General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Manual Pharmacy, Unit 1, Verda Park, Hithercroft Road, Wallingford, OX10 9SJ

Pharmacy reference: 9012134

Type of pharmacy: Internet / distance selling

Date of inspection: 13/11/2023

Pharmacy context

This is a distance selling pharmacy located in a business park in Wallingford in Oxfordshire. The pharmacy dispenses lifestyle treatments including erectile dysfunction, hair loss, weight loss, sleep and testosterone replacement therapy prescribed by healthcare professionals in its prescription service team. This is the first inspection of the pharmacy following its re-location to the current premises.

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 does not always manage the risks it has identified in relation to medications it prescribes and supplies. The pharmacy's documented policies and service outlines do not always adequately reflect the risks associated with using some medicines or the actions which it should take to manage those risks.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	Regarding the prescribing service: there is sometimes a lack of independent verification of medical history and lack of monitoring in place before initial or repeat supplies of medication are made. The pharmacy and the prescribing service does not always have the person's consent to share prescribing information with the person's doctor
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy’s documented policies and service outlines do not always adequately reflect the risks associated with using some medicines or the actions it should take to manage those risks. This means people can obtain more medicines without the risks being managed. But, the pharmacy's working practices are generally safe and effective. The pharmacy monitors and assesses how effective and safe its services are through audits and clinical meetings. The pharmacy provides up-to-date clearly written procedures which tell team members how to work safely if they follow them. It encourages people to give their views and acts on negative feedback so it can improve its services. The pharmacy's team members mostly keep all the records they need to by law. The pharmacy's team members are trained in protecting the welfare of vulnerable people. And they keep people's private information safe.

Inspector's evidence

The pharmacy provided an online prescribing service for medicines to manage a range of conditions. The conditions the pharmacy offered to treat included weight management, sleep problems, hair loss and erectile dysfunction. Its prescribing service was provided by Pharmacist Independent Prescribers (PIPs). And there were other registered medical professionals who supported the prescribing service.

The pharmacy had a policy to cover the prescribing service. This outlined the roles and responsibilities of clinical team members. And cited guidance from the General Medical Council (GMC) and the Medicines and Healthcare Products Regulatory Agency (MHRA). Additionally, there were documented service outlines for each condition the prescribing service treated. And these included information on those who could be treated with medicines and those who could not, depending on their clinical characteristics.

The pharmacy’s policy included a medicine-specific risk assessment which graded each medicine which the pharmacy could prescribe for each condition treated. The pharmacy risk-assessed medicines for erectile dysfunction, hair loss and sleep problems as low risk. Medicines for weight loss (semaglutide, liraglutide, dulaglutide, orlistat, tirzepatide) were assessed as medium risk. The document stated that these medicines ‘… have a good safety profile and do not cause hypoglycemia.’ Hypoglycaemia is when the levels of glucose (sugar) in the blood is too low, and it can be a serious condition. The manufacturers of these medicines (except Orlistat) highlighted that hypoglycaemia was either a very common (10% or more) or common (less than 10%) side effect if used with other medicines to treat type 2 diabetes.

The pharmacy’s service outline for weight loss stated that people with type 2 diabetes could be treated for weight loss with these medicines. And it listed hypoglycaemia as one of the most common side effects of semaglutide, liraglutide and dulaglutide (GLP-1 medicines). The service outline did state that GLP-1 medicines should not be prescribed for people taking certain medicines for type 2 diabetes, such as insulin and sulfonylureas (a class of medicines used to treat type 2 diabetes). But it did not address the risk of hypoglycaemia for people taking other medicines for type 2 diabetes, which the manufacturers of these medicines highlighted as a common adverse effect. So the pharmacy’s risk assessment did not accurately reflect the risk of hypoglycaemia associated with some medicines prescribed for weight loss. And the service outline for weight loss did not outline how this risk was managed.

