General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Treated Pharmacy, Unit 18, Waters Meeting Business Park, Britannia Way, Bolton, Lancashire, BL2 2HH

Pharmacy reference: 9010946

Type of pharmacy: Internet / distance selling

Date of inspection: 14/11/2023

Pharmacy context

This pharmacy provides its services to people through its website (www.uk.treated.com). The website allows people to access the pharmacy's online prescribing service which offers prescription medicines for a wide range of conditions. The prescribing service is regulated and inspected by the Care Quality Commission (CQC). The pharmacy mainly supplies medicines for the treatment of erectile dysfunction and menopause as well as medicines used for contraception and weight loss. People do not visit the pharmacy in person. The pharmacy has an NHS contract, and it dispenses a small number of NHS prescriptions.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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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	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
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 reviews and monitors the quality of its services and it takes some action to improve patient safety. But the pharmacy could not confirm whether patient's weights were appropriately verified before weight loss treatments were prescribed. So, it can not provide an assurance that the medicines it supplies are always suitable. Team members respond appropriately when mistakes happen during the dispensing process. They complete the records that are needed by law. And they keep people's private information safe.

Inspector's evidence

The pharmacy's main activity was the supply of prescription only medicines (POMs) against private prescriptions issued by its own prescribing service. The prescriptions were issued by a medical prescriber and two pharmacist independent prescribers (PIPs). The prescribing service only offered treatments to people aged over 18 years and living in the UK. The medical prescriber was the clinical director of the prescribing service. He was registered with the General Medical Council (GMC), and the prescribing service was regulated by the Care Quality Commission (CQC).

People accessed the pharmacy's services via its website. People using the pharmacy's prescribing service were required to complete an online consultation before a prescription would be issued. Some people subscribed to receive medicines on a regular basis, in which case they did not need to complete a consultation for every supply but were required to inform the prescriber if there were any changes.

The pharmacy had a set of standard operating procedures (SOPs) which had been issued in February 2019 and their stated date of review was October 2024. Members of the pharmacy team had signed to say they had read and accepted the SOPs. Roles and responsibilities of the pharmacy team were described in individual SOPs. When questioned, a dispenser was able to explain what their responsibilities were and was clear about the tasks which could or could not be conducted during the absence of a responsible pharmacist (RP). The correct RP notice was on display. Records for the RP, private prescriptions and unlicensed specials appeared to be in order. A current certificate of professional indemnity insurance was on display. The SI confirmed that there were separate insurance arrangements for the prescribing service.

The pharmacy team was not able to confirm that people's weights were independently verified before weight loss medicines were prescribed. So, the pharmacy could not provide assurance that the treatments were always appropriate. The prescribing service had recently added some extra questions to the consultation which asked for the person's weight, circumference, and ethnicity.

The pharmacy had carried out two recent clinical audits, one on asthma inhalers and one on hormone replacement therapy. An internal audit had been completed between 1st June 2023 to 31st August 2023 on how compliant they were in independently verifying asthma diagnosis. The audit indicated that there were some instances where people requesting medication for asthma had not had their medical history independently verified. As part of the next steps, pharmacists who worked in the dispensary had been asked to note information when checking SCR as the audit had found this was the most common way in which diagnosis of asthma was confirmed. Pharmacists were also requested to double-check

with prescribers if the diagnosis had not been confirmed.

Clinical meetings were held between the directors and clinical team every couple of months The clinical director carried out audits involving the prescribing service to review prescribing trends and habits. The findings from the audits were then discussed with the prescribers and the SI at the clinical meetings The pharmacy's risk register, regulatory changes, incidents, safeguarding, training, complaints, and feedback were also discussed at these meetings.

People using the pharmacy's online services were required to set up an account. Duplicate accounts were screened using IP addresses, email address, billing address, payment method and shipping address. Any duplicate accounts found were blacklisted. Identification (ID) checks were carried out using a third-party identity checking service. This checked the patient's ID using address, first name, second name and date of birth. If these failed the pharmacy would ask for further ID proof by means of a valid passport or driving license. If two people ordered from the same address an automated flag would notify customer care and they would need to validate the two separate customers at the same address. The patient's previous order history was checked by the prescriber, and by the pharmacist during the clinical screening to identify any inappropriate requests, because the system did not flag repeat or multiple requests automatically.

