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:** Internet / distance selling

**Date of inspection:** 05/10/2020

## 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. Medicines are prescribed by the online provider for both adults and children. 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. An intelligence-led inspection was carried out which focussed on the services that the pharmacy provides in relation to the online provider. The online provider offers treatments for transgender patients and gender dysphoria.

## 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 pharmacy has not identified all of the risks associated with dispensing medicines against prescriptions from the online provider. It is not able to show that it has risk assessed all of the services it provides or the medicines it supplies in respect of these prescriptions. So it cannot provide assurance that patients always receive medicines that are safe and appropriate for them. |
| | | 1.2 | Standard not met | The pharmacy has no system in place to review the quality of services that it is providing in relation to the supply of medicines prescribed by the on-line provider. So, it is not able to provide assurance that all medicines are being supplied safely. |
| | | 1.8 | Standard not met | The pharmacy regularly dispenses medicines for transgender patients and people with gender dysphoria. But its safeguarding policy does not specifically address the risks and vulnerabilities associated with supplying medicines against prescriptions from a non-regulated provider to this client group. |
| **2. Staff** | Standards not all met | 2.2 | Standard not met | The pharmacy is unable to demonstrate that the pharmacy team has the appropriate skills and competence to support people prescribed medicines for gender dysphoria treatment. |
| **3. Premises** | Standards met | N/A | N/A | N/A |
| **4. Services, including medicines management** | Standards not all met | 4.2 | Standard not met | The pharmacy has not taken steps to identify which of the medicines it supplies are higher-risk or require on-going monitoring. And it is not able to provide assurance that effective safeguards are in place to make sure the medicines supplied are being used safely. |
| **5. Equipment and facilities** | Standards met | N/A | N/A | N/A |

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

### Summary findings

The pharmacy is not effectively managing all of the risks involved with supplying medicines prescribed by the online provider. And the pharmacy team supplies medicines to people without fully understanding how their treatment is being managed. This means the pharmacy cannot provide assurance that the medicines are always safe and appropriate. And it is not carrying out appropriate audits or reviews to make sure that the medicines are being used safely. The pharmacy has procedures in place to help it safeguard vulnerable patients. But they do not always reflect the particular risks involved with the services it provides or the people it supplies medicines to. For example, when supplying medicines for trans-gender health.

### Inspector's evidence

The pharmacy works with an online provider, based overseas, that is not registered with the CQC. The online provider was previously within UK but moved abroad, and so it is no longer within the oversight of UK regulators. The pharmacy supplied medicines to UK patients against private prescriptions written by a Romanian doctor. It supplied medicines to approximately 800 patients a month, all of whom were UK residents. The prescriptions were for both adults and children. Most of the medicines were for the treatment of transgender patients and people with gender dysphoria, including hormone treatments and puberty blockers. There was little evidence that the pharmacy had considered the significant extra risks that this arrangement could create for people. There was no documented risk assessment of the services it provided in connection with the online provider, or the medicines it supplied against private prescriptions issued by the online provider. The pharmacy was unable to give adequate examples of any safeguards being put in place to manage the specific risks associated with this service.

The pharmacy did not advertise the services offered by the online provider on its own website, but the pharmacy was mentioned on the online provider's website. The pharmacy dispensed electronic prescriptions that it received directly from the prescribing service in Romania. The online provider gave its patients the options of using the electronic prescription service or having a printed prescription that they could take to a pharmacy of their choice.

The pharmacy had checked that the prescribing doctor was registered with the Ministry for Health in Romania and that she had professional indemnity insurance in place. The pharmacy had also checked her passport identification. But the pharmacy provided no information about the prescriber's knowledge or experience of gender dysphoria treatments. There was some information on the website of the online provider about their services, but other than basic checks, the pharmacy had not taken steps to explore or verify the prescriber's competence or experience.

