General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: mychemistplus Pharmacy, 327 Halliwell Road, Bolton, Greater Manchester, BL1 3PF

Pharmacy reference: 9011081

Type of pharmacy: Internet

Date of inspection: 27/02/2020

Pharmacy context

This is a pharmacy which offers its services to people in the UK through its website (www.mychemistplus.co.uk). People cannot visit the pharmacy in person. The website has a prescribing service provided by a pharmacist prescriber who works at the pharmacy. The website offers prescription medicines for a range of conditions, but the pharmacy mainly supplies asthma inhalers and antibiotics for dental care. The pharmacy's website provides information about the pharmacy and it advertises the sale of over-the-counter medicines, but none have been supplied.

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	1.1	Standard not met	The pharmacy's risk assessments do not adequately identify the risks of the service including supplying medicines online and the SI's dual role of prescriber and pharmacist. And they do not fully identify the risks relating to individual medicines or treatments, or explain how these are managed. Services are not audited, and there is some evidence of prescribing which is not in line with UK guidance.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	There are no pharmacy specific evidence-based prescribing policies or protocols which indicate in what circumstances each individual medicine is prescribed or requests are declined, and what counselling, follow up and ongoing monitoring should take place. The pharmacy supplies medicines without informing the patient's regular doctor, and the prescribing relies solely on information provided by the person completing the online questionnaire, without necessarily seeking further confirmation of a diagnosis or what previous treatments have been provided.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy has not thoroughly considered the risks associated with the service or taken sufficient steps to manage them. Prescribing is not audited and it is not always in line with UK guidance. The pharmacy generally keeps the records required by law, but these are sometimes inaccurate, which could make it harder to understand what has happened if queries arise. It has written procedures and policies on keeping people's private information safe, but procedures on safeguarding vulnerable people are not tailored to the online business.

Inspector's evidence

The pharmacy started operating in November 2016 and relocated into the new premises in February 2019. The pharmacy had up-to-date standard operating procedures (SOPs) for the services provided. They had been prepared by the pharmacist superintendent (SI). The only other member of the pharmacy team was a dispenser. There were signatures on some of the SOPs indicating that he had read and accepted them. However, some SOPs relevant to his role, such as the 'labelling and assembly' SOP had not been signed by him. The SI confirmed that he had read all the SOPs, but said he might have forgotten to sign some of them. She said she would ensure that he went through and signed any that he had missed. Roles and responsibilities were set out in the SOPs.

The SI was working as responsible pharmacist (RP) and her name was displayed in the pharmacy. Her name and registration details were displayed on the website. She was an independent prescriber and the only prescriber for the pharmacy's prescribing service. The dispenser assembled each prescription and then the SI carried out the clinical and accuracy check. This introduced an element of risk, as a second suitably competent person, rather than the prescriber, should usually be involved in carrying out the final accuracy check and the check for clinical appropriateness. The SI said she minimised this risk by prescribing in the morning and checking in the evening or prescribing the day before checking.

A very small number of prescriptions were supplied each day. Between 1 February 2010 and 27 February 2020, 66% of the prescriptions were for asthma inhalers (Ventolin and salbutamol), 30% were for antibiotics (amoxicillin and metronidazole) and 4% were for omeprazole (PPI -proton pump inhibitor). The SI confirmed this was typical although there had also been occasional supplies made for the treatment of erectile dysfunction (ED) and contraceptives in previous months. The business model was based on repeat prescribing. The SI explained that she did not diagnose and only supplied the medicine if the patient had it previously prescribed by their GP. She said people used the service for convenience or because it was less expensive than going to their own GP. The SI said many GPs limited people to one inhaler a month, and people liked to have two or three so they could leave one at work or take one to the gym, for example. She said other people used the service because they had lost their inhaler and their GP would not issue another prescription until the following month.

Pharmacy medicines including two codeine containing products (soluble Solpadeine and Nurofen Plus) were offered for sale on the website. The SI said she had not supplied any of these and had refused requests for other codeine containing medicines such as codeine linctus, as she did not feel the supply would be appropriate. The two codeine containing medicines were removed from the website following the inspection.

