General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Medisina Pharmacy, 11 Canford Close, Highgate, BIRMINGHAM, B12 0YU

Pharmacy reference: 1110087

Type of pharmacy: Community

Date of inspection: 26/07/2021

Pharmacy context

This is an independently owned pharmacy in a small parade of shops in a residential area of Birmingham. The pharmacy is open extended hours, seven days a week. It mainly dispenses NHS prescriptions and it provides some medicines in multi-compartment compliance packs to help people take their medicines at the right time. The pharmacy offers other services such as sexual health services under the Umbrella scheme, treatment for urinary tract infection under the Pharmacy First scheme and seasonal flu vaccinations. This targeted inspection took place in response to information received by the GPhC indicating that the pharmacy was dispensing prescriptions on behalf of an online prescribing service (https://eumeds.com/), which was based outside of the UK regulatory framework. As the inspection is targeted, there are some standards which were not inspected. The inspection took place during the COVID-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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 does not identify and manage all of the risks associated with its services. It cannot show that it has adequate risk assessments to ensure that the supply of prescription medicines is safe and that people do not gain access to high-risk medicines which may cause them harm.
		1.2	Standard not met	The pharmacy cannot demonstrate that it effectively monitors the prescribing and supply of high-risk medicines via the online prescribing service to prevent misuse or abuse.
		1.8	Standard not met	The pharmacy does not have sufficient safeguards to make sure that supplies of high-risk medicines are appropriate or that these medicines are not being abused or 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 supplies large quantities of high-risk medicines which are liable to abuse and misuse. But it does not make enough checks to make sure supplies are suitable for the person concerned. The pharmacy cannot provide assurance that the online prescribing service proactively shares all relevant information about prescriptions with other health professionals involved in the care of the person, or that appropriate monitoring is in place.
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 identify and manage all the risks associated with the services it provides. It works with a third-party online prescribing service which is based outside of UK regulatory control, but has not completed adequate assessments of the risks that are involved. It does not make checks about how the prescribing service shares and receives information from people's own GPs to make sure this information is used effectively to protect people's health and wellbeing. There has been no direct contact with the prescriber and the limited clinical information available to the pharmacy is not always utilised. This means that people may be able to access high-risk medicines that are not suitable for them.

Inspector's evidence

The responsible pharmacist (RP) notice was clearly displayed near to the medicine counter and the RP record was in order. The RP on the day was also the superintendent pharmacist (SI). The pharmacy maintained an electronic record of private prescriptions, but the details of the prescriber were not always recorded, so the record did not fully comply with requirements.

About seven weeks previously the pharmacy started dispensing prescriptions provided by a third-party online prescribing service. The website for the online prescribing service stated that the company was registered in Dubai, United Arab Emirate (UAE) and used EEA prescribers. This meant the prescribing service was not registered with a UK regulator. The pharmacy had printed a batch of prescriptions that were due to be dispensed that morning.

The RP explained that before entering a contract for the online prescribing service he had checked with the pharmacy's insurance provider, who had provided information about the legality of prescriptions for schedule 4 and 5 controlled drugs issued by prescribers in the European Union. But he had not completed a robust risk assessment to make sure that all of the risks associated with the service had been identified and to provide assurance that the service was operatign safely. Since beginning the service, the pharmacy had supplied between 30-50 prescriptions per day. Almost all of the prescriptions were for high-risk medicines, including opioid-based pain killers, Z-drugs, diazepam and modafinil. These medicines are known to be liable to abuse, misuse and overuse. But the pharmacy had not carried out any assessments of the risks associated with supplying these medicines in response to an online consultation. There were no standard operating procedures in placeto specifically cover this service and there was no clarity about the roles and accountabilities of those involved.

Prescriptions from the prescribing service were issued by an EEA prescriber, based in Germany. The pharmacy had been provided with some details about the prescriber, but had not independently verified this information. And no checks had been completed to ensure that the prescriber was registered within their home country and could lawfully issue prescriptions to people in the UK. The RP admitted that he did not know how to make these checks. The pharmacy had not had any direct contact with the prescriber. Any queries related to prescribing were dealth with by designated customer service personnel who were contactable via phone and email.

A sample of the dispensed prescriptions was reviewed, and multiple examples were found where people had received repeat supplies of high-risk medicines. Several of these supplies were seen to have been issued earlier than the minimum dispensing frequency stated in the 'dispensing frequency policy' published on the online prescribing service website. For example, a repeat supply of 100 dihydrocodeine 30mg tablets had been made after 14 days and in another instance 22 days. Two other patients had been supplied repeat prescriptions for 100 codeine phosphate 30mg tablets after just 10 days. The RP confirmed that he did not check for premature repeat requests and believed that this was the responsiblity of the online prescribing service. He was aware that other pharmacies within the locality were also dispensing for this prescribing service but did not know whether there were any safeguards in place to prevent duplicate supplies being made from other locations. The RP did not know whether any contact was made between the online prescribing service and the patients GP prior to a prescription for a high-risk medicine being issued, He pointed out a disclaimer at the end of a consultation form, which stated that patients agreed to inform their GP of any medication supplied to them, if appropriate.

