General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: FCL Chemist, 32 Longbridge Lane, Derby, Derbyshire, DE24 8UJ

Pharmacy reference: 9010900

Type of pharmacy: Internet / distance selling

Date of inspection: 04/10/2019

Pharmacy context

This pharmacy started operating in May 2018. The pharmacy does not have an NHS contract and the main activity is dispensing private prescriptions issued by an online prescribing service. Requests for medicines are made via the website MyMedsUK.com. The website offers prescription medicines for a range of conditions but mainly supplies medicines for the treatment of pain, and sleeping tablets. The online prescribing service is not registered with CQC as it is based in Romania. The pharmacy also dispenses prescriptions for aesthetic medicines and medical devices through www.fillerworld.com and veterinary prescriptions and pet medicines through www.smartvetmeds.com. The pharmacy has a MHRA Wholesale Dealers Licence.

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 are not effectively managed. And the pharmacy cannot provide assurance that prescribing is undertaken in line with good practice guidance and UK national guidelines (including GMC guidance)
		1.2	Standard not met	The pharmacy cannot provide assurance that it effectively monitors and reviews prescribing to prevent misuse or abuse.
		1.5	Standard not met	The pharmacy cannot demonstrate that both it and the prescriber it uses have adequate professional indemnity arrangements.
		1.6	Standard not met	There are no clear records to justify prescribing decisions when the person has not provided GP details or consented for the GP to be contacted.
		1.8	Standard not met	The pharmacy does not have sufficient safeguards to make sure supplies of opiates and sleeping tablets 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. And it is possible to change answers to consultation questions, without record, to circumvent the system.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy supplies a range of POMs including large quantities of opioids and other medicines liable to abuse. But it is not able to demonstrate that adequate safeguards have been put in place 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

Principle	Principle finding	Exception standard reference	Notable practice	Why
				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 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.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy works with a prescribing service that deliberately avoids registration with UK regulators by being based in Romania. And the pharmacy does not know whether the prescriber is following UK guidelines. This means the pharmacy cannot show that the prescribing service is safe. The pharmacy does not manage all of the risks involved with its services. And it does not always make a reliable check of a person's identity before medicines are supplied. This means that there are risks to patient safety.

Inspector's evidence

The pharmacy's business involved the supply of prescription only medicines (POMs) to patients in the UK through a third-party website MyMedsUK (the "website"). The website was owned by a separate legal entity, which partnered with FCL Chemist for the provision of pharmacy services. Both companies had the same directors. Medicines were supplied against private prescriptions issued by a General Medical Council (GMC) registered doctor, who was based in the UK but used an address in Romania for the prescribing service. The superintendent pharmacist (SI) explained this was done for the purpose of avoiding CQC registration. This meant that the prescribing service was not subject to inspection by UK regulators. MyMedsUK used the same prescriber to generate all of the prescriptions.

During the inspection the SI arranged for the MyMedsUK website to temporarily stop taking new orders due to the issues being identified. The website was still accessible, but a message was added to the front screen which referred people to their GP and medicines were marked as temporarily unavailable which prevented an order being placed. An updated website was in development, so the business did plan to continue operating in the future.

The prescribing service could only be accessed via the MyMedsUK website. Most of the medicines prescribed were opioid painkillers (dihydrocodeine and codeine) or sleeping tablets (z-drug sedatives, e.g. zopiclone). A range of other medicines were available and modafinil, emergency hormonal contraception, hormonal contraception and propranolol appeared to be dispensed regularly.

A range of standard operating procedures (SOPs) were in place to cover the operational activities of the pharmacy and the services provided. The SOPs had been prepared by the SI prior to the pharmacy opening in May 2018 and some had been updated to reflect the changes to the services offered. The pharmacy had started dispensing prescriptions for MyMedsUK in August 2018. The dispensers and accuracy checking technician (ACT) had read and signed the SOPs relevant to their job roles and used a signature sheet as evidence of training. Roles and responsibilities of staff were highlighted within the SOPs.

The contents of some of the SOPs was quite vague and there were no documented internal procedures to show how the pharmacy managed the risks associated with the higher-risk activities. For example, the pharmacy did not have a policy document for reviewing and updating the list of questions asked during an online patient questionnaire or how to respond to regulatory or prescribing updates. Members of the pharmacy and customer services teams appeared to understand their roles and discussed these during the inspection.

