General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Halliwell Midnight Pharmacy, 34 Halliwell Road, BOLTON, Lancashire, BL1 3QS

Pharmacy reference: 1099351

Type of pharmacy: Community

Date of inspection: 10/10/2019

Pharmacy context

This is a busy pharmacy located on a main road close to the centre of town. It stays open for 100 hours per week, opening early in the morning and closing at midnight every day except Sundays. The pharmacy dispenses NHS prescriptions and sells a range of over-the-counter medicines. It supplies a large number of medicines in multi-compartment compliance aid packs to help people take their medicines at the right time. The pharmacy also provides an online prescribing service (www.prescriptiondoctor.com) and the prescriber is an Italian doctor based in Romania. People can request a prescription by filling in an online questionnaire which is then assessed by the prescriber and pharmacist before the pharmacy supplies the medicine. The website offers prescription medicines for a range of conditions but mainly supplies codeine containing medicines for the treatment of pain.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; Statutory Enforcement

Follow this link to find out what the inspections possible outcomes mean

Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The risks involved with supplies of high-risk medicines and the non-UK regulated prescribing service are not consistently managed. And the pharmacy cannot provide assurance that prescribing is always undertaken in line with good practice guidance and UK national guidelines (including GMC guidance)
		1.5	Standard not met	The pharmacy cannot demonstrate that both it and the prescriber it uses have adequate professional indemnity arrangements.
		1.8	Standard not met	The pharmacy does not consistently use the safeguards it has in place to make sure supplies of opioids, cyclizine and modafinil are appropriate or that these medicines are not being abused or misused.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's systems do not ensure that people always receive the most appropriate medicine for effective treatment. Its website is arranged so that a person can choose a medicine and its quantity before there has been an appropriate consultation with a prescriber.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy supplies a range of medicines through the online prescribing service , including large quantities of opioids and other medicines liable to abuse. It is not able to demonstrate that the safeguards that have been put in place are consistently utilised to make sure they are clinically appropriate, including: that the prescriber will proactively share all relevant information about the prescription with other health professionals involved in the care of the person (for example, their GP); that the prescriber has contacted the person's GP in advance of issuing a prescription and that the GP has confirmed to the prescriber that the prescription is appropriate for the patient and that appropriate monitoring is in place; that

Principle	Principle finding	Exception standard reference	Notable practice	Why
				the prescriber has made a clear record setting out their justification for prescribing in circumstances where they have decided to issue a prescription when the person does not have a GP or does not consent to share information.
		4.3	Standard not met	The pharmacy can not provide assurance that the temperature of the medical fridges are appropriately monitored. It does not properly restrict unauthorised access to some medicines and it stores multi-compartment compliance packs which have not been sealed for extended periods. There is no robust date checking procedure and medicines which have passed their expiry date are not always separated from current stock. Some medicines are not stored in their original packaging and have not been appropriately labelled.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy does not consistently manage all of the risks involved with its online prescribing service. This means that there are some risks to patient safety. The pharmacy works with an Italian doctor and the prescribing service is based in Romania and not registered with UK regulators. And the pharmacy cannot demonstrate that the prescriber always follows UK guidelines and has appropriate insurance arrangements for these activities. This means the pharmacy cannot show that the prescribing service is safe and vulnerable patients might be able to obtain medicines that could cause them harm. The pharmacy team generally keep the records required by law, but some details are missing, which could make it harder to understand what has happened if queries arise. Team members do not make full records or review their mistakes, so they may be missing out on some learning opportunities.

