General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Sparkbrook Pharmacy, 153A Stratford Road, Sparkhill, BIRMINGHAM, West Midlands, B11 1RD

Pharmacy reference: 1097725

Type of pharmacy: Community

Date of inspection: 23/07/2021

Pharmacy context

This community pharmacy is located on a busy road in Sparkhill, Birmingham. It dispenses NHS prescriptions and sells a range of over-the-counter medicines. The pharmacy supplies some medicines in multi-compartment compliance aid packs to help make sure people take them at the right time. It also offers a substance misuse service. 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 is based outside of the UK regulatory framework. As the inspection was 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: Improvement Action Plan; 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 the online prescribing service it works in partnership with. It cannot show that it has adequate systems or risk assessments to ensure that the supply of high-risk prescription medicines is safe.
		1.2	Standard not met	The pharmacy cannot provide assurance that it effectively monitors and audits the supply of high-risk medicines issued by the online prescribing service to prevent misuse or abuse.
		1.8	Standard not met	The pharmacy does not have sufficient safeguards in place to make sure that supplies of high-risk medicines are appropriate or that these medicines are not being abused or misused.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy's team members cannot always demonstrate that they are completing appropriate training or hold suitable qualifications for their roles. This means that they may lack some of the skills and knowledge needed for the roles in which they are working.
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 get sufficient information or make enough checks to make sure medicines 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 manage and identify the risks associated with the online prescribing service that it works with. The prescribing service is based outside of the UK regulatory framework, and the pharmacy has not completed appropriate assessments of the risks involved to ensure that their working practices are safe. The pharmacy team has a limited understanding and working knowledge of the online prescribing service's policies and procedures, and it has no direct contact with the prescriber. This means that people may be able to access high-risk medicines which may not be suitable and could cause them harm.

Inspector's evidence

A locum pharmacist was working as the responsible pharmacist (RP). The correct RP notice was clearly displayed near to the medicine counter and the RP log was in order.

About seven weeks prior to the inspection, the pharmacy had 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, so it fell outside of the UK regulatory framework. The locum pharmacist explained that the superintendent (SI) pharmacist had paused the service a few days before the inspection.

Prior to initiating the service with the online prescribing service, the SI pharmacist had contacted the pharmacy's insurance provider to confirm the legality of prescriptions issued by an EEA prescriber, but a robust risk assessment of the service had not been completed. Since beginning the service, the pharmacy had supplied between 20-40 prescriptions per day to people living throughout the UK. The overwhelming majority of supplies were for high-risk medicines, including opioid-based pain killers, Z-drugs, diazepam and modafinil. These medicines are known to be susceptible to abuse, misuse and overuse and an assessment of the risks associated with supplying these types of medicines following an online consultation had not taken place. The pharmacy had a set of standard operating procedures (SOPs) in place covering most of its operational activities. But these procedures did not extend to the online prescribing service.

Prescriptions from the online prescribing service were issued by an EEA prescriber, based in Germany. The prescribing service had issued the pharmacy with some details about the prescriber, but this information had not been independently verified by the pharmacy. And no checks had been completed to ensure that the prescriber was registered within their home country without restrictions and could lawfully issue prescriptions online to people living in the UK. At the time of the inspection the pharmacy had not had any direct contact with the prescriber and any queries related to prescribing were referred to designated customer service personnel at the online prescribing service, who were contactable via telephone and email.

The pharmacy team members were unaware of the specific policies and procedures that were in place to help prevent regular repeat requests for medicines from being supplied to patients. They were aware that other pharmacies within the locality were also providing a similar service, but they did not know if

there were any safeguards in place to help ensure that duplicate supplies were not made from other locations. And they did not know how the prescribing service completed identity checks to help ensure that supplies were made to legitimate patients.

Private prescription records for the online prescribing service were maintained separately from other private prescription records received by the pharmacy. Multiple examples were seen where people had received repeat supplies of high-risk medicines, in the short number of weeks the service had been operating. 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 services website. For example, a resupply of 28 diazepam 10mg tablets had been made after seven days. In another case, a resupply of 100 dihydrocodeine 30mg tablets had taken place after 13 days. There was no evidence of any prescribing interventions having been made by the pharmacy about the nature or frequency of supplies. Following the inspection, the SI pharmacist informed the inspector that he had raised some queries with online prescribing service customer services team and provided an example of a prescription query for a patient whose billing address was in Spain.

Dispensing incidents were reported directly to the online prescribing service. And an example was seen where the prescribing service customer service team had informed the pharmacy of a dispensing incident. The pharmacy had rectified the error, but there was no evidence that the incident had been documented in line with the pharmacy's dispensing incident procedure, or that a root cause analysis or any further investigation into the cause of the incident had taken place. So, opportunities for learning and improvement may have been missed.

