General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Barons Pharmacy, 3 Margravine Gardens, LONDON, W6 8RL

Pharmacy reference: 1041445

Type of pharmacy: Community

Date of inspection: 23/03/2022

Pharmacy context

This pharmacy is located in a residential area in West London. It provides a range of NHS services and also dispenses prescriptions issued by an online prescribing service that operates remotely and uses a pharmacist independent prescriber (PIP). The online prescribing service is accessed via the pharmacy's website and offers treatments for various conditions, including hair loss, erectile dysfunction, and weight loss. The pharmacy currently has conditions in place on its registration that prevent some services being provided. These conditions were imposed after previous information was received by the GPhC, and they remained in force at the time of this inspection. The inspection took place during the Covid-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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 prescribing service risk assessments are incomplete and some risks associated with higher-risk medicines are not being adequately addressed. The pharmacy's standard operating procedures are not always relevant to its services, and there is no assurance that the team understand them. So, members of the team may not always be clear what is expected of them.
		1.2	Standard not met	The pharmacy cannot demonstrate that it learns from things that go wrong. And it cannot provide any evidence that it reviews the safety or effectiveness of its prescribing service.
		1.6	Standard not met	The pharmacy does not keep adequate records of its prescribing decisions. It does not maintain a complete record of private prescriptions it has dispensed and the records of patient-returned medicines are inadequate.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website allows people to start a consultation from the page of an individual prescription-only medicine.
		3.4	Standard not met	The pharmacy does not adequately protect all areas from unauthorised access.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not always share information with people's regular prescribers when it prescribes medicines for long-term conditions which require ongoing monitoring. And there is some evidence of inappropriate supplies of inhalers to people who have indicated that they do not take other asthma treatments.
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 always identify and manage the risks associated with its prescribing service, particularly when prescribing medicines for conditions which require ongoing monitoring. The prescriber does not keep records of their prescribing decisions, so is not able to show whether medicines are being prescribed appropriately. The pharmacy cannot provide assurances that its team members fully understand its policies and procedures. So, they may not always work effectively or know what is expected of them. The pharmacy keeps most of the records it needs to by law, but some records are missing. So, it may not be able to show that its medicines have been properly managed and supplied. Dispensing mistakes are not always recorded, so, the team might be missing opportunities to learn and make the services safer.

Inspector's evidence

The pharmacy had a set of written standard operating procedures (SOPs). They were dated February 2021 and were due to be reviewed in 2023. Many of the SOPs were not relevant to the pharmacy's services, which made them difficult to follow and could cause confusion. There were no training records for the SOPs and it was not clear whether the pharmacy team had read them, which meant members of the team may not have always fully understood what was expected of them. There were no SOPs available at the pharmacy in relation to the prescribing service. The Responsible Pharmacist (RP) explained that he had only started working at the pharmacy one week ago, so he did not know much about the prescribing service and was not sure whether any SOPs existed. Following the inspection, SOPs and policies for the prescribing service were provided to the inspector and the PIP was also spoken to by video call to discuss the prescribing policies and practices.

Prescribing policies for asthma, weight-loss and contraception included information on dose, side effect profile, inclusion and exclusion criteria, as well as the patient journey.

There were no SOPs, risk assessments, or prescribing policies for the prescribing service on site and the RP was not sure if there were any, and was not familiar with them. The SOPs covering the prescribing service were sent to the inspector following the inspection. These were not available at the pharmacy during the inspection and therefore were not accessible to team members.

The prescribing policy for asthma identified asthma as a high-risk condition and stipulated that a letter should be sent to notify the person’s GP when asthma medication was prescribed. The PIP demonstrated that patients completing an asthma questionnaire were required to give consent for the pharmacy to contact their GP. However, the PIP did not know where the consent was recorded or what the letter to the person's GP looked like. He assumed that a letter was being sent to the GP by an automated process, but had no assurance it was actually being done. The pharmacy did not obtain consent to contact GPs for conditions other than asthma. The policy also stated that when prescribing asthma treatments, the person’s Summary Care Record (SCR) would be checked for up-to-date information about their medicines. But the PIP admitted this was not done.