The policy also highlighted that risks associated with prescribing medicines which were outside the terms of their product licence (so called 'off-label' prescribing) and medicines without a product licence should be communicated to people seeking these medicines, 'Risks around prescribing of unlicensed medicines will always be explained to patients prior to prescribing, and relevant consents obtained and recorded.' But these discussions between PIPs and people prescribed these medicines were not documented in consultation records. So, it appeared that people may not have been properly informed about the risks associated with prescribing their medicines off-label, or without a product licence.

The risk assessment for weight loss medicines stated that 'Weight loss medicines we consider medium risk as they are classified as new medicines and require more patient support, titration and monitoring of side effects.' The risk assessment later stated that 'all patients are provided with a programme of coaching calls…the coaching call gives further opportunity for patient contact and monitoring.' But these coaching calls were not mandatory. And there was evidence that people repeatedly obtained medicines for weight loss when no coaching calls were made. So, in these situations the pharmacy did not manage the risks it had identified in its rosk assessment relating to medicines for weight loss.

The pharmacy had a schedule in place to audit its prescribing practices. This was designed to measure clinical activity against the service outline documents and the standard operating procedure (SOP) for approving orders. The prescribers audited each other's consultation notes as a quality assurance measure and provided feedback on different aspects of the consultation. And this included whether medical advice was communicated to the person or if the person's concerns were addressed and a score for empathy and tone of voice. The pharmacy also completed an audit on weight loss treatment for consultations between July 2022 and September 2023. The aim of this audit was to assess how effective weight loss treatment was and if coaching in addition to weight loss medicines resulted in greater weight loss. This audit highlighted potential barriers that could prevent people not meeting their weight loss target. But it did not highlight the proportion of people who were treated for weight loss who took up the offer of coaching in addition to medicine.

The pharmacy held clinical team meetings where prescribers and other clinicians, such as registered medical professionals, discussed clinical topics. Minutes of these meetings were provided by the SI and outlined the types of discussions which occurred at these meetings. Examples included patient safety incidents, clinical updates and teaching. The pharmacy monitored any patient safety incidents, and a log was completed. Examples of incidents recorded on the log included an incident where the incorrect dose of a medicine for weight loss (Ozempic) was prescribed.

The dispensary team had systems to review dispensing errors and near misses. Members of the team recorded near misses on a sheet and discussed the mistakes they made to learn from them and reduce the chances of them happening again. The accuracy checking dispenser (ACD) explained that the pharmacy stocked a limited range of medicines relevant to the services provided. The dispensary team dispensed prescriptions for each service at designated workbenches. For instance, prescriptions for erectile dysfunction (ED) were dispensed at one bench with ED medicines stored at the far end of the bench. The ACD had identified a trend of picking errors when stock was re-arranged. To help minimise picking errors, the team highlighted different strengths of the same medicine with colour-coded bulk labels indicating the storage place for each strength. If people who used the pharmacy's services reported a dispensing error, the pharmacy team referred it on to the pharmacist to complete a root cause analysis to identify why the mistake happened and to help prevent the same mistake happening again.

Following a successful consultation, the clinician issued an electronic prescription with a digital

signature. The clinician completed a clinical check by reviewing the answers provided in the consultation questionnaire and contacting the person for more information if needed. If the clinician approved the prescription, they completed an audit trail and sent the prescription to the pharmacy to be dispensed. The pharmacy had designated dispensary benches for different conditions where prescriptions for that condition were dispensed. The pharmacy generally stored the stock used to treat the condition on shelving at the end of the bench which helped to improve workflow during the dispensing process. When team members received a prescription for testosterone replacement therapy (TRT) at one bench they checked the person had recent blood test results before processing the prescription.

Team members put the labelled items along with tissue paper and the address label into an assembled outer carton awaiting final check before sealing and placing in the courier's sack ready for dispatch. The ACD or responsible pharmacist (RP) completed the final check and contacted the clinician or customer services regarding any issues flagged up by the pharmacy computer system such as a medicine prescribed for someone in an at-risk group. The superintendent pharmacist (SI) was also the RP most of the time. The ACD demonstrated how the colour-coded dispensing audit trail was maintained electronically. Although the pharmacy did not supply valproates in connection with any services, during the visit recent changes in regulations were discussed such as supplying a valproate in the manufacturer's original packaging.