Two basic risk assessments had been completed on 'delivery and returns' and 'private prescription

processing' but the risk assessments did not include website and data security, the SI's dual role of prescriber and pharmacist or the behaviour of people using the pharmacy service. The SI explained that the security of the website was assured by Hypertext Transport (or Transfer) Protocol (http) and 'Global sign' Secure Sockets Layer (SSL). There were 'risk assessments' for some of the individual medicines supplied. The SI explained that she had prioritised the medicines supplied most, so they were available for Ventolin, salbutamol, sildenafil and omeprazole and she was in the process of completing 'risk assessments' for metronidazole and amoxicillin. The 'risk assessments' covered indications, doses, warnings, precautions and interactions but they did not indicate in what circumstances the particular medicine would be prescribed or declined. And they did not cover the risks identified for supplying the medicines online and how they would be managed, including counselling, follow up and ongoing monitoring. 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.

The SI said she followed UK national prescribing guidelines such as National Institute for Health and Care Excellence (NICE), British National Formulary (BNF) and the Summary of Product Characteristics (SmPC) from the electronic Medicine Compendium (eMC). She said she had based the online consultation questions on these. The SI stated she had not carried out any prescribing audits because she was the only prescriber and she knew that her prescribing was always in line with this guidance. However, the private prescription register indicated that Ventolin inhalers were routinely labelled 'two puffs four times a day'. This was not in line with the 'risk assessment' which the SI had provided for Ventolin and did not appear to be in line with the dosage outlined in the BNF. The SI said they were labelled with this dosage because the patient medication record (PMR) system defaulted to this, but she did not change it before supply.

There was a 'Clinical Governance incorporating incidents and complaints' SOP. There were no documented dispensing incidents and the SI confirmed there had not been any dispensing errors. There had been one near miss recorded during a two week audit. It had been a labelling error and the SI introduced a break after 30 minutes of work, as a result of this near miss.

There was a 'Patient Feedback' SOP. A complaint policy was in the terms and conditions on the website, but how to raise concerns about the pharmacy was not prominently displayed on the website, so people might not be clear about this. The SI said they had not received any formal complaints but Trust Pilot was used to monitor customer service and they had a 'trust score' rating of 4.2 out of 5. The SI said she generally responded to reviews on Trust pilot.

A current certificate of professional indemnity and liability insurance was available in the pharmacy. Insurance was provided by the National Pharmacy Association (NPA) and the SI confirmed she had explained the business model to an advisor at the NPA and they understood that she was carrying out both the role of prescriber and pharmacist. Private prescription records were maintained electronically. These records were not accurate as they showed all prescriptions which had been requested, including some which had not been supplied due to failure to pay. This had been corrected on the patient's individual medication record, and the SI said she would go through the private prescription electronic register and delete the prescriptions which were not supplied, to ensure that it was accurate too. The RP record was appropriately maintained.

There was a 'Patient consent' SOP and people using the pharmacy's services were required to complete 'patient registration' and read the terms and conditions. The patient's date of birth was recorded as part of this process and the pharmacy did not supply children. If a lack of capacity was suspected then additional checks would be carried out and notes recorded on their patient medication record (PMR). There was a General Data Protection Regulation (GDPR) SOP and patients using the pharmacy had been sent information required under GDPR in an email. There was an information governance (IG) policy

and the pharmacy's privacy policy was available on the website. People using the website were required to confirm they had read it as part of the 'check-out' process. Confidential waste was collected in a designated bin which was locked until collection by a specialist waste company. There was a template available of the pharmacy's confidentiality clause. The dispenser had not signed it but the SI confirmed that he had a good understanding about the confidentiality requirements in the pharmacy.

The pharmacist had completed a level 2 training on safeguarding children and vulnerable adults. There was a safeguarding SOP but there was nothing to suggest the supply of contraceptives online might be a safeguarding risk, and the SI admitted that she had not considered this risk. The contact numbers of who to report safeguarding concerns to in the Bolton area was available, in case of a local query. The SI said she would look up the relevant details if she had a safeguarding concern in a different part of the country.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy team is small, but the current workload is manageable. Team members have the right qualifications for the jobs they do and they discuss any issues informally together.

