General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Delivery Pharmacy, 25 Coton Road (Second Floor), NUNEATON, Warwickshire, CV11 5TW

Pharmacy reference: 1098223

Type of pharmacy: Internet / distance selling

Date of inspection: 06/02/2020

Pharmacy context

This is a closed pharmacy in Nuneaton, Warwickshire that provides its services from a distance. The pharmacy dispenses NHS and private prescriptions. It delivers medicines to people's homes, supplies medicines to residents in a care home and provides multi-compartment compliance packs to people if they find it difficult to take their medicines on time. The pharmacy also has an online website from where people can buy over-the-counter medicines through a separate company.

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 risks associated with providing pharmacy services are not appropriately identified and managed. There is evidence that a mistake has happened because of this as described under Principle 4 and the pharmacy has not handled this incident appropriately. It has weak governance procedures in place. And it has no risk assessments or audits completed to verify that the services that it provides at a distance are safe.
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 robust procedures in place to raise concerns when medicines or medical devices are not fit for purpose. There is evidence that people's safety has been compromised by failing to act or raise concerns about medicines that have been recalled. The pharmacy is not receiving all of the drug alerts issued by the Medicines and Healthcare products Regulatory Agency. And it cannot demonstrate that it has actioned the drug alerts appropriately.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy doesn't effectively identify and manage risks associated with its services. In the absence of supporting information, the pharmacy is limited in demonstrating that it has assessed the risks associated with the services that it provides. And the team does not always handle incidents in line with its written instructions. The pharmacy's team members do understand how to protect the welfare of vulnerable people. And the pharmacy adequately maintains most of its records, in accordance with the law. But some records don't have enough details recorded. This means that team members may not have all the information they need if problems or queries arise.

Inspector's evidence

The pharmacy's inspection was triggered by a complaint that had been made to the General Pharmaceutical Council (GPhC). The pharmacy held a range of documented standard operating procedures (SOPs) to support its services; they were marked as reviewed in 2018. Staff had read and signed them except for the responsible pharmacist (RP) who stated that she had read them. The team's roles and responsibilities were not routinely defined within them although staff understood their roles and knew the activities that were permissible in the absence of the RP. However, the SOPs were a generic set, produced by the particular company. In line with the GPhC's guidance for registered pharmacies providing services at a distance, including the internet, there were no risk assessments seen and no details seen recorded or information about any audits for the services that were provided at a distance. The pharmacy did not have an SOP that matched the procedure involved for the online sales of medicines through a third party (see Principle 3).

The pharmacy was generally quite organised. There was an adequate amount of work space available to dispense prescriptions and separate areas for prescriptions to be processed, assembled and accuracy-checked by the RP. The workflow and each of the different stages were laid out so that the processes flowed around the pharmacy in a circular motion with easy access to medicines. This helped to prevent errors. In addition, more than one member of staff was involved in the various processes which helped identify errors. There were also caution notes on the shelves which highlighted look-alike and sound-alike (LASA) medicines.

The pharmacy had processes in place to record and learn from internal mistakes. However, the team had not always followed them or in some instances, it could not be verified that they had. Staff and the RP recorded near misses. They were described as reviewed every week and month with records retained by the pharmacy downstairs. However, there were gaps where details of who had dispensed or checked the medicine(s) involved had not been recorded. Only a few near misses were seen recorded for the last month and despite being asked a few times to provide details of the monthly reviews and previous records, no details were located or brought to the attention of the inspector. This limited the ability of the team to demonstrate that appropriate action had been taken to mitigate risks in the dispensing process and learn from mistakes.