The pharmacy was not able to demonstrate that it had a good understanding of the procedures and treatments used by the online provider. And it had not proactively sought assurances from the online provider about their management of risk and safety. The online provider had given verbal assurances that appropriate clinical pathways were followed and that it employed a team of clinicians, including psychotherapists. However, the pharmacy team's understanding of the service was very limited, and it did not know at what stage the prescriber in Romania became involved in the clinical pathway for treatment. The pharmacy was unable to demonstrate whether the online provider followed any recognised guidelines for the treatments provided.

The pharmacy supplied medicine to many patients between the ages of 10 and 18. But it had not developed systems to ensure that these people were safeguarded and that they always received medicines that were safe and appropriate for them. The pharmacy would only supply medicine to a child if a parent or legal guardian 'approved' the supply. However, this approval consisted only of the pharmacy sending a link to the parent or legal guardian to complete the order and cross-referencing the prescription address with the delivery and billing addresses, to make sure they all matched.

The pharmacy did not always have sufficient information about their patients to ensure that all medicines were supplied safely and effectively. In the previous 18 months, there had been no clinical intervention with any of the online providers' prescriptions other than to check factual information. Evidence was seen of some emails between the pharmacy and the online provider where the pharmacy had queried the quantity, dose, date of birth, or where the prescription had expired. But the pharmacy had no access to information about the patient's treatment plan (which could be relevant to ongoing monitoring and follow up arrangements), or the patient's medical or drug history. The pharmacy had an NHS contract and there was the facility to access summary care records (SCR). However, the pharmacy had not arranged to access the SCR for any patients where it was supplying medicine for the online provider.

Before supplying medicine against prescriptions from the online provider, the pharmacy would not know whether or to what extent the patient's usual GP was aware of their treatment or the prescription. The pharmacy had been given assurance that the online provider asked patients if they consented to share information with their GP. But if the patient declined to do this, prescriptions could still be issued. The pharmacy was not informed which patients had consented and which ones had declined to consent, but they would supply the medicine anyway. The pharmacy only carried out basic identity checks on patients, via its payment provider. The pharmacy had received verbal assurance from the online provider that further identity checks on all patients were carried out, but no evidence was provided to support this claim.

The pharmacy had a generic standard operating procedure (SOP) in place in relation to safeguarding children and vulnerable adults. The policy gave an overview about dealing with concerns, but it provided no evidence that the pharmacy's systems, processes and procedures had been tailored to the risk profile of the pharmacy or the users of their services. All team members had signed a declaration to confirm they had read the procedure and the SI had completed safeguarding level 2 training.

The pharmacy provided up-to-date details of local safeguarding contacts who could be used to raise concerns. But there were no written details of contacts outside the local area. Copies of the up-to-date professional indemnity insurance certificate and employer's liability insurance certificate were displayed. The correct responsible pharmacist (RP) notice was displayed conspicuously in the pharmacy. A formal complaints procedure was in place, and a customer feedback option was available through the website. Assurance was given during the inspection that the pharmacy had not received any complaints in relation to the prescriptions that it had dispensed for the online provider.

## Principle 2 - Staffing **Standards not all met**

### Summary findings

The pharmacy has enough staff to manage its workload safely. But no members of the team have completed training about gender dysphoria treatments, even though the majority of the pharmacy's business involves dispensing these medicines. And patients are not usually given advice about the medicines they are taking unless they ask for it. This means the pharmacy cannot provide assurance that people are fully informed about their treatment. Or that members of the team have the skills and knowledge they need to identify concerns and ensure patients are taking their medicines safely.

### Inspector's evidence

The SI worked regularly at the pharmacy as the responsible pharmacist. The pharmacy also employed three NVQ level 2 trained dispensers, an order packer, and a website development assistant who also did general administration work. The order packer only packed general sales list medicines for despatch.

