General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: The Independent Pharmacy, Unit 19-20, Bonville

Business Centre, Bonville Road, Bristol, Somerset, BS4 5QR

Pharmacy reference: 9011543

Type of pharmacy: Internet / distance selling

Date of inspection: 05/08/2022

Pharmacy context

This is a pharmacy that offers its services to people only through its website. It is a distance selling pharmacy and provides an online doctor service for which people can seek treatment for a range of conditions. People cannot visit the pharmacy in person and all medicines are delivered. The pharmacy is located on an industrial estate on the outskirts of Bristol. The pharmacy delivers medicines throughout the United Kingdom. The pharmacy also dispenses NHS prescriptions, dispenses private prescriptions, and sells medicines through its website. The pharmacy is also registered with the Care Quality Commission (CQC) and the Medicines and Healthcare products Regulatory Agency (MHRA).

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 met	N/A	N/A	N/A
2. Staff	Standards met	2.2	Good practice	The pharmacy team can access training to keep their knowledge up to date and receive time to complete it.
		2.4	Good practice	The pharmacy team members maintain a clear and embedded culture of openness, honesty and learning.
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website is laid out in such a way that it gives the impression people can choose a prescription only medicine before having an appropriate consultation. It also has a search facility which allows people to search for, and find, prescription only medicines.
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✓ Standards met

Summary findings

The pharmacy has satisfactory written procedures to help make sure the team works safely. Pharmacy team members have procedures in place to record and review mistakes when they happen. They use this information and learning to avoid future mistakes. Pharmacy team members are clear about their roles and responsibilities. The pharmacy asks its customers and staff for their views and uses this to help improve services. It manages and protects people's confidential information, and it tells people how their private information will be used. The pharmacy has appropriate insurance to protect people when things do go wrong.

Inspector's evidence

The pharmacy team had taken measures to mitigate the risk of transmission of COVID-19. Risk assessments had been completed assessing the impact of COVID-19 on the pharmacy premises and the individual pharmacy staff members. Processes were in place for identifying and managing risks. Near misses were recorded and reviewed when they occurred and the pharmacist would discuss the incident with the members of the dispensary team. The pharmacy team used barcodes throughout the dispensing process to identify near misses. This also maintained audit trails to show who had dispensed and checked the medicine. The pharmacy demonstrated that that near misses were significantly reduced following the implementation of barcode technology.

There was a process in place to report dispensing errors and this included a root cause analysis as part of the process. The pharmacy dispensary team held fortnightly dispensary meetings to discuss error rates which were based on dispensing and medicine selection. Reports were generated and these included proposed changes to mitigate the risk of mistakes happening again in the future.

The pharmacy also had also identified there was a risk of error if prescriptions written by the Pharmacist Independent Prescribers (PIPs) were not second checked. Clinical checks of prescriptions were carried out by another pharmacist prescriber, and this included accessing the prescriber's consultation notes. The prescribing team worked on site and in an open plan office. Therefore, if there were any concerns with prescriptions these could be addressed directly and efficiently with the prescriber.

Regular audits were used to inform risk assessments. Examples included auditing what prescribing activity had been undertaken and if any concerning prescribing occurred this was discussed with the prescriber. The pharmacy used a clinical decision-making sheet to identify errors and look for improvements. Samples of prescriptions for each prescriber were reviewed each month to identify prescribing practices and identify areas for improvement.

The prescribing team met with the clinical advisor regularly to review clinical queries raised from prescribers. These meetings were documented, and the information was shared with other prescribers to facilitate shared learning. The clinical advisor worked remotely but was available to all prescribers should they have any urgent clinical queries. An example was a patient who experienced a rash following the use of a cream. This was sent to the clinical advisor who provided clinical advice. This was an example of team-led decision making which resulted in the medication being stopped. This information was also added to the patient record at the pharmacy and communicated to their own GP.

Another example was a photograph from a patient of suspected acne under their armpit. The clinical advisor was able to remotely advise the prescriber at the pharmacy and treatment was arranged.

There was separation of prescribing and clinical checking of prescriptions as these were done by different individuals. The clinical check of the prescription by the dispensing pharmacist included a check of the clinical notes used to prescribe the medicine. The prescribing process had in-built safeguards to support safe prescribing. An example of this was the removal of automatic processes relating to allergy status. The prescriber had to manually check allergy status of the patient.