The pharmacy held a documented complaints process and the RP described handling incidents by assessing the level of harm, investigating and resolving the situation. However, the pharmacy's website held no details about its complaints process which could make it difficult for people to raise their concerns easily. In addition, an incident had been brought to the attention of the pharmacy as well as

to the GPhC in January 2020. This involved a recalled product that had been supplied to a care home resident. There had been no details documented about this (see Principle 4). This was not in accordance with the pharmacy's SOP for handling incidents. The RP explained that a letter about the situation had been sent to the care home manager but a copy of this had not been retained at the pharmacy to verify. In response to the incident, the RP stated that she had advised the care home about where they could obtain information about drug alerts and staff had been briefed about the situation. The incident report was completed after the inspection and a copy of the letter forwarded to the inspector.

Confidential information was contained within the pharmacy and confidential waste was separated before it was shredded or taken to another one of the pharmacy's branches to be disposed of. However, there was no information on the website to provide information about how the pharmacy protected people's private information. The owners NHS smart card to access electronic prescriptions had also been left within a computer slot in the dispensary. His PIN number was included on the card which made it easy for anyone to readily access information that needed to be kept more secure. Staff stated that he had been present first thing, but his card had not been removed when he had left. The team had then continued to access the system with this. Staff were trained to safeguard the welfare of vulnerable people. The RP was trained to level 2 via the Centre for Pharmacy Postgraduate Education. The team could readily access contact details for the local safeguarding agencies.

The correct responsible pharmacist (RP) notice was on display and this provided details of the pharmacist in charge on the day. The pharmacy's professional indemnity insurance was through the National Pharmacy Association (NPA) and due for renewal after 25 February 2020. The team kept daily records of the minimum and maximum temperatures for the fridge and this verified that temperature sensitive medicines were stored appropriately. Records for emergency supplies, private prescriptions and controlled drugs (CDs) in general, were maintained in line with the legal requirements. The occasional crossed out entry was seen in the latter without the appropriate amendment being made. Records for unlicensed medicines were sometimes missing prescriber details and the electronic RP record had gaps where pharmacists had failed to record the time that their responsibility ceased.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely. Most of the team is trained and suitably qualified. And team members are provided with some resources to help keep their skills and knowledge up to date.

Inspector's evidence

At the time of the inspection, staff present included the RP, who described herself as a second pharmacist although the superintendent pharmacist (SI) and owner stated that she was the pharmacy manager. The SI was the RP for the pharmacy situated on the ground floor of the building and was seen at the beginning as well as at the end of the inspection. There were three dispensing assistants present. Two of the latter had been trained through accredited routes, the third was also the delivery driver and had recently started undertaking dispensing activities (since December 2019). The latter described other members of the team processing prescriptions and selecting stock into baskets before she assembled the medicines into multi-compartment compliance packs. Ensuring this member of staff was enrolled onto the appropriate accredited training within three months of her commencing this role was discussed at the time.

Staff wore name badges. Their certificates to verify the qualifications obtained were not seen. Contingency cover could involve staff rotating from the company's other branch which was located downstairs. To assist with training needs, staff described using booklets and online resources. The use of other resources which would provide a more structured approach to ongoing learning was discussed at the time. They were a small team, so they could communicate verbally. There was also a noticeboard present in the pharmacy to provide relevant information as well as updates. Team members also left messages for one another. Formal appraisals were completed annually to monitor the team's progress.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy provides an appropriate environment to deliver its services. It has enough space to store its medicines and provide services safely. But some details on its website are missing.

Inspector's evidence

The pharmacy's premises consisted of a small but adequately sized room which extended into an office on one side. This pharmacy was located on the first floor of a building that had a pharmacy from the same company operating from the ground floor. There was shared kitchenette and WC facilities as well as a stock room that was used by the ground floor pharmacy. The same building also contained rooms that were used by a local physiotherapy clinic and people were seen on the same floor as the pharmacy. Access into the pharmacy's areas were restricted by key coded entry. The pharmacy was adequately clean, lit and appropriately ventilated. There was enough space to dispense prescriptions as well as to store stock. As the pharmacy was closed to the public and did not currently provide additional or private services, there was no consultation room on its premises.