Inspector's evidence

The pharmacy had a large NHS business of around 11,500 items per month, but also supplied around 2000 prescription only medicines (POMs) per month on private prescriptions to patients in the UK through a website (www.prescriptiondoctor.com). Medicines were supplied against private prescriptions issued by a doctor. The doctor resided in Italy but he worked for an agency based in Romania and this address was on the prescriptions. The prescribing service was not registered with the Care Quality Commission (CQC) as it was based outside the UK. This meant that the prescribing service was not subject to inspection by the UK regulators. The superintendent pharmacist (SI) explained the doctor started working for Prescription doctor in 2017 when he was working as a GP in England and he had met him in person. At this time the doctor was registered with the General Medical Council (GMC). However, he was no longer registered with the GMC. The Prescription doctor prescribing service used the same prescriber to generate all of the prescriptions and the prescribing service could only be accessed via this website. No other pharmacies received prescriptions from the website. On the previous day around 116 private prescriptions were supplied from the website and 93 of them were for opioid painkillers (67 codeine, 23 co-codamol and 3 dihydrocodeine). A range of other medicines had been supplied including modafinil and cyclizine, both of which can be abused, and asthma inhalers, antibiotics, levothyroxine and treatment for erectile dysfunction (ED). Contraceptives including emergency hormonal contraception (EHC) were also offered on the website.

The questionnaires for the opioids (codeine and dihydrocodeine) and modafinil were taken off the website following the inspection. This was because the SI had decided to put a block on the request and supply of these medicines in light of the risks identified at the inspection.

There was an order processing guide which outlined how the team processed the requests. Duplicate accounts were identified by the customer service team checking IP addresses, email address, billing address, payment method and shipping address against their registered address. There was an identity (ID) policy and all people using the prescription doctor service had their ID checked by Equifax. This checked the person's ID by address, first name, second name and date of birth. For certain medicines or if the person failed Equifax check then the pharmacy would ask for further ID proof by means of passport, driving licence and utility bills, however there was no face to face correspondence so this did not prevent a person using somebody else's identity, with or without their consent. This was a possible

safeguarding concern as a child could use their parents ID or a vulnerable person obtain medicines from a third party.

Reorder time limits were set for opioids, modafinil and inhalers and these were stated on the website. These were the maximum quantities that would be supplied within a set period of time. This was intended to prevent people from ordering too many medicines. The pharmacy had introduced medication ordering alerts built into the prescribing portal which was programmed to alert when orders were placed sooner than the expiry of the time limits. However, the customer service team would process these alerts manually and notify the patient that their order had been placed on hold until the time limit expired. Patients could choose to accept to be put on hold or request a refund. In exceptional circumstances and upon the patient request the customer service team would transfer the order to the prescriber to assess the appropriateness of these requests and consideration for off policy supply. Several incidents were seen when patients were supplied with medicines sooner than the time limits without documented explanation. There was no evidence of an audit trial to identify these incidents or to evaluate the compliance of the customer service team with this function. There were several orders waiting for the 'due date' and this practice did not seem to concern the team despite the early ordering being a potential sign of abuse or misuse. There was an early order policy for exceptional circumstances, for example, when patients were going on holiday. People were required to provide evidence of this.

People requesting prescription medicines from the prescribing service were asked a series of questions and the responses were sent to the prescriber for approval before supply was made. The response could be viewed by both the pharmacy and the prescriber. Patients using the prescribing service communicated with the prescriber, pharmacy or customer service team via a chat messaging system and all the messages could be viewed by the prescriber, customer service team and pharmacist. 'Tags' were applied to patients records building up a profile of the person and included :- duplicate account, EQ approved/failed, ID verified, no more orders (if the prescriber has declared this), does not provide consent. A large number of requests were refused, either by the prescriber, customer service team or pharmacist. There were over 800 pages of declined orders with around 20 people on each page. Tags showed the reasons for the refusals. Of the sample of 20 checked, reasons given for the refusal were :- the request was made too soon after the previous request; no consent was received to sharing information with the GP; request was for dihydrocodeine; the patient was under 25. One example was seen when the prescriber approved the prescription of 100 codeine 30mg tablets but the pharmacist superintendent (SI) decided not to supply the medication. This was because when the SI reviewed the person's records including the chat messages he did not feel it was a genuine request. An example of a refusal from 8 October 2019 was seen when a patient's request was declined because they did not provide consent for the prescriber to contact their GP and the prescriber felt it was important that the conditions was monitored. The chat messages recorded this decision and a refund was provided.

