General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: AYP Healthcare, 160-164 Lancaster Road North, Preston, Lancashire, PR1 2PZ

Pharmacy reference: 9011523

Type of pharmacy: Internet / distance selling

Date of inspection: 07/11/2022

Pharmacy context

This is an online pharmacy which people access using the website http://ayp.healthcare. It is situated within a warehouse near to Preston City Centre. The pharmacy sells 'over the counter' medicines through its website. It also sells a range of healthcare sundries. But it does not dispense prescriptions or provide any other pharmacy services.

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 cannot demonstrate how it identifies and manages the risks associated with its services. And it does not have effective controls in place to prevent inappropriate sales of medicines.
		1.2	Standard not met	The pharmacy does not review sales data to audit whether there are sufficient safeguards in place to prevent overuse, abuse or misuse of medicines.
		1.5	Standard not met	The pharmacy has not demonstrated whether it has appropriate professional indemnity arrangements in place.
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 does not always get enough information for the team to assess whether the medicines it sells will be used safely. And there is evidence that some medicines are supplied without intervention even when the pharmacy's policies should have prevented the supply.
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 of the risks associated with its services. It sells a large volume of 'pharmacy only' medicines via its website. But it does not have effective controls in place to make sure they are being used safely. Which means people might be able to obtain medicines that are not appropriate for them. And it has not provided any evidence to show it has professional indemnity arrangements in place.

Inspector's evidence

The pharmacy had a set of standard operating procedures (SOPs). Members of the pharmacy team had signed to say they had read and accepted them. Roles and responsibilities of the pharmacy team were described in the SOPs. A member of the pharmacy team, who had completed their medicines counter assistant (MCA) course, was able to explain what her responsibilities were and was clear about the tasks which could or could not be conducted during the absence of a pharmacist. The responsible pharmacist (RP) had their noticed displayed in the pharmacy. The pharmacy's website had a link to an RP notice, but it was for a pharmacist who had never worked there as the RP. This was misleading and may cause confusion. RP records were maintained and appeared to be in order.

The pharmacy had a spreadsheet which listed the medicines it sold on its website and the maximum quantities permitted per order. The pharmacist explained she had developed the spreadsheet with the superintendent pharmacist (SI) and one of the owners. It contained reasons for the maximum quantities, for example, it stated 'manufacturer's pack size' for an antihistamine which was available in a bulk container of 500 tablets, and 'CKS NICE guidance', referring to clinical guidance used for managing health conditions. But the risks associated with selling large quantities through an online platform did not seem to have been considered. The pharmacy had not implemented a 'lock-out' period between orders. This meant any repeat orders relied upon members of the pharmacy team to flag them to the pharmacist to review.

A sample of the pharmacy's sales records were reviewed, and a number of supplies were identified that appeared inappropriate. There was no evidence of intervention by the pharmacy team to question why the medicines were required. And no reasons had been recorded to explain why the supplies could be justified. These included:

- A single order for six fluconazole 150mg capsules. Fluconazole is used to treat fungal infections, including vaginal thrush. The normal dose is a single tablet to treat the infection. Patients should not normally take more than two treatments in a 6-month period without consulting their GP. And the pharmacy's questionnaire for fluconazole asked the person to confirm they would only use it on two occasions within 6 months, unless directed by their GP.
- 18 fluconazole 150mg capsules had been supplied to one person within a 5-month period.
- Three separate orders had been sent to a person on the following dates: 12th July – 120 Laxido sachets and 3 x 150ml Senokot liquid, 22nd August – 180 x Laxido sachets, and 23rd October – 150 x Laxido sachets, 1 x 300ml Dulcolax liquid and 3 x 150ml Senokot liquid. All of these medicines are laxatives for treatment of constipation The normal adult dose for Laxido is 1 to 3 sachets a day. The normal adult dose of Senokot is 5-10ml a day. The normal adult dose of Dulcolax is 5-10ml a day. Laxatives are known to be commonly misused by people with eating disorders. The

NHS website advises people to consult their GP if constipation persists after taking laxatives for a week.

The pharmacy website included contact details and information about how to return items back to the pharmacy. The pharmacy had a complaints procedure but there was no information on the website about it, so people may be unsure how they can raise concerns. Any complaints the pharmacy received were usually responded to by email. If the pharmacy received a report that a person had received the incorrect medicines, the incident was investigated, and a record was kept. The pharmacist said that there were few errors made due to the automated systems and barcode scanning technology they used. But that if they found an error had been made, they would give further training to the members of the team involved. The pharmacy did not have a certificate of professional indemnity insurance available, and it has not responded to requests to provide evidence that it has appropriate indemnity arrangements in place.

An information governance (IG) policy was available. Each member of the team had signed a confidentiality agreement, and these were stored in the SOP folder. When questioned, the MCA was able to describe how she would deal with requests for people's information on the telephone. A privacy notice was available on the pharmacy's website. Safeguarding procedures were included in the SOPs. The pharmacy manager had completed level 2 safeguarding training. Contact details for national safeguarding teams were available.

Principle 2 - Staffing ✔ Standards met

Summary findings

There are enough staff to manage the pharmacy's workload. And they are trained for the jobs they do.

Inspector's evidence

The pharmacy team included a pharmacist and a number of assistants. Some of the assistants worked in customer services and approved some of the pharmacy orders. To perform these roles the pharmacy used either assistants who had, or were, completing a dispenser or medicine counter assistant training course. A number of the assistants worked in the warehouse and were not pharmacy trained. The volume of work appeared to be managed adequately. Staffing levels were maintained by part-time staff and a staggered holiday system.