Inspector's evidence

The SI was on an advanced practitioner course at university. She had completed modules on diagnostics, clinical skills and the biological basis of disease, so far on the course. She has had previous experience as a practice independent pharmacist in an NHS GP practice, where she prescribed and held asthma clinics. She considered herself competent in all the treatment areas on the website and in particular long term conditions such as asthma and acute medicines including antibiotics. The SI had completed the CPPE training on Summary Care Records (SCR).

The current workload was very small and the team were only in the pharmacy for a short time each day. The dispenser had recently completed a NVQ2 equivalent qualification in dispensing but there was no other training records for him. He was given formal appraisals as part of the dispensing course and discussed other issues informally with the SI as they arose. There was a whistleblowing policy. The SI said she felt empowered to exercise her professional judgement and could comply with her own professional and legal obligations. For example, refusing to prescribe a medicine, because she felt it was inappropriate. She said there were no targets apart from self-imposed business targets.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises provide a professional environment for people to receive healthcare services from. However, the website layout allows people to select the prescription only medicines and its quantity before having a consultation with the prescriber. This increases the likelihood that people may sometimes receive medicines which are not necessarily suitable for them.

Inspector's evidence

The pharmacy was in a secure, closed unit on the first floor of a building. The pharmacy premises were in a reasonable state of repair and the fixtures and fittings were in fairly good order. The temperature and lighting were adequately controlled. The team had access to a private kitchen area, where there was hot and cold running water and a WC with a wash hand basin and antibacterial hand wash. There were a couple of separate offices on the first floor. They were not part of the registered premises and were unused. Access into the premises was via a locked door on the ground floor, and people needing access such as wholesale drivers, were required to ring a bell to gain access.

The currently active website allowed people to select the medicines they wanted, and the quantity, before they had an appropriate consultation with a prescriber. The SI demonstrated a new website which she said was almost ready to go live and the changes to the website were more consistent with GPhC guidance. The website contained the Medicines and Healthcare products Regulatory Agency (MHRA) internet logo but it did not have the correct address for the pharmacy. The SI said she would check this with the MHRA, but believed it was an error on their part as she had informed them when the pharmacy relocated. Subsequent to the inspection the address was corrected. The GPhC registration number could be seen on the GPhC voluntary logo, but the pharmacy had not applied before displaying the logo, so was asked to take it down until the appropriate application process had been completed.

There were references to the 'online doctor service' and 'UK registered doctors' on a video clip and in the online questionnaires. This was misleading as the only prescriber was the pharmacist prescriber and no 'doctors' currently prescribed for the service. The SI said she would remove any references to 'doctors' to avoid any confusion on the new website.

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

Summary findings

The pharmacy does not make enough checks to ensure medicines are appropriate to supply. It supplies medicines without informing the patient's regular doctor, and the prescribing relies solely on information provided by the person completing the online questionnaire. This is a risk because people's conditions might not be properly monitored, and their use of medication may not be appropriately controlled. The pharmacy generally sources, stores and supplies medicines safely.

Inspector's evidence

Services provided by the pharmacy were outlined on the website and people could communicate with the pharmacist via the telephone or by email. Some signposting information was available on the website with links to the www.NHS.uk website. Some healthcare blogs were posted on the website during 2017 and 2018, but nothing more recently.

The assembled prescriptions were posted on a special delivery Royal Mail service. This was a 'signed for service and could be tracked by the pharmacy. Customers wishing to purchase over-the-counter (OTC) medicines via the internet were required to complete an algorithm of relevant questions. The SI said she had not supplied any OTC medicines but she would telephone the customer each time and ask additional questions and then write a prescription if she decided a supply was appropriate.

All customers were screened using 'Verifyage.co.uk'. The SI explained that it checked the name and date of birth against the electoral role records and she cross-checked this with payment details. She described this as a 'soft' identity (ID) check and said photo ID would be required to be uploaded as part of the registration process when the new website went live, to make it more robust.