People ordering opioids were made aware that the medicine was addictive. There was evidence of the potential overprescribing of codeine for individual patients over a short period of time without any evidence of review of their pain conditions or follow up by their local GP. One patient was supplied with 1012 codeine tablets over a 12-month period without their GP consent or knowledge. She was sent a message on 8 October 2019 stating that was her last supply unless she provided her GP details and consent to inform them. One patient had 1112 codeine 30mg tablets over a 12-month period and 200 were supplied on 10 June 2019. Another patient was issued with two repeat prescriptions of codeine 30mg (1x 200 tablets and 1x 112 tablets) between September 2019 and October 2019. Both of these examples breached Prescription doctor's own opioid policy as supplies of 112 tablets and more of codeine 30mg had been made in a period of less than 28 days (the time limit for reordering of codeine stated in the policy).

There was also evidence of potential over prescribing for cyclizine. The misuse and/or abuse of cyclizine is well established. Therefore, the majority of local and national clinical guidance restricts cyclizine use for short and acute courses and as a second or third choice to other anti-sickness medicines. A patient had received six repeat prescriptions of 100 cyclizine tablets between May 2019 and September 2019. The patient had refused to give permission for her GP to be contacted and the information on the questionnaire did not justify the prescribing of these large quantities outside the recommended indication. Cyclizine was indicated for travel sickness on the prescription doctor website and the medication label for these supplies stated 'to be taken prior to travelling'. This could also be considered as a failure to take the appropriate actions to refer the patient to her GP to receive the appropriate level of care for her condition. Another patient had been supplied with four repeat prescriptions of 100 cyclizine tablets between February 2019 and September 2019. Her dispensing records also showed regular repeat prescriptions of Co-Codamol 30mg/500mg until March 2019 with quantity ranging from 100 to 200 tablets per supply. The patient had refused permission to share information with her GP despite confirming that her GP was aware of her condition. On the questionnaire she stated that she used cyclizine for travel sickness due to regular overseas travel and she experienced nausea on a daily basis. There was no evidence of any attempt to communicate with the patient's GP to discuss her conditions or follow up arrangements. This was a safeguarding issue given the previous history of opioid use and the frequent ordering of cyclizine.

The assessment questionnaires were developed jointly by the prescriber and the customer service manager. However, the development and maintenance of these questionnaires was not governed by a specific policy setting the standards for development, frequency of updating the clinical content and version controls. The prescriber stated he had good experience in managing British patients and always followed UK prescribing guidelines. However, one patient was prescribed metronidazole for the treatment of bacterial vaginosis (BV) which was being prescribed in a different dose to that recommended by UK clinical guidance. The recommended oral metronidazole dose and duration for BV is 400 mg twice a day for 5 to 7 days and if adherence to treatment is an issue, a single oral dose of 2g may be used. However, the prescriber had issued 800mg to be taken immediately followed by 400mg every 8 hours and the course duration was less than 5 days. The SI was unable to explain the reason for such deviation to usual and current practice. There was no evidence to support the efficacy of this unexplained prescribing practice and this was falling short of a good antimicrobial stewardship.

There were clinical governance guidelines signed by the prescriber dated 4 August 2017 and reviewed in April 2019. This included a statement that notes should be securely notified to the patient's registered doctor to advise on information received from the patient and the treatment prescribed by the remote prescriber. This was intended to ensure the patient was giving the correct information to the remote prescriber, receiving the correct treatment and not being under or over treated. The guidelines also stated that an audit of 5% of randomly selected prescriptions was to be carried out annually to ensure compliance with the prescribing protocol. The SI and customer service manager said that there had been not any such audit yet. The patients registered doctor was rarely advised as people did not usually provide their GPs details or consent for the information to be shared.

Prescriptions were issued electronically through a specialised computer system. The prescriber had his own access to the computer system and the IP address was shown on the prescription and checked to ensure the prescription was authentic. The pharmacy team used printed copies of the private prescriptions to assemble against. This activity was carried out during the afternoon. When they had been checked by the pharmacist, a packing assistant packed the prescriptions up and placed them in mail bags which were sealed ready for collection by Royal Mail each day. This process was outlined in the pharmacy processing guidelines.

