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: 16/09/2019

Pharmacy context

This is a pharmacy which provides its services to people through its own website and three other third-party websites. People do not usually visit the pharmacy in person. It has a substantial turnover and around 75% of medicines are supplied to European patients outside the UK and the pharmacy's website is translated into different languages for patients in around nine different European countries. They can request a prescription medicine by filling in an online questionnaire which is then assessed by a prescriber. If the prescriber considers the request appropriate they issue a prescription to the pharmacy and the medicine is supplied. The pharmacy's website offers prescription medicines for a wide range of conditions, but mainly supplies medicines for the treatment of erectile dysfunction, contraception, menopause and weight loss. It supplies some over the counter medicines and a large number of testing kits for conditions including sexually transmitted infections and diabetes. The pharmacy has an NHS contract and a very small number of NHS prescriptions are dispensed.

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	1.5	Standard not met	The pharmacy is not able to demonstrate that the prescribers it works with from the third-party websites have appropriate indemnity insurance cover.
		1.8	Standard not met	People in non-UK countries can purchase medicines including contraceptives without providing proof of their name, address or their age, which is a safeguarding concern.
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 website and the third-party websites are arranged so that a person can choose a prescription only medicine (POM) and its quantity before there has been an appropriate consultation with a prescriber. The third-party websites have inadequate information about their prescribers and the pharmacy.
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 not all met**

Summary findings

The pharmacy monitors the service delivery and takes some action to improve patient safety. But people from outside the UK can obtain medicines without providing proof of their name, address or their age. This may mean they receive medicines that are not appropriate and could present a safeguarding concern. The pharmacy supplies some prescription medicines on behalf of third-party websites who use prescribers who are not registered with UK regulators. This makes it harder to verify the quality of the services they provide and creates an extra risk for people. And it is not clear if these prescribers have appropriate indemnity insurance cover for their prescribing activities.

Inspector's evidence

The pharmacy's main business was the supply of prescription only medicines (POMs) to patients in the UK and around nine other European countries. Around 95% of these medicines were supplied against private prescriptions issued by three UK-based medical prescribers and an independent pharmacist prescriber, using the pharmacy's own website (treated.com). Two of the medical prescribers were GMC registered. A third medical prescriber was registered with the Irish Medical Council. This prescribing service had a clinical director and was regulated by the Care Quality Commission (CQC). It was rated good at the last CQC inspection in May 2019. The website offered treatments for male health, female health, chronic conditions, acute conditions and lifestyle including smoking cessation, weight loss and antimalarials. The pharmacist superintendent (SI) and clinical director stated that erectile dysfunction (ED) was probably their largest treatment area. Other demand areas included contraception, menopause, weight loss (Ali and Saxenda), hormone replacement therapy (HRT) and EMLA (for premature ejaculation).

Around 5% of prescriptions came from three third party websites (dokteronline.com, xpressdoctor.com and netpharm.nl). These offered a range of medicines including high-risk medication such as opioids. The SI confirmed that the pharmacy did not dispense any prescriptions for opioids from the pharmacy's website or from the third-party websites, and the last time the pharmacy dispensed an opioid prescription was in 2017. The third-party websites were not registered with the CQC and some of the prescribers they used were non-UK registered, based in Germany and Romania. The SI said a check was made that the prescribers were registered, and she believed they were eligible to prescribe. She said all electronic prescriptions that came into the pharmacy came from an already registered IP address and secure server. The system was a closed loop and the pharmacy could not take in prescriptions from any prescribers that were not already registered and approved on their system. The SI said a copy of the doctor's registration and ID was on file but admitted that checks on registration status was only made on an annual basis, so any changes to their status might be undetected. Subsequent to the inspection the SI confirmed that they had introduced a quarterly checklist of the registration status, qualifications and indemnity cover for all their prescribers, including those from the third-party websites.

The pharmacy was partnered with 'The Doctor's Laboratory', a UK based clinical laboratory providing screening, monitoring and diagnostic services. People selected which testing kit they preferred via the website and these were dispatched by post. UK based patients returned their test kits for chlamydia, gonorrhoea, liver function tests, '7 in 1' sexually transmitted infections (STI) screening and diabetes to The Doctor's Laboratory. The results of these tests were screened by a prescriber who then

communicated the results to the patient and prescribed any necessary treatment. The pharmacy regularly supplied self-check test kits to patients across Europe. These were usually for bowel screening, chlamydia, gonorrhoea, gluten intolerance and menopause. Only the patient received the results for these self-check tests.

