General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Star Pharmacy, 295 Walsall Road, Perry Bar, BIRMINGHAM, West Midlands, B42 1TY

Pharmacy reference: 1038168

Type of pharmacy: Community

Date of inspection: 28/07/2021

Pharmacy context

This is an independently owned community pharmacy situated on a busy main road in the suburbs of Birmingham. It dispenses NHS and private prescriptions. And it sells a range of over-the-counter medicines. This was a targeted inspection in response to information received that the pharmacy was dispensing private prescriptions on behalf of EU Meds Ltd, an online prescribing service, which is based outside of the UK regulatory framework. This inspection was undertaken during the Covid-19 pandemic. And not all standards were inspected during this visit.

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 the risks associated with dispensing prescriptions generated by an online prescribing service operating outside of UK healthcare regulatory control. And it does not have standard operating procedures in place for the provision of this service. The pharmacy has not undertaken risk assessments to ensure that the supply of medicines which can be misused, abused or over-used to people is safe and clinically appropriate.
		1.2	Standard not met	The pharmacy cannot demonstrate that it audits and monitors the prescribing and supply of medicines via a third party online prescribing service to prevent misuse or abuse.
		1.6	Standard not met	The pharmacy's private prescription records for the supplies it makes on behalf of the online prescribing service are not kept in line with requirements.
		1.8	Standard not met	The pharmacy does not have robust safeguards in place to address the risks of supplying certain medicines to vulnerable people who may be using the online service to obtain medicines which are not clinically appropriate for them and which could lead to patient harm.
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 dispenses large quantities of medicines which can be abused, misused and overused. But members of the pharmacy team do not routinely refer to information provided by people or make clinical interventions. And the pharmacy is unable to provide assurances that relevant information or details about people's prescriptions are shared with other healthcare providers to support their

Principle	Principle finding	Exception standard reference	Notable practice	Why
				ongoing care.
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 risks associated with working with an online prescribing service which is based outside of the UK regulatory framework. And it is unable to demonstrate that it has robust safeguards in place to ensure that the supplies of medicines through this route are clinically appropriate and do not pose a risk of harm to people. The pharmacy has not completed relevant risk assessments before working with the online prescribing service to provide assurances that its working practices are safe. And it does not have relevant standard operating procedures in place for the provision of this service. The pharmacy's private prescription records are not all kept in line with requirements.

Inspector's evidence

The superintendent pharmacist (SI) was the responsible pharmacist (RP) on duty on the day of the visit. The correct RP notice was displayed by the medicine counter. The RP log had been completed and the RP records were kept in line with requirements.

Since the beginning of June 2021, the pharmacy had started dispensing private prescriptions provided by a third-party online prescribing service. The SI said that the motivation behind dispensing these prescriptions was to recover some of the losses the pharmacy had made during the pandemic year. And to help people obtain medicines that people couldn't get from their GPs, as access to GPs during the pandemic was extremely limited.

The website people used to access the prescribing service stated that the company was registered in the United Arab Emirates (UAE), meaning that it was outside of UK healthcare regulatory oversight. And the prescribers used to supply prescriptions for the online service were doctors registered in the European Economic Area (EEA). So, the prescribers were also outside of UK healthcare regulatory oversight.

The pharmacy was unable to show that it had completed a robust risk assessment prior to starting this service to provide assurances that all the associated risks associated had been identified and mitigated. And it did not have standard operating procedures in place for the provision of this service.

Prior to commencing the dispensing service for the online prescriber, the SI said that he had tried to telephone the prescriber who was based in Germany. But he had not managed to speak to him to confirm his credentials. And he had completed no independent checks to ensure that the prescriber was registered within their home country without restrictions and could lawfully issue online prescriptions to people living in the UK. The SI said that he had visited the prescriber's own website (not the one that people from the UK visited) but found it difficult to understand as it was in German. The pharmacy was largely reliant on information and assurances provided to it that the service was legal and that all the background checks about the prescriber had been undertaken by the company who operated the prescribing platform.

The SI said that he did not consider it necessary to seek advice from the pharmacy's indemnity insurance provider as dispensing private prescriptions was covered under their current indemnity arrangements.

Prescriptions issued by the online prescribing service were dispensed from a separate room on the first floor of the pharmacy. This activity was mainly managed by the SI's brother (a qualified advanced practitioner) who was also present on the day of the visit. Prescriptions from the online prescriber were mainly received via email. Since the beginning of the service, the pharmacy had generally dispensed between 20 and 130 prescriptions per day. The superintendent pharmacist said there were some days where the pharmacy did not dispense any prescriptions for the online prescribing service. Almost all the prescriptions were for medicines which can be abused, misused or over-used, including opioid-based pain killers, Z-drugs, diazepam, amitriptyline and modafinil.

The pharmacy did not keep complete records about the supplies it had made against private prescriptions issued by the online prescriber. It did not make entries on its patient medication record system. And it did not record these supplies in its usual private prescription record. Instead, it kept a printed copy of the prescription filed in a lever arch folder with a reference number annotated on the prescription. This increased the chances that information about supplies made by the pharmacy could be lost. And the pharmacy could not easily cross-reference against previous supplies when making clinical checks.

