General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Eucalyptus, Units 17-18, Union Way, Aston, Birmingham, West Midlands, B6 7FH

Pharmacy reference: 9011842

Type of pharmacy: Internet

Date of inspection: 20/03/2023

Pharmacy context

This private distance selling pharmacy is a subsidiary of an Australian company Eucalyptus. It is situated in an industrial estate in Aston, Birmingham. Its main activity is providing an on-line weight loss service and supplying medicines for weight loss after an on-line consultation via its website www.myjuniper.co.uk. The prescriptions for its service are issued by Pharmacist Independent Prescribers (PIPs). The pharmacy does not offer any NHS funded services and its premises are not accessible to members of the public.

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 has not fully considered and managed all the risks involved in supplying higher-risk medicine by solely relying on an on-line questionnaire model. It cannot show that it gets all the information it needs to prescribe weight loss treatments safely.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website allows people to start a consultation from the page of an individual prescription-only medicine. This does not meet the GPhC requirements.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy cannot show that it gets enough, accurate information to make sure the medicines it supplies to people are clinically appropriate.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy carries out risk assessments and audits for its services. And it has adequate systems in place to check the identity of people who use its prescribing service. But the pharmacy cannot show that it adequately manages all the risks associated with its on-line prescribing service. Its prescribers often do not independently verify relevant clinical information about people requesting treatments. For example, by making a visual assessment of a person or by requesting additional information about a person's medical history. So, there is an increased risk that weight loss medicines are supplied to people for whom the treatment is not clinically appropriate. The pharmacy also cannot show that it monitors people's progress and on-going treatment appropriately and that the treatment it supplies is compatible with any other treatments a person may be receiving. However, the pharmacy generally keeps the records it needs to by law.

Inspector's evidence

The pharmacy service was managed by the superintendent pharmacist (SI) and the responsible pharmacist (RP). The pharmacy specialised in providing weight loss treatments which people accessed through its website. It mainly offered meal replacement high-protein shakes, orlistat capsules and semaglutide injections (Ozempic brand).

The pharmacy had a range of current standard operating procedures (SOPs) and these had been signed by the SI and RP. It also had risk assessments which had been designed with the help of various Australian and UK healthcare professionals including an endocrinologist, GPs, and pharmacists. These only covered the prescribing guidance for semaglutide (Ozempic) . The risk assessments were accessible to both the prescribers and members of the pharmacy team, and they covered the rationale behind prescribing semaglutide (Ozempic) as an off-licence treatment based on the evidence of studies undertaken. Furthermore, it covered the rationale and evidence why the pharmacy chose to prescribe semaglutide (Ozempic) over Saxenda which is a licensed treatment for weight loss in the UK. The risk assessments also helped support the prescriber in making prescribing decisions based on clear inclusion and exclusion criteria and what course of action to take in the event of any cautions identified from the questionnaire.

People using the on-line service created an account and completed an on-line questionnaire which covered the physical, social, and psychological aspects of a person's history and helped identify any risk factors that could preclude the person from accessing the treatment. The questionnaire also asked people questions about their height and weight so that their body mass index (BMI) could be calculated. Generally, people with a BMI greater than 30 or a BMI between 27-30 with at least one weight related co-morbidity such as high blood pressure or high cholesterol could qualify for the treatment. There were also varying thresholds for treatment for people based on ethnicity. In those cases, a BMI greater than 27 or a BMI between 24.5-27.5 with at least one weight relation co-morbidity could also qualify for the treatment. The SI explained that the rationale for BMI thresholds was based on national guideline for obesity.

Anyone signing up to the website had their identify checked using an identity checking service. Weight verification was mainly done via the on-line questionnaire, but prescribers could request photographic evidence if needed. Questionnaires were then reviewed by one of two pharmacist independent prescribers (PIPs) who worked remotely and who would issue an electronic private prescription if a

supply was deemed appropriate. People with a BMI of between 27 and 30 and with no other co-morbidity had to provide photographic evidence. However, the pharmacy's protocol did not require prescribers to obtain photographic evidence from people who stated in their questionnaire responses that their BMI was above 30. On-line questionnaires checked during the inspection showed that the PIPs had requested photographic evidence for people whose BMI was below 30. But there was no evidence found that visual checks had been made for those with a BMI of 30 or more. The pharmacy did not mandate people to give consent for their regular GP to be informed about the treatment they were receiving. And most people did not consent for information about the treatment they received from the pharmacy to be shared with their GP.