The pharmacy supplied a small range of over-the-counter medicines including Ali and Viagra Connect. A questionnaire was completed for these which was reviewed by a pharmacist before supply. Records of sales were recorded for each customer, so patterns could be monitored. The pharmacy had an NHS contract and had dispensed a very small number of NHS prescriptions. Patients accessed this service via the website or an App. Once registered and nominated for the electronic prescription service (EPS), the patient could request repeat NHS prescriptions via the App or via the customer service team at the pharmacy.

The pharmacy had completed a self-assessment action plan following the introduction of the new GPhC guidance for registered pharmacies providing pharmacy services at a distance (April 2019). Actions included adding a pharmacy tab to the risk register and updating it to include pharmacy risks. The pharmacy was still in the process of working through the action plan and updating the risk register.

Duplicate patient accounts were flagged by IP addresses, email address, billing address, payment method and shipping address. Deliveries could be sent to collection points, but the collection point owner was obliged to check the identification of the person collecting. An example was shown where the system flagged a couple at one address were both ordering Saxenda. All UK patient's identity (ID) checks were carried out using Equifax. This checked the patient's identity by address, first name, second name and date of birth. If Equifax failed the pharmacy would ask for further ID proof by means of passport or driving license. Equifax did not operate outside UK so this was not used for non-UK patients. The pharmacy relied on their payment providers and 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 obtain medicines that are not suitable for them. And there might be a risk that medicines such as contraceptives or medicines to treat STIs were supplied to third parties, which could present a safe guarding concern. The SI stated that they would be introducing a mandatory upload of patient's ID card before the end of the year. The SI stated that the third-party websites carried out ID checks but did not know the details of this.

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 the pharmacist during the clinical screening. If patient's ordered prescriptions which were inappropriate or early (before they were due to run out) this would need to be picked up manually. Examples of a pharmacist picking up early orders was seen on the interventions record that the pharmacy held. An example of this was seen where a patient from Sweden was requesting azithromycin for treatment of chlamydia within a three-month time frame. This raised questions around the need for counselling around safe-sex, potential abuse and treatment failure. The example seen showed that the patient had been signposted to their GP. Communication that was sent to the patient was seen in English. It was explained that the customer services manager for that country would translate the message and send it to the patient, an audit trail was available showing the original English message and translated message.

As part of the risk assessment, for each medical condition on the pharmacy's website there was an in-house conditions booklet, which had been developed by the clinical director. It contained information on maximum quantities that should be supplied for each drug per month. These were informed by UK national guidance such as the National Institute for Health and Care Excellence (NICE), 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.

A clinical interventions audit had taken place over a three-week period when interventions made by pharmacists on 5000 prescriptions were reviewed. Ten interventions were identified. The main issue identified was men ordering oral contraceptives for their partner. Following the audit, changes were made so that all contraceptives and HRT prescriptions had an automated blocker so that male customers could not order them. An NHS England clinical audit was carried out in November 2018 and a letter was sent to three patients with diabetes, who were identified, highlighting the importance of flu vaccination. Prescribing reviews took place. For example, following a review of finasteride prescriptions between October and December 2017, the pharmacy implemented a new quality standard to not supply finasteride to patients under 35 and these patients would be signposted to their GP. The clinical director reviewed prescribing in terms of frequency of prescriptions declines, how often Summary Care Records (SCR) were accessed and whether prescribing was within guidelines. He did not prescribe large quantities himself (10-15 items per week) but one of the other prescribers reviewed his prescribing. The clinical director stated that he reviewed the pharmacist independent prescriber monthly and had found that he generally declined if he was unsure and was cautious in his prescribing. He said he had suggested to the pharmacist independent prescriber to provide more detailed documentation and communication to the patient when declining a prescription. Other audits had been completed on failed identity (ID) checks (September 2017- 18), prescribing of combined hormonal contraception (January 2018- February 2018 and June - July 2018) and prescribing of weight loss medication (January to March 2018 and July- September 2018). The SI stated that they did not manage the prescribers from the third-party websites and did not audit their prescribing but did review the prescriptions against the questionnaires provided. She confirmed that they found their prescribing to be within national guidance and if they were ever faced with unfamiliar dosages, these were queried or declined.

