General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: A+ Pharmacy, 311 Bordesley Green East, Stetchford, BIRMINGHAM, West Midlands, B33 8QF

Pharmacy reference: 1037901

Type of pharmacy: Community

Date of inspection: 26/07/2021

Pharmacy context

This community pharmacy is situated in a row of local shops opposite a large healthcare centre which contains a GP surgery, a district nurse base and out of hours GP services. 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 EU Meds Ltd, an online prescribing service, which is based outside of the UK regulatory framework. The inspection took place during the COVID-19 pandemic, and as the inspection was targeted, there are some standards which were not fully inspected during this visit.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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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 which 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	2.6	Standard not met	The profit margins associated with dispensing prescriptions for online prescribing services may disincentivise any refusal to supply, which may prejudice professional judgement.
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 without obtaining sufficient information or making enough checks to make sure they 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.
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 cannot demonstrate it has adequate safeguards in place to address the risks associated with this type of service. And it has not completed appropriate risk assessments before working with the prescribing service to ensure that its working practices are safe and legal. 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

About six-weeks prior to the inspection, the pharmacy had started dispensing prescriptions provided by a third-party online prescribing service. The website 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.

Prior to initiating the service with the online prescribing service, the Superintendent Pharmacist (SI) had contacted the pharmacy's advisors on legal and professional matters to confirm the legality of the prescriptions, but a formal risk assessment of the new service had not been completed. At the time of the inspection, the pharmacy was supplying between 50 and 150 prescriptions per day to people living in the UK, and this number was growing. The overwhelming majority of supplies were for high-risk medicines, including opioid-based pain killers, z-drugs, diazepam and modafinil. The 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 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, email and instant message. And the pharmacy generally had no direct contact with people accessing the service to pro-actively offer counselling on how to take the prescribed medication.

The pharmacy team members were unaware of the specific policies and procedures that were in place to help prevent regular repeat requests 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 being made from other locations. The computer system did not show if the other pharmacies had made supplies to patients.

Private prescription records for the online prescribing services were maintained electronically, however, the pharmacy was behind on making some of the legally required entries within the

appropriate time period due to their workload. Multiple examples were seen where people had received repeat supplies of high-risk medicines in the short number of weeks that the service had been operating. There was no evidence of any prescribing interventions having been made by the pharmacy about the nature or frequency of supplies. The Responsible Pharmacist (RP) notice showed the correct details and was displayed so members of the public could view it. The RP log was recorded electronically. A current certificate of professional indemnity insurance was on display.

Dispensing incidents were reported directly to the online prescribing service. And an example was seen where the online prescribing service had informed the pharmacy of an allegation of a dispensing incident. The pharmacy had investigated the allegation and the outcome was that there was no wrongdoing and it was considered that the patient had made the allegation in order to obtain additional medication. The SI explained that accounts could be blocked by the online prescribing service if they thought the person was making repeated and unfounded allegations about not receiving the correct quantity of medication. However, this had not raised alarm bells with the SI about the nature and frequency of high-risk medicines being supplied by the service.

No routine checks were in place to ensure that a person's usual GP was contacted before making a supply of a high-risk medicine to ensure it was suitable for them. There were a number of potential safeguarding issues that had not been identified or addressed, for example, there was no way of assessing a patient's mental capacity to determine whether a remote consultation was appropriate and there were examples of regular supplies of medicines likely to be abused or misused. On one questionnaire, a patient had answered indicating that they did not have the mental capacity to make decisions about their own healthcare, but they had been supplied with a high-risk medicine regardless of this. The SI said that the prescriber only issued prescriptions when these types of queries had been resolved, however, there were no notes on the computer system to show this was the case.

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

Summary findings

The pharmacy generally has enough team members to manage the current workload and the services that it provides. But the workload has recently increased due to the number of prescriptions generated by the online prescribing service. Team members receive the appropriate training for the roles in which they are working.

Inspector's evidence

During the inspection, the pharmacy team comprised of the superintendent (RP), trainee pharmacist, dispensing assistant and trainee dispensing assistant. The superintendent and dispensing assistant were directors of the company.

