General Pharmaceutical Council

Registered pharmacy inspection report

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

Pharmacy reference: 9010946

Type of pharmacy: Internet / distance selling

Date of inspection: 30/03/2022

Pharmacy context

This pharmacy provides its services to people through its websites (www.treated.com and www.eveadam.co.uk). The websites allow 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, contraception and menopause. And it supplies a small number of over-the-counter medicines and testing kits. People do not visit the pharmacy in person, and over half of the medicines it supplies are for people living outside the UK. The pharmacy has an NHS contract, and it supplies a small number of NHS prescriptions. The inspection was undertaken 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 met	N/A	N/A	N/A
2. Staff	Standards met	2.2	Good practice	The team members have the appropriate skills, qualifications and competence for their role and the pharmacy supports them to address their ongoing learning and development needs.
		2.4	Good practice	The team is fully involved in improving the delivery of services and learning is shared both within and outside the organisation.
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's websites are arranged so that a person can choose a prescription only medicine before there has been an appropriate consultation with a prescriber.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	People in non-UK countries can purchase medicines without providing proof of their name, address or their age.
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 takes action to improve patient safety. Pharmacy team members work to professional standards and they are clear about their roles and responsibilities. They record their mistakes so that they can learn from them and they act to help stop the same sort of mistakes from happening again. Team members complete the records that are needed by law and keep people's private information safe.

Inspector's evidence

The pharmacy's main business was the supply of prescription only medicines (POMs) to people living in the UK and Europe. These medicines were supplied against private prescriptions issued by two medical prescribers and an independent pharmacist prescriber. People accessed the services via the pharmacy's own websites (treated.com and eveadam.co.uk). Both medical prescribers were registered with the General Medical Council (GMC) and the Irish Medical Council and the service was regulated by the Care Quality Commission (CQC). One of the medical prescribers was the clinical director of the prescribing service. The treated.com website offered treatments for male health, female health, infections, skin health, chronic conditions, acute conditions and lifestyle including smoking cessation and weight loss. The eveadam website was a subscription website where people could subscribe to receive medicines on a regular basis for erectile dysfunction (ED), contraception, hormone replacement therapy (HRT), weight loss, hair loss, stop smoking and vitamin D.

There were standard operating procedures (SOPs) for the services provided, with signatures showing that members of the pharmacy team had read and accepted them. The pharmacist superintendent (SI) was in the process of reviewing the SOPs. Roles and responsibilities were set out in SOPs and the pharmacy team members were performing duties which were in line with their role. There was a SOP for legal and clinical checks that the pharmacist should carry out. This contained a step-by-step clinical check and included allergy checks and interacting drugs. The SOP explained what to do if an intervention was required and included information about making records and referring to the prescriber. The SOP highlighted actions to take for suspected fraudulent activity.

Dispensing incidents were recorded and discussed with the pharmacy team to ensure learning was shared. Coloured medicine descriptors were used to allow better identification of medicines with different strengths, such as sildenafil, to reduce errors. This had been the suggestion of a dispenser. Near misses were recorded and had been reviewed quarterly. A copy of the latest review dated September 2021 – December 2021 was provided. The IT system had an additional safety feature which identified if the wrong medicine was selected. Each prescription had a unique barcode that related to the medicines prescribed. Once the medicine had been picked by a dispenser, the barcode on the medicine container was scanned and if there were any discrepancies between the medicine container and the prescription barcode, the IT system flagged this as an incorrect selection. A dispenser explained that errors identified by this system were recorded as near misses, to help with learning. The SI confirmed that the number of errors in the pharmacy had reduced since this additional safety feature had been introduced.

The pharmacy was in the process of completing a self-assessment action plan following the introduction

of the updated GPhC guidance for registered pharmacies providing pharmacy services at a distance (March 2022). Actions included introducing performance monitoring of courier services and ensuring the websites layout was in line with the guidance. The SI confirmed she had considered the risks of coronavirus to the pharmacy team and had introduced several steps to ensure infection control. The pharmacy was spacious which allowed team members to socially distance. Face masks had been worn until the regulations were lifted in England, and hand sanitizer gel was freely available.

