Medicines were mostly supplied to the care homes as original packs and for a few people, de-blistered into multi-compartment compliance packs. The care homes ordered prescriptions for their residents and the pharmacy was copied into these requests. Admin staff at the pharmacy checked for any discrepancies or errors. An audit trail about missing items was maintained and monitored by the admin team. The pharmacy used a specific electronic integrated processing system which generated electronic medication administration records (MARs). Details about allergies and sensitivities were included. In addition, specific checks by staff and the pharmacist were embedded into the pharmacy's working practices when they processed and accuracy-checked prescriptions using this system. The care homes were supplied with a file containing patient information leaflets (PILs), which was checked when they were audited by the pharmacy and updated annually. Staff had not been approached to provide advice regarding covert administration of medicines to care home residents. Interim medication was not always supplied by the pharmacy. However, staff liaised with local pharmacies and the care homes to ensure the medicine(s) were received. They therefore had access to the relevant details.

The pharmacy supplied medicines inside multi-compartment compliance packs to a few people in the residential care homes. The team identified any changes that may have been made, any queries were checked with the prescriber and the records were updated accordingly. The compliance packs were sealed as soon as they had been prepared and not left open overnight. Descriptions of the medicines inside the packs were provided, and PILs were routinely supplied.

The pharmacy delivered dispensed prescriptions to the care homes. Two members of staff packed the dispensed prescriptions once they were ready. The manager explained that they used the delivery sheets, read each resident's name, and ticked when their medicines were placed inside the box to be taken by the driver. They also checked for extra bags. There were records available to demonstrate

when medicines had been delivered to the care homes. CDs and fridge items were identified, there was a separate audit trail used for delivering CDs and the driver used an ice pack for refrigerated items. He also logged the temperature if his route was further away from the pharmacy. Failed deliveries were brought back to the pharmacy and staff at the care homes were called to inform them of the attempt made to deliver the medicines. No medicines were left unattended.

Staff were aware of the additional guidance when dispensing sodium valproate and the associated Pregnancy Prevention Programme (PPP). They ensured the relevant warning details on the packaging of these medicines were not covered when they placed the dispensing label on them. At the point of inspection, no one in the at-risk group had been supplied this medicine. However, there was no educational material available to provide to people upon supply of this medicine, if required. Additionally, staff were not routinely identifying prescriptions for other higher-risk medicines, they did not ask relevant questions or request specific details about people's treatment from the care homes nor did they record this information.

The pharmacy used licensed wholesalers to obtain medicines and medical devices. Medicines were stored in an organised way. The team checked medicines for expiry regularly and kept records of when this had taken place. Short-dated medicines were routinely identified. Fridge temperatures were checked daily. Records verifying this and that the temperature had remained within the required range had been appropriately completed. Out-of-date and other waste medicines were separated before being collected by licensed waste collectors. Medicines which were collected by the driver from the care homes and returned to the pharmacy for disposal, were accepted by staff, and stored within designated containers. Details about the necessary waste licence for this activity was seen. This did not include sharps or needles which were referred elsewhere. However, some team members did not know which CDs when returned for disposal could be destroyed at the pharmacy.

The manager said that drug alerts and product recalls were received through the superintendent pharmacist, and they went direct to her or to the other pharmacy owned by the same company. There was no documented information present to verify receipt of the recalls, and staff could not describe the appropriate process to follow. Nor were details being passed to the care homes for them to make any necessary checks. The pharmacy therefore could not show that it had taken the appropriate action in response to affected batches of medicines.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has a sufficient range of equipment and facilities available. Its equipment is suitably clean. And used in an appropriate way to help protect people's personal details.

Inspector's evidence

The pharmacy was equipped with relevant equipment. This included counting triangles, standardised conical measures, a pharmacy fridge, legally compliant CD cabinet and a clean sink that was used to reconstitute medicines. Hot and cold running water was available as well as hand wash. Staff could store their personal belongings inside lockers. The pharmacy's computer terminals were positioned in a way and location that prevented unauthorised access. The team also had cordless phones available and telephones in other rooms so that private conversations could take place away from the main dispensary if needed.

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.