The pharmacy segregated confidential waste and disposed of it in a secure manner. Team members understood the principles of confidentiality and data protection. But they were not aware of the information sharing arrangements in place with the online prescribing service which they were partnered with, or how people's information was kept secure if they opted to use this service.

The locum pharmacist had completed safeguarding training and he discussed some of the types of concerns that might be identified. He was aware of the potential safeguarding concerns that may arise when medicines were purchased online.

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

Summary findings

The pharmacy has enough team members to manage the current dispensing workload. But some of the pharmacy's team members are not able to demonstrate that they are completing appropriate training or hold suitable qualifications for their roles. This means that they may lack some of the skills and knowledge needed for the roles in which they are working.

Inspector's evidence

The locum pharmacist was working alongside four other pharmacy team members. This included a dispenser, who was completing an NVQ3 pharmacy technician training programme, two dispensing assistants and a medicine counter assistant (MCA). One of the dispensing assistants was unable to confirm what training they had completed for their role, or the length of time they had been working at the pharmacy. The superintendent pharmacist later confirmed that this team member had been working at the pharmacy on a part-time basis since October 2020, and that they had not yet been enrolled on an accredited training programme. The superintendent pharmacist provided the relevant training details for other team members post-inspection. The team appeared to work well together and were able to manage the current dispensing workload.

The pharmacy team members were familiar with the general procedures in the pharmacy. A dispenser said that some brief training had been provided when they began working with the online prescribing service, but they did not understand the end to end processes associated with the prescribing services.

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

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is generally clean and tidy and provides a suitable environment for the delivery of healthcare services. It has a consultation room, so that people can speak to the pharmacist in private when needed.

Inspector's evidence

The pharmacy was in a good state of repair and was generally clean and tidy. There was appropriate lighting throughout and an air conditioning unit was fitted in the main part of the split-level dispensary, to help maintain a temperature 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.

The website of the prescribing service which the pharmacy works with was arranged so a person could select a prescription only medicine and its quantity before having an appropriate consultation with a prescriber. This layout is unprofessional and transactional in its approach and, could mean that people may not always get the most appropriate treatment. The website does not display the name and qualifications of the prescriber, so people may not have access to all the information they need to make an informed decision.

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

Summary findings

The pharmacy does not always carry out enough checks to make sure that medicines are safe and appropriate for the people it supplies. It cannot confirm whether the prescriptions it dispenses for the online prescribing service are meeting legal requirements, or that people receiving these high-risk medicines are who they say they are. And it cannot demonstrate that the online prescribing service shares information with a person's regular doctor to make sure their health and wellbeing is protected.

Inspector's evidence

The pharmacy was accessible from the main street and some of the NHS services were promoted by the pharmacy. The online prescribing service was not advertised on the pharmacy premises and people accessed the service directly via its website. The pharmacy team did not know whether people were able to choose which pharmacy dispensed their prescription and information about the pharmacy was not included on the website.

The pharmacy received the prescriptions from the online prescribing service via email. The team were not informed of how many prescriptions would be received each day. The prescriptions were received as a PDF attachment which the pharmacy team printed out. 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 which included the dosage instructions. A standard number of pre-printed labels were issued, regardless of the quantity of medicine being supplied, which could increase the risk of a dispensing incident. Team members signed the pre-printed dispensing labels as an audit trail for dispensing and checking. Each prescription supply was recorded on the pharmacy's patient medication record system, as well as in the private prescription register. Once the prescription had been dispensed it was scanned into the online prescribing services website 'back end' system, so that orders could be tracked. This system provided the pharmacy team with access to the medical questionnaires which had been completed by the patient. The pharmacy had not contacted any patients to provide additional counselling, review their use of medication, or check monitoring arrangements. The pharmacy team members did not know whether the 'back end' system provided them with the patient's contact details to enable them to do this. And they did not know what identity checks were completed when people ordered medication, so they could be confident they were supplying genuine patients. They relied on verbal assurances from the online prescribing service that these checks were completed.

Dispensed prescriptions were collected from the pharmacy by a courier arranged by the prescribing service and sent to another location, where they were collected by Royal Mail for onward delivery. The SI pharmacist was unsure as to 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. This meant that the pharmacy was unable to verify whether the medicines it supplied reached the patient safely. And it could not demonstrate that returned medicines were securely handled and disposed of safely.

The pharmacy sourced its stock from a range of licensed wholesalers and stock was arranged in an organised manner, in the original packaging provided by the manufacturer. No expired medicines were identified during random checks and the pharmacy had suitable medicines wate 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. 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.

Pharmacy team members had access to items of personal protective equipment. This was not being worn by all team members at the time of the inspector's arrival, but team members wore face masks after this was discussed.

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.