The pharmacy had competed risk assessments for each medical condition on its websites. As part of this the clinical director had developed in-house conditions booklets. These contained information on maximum quantities for each drug which should be supplied to an individual patient per month. These were informed by UK national guidance such as the National Institute for Health and Care Excellence (NICE) and the Faculty of Sexual and Reproductive Healthcare (FSRH), which were referenced in each booklet. It also included a summary of product characteristics and had information for their indication for use. There were new clinical frameworks (clinical discussion templates) being developed jointly between the SI, clinical director and pharmacist prescriber which would eventually replace the conditions booklets. These would be peer reviewed by another prescriber.

The clinical director reviewed prescribing in the team and carried out prescribing audits. The clinical director discussed details of audits with the prescribers and the SI at clinical meetings. Regulatory changes, near miss incidents, safeguarding, training, complaints and feedback were also discussed at these meetings. The SI provided copies of minutes from a meeting in September 2021. The pharmacy had carried out a separate audit on HRT and contraceptive orders that were not fulfilled due to the product being out of stock. A plan of action had been developed to try to minimize out-of-stock issues. This included regularly monitoring out-of-stock and discontinued HRT and contraceptives and keeping the information up to date on the website.

The complaints procedure was explained on the pharmacy's websites with the details of who to complain to and relevant links. There was a customer service team in the pharmacy and there was a facility on the website so people could chat with a member from this team. The pharmacy used Trust Pilot to monitor customer service and the policy was for any one or two-star reviews to be responded to. A current certificate of professional indemnity insurance and insurance policies were available in the pharmacy. The SI confirmed that there was separate insurance arrangements for the prescribing service, and the prescribers were named on it.

The name of the responsible pharmacist (RP) was displayed as per the RP regulations. The RP record was appropriately maintained. Private prescriptions were recorded electronically. There was a controlled drug (CD) register. There had been no records in the last four years as the pharmacy had not supplied any schedule 2 CDs during this time.

All members of the pharmacy team had signed a confidentiality clause. They completed training on information governance (IG) and the General Data Protection Regulation (GDPR) and this was refreshed annually. Confidential waste was collected in a designated place and shredded. A member of the team correctly described the difference between confidential and general waste. A data handling and cookie policy was available on the pharmacy's website.

There was a safeguarding policy and the contact numbers of who to report concerns to in the local area was available. The SI said she would look up the details if the person she was concerned about was outside the local area. The SI and dispensers had completed level 2 training on safeguarding children and vulnerable adults. Other members of the team had competed safeguarding training relevant to their role in the pharmacy.

Principle 2 - Staffing ✔ Standards met

Summary findings

Team members are well trained, and the pharmacy provides the team with opportunities to share ideas and learning both inside and outside of the organisation. The pharmacy encourages its team members to keep their skills up to date and supports their development. Team members are comfortable providing feedback to their managers and they receive feedback about their own performance.

Inspector's evidence

There was the superintendent pharmacist (SI), three dispensers (NVQ2 or equivalent), three customer service representatives, the operations director, and the operations manager on duty. The staffing level was adequate for the volume of work during the inspection and the team were observed working collaboratively with each other. Planned absences were organised to ensure staffing levels were appropriate and details were recorded on team rotas. The pharmacy team members were allocated specific tasks on a daily, weekly and monthly basis, with an audit trail for the task and its completion.

The clinical director led the prescribing team and monitored the team's prescribing. He and the other medical prescriber had experience as GPs and had prescribed for the pharmacy for several years. The pharmacist independent prescriber had worked for the pharmacy for a couple of years and he had experience of working in a GP practice. There was an e-Learning platform for the prescribers' training which included safeguarding, note keeping, confidentiality, privacy and work environment. Training modules were completed for each drug and condition before the prescribers were allowed to prescribe in a specific area. Updates to national guidance such as NICE guidance and significant events were discussed at clinical meetings. The company had been part of a CQC digital health providers forum over the last few years. They shared any internal significant events at this forum.