The pharmacy had an SOP for identity assurance. To avoid inappropriate or multiple supplies being made to people, the pharmacy computer system flagged up issues such as duplicate post codes, patient details, repeat orders for prescription only medicines (POMs) too soon after the previous order and rejected orders for POMs in the past. The pharmacy restricted the quantity of some items that could be supplied each time such as products to help people sleep.

The pharmacy removed tablets such as finasteride 1mg or sildenafil from their original manufacturer's packaging and repacked them in the pharmacy's own packaging showing the Manual logo. The SI had previously explained the process in relation to a concern received by the GPhC. And the purpose of repacking was to create a unique selling point (USP). During the visit, the process was observed. The SI explained that members of the warehouse team operating the automated equipment had not completed accredited training in relation to this task. Following the visit, the SI enrolled team members who operated this equipment on accredited training which would be completed within a stipulated timeframe.

They recorded the batch number and expiry date for tablets as part of the process to help produce an audit trail so individual batches could be traced in the event of a recall. The SI explained that there was personal protective equipment (PPE) such as gloves and masks for team members to help minimise the risk of contact with medicines which have been removed from their packaging. Pharmacy team members were not seen using PPE during the visit although the pharmacy's standard operating procedure (SOP) for de-blistering did explain the risks of contact with finasteride tablets, especially when crushed. The risk assessment set out the risks associated with de-blistering medicines and included a link to a website regarding the suitability of medicines to be removed from their manufacturer's blisters. Following the visit, the pharmacy updated its de-blistering risk assessment and implementation to enforce members of the team wearing of appropriate PPE.

The pharmacy's medicines management and prescribing policy outlined the roles and responsibilities of clinicians and the registered manager. And the pharmacy had systems in place to ensure that electronic signatures for prescriptions had an audit trail in place to identify who authorised the prescription. The pharmacy's customers were aged 18 years and over and based in the UK. Identification checks were

completed after the consultation. After the inspection visit, the pharmacy clarified how age verification was undertaken directly by clinicians reviewing photo ID uploaded by the patient as per the medicines management and prescribing policy, for medium and high risk medications.

There were SOPs in place for the pharmacy and its clinical services.
The pharmacy had SOPs for most of the services it provided. And these had been reviewed by the SI. Members of the pharmacy team were required to read and understand the SOPs relevant to their roles and follow them. The pharmacy allocated all new members of the team protected learning time to read SOPs and a digital audit trail of completed training was maintained. The most recent SOP related to warehouse activities. The RP SOP required a review to clarify which activities that team members could and could not carry out in the absence of the RP. Following the visit, the SI amended the RP SOP to reflect a new start time for the RP in charge to ensure that there was appropriate RP supervision to cover activities being undertaken in the pharmacy. The updated SOP included a matrix of activities, highlighting those which required the RP to be available and those which team members could carry out during the RP's absence. A team member explained that if a pharmacist was not present, they would not hand over prescriptions for delivery when the courier called to collect them.

There was a system in place for people who used the pharmacy to provide feedback and raise concerns if they wished. The main way of providing feedback was using the pharmacy's website and a third-party review service. There was a customer care team who supported people with questions and queries. And this team proactively contacted people who left a negative review on the third-party website so they could better understand the person's experience.

The complaints policy on the pharmacy's website showed details of how to complain about services provided by Menwell. And "Terms and Conditions" on the same website referred to raising a complaint in relation to any aspect of the treatment services provided via named subsidiary companies "Optimale" and "Vitalia." The pharmacy had Public and Employers (and Product) liability insurance in place at the time of the inspection.

The pharmacy's complaints policy signposted people to The Centre for Effective Dispute Resolution (CEDR) whose role was to help customers and businesses to resolve disputes if they were unable to resolve their complaints directly through the organisation's own complaints procedure. The SI provided an incident form showing examples of previous incidents reported and resolved. People could leave feedback via Trustpilot and an email address in "Terms and Conditions." The pharmacy's customer service team followed up negative reviews.

