General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Clear Chemist, Unit 20, Brookfield Trade Centre, Brookfield Drive Aintree, LIVERPOOL, L9 7AS

Pharmacy reference: 1123405

Type of pharmacy: Community

Date of inspection: 07/12/2021

Pharmacy context

The pharmacy is located in a unit on an industrial estate in Liverpool. It is a distance selling internet pharmacy, trading as clearchemist.co.uk. The pharmacy premises are not open to the public. The pharmacy's main activity involves dispensing prescriptions that are issued by an online prescribing service for patients of Gender GP ('the online provider'), which is an online clinic that operates outside UK regulation. The online provider is registered as a company in Hong Kong and the prescriptions are issued by a doctor who is registered and based in Romania. The online provider offers treatments for transgender patients and gender dysphoria. Medicines are prescribed by the online provider for adults. Some of the medicines that the pharmacy supplies to patients of the online provider are higher risk because they require effective monitoring and management. The pharmacy also dispenses approximately 200 NHS prescription items each month and sells a range of over-the-counter medicines.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy generally manages the risks associated with its services and protects peoples' information. Members of the pharmacy team are clear about their roles and responsibilities. They record their mistakes so that they can learn from them. And act to help stop the same sort of mistakes from happening again. The pharmacy carries out some audits to assess whether the prescribing service it works with follows appropriate protocols. But the scope of these audits is limited. So the pharmacy cannot provide full assurance about the treatment its patients receive.

Inspector's evidence

There were up to date electronically held Standard Operating Procedures (SOPs) for the services provided, with electronic signatures showing that members of staff had read and accepted them. Roles and responsibilities of staff were set out in SOPs. A dispenser was seen to be following the 'dispensing' SOPs and she was able to clearly describe her duties. The staff were clear on their roles and responsibilities which were defined in the SOPs.

The pharmacy had completed a risk assessment to identify the risks associated with all the medicines that they supplied, including medicines for gender dysphoria. Medicines had been given a risk rating of low, medium or high risk. This was used to help them determine the maximum quantities of medicines that would be allowed per month. Following the risk review the pharmacy had decided that certain medicines would not be appropriate. For example, benzodiazepines, Z drugs and weak opioids were not supplied from the pharmacy because they were liable to misuse. The pharmacy had also decided not to supply some antibiotics because they would not be able to determine sensitivities of infections. The risk review had identified a range of other risks and the pharmacy had put some arrangements in place to help mitigate those risks. In some cases, they had changed the risk rating after implementing a mitigating action. Examples of risks that had been identified included patients not giving consent for the pharmacy to contact their regular GPs, working with a doctor not based in the UK and inappropriate prescribing. The pharmacy had also reviewed the risk of supplying medicines for gender dysphoria to children under the age of 18 and had adopted a policy that these prescriptions would either be referred back to the prescriber or referred to a pharmacy near to the patient for dispensing.

The pharmacy worked with three third-party prescribing services. One of these was registered with the CQC but the others were not because they used an EU prescriber and were based overseas. The pharmacist explained that they only received prescriptions from one EU prescriber, but that prescriber worked for two different prescribing services. The pharmacy carried out regular checks to confirm that the EU prescriber was registered in the country they were based and had appropriate indemnity insurance. The superintendent pharmacist also held video calls with the online provider to check that the prescriber had completed appraisals, CPD and competency checks. The pharmacist explained that the superintendent kept records of these checks and was shown the documentation during the videocalls, but the online provider would not share copies of the documents so they were not available for inspection.

The pharmacy had been informed about the protocols that the online providerused and had access to a reference guide for feminising and masculinizing treatment protocols, which they used as part of their clinical checks. These protocols included information about treatments, dosages, and monitoring.

However, the protocols were not referenced and so it was not clear whether they were based on any accepted guidance. The pharmacy also had access to international guidance that the online provider stated they used when providing treatment to patients.

The pharmacy had an up-to-date business continuity plan in place, which was kept under constant review, and modified when necessary. Dispensing errors were reported and near miss incidents were recorded and discussed with the pharmacy team member at the time they were identified. A dispenser gave an example of a near miss incident with two fridge medicines being mixed up. To avoid this being repeated the medicines were now clearly seperated. Near miss records were reviewed by the pharmacist, and discussed during team meetings which took place every 2-3 weeks and were minuted.