Informal team meetings were held to discuss issues. The pharmacy had a communications board, covering topics such as training, team members tasks and competency, pharmacy team rotas and useful information such as whistleblowing and safeguarding policies. Notices showing GPhC standards were on display. There were detailed training records for all team members and a training matrix was displayed. Certificates showing completed training were on display. Pharmacy team members completed a variety of e-Learning modules. A record of this was on the e-Learning platform. The SI confirmed that the pharmacy team were all up to date with their training requirements. The pharmacy allocated specific time for the team members to complete training.

The pharmacy team members were given feedback from the SI on an ongoing basis. For example, when a near miss or dispensing error had occurred. Team members were encouraged to give suggestions and a dispenser had instigated highlighting all medicines with two or more strengths with coloured medicine descriptors to reduce near misses. Team members felt that the SI was supportive and approachable, and they would be comfortable discussing issues and concerns with her. Team members received a probationary review after three months in their role and a formal appraisal on an annual basis, where performance and development were discussed. Team members were empowered to exercise their professional judgement and the pharmacy had the option to refuse to supply a prescription if they did not feel it was clinically appropriate. There were no formal targets or incentives for pharmacy's services, so the team did not feel under pressure.

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

Summary findings

The physical premises are clean, hygienic, properly maintained and fitted to a high standard. They provide a professional environment for the services carried out. The pharmacy's websites allow people using the prescribing service to select a prescription only medicine before having a consultation with a prescriber. This gives people the impression that they can choose the medicines they wish to buy, and they may not always receive the most suitable medicine for their needs.

Inspector's evidence

The pharmacy was situated in a large unit in a business park. It was closed to the public and there was no external signage highlighting the fact that it was a pharmacy. Working areas were clean, spacious, free from obstructions and professional in appearance. The pharmacy had been fitted out to a very high standard, with a bespoke design, and the fixtures and fittings were good. A cleaner was employed on a part-time basis. All areas of the premises were cleaned regularly. The temperature in the pharmacy was controlled by air conditioning units. Lighting was adequate. The pharmacy premises were well maintained and in a good state of repair. Maintenance problems were reported to the operations manager and dealt with accordingly.

The premises were extensive and covered two floors of the building. Staff facilities included offices, a board room, a prayer room, break rooms and games areas. There was a canteen with a kitchen area containing a kettle, fridge and sink. Separate ladies, gents' and accessible WCs with wash hand basins and antibacterial hand wash were available. There was a separate dispensary sink for medicines preparation with hot and cold running water.

The pharmacy's name, address, GPhC registration number, e-mail address and phone number were displayed on the pharmacy's websites. There were links from the pharmacy's websites 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 registration details of the prescribers.

The pharmacy's websites were arranged so that a person could choose a prescription only medicine (POM) before filling in the consultation questionnaire. This gave the impression that the person could choose the specific medicine they wanted to buy. And it could mean people may not always receive the most suitable medicines for their needs. The SI confirmed that the team were in the process of addressing this issue, and agreed to take immediate steps to make the necessary changes to both websites.

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

Summary findings

The pharmacy services are generally well managed and easy for people to access. It gets its medicines from licensed suppliers and the team carries out some checks to ensure medicines are in suitable condition to supply. But people from outside the UK can obtain medicines without providing proof of their name, address or their age. This means that people are not effectively safeguarded, and they may be able to obtain medicines which are not appropriate. And the pharmacy doesn't always seek assurance that the prescribing service confirms a diagnosis or informs the patient's usual doctor when prescribing medicines which require ongoing monitoring.

Inspector's evidence

People accessed the pharmacy's services via the associated websites and could communicate with the pharmacist and team members via the telephone or email. People from Europe could view a website which had been translated into their own language. An instant messaging system was used to communicate messages between the pharmacy's prescribers and patients and supported a chat facility for two-way communication. Prescriptions were generated once the consultation was approved and sent electronically to the pharmacy. The prescription also linked to a messaging system so communications with the patient could be observed by the pharmacy team members and they were also 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. There was some signposting available when completing the consultation questionnaires on the pharmacy's websites. For example, when a person entered details which indicated that they were overweight, a link to the weight loss pages on an NHS website was displayed. Information on peak flow testing and inhaler technique could be accessed from the asthma questionnaire. The pharmacy took part in healthy living campaigns. For example, people requesting a smoking cessation medicine were sent leaflets to help support them.