Members of the pharmacy team did not have any direct contact with the people to whom they supplied these medicines. People completed online questionnaires as part of the consultation process but the pharmacy had limited knowledge about how to access these questionnaires and so did not review them. The pharmacy did not have any input into the prescribing decisions or make any clinical interventions on individual person's prescription.

The pharmacists had assumed that the prescribing service had checked the questionnaires and had made all the necessary contact with people where appropriate. Members of the pharmacy team said that the company representative had provided some assurances that they were liaising with people's GPs but the pharmacy had sought no additional evidence about this. The pharmacy did not complete its own ID checks to ascertain that it was supplying to genuine people; it relied on the assurances provided by the third party that they completed checks to confirm people who were they said they were.

Members of the pharmacy team were not aware of any specific policies or procedures that the online prescribing service had in place to safeguard vulnerable people and to help prevent unsafe supplies to people. They were aware that the medicines being prescribed and dispensed could be abused, misused or over-used. And admitted feeling somewhat uncomfortable as it involved controlled drugs. But they had not thought about all the risks associated with this type of service, including the risks to vulnerable people who might be using the prescribing service to obtain medicines which were not clinically appropriate for them and which could lead to patient harm.

Members of the pharmacy team were aware of other pharmacies who were also dispensing prescriptions issued by the same online prescribing service. So there was a risk that people were being supplied medicines from several different pharmacies. But this pharmacy did not know what the online prescribing service was doing to help prevent people over-ordering, given the nature of the medicines being supplied.

Principle 2 - Staffing ✔ Standards met

Summary findings

Members of the pharmacy team work well together and can adequately manage the current workload in the pharmacy.

Inspector's evidence

The SI was working alongside three other pharmacy team members in the dispensary downstairs. The team appeared to work well together and were able to manage their workload well. Dispensing the prescriptions issued by the online prescriber was managed by the SI's brother. His workload had increased in recent days and a batch of prescriptions had been printed on the morning of the visit awaiting dispensing.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is generally clean and tidy. And it provides a suitable environment for the provision of healthcare services.

Inspector's evidence

The premises were accessible from the main street and the entrance door was wide enough to accommodate people with mobility difficulties. The pharmacy's opening hours and a list of NHS services offered were advertised in the window.

The pharmacy was in a good state of repair and it was generally clean and tidy. There was appropriate lighting throughout the premises and the room temperature was suitable for storing medicines. The pharmacy stocked a range of healthcare products and pharmacy-only medicines couldn't be self-selected. A consultation room was available for people wishing to have a private and confidential consultation with the members of the pharmacy team. The pharmacy was secured against unauthorised access.

The website of the online prescribing service which the pharmacy was associated with did not meet the GPhC's guidance for registered pharmacies providing services at a distance. The website allowed a prescription-only medicine and its quantity to be selected before an appropriate consultation with a prescriber took place. This made the process appear transactional and could mean that people may not always get the most clinically appropriate treatment.

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

Summary findings

The pharmacy does not always carry out enough checks to make sure that the medicines it supplies to people are safe and clinically appropriate. It cannot provide assurances whether the prescriptions it dispenses on behalf of an online prescribing service are meeting the legal requirements. And it cannot demonstrate that the online prescribing service shares information with a person's GP to make sure their health and wellbeing is protected. Members of the pharmacy team cannot provide assurances that undelivered medicines are securely handled and disposed of safely.

Inspector's evidence

People accessed the online prescribing service directly by going to a separate website operated by a third party and the pharmacy did not advertise the prescribing service. Members of the pharmacy team did not know whether people using the prescribing service had a choice of which pharmacy dispensed their prescriptions. And information about the pharmacies involved in dispensing and supplying medicines to people was not stated on the website.

The pharmacy received the private prescriptions issued by the online prescriber via email. The prescriptions were received as a PDF attachment which was printed by members of the pharmacy team. It was unclear whether the signature on the prescription met the requirements for an advanced electronic signature. Prescriptions were received together with pre-printed postage and dispensing labels. Dispensing labels included the name and the address of the pharmacy and dosage instructions. A standard number of pre-printed dispensing labels were issued, regardless of the quantity supplied, which could create confusion and increased the risk of a dispensing incident.

Members of the pharmacy team initialled the pre-printed labels to keep an audit trail to show who had dispensed and checked the medication. And patient information leaflets were supplied to people by the pharmacy. Once the prescription had been dispensed, it was scanned into the website's system so that orders could be tracked. The system provided access to consultation questionnaires. But members of the pharmacy team were not sure how to look at these. And they had no direct contact with people to provide any additional counselling or review their use of medication.

Dispensed medicines were collected from the pharmacy by a driver for onward delivery by Royal Mail. But members of the pharmacy team had not noticed that the return address for undelivered medicines on the packaging labels was for an address in Nottingham and which was not a registered pharmacy. This meant that the pharmacy was unable to verify that undelivered medicines were securely handled and disposed of safely. The pharmacy sourced most of its stock medicines from AAH, Alliance, Sigma and Bestway.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for the services it provides. And it maintains these appropriately.

Inspector's evidence

Members of the pharmacy team had access to reference sources including a British National Formulary and internet access. Electrical equipment appeared to be in good working order. Computer systems were password protected and no confidential information was visible from the public area of the pharmacy.

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.