The prescribing service was high-risk and although the IT system was sophisticated there was a lack of

measures to evaluate the quality of the prescribing activities. The SI was not able to confirm if the system could produce data to help evaluate prescribing trends. For example, the top 10 prescribed medicines. In addition, the IT manager could not provide information on the percentage of patients who had given permission for their GPs to be contacted or the percentage of declined orders due to failure to communicate with the patient's GP to confirm their medical history.

There was a risk assessment for the prescribing service which had been started on 23 September 2019 by the IT and customer service managers, in response to the new GPhC guidance for online pharmacies. The risk assessment included web site and data security. There was an IT security policy dated March 2019 with a statement that the user agreed to comply fully with the Company's Data Protection Policy and the General Date Protection Regulation. (GDPR). There was separate portal access with individual username and passwords for the prescriber, pharmacy, dispatch and Prescription doctor employees. There was cloud based storage system, with regular server scans and daily backups. Secure Sockets Layer (SSL) protection was used on the webserver. This was a computing protocol that ensured the security of data sent via the internet by using encryption.

There were standard operating procedures (SOPs) for the pharmacy's services which were prepared in March 2014. Their stated period of review was every 12 months but there was no documented review, so they may not reflect current practice. Some of the pharmacy team had signed the SOPs in 2014 to indicate they had read and understood them. But some members of the team who had started their employment since 2014 had not. So, they may not understand the procedures and where responsibility lies. The delivery driver who had worked in the pharmacy for three days said he had not completed any training or read anything about the delivery procedure or confidentiality. He had a basic understanding of patient confidentiality which he said he had obtained from a previous job. A delivery SOP could not be located. There were separate folders of policies and standard operating procedures (SOPs) for the prescription doctor prescribing service which had been prepared and reviewed recently. They had been signed by the customer service team.

There was a paper log to record near miss incidents in the pharmacy. None had been recorded in the past 12 months. Members of the pharmacy team said when near misses occurred the pharmacist would highlight the mistakes and ask them to rectify their own errors. A dispenser discussed previous examples of action taken, such as segregating stock which had similar looking packs. The RP discussed what he would do in the event of a dispensing error. But he was not able to show the records or provide examples of previous errors and the actions which had been taken. There was a separate error protocol for the Prescription doctor service which included the pharmacist on duty being notified and contacting the patient to offer advice on the appropriate action to take. The patient was asked to provide photographic evidence of the medication received. There were incident report form templates available, although no completed ones were seen.

Roles and responsibilities of the pharmacy team were described in individual SOPs. The dispenser was able to describe her responsibilities and said she had read the SOPs. She provided some examples of what could and could not be carried out during the absence of a pharmacist. One of the tasks she described which could be carried out was the hand out of assembled and checked medicines, which was not in line with RP regulations. However, she did not remember ever supplying medicines in the absence of the pharmacist. The responsible pharmacist (RP) said he would retrain the team in the SOP related to working in the absence of a pharmacist. Some staff wore uniforms but nothing to indicate their role, so this might not be clear to members of the public.

The pharmacy had a complaints procedure which included recording them and referring them to SI to be followed up. There were no details about the procedure on display in the retail area, so people might not know how to raise a concern or give feedback. The prescription doctor website gave the

contact details of customer service and there was a form to report complaints on. They used trust pilot to monitor customer service and had 4.8 out of 5 rating.

A previous certificate of professional indemnity insurance which expired in July 2019 was on display in the pharmacy. Subsequent to the inspection the pharmacy provided an e-mail from their insurance providers stating that 'subject to compliance with the recent GPhC guidance on the dispensing of online prescriptions', they would cover the dispensing of items, from the pharmacy, prescribed by the doctor in Italy. The pharmacy was not compliant with all GPhC guidance for registered pharmacies providing pharmacy services at a distance so there was a risk that the insurance might be invalid. This pharmacy's insurance did not cover the prescriber's indemnity. A document was provided for the prescriber which was in Italian and even when translated did not provide assurance that it covered his remote prescribing activity for patients in the UK, or the level of indemnity in the event of a claim.