The SOP for weight-loss treatments stated that weight-loss medicines should be used for three months (orlistat) or four months (Saxenda or Mysimba), after which people would be expected to have lost 5% of their initial bodyweight. If this had not been achieved, the pharmacy would discontinue treatment. The PIP explained that this would be checked when people requested future treatments by reviewing

the weight the person had declared on the consultation form. But there was no evidence of any steps being taken to verify the information that people provided.

The general prescribing SOP stated that the pharmacy would 'make appropriate arrangements for after care and, unless the patient objected, share all relevant information with colleagues and other health and social care providers involved in their care to support ongoing monitoring and treatment'. But there was no evidence that this was happening.

Risk assessments for the prescribing service were also provided following the inspection for specific medicines Ventolin, Saxenda, Evra, Microgynon, Yasmin, Orlistat and Mysimba. They had been written and reviewed by the PIP and included an overview of the condition, hazards identified, control and safeguard measures, recommendations for improvement, and reference sources. Weaknesses and risks in the system that had been identified were followed up with recommendations.

A number of deficiencies were identified in these risk assessments. For example, the risk assessments addressed communication with the person but did not consider communication with the person's regular practitioner or access to SCRs. The risk assessments considered the risk of medicines being abused, but maximum quantities or dosages were not included.

There was no mention of inhaled corticosteroids within the risk assessment for Ventolin. The risk assessments for Saxenda, Mysimba and orlistat did not sufficiently cover the risks of supplying these medicines at a distance. For example, they identified the abuse potential as low, however as these medicines supported weight loss, there was potential for abuse by vulnerable people or those seeking to rapidly lose weight. There was no mention of maximum supplies especially in the event a person did not lose the recommended percentage weight loss (5% in 12 weeks). It also did not mention the need for counselling for the injectable treatments and the pharmacy could not demonstrate that any counselling had been provided.

The prescribing policies stated, "clinical patient information not present in the questionnaire must be recorded in the patient notes". There was a facility for this information to be entered on the computer system, but there was no evidence of any prescribing decisions being recorded. A sample of prescribing was reviewed but no records were seen showing the justification for prescribing. Some examples were found where patients had stated they were not using their Ventolin inhaler frequently but they appeared to be running out every one to two months and reordering. The PIP argued that he would prefer that a person to be supplied with an inhaler rather than have an asthma attack. But this view did not seem to recognise that if a person needed a reliever immediately, there would be quicker alternatives than the medication being ordered online and posted. The consultation also stated that the medicine was not supplied for emergency use.

The PIP explained that the management team would complete regular performance reviews including a quarterly audit of prescribing related work. Feedback would be provided to the prescriber. However, the service had only resumed a few days before the inspection, so no audits had yet been done. And there was no evidence of any audits being completed prior to the service being suspended.

The RP was unsure if a Covid-19 staff risk assessment had been carried out at this branch. Team members were observed wearing face masks. Additional PPE, such as aprons and gloves, was also donned for some services such as the Covid-19 testing service. The RP said that the consultation room was disinfected after every person. PPE was also provided to delivery drivers.

The RP described the process he would follow to deal with any dispensing mistakes which were handed to a person (dispensing errors). This included rectifying the error, contacting the person's GP and

reviewing SOPs if necessary. He was not aware of any dispensing errors being made since he started at the pharmacy and admitted that he did not know where he would document dispensing errors.

Near misses (where a dispensing mistake was identified before the medicine had reached a person) were highlighted with the team member involved. A near miss record was available but no near misses had been recorded for more than a year. The RP said that since he had started he had instructed all team members to record their near misses. He said that he intended to review the record to help identify any contributing factors and discuss ways in which to minimise near misses with the team.

The pharmacy had current professional indemnity insurance cover. The incorrect RP notice was displayed. This was changed during the inspection. The RP record, emergency supply record, and controlled drug (CD) records all appeared to be in order. The physical stock of a random CD was checked and matched the recorded balance. The pharmacy's private prescription register included details of private prescriptions dispensed, but not for those which had been issued by the prescribing service, which did not meet record-keeping requirements. Records for unlicensed medicines could not be found and the RP said that these were not commonly dispensed. Invoices and certificates of conformity for unlicensed medicines would be sent to head office at the end of the month.

