General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: New Health Supplies Ltd, Unit 5, Archdale Business Centre, Brember Road, Harrow, HA2 8DJ

Pharmacy reference: 9011219

Type of pharmacy: Internet / distance selling

Date of inspection: 11/01/2023

Pharmacy context

This is a pharmacy which is closed to the public, provides its services at a distance and is on an industrial estate in Harrow, Greater London. The pharmacy provides and delivers medicines inside multi-compartment compliance packs for people who live in residential care homes. The pharmacy also has a Wholesale Distribution Authorisation (WDA); this activity is regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).

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. The pharmacy does not have the full range of standard operating procedures (SOPs) in place to provide effective guidance to its team members. There is no evidence that all of the current team has read the pharmacy's SOPs.
		1.2	Standard not met	The pharmacy team does not have a robust process in place to continually assess, review or monitor the safety and quality of the pharmacy's services. Staff are not routinely recording all the details about near-miss mistakes, and there is limited evidence of review, remedial activity or learning occurring in response to mistakes.
		1.3	Standard not met	The pharmacy's team members do not fully know or understand their role(s) or the activities that can take place in the absence of the responsible pharmacist (RP). The team has been opening and running the pharmacy in the absence of the RP. The superintendent pharmacist does not fully understand her role or accountability in ensuring the safe and effective running of the pharmacy.
		1.7	Standard not met	The pharmacy is not fully protecting the privacy, dignity and confidentiality of people who receive its services. There is no specific guidance for the team on data protection. Members of staff are also using other people's NHS smart cards and share passwords.
		1.8	Standard not met	The pharmacy has no procedures to safeguard the welfare of vulnerable people. There is no SOP to provide guidance to the team, staff cannot demonstrate how to safeguard the welfare of vulnerable people and there are no local contact details of relevant agencies if concerns require escalating.
2. Staff	Standards	2.2	Standard	The pharmacy team does not have the

Principle	Principle finding	Exception standard reference	Notable practice	Why
	not all met		not met	appropriate skills, qualifications and competence for their role and the tasks they carry out. The pharmacy is not meeting the GPhC's 'Requirements for the education and training of pharmacy support staff' as all the members of the pharmacy's current team have been working at the pharmacy for longer than three months and are undertaking tasks without being enrolled on accredited training appropriate for this. This includes the pharmacy owners.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.3	Standard not met	The pharmacy's management of its medicines is inadequate. The pharmacy does not have any documented or electronic procedures in place to provide guidance on how to manage the pharmacy's stock. Team members cannot show that they have been consistently checking medicines for expiry. Significant quantities of medicines are present as loose blisters or poorly labelled when removed from their original containers.
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 fully identify and manage the risks associated with its services. It does not have a sufficiently wide range of procedures in place to help guide its team on all the pharmacy's activities. The pharmacy's team members do not fully understand some aspects of pharmacy law. The pharmacy does not adequately protect people's private information. And team members do not understand their role in safeguarding vulnerable people. But the pharmacy generally maintains its records as it should.

Inspector's evidence

The pharmacy had documented standard operating procedures (SOPs) in place to provide guidance to the team about the services it provided. The staff said that they had read and signed them, and the SOPs seen were specific to the nature of the pharmacy's business. However, they had no date on them to indicate when they had been implemented or were due for review, no details of the superintendent pharmacist and no details to define the team's roles or accountabilities. So, it was unclear which members of the team the procedures were meant for. In addition, there was no sign-off sheet or signatures to verify that the team had read and signed them. They also did not include the full range of SOPs covering the pharmacy's activities such as those providing guidance about the pharmacy's incident management and complaints process, information governance, safeguarding the welfare of vulnerable people or date-checking.