The incorrect name of the RP was on display at the start of the inspection but this was corrected when pointed out. The RP was correctly signed in to the RP register. The GPhC registration number of the RP was not always written in the record as was legally required and there was no RP recorded for Saturday 7 September 2019. The controlled drugs (CDs) registers were electronically maintained and running balances were recorded. The pharmacist said these were audited weekly, but this was not consistent. Two random balances were checked and both found to be accurate. A designated patient return CD book was available although it was not always completed. Records for private prescriptions, emergency supplies and unlicensed specials appeared to be in order.

The pharmacy team said they had signed a confidentiality agreement when commencing employment. A dispenser said she covered information governance (IG) as part of her training course but had not completed any further learning at the pharmacy. A dispenser was able to describe the process for separating and destroying confidential waste which was shredded on-site. The pharmacy had a certificate of registration with the Information Commissioner's Office (ICO) on display. There was no information on display about the pharmacy's privacy policy, or about how people's information was handled and stored. However, this information was available on the Prescription doctor website.

Historical safeguarding procedures written by the Royal Pharmaceutical Society of Great Britain (RPSGB) were available in the SOP folder which the pharmacy team said they had read. The RP said he had completed level 2 Centre for Pharmacy Postgraduate Education (CPPE) safeguarding training. A dispenser said she would initially report any concerns to the pharmacist on duty. Contact details of the local safeguarding board were not immediately available. The IT manager confirmed that there had been a few members of people's family reporting abuse of medicines obtained from the Prescription doctor website. A stop had been placed on their accounts to prevent future supplies until they supplied their GP details. There was no way of assessing a patient's mental capacity, to determine whether a remote consultation was appropriate which was a potential safeguarding issue.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload and the pharmacy team members are qualified for the jobs they do. They get some ongoing training to help them keep up to date. But they do not record this, so they might not always identify gaps in their knowledge. The team members work well together, and they are comfortable providing feedback to their manager.

Inspector's evidence

There was a regular locum pharmacist (RP), three NVQ2 qualified dispensers (or equivalent), a trainee dispenser, a medicines counter assistant (MCA), three unqualified assistants and a delivery driver on duty in the pharmacy at the time of the inspection. The staffing level was adequate for the volume of work during the inspection and the team were observed working collaboratively with each other and the patients. One of the unqualified assistants was in her first week and she was shadowing the qualified MCA. One said he did not sell pharmacy medicines or work in the dispensary but assisted in tasks such as date checking and cleaning. The other was a packing assistant who packed the assembled prescriptions from this service into boxes and got them ready for postage. The RP worked two or three days each week and the SI worked at least once a week. The SI was present for a short time during the inspection, although it was his day off. He explained that he also worked at the other pharmacy he owned. The RP explained there had been a high turnover of staff recently and a lot of sickness, but there was quite a large pharmacy team and some part time staff who were flexible with their hours.

There was an IT manager, a customer service manager and an IT/customer service assistant in a separate room above the dispensary where the Prescription doctor prescribing service operated from. The SI referred to the IT manager as the manager of Prescription doctor. The customer service manager was a pharmacy graduate so had a good understanding of pharmacy.
Members of the pharmacy team completed some ad hoc training, for example when medicine representatives visited the pharmacy and provided training about new products. Some certificates were available showing completed training but training was not provided in a structured or consistent manner. The pharmacy team said they would have informal chats about their work and performance, but this was not documented or part of a formal programme. So, learning and development needs may not always be fully addressed.

The RP said he felt able to exercise his professional judgment and this was respected by the SI and the pharmacy team. A dispenser said she felt a good level of support from the pharmacists and was able to ask for further help when she needed it. Another dispenser said if she had any concerns about the pharmacist being fit to work, she would raise it with the SI. There were no service based targets set by the pharmacy.

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

Summary findings

The premises generally provide a professional environment for people to receive healthcare. But the pharmacy uses a website that allows people to select the prescription only medicines they want before they have a consultation with a prescriber. This means people may receive medicines that are not the most suitable for them. Some parts of the pharmacy website are unclear, and it does not provide the name and address of the prescriber or full information about the pharmacy. This means people may not have enough information to make an informed decision about their care.