The pharmacist used a task list to allocate duties to individual members of staff. The list included tasks such as; check P orders, labelling, dispensing, checking stock, filing prescriptions, contacting patients, and checking emails. This helped make sure that all the tasks were completed, particularly when some staff members were off work.

The pharmacy had a thorough audit plan in place, which was comprehensive and covered various areas of their service. Some aspects of the audit plan linked to the risk assessment which showed that the pharmacy was proactively attempting to monitor the risks that had been identified. However, the sampling and outcomes within some audits was not clear. To audit the monitoring arrangements of the online provider, the pharmacy reviewed five of their prescriptions each month. The audit was intended to ensure that, where relevant, blood tests had been taken for medicines prescribed, within the appropriate time frame and as per the protocol. The audit did not assess whether prescribing was in line with guidance and protocol. And the sample size of the audit (5 prescriptions) was particularly small considering the pharmacy supplied over a 1000 prescriptions per month (approximately 0.5% audited). This meant that the pharmacy may not be able to provide assurance about the quality of prescribing and follow up treatments provided by the online provider.

A customer satisfaction survey had been carried in 2018-2019 and the results were available on the website. An updated online customer satisfaction survey was due to go live on the website at the beginning of 2022. Customers were also able to give feedback or raise concerns via the pharmacy website. And the complaints procedure was accessible on the website.

A copy of the professional indemnity certificate and employer's liability insurance was displayed in the dispensary. The correct responsible pharmacist (RP) notice was displayed. The private prescription record, fridge temperature record and responsible pharmacist (RP) record were in order. The CD register was generally in order but had headers missing from some pages. This could increase the likelihood of records being made in the wrong place. The pharmacy did not have any records of unlicensed specials or emergency supplies but the pharmacist explained none had been supplied.

Confidential waste was placed in a designated bin to be collected by an authorised carrier for destruction. All team members had read and signed a confidentiality agreement as part of the terms and conditions of employment. Computers were password protected. Staff had read and signed the information governance SOP and completed GDPR training with the NPA. The pharmacist explained that the pharmacy website was PCI compliant and had a custom firewall to protect patient information. The pharmacy used encrypted email for communication with patients. A privacy notice was present on the website.

The pharmacy had a safeguarding policy which showed procedures which had been tailored to the risk profile of the pharmacy and the users of their service. For example, the risks of cessation of therapy for patients treated for gender dysphoria, risk of suicide and mental health issues, and risk of abuse. The

policy had been integrated into the pharmacy's audit cycle to ensure it was being followed. The pharmacist and pharmacy team members had completed safeguarding level 2 training. The up-to-date contact details for raising a safeguarding concern nationally were available. The pharmacy's risk assessment also highlighted some safeguarding risks and some actions to mitigate them.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely. Members of the pharmacy team have completed the training they need to do their jobs. And they have access to ongoing training to keep their knowledge up to date.

Inspector's evidence

The pharmacy employed a pharmacist manager and two dispensers. There was also a warehouse manager and a warehouse assistant who were not pharmacy trained and not involved in any registrable activities. The workload appeared to be managed adequately. Detailed training records were kept for the pharmacy team. Staff training opportunities included completing electronic learning modules. For example, all team members had completed GDPR training in June 2021, and pharmacy quality scheme (PQS) training around December 2020, which forms part of the Community Pharmacy Contractual Framework (CPCF). The pharmacist kept a record of training he had completed. This included gaining knowledge in the treatment of gender dysphoria.

The pharmacy was able to provide examples of shared learning that had been carried out between the overseas prescriber and the SI of the pharmacy. An example from February 2021 related to telemedicine and hormone prescribing. Pharmacy team members were given feedback informally to help them improve. For example, when a near miss incident or dispensing error had occurred. A dispenser said that the pharmacist was very supportive, approachable and she was happy to ask him questions if needed. The pharmacy team were aware of the whistle blowing policy in place if they needed to raise any concerns.

Staff appraisals had been completed by the warehouse manager and copies of these were available. A dispenser explained that she was happy to provide feedback to the pharmacist, and that the pharmacist was supportive. The pharmacist explained that there were no formal targets or incentives for any aspects of pharmacy service.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is safe, clean, and properly maintained. The layout is appropriate for the services provided.