Online activity: The pharmacy's website (https://www.deliverypharmacy.co.uk/) was checked prior to and during the inspection. A distance selling EU internet logo issued by the Medicines and Healthcare products Regulatory Agency (MHRA) was present on the pharmacy's website. On clicking this, the website directed to a page provided by the delivery pharmacy that stated a third-party provider HI Weldricks Ltd, fulfilled requests for on-line retail sales on its behalf. This was another online pharmacy and meant that all requests for sales of medicines were processed and handled directly by HI Weldricks Ltd. However, this logo did not directly refer people to the MHRA's seller registration details to help verify that HI Weldricks had the authority to supply medicines online. In addition, other than this logo, there was no other information directly available on the website to inform people about this situation. Aside from a contact telephone number for the pharmacy, there were no contact details for HI Weldricks Ltd and it was unclear for people who they were supposed to contact in the event of a query or concern associated with online sales.

The pharmacy's name, operating address and contact telephone number were present on the website at the bottom of the home page. The name of the superintendent pharmacist was also present. However, the pharmacy's GPhC registration number was included here under 'company registration' but it was unclear that this related to its GPhC registration. There was no information on the website about how people could check the registration status of the pharmacy and the superintendent pharmacist. There were also no details of how people could give feedback and raise concerns (as described under Principle 1). The RP and superintendent pharmacist were advised to familiarise themselves with the GPhC's guidance on pharmacy's providing services at a distance, including the internet to ensure they were complying with this going forward.

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

Summary findings

The pharmacy does not always provide its services appropriately. The pharmacy has not been taking the appropriate action in response to safety alerts. This risks people receiving medicines and devices that are not safe to use. And the pharmacy's team members are no longer making any checks to help people with higher-risk medicines take their medicines safely. But the pharmacy sources its medicines from reputable suppliers. And it delivers medicines to people's homes safely.

Inspector's evidence

The pharmacy was advertising its services through its website. The pharmacy's opening hours were displayed here. Staff described using representatives for people who were partially deaf, or carers and some team members spoke Urdu and Punjabi to assist in communicating with people whose first language was not English. For some people with visual impairment, medicines were also de-blistered into bottles to help them take their medicines more easily. The team used baskets during the dispensing process to hold prescriptions and medicines. This helped to prevent any inadvertent transfer. Staff routinely used a dispensing audit trail through a facility on generated labels. This helped identify their involvement in dispensing processes. After prescriptions were assembled, they were attached to bags before being delivered.

The complaint received at the GPhC was due to the pharmacy providing a batch of ranitidine effervescent tablets to a resident within a care home, that had been recalled. This had been identified by an inspection carried out by the Care Quality Commission (CQC) in January 2020. The recall was issued by the MHRA in October 2019 and the medicine had been supplied in December 2019. The RP initially stated that drug alerts were received by email, staff were described as checking stock and compiling a report of who had received this medicine so that this could be checked. On checking the pharmacy's email system, the pharmacy had its own email account and could access the email account for the pharmacy that was situated on the ground floor.

However, at the point of inspection, only the ground floor pharmacy had subscribed to the MHRA's drug alerts and this meant that some alerts may have been missed by this pharmacy and it did not hold a full audit trail. In addition, some of the emails had not been opened. The emails about recalled products were also mixed into the pharmacy's other emails rather than being moved into a separate folder. This further limited the pharmacy's ability to verify that the appropriate checks had been made. On confirming with the staff about the process involved, they stated that they did not check who had received the affected medicine but only checked for stock in the dispensary. The care home had also not been routinely provided with information about drug alerts which meant that they had been unable to check if they had received any affected batches of medicines. These points were identified by the inspector as opposed to the pharmacy team despite the concern being raised to them and an incident happening.