Inspector's evidence

The pharmacy premises including the shop front and facia were in an adequate state of repair. The retail area was free from obstructions, professional in appearance and had a waiting area with three chairs. The temperature and lighting were adequately controlled. Maintenance problems were reported to the SI who organised the required work, and the response time was appropriate to the nature of the issue.

There was a separate room on the first floor where excess stock was stored and the multi-compartment compliance packs for patients in care homes were assembled and stored. Staff facilities included a small kitchen and a WC with a wash hand basin and hand wash. There was a separate dispensary sink for medicines preparation with hot and cold running water. The consultation room was large but it was cluttered with paperwork, empty fridges and many part-dispensed multi-compartment compliance packs for community patients. It did not present a professional image. A dispenser explained they would use this room when carrying out the services and when customers needed a private area to talk.

The website contained the mandatory (MHRA) internet logo and the voluntary GPhC logo. The name and physical address of the pharmacy was not displayed on the website although it could be found by following the link from the GPhC logo, but people might not be aware of this. The location of the prescribing service was not clear. The website did not display the name of the prescriber, their address or their registration number. The indemnity arrangements were not made clear for the prescriber. And there was misleading information because the website stated the GMC was the regulator of UK- based doctors, but the prescriber was not registered with the GMC. The SI said this was an over sight because the doctor was previously registered with the GMC and he had not realised it was still showing on the website.

The website was arranged so that the patient chose the POM and the quantity before filling in the consultation questions. This means people may not always receive the most suitable medicines for their needs. The IT manager confirmed that the work was underway to change this to the consultation first in line with the GPhC guidance and suggested this work should be completed within a month.

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

Summary findings

The pharmacy does not make enough checks to ensure medicines supplied through the prescribing service are appropriate for the people they supply. And it supplies some medicines which may not be appropriate for supply via a remote consultation because they require physical examination, blood tests or monitoring. The pharmacy routinely supplies medicines without informing the patient's regular doctor or making sure they agree to the supply. This means people's conditions might not be properly monitored, and their use of medication may not be appropriately controlled. The pharmacy offers a range of healthcare services which are easy for people to access. The pharmacy gets its medicines from reputable sources but does not always store them appropriately. And the fridge temperature is not properly monitored so the pharmacy cannot show that it stores medicines requiring refrigeration at the correct temperature.

Inspector's evidence

The pharmacy, consultation room and pharmacy counter were accessible to all, including patients with mobility difficulties and wheelchair users. Some services were advertised in the window such as flu and travel vaccinations but other services were not advertised, so people might not know they were offered. There was a small range of healthcare leaflets and some information on healthy living. Some information on the conditions and medicines available was displayed on the Prescription doctor website and there was signposting information to support groups and organisations for people suffering from pain or with addiction. The website contained some information about the treatments that were available. But general sales list (GSL) and Pharmacy (P) medicines were not advertised or available via the website, which limited patient choice to more potent treatments. The pharmacy used google optimisation to promotes the website and some patients were given a 30% discount using a discount code made available via google. This risked encouraging the use of prescription only medicines.

The assessment questionnaire contained two parts, the first part was standardised for all medicines and checked if the patients' GP was aware and/or has seen the patient about their condition. The system flagged the negative response to this question and allowed the patient to change their answer. Asking patient's consent to share information with their GP was not mandatory, apart for people requesting opioids which had become mandatory around four weeks ago. The scope and the capability of the service provided by this website was limited to issuing medicines to patients with the assurance that they were regularly monitored and followed up by their GP or hospital specialist. However, the current format did not provide the assurance that the patient was appropriately managed by their GP and/or hospital specialist.

The second part of the questionnaire was specific for individual medicines. There was inconsistency with regards to the content and layout of some questionnaires. For example, modafinil and levothyroxine questionnaires alerted the patient for negative responses that might affect the supply. It also allowed amendments to be made so the patient could change their answers and the prescriber would not be able to see or track these amendments. The IT manager explained that the consultation questionnaire for opioids had been redesigned around two weeks ago so that the person completing it was not told if a particular answer would mean the prescriber would not approve the supply. It also included more free type boxes. This was to reduce the risk of people deliberately entering incorrect

information to achieve approval for their desired medicine.