Inspector's evidence

The pharmacy was clean, free from obstructions and professional in appearance. Pharmacy team members were responsible for cleaning, with all areas of the premises cleaned regularly. The temperature was controlled by heating units and the lighting was adequate. The pharmacy premises were maintained and in an adequate state of repair.

The pharmacy website included drop down sections for; baby, beauty, CBD, Covid testing, Dental, Conditions, Fragrances, Pharmacy and Sexual. It also included detailed information about the pharmacy and how to contact them. The pharmacy registration number and details of the responsible pharmacist on the day were displayed. Details of service provision and a link to some of the pharmacy's policies were present. For example, privacy, security, and terms and conditions.

Staff facilities included a kitchen area with kettle, fridge, and sink. Separate ladies and gents' WC with wash hand basins and antibacterial hand wash were available. The pharmacy had cordless telephones available, which were used these to hold a private conversation with patients if necessary.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's services are accessible to most people and they are generally managed adequately. The pharmacy has some safeguards in place to help make sure that the medicines they supply will be used safely. It works with online providers that are not registered with UK regulators. But it does not carry out many checks to make sure that they are operating effectively or following UK guidelines. So it has to rely on assurances that the online providers give it.

Inspector's evidence

The pharmacy was closed to the public but people could access its services via its website or by telephone, or email. The pharmacy team knew where to signpost people who wanted services that the pharmacy did not provide. For example, emergency supplies of medicines.

The pharmacy dispensed prescriptions issued by online prescribing services. Most of the prescriptions were received from the online provider that specialised in gender dysphoria treatments. These prescriptions were received electronically and were issued by a prescriber who was registered in Romania. The pharmacy also dispensed prescriptions for a separate prescribing service, Kiwi Medical, which were issued by the same prescriber and were typically for treatment of erectile dysfunction, statins or salbutamol. These included injectable medicines for erectile dysfunction, such as caverject. The pharmacist explained that he did not normally counsel patients about the correct use of these medicines but felt it was not necessary because he understood that medications would only be prescribed for patients who had previously used the treatments and not to new patients. However, it was unclear how the pharmacy determined this and so there was a possibility that patients could be obtaining medicines without full knowledge of how to use them.

The pharmacist explained that people had remote consultations with the prescriber before prescriptions were issued. He understood that people being treated for gender dysphoria would also have multiple assessments with other professionals including a psychology assessment. But no evidence to substantiate this was available. He believed that people using the Kiwi Medical service were required to answer consultation questions but was unsure whether this was by telephone or video consultation. The pharmacy had set maximum quantities that they were prepared to supply for each of the medicines they dispensed. This was built into their risk assessment and helped the pharmacy to ensure that their patients did not receive excessive quantities of medicines that may be unsafe for them.

The pharmacy had access to the online provider's computerised records system, which held details of patients' treatment and monitoring. The pharmacist was unsure on how to access the system but one of the dispensers was able to gain access. However, it was last updated in September 2021 which meant the pharmacy did not have access to up-to-date records. Following the inspection, the pharmacy explained that the online provider was no longer allowing them unlimited access to their patient records. This was because they had decided it was potentially a disproportionate amount of unnecessary access and so did not comply with GDPR. The pharmacy was still able to check records for the random sample of five prescriptions that they used to audit the monitoring and follow up arrangements in place.

The pharmacy had a quick reference guide for medications used for gender dysphoria. This included a

summary of maximum doses, maximum quantities and monitoring requirements for medications. Some of the pharmacy's patients required close monitoring and follow-up arrangements because of the nature of the medicines that were being prescribed. The pharmacy gave examples of occasions where they had communicated with the online provider after patients had contacted the pharmacy because their medicines had not been supplied. And the online provider had confirmed that these prescriptions had not been issued because the patients had not yet had their routine blood monitoring carried out. However, the pharmacy no longer had routine access to patient records' so they were not able to routinely check that the necessary monitoring and follow up action had been completed for all patients. And the pharmacy did not carry out any audits to show whether prescribing was in line with UK guidance or the online provider's protocols. This meant they had to rely on the assurances they received from the online provider that appropriate governance arrangements were in place.