People were able to give feedback or raise concerns online or verbally. The pharmacy normally conducted annual patient satisfaction questionnaires but had not done these since the start of the pandemic

The RP did not know whether members of the team had received any training on information governance or the General Data Protection Regulation (GDPR). SOPs covering confidentiality were in place but had not been signed by current team members. Confidential waste was kept in separate bags and stored in a cupboard before being collected by head office. The bags were not always stored securely. The RP said that he would review their storage and ensure they were stored securely. Computers were password protected and smartcards were used to access the pharmacy's electronic records. Cordless telephones were available so that members of team could have private conversations away from people.

The pharmacist had completed the Centre for Pharmacy Postgraduate Education (CPPE) training on safeguarding vulnerable people and the trainee dispenser had received some in-house training on the subject. The trainee dispenser could not describe signs of abuse or neglect and did not know who the local safeguarding team were. She said she would report any concerns to the pharmacist or manager. Safeguarding vulnerable individuals had not been considered in the prescribing SOPs. So, was unclear how safeguarding concerns would be dealt with for people requesting medicines.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to manage its workload. Team members have clearly defined responsibilities, and they do the right training for their roles. And they complete some ongoing training to help keep their knowledge up to date.

Inspector's evidence

There was the RP and one trainee dispenser working during the inspection. The trainee dispenser normally worked at another branch but was helping at this branch until another person was employed. They worked well together and communicated effectively. Another two trainee dispensers helped cover shifts at the pharmacy. The RP had only recently started working at the branch and was still in the process of familiarising himself with processes and completing training on all the services. Some services had been suspended whilst he completed training, such as blood pressure monitoring and vaccinations.

The team appeared to be managing the workload. The RP said that a team meeting was held every morning to discuss the work and priorities. He said that staff involved in the prescribing service had a telephone communication platform which included the PIP, web developer and dispensing assistant. The RP was not able to demonstrate this because he had not been added to the system and the dispenser did not have access. This meant that the RP did not currently have a way to communicate any concerns about prescriptions to the PIP. The RP was not aware whether consent to contact a GP was sought prior to the prescription being issued. This was subsequently discussed with the PIP, who stated that the RP and dispenser were both sent links to access the chat platform prior to the service starting but that they had not registered. He confirmed that the RP had now gained access.

The RP said that he had time to help at other branches, for example, checking multi-compartment compliance packs. The trainee dispenser was observed dealing with queries efficiently. She was aware of her role and responsibilities and said she would not sell prescription-only medicines (POMs) or Pharmacy-only medicines (P-medicines) in the absence of the RP. She asked several questions before selling P-medicines and described when she would refuse a sale, for example, multiple requests for higher-risk medicines.

The RP kept up to date by completing training modules and continuing professional development (CPD) cycles in his spare time. He was looking to complete a CPD cycle on inhaler techniques as the pharmacy had many people using a variety of inhalers and he wanted to know more about each one in detail.

During the virtual call the PIP confirmed that he had completed his independent prescribing course specialising in hypertension. He was familiar with the medicines that he was prescribing (asthma, contraception, weight loss) through his practice in other roles. This included working at other prescribing service providers. The prescriber provided some examples of training he had completed to prescribe the range of medicines provided at the pharmacy. For example, he shared certificates for webinars he had attended on asthma, women’s health, and Saxenda. The certificates did not have a name on it but contained brief details of what the webinar included. There was no evidence of training for other weight loss treatment such as orlistat or Mysimba. There was good reference to national guidance within the SOPs and risk assessments, which could indicate the prescriber’s familiarity of

evidence-based medicine. However, the review of a sample of orders, particularly those for asthma treatments showed that best practice guidance was not always considered. For example when supplying salbutamol inhalers to people with knowledge that they did not have other asthma treatments, such as an inhaled corticosteroid (preventer). The PIP explained that he had been recruited to risk assess the prescribing service. He had updated and formed new consultations and had written the SOPs. He said that more treatments would be made available as risk assessments were finalised. An example of an improvement that he had implemented was the ability for the prescriber to see the order history and communication with people requesting medication online.

The trainee dispenser said that the workload was manageable and that she had learnt a lot from the current and the previous pharmacists. She usually worked in the online pharmacy section at another branch and did not have experience in NHS community pharmacy prior to starting at this branch. She completed her training modules during working hours, but only if there were quieter moments. She said that the RP was helpful and supportive. He had sent her some additional training material, for example, documents and booklets about over-the-counter medicines. She said she was hoping to complete the technician training course once she had finished the dispensing course.