The SI said he had completed a risk assessment for the pharmacy in January 2019. He was aware of the requirement to submit a completed risk assessment to the GPhC by 16th October 2019 and said he was

working towards this deadline. Subsequent to the inspection the SI provided a copy of a risk register. The document indicated that risk assessments had been carried out on 9 January 2019, 12 May 2019 and 7 October 2019 and new risks had been added on each occasion. A number of risks were identified relating to the services provided and there were some action points indicated to mitigate the risks. Several of the action points had not yet been put into operation.

Around 95% of prescriptions dispensed were for opioids and z-drugs. There were opioid and z-drug policies displayed on the website. Further details were available in the pharmacy which specified the maximum quantities that would be supplied and how frequently repeat supplies could be made. These policies were intended to prevent people from ordering too many medicines. The website had a 'lock-out' function which prevented people from completing a request if it was too soon after their previous order. The website would automatically notify the person, by email, to inform them that the lock-out period had passed so they could attempt to place their next order. This practice did not prevent regular orders and did not recognise that early ordering could be a sign of abuse or misuse.

People ordering opioids or sleeping tablets were required to confirm that they were aware that the medicine was addictive and declare that they would inform their own GP and read the patient information leaflet. The person had the option of supplying their GP details during the registration process and ticking a box to confirm they were giving consent for details to be shared with their GP. The SI said that only around 1-2% of people chose to enter their GP details, but medicines were still supplied to those who did not. When people registered with the service they were not asked to provide proof of identity. The identity checking system that they used was not very sophisticated and did not automatically detect potential fraudulent or dishonest activity, or abuse. It relied on the vigilance of the prescriber and the pharmacy team to detect this by spotting duplicate accounts for the same address. If the person's details were not complete or the address did not look correct, the person was contacted by the customer services team and asked to produce identification before they could order a prescription. This occurred in approximately 5-10% of new registrations.

The patient medication record (PMR) recorded when a request for a medicine had been refused. This was usually because the responses to the questionnaire were incomplete or that the person had attempted to make another request after the prescriber had informed them that they would need to submit evidence that they had seen their GP or specialist before the next supply could be made. This could be an indication that people were overusing or abusing the medicine. If the person had reached their maximum number of supplies that could be made before providing additional information, the prescriber added a note to the PMR and the pharmacy passed on this message to the person with their medication. The person was then required to submit evidence, in the form of a GP intermediate summary printout, and this was sent to the prescriber so he could review the information.

Records of decisions to refuse were stored on the PMR and an e-mail was sent to the patient explaining that a supply could not be made. The person could then contact the customer services team for more information about why the prescription had been refused. Examples of queries sent between the customer services team and the prescriber and the SI and the prescriber were seen. These included requests to unlock accounts or for further information on why the prescription had been refused.

Prescriptions were issued through a bespoke computer system. The SI confirmed that the electronic signature complied with requirements and it could not be changed at the pharmacy. He said the prescriber had his own access to the computer system and he had shown the SI what he could see to support his prescribing decisions and then generate a prescription. The prescriber communicated with patients through the customer services team. He emailed the questions to the customer services team for forwarding if there were any questions for the person about their request. There did not appear to be any direct contact available between the person and the prescriber.

The prescriber sometimes added notes to the prescription if he considered advice needed to be provided to the patient. Subsequent to the inspection the SI provided a record of an audit of this advice that the pharmacy had apparently carried out over a two-week period in June 2019. The document indicated that advice had been added to 239 of the 1225 prescriptions issued during that time period, 217 of these related to opioids. There were 26 different pieces of advice that had been issued. The most frequent piece of advice, which had been issued on 142 occasions, was 'I would not advocate regular opioid use. I would suggest that after this order if you require this medication again next month that you source it from your own GP before potentially ordering from us again the month after. This is to ensure you have a medication review with your own GP to make sure it is still the right medication for you.' The report stated that up to 19% of the patients involved had their orders frozen on the next time they tried to order, and that following advice being given orders were flagged and not allowed to order the medicine/treatment again. The flagged accounts were only allowed to reorder if the patient submitted a review with their GP, which could be a document or a review note that proved such a conversation. There was no follow up information included to provide assurance that the advice had been followed.