The team appeared to work well together and were able to manage the current dispensing workload although this had increased in recent week due to the online prescribing service. The team were behind on some administrative tasks, such as making private prescription register entries, which were a legal requirement. The pharmacy team members were familiar with the general procedures in the pharmacy.

The pharmacy was paid for each prescription it dispensed on behalf of the online prescribing service and did not receive payment if they rejected a prescription. The only reason that the pharmacy had rejected a prescription was if they had not got sufficient stock to dispense it before the prescriptions were collected.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is 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 website of the prescribing service which the pharmacy was associated with was arranged in a way which allowed a person to select a prescription only medicine and its quantity before having an appropriate consultation with a prescriber, which could mean the patient may not always get the most appropriate treatment. Various additional details were missing from the website, such as the prescriber's details and information about the pharmacy.

The dispensary was an adequate size for the services provided; an efficient workflow was seen to be in place. NHS dispensing and checking activities took place on separate areas of the worktops. The online prescribing service prescriptions were dispensed and stored in another separate area. A dispensing robot was positioned in the centre of the dispensary and prescriptions were dispensed from 3 'shoots' with a PMR terminal attached to each.

There was a private soundproof consultation room which was signposted to patients. The consultation room was professional in appearance. The door to the consultation room remained closed when not in use. The premises were smart in appearance and appeared to be well maintained. Any maintenance issues were reported to the directors/owners.

The dispensary was clean and tidy. The sinks in the dispensary and staff areas had hot and cold running water and hand soap available. The pharmacy had air conditioning and the temperature in the dispensary felt comfortable during the inspection. Lighting was adequate for the services provided. Various COVID-19 measures were in place, such as, limiting the number of people in the pharmacy at any one time and plastic screens at the medicines counter.

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 the legal requirements. And it cannot demonstrate that the online prescribing service shares information with a person's usual doctor when it supplies high-risk medicine to make sure their health and wellbeing is protected.

Inspector's evidence

The pharmacy had a step free access from the pavement, a home delivery service was available for people who could not easily access the pharmacy and free parking was available outside.

The online prescribing service was not advertised on the pharmacy premises, and people accessed the the online prescribing service directly via their website. The pharmacy had received some telephone calls from patients about medication that they had supplied on behalf of the online prescribing service. The SI presumed that the patient had searched the internet for the pharmacy's telephone number as it was not printed on the dispensing label.

The pharmacy received prescriptions from the online prescribing service via email. The team were not informed of how many prescriptions would be received each day, which made it difficult to plan for any unexpected increases in workload. The number of prescriptions received had increased over previous days. 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.

In order to create a private prescription record, each prescription supply was recorded on the pharmacy's patient medication record system. The SI created this record after the prescription had been dispatched and there was a backlog in entering them to the system. Once the prescription had been dispensed it was scanned into the online prescribing service websites 'back end' system so that orders could be tracked by the online prescribing service and the patient. This system provided the pharmacy team access to the medical questionnaire which had been completed by the patient. The SI confirmed that he did not routinely review the answers provided on the questionnaires and he thought that the prescriber queried any issues prior to issuing the prescription, although there was no evidence of this being recorded on the system. The pharmacy had not pro-actively contacted any patients to provide additional counselling or review their use of medication and check monitoring arrangements.

Dispensed prescriptions were collected from the pharmacy by a courier arranged by the online prescribing service and sent to another location where they were collected by Royal Mail for onward delivery. The SI was unsure as to what happened if medications were not successfully delivered to the patient and thought that the online prescribing service dealt with that. 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 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 a range of up to date reference sources, including the BNF and the children's BNF. Internet access was available. Patient records were stored electronically and there were enough terminals for the workload currently undertaken. A range of clean, crown stamped measures were available A maintenance contract and ongoing technical support was provided for the robot. There were override mechanisms in place so that staff had access to the medicines contained in the robot in the event of power failure. Computer screens were not visible to the public as they were excluded from the dispensary.

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.