Team members had not had appraisals. The trainee dispenser said she was happy to raise concerns to the RP or to another member of staff at head office. Targets were not set for the team. The PIP was not employed by the pharmacy and was paid for each consultation. This did not depend on whether a prescription was generated and therefore there was no financial incentive to approve prescriptions.

Principle 3 - Premises **Standards not all met**

Summary findings

The pharmacy premises are generally well maintained and fit for purpose. But parts of the pharmacy are not adequately protected from unauthorised access. And the pharmacy's website allows people to start a consultation from the page of an individual prescription-only medicine.

Inspector's evidence

The pharmacy had new fittings which were modern, clean, and well maintained. The dispensary comprised of one long workbench and several shelving units. There was limited workspace, but the workbench was kept tidy. Access into the dispensary was via two low swing doors on either end of the dispensary. A sink, with hot and cold water, was fitted in the dispensary. A consultation room was available for services and private conversations. The room was clean and fitted with a sink. The retail area was tidy and had a small, cushioned bench for people wanting to wait for a service.

The online part of the pharmacy business was located in the basement. The room was bright and comprised of two long workbenches, several storage shelves, a kitchenette, and a toilet. It was fitted with two computers. The room was accessible to members of the public directly from the retail area and so it was not secure from unauthorised access. On the day of the inspection the pharmacy's website allowed people to select a POM before an appropriate consultation. The website was updated following the inspection. However, the website still allowed a consultation to be started directly from the page of the individual POM.

The ambient temperature and lighting were adequate for the provision of pharmacy services. The building the pharmacy was in could be secured from unauthorised access when the pharmacy was closed.

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

Summary findings

The pharmacy doesn’t take enough care to make sure it always prescribes medicines safely. It does not always share information about the medicines it prescribes with people’s normal doctor or follow up about treatments that need ongoing monitoring. And there is some evidence of inappropriate supplies of inhalers to people who have indicated that they do not take other asthma treatments. However, the pharmacy's services are accessible to people and it orders its medicines from reputable suppliers and generally stores them properly.

Inspector's evidence

The pharmacy entrance had a small step which could make access more difficult for some people. But the pharmacy had an all-glass front and team members had a clear view of the main entrance and could help people into the premises where needed. A bell was fitted to alert team members when a person entered the pharmacy. Services and opening times were clearly advertised, and a variety of health information leaflets was available. There was a cushioned bench available in the retail area for people wanting to wait for a service. Some members of the team were multilingual and also described using an online translator.

The pharmacy provided an online prescribing service to people living anywhere in the United Kingdom. Dispensing for this service was carried out in a separate dispensary located on the lower ground floor. The service had started in August 2020 but had been suspended in December 2021. The pharmacy had restarted the service in March 2022, only a few days before the inspection.

To request medicines via the online prescribing service people needed to complete an online consultation. During the consultation the person could select the medication they wanted and its quantity. This was done prior to the end of the consultation. If there were any responses to the consultation which would result in a supply not being approved, the person automatically received a notification to inform them the consultation was unsuccessful. People continued to checkout if their consultation had been successful. If the order was approved and the prescriber had any comments or advice, these would be added to the confirmation email. There was evidence of some messages being sent to people, for example, requesting weight and height and providing standardised counselling points. Once payment was confirmed, the person were requested to upload their ID. The person's ID could be verified by the dispenser or the website developer. The ID was blurred once verified so it could not been seen by the prescriber. The dispenser stated that payment card details were not checked as part of ID checking and were not known to the pharmacy. The credit checks were being carried out by a third-party system. Refused consultations could not be seen by the pharmacy team.

The PIP explained that he used the information people provided in online questionnaires to inform his prescribing decisions. He believed it was reasonable to expect patients to provide true and accurate information. There was no evidence of the pharmacy sharing any information with patient's GPs about the treatments it had prescribed, but the PIP pointed out that terms and conditions of the online service required the patients to inform their GPs themselves. The questionnaires had been updated when the prescribing service had recently restarted and more questions had been added. However, they were still fairly basic and largely involved yes/no questions or check boxes. There was a tab on the system which stated "global quota exceeded". The PIP explained that this was a limit that the pharmacy

could place on certain lines. However, none were set as he felt this should be the prescriber's decision in each individual case.