The SI said that he worked collaboratively with the prescriber to develop and maintain the online questionnaires. The SI provided emails to show the discussion with the prescriber about updating the questions asked when a person wanted to obtain a prescription for zopiclone. The updated version included a change to the order of questions and other editorial modifications. However, there was no policy for the development and maintenance of these questionnaires. There was no system in place to ensure that the clinical content of the questionnaires was regularly checked for clinical appropriateness and validity. Also, the questionnaires did not have expiry dates to ensure that they were regularly updated to accommodate any changes to clinical practice.

The SI explained that as the prescriber was a GMC registered prescriber and practicing as a GP, he trusted that he would be up-to-date with current prescribing guidance and GMC guidance on remote prescribing. As the prescribing service was not registered with CQC there were no independent safeguards in place to check this.

There was evidence of the potential overprescribing of z-drug sleeping tablets as some people had received multiple courses, even within the lock-out periods that were displayed in the pharmacy. This clinical practice does not comply with current clinical guidance for short term insomnia which recommends referral for cognitive behavioural therapy if z-drugs are required for more than two weeks.

The SI stated that he was aware that modafinil was probably being ordered by students to help them stay awake during exam revision rather than to genuine people with narcolepsy (the only licenced use of modafinil) but it was still supplied.

The prescriber was contacted after the inspection. He explained that the prescribing activity was limited to medicines that had previously been prescribed for the person and he was issuing a 'repeat prescription'. He stated that he depended on the person answering the online consultation honestly and that the GP would be responsible for monitoring, follow up and the duration of treatment. He said that he used his professional judgment to recognise any lack of consistency in ordering and would request further evidence form a specialist or GP if required. He confirmed that there was no written policy or procedure to support this.

No routine checks were in place to contact a person's GP before making a supply and supplies would still be made if the person had provided GP details but had not consented for them to be contacted. The customer services team provided a copy of a GP intermediate summary printout that had recently

been supplied to them as evidence to support a request for a repeat supply. The pharmacy had previously supplied the person with 100 codeine phosphate 30mg tablets on six separate occasions within a five-month period. The person had refused to give consent to contact his GP and before the seventh supply could be made he had been asked to supply a GP intermediate summary printout. This showed that codeine (co-codamol 30/500) had only been prescribed by the GP on one occasion, which was after the person had received six supplies from the pharmacy, and it was listed as an acute medicine. The medical history on the intermediate summary printout did not match the medical condition declared by the person on the MyMedsUK questionnaire. Also, according to the intermediate summary printout the last time the person had visited his GP was over a year ago despite him stating in the questionnaire that he had regular GP and physiotherapy appointments to manage his pain conditions.

A procedure was in place for dealing with dispensing incidents. A few near misses and dispensing errors had been recorded. Learning points were recorded, and action that had been taken to prevent reoccurrence. There was a record of a dispensing incident when the wrong medicine had been supplied and the person had been asked to provide photographs as evidence.

Customers were able to provide feedback or raise a concern via the 'contact us' tab on the website. The refund policy and privacy policy were available on the website. The customer service team explained that most of the queries they received were related to people being locked-out and unable to order or a prescription being rejected. There were comments about the pharmacy on Trust Pilot and the pharmacy had a four-star rating with some comments about incorrect quantities, rejected orders and dispensing errors. The pharmacy team could not locate a complaints SOP or written complaints procedure. The customer services team explained that they would refer to the complaints policy on the website. But this was not easy to understand due to the legal terminology used and was point 22 in the terms and conditions section entitled 'disputes and complaints'.

Details of the pharmacy's professional indemnity insurance were provided. The insurance may be invalid as the statements of fact included the following term 'you follow the General Pharmaceutical Council Guidelines'. The pharmacy is not currently compliant with the GPhC guidance for registered pharmacies providing pharmacy services at a distance. No evidence has been provided to show that the pharmacy's professional indemnity insurance or the prescriber's professional indemnity insurance is adequate for the activity being undertaken.