The RP was aware that the medicines being prescribed were liable to abuse and misuse and admitted feeling some discomfort when making supplies. But he had not taken any steps to ensure that vulnerable people were not able to access medicines that could cause them harm.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy team members work well together and are able to manage the current dispensing workload in the pharmacy.

Inspector's evidence

The RP was working alongside a qualified dispenser who worked full-time. The pharmacy team was able to manage the dispensing workload. But was unsure of the number of prescriptions that would be received from the online prescribing service each day. This may make it difficult to plan for any unexpected increases in the workload.

The pharmacy received a payment for each prescription that was dispensed from the online prescribing service, plus reimbursement for the cost of the medicines supplied.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is generally suitably maintained, but the dispensary and consultation room are small, which makes it more difficult to work effectively.

Inspector's evidence

The pharmacy was in a suitable state of repair, but the premises were small which impacted overall organisation and workflow. There was appropriate lighting throughout and the temperature was suitable for the storage of medicines.

The pharmacy stocked a range of healthcare-based products and pharmacy only medicines were restricted from self-selection. There was a consultation room accessible from the retail area for people to provide a space for private and confidential discussions, but this was small and cluttered which may limit accessibility.

The website of the prescribing service which the pharmacy worked with was arranged in a way which allowed a prescription only medicine and its quantity to be selected before there has been an appropriate consultation with a prescriber. This makes the process seem transactional and could mean that the patient may not always get the most appropriate treatment.

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

Summary findings

The pharmacy does not make enough checks to ensure that the medicines it supplies are appropriate for people. Or make sure that people receiving medicines are who they say they are. And it is not able to confirm whether the prescriptions it dispenses always meet legal requirements.

Inspector's evidence

The pharmacy was accessible from the main street and advertised some of the services available. The online prescribing service was not advertised from the pharmacy premises. People accessed the service directly via the online prescribing service website. The pharmacy team did not know whether people were able to choose which pharmacy dispensed their prescription.

The pharmacy received the prescriptions via email, as a PDF attachment. It was unclear whether the prescription met the requirements for an advanced electronic signature. Prescriptions were received with pre-printed labels which detailed the dosage instructions. A standard number of pre-printed labels were issued, regardless of the quantity of medicine being supplied, which may increase the risk of error. Team members signed the pre-printed dispensing labels as an audit trail for dispensing and checking. And an entry was recorded on the pharmacy's patient medication record system, as well as in the private prescription register.

A dispenser showed the inspectors a 'back end' system to the online prescribing service website, which was accessible to the pharmacy. This system was used to track the progress of prescriptions and allowed patients to follow the progress of their order. The system provided the pharmacy with access to the medical questionnaire which the patient had completed, but the RP told the inspectors he would only refer to this if he felt he needed to. So, the pharmacy was not effectively monitoring prescribing practices or determining that the prescriber was working within national guidelines for the UK. The pharmacy did not routinely contact patients to provide counselling. Approximately two patients had contacted the pharmacy directly about the service and in each case, they had been referred to the customer service team for the online prescribing company. The customer service representatives were accessible to the pharmacy team members via email and personal phone, and the RP had also been provided with a generic customer service landline number. The pharmacy did not make checks to confirm the identity of the patients who they were dispensing prescriptions for. The SI relied on assurances provided by the prescribing service that these checks had been completed, but they did not know what this procedure entailed.

Dispensed prescriptions were collected from the pharmacy by a courier. They were then sent to a location, associated with the prescribing company, for them to be posted via a tracked Royal Mail service. The RP was unsure what happened if medications were not successfully delivered to the patient. The return address on the pre-printed postage label was a different address to the pharmacy and the RP was unaware of any links between the return address and the online prescribing service. This means that the pharmacy was unable to verify whether the medicines it supplied had reached the patient safely and securely.

The pharmacy sourced its stock from a range of licensed wholesalers. Stock was generally organised well on the dispensary shelves and medicines were stored in the original packaging provided by the manufacturer. No expired medicines were identified during random checks and the pharmacy had suitable medicines waste bins available.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services and team members use the equipment in a way that protects people's privacy.

Inspector's evidence

The pharmacy had access to reference materials including a British National Formulary and internet access to facilitate additional research. Electrical equipment appeared to be in working order. Computer systems were password protected and screens faced away from public view. A cordless phone was also available to allow for conversations to take place in private.

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.