The pharmacy kept a record to show who was the RP and when. And displayed a notice that told people who the RP was. The pharmacy team recorded the private prescriptions dispensed daily and collated the records to create a private prescription register which was printed out and filed. Members of the pharmacy team recorded Interventions on a secure messaging tool and contacted the prescriber if necessary. The SI could see clinical records and print off letters regarding treatment to the person's usual prescriber. The pharmacy retained certificates of conformity for the unlicensed medicines it obtained for supply on prescription. It did not obtain or supply any controlled drugs (CDs) which had to be recorded in a CD register. The pharmacy team stored certain medicines in medical fridges in the dispensary and they did monitor the minimum and maximum temperatures on a daily basis. But when the temperature was out of range two to eight Celsius there was a lack of audit trail explaining the deviation and remedial actions taken by the team to restore the correct storage conditions. After the inspection, the pharmacy put a new Pharmacy Practice - Fridge Monitoring in place, to manage and document temperature excursions.

The pharmacy maintained electronic records for people who used the prescribing service. A sample of

electronic records were viewed during the inspection visit. And copies were provided by the SI following the inspection. The consultation records included people's responses to the online questionnaires, photographs, details of people's regular prescriber, such as their GP, if they provided them, messages between people and the pharmacy team, and their photographic ID. Consultation records were accessible to the SI and PIPs. And PIPs were able to add information obtained through discussion with people who used the prescribing service.

PIPs signed prescriptions electronically and these were sent directly to the pharmacy's dispensing hub at the registered premises. PIPs had individual login details and used multi-factor authentication when they accessed the prescribing system. So each prescription had a digital trail of who authorised it. Prescriptions mostly contained the required information by law. But the particulars of the prescriber only stated their name and that they were a clinician. So it was not clear that the prescribers were pharmacists from the prescription alone. When a PIP issued a prescription, the person being treated also received a written Treatment Plan and a manufacturer's patient information leaflet (PIL). PIPs provided advice via email to people receiving medicines.

The pharmacy had their computer servers backed-up every night by a third-party service. Sensitive information, such as photographs provided by people using the weight loss service, were only accessible by appropriate members of the team. The pharmacy had two-factor authentication in place for team members to access the pharmacy's systems. And notifications to people's usual prescriber, such as their GP, were delivered by post.

The SI was working in association with the company's data security team to make sure the pharmacy and its team processed and protected personal data. The pharmacy was registered with the information commissioner's office (ICO) and displayed the privacy notice on the website telling people how their personal information was gathered, used and shared by the pharmacy and its team. The SI explained that the pharmacy computer system had different levels of access as needed by team members. The pharmacy team members disposed of confidential wastepaper securely.

The pharmacy team had completed safeguarding training and the SI was signposted to the NHS safeguarding App. The SI described identifying potential safeguarding risks and issues by monitoring patient details for incorrect information leading to multiple orders or indicating mental health issues such as body dysmorphia or eating disorders.

Pharmacy team members completed level 1 safeguarding training. And members of the clinical team completed level 2 safeguarding training. The pharmacy safeguarding lead had completed level 3 training. The SI explained that clinical team members communicated with each other using a dedicated messaging platform. And were able to highlight orders which they felt were a concern from a safeguarding perspective and seek advice if needed. The SI explained that the pharmacy only supplied small quantities of a single medicine for sleep problems at a time. And did not permit multiple medicines to be prescribed for this condition. Historic prescribing records were reviewed before PIPs authorised a new supply of medicine for sleep problems to ensure the person was not provided with medicine earlier than they needed.

For people seeking treatment for weight loss, the pharmacy's prescribing system had alerts built-in to flag if the body-mass index was outside the range in the service outline and highlighted multiple orders for the same person. But people using this service did not have their self-reported medical and drug histories independently verified before medicines were prescribed. And the pharmacy relied on people's usual prescribers, such as their GP, to highlight if medicines for weight loss were clinically inappropriate. But not everyone provided GP details as this was not mandatory. And when there was no contact with the GP the pharmacy did not always document the prescribing decision without being able

to verify self-reported medical history. So there was a risk that people could be prescribed medicines for weight loss when it was clinically inappropriate.