Standard operating procedures (SOPs) were in place for the services provided and these had been recently reviewed. There was a complaints procedure in place and staff were all clear on the processes they should follow if they received a complaint. There was information for people about how to complain on the company website. Recent feedback about the pharmacy had been largely positive. The pharmacy team had not recently completed a Community Pharmacy Patient Questionnaire (CPPQ) but intended to start these again in the future.

A certificate of public liability and indemnity insurance was held with the NPA and was valid and in date at the time of the inspection. The superintendent (SI) pharmacist confirmed that Beazley's insurance was held for the prescribing service. This covered all of the prescribers, even those who had their own indemnity arrangements. This also included cover for remote prescribing.

The pharmacy did not dispense controlled drugs (CDs) and therefore a register was not kept. A responsible pharmacist (RP) record was retained. The fridge temperatures were recorded daily and were within the two to eight degrees Celsius range. Date checking was carried out regularly and records of this were seen to be completed appropriately. The private prescription records were kept in two different locations, so it was not clear which one was the legal record. A sample of selected entries on an electronic record omitted the name of the prescriber. The superintendent pharmacist agreed to address this. The specials records were retained but some were missing the prescriber's name and address details.

The clinical check undertaken after the prescribing process included a check of the prescriber's notes. This meant that the pharmacist performing the clinical check had access to relevant information to determine to appropriateness of the prescription. Comprehensive notes were completed, and these were available to other prescribers in future should the patient present again. Clinical consultation notes were linked with the customer service notes. Prescribers recorded when they had the person's consent to contact their own GP.

Confidential information was collected for appropriate disposal. An information governance policy (IG) was in place. Staff had completed a training package on the General Data Protection Regulation (GDPR). Some people were asked for photographs to inform the consultation and prescribing process. These photos were stored on an encrypted server. Old photos were deleted if a new photo was uploaded. Consultations notes were stored securely.

The pharmacy had a robust identity checking process in place for people using its services which included age-checking. The pharmacy team had the ability to prevent people from using the online ordering system if there were concerns relating to their overuse or misuse of medicines. This was also the case for people whose own GP advised the pharmacy not to supply medicines to them. All staff were trained to identify safeguarding concerns, with prescribers having completed the CPPE level 3 safeguarding package. All prescribers had access to contact details for safeguarding leads depending on region in country where patient is. Prescribers had also completed training on contraception and

Female Genital Mutilation.						

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy's team members have the appropriate skills, qualifications and training to deliver services safely and effectively. The pharmacy team members work well together. They are comfortable about providing feedback and raising concerns and are involved in improving pharmacy services.

Inspector's evidence

There were three pharmacist independent prescribers (PIPs), two pharmacists, one accuracy checking technician and nine dispensing assistants present during the inspection. There was sufficient staff for the services provided during the inspection. Staff were seen to be working well together and supporting each other when required. All staff had completed appropriate training courses for their roles or were on a training course.

The pharmacy team was supported through regular one-to-ones and both the superintendent pharmacist (SI) and another pharmacist director were on-site and worked amongst the team. The pharmacy team explained that this meant that any concerns or suggestions could be raised more easily. The pharmacy team had formal appraisals twice a year and details of these meetings were held on the employee record.

The clinical team consisted of five PIPs who were supported by a clinical advisor who was a General Practitioner (GP) by background. The pharmacy team, except for the clinical advisor, were based onsite. This meant that the prescriber was accessible to the pharmacist carrying out the clinical check and the wider pharmacy team. The SI explained that a minimum of two PIPs would be working at any one time. This allowed for one of the prescribers, who would acting as the responsible pharmacist, to clinically second check each prescription. The SI explained the pharmacy had an aim to have all prescribers skilled to a baseline level to allow consistency across services and that complex cases were managed by all prescribers.

All PIPs completed an induction period and read and signed all clinical guidelines. They were then audited on a condition-by-condition basis on an increasing scale of difficulty. The purpose of this was to identify their understanding of the process and knowledge of the clinical guideline. The induction period covered all clinical conditions for which prescribing occurred. A new prescriber had joined two months before and had not prescribed or clinically checked as the pharmacy team focused on improving their knowledge and training in the various clinical areas. Once the initial training had been completed, new prescribers would only prescribe in a small area first and had their prescribing clinically checked by a senior clinician. Training logs were kept by prescribers detailing their development over time and what activities they had completed to develop themselves and keep their skills up to date.

The pharmacy used a communication software tool to connect colleagues. The prescribing team used this to communicate to both the clinical advisor and to the pharmacy team. Conversations between teams were stored on the communication software tool. Minutes of clinical meetings were shared on this platform amongst pharmacist prescribers to facilitate shared learning. The prescribing team held regular team meetings to discuss clinical queries and seek advice from one another. All the pharmacy team, including the dispensary staff, engaged in regular team building exercises and staff social outings to promote a healthy team rapport.