Some of the medicines that were available for selection would not normally be appropriate for supply at a distance due to monitoring requirements, dose adjustments and potential for misuse, such as, modafinil, which is a stimulant, advertised for the treatment of narcolepsy but is often misused. The drug requires regular monitoring of blood pressure and recommendations suggest an electrocardiogram (ECG) before initiation. It also requires dose adjustments in some medical conditions. The clinical contents of some questionnaires failed to capture some important information to inform an appropriate prescribing decision. For example, the levothyroxine questionnaire did not ask for TSH levels or when it was last tested. Current clinical guidance recommends annual testing of TSH and a consequent dose adjustment to keep TSH levels within the reference range. The modafinil questionnaire did not assess the length of treatment or how often was the patient being monitored and followed up by their GP. Current clinical guidance recommends regular monitoring of ECG and blood pressure as well as re-evaluating the treatment for extended periods (9 weeks) as long-term benefit of modafinil is not established.

The Ibuprofen (non-opioid pain killer and anti-inflammatory) questionnaire was of good quality from the clinical and patient safety point of view. It contained questions to assess the severity score and nature of pain, any other associated symptoms, red flags which would require urgent medical referral, and other appropriate assessment questions.

Neither the SI, customer service manager or IT manager knew what percentage of people provided consent to share information or provided their GP details. This had not been audited but appeared to be a very small number. For the sample of four supplies of codeine made on 9 and 10 October which were checked, none had provided consent to share the information with their GP and the supplies were still made. There was a one-off issuance policy where in 'exceptional circumstances, taking into account patient consultation and severity of condition', a one-off supply could be issued. For one of the supplies made the previous day the exceptional circumstance was not being registered with a GP. A message was sent from the prescriber asking the person to register with a GP and that it was their last supply until confirmation was received from their GP. The prescriber recorded very brief messages as justification of supplying without the patient providing consent to share information with their own prescriber. For example, 'occasional usage' or 'one off prescription'.

There was a delivery service for NHS prescriptions. Signatures were not obtained from the recipient unless the medicine included a CD, so there was not a reliable audit trail for the safe delivery of medicines. A note was generally left if nobody was available to receive the delivery and the medicine was returned to the pharmacy. But the delivery driver said he would post the medicine through the letter box if it would fit. The delivery driver had started working at the pharmacy a few days earlier. He said he had not read any written procedures but another driver had explained the procedure. He had been told it was not necessary to obtain signatures. It was not clear whether there was a delivery SOP but it could not be located during the inspection. There was a medication delivery policy for the posting of private prescriptions from the Prescription doctor service using Royal Mail. This was a 'signed for' service which could be tracked by the customer service team in the pharmacy. Fridge lines were transported in a cold pack of which there was assurance of being kept at the correct temperature for 48 hours. Unwanted medicines which were returned in the post were destroyed and not re-used.

Space was adequate in the dispensary, but the work flow was not well organised. The dispensary shelves were full and untidy and some stock was stacked in piles on the floor. Dispensed by and checked by boxes were initialled on some medication labels to provide an audit trail. But this was not the case for methadone and buprenorphine where there were no initials and it was not clear who had dispensed or checked them, limiting the information available if there was an error.

Stickers were put on assembled prescription bags in the pharmacy to indicate when a fridge line or CD was prescribed. 'Speak to Pharmacist' stickers were used to highlight counselling was required. The RP said high-risk medicines such as warfarin and methotrexate were targeted for extra checks and counselling. He said INR levels were checked if there had been a change in dose for a patient taking warfarin, but this was not recorded. The RP was aware of the valproate pregnancy prevention programme. He did not know if an audit had been carried out to identify any regular patients in the at-risk group. The valproate information pack and care cards could not be located so there was a risk that people in the at-risk group might not be given the appropriate information and counselling.