People qualifying for weight loss treatment were made aware that semaglutide (Ozempic) was being prescribed outside its product licence (known as off-label use) by their prescriber. Ozempic is licensed as a treatment for diabetes. People were also informed about this via a treatment letter; they were required to sign the letter to confirm that they had understood the off-label use before the treatment could proceed. In addition, the pharmacy also included a patient information leaflet to explain that the treatment they were receiving was being used off-label.

The SI undertook regular clinical audits to identify whether PIPs' prescribing decisions aligned with national guidelines and to assess whether adequate clinical decisions and justifications for prescribing were made, or suitable information was provided to the person throughout the consultation process. Overall, the SI said that they found PIPs were adhering to the pharmacy's prescribing guidance. A sample of records checked during the inspection showed that the PIPs were prescribing in line with the pharmacy's risk assessments and were rejecting inappropriate requests. Members of the pharmacy team contacted people by email if they were identified as not being suitable for the treatment and they were given an explanation, a refund, and signposted to other healthcare providers where appropriate. Prescribing decisions were also reviewed by the clinical lead by checking a sample of people's consultation forms and PIPs' decision making processes. There was evidence to show the feedback given by the clinical lead given to the prescribers about how they could improve their consultations and key points for them to consider when assessing people. The SI also undertook an audit to check if the pharmacy team was sending out letters to GPs where people had consented to share their information with their GPs. And evidence of this happening was also seen during the inspection.

The pharmacy had systems in place to monitor and review mistakes made during the dispensing process. Dispensing mistakes which were identified before the medicine reached a person (near misses) were recorded and reviewed routinely. Dispensing mistakes that had reached people (dispensing errors) were recorded and reviewed by the SI. The RP said that near misses were rare and most of the errors involved incorrect data entry. The pharmacy's advanced patient medication record (PMR) system also alerted team members when an incorrect product had been selected. Members of the pharmacy team had monthly huddles to discuss dispensing incidents and shared learnings. The SI gave an example of shared learning and said that following feedback from the RP, he had discussed with the software developers to include the BMI and ethnicity of the person on the prescriptions issued, to help the RP complete a thorough clinical check.

The pharmacy's current professional liability and public liability insurance was covered by its parent company based in Australia. And the SI confirmed that PIPs had their own professional indemnity insurance. The pharmacy did not stock any controlled drugs. Its private prescription records were kept in line with the requirements. There was a clear audit trail to show which PIP had undertaken each consultation and whether the person had had any discussions with the health coach. Several records checked during the inspection showed that the pharmacy kept comprehensive records of the treatment plans, and any discussions between the prescriber and the person were well documented. Members of the pharmacy team and the PIPs had access to any communications that took place between the

person and the customer service team.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to deliver its services safely and effectively. Members of the pharmacy team including the prescribers are suitably qualified for their roles and responsibilities.

Inspector's evidence

At the time of the inspection, the pharmacy team comprised of the SI, RP, a locum dispenser and three support staff who were involved in the dispatch process. The team members were managing their workload adequately.

The SI said prior to recruiting PIPs, he had checked to make sure that the PIPs had completed an independent prescribing course, were registered with the GPhC, and had completed weight loss training. Furthermore, the PIPs had to undergo induction training with the medical director and confirm that they had understood the pharmacy's SOPs and risk assessments. PIPs kept their own professional development portfolio and received on-going training by the consultant endocrinologist to help keep their skills and knowledge up to date. And they received regular feedback and support from the medical team if they had any specific clinical questions. There were no targets or incentives set. The SI explained that PIPs were paid per session and they were not incentivised based on the number of prescriptions issued. There was evidence of rejected requests where PIPs felt that it was unsafe to prescribe.

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

Summary findings

The pharmacy’s premises are secure and they are suitable for the services it provides. But the pharmacy’s website does not meet GPhC guidance about online consultations and how people access prescription only medicines. The website allows people to choose a medication before having a consultation with the prescriber. This means that there is a greater risk that people receive treatment that is not suitable for them.

Inspector's evidence

The pharmacy was situated in a gated industrial estate which was closed to the public. The unit was sufficiently spacious and fitted to a basic standard. There was ample storage and workspace available to allow safe working. A clean sink with hot and cold water was available and the ambient temperatures and lighting were suitable for the services provided. The premises were secured from unauthorised access.