The responsible pharmacist (RP) notice showed the correct details and was clearly displayed in the dispensary. The RP log was maintained in a record book and seen to be complete. Private prescriptions for MyMedsUK were recorded electronically. Prescriptions for Fillerworld and SmartVetMeds were written in a record book. The electronic and paper records complied with requirements. There were no records kept to justify decisions to issue a prescription without the patients consent to contact their GP.

Patient information was secured in a number of ways. 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. The pharmacy used a password protected computer and access to the pharmacy was limited. Confidential waste was shredded. Pharmacy staff had signed confidentiality agreements. The privacy policy was available on the MyMedsUK website.

The pharmacy had a safeguarding policy and details of safeguarding contacts were available. The SI said there had been an incident when a social worker had contacted the pharmacy with concerns that a person was abusing medicines obtained from the pharmacy. He said there had also been a handful of members of people's family reporting abuse. Red flags were added to these people's notes to prevent future supplies. There were a number of potential safeguarding issues that had not been identified or

addressed, such as, supplying contraceptives (including emergency hormone contraception without verification of identity or age and there was no way of assessing a patient's mental capacity, to determine whether a remote consultation was appropriate.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to manage the current workload and the services that it provides. The pharmacy's team members can raise concerns about the service. However, they are not always supported to act in the best interests of people.

Inspector's evidence

The pharmacy team consisted of the superintendent, pharmacy technician, operations manager (dispensing assistant), dispensing assistant and two customer services representatives. Dispensing assistant training certificates were on display in the dispensary as evidence of training. Requests for annual leave were made in advance to support forward planning and a locum pharmacist was available to cover the SI's annual leave. The pharmacy team appeared to work well together during the inspection.

The SI had meetings with the prescriber and communicated regularly by email. Minutes of a meeting between the SI, prescriber and other stakeholders in May 2019 showed that the updated GPhC guidance for registered pharmacies providing pharmacy services at a distance had been discussed and some actions had been identified but had not yet been addressed. Some other areas of non-compliance with the guidance had been identified but they had decided not to address these. For example, the online prescriber not proactively contacting a person's GP before issuing a prescription for high-risk medicines.

There was a whistleblowing policy in the SOP folder, but some staff members were unsure of external whistleblowing contacts if they did not feel it was appropriate to speak to the SI about their worry.

The RP and pharmacy technician were able to make interventions with prescriptions and some examples were given of prescriptions that had not been dispensed. The SI stated that he felt under some pressure from the owners and had experienced resistance from them about making changes to the website to comply with GPhC guidance.

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

Summary findings

The pharmacy is clean, hygienic, properly maintained and provides a suitable environment for the services carried out. 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 was closed to the public and was located in a large business unit. The upstairs part of the unit was used by another part of the business. The pharmacy area had been purpose-built and was well maintained and in a good state of repair. The pharmacy had been fitted out to a high standard, and the fixtures and fittings were in good order. The temperature and lighting were adequately controlled. Staff had access to a communal kitchen area and WCs with wash hand basins. The pharmacy held an MHRA Wholesale Dealers Licence (WDL) and a separate room was specifically used for storage of wholesale goods.

The MyMedsUK website (the “website”) contained the mandatory (MHRA) internet logo and two GPhC voluntary logo’s were displayed. MyMedsUK used two pharmacies to dispense prescriptions and the details of both pharmacies could be found by following the links from the logos. Following the inspection, the GPhC logo for the other pharmacy was removed from the website. People using the website could not choose which pharmacy dispensed their prescription and the terms and conditions stated ‘MyMedsUK.com work with a number of GPhC registered pharmacies for dispensing’. The website did not prominently display the details of the pharmacy such as, the details of the superintendent, the owner of the pharmacy and the name and physical address of the pharmacy.

The website provided little information about the prescribers. The location of the prescribing service was not clear as the address for MyMedsUK in the ‘contact us’ section of the website was the pharmacy address and the prescriber was not based there. The website had a statement that ‘Consultations are carried out by Medical Independent EU Consultants and Physicians S.R.L’ but there were no further details about this. The website did not prominently display the name of the prescriber, their address or their registration number.

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 website contained some information about the treatments that were available. But the information supplied for some of the treatments was not clinically appropriate, such as modafinil ‘is used to treat excessive sleepiness caused by sleep apnoea, narcolepsy, or shift work sleep disorder’ when it is only licenced for narcolepsy.