There were up-to-date standard operating procedures (SOPs) for the services provided, with signatures showing that all members of the pharmacy team had read and accepted them. Roles and responsibilities were set out in SOPs and the pharmacy team members were performing duties which were in line with their role. Generic job descriptions were on display. A locum dispenser who was working in the pharmacy had not read and signed the SOPs. She explained that she had only worked there on a small number of occasions and had received training on the procedures from the pharmacy team leader and a pharmacist. She said she would seek advice when needed. She had a clear understanding of her role and was carrying out duties in line with her level of training. Subsequent to the inspection the operations manager confirmed that the locum dispenser would be given time to read and sign the relevant SOPs. 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 contained information about 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. The name of the responsible pharmacist (RP) was displayed as per the RP regulations. A business continuity plan was in place which gave guidance and emergency contact numbers to use in the case of systems failures and disruption to services.

Dispensing incidents were recorded and discussed with the pharmacy team at weekly team meetings to ensure learning was shared. For example, following an incident when a diabetes testing kit was sent out instead of a testosterone testing kit, the kits had been better separated and colour stickers used to identify them. An error when an incorrect quantity was supplied had been recorded and discussed with the staff involved. Cardboard separators were ordered to allow better separation of medicines with different strengths, such as Cialis, to reduce errors. This had been the suggestion of a dispenser. Near misses were recorded and had been reviewed quarterly until March 2019 when it was identified that

the introduction of the Falsified Medicine Directive (FMD) had led to a vast reduction in near misses. The FMD system had an additional safety feature which identified if the wrong medicine was selected. One near miss identified in the March review was that two orders had been put into one basket. The learning was for dispensers to double check before signing the medication label and passing to the pharmacist for the final accuracy check.

The complaints procedure was explained on the pharmacy's website 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 to 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. Feedback surveys were undertaken and included pharmacy specific questions. Following a phone call from a GP querying whether an EpiPen prescription supplied to one of their patients was appropriate, a reply was sent to the GP and the incident led to a review of the questionnaire for the adrenaline auto-injector. This was added to the clinical meeting agenda for discussion and to share learning.

Insurance arrangements were in place for the pharmacy's activities and the SI confirmed it covered the dispensing of private prescriptions from both UK and EU prescribers.

A current certificate of professional indemnity insurance and insurance policies were available in the pharmacy. The pharmacy had separate insurance policies for the medical prescribers on the pharmacy's website, which listed their names and included an outline of their on-line prescribing activities. There was a limit of liability of £5million for medical malpractice. There was a separate insurance policy for the pharmacist independent prescriber which had a limit of liability of £5million. The SI stated that the pharmacy was not responsible for the prescribing activity of the prescribers from the third-party websites and the indemnity for this relationship came into force from a dispensing service role. They asked for copies of the prescriber's indemnity and kept them on file. They were not available for all the prescribers and were not in English, so it was not possible to confirm that they covered their online prescribing activities for UK patients or that the level of indemnity was appropriate.

The responsible pharmacist (RP) record was appropriately maintained. Private prescriptions were recorded electronically as a list of despatched orders using a number rather than the patient's name. There was a link to the electronic prescription where the rest of the details such as the name and address of patient and prescriber could be viewed. This did not strictly meet statutory requirements because it was not a computerised (or written) record kept for that specific purpose and did not clearly show all the required information such as the name and address of patient and prescriber. A private prescription from the treated.com prescribing service was seen with the prescribers address in Romania. This was surprising because the SI and clinical director had stated that all the prescribers for the pharmacy's prescribing service were UK-based. The clinical director advised that the address on the prescription was likely to be incorrect and that he would look into this. He said he thought this might be because the pharmacy used to have Romanian prescribers, so the address could have been placed on the prescription in error. He said alternatively it may have been the prescriber's original home address in Romania, where she had completed her training. This inaccuracy risked there being an unreliable audit trail in the event of a problem or query and was not in line with regulations. There was a controlled drug (CD) register. There had been no transactions in the last two years as the pharmacy had not supplied any schedule 1 or 2 CDs during this time.