The pharmacy was partnered with a recognised UK-based clinical laboratory providing screening, monitoring and diagnostic services. The laboratory was UKAS registered. It processed the Covid-19s tests supplied, although demand for this service was currently low. There was a range of other test kits available on the treated.com website. The most popular tests were for sexually transmitted infections (STIs) and liver function, but demand for these tests was also low. The results from the laboratory were screened by a prescriber who then communicated the results to the patient and prescribed any necessary treatment. A small number of antibiotics were prescribed following results from a test for a STI or urinary tract infection (UTI).

The pharmacy supplied two over-the-counter medicines: Alli for weight loss, and Viagra Connect for ED. A questionnaire was completed for Alli which was reviewed by a pharmacist before supply. Records of sales were kept for each customer, so patterns could be monitored. The questionnaire for Viagra Connect was reviewed by a prescriber as part of the ED consultation. The pharmacy had an NHS contract and had dispensed a small number of NHS prescriptions. Once registered and nominated for the electronic prescription service (EPS), people could request repeat NHS prescriptions via the customer service team at the pharmacy.

There were various conditions and associated medicines listed on the treated.com website under

chronic conditions. The majority of these medicines stated 'discontinued'. The SI explained the medicines were still listed to provide information for people but agreed this might be misleading and the team would discuss removing them from the website.

People were required to set up an account when they started using the pharmacy's online services. Duplicate patient accounts were flagged by IP addresses, email address, billing address, payment method and shipping address. All UK patient's identity (ID) checks were carried out using a third-party identity checking service. This checked the patient's identity by address, first name, second name and date of birth. If these failed the pharmacy would ask for further ID proof by means of passport or driving license.

The third-party identity checking service did not operate outside UK so this was not used for non-UK patients. The pharmacy relied on their payment provider's systems to confirm the patient was who they claimed to be and over 18. This system of checking ID was not sufficiently robust and means people could potentially obtain medicines that were not suitable for them. And there was a risk that medicines such as contraceptives or medicines to treat STIs could be supplied to third parties, which could present a safeguarding concern. The SI acknowledged that this was an issue and shortly after the inspection confirmed that the team had made the decision to stop supplying medicines to patients outside of the UK.

If two people ordered from the same address an automated flag would notify customer services and they would need to ensure validity of 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 ensure any inappropriate requests were identified. However, this would need to be picked up manually. Examples of a pharmacist picking up inappropriate orders were seen on the clinical intervention log, such as females requesting ED and males requesting contraceptives.

The prescribers produced prescriptions based on the information people provided when completing the consultation questionnaires. There was no system in place to verify a diagnosis of asthma or the date of the last asthma review before supplying inhalers. There were questions to help identify poorly controlled asthma, and the answers to some questions indicated that a call with the prescriber was necessary, however these answers could be altered to avoid the need for a phone call. Consent to inform the patient's GP was requested in all consultations and was mandatory for supplies of levothyroxine and salbutamol, but only for patients in the UK. The SI explained that the prescribers informed people's GP and copies of the notifications could be seen on the patient's records. Where consent was provided, GPs were informed in retrospect of the supply, so this meant that a supply could be made which the patient's own GP did not agree to. However, following notification, if a GP indicated that the patient was unknown to them, or believed the supply was not clinically appropriate, then a note would be added to the patient's profile, so no more prescriptions would be supplied to them. People were not usually able to request more than two asthma inhalers at a time. The patient's history was always checked and if a person was considered to be ordering excessively then the supply would be refused by the prescriber and the patient referred to their own GP for an asthma review. A sample of PMRs for people receiving asthma inhalers was checked. There was no evidence of excessive ordering of inhalers. One patient had received six inhalers in four years and another patient had received four inhalers in three years. The pharmacy could access the patient's Summary Care Records (SCR) with their consent. This was not requested during the asthma questionnaire, but the SI said she would discuss this with the clinical director, so a diagnosis could be verified and medical records checked. Following the inspection the SI confirmed that request to access SCRs had been added to the asthma questionnaire and was mandatory.

