General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: 121 Pharmacy, Unit 1 Caxton Park, Caxton Road, Elms Farm Industrial Estate, Bedford, Bedfordshire, MK41 0TY

Pharmacy reference: 9011211

Type of pharmacy: Internet / distance selling

Date of inspection: 07/12/2020

Pharmacy context

The pharmacy has a distance selling contract with the NHS and dispenses prescriptions, mostly delivering them to people in the local area. It has a website which supports this part of the business (https://121pharmacy.co.uk). The pharmacy also sells over-the-counter (OTC) medicines through third party sellers such as eBay and Amazon. It was inspected during the COVID-19 pandemic.

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 assessing and managing all the risks associated with supplying medicines online.
		1.2	Standard not met	The pharmacy cannot show that it is monitoring and reviewing the risks associated with selling medicines through third-party websites. It is selling unusually large volumes of some medicines that can be misused.
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	4.2	Standard not met	The pharmacy's systems for monitoring some over-the-counter medicines sales are not robust, meaning that some people may be able to obtain medicines which are not suitable for them.
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 manage all the risks associated with its services, including sales of medicines online. Its written procedures do not cover all aspects of its services. And it doesn't keep good records about medicine sales, making it harder for the pharmacy to monitor and review how this service is working. So, some people may be able to purchase medicines which are not suitable for them. However, the pharmacy's dispensing process is managed well.

Inspector's evidence

There were two main parts to the pharmacy's activities. Its NHS dispensing service was mainly monthly repeat prescriptions which people would order with their own GPs, and these arrived electronically at the pharmacy. The dispensed medicines would be delivered by the pharmacist or posted to the person using Royal Mail if outside the local area. There was a very small number of people receiving their dispensed medicines in multi-compartment compliance packs. The prescriptions for these were ordered by the pharmacy team and the packs were sent using the Royal Mail Track and Trace service. The other significant pharmacy activity was supplying on-line orders of over-the-counter (OTC) medicines through third-party selling platforms.

The pharmacy had standard operating procedures (SOPs). The SOPs covered the services that were offered by the pharmacy for NHS dispensing. They did not cover all the aspects of the OTC sales the pharmacy made. They had not been signed by the pharmacy's team members to indicate they had been read and they did not always reflect the processes in place in the pharmacy. For example, the 'Contingency Planning' SOP stated that it should be trialled annually, and this had not been done. There was no COVID-19 SOP and the superintendent pharmacist (SI) had not done risk assessments for the premises or his staff to be able to comply with COVID-19 guidelines. None of the staff were wearing masks although these were available for them to use. The SI had not done a risk assessment of his pharmacy business since it opened in August 2019.

Supplies of OTC medicines were a large part of the business. These sales involved supplies of General Sales List (GSL) and pharmacy-only (P) medicines. There were risks in this service which had not been identified fully or addressed and so the pharmacy could not always show how it was protecting the people using the service. Before opening the pharmacy, the SI had identified some medicines which could be used inappropriately and had decided not to sell these. But some items that were offered for sale could be misused (mainly laxatives). The orders were via third-party sites which limited some of the safeguards available to the pharmacy. For example, the SI said that it was difficult to obtain further information from customers before a sale took place. There was a system in place to highlight people who had made previous purchases, but the information did not show the pharmacist what the previous or current purchases were and it only covered P medicines. The questionnaire filled in by the purchaser did not ask for information about whether or not they had had the item before. These issues would make it difficult for the pharmacist to make professional decisions about whether or not the requested purchase was suitable for the person buying it.

Guidance for pharmacies providing services at a distance indicates that a pharmacy should keep a

record of decisions to make or refuse sales and audit this regularly to ensure the safety of its customers. But the pharmacy was not doing so.

The pharmacist and dispenser had both undertaken safeguarding training at a suitable level for their roles and had access to the local telephone numbers to contact the safeguarding boards, if needed.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to provide its services, and they work effectively together and are supportive of one another. They have the appropriate skills, qualifications and training to deliver services safely and effectively. A more formal approach to ongoing training and review may help to identify and support any learning needs.

Inspector's evidence

There was a regular pharmacist, a dispenser and a person who packed the items present during the inspection. During the inspection the pharmacy team managed the workload effectively. The dispenser had completed the relevant training course when working at another pharmacy. The pharmacist was reminded about the new requirement for all staff working as part of a pharmacy team and he said that he would look into suitable training for the person who packed medicines if it was needed. The team had regular informal training from the pharmacist, but there were no plans for more formal training to be implemented.