All members of the pharmacy team were required to sign a confidentiality clause. They completed training on information governance (IG) and the General Data Protection Regulation (GDPR) which 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. An incident had been recorded when a customer had made a request for their information to be destroyed. The clinical

director had dealt with this and recorded his action and justification for this. A data handling and cookie policy was available on the pharmacy's website.

There was a safe guarding policy in place and the contact numbers of who to report concerns to in the local area was on display. The SI said she would look up the details if a safeguarding concern was in a different part of the country or elsewhere in Europe. She had completed the Centre for Pharmacy Postgraduate Education (CPPE) level 2 training on safeguarding children and vulnerable adults. Other members of the team had competed safe guarding training relevant to their role in the pharmacy.

Principle 2 - Staffing ✔ Standards met

Summary findings

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

Inspector's evidence

There was a superintendent pharmacist (SI), a locum pharmacist (RP), four dispensers (NVQ2 or equivalent), a trainee dispenser, two packing assistants, three customer service representatives 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. Qualified locum dispensers and pharmacists were employed when necessary to ensure adequate staffing levels, and a locum dispenser and locum pharmacist were on duty at the time of the inspection. Two pharmacists usually worked together on Mondays as this was when the pharmacy's workload was the heaviest. 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. There was a dedicated shipping area within the pharmacy and two assistants employed by Parcel Expert were working in the pharmacy. These assistants had carried out appropriate training relevant to their role including confidentiality and data protection training.

The clinical director worked for the pharmacy four days each week and carried out some locum work for the NHS. The other GMC registered prescriber had her own NHS practice and worked remotely for the pharmacy a couple of hours per day. The clinical director was in touch with her two or three times per week. The pharmacist independent prescriber had worked for the pharmacy as a prescriber for the last three months. Previously he had under taken some work for the company when he reviewed the content on the website relating to medicines and conditions following advice from CQC. He had experience of working in a GP practice. A clinical governance manager had been recruited and was due to start shortly.

Prescribers used the conditions booklets for information on indications and maximum quantities. They 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 clinical director acknowledged that some factors were discretionary. For example, the number of supplies made without contacting the patient's regular health care practitioner and said he was reviewing this to build in forced reviews by prescribers. Requests for medication were allocated to available prescribers based on competence of the prescriber, availability of prescriber and preference of patient to their request for review by a male or female doctor. Training modules were completed for each drug and condition before the prescribers were allowed to prescribe in a specific area. Adjustments were made if there was an update to any national guidance. For example, following the update for treatment of vaginal dryness, prescribers were restricted from prescribing Blissel until appropriate training had been completed. This was documented in the clinical meeting notes. There was an e-Learning platform for the prescribers' statutory and mandatory training which included

safeguarding, note keeping, confidentiality, privacy and work environment. Most prescribers were up to date on all training and this was documented in the clinical governance folder. New or updated NICE guidance was looked at every month at clinical meetings and discussed to consider whether changes were relevant to the business and applied where appropriate. For example, the updated guidance on contraception where women should be offered and counselled on various contraception methods prior to prescribing. All considerations were documented on a NICE tracker. The clinical governance folder contained significant event reports and the actions carried out. Significant events were discussed in clinical meetings. For example, where one of the prescribers prescribed Mysimba for a patient taking citalopram. The prescriber was asked to complete a reflection and learning. The clinical director carried out yearly appraisals and ensured that prescribers carried out some reflection relating to online prescribing in their revalidation. The company had been part of a CQC digital health providers forum over the last couple of years. They shared any internal significant events at this forum.

The pharmacy had a communications board prominently displayed, covering topics such as training, team members tasks and competency, pharmacy team rota's, minutes of weekly team meetings and useful information such as whistle blowing and safeguarding policies. Notices showing GPhC standards were on display and the team had undertaken a 'mock GPhC inspection' in June 2019, led by a pharmacist from another online provider. Actions arising from this were being addressed. There were detailed training records for all team members and a training matrix was displayed on the communications board. Certificates showing completed training were on display. Pharmacy team members were expected to complete a different e-Learning module each month. A pharmacy team member logged into the e-Learning platform and demonstrated that she had completed training modules on a regular basis over the last 12 months. The pharmacy allocated specific time for the team members to complete training.