The website was suspended during the inspection and was later relaunched after a number of alterations had been made to address some of the concerns that had been identified.

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

Summary findings

The pharmacy does not make enough checks to ensure medicines 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 supplies high-risk 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.

Inspector's evidence

There was ample space in the dispensary, and the work flow was organised into separate areas. Baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. The baskets were stacked to make more bench space available. A dispensing audit trail was in place for prescriptions through the practice of staff signing their initials on the dispensed and checked by boxes on dispensing labels. All dispensed medicines were sent by DPD courier or posted with Royal Mail. Both these services were ‘signed for’ services and could be tracked by the pharmacy.

Some signposting information was displayed on the website, such as NHS information, support groups and organisations for people suffering from pain or with addiction. General sales list (GSL) and Pharmacy (P) medicines were not advertised or available via the website, which limited patient choice to more potent treatments.

People requesting medicines 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. There was no face to face communication. People contacted customer service if they wanted to know the reason for a request being denied but could not communicate directly with the prescriber.

People were asked for consent to share information with their usual prescriber/GP as part of the registration process, but only 1-2% of people consented to this and provided the details. The SI said that even when people provided consent to share information with their GP, the GP was not contacted or informed that a supply had been made. The only exception was when the prescriber felt there was a specific problem and the person had been referred to their GP. This is a concern because people may be under the impression that their own GP had been informed, when in fact they had not.

When the online questionnaires were completed it was possible for the person to enter incorrect information, either accidently or deliberately. When a person answered yes to questions that required a negative response e.g. 'are you pregnant or breastfeeding?' a note appeared which stated that the person should have a face to face consultation with their own GP. But the person was then able to change the response to proceed. The SI did not know whether the system had been designed so that the prescriber could see when answers had been changed during completion of the online questionnaire.

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, and no records were provided by the prescribers to justify their decisions to prescribe. For example, modafinil, which is a stimulant, was advertised for the treatment of narcolepsy but is often misused. There were questions around having a GP appointment for the condition or whether the patient was treated under a psychiatrist. But, it did not request proof of ID, address or previous prescription. 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.

There was evidence that a person had been supplied with modafinil on a regular basis and neither the pharmacy nor the prescriber had sought assurance from her GP to ensure that she had been receiving ongoing monitoring. Longer term (more than nine weeks) effectiveness of modafinil has not been evaluated and according to the manufacturer summary of product characteristics people who are receiving extended courses should be closely monitored for side effects (such as, ECG and blood pressure monitoring) and the treatment outcomes should be regularly evaluated.

The pharmacy website listed a number of conditions for which various treatments could be requested. This section included pain in rheumatoid arthritis and metformin for diabetes. These conditions would normally be managed by a GP or hospital doctor, in which case the patient would be able to obtain a repeat prescription.

Aesthetic medicines and medical devices were available using the website; www.fillerworld.com. This site was used for sales (GSL and medical devices) and these were dispatched from a site in West Bromwich (not a GPhC registered premises). The company had extended their service last year so that healthcare professionals could write prescriptions for individual patients and be exempt from paying V.A.T. The SI had checked the requirements for advanced electronic signatures. He explained that the fillerworld website was a ‘closed system’ so once the prescriber had registered and had been approved, their ‘prescription’ was automatically generated by the information that they inputted into the order i.e. name and address of the prescriber, name and address of the patient, date and details of the product. The ‘signature’ was created by the prescriber having password protected access to the system. The SI was unaware that the GPhC distance selling guidance had included requirements for aesthetic medicines so was not checking whether prescribers had undertaken face-to-face consultations with patients before issuing a prescription.

There was a large medical fridge in place to hold stock medicines. The medicines in the fridge were stored in an organised manner. The pharmacy did not stock any controlled drugs that require safe custody, and there was no CD cabinet. Out of date and returned medicines were stored separately from stock medicines in designated bins. Drug alerts were received directly via email from the MHRA and stored in a file.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide services safely. And the team uses in a way that keeps people's information safe.

Inspector's evidence

The pharmacy had a range of up to date reference sources, including online access to the BNF. Internet access was available. Patient records were stored electronically and there were enough terminals for the workload currently undertaken. Screens were not visible to the public as members of the public were excluded from the dispensary.

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.