Licensed wholesalers such as Lexon, AAH and Alliance Healthcare were used to obtain medicines and medical devices. Staff were aware of the process involved for the European Falsified Medicines Directive (FMD); relevant equipment and software was present, and the pharmacy team had been complying with the decommissioning process where possible. Medicines were stored in an organised manner. This included the appropriate storage of medicines in the fridge. CDs were stored under safe

custody. The keys to the CD cabinet were maintained in a manner that prevented unauthorised access overnight. Staff checked expiry dates of stock every three months. They identified medicines approaching expiry and had maintained a date-checking schedule to verify when this process had taken place. There were no date-expired medicines or mixed batches of medicines seen.

The pharmacy team used designated containers to hold and dispose of medicines when they were no longer required by people. People requiring sharps to be disposed of were referred to the council. Returned CDs were brought to the attention of the pharmacist, details were noted, and they were segregated in the CD cabinet before being destroyed. However, the pharmacy did not have a waste license to enable them to transport unwanted medicines in this manner. As the pharmacy is providing a waste collection service from people's homes, it requires a license or registration as waste carriers as per the Department of Health guidance on the management and disposal of healthcare waste. This was discussed with both the RP and SI.

The pharmacy provided a delivery service and audit trails to verify this service had been maintained. CDs and fridge items were highlighted, and people's signatures were obtained once they were in receipt of their medicines. Failed deliveries were brought back to the pharmacy and a note was left to inform people about the attempt made.

Compliance packs were initiated to people after the GP requested this or the RP carried out an assessment. Prescriptions were ordered by the pharmacy for vulnerable people and when received, the details were cross-checked against repeat slips or people's records on the system and backing sheets. If any changes were identified, staff confirmed them with the prescriber. The team kept an audit trail to verify any checks that had been made. The compliance packs were not left unsealed overnight. Descriptions of the medicines within them were provided and patient information leaflets (PILs) were routinely supplied. Mid-cycle changes involved supplying the medicine(s) separately until the change could be incorporated from the next cycle.

Medicines were also supplied to the care home as compliance packs. The pharmacy ordered prescriptions on behalf of the home and obtained copies of the repeat requests once the home provided this. On receiving the prescriptions at the pharmacy, they were checked against the requests to ensure all items had been received. Information about missing items were checked with the prescriber. Interim or mid-cycle items were mostly dispensed at the pharmacy and obtaining details of the supply when this didn't happen was discussed during the inspection. There were no residents prescribed higher-risk medicines. Staff had not been approached to provide advice regarding covert administration of medicines to care home residents. Descriptions of the medicines inside the compliance packs were provided. However, PILs were not routinely supplied to the home and there had been an issue identified with drug alerts (as described above). This meant that people may not have received all the relevant information about their medicines. This situation was discussed at the time.

Staff were aware of the risks associated with valproates during pregnancy. A poster was on display to highlight relevant risks and educational literature could be provided to people upon supply. People at risk had been counselled appropriately when prescriptions were seen for this medicine. Prescriptions for people prescribed higher-risk medicines were not routinely identified and marked for additional counselling. Staff stated that they previously used to obtain details of therapeutic monitoring and blood test results but no longer made any relevant checks because people were now monitored by a local clinic and at the hospital.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the appropriate equipment and facilities it needs to provide its services safely. Its equipment is largely used in a way that helps protect people's privacy.

Inspector's evidence

The pharmacy had access to the necessary equipment and resources in line with its dispensing activity. This included online resources as well as current versions of reference sources and counting triangles. Staff described rarely seeing prescriptions for medicines requiring reconstituting and as the pharmacy did not have a dispensary sink for this purpose, the team used the sink in the downstairs pharmacy or in the staff room. Hot and cold running water was available in the building. A legally compliant CD cabinet and a very small medical fridge were present. The latter was observed to be adequate to hold medicines that required cold storage. Aside from the situation with the owner's NHS smart card as described under Principle 1, staff held their own smart cards to access electronic prescriptions and took them home overnight. A shredder was available to dispose of confidential waste. Computer terminals were password protected and held in the pharmacy where unauthorised access was restricted.

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.