Staff had not had formal appraisals. However, the pharmacy team worked together all the time and feedback about improvements to its processes could be discussed within the team at any time. Team members said that they felt comfortable about raising any concerns or making suggestions about how to improve the service. The team were not wearing PPE although there were masks available for them to use. The small number of members of the staff team meant that if one member of the team was off sick, it would be difficult for the rest of the team to deal with the workload.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are clean and provide a safe, secure and professional environment for people to receive healthcare. The pharmacy has adequate security. The pharmacy's own website displays all the necessary information for people. But it is harder for the pharmacy to maintain all the same information on sites operated by third parties.

Inspector's evidence

The pharmacy was clean, tidy and bright. It was situated in a shared building to which the other occupants shared the front door access. The dispensary area was adequate for the volume of prescriptions dispensed. And there was enough bench space for dispensing prescriptions safely. Each member of staff had their own workbench allowing them to socially distance from each other most of the time. The prescriptions were dispensed on one side of the room and the OTC products were packed and supplied from the other.

The pharmacy's own website allowed people to register the pharmacy as their nominated one so that electronic prescriptions could be directly sent to them. There was no prescribing service associated with this website. The name and address of the pharmacy, the name of the superintendent pharmacist and the telephone number of the pharmacy were all conspicuously displayed on the site as well as the EU logo. The pharmacy also used third-party websites to sell medicines. The SI regularly added his name and registration number to the third-party sites, but the third-party providers then removed it, and they would not let the pharmacy display its telephone number. But it was clear to the customer who was supplying the medicines, and that they were a registered pharmacy.

Staff had access to toilet facilities which had suitable handwashing facilities. And the dispensary had its own sink, with hot and cold running water.

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

Summary findings

The pharmacy's systems for monitoring some over-the-counter medicines sales are not robust, meaning that some people may be able to obtain medicines which are not suitable for them. The changes put in place immediately after the inspection should help to reduce the risks of this happening. But opportunities to counsel people may still be missed. The pharmacy gets its medicines from reputable sources. And the pharmacy team manages and delivers the dispensing process safely.

Inspector's evidence

Sales of OTC medicines were made through third-party websites. There was a questionnaire for people to complete in order to purchase the medicines. There was no evidence of the pharmacist following up any answers to get more clarification from the purchaser, which he said was difficult from the third-party sites. He said that he had standard reasons for refusal which he would send to people, but there was little counselling. For example, the reason given might be "too many items ordered". He said that he had little opportunity to give extra information about products, other than what was published on the website .

OTC orders were generally picked by the dispenser and then the other assistant packed the items ready for posting. For GSL medicines, the pharmacist did not have any input into their supply. Any P medicines were put into a red basket for the pharmacist to check before they were posted out. The system relied on the dispenser identifying P lines from flags on the computer system. The pharmacist checked the dispensing and P medicine sales prior to their packing, and these were delivered either by the pharmacist or by Royal Mail.

Multiple purchases of P lines were highlighted for the pharmacist on a spreadsheet of sales data. There were multiple address checks for P medicines, but this did not extend to GSL products, some of which were liable to abuse. Following the inspection, the pharmacist changed the status of medicines liable to abuse so that address and postcode checks were made on them.

The pharmacy dispensed medicines for mostly NHS patients. The prescriptions were received electronically and were ordered by the patient. The use of baskets helped to ensure that orders and prescription items were kept together and were easy to move from one area of the pharmacy to another. Computer-generated labels attached to dispensed medicines included relevant warnings and were initialled by the dispenser and checker which allowed an audit trail to be produced.

When people taking higher risk medicines such as warfarin, lithium or methotrexate were reminded to reorder their prescriptions, they were asked about any recent blood tests. Some people chose to send their results letter to the pharmacy's mobile telephone via WhatsApp, and others told the pharmacist about their latest results. So, the pharmacy could show that it was monitoring these patients in accordance with good practice. People in the at-risk group who were receiving prescriptions for valproate were routinely counselled about pregnancy prevention.

A few people were being supplied their medicines in multi-compartment compliance packs. The packs were labelled with all the information the person needed to take their medicines in the correct way. The packs had advisory warnings and cautionary labels on them. The packs had descriptions of the different medicines to identify them.

The pharmacy got its medicines from licensed wholesalers and stored them on shelves in a tidy way. Regular date checking was done. No out-of-date medicines were found during the inspection. Drug alerts were received, actioned and filed appropriately to ensure that recalled medicines did not find their way to people who used the pharmacy.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the right equipment for its services. It makes sure its equipment is safe to use.

Inspector's evidence

There were various sizes of glass, crown-stamped measures. The pharmacy had access to up-to-date reference sources. This meant that people could receive information which reflected current practice. The pharmacy had a separate triangle marked for use with methotrexate tablets ensuring that dust from them did not cross-contaminate other tablets. Electrical equipment was due to be tested. Stickers were affixed to some electronic equipment and displayed the next date of testing.

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.