The pharmacy team members were given feedback informally from a pharmacist 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 separating all medicines with two or more strengths with cardboard separators to reduce near misses. A member of the team said that the SI was very supportive and approachable, and she 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. A member of the team provided a copy of her last appraisal. She explained that she had received the appraisal in the last 12 months and it had been very useful to help her develop in the role of team leader. The RP explained that there were no formal targets or incentives for any aspects of pharmacy's services, so did not feel under pressure.

The pharmacy liaised with third party website teams when there were queries. But there were no regular meetings with these organisations or feedback mechanisms to enable learning or promote best practice.

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

Summary findings

The physical premises are clean, hygienic, properly maintained and of a notable high standard. They provide a professional environment for the services carried out. The pharmacy's website and third-party websites enable patients using the prescribing service to select the medication and the quantity required before having a consultation with a prescriber, which means people may receive medicines which are not the most suitable for them. The third-party websites do not provide enough information about their prescribers and the pharmacy, so people might not be able to make an informed choice.

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 bespoke design, and the fixtures and fittings were good. The pharmacy team were responsible for keeping the pharmacy clean and 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 had cordless telephones and a pharmacy team member explained the staff used these to hold a private conversation with people if necessary.

The pharmacy's name, address, GPhC registration number, e-mail address and phone number were displayed on the pharmacy's website. There was a link from the pharmacy's website to the GPhC register showing the registration details of the pharmacy via the voluntary GPhC logo. The name and details of the SI was displayed on the pharmacy's website, although this was not easy to find. The Medicines and Healthcare products Regulatory Agency (MHRA) EU distance selling logo was displayed on the pharmacy's website.

The name and details of the clinical director and one of the other prescribers were available on the pharmacy's website and there was a link to check registration details of these prescribers. The details of the pharmacist independent prescriber were missing from the pharmacy's website, but these were added following the inspection. Details of the medical prescriber registered with the Irish Medical Council was not on the English version of the pharmacy's website. The clinical director explained that her details were only available on the country's websites of the patients that she prescribed for.

Third-party websites did not include the pharmacy's details or information about the prescribers, so people might not have sufficient information to make informed decisions when using these websites.

The pharmacy's website and the third-party websites were arranged so that the patient chose the

prescription only medicine (POM) and the quantity before filling in the consultation questionnaire. This means people may not always receive the most suitable medicines for their needs and was not in line with the new GPhC guidance. The SI explained that actions had been taken to address this situation on the pharmacy's own website. The operations manager confirmed this and provided wireframes demonstrating their direction in meeting the guidance indicating this would be towards the end of the year.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy services are suitably managed for people receiving medicines via the pharmacy's own website. But the pharmacy cannot provide the same level of assurance for people receiving their medicines from third-party websites. It sources medicines appropriately and generally manages them safely.

Inspector's evidence

People access the pharmacy's services via the associated websites. Patients could communicate with the pharmacist and staff via the telephone or email. Patients could communicate with the pharmacist and staff via the telephone or e-mail. A system called Syscare 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 Syscare so communication with the patient could be observed by the pharmacy 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 to other services in the locality. For example, when an emergency supply of a medicine was required. A pharmacist explained that the pharmacy team used a signposting directory when necessary and there was some signposting available when completing the medical questionnaires on the pharmacy's website. 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. The pharmacy took part in healthy living campaigns. For example, the pharmacy had obtained relevant resources for 'Stoptober'. Appropriate UK based patients were targeted for each campaign and health information sent out to them. For example, females aged 18-50 and people ordering contraceptives were sent information on cervical cancer during a previous campaign. Facebook and Twitter were used to promote the pharmacy.

There were various conditions and associated medicines listed on the pharmacy's website under chronic conditions, however the majority of these medicines stated 'discontinued'. Only levothyroxine or liothyronine, various brands of salbutamol, cholesterol testing kits, diabetes testing kits and glucose testing strips could be prescribed and supplied for chronic conditions . The SI and clinical director confirmed that following feedback from CQC they were reviewing the way they supplied medications for chronic conditions online. Consent to inform the patient's GP was requested in all consultations and was mandatory for some medications, but not all. 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. The pharmacy could access the patient's Summary Care Records (SCR) with their consent, as they had an NHS contract and had received confirmation from NHS England that they were able to use the SCR for private prescriptions. The pharmacy kept a record of GP correspondence and examples of GPs querying certain prescriptions was seen along with responses from the pharmacy and any actions taken as a result. These were discussed in clinical meetings.