The pharmacy team recorded details of any near miss incidents that occurred. The pharmacist reviewed the records and discussed any learning points during team meetings. But the reviews were not completed frequently. For example, the most recent review was for records between January and August 2023. So, there may be some delay before risks are identified. The SI explained that dispensing errors would be recorded and discussed with the pharmacy team at monthly team meetings, but no examples were available. Pharmacists carried out a clinical check when prescriptions were dispensed and made records on a clinical interventions log if they had identified an issue. The records included who the prescriber was, who the checking pharmacist was, the issue, and what action was taken. A dispenser gave an example about how she would query the dose on a prescription if she felt it seemed excessive. This involved speaking with the pharmacist before contacting the prescriber. The pharmacy kept a record of any prescribing interventions they made. Some of the interventions identified incorrect starting doses, and shorter than expected prescribing patters. The records contained details of the outcome from these interventions.

The pharmacy had a complaints procedure which was explained on its website, with the contact details for the customer care team. The pharmacy used Trust Pilot to monitor customer service, and reviews could be seen on the website. People were sent a feedback form with every order. The team were sent an alert for any one or two star reviews, which were then investigated. The management team said these were mostly due to delivery issues.

An information governance (IG) policy was available, and the pharmacy team completed annual IG training. When questioned, a dispenser explained confidential waste was separated and destroyed using the on-site shredder. Details about how the pharmacy used and stored people's information was detailed in the privacy policy on the website.

Safeguarding SOPs were available the pharmacy team had completed safeguarding training. The pharmacist had completed level two safeguarding training and the PIPs had completed level three training. Members of the team knew where to find contact details for the relevant safeguarding board. A dispenser explained she would initially report any concerns to the pharmacist on duty. The clinical intervention log showed an example of where the pharmacist checking prescriptions had flagged that someone had answered that they felt pressured to have sex on a questionnaire for contraception. The pharmacist had flagged this, and the person had been sent links for support groups.

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 complete the right training for their roles. And they complete ongoing training to help keep their knowledge up to date. Team members are comfortable providing feedback to their managers and they receive feedback about their own performance to help them improve.

Inspector's evidence

The dispensary team included two locum pharmacists, two dispensers, and an assistant who dealt with packaging and shipping. All members of the team had completed the necessary training for their roles. The volume of work in the dispensary was manageable. Staffing levels were maintained by a staggered holiday system.

The pharmacy provided members of the team with a structured e-learning training programme. And the training topics appeared relevant to the services provided and those completing the e-learning. Training records were kept showing ongoing training was up to date. Team members were given protected learning time to complete training.

The pharmacy completed annual appraisal with its team members to discuss performance, training requirements and areas for improvement. A dispenser described how she received a good level of support from the pharmacist and SI. She explained that the appraisal was a two-way conversation, and she was given the opportunity to express her views and raise any concerns. The team held regular huddles to discuss any issues that arose. There was also a formal team meeting held each month, and a record of these meetings was maintained. During the meetings the team discussed any learning from incidents, shared details of product recalls or alerts, and celebrated any good news. Team members were aware of the whistleblowing policy and said that they would be comfortable reporting any concerns to the SI.

The prescribing service had a clinical lead, who was a GMC registered doctor, and two pharmacist independent prescribers (PIP), one of whom was the SI. The SI had completed training to prescribe for certain conditions and held one-to-one reviews with the clinical lead to discuss case scenarios. However, there was no formal competency sign-off process. And there were no records of the discussions with the clinical lead. The SI did not prescribe weight loss medicines as she did not yet feel competent to prescribe in this therapeutic area.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy’s website gives information about the pharmacy and the prescribing service so that people can understand the services that are available. But some of the wording used on the website is misleading. So, people may believe that they are buying prescription only medicines rather than asking a prescriber to decide on the best treatment for them. The pharmacy premises are clean and tidy, and suitable for the services being provided.