The correct notice to identify the pharmacist responsible for the pharmacy's activities was on display. Whilst the main dispensing assistant was knowledgeable about his role and observed to be competent at what he did, staff lacked knowledge on the activities that could take place in the absence of the responsible pharmacist (RP). As the pharmacy's workload varied on a regular cycle, the inspector was told that if the pharmacy had no medicines or prescriptions to prepare for the care homes, there would be no RP present for the whole day, but the pharmacy remained open. Staff still put stock away, dealt with queries, picked stock, assembled prescriptions by generating labels and dispensed prescriptions during this time. Some of these activities however, required an RP to be present and to be in charge of the premises (although they could be absent for up to two hours). The superintendent pharmacist was present during the inspection, she also lacked key understanding about her role versus the RP and her overall accountability. The pharmacy's practice was discussed at the time. Team members were advised to seek further guidance, advice was given as well as an

assurance obtained that this practice would not continue. The repercussions of doing so, were also discussed. The inspector noted that team members were very open and honest. They said that they had very recently been talking about this situation. It was clear that they had not sought to deceive the inspector at any point and this practice appeared to be occurring because the team required further training on this aspect of pharmacy law (see Principle 2).

Staff had their own set tasks and responsibilities. They worked in different areas and the RP checked the multi-compartment compliance packs from a separate area. This helped minimise distractions and ensured mistakes could be easily found. There was some evidence that near miss mistakes were recorded but only limited details were present. The last records were from 2021 and May 2022. Staff said that there had been no mistakes made since then. As the pharmacy was closed to the public, there were fewer distractions, and a lower likelihood of mistakes occurring because the team could effectively concentrate more easily. However, there were missing details in the near miss records such

as the next steps taken. There was also no evidence of a monthly or formal review taking place. The team confirmed that the pharmacy had not had any dispensing incidents or received any complaints. The RP's process to manage incidents was suitable. However, there was no documented policy or procedure in place, either written or electronic, for people to learn from their mistakes. There was no complaints policy either.

The pharmacy had some processes in place to protect people's confidential information. There were no sensitive details left in the premises that could be seen from the warehouse. Computer systems were password protected and confidential waste was shredded. However, as described above there were no documented or electronic processes in place to provide guidance to the team on protecting people's private details. Team members were also using other people's NHS smart cards to access electronic prescriptions. Two people's NHS smart cards had been left within a computer terminal and were being used at the inspection despite these members of staff not being on the premises at the time and their passwords were known. This limits the pharmacy's ability to control access to people's private information. Staff had not been trained to safeguard the welfare of vulnerable people. There was no SOP about this, no contact details available for the local safeguarding agencies or for the areas that the pharmacy provided compliance packs to. And the level to which the RP had been trained on this was also unclear, she described attending a 'PCT event' in the past.

The pharmacy's records were mostly compliant with statutory and best practice requirements. This included a sample of registers seen for controlled drugs (CDs). On randomly selecting CDs held in the cabinet, their quantities matched the stock balances recorded in the corresponding registers. Records of CDs that had been returned by people and destroyed at the pharmacy were kept. The pharmacy had suitable professional indemnity insurance arrangements in place. This was through the National Pharmacy Association (NPA) and due for renewal after 11 May 2023. Records verifying that fridge temperatures had remained within the required range had been appropriately completed. The pharmacy had not supplied any medicines against private prescriptions nor made any emergency supplies. However, some records about supplies of unlicensed medicines lacked key details. This was discussed at the time.

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

Summary findings

The pharmacy allows some members of its team to carry out tasks that they are not trained for or qualified in. And it does not provide enough resources to help keep its team members' skills and knowledge up to date. This could affect how well they carry out tasks and adapt to change with new situations. But the pharmacy does have enough staff to manage its workload. And its team members work well together.

Inspector's evidence

The pharmacy's team members consisted of two regular, part-time pharmacists, one of whom was the superintendent, two dispensing assistants and two non-pharmacy professional owners. One of the dispensers was full-time, the rest of the team worked part-time. The full-time dispenser was a qualified pharmacist from India and had been working in a dispensing capacity since 2020. The owners also occasionally helped dispense, deliver medicines or provide contingency cover. There was enough staff to manage the pharmacy's workload and the team was up to date with this. However, at the point of inspection none of the team had been enrolled onto the appropriate accredited training in line with their roles. This was therefore not in line with the GPhC's 'Requirements for the education and training of pharmacy support staff' which specifies that support staff must be enrolled on a training course as soon as practically possible and within three months of starting their role.

They were a small team, communicated verbally and regularly discussed things with one another. It was clear that they liked working at the pharmacy. They were also observed to be open and honest about their working practices with the inspector, acknowledging their shortcomings and willingness to learn. The pharmacy did not have a formal or ongoing training programme to keep the team informed about new developments. Advice about this was provided at the time. The team's progress was monitored informally.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are secure and suitable for the activities the pharmacy undertakes. The pharmacy has enough space to deliver its services safely. And the premises is sufficiently clean.