An MCA was the nominated first aider and had completed a first aid course. All members of the team completed the mandatory training required for their roles. But there was no structured ongoing training. So learning needs may not always be fully addressed. When questioned, an MCA said she felt well supported and was able to ask for further help if she needed it. Team members were aware about the whistleblowing policy and said that they would be comfortable reporting any concerns to the manager or SI. There were no professional targets in place.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are suitable for the services provided. And the pharmacy's website informs people about who are providing the pharmacy services.

Inspector's evidence

The pharmacy had a website which was used to access its services. The website displayed the GPhC logo which linked to the register entry for this pharmacy.

The pharmacy was located inside an industrial unit closed to members of the public. It was clean and tidy, and appeared adequately maintained. The size of the premises was sufficient for the workload. Various heaters helped to control the temperature. Lighting was sufficient. Members of the team had access to a kitchenette and WC facilities.

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

Summary findings

The pharmacy uses questionnaires when selling medicines to help the team decide whether they are suitable to supply. But it does not always get enough information for the team to assess whether the medicines will be used safely. And there is evidence that some medicines have been supplied without intervention even when the pharmacy's policies should have prevented the supply. So people may be able to obtain medicines that they misuse.

Inspector's evidence

The pharmacy's website had an electronic contact form and a telephone number for the pharmacy. Over-the-counter medicines were listed under the conditions they were used for. When a medicine was selected, the website displayed information about how to use it. But there was no general healthcare information or advice about the various conditions being treated.

In order to purchase a medicine from the website, people were required to complete a questionnaire. This was intended to help the pharmacy team to determine whether the medicine was suitable. The questions asked were specific to the chosen medicine. But the questionnaires used closed questions with little opportunity to add any additional comments. And there were normally only three to five questions. This meant the pharmacy did not always get enough information to properly assess whether the medicine would be used appropriately. For example, fluconazole, which is used to treat thrush, was one of the top 10 items the pharmacy sold. The questionnaire for fluconazole stated 'This product is to be used a maximum of twice in six months. If you require this item regularly, please confirm if you are taking this item according to your GP advice and supervision.' But the pharmacy had routinely provided up to 6 treatments in a single order. The pharmacist suggested that this was because they would have assumed that the patient's sexual partner may also require treatment. But the person was not asked for this information and there was no additional questioning to check whether people were taking the medicines appropriately.

The pharmacy's software linked orders for previous purchases which had involved the same delivery address or email address. This information was used by team members as part of their decision making. Some of the email addresses that had been supplied were noted to include the name of the pharmacy, suggesting they may have been created specifically to order from that pharmacy's website. The company director said the pharmacy team would also manually check the IP addresses which had been recorded during an order. But team members were unable to demonstrate how to carry out this check. The director also said the delivery address had to match the billing address of the payment card used, or the transaction would be declined. But an order was seen where a supply had been made when the addresses did not match. So it was possible that people could be using multiple accounts to by-pass the restrictions.

Orders containing 'pharmacy only' medicines were held on an electronic dashboard, so they could be reviewed and authorised by a member of the pharmacy team. Some medicines were permitted to be authorised by a dispenser, provided they met certain criteria such as the person not breast feeding or being pregnant. If the dispenser was not permitted to authorise the sale, they would refer the order for the pharmacist to review. The pharmacist described how she would check the answers provided to the questions and the person's order history. When the order had been authorised, team members were

able to print an order sheet for picking. A robot was used to store and select smaller items of stock. It ejected the required medicines through chutes, and they were placed in a basket with an address label and delivery note. Any bulky stock that could not be stored in the robot would be picked from a numbered location and placed with the other medicines in the basket. Baskets were then sorted and packaged by an operator, who would stamp the printed order to provide an audit trail.

The pharmacy's software required members of the team to log in before it could be accessed. But different members of the pharmacy team used the same log in details to authorise pharmacy-only medicines. A protocol to 'escalate' orders to a pharmacist was used by non-pharmacist team members. And the team members could use their own judgement to escalate orders outside of this protocol, such records of recent purchases for the same medicine. When an order was escalated to the pharmacist, they would use their professional judgement to assess whether it was suitable to supply the medicine. But the system did not provide an audit trail to help show who had made the decision to supply or refuse a medicine. A list of current escalated orders was seen, some of which had been refused by the pharmacist for reasons such as people who were breastfeeding or were pregnant.

Medicines were packaged and sent using a variety of couriers, such as Royal Mail. Tracking was used as an audit trail of where the medicine was, and a signature was required from the recipient to confirm receipt.

Medicines were obtained from licensed wholesalers. Stock was date checked every 3-months. A date checking matrix was signed by staff as a record of what had been checked, and short-dated stock was highlighted in a diary for it to be removed at the start of the month of expiry. There was a clean medicines fridge with a thermometer. This was used to store pharmacy flu vaccinations for a nearby branch belonging to the same company. The minimum and maximum temperature was being recorded daily and records showed they had remained in the required range for the last 3 months. Unwanted medication was disposed of in designated bins located away from the dispensary. Drug alerts were received by email from the MHRA. Any alerts which required action would be recorded, with the details about who dealt with the alert and when.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

Members of the pharmacy team have access to the equipment they need for the services they provide. And they maintain the equipment so that it is safe to use.

Inspector's evidence

The staff had access to the internet for general information. This included access to the BNF, BNFc and Drug Tariff resources. All electrical equipment appeared to be in working order. Equipment was kept clean. A forklift was located in the pharmacy premises. The director confirmed he had the necessary forklift training and license to operate the machinery and only permitted staff were allowed to use it.

Computers were password protected. A cordless phone was available in the pharmacy which allowed the staff to move to a private area if the phone call warranted privacy.

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.