Inspector's evidence

The pharmacy was located within an industrial unit. It was clean and tidy, and appeared adequately maintained. The dispensary was spacious, and an appropriate size for the workload. The security and lack of windows meant confidential information could not be seen by unauthorised people outside of the unit. The temperature was controlled by using air conditioning units. Lighting was sufficient. Members of the team had access to a kitchenette area and WC facilities.

The pharmacy's website allowed people to view the various treatments that were offered by the prescribing service. If a specific treatment was selected, the person would be directed to a holding page. This explained that they would need to provide information so that a prescriber could decide on the most appropriate treatment for them. They then clicked a button to start an online consultation. The page also provided information on other treatments available for that particular condition. However, it did not provide any information about the condition. So, people may not have understood the service they were being offered. Some of the wording used on the website including references to buy certain medicines online which may give people a false impression that they were buying prescription only medicines instead of a prescriber deciding the most suitable treatment for them. The SI gave an assurance that the wordings and other changes would be made to the website. The pharmacy's name, address, GPhC registration number, e-mail address and phone number were displayed on the websites. There were links to the GPhC register showing the registration details of the pharmacy via the voluntary GPhC logo. The name and details of the SI, clinical director and prescribers were available on the websites and there was a link to check their registration details.

Principle 4 - Services ✔ Standards met

Summary findings

People can access the pharmacy's services easily. The pharmacy's services are largely managed effectively, to protect people's health and wellbeing. The pharmacy gets its medicines from licensed suppliers and stores them safely. This helps make sure that medicines and devices are safe for people to use. The pharmacy team has professional oversight of all orders for medicines being processed and systems to intervene when there are issues with prescriptions. However, the pharmacy does not always seek assurances that the prescribing service it works with carries out checks to help make sure the medicines it prescribes are appropriate for people.

Inspector's evidence

People accessed the pharmacy's services via the website and could communicate with the pharmacist and team members via telephone or email. A messaging system was used to communicate between the pharmacy's prescribers and the person requesting the medicine. Negative responses were not highlighted to people as they completed the questionnaire. So, people were not able to change answers to obtain medicines that were not suitable for them. Prescriptions were generated and sent electronically to the pharmacy once the consultation was approved. The prescription also linked to the messaging system so communication with people were visible to the pharmacy team members. And they were able to see the consultation questionnaire. The services were advertised on the pharmacy's website and the pharmacy team were clear about what services were provided and when to refer people elsewhere. The pharmacy website contained information on different health conditions which had been written by the clinical lead.

The pharmacy had an NHS contract and dispensed a small number of NHS prescriptions. Once registered and nominated for the electronic prescription service , people could request repeat NHS prescriptions via the customer care team at the pharmacy. The SI explained that NHS prescriptions were usually received for medicines which were in short supply at high street pharmacies, such as HRT.

The prescribers issued prescriptions based on the information people provided when completing the online consultation questionnaires. Consent to inform people's GP of any medicines supplied was requested in all consultations, but most people did not provide consent. However consent was mandatory for levothyroxine and salbutamol to be prescribed, so the GP was always notified when these medicines were supplied. The SI explained that when consent was provided, the prescribers informed people's GP by letter. In the event that there was a failed delivery of the letter to the GP, the team would contact the person and attempt to send the letter again. Copies of the notifications were kept on the person's records. GPs were informed after a medicine had been supplied, so the GP would not be able to intervene to prevent the supply. The SI explained that if a GP responded to say that the patient was unknown to them, or they believed the supply was not clinically appropriate, a note would be added to the patient's profile, so subsequent prescriptions wouldn't be issued or supplied to them. For subscription services such as for salbutamol, the letter was sent to a person's GP after the first supply of the medicine. But the letter did not state that the supply was part of a subscription and the possibility of further supplies of the same medicine. The SI agreed that the template letter would be changed to make this clear.

The pharmacy could access people's Summary Care Records (SCR) and consent was requested during

the asthma questionnaire, but this was not mandatory. The consultation questionnaire included questions that aimed to help identify poorly controlled asthma. Some people had subscription plans which allowed them to request subsequent supplies of salbutamol inhalers for a twelve-month period. The pharmacy's clinical framework for asthma did not include the maximum number of inhalers (including salbutamol) it was willing to supply to people. The SI said people would usually be supplied with two inhalers every four months and any more frequent requests were reviewed by the prescriber. SCR for people on the subscription service was only checked with the initial supply and not for any subsequent supplies. So, the pharmacy may not be aware if the patient's circumstances had changed.