Inspector's evidence

The pharmacy premises were located inside a warehouse unit and consisted of a long room with staff areas and WC. The pharmacy was kept clean, ventilated and bright. There was enough space in the dispensary to prepare medicines. However, benches here were cluttered and full of baskets or paperwork. Most of this was work in progress and staff explained that they usually kept the dispensary much clearer. This was discussed at the time. 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 access the pharmacy without team members being present.

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

Summary findings

The pharmacy does not satisfactorily manage its stock. It does not have a robust enough process to adequately demonstrate that its team routinely checks expiry dates of medicines. And that it stores medicines appropriately. The pharmacy maintains its records appropriately and sources its medicines from reputable suppliers.

Inspector's evidence

The pharmacy was located on the first floor of the warehouse unit. It had some parking spaces outside the warehouse, but the premises was closed to the public, so access was limited. The pharmacy predominantly provided medicines to people in residential care homes. They were supplied inside different forms of multi-compartment compliance packs. The care homes ordered their own prescriptions which were then sent electronically to the pharmacy. The team identified any changes that may have been made, maintained records to reflect this and queried details if required. All the medicines were de-blistered into the compliance packs with none supplied within their outer packaging. Descriptions of the medicines inside the compliance packs were provided for some packs but not for others and patient information leaflets (PILs) were regularly supplied. There had been no requests made to administer medicines covertly and no residents currently receiving higher-risk medicines. Medication Administration Records (MAR charts) were routinely provided. They contained details of the administration, allergies and pictures of the residents to enable easy verification. The pharmacists also routinely completed audits at the care homes.

There was an established workflow in place and a notice board highlighting which weeks certain care homes were due. This helped ensure the team could work effectively to deadlines. The workflow involved prescriptions being prepared in one area, the RP checked medicines for accuracy from another section. The team used baskets to hold prescriptions and medicines during the dispensing process. This helped prevent any inadvertent transfer between them. After the staff had generated the dispensing labels, there was a facility on them which helped identify who had been involved in the dispensing process. Team members routinely used this as an audit trail.

Once the compliance packs had been assembled, checked, and packed, one of the owners delivered them to the care homes. The pharmacy used in-house, documented checking processes to ensure they had the required packs and number before delivering. The pharmacy had been keeping verifiable audit trails about the delivery process. There had been no failed deliveries as there were always staff present at the care homes to accept medication and they knew when to expect delivery.

The pharmacy used licensed wholesalers such as AAH, Alliance Healthcare, Colorama and Sigma to obtain medicines and medical devices. The superintendent pharmacist described date-checking medicines for expiry regularly and short-dated medicines were identified. There were no date-expired medicines or mixed batches seen. Although the team described date-checking medicines for expiry regularly, there were no SOPs to guide the team on this activity and no records to help demonstrate how often this took place. And there were several containers present which had medicines that had been de-blistered into them. They were not always labelled with the correct details such as the batch number, name of the product and the expiry but some had full details. This was discussed at the time. The pharmacy's high use of this practice is discouraged. De-blistering medicines in this manner meant

that the pharmacy was no longer storing the medicines inside their original packaging and under the optimal conditions. This could impact the medicine's overall stability and efficacy. In addition, there were also significant numbers of loose blisters present.

CDs were stored under safe custody. Medicines returned for disposal, were accepted by staff, and stored within designated containers, except for sharps or needles which were referred appropriately. Drug alerts were received electronically or through wholesalers and actioned appropriately. Records were kept verifying this. Medicines returned for disposal from the care homes were collected and brought back to the pharmacy, but the pharmacy did not hold a waste licence to enable staff to transport this.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment and facilities it needs to provide its services safely. And its equipment is kept clean.

Inspector's evidence

The pharmacy was equipped with an appropriate range of facilities and equipment. This included current reference sources, a shredder, a legally compliant CD cabinet and appropriately operating pharmacy fridges. The equipment was clean and maintained appropriately. Computer terminals were password protected and positioned in a manner that prevented unauthorised access.

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.