People requesting levothyroxine were required to prove that they had a thyroid disorder by selecting

one of three options: (a) uploading a thyroid function test result showing their name and the date of the test (b) uploading a prescription counterfoil showing their name, the date of the prescription issue and the relevant medication or (c) give consent to share information from their SCR. Medication was only provided if the uploaded evidence or SCR information indicated that supplying this medication was appropriate. The pharmacy had accessed SCR on the sample checked. The date the SCR was accessed and the dosage of the previously prescribed levothyroxine was recorded on the patient's record. The consultation requested that an electrocardiogram (ECG) was conducted prior to starting levothyroxine, but it wasn't necessary to provide evidence of this.

The consultation questionnaires often alerted people to a response that would mean they would not receive a supply and so they had an opportunity to alter it. For example, during the orlistat consultation the customer's body mass index (BMI) was calculated and the customer was informed if the request was accepted. If the customer was only marginally overweight and the supply was initially refused on this basis, it then allowed the patient to change their response. The SI believed this was auditable once the patient submitted the questionnaire. She was not able to demonstrate this during the inspection but provided a screen shot showing the facility following the inspection. There was a tracker system on patient's accounts that logged the patient's weight so that the prescriber could easily monitor a patient's weight loss, when additional requests were made, such as at the 12 week stage, when medication such as Saxenda should be stopped if not proving effective. Physical examination, face-to-face consultation or sharing information with the patient's usual GP was not part of the process when prescribing weight loss products. The risk of supplying vulnerable people with eating disorders had not been sufficiently addressed. More robust controls such as a video call had been considered but not yet introduced. This could mean vulnerable people with eating disorders may be able to obtain medicines which might not be suitable.

Pharmacists contacted prescribers by telephone, the messaging system and email and the SI said the clinical director and prescribers were very accessible. The prescribers had access to a British National Formulary (BNF), and there were in-built functions in the system that prevented certain prescribing activities. For example, the prescribing of two drugs of the same class. The pharmacy kept a record of queries with prescribers, and any actions taken as a result, on a clinical interventions log. For example, a missing dose of levothyroxine. In this case the prescriber requested that the RP accessed the patient's SCRs for clarification of their usual dose. The SI confirmed that the patient had given consent for their SCR to be accessed. The pharmacy also kept records of clinical queries on the patient medication record (PMR).

Medicines and tests were supplied by two different couriers or Royal Mail, at the choice of the patient. All deliveries were 'signed for' and could be tracked. Medicines returned by couriers due to failed delivery were not re-used. Medicines requiring refrigeration, such as Saxenda, were sent by next day service in a special container with ice packs, to ensure they were maintained at the correct temperature during delivery. Medications which were supplied outside the UK were labelled in English. The cautionary and advisory labels were provided on a separate sheet in the patient's own language.

The dispensary was spacious and the work-flow was organised into separate areas with designated areas for clinical screening, assembly, checking, packing and shipping. The dispensary shelves were well organised, neat and tidy. Medicines were stored in their original containers at an appropriate temperature. There was a robust process in place for date checking. Dispensed by and checked by boxes were completed on the medication labels to provide a dispensing audit trail. Different coloured baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. There was a CD cabinet which was securely fixed to the wall, but the pharmacy did not currently stock any CDs requiring safe storage.

Recognised licensed wholesalers were used for the supply of medicines. No extemporaneous dispensing was carried out and no medicines were obtained from 'Specials'. Alerts and recalls were received via email from the NHS and MHRA. These were read, acted on by a member of the pharmacy team and a detailed record was kept. This ensured that the team could easily respond to queries and provided assurance that the appropriate action had been taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

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

Inspector's evidence

The pharmacy team had access to the BNF and were able to use the internet to access websites for up-to-date information. For example, Medicines Complete. Any problems with equipment were reported to the operations manager. There were two medical fridges, one for stock and the other for assembled prescriptions awaiting distribution. Both fridges were fitted with internal thermometers and the minimum and maximum temperatures were being recorded daily. All electrical equipment appeared to be in working order and had been PAT tested for safety. There was a selection of liquid measures with British Standard and crown marks. The pharmacy had equipment for counting loose tablets and capsules, including tablet triangles.

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. Microsoft Azure was used, and the website was https secured.

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.