The SI explained that the pharmacy supplied a small number of people with weight loss medicines. Injectable medicines were more popular but there had been ongoing stock issues, some of which had been resolved recently. The questionnaire for weight-loss treatments had a statement related to the off-label use of Wegovy where it was being used for weight-loss, but the BMI was outside of the treatment criteria. In such situations, it was up to the prescriber to make the judgement. For example, if the person's BMI was lower than that specified in the licensing of the medicine, the prescriber made a note justifying their reasoning for prescribing. The pharmacy website had a page with information about off-licensed medicines which explained to people what it was, and people were referred to this page via email.

The pharmacy supplied medicines to people for hypothyroidism but did not offer a subscription service for these medicines as it could not provide ongoing blood testing and monitoring. Metformin was also available on the pharmacy's website. The SI explained that this was supplied only when someone had run out of their medication.

Pharmacists and prescribers communicated by telephone, messaging system and email, and the SI said the clinical director and prescribers were easily contactable. The pharmacy kept a clinical interventions log of queries with prescribers, and any actions taken as a result. Prescribers asked the pharmacist to access SCR, when appropriate and asked general questions about stock issues and medicine storage. The pharmacists queried any discrepancies between the patient's address on SCR and the one on the pharmacy computer , which had to be verified, before a supply could be made. Other interventions recorded included when a pharmacist had questioned the initial strength of Wegovy prescribed and when a prescription for a contraceptive had been queried because of the responses submitted on the questionnaire.

Both NHS and private prescriptions were supplied by courier. All deliveries could be tracked, and packages were not left with neighbours or in a safe place if people were not available to receive the delivery. Medicines requiring refrigeration, were sent using a next day service. They were packaged in a special container, to maintain at the correct temperature during delivery. The pharmacy team had carried out checks at different points in the year to ensure the packaging was effective.

The dispensary workflow was organised into separate areas with designated areas for clinical screening, assembly, checking, packing, and shipping. Team members all had individual log in details and the system logged who had completed each part of the process which included pharmacist clinical and accuracy checking and packing. The dispensary shelves were well organised and tidy. Dispensed by and checked by boxes were initialled on the dispensing labels to provide a dispensing audit trail. Different coloured baskets were used to organise workload and prevent prescriptions becoming mixed up.

The pharmacy had not dispensed any medicines containing sodium valproate. Other than the pharmacists, team members were not aware of the guidance for dispensing sodium valproate or the additional labelling requirements. The RP agreed to ensure team members were informed of the guidance.

Medicines were obtained from licensed wholesalers, and any unlicensed medicines were sourced from a specials manufacturer. Stock was date checked monthly. A date checking matrix was signed by team members to show what had been checked. Short-dated stock was recorded in a diary for it to be removed at the start of the month of expiry. A controlled drugs cabinet was available, but it did not currently contain any stock. There were clean medicine fridges, each equipped with a thermometer. The minimum and maximum temperatures were recorded daily and had remained in the required range over the last three months. Patient returned medication was disposed of in designated bins and there was information on the website about how people could return any unused medicines. Drug alerts were received by email from the MHRA. Alerts were printed and a record was made showing what action was taken, by whom and when.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for its services. It maintains the equipment so that it is safe to use.

Inspector's evidence

Team members had access to the internet for general information. This included access to the British National Formulary (BNF), BNFc and Drug Tariff resources. The pharmacy had counting triangles for counting loose tablets. Equipment was kept clean. All electrical equipment appeared to be in working order and a PAT certificate was available showing equipment was checked each year. A folder contained service contracts regarding facility management and pest control indicating they had up to date checks.

Computers were password protected. A cordless phone was available in the pharmacy which allowed team members to move to a private area if the phone call warranted privacy. As the pharmacy was closed to the public this helped to protect people's confidentiality.

An in-house IT system was used, and IT support was available on site. Confirmation was given that IT met the latest security specification. Computers and the patient medication records (PMR) were password protected and passwords were changed frequently.

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.