Following the national patient safety alert regarding off-label use of GLP-1 medicines for weight loss, the SI explained these medicines were still prescribed for people who were established on treatment due, in part, to the risk of worsening mental health if weight loss treatment was interrupted. So the pharmacy identified a potential risk of mental health conditions in some people who used the weight loss service. But there were no additional considerations regarding mental health in the service outline or the risk assessment for weight loss treatment. So the pharmacy may not have had the necessary safeguards in place for people who received treatment for weight loss and who were at risk of worsening mental health.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough suitably trained team members to deliver its services safely and they work well together to manage the workload. The pharmacy supports its team members in keeping their knowledge and skills up to date, so they work effectively within their level of competence. And they know how to get advice relating to prescribing. The pharmacy makes appropriate checks to satisfy itself that new prescribers are suitably qualified to prescribe its medicines safely. Pharmacy team members can provide feedback and raise concerns about the pharmacy. There is an expectation for PIPs to approve orders within a specified timeframe although there is no financial incentive for them to do so

Inspector's evidence

The SI was supported by locum pharmacists when needed, a team of seven full-time dispensing assistants and three ACDs. In addition, there was a warehouse team with two vacancies. The pharmacy's prescribing service consisted of eight PIPs who either worked at home or from the pharmacy's head office in London. The pharmacy employed ten registered dieticians and nutritionists and three medical professionals to support the weight loss service. They did not work at the registered pharmacy premises. The PIPs provided the prescribing service from 0800 to 1730 Monday to Friday except on Tuesday and Wednesday evenings when they finished at 2000. The PIPs were available Saturday and Sunday for five hours of clinical cover. They worked to a rota system to help manage the time allocated to their roles. The SI explained that working to a rota helped the pharmacy to monitor clinician utilisation, encourage time for self-development and learning, and encourage parity between staff regarding workload. The SI said that the pharmacy's capacity plan tended to overstaff the operation and it was possible to ask customer service to delay orders if needed.

The customer experience team was based at the pharmacy's office in London. The SI described the onboarding and induction processes to support new team members outlined in the Learning and Development Policy. The policy included competencies, specific training for job roles and mandatory training. Clinical and non-clinical team members completed a training matrix specific to the job role. Mandatory Training was completed online via 'Florence', monitored by line managers and reported monthly at the Quality Committee. All patient-facing team members completed:

- **Safeguarding adults and children**
- **Eating disorder awareness**
- **Mental health awareness**
- **Understanding learning disabilities and autistic spectrum disorder**
- **Working in a person-centred way**
- **Conflict resolution and complaints handling**
- **Data Security Awareness (information governance and GDPR)**
- **Equality, Diversity and Human Rights**
- **Fire safety**
- **Health, Safety and Welfare**
- **Anti-bribery and Corruption**

The pharmacy had an escalation policy to manage clinical emergencies and a complaints policy to support staff with complaints. The SI explained that PIPs were recruited by the clinical lead and deputy

medical director who completed due diligence checks of PIPs' registration and qualifications to prescribe. PIPs received annual appraisal and regular one-to-one sessions with team leaders. These one-to-one sessions were documented and included discussions around how the PIP was feeling, what areas they liked to celebrate and any developmental goals they had.

PIPs completed a training matrix document which documented what training they had completed and which policies and SOPs they had read. Each training matrix had initials and dates added to demonstrate when training and required reading were completed. The pharmacy allocated all new team members protected learning time to read SOPs appropriate to their roles.

The SI confirmed that all pharmacy staff including the warehouse team were suitably trained for the roles they undertook. Following the visit, the SI had enrolled warehouse team members, who were involved in de-blistering and re-packing medicines, onto a GPhC accredited 'Medicines Stock Assistant Course' which he said covered ordering, receiving and maintaining pharmaceutical stock. The training would be completed by the end of February 2024. The pharmacy team members had periodic appraisals to discuss performance and areas for development. And they could provide feedback on an ongoing basis or during 'one-to-one' meetings with the SI. For instance, team members had suggested rearranging the shelving to modify the layout of the dispensary.