Patients were required to consent to share information about the care provided when ordering salbutamol inhalers and thyroid medication. Patient requesting levothyroxine or liothyronine were required to prove that they have 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 consultation also requested electrocardiogram (ECG) prior to starting levothyroxine.

The consultation questionnaire gave a pop-up to a negative response and the answers could then be altered. The clinical director said this was auditable for some key questions once the patient submitted the questionnaire, and the prescriber could view the number of times the response had been changed. This could not be demonstrated during the inspection, but the clinical director provided screenshots for one 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. However, the clinical director said that this response was auditable and the prescriber could see the relevant information that had been changed. He said there was a tracker system on patient's accounts that logged the patient's weight so that they could easily monitor patient's weight loss and be able to identify potential misuse situations. Each product had a safety net and red flag email associated with it which was sent to people ordering the product. The email contained information on when to expect the symptoms to alleviate and what to do if certain situations arise. For example, for STI treatment the email contained information about partner notification and retesting. This could also be communicated by using Syscare. The emails were tailored per country. For example, in some countries it was an offence not to notify the partner (e.g. Sweden) so this would be reiterated in the leaflet.

Pharmacists contacted prescribers by telephone, Syscare and email. The pharmacy kept a clinical interventions log. This contained information of the date of intervention, the prescriber the prescription was issued by and concern or the issue on the prescription. The pharmacy also kept records of clinical queries on the patient medication record (PMR), that had been made by a pharmacist. The RP demonstrated that the PMR system had a query tab used to highlight any clinical queries she had. For example, a prescription received for Cialis was queried with the prescriber as the patient was being prescribed other medication that interacted with this medication.

For the third-party websites, the SI explained that the pharmacy had full visibility of prescriptions and past prescriptions that arrived into their system. The pharmacy received a copy of the medical questionnaire so could see the consultation between the prescriber and the patient and all prescriptions received into their pharmacy were subject to the pharmacist check. She stated that they were not responsible for the prescribing activity of these websites but variance from national guidance would be queried or declined.

Medications which were supplied outside the UK were labelled in English and the patient's own language. The SI said the translations were made by multi-lingual staff in the customer services teams. The assembled prescriptions were sent by either UPS, DHL or DPD couriers or Royal Mail. All deliveries could be tracked. The SI said her understanding, after seeking legal opinion and following discussions with the MHRA, was that the supply to patients outside the UK (within the European Union) was in line with regulations. This was because the medicines were supplied in the UK and the recipient paid the courier to collect their prescription from the pharmacy on their behalf. Medicines returned by couriers due to failed delivery (one or two each day) were added back into stock if the packaging was unopened and it was returned within 10 days of leaving the pharmacy. A member of the pharmacy team explained that a maximum 10-day time limit had been set to comply with the Falsified Medicines Directive (FMD). There was a SOP in place for this procedure, but re-using these medicines meant that the pharmacy was not able to guarantee they had been stored appropriately whilst away from the pharmacy and might not be fit for purpose. Subsequent to the inspection, the SI advised that this practice had been

reviewed and returned medicines were not re-used unless they were re-delivered to the original patient. A new SOP had been prepared and was forwarded to the inspector. The pharmacy had a bespoke system to ensure compliance with FMD and were scanning to verify and decommission medicines when they were supplied. Medicines requiring refrigeration were sent in special 'Woolcool' system of ice packs, liners and blockers to ensure they were maintained at the correct temperature during delivery.

The dispensary was spacious and the work flow was organised into separate areas with designated areas for clinical screening, assembly, checking and packing. The dispensary shelves were well organised, neat and tidy. Medicines were stored in their original containers at an appropriate temperature. Date checking was carried out and documented. 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. High-risk medicines such as warfarin, lithium, methotrexate and valproate were not currently supplied from the pharmacy. There was a CD cabinet which was securely fixed to the wall, but the pharmacy did not currently stock any CDs requiring safe storage and it was empty.

Recognised licensed wholesalers were used for the supply of medicines. No extemporaneous dispensing was carried out and no medicines 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 the equipment and facilities they need for the services they provide. They maintain the equipment so that it is safe to use and use it in a way that protects privacy.

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. A cordless telephone was available in the pharmacy which was used to hold private conversations with people when needed.

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.