A questionnaire was seen in relation to a supply of Saxenda for weight loss. In response to a request for information about their lifestyle the person had stated the number “76”. The PIP said that he had assumed the person meant they wanted to lose weight, and weighed 76kg. But the PIP had not followed this up with a call or communication to confirm this understanding or seek further information. The PIP felt that because the person had provided their BMI, he had the information to make a prescribing decision but he had not documented the reasons for this decision.

If the prescriber had a query, they were able to obtain the person’s telephone number or email for contact. However, the PIP confirmed that to date he had not yet contacted anyone. He said if the person needed to make contact, they could email the customer services team who would then contact the prescriber. Any communications that were made via customer services team were automatically logged. If the order was rejected or the consultation failed this was also logged on the system and any future attempts at another order were flagged up.

The pharmacy provided a 'fit-to-fly' Covid-19 testing service and used the consultation room to provide the service. The RP said that people were provided with the kit and carried out the tests themselves. The sample was then sent to the laboratory via a courier. Results were sent directly to the person. The RP wore a face mask, apron, and gloves when observing people carrying out the tests, and disinfected surfaces before and after each person.

The RP said that a double check was always performed when medicines were dispensed to help reduce the risk of error. Baskets were used to prevent prescriptions being mixed up during dispensing. Dispensing labels were not always initialled to show who had dispensed and checked the medicines. This meant it could be difficult to identify who had been involved in these processes, for example, if a dispensing mistake occurred. Dispensed medicines awaiting collection were filed in alphabetical order but those for Schedule 3 and 4 CDs were not highlighted in any way. When questioned, the trainee dispenser did not know how long these prescriptions were valid for. A prescription for zopiclone, dated 10th February 2022, and therefore no longer valid, was found still with the bags of dispensed medicines awaiting collection. This meant that there was a risk that CDs could be supplied after prescriptions were no longer valid.

Multi-compartment compliance packs were assembled in the dispensary by a trainee dispenser. Prepared packs present had been labelled with product descriptions and mandatory warnings, and patient information leaflets were routinely supplied. The pharmacy managed the prescription ordering on behalf of people receiving these packs and had clear audit trails for the service. This helped keep track of when people were due their packs, when their prescriptions had been ordered, and when their packs were supplied.

The pharmacy offered a delivery service to people's homes. Records were maintained but people were no longer being asked to sign the records due to the pandemic. Medicines were at times posted through the letterbox, but the RP said that the pharmacy checked if pets or children lived at the person’s home. The pharmacy did not keep any records to show whether people had given consent. The RP added that people were contacted beforehand to arrange delivery of their medicine, and this helped reduce missed deliveries.

The RP was aware of the checks and labelling requirements of dispensing sodium valproate to people in the at-risk group and said he would provide booklets or alert cards, but these could not be found. The RP said he would order additional supplies. The trainee dispenser was not aware of the valproate

guidance and said she would familiarise herself with it. The RP explained that he always checked whether women taking Roaccutane were on the Pregnancy Prevention Programme. He did not routinely check if people taking other higher-risk medicines, such as lithium and methotrexate, were being routinely monitored, but he said that local GPs made a note on the prescription when a person was due a blood test. Team members said they wore gloves when dispensing cytotoxic medicines.

The pharmacy used recognised wholesalers to obtain its pharmaceutical stock. It kept its medicines and medical devices tidily on the shelves within their original manufacturer's packaging. The pharmacy team said they checked the expiry dates of medicines at regular intervals. The last check was seen to have been done in January 2022, but records for previous checks could not be found. No expired medicines were found on the shelves in a random check in the dispensary. The fridge temperature was monitored daily. Records indicated that the temperatures were maintained within the recommended range. Waste medicines were stored in appropriate containers and collected by a licensed waste carrier. The RP said that he checked the MHRA's website regularly for drug alerts and recalls and actioned them, but he did not maintain any audit trails and so was not able to demonstrate the action that had been taken. He said he would maintain records in the future.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely.

Inspector's evidence

Suitable equipment for measuring liquids was available. Several triangle tablet counters were available. Up-to-date reference sources were available in the pharmacy and online. The phone in the dispensary was portable so it could be taken to a more private area where needed. The fridge was clean and suitable for the storage of medicines. The SI said that the pharmacy was not currently using the blood pressure monitor or the blood glucose meter. Both would be replaced once the services resumed. There were masks, gloves, and hand sanitiser available for team members to use to help minimise the spread of infection.

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.