A large number of multi-compartment compliance aid packs were assembled in the pharmacy. There were around 14 care homes with up to 40 patients in each and around 60 community patients. There was a partial audit trail for changes to medication but it was not always clear who had confirmed the changes and the date the changes had been made. A dispensing audit trail was not usually completed, so it was not clear who had assembled and checked the packs and this might limit the available information if something went wrong. Packaging leaflets were not usually supplied and cautionary and advisory labels were missing so patients and their carers might not have all the required information to take them medicine safely and effectively. Medicines supplied as 'extras' with multi-compartment compliance aid packs were also missing the cautionary and advisory labels. Medicine descriptions were usually included on the labels to enable identification of the individual medicines. Most of the multicompartment devices were left unsealed, for prolonged periods of time which risked contamination and increased the risk of mistakes.

A dispenser knew what questions to ask when making a medicine sale over the counter and when to refer the patient to a pharmacist. She was clear which medicines could be sold in the presence and absence of a pharmacist and understood what action to take if she suspected a customer might be abusing medicines such as a codeine containing product. Pharmacy medicines were stored behind the medicine counter so that sales could be controlled.

There were two medical fridges, a large one where most of the stock was stored and a smaller fridge in the consultation room where vaccinations were stored. The minimum and maximum temperatures had been recorded regularly for one fridge (and within 2-8-degree Celsius range) but they did not appear to be accurate. The built-in thermometer was reading a maximum air temperature of 22 degrees Celsius and a maximum load temperature of 17.3 degrees Celsius. The fridge was showing an alert symbol 'Hi' and a temperature of 9.6 degrees Celsius during the inspection. The RP said it was because the door had been opened for a short period of time. He said he would monitor it and thought perhaps he had not re-set the fridge thermometer properly which was why it was reading such high maximum temperatures. There were no temperature records for the small medical fridge, which was full of vaccines. The RP said he had not recorded the temperature because he had not realised there was stock in it. The thermometer was recording 4 degrees Celsius throughout the inspection but a maximum temperature of 23 degrees Celsius, indicating the thermometer had not been reset since it had been turned on.

Licensed wholesalers were used for the supply of medicines and appropriate records were usually maintained for medicines ordered from 'Specials'. No extemporaneous dispensing was carried out. The pharmacy was not compliant with the Falsified Medicines Directive (FMD). They had the hardware but not the software needed to comply with the requirements. The SI confirmed they were registered with SecureMed and had taken some steps towards complying.

Some of the pharmacy team were performing date checking during the inspection but this was ad hoc and not recorded. A date checking matrix was available, but the last record was made in February 2018. A spot check of medicines found a box of buspirone tablets which had expired in April 2019. A number

of medicines were stored on the dispensary shelves that were not labelled with all of the information required. For example, batch numbers and expiry dates. Some tablets had been de-blistered and were stored outside of their foil strips inside boxes.

The RP said alerts and recalls were received electronically as part of the electronic CD register system. He said they were read and acted on but a paper copy was no longer retained as they were trying to go paper-free as much as possible. It was not clear if there was any record made of the action taken in response to the alerts and to provide assurance that the appropriate action has 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.

Inspector's evidence

There were several old versions of the British National Formulary (BNF) in various places in the pharmacy so there was a risk that out of date information could be used. However, the pharmacy team could access the internet for the most up-to-date information. For example, the electronic BNF and medicines compendium (eMC) websites.

Electrical equipment appeared to be in good working order. There was a small selection of clean glass liquid measures with British standard and crown marks. Separate measures were marked and used for methadone solution. The pharmacy had a small range of equipment for counting loose tablets. There was a separate tablet triangle that a dispenser said was used for cytotoxic drugs but it was not marked and did not look very clean, risking contamination. Most medicine containers were appropriately capped to prevent contamination, although a couple were seen which did not have caps on them.

Computer screens were positioned so that they weren't visible from the public areas of the pharmacy. Patient medication records (PMRs) were password protected. Cordless phones were available in the pharmacy, so staff could move to a private area if the phone call warranted privacy.

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.