There was time each day for the PIPs to focus on their development. An example of prescribing team development was shared where the team had recently viewed a webinar about the menopause as a way of improving practice in this area. Prescribers at the pharmacy had quarterly meetings sessions with the GP clinical advisor. These consisted of thirty minutes for each prescriber to discuss any clinical topic they wish to learn more about.

The pharmacy team felt empowered to exercise their professional judgement in the best interests of their patients. A patient had ordered orlistat for weight-loss. This was a repeat order. The patient was nearing a healthy body mass index and so the prescriber sent a letter by email to inform them that this would be their last supply. Staff were aware of the whistleblowing policy and felt comfortable to use this if necessary. There were no targets or incentives for prescribing. There was a bonus structure in place that was linked to quality performance measures such as the telephone manner of staff, for example.

Principle 3 - Premises Standards not all met

Summary findings

The pharmacy's website is laid out in such a way that gives people the impression that they can choose a prescription only medicine before having an appropriate consultation with a prescriber. This could mean they may not always receive the most suitable medicine for their needs. The premises themselves provide a professional, safe and secure environment from which the pharmacy provides its services.

Inspector's evidence

The pharmacy was based in two large units on an industrial estate, and it was closed to public access. The upper levels were used as offices for the pharmacist prescribers and for medicines storage. The bottom levels were equipped with machinery for packing and dispatching medicines. The two units were well laid out, well organised and all areas appeared clean and were presented in a professional manner. Medicines were stored in a generic and alphabetical manner.

The pharmacy's website showed the responsible pharmacist's details and a photograph. There was a selection of treatments available online and links for people to follow and start a consultation. Those condition pages examined did not have a button or link for people to start a consultation on the condition itself. Instead, each condition on the website listed the different products available and their prices. Against each product was a button labelled 'view details' which then led to a page for that individual product. There was then a 'start consultation' button on each product page which gave the impression that the person could choose the specific medicine they wanted to buy before actually starting the consultation. This meant people may not always receive the most suitable medicines for their needs. There was also a search facility which directed people to a selected prescription only medicine, from where they could again click through to the consultation page. The consultation is questionnaire based and in some instances a pop-up appears for a negative answer to a question. This means that the questionnaire may direct people through it to obtain a medication that is not suitable for them.

The pharmacy's website had a robust identity checking process in place. They used an external software application to verify the identity of people. These checks included the person's name, billing and delivery addresses and phone number and email where given. If the software identified a failure in the information submitted, it notified people through their account. People would then be given an opportunity to re-submit information but would need to submit additional details such as their passport number or driving licence number. The pharmacy also had an automated software in place that highlighted when duplicate accounts were created.

There were sinks available with hot and cold running water with hand sanitiser to allow for hand washing. The ambient temperature and lighting throughout the pharmacy were appropriate for the delivery of pharmaceutical services.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy's services are accessible, effectively managed and delivered safely. The pharmacy obtains, stores and manages medicines safely and ensures that all of the medicines it supplies are fit for purpose. The pharmacy team helps advise people on how to take high-risk medicines safely. The pharmacy team takes appropriate action where a medicine is not fit for purpose.

Inspector's evidence

This pharmacy was a distance selling pharmacy and provides an online doctor service. It was closed to the public. Treatments for a wide range of conditions were advertised on the website. Some of which are long term conditions that require on-going monitoring and follow-up. Examples of these include, but are not limited to, medicines for asthma, erectile dysfunction, hair loss, contraception, and weight loss. The pharmacy also provides treatments for acute conditions such as antibiotics for urinary tract infections and treatments for sexually transmitted infections (STIs). Callers were given options to direct their call to the pharmacy or to customer service, depending on the nature of their query. Customer service advisors directed any clinical queries to the pharmacy team. All orders were processed via the website. Some support was available over the phone, but no orders were processed this way. As orders passed through the checkout function on the website, the ID check was completed (see principle 3).

All medicines were delivered to patients. There was a delivery policy in place and medicines were sent using tracked delivery. Fridge items were sent with cooling packs to maintain the temperature of the medicine between two to eight degrees Celsius. The superintendent pharmacist confirmed that medicines were not posted through letterboxes.