Trained staff always handled the pharmacy medicines and prescription only medicines. The SI had not completed any specific training in relation to transgender healthcare. In his view, no queries or questions had arisen which he had felt unable to answer. The pharmacy would not routinely contact patients to provide counselling, but on occasions, advice or counselling was given in response to questions that the patient asked. These questions were normally general queries about how to take or use the medicines they had received. The pharmacy provided a leaflet with each prescription supplied. It offered patients the opportunity to contact the pharmacy team, if they had any questions on aspects of their medicine.

The pharmacy supplied some medicines in relation to treatments that carried additional risks of adverse effects. There was evidence that the pharmacy supplied some cross-sex hormones which may increase the chance of a patient having a blood clot. The pharmacy did not provide counselling or signposting for this. And it was not able to confirm whether the online provider or the prescriber in Romania provided ongoing monitoring and follow up activity.

There was no evidence of shared learning between the online provider and the pharmacy, and the online provider had provided no training materials to inform the quality of care that the patient would receive. The pharmacy team communicated with the online provider by email or telephone, for example, to deal with a prescription query.

The pharmacy had gained "Pride in Practice" recognition from the LGBT foundation, in recognition of their work to support the trans community.

## Principle 3 - Premises ✔ Standards met

### Summary findings

The pharmacy premises are clean and tidy and are suitable for the services provided.

### Inspector's evidence

The pharmacy was clean, free from obstructions and professional in appearance, and pharmacy team members were responsible for keeping the premises clean and tidy. The pharmacy premises were kept secure and were maintained in an adequate state of repair. Staff facilities included a kitchen area with kettle, fridge and sink.

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

### Summary findings

The pharmacy has systems in place to help make sure it correctly supplies the medicines that are ordered on prescriptions. But it has not taken steps to identify which of the medicines it supplies are higher-risk or require on-going monitoring. And it has not put enough safeguards in place to provide assurance that people are being properly monitored and are using their medicines safely.

### Inspector's evidence

The pharmacy process in relation to supplies for the online provider involved the receipt of electronic prescriptions (an email and PDF copy of the prescription) from the prescriber in Romania. A dispenser selected the medicine and its quantity on the pharmacy system and sent a link with the electronic basket to the patient (or their parent or legal guardian if under 18). The patient followed the link to complete the order which sent a message back to the pharmacy. The email address and postcode for delivery were then checked to ensure they matched the prescription. Any order received without a prescription would not be processed. All prescriptions were stamped with a private prescription reference number. The dispenser and pharmacist initialled the dispensing labels to provide an audit trail. Medicines were despatched using Royal Mail tracked delivery, or DPD tracked delivery service.

The pharmacy had not taken steps to identify which of the medicines it supplied for the on-line provider were higher-risk or which ones required on-going monitoring, taking account of the age range of the patients and the care pathways within which the on-line provider operates. Several patients were seen to have been prescribed medicines that required ongoing monitoring and management. For example, spironolactone which is a potassium sparing diuretic, would require monitoring to ensure that a person’s potassium level was not above normal range. If potassium levels were too high, treatment with spironolactone may need to be withheld as high levels can lead to symptoms such as (but not limited to) muscle weakness, numbness and tingling, and abnormal heart rhythms. Other medicines such as estradiol may require dose adjustment based on levels of circulating drug in the blood. Some cross-sex hormones may cause elevated liver enzymes and so would require on-going management.

The pharmacy had not developed or put in place safeguards to ensure that all patients were using their medicines safely. There was a lack of understanding about the controls in place further up the chain of supply. For example, the SI believed that the online provider used a UK based company for blood monitoring and that the pharmacy had emailed the online provider on occasions to check whether blood test monitoring had been carried out. There was some evidence of these checks, but the pharmacy was not able to demonstrate that all medicines requiring blood monitoring and management were reviewed on an ongoing basis. The systems in place to safeguard patients were weak and took insufficient account of the service delivery model and the patient cohort.

## Principle 5 - Equipment and facilities ✔ Standards met

### Summary findings

This principle was not assessed because the inspection focused on other key areas.

### Inspector's evidence

The principle was not assessed because the inspection focused on other key areas.

## 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. |