The pharmacy's website included the details of the pharmacy such as the premises address, services offered, the name of the SI, the pharmacy's GPhC registration number and the names of the prescribers. However, the pharmacy's website allowed people to choose a medicine prior to starting a consultation which is not in line with the GPhC's Guidance for registered pharmacies providing pharmacy services at a distance.

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

Summary findings

The pharmacy cannot fully demonstrate that its online prescribing service is operating safely. It does not independently verify a person's medical history or make additional checks about most people's weight to justify a supply of treatment for weight loss. When taken into consideration with evidence that most people do not consent for information about treatment received to be shared with their GP, and that most people receiving weight loss teatment do not use the additional support available to them from the health coaches, there is an increased chance of the pharmacy supplying medicines to people when they are not clinically appropriate. However, the pharmacy sources and stores its medicines safely. And it has a system to address concerns about medicines which are not fit for purpose.

Inspector's evidence

The pharmacy's current activity was predominantly supplying treatments for weight loss. The most commonly prescribed treatment, semaglutide (Ozempic), is currently not licensed for weight loss in the UK, so was being prescribed off-label. The pharmacy provided information on its website about clinical trials and data to support the evidence behind the off-label use of semaglutide for weight loss.

The pharmacy advertised its service on-line, and members of the public within the UK could access its services remotely via the internet, telephone, or by contacting the customer services team. The pharmacy also offered people personal lifestyle health coaching and measurement of their biometrics via an online weight tracker. Most people did not opt in for the additional support offered by the health coaches.

People wishing to access the pharmacy's services were required to create an account on the pharmacy's website before completing an on-line consultation questionnaire. Some responses required from people were by completing free text boxes and others were answered by selecting answers from a list. The person had the option to consent for information about the treatment provided by the pharmacy to be shared with their GP. Most people did not consent for their information to be shared.

Identity checks for people accessing the pharmacy's services were carried out by a third-party organisation. If there was an issue with the person's ID check, team members would contact the person directly to obtain further information. Confirmation of identity, which had to be a formal documentation such as driving licence or a passport, was uploaded on the pharmacy's platform. The RP said people's prescriptions were not processed if this documentation was not provided. The pharmacy's computer system did not allow a new account to be created with the same name, address, and date of birth as an existing one. This mitigated the chances of people creating multiple accounts.

Completed questionnaires were reviewed by PIPs before a decision could be made if the person was suitable for the treatment. If the person qualified for the treatment, the PIP would contact the person via the on-line communication platform or telephone. The PIP had an option of requesting further evidence such as a person's photo, but this was rarely done. Requests from people who entered information that indicated they had a low BMI were automatically rejected. However, the PIPs did not independently verify the person's medical history including their weight, or what medication they were already taking. This meant that there was a risk of people receiving treatment that was not clinically appropriate.

People receiving the treatment received weekly emails from the pharmacy to touch base if the person had any queries about their treatment. Further supplies of semaglutide required the PIP to confirm that the person had lost weight by using the medication. And people had a six-month review with the PIP to assess their weight loss and whether it was safe to continue the treatment. Again, there was no independent verification of the weight loss the person had achieved over that six-month period. This meant that there was a risk that a person may continue treatment when it was not clinically appropriate.

Prescriptions generated by the PIPs were clinically checked by the RP. Where the person had consented to share information with their GP, a standard template was used to inform the GP which included relevant information such as contact details of the pharmacy, the person's name, prescribed medication, dose, quantity, and the date of supply. Evidence of this was seen during the inspection.

Medicines and medical devices were obtained from licensed wholesalers. And they were date-checked at regular intervals. No date-expired medicines were found in amongst in-date stock. Fridge temperatures were monitored daily and recorded. The records showed temperatures had been maintained within the required range of between two and eight degrees Celsius. Medicines were mainly dispatched using a courier company to people residing in the UK only. The pharmacy used Woolcool ™ thermal insulated packaging to dispatch the medication which generally maintained the cold chain supply for 48 hours.

Medicines returned to the pharmacy for disposal were managed appropriately and stored in designated containers. Drug recalls were received via email. And members of the pharmacy team explained the action they would take in response to these and relevant records were kept verifying this.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for its services. It generally uses its equipment to help protect people's personal information safely.

Inspector's evidence

Members of the pharmacy team had access to current reference sources. The electronic patient medication record system was password protected and there were enough computer terminals to manage the current workload safely. Confidential waste was appropriately managed. As the pharmacy was closed to the public this helped protect people's confidentiality. All electrical equipment appeared to be in good working order.

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.