The superintendent pharmacist (SI) reported that the most common treatments for which medicines were supplied included erectile dysfunction, weight loss, hair loss and malaria. The SI reported that lifestyle medicines tended to be the most common choice by patients. The pharmacy did not supply controlled drugs such as codeine, dihydrocodeine and gabapentin on their website. They also did not supply medications which they viewed as liable to abuse such as modafinil. The SI explained that he did not feel comfortable supplying liraglutide injections as a treatment option for weight loss as he did not feel that online prescribing was safe for this medicine. The SI explained that risks associated with medicines were considered when deciding which medicines should be available for online prescribing. Some medicines had quantity and frequency limits in place to prevent people over-ordering. An example was salbutamol inhalers for asthma management. The pharmacy imposed a quantity limit of two inhalers and a frequency limit of six months. This meant a person could only obtain a maximum of four inhalers in a year from the pharmacy.

The pharmacy team use national frameworks and guidance to aid in the prescribing of medicines to people. This was evidenced through their internal clinical guidance documents. An example which was discussed was STI ordering limits and timeframes based on the British Association on Sexual Health and HIV (BASHH) guidance.

The pharmacy kept a range of clinical guidelines for reference by pharmacist prescribers. These were written and reviewed regularly and included details on order quantities and frequencies, details of medical history to consider when prescribing, prescribing criteria, information on safety and side effects

and details of what information to communicate to people using these medicines. There was evidence of pharmacist independent prescribers communicating with patients via telephone to obtain further information and this was followed up by email. There were several template letters which the pharmacy could email to patients where appropriate. This included information for signposting if the supply was inappropriate, counselling for the medicine or general lifestyle advice.

Consent to view Summary Care Records (SCR) was obtained for some treatment areas but not others. SCR access was only available for people registered with a GP in England. Whether or not the SCR was used to inform prescribing was based on risks associated with the medicine. Certain medicines required data sharing, particularly those which related to long-term conditions, such as asthma, menopause, and high cholesterol. Other medicines did not, such as antibiotics for STI treatment.

Treatment for weight-loss, with a medication known as orlistat, did not require mandatory consent to access people's SCR or data sharing with people's GP. This could pose a risk as medicines used as weight loss treatments can be liable to abuse, misuse and overuse. Orlistat requires ongoing monitoring as the licensing for the medication suggests that a patient must lose 5% of their initial body weight in 3 months, or treatment to be discontinued. The pharmacy did not verify the accuracy of information in relation to the person's weight.

The pharmacy team had an awareness of the strengthened warnings and measures to prevent valproate exposure during pregnancy. Valproate patient cards were available for use during valproate dispensing to female patients. The pharmacists reported that they would check that that the patient's prescriber had discussed the risks of exposure in pregnancy with them and that they were aware of these and query if they had effective contraception in place.

The pharmacy used recognised wholesalers such as AAH, Alliance Healthcare and Sigma Pharmaceuticals to obtain medicines and medical devices. Specials were ordered from BCM specials. Destruction kits for the destruction of controlled drugs were available. Designated waste bins were available and being used for out-of-date medicines. A bin for the disposal of hazardous waste was also available for use. Waste was collected regularly, and the pharmacy team explained they would contact the contractors if they required more frequent waste collection.

Medicines and medical devices were stored in an organised fashion. Pharmaceutical stock was subject to date checks which were documented and up to date. Short-dated products were appropriately marked. The fridge was in good working order and the stock inside was stored in an orderly manner. MHRA alerts came to the pharmacy electronically and the pharmacist explained that these were actioned appropriately. Records were kept to verify this.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has access to the appropriate equipment and facilities needed to provide the services it offers. These are used in a way that helps protect patient confidentiality and dignity.

Inspector's evidence

There was a satisfactory range of crown stamped measures available for use. Amber medicines bottles were capped when stored. Electrical equipment appeared to be in good working order and was PAT tested annually. Pharmacy equipment was seen to be stored securely from public access. The pharmacy used automated packing machine equipment which used lasers to detect how to efficiently pack medicines. This meant that the pharmacy used less filler in the individual boxes and so the packaging was more environmentally friendly. These packing machines had regular servicing and maintenance and were cleaned frequently by staff.

Up-to-date reference sources were available including a BNF, a BNF for Children and a Drug Tariff. Internet access was also available should the staff require further information sources. The pharmacist prescribers had access to a range of additional reference sources to inform their prescribing. Examples of these included Martindale, the electronic medicines compendium and ToxBase.

There was one fridge in use which was in good working order. The maximum and minimum temperatures were recorded daily and were seen to be within the correct range. Designated bins for storing waste medicines were available for use and there was enough space to store medicines. The computers were all password protected and patient information was safeguarded.

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.	