There was a SOP defining the procedure in which the online prescribing service would prescribe medication. This outlined that the prescription would only be issued if the information provided in the patient questionnaire was deemed sufficient to prescribe the medicine safely and the patient would be contacted by phone or email if it was not. If any concern was raised that the person completing the questionnaire lacked capacity then the person would be contacted for further information. Details of the prescriber's reason to prescribe or not were recorded on the patient's record. However, there were no documented pharmacy-specific prescribing policies or protocols to base these decisions on, and nothing to indicate what follow up and monitoring should take place. A book was also used to record some of the SI's justification for declining prescriptions and recorded when she had signposted the person to their own GP. For example, a patient who had stated they used up two blue (salbutamol) inhalers a week. The SI declined the sale and referred them to their GP for an asthma review, compliance and inhaler technique, as she explained this indicated that the asthma was poorly controlled. The person agreed to make an appointment with their own GP.

People were asked for the contact details of their GP and consent to contact them to share the information about their online treatment, but the SI said nobody had consented to this, so she had not informed anyone's GP. A letter was sent out with each prescription medicine stating it was important to share information with their GP and asking if they changed their mind about this to contact the pharmacy. The SI explained that she had organised access to Summary Care Records (SCR) and confirmed people's consent would be obtained before accessing them. She said access to SCR would be mandatory following the introduction of the new website, if the patient did not provide consent for the

pharmacy to contact their GP to verify the information they had provided. However, SCRs were not currently used to verify the information provided during the online consultation, so there was no way of checking that the information currently being entered was correct, and this meant there was a risk that people received medication which was not clinically appropriate. When the questionnaires were completed on the website, it was possible for the patient to enter incorrect information, either accidently or deliberately and changes to answers were not auditable.

All supplies were recorded on individual patient medication records so that they could be monitored and the records included the questions that had been asked and the responses that were received. The SI stated that she checked these records to help her identify inappropriate requests such as multiple or frequent orders, however there was nothing built into the system for this and no documented prescribing policies or protocols. The SI stated that she did not allow more than one supply of metronidazole or amoxicillin within six months, which she felt was in line with good antimicrobial stewardship. She said the choice of antibiotic was down to the patient, but amoxicillin was usually prescribed first. She had not completed a 'risk assessment' for these antibiotics.

A letter was sent out with some prescription medicines stating that they should arrange to have their blood pressure tested as the previous reading was six months ago and a new reading was required when ordering medication next time. A letter was sent with antibiotics for dental care reminding the person that they had agreed to consult their dentist as part of the consultation and stating that a repeat order would not be allowed in the next six months. Other letters were available such as one advising the person that if their symptoms persisted or worsened they must book an appointment with their GP.

Space was adequate in the dispensary. A very small amount of stock was stored in dispensary drawers which were well organised, neat and tidy. Dispensed by and checked by boxes were initialled on the medication labels to provide an audit trail.

Medicines were stored in their original containers at an appropriate temperature. Date checking was carried out and documented. No medicines requiring refrigeration were supplied by the pharmacy and there was no medical fridge. No controlled drugs (CDs) requiring safe storage were supplied by the pharmacy and there was no CD cabinet or CD register. The SI confirmed that they were scanning medicines to verify and decommission them in line with the Falsified Medicines Directive (FMD). Medicines which were returned to the pharmacy as 'failed deliveries' were not returned to stock and they were destroyed. Alerts and recalls were received via email messages from the MHRA. If they were relevant they would be acted on and a copy retained in the pharmacy with a record of the action taken, so the team were able to respond to queries and provide assurance that the appropriate action had been taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely.

Inspector's evidence

A current version of the BNF was available and the pharmacist could access the internet for the most up-to-date information. IT provisions were outsourced. All electrical equipment appeared to be in good working order. Patient medication records (PMRs) were password protected. There was a separate prescribing portal which only the prescriber had access to. All medicines were supplied in original packs so there was no measuring or counting equipment.

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.