The pharmacy had an SOP for sharing information with GP's where consent was given. The SI had a created a spreadsheet which contained details of all GP surgeries in the UK with their respective phone numbers, email addresses and fax numbers. The pharmacist was unsure how information was shared with the GP, but a dispenser explained that where consent was provided a template letter would be sent to the GP by email or fax. This would only happen at the start of treatment unless there was a change in the medication. The pharmacy's patient medication record (PMR) system would automatically detect when there was a medication change and generate an alert that a new letter would need to be sent. The PMR kept a record of whether or not a patient had given consent to share information with their GP, and details of any communications that were sent. The pharmacy had a quick reference guide for medications used for gender dysphoria. This included a summary of maximum doses, maximum quantities and monitoring requirements for medications. Staff admitted that most people did not give consent for their information to be shared. But if they refused, the pharmacy sent them a leaflet by email explaining the benefits of their GP knowing about their treatment. This helped ensure that the patient was aware of the issues that could arise if their GP did not know about their full treatment history. The pharmacy also provided leaflets to patients receiving certain medicines to advise them about possible side effects/ adverse effects. For example, leaflets were provided when finasteride or dutasteride were supplied to advise about the risk of breast cancer.

The pharmacy used an age checking system to verify their patient's ages. They had been assured that ID verification was also carried out by the online provider. Prescriptions were normally only sent to the billing address, however if a patient asked for their medication to be shipped to an alternative address the pharmacy would ask to see an identity check of the patient and also notified the online provider that the shipping address was changed. This ensured that the provider was aware so that they could consider any possible safeguarding issues.

The pharmacy endorsed each prescription they dispensed to indicate who had dispensed and accuracy checked it. Dispensing labels were also initialled to provide an audit trail. Multi-compartment compliance aids were used to dispense medicines for some patients with compliance difficulties. They were not labelled with descriptions, therefore, patients may find it more difficult to identify individual medicines. Patient Information Leaflets were always supplied. Each compliance aid patient had their own record sheet which was used to record current medication and document any changes so that prescriptions could be checked before they were dispensed. Baskets were used to separate different prescriptions to avoid them being mixed up during dispensing.

A dispenser explained that patients had to answer a set of WWHAM questions as part of an online questionnaire, before being able to purchase pharmacy only "P" medicines via the website. She said that once the order for a P medicine had been received, it would be checked for appropriateness to supply by a dispenser in the first instance then the pharmacist if necessary. For example, if the request was for a medicine that contained codeine it would need to be approved by the pharmacist.

She demonstrated that the pharmacy had refused sales of co-codamol on seven occasions between 1 November 2021 and 30 November 2021. The pharmacist said any P medicine that could be abused was closely monitored, with maximum supply quantities defined in the risk assessment. And when a sale was refused, the person was sent a detailed message explaining the reason why the sale was not allowed and sign-posting them to their GP.

Fridge medicines were despatched using a Techni ice pack which was sealed in a refrigerator bag along with the fridge medicine, before being placed in the outer packaging. The pharmacist explained that all medicines were supplied to patients using a tracked and signed for courier service. The two main couriers used were Royal Mail and DPD.

The workflow in the pharmacy was organised into separate areas, with an area for labelling, dispensing POMs, assembly area for P medicines, assembly area for GSL and health and beauty. Stock medicines were obtained from licensed wholesalers. A date checking record was in place. A random sample of medicines were checked and no expired medicines were found. The pharmacist was aware of the risks associated with the use of valproate during pregnancy and the need to counsel patients. The pharmacy had no female patients prescribed valproate. Drug alerts and product recalls were received via e-mail. These were read and acted on by the pharmacist and a computer record was kept. The pharmacy website clearly explained the limitations of supply for specific medicines in the EU. Information regarding Customs rules and regulations were also provided on the website.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide services safely. It is appropriately maintained, and it is used in a way that protects privacy.

Inspector's evidence

The pharmacy team used the internet to access websites for the most up to date information. For example, EMC, BNF and BNFc. There was a clean fridge used for storage of medicine with an online monitoring thermometer that was calibrated for use. The minimum and maximum fridge temperature was being monitored and recorded continuously and the pharmacist was notified if the fridge temperature was outside the normal range. The pharmacist demonstrated how the fridge temperature record was kept and monitored online.

The electrical equipment appeared to be in working order and had been PAT tested for safety in November 2020. There were conical liquid measures with British Standard and Crown marks on. There were clean tablet triangles used in the pharmacy for counting loose tablets and capsules. Cordless phones were available in the pharmacy and the staff said they moved 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.