PIPs working for the pharmacy's prescribing service were able to reject orders they felt were not clinically appropriate or outside the service outlines for the conditions treated. Evidence of rejected orders was provided by the SI from May 2023 to October 2023. The proportion of orders either archived or rejected ranged from 4.15% (August 2023) to 8.53% (September 2023). The SI provided prescribing data for the six months before the inspection. The data showed an average of 93.73 orders were approved per clinician per day with an average of 12.5 orders approved per clinician, per hour over the period of May 2023 until October 2023. This equated to an average of 4.8 minutes per approval. The pharmacy had key performance indicators (KPIs) in place monitoring orders being dispatched to people within a timeframe. The pharmacy had systems in place to avoid the prescribing of inappropriate quantities of medicine. For higher risk medicines , no more than one month supply was dispensed at a time.

The SI explained that the pharmacy had a whistleblowing policy in place and that the pharmacy encouraged an open culture on raising concerns. A recent whistleblowing case was discussed where a weight loss coach raised concerns about a treatment which was prescribed that they felt was clinically inappropriate, due to the person's reported body mass index. The SI explained that this was currently being investigated by himself and the leadership team.
The SI explained that PIPs did not have any financially incentivised targets and that they were able to use their professional judgement when authorising supplies of medicine to people. But there were key metrics which PIPs were expected to meet. These included 95% of orders approved on time. And 'on time' was defined by the approval SOP as being within two hours of the order being placed. Prescribing data for the six months before the inspection was provided by the SI. An average of 93.73 orders were approved per clinician per day with an average of 12.5 orders approved per clinician, per hour over the period of May 2023 until October 2023. This equated to an average of 4.8 minutes per approval.

The expectation to approve orders within two hours of placement, combined with the high rate of approvals per clinician per hour, could mean that PIPs did not always have adequate time to complete necessary checks before approval. There was evidence that elements of safe prescribing such as verification of medical information and monitoring of response to treatment did not always happen.

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

Summary findings

The pharmacy keeps its website up to date with the pharmacy's name, owner, address, SI and registration details. And it displays current information about its PIPs and online prescribing services. But some terminology used on the manual.co website is potentially misleading. The pharmacy's premises are clean, secure and suitable for the provision of its services. The pharmacy prevents people accessing its premises when it is closed so that it keeps its medicines and people's information safe.

Inspector's evidence

The pharmacy had two websites at the time of the inspection visit. One was fully operational; manual.co. And one was publicly available but was not set up to accept orders; joinvoy.com. JoinVoy.com will be wholly dedicated to one type of treatment, Manual.co will continue to offer weight loss services, amongst other treatment categories.

The manual.co website was designed so there were promotional offers and discounts on both websites relating to POMs, such as a 35% discount for the initial order of medicines for weight loss. Some terminology used on the manual.co website was potentially misleading, such as this statement regarding GLP-1 medicines for weight loss; 'All the GLP-1 medicines we offer have undergone rigorous clinical trials to establish long term suitability for long term use.' This had the potential to mislead people using the website as not all GLP-1 products offered by the pharmacy for weight loss treatment had been tested and approved for weight loss. There were also several instances of 'UK Licensed medication' icons on manual.co webpages where medicines were listed for conditions they were not licensed to treat. So this could also have the potential to mislead people using the website. These matters have been referred to the MHRA.

The pharmacy's premises were in a unit in a business park on the outskirts of Wallingford in Oxfordshire. The access to the premises was secure, the pharmacy was clean and well-lit with natural light and air-conditioning controlled the environment. The pharmacy, its facilities and equipment were cleaned regularly. The SI explained that PIPs undertook consultations in sound-proof booths in the pharmacy's head office.

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

Summary findings

The pharmacy's services are easily accessed via their websites, telephone or email. The pharmacy's prescribing service has safeguards in place to manage the risks associated with providing this service but the safeguards, are not always applied. So some medicines may not be prescribed and supplied appropriately. The pharmacy and the prescribing service does not always have the person's consent to share prescribing information with the person's doctor. So the pharmacy and the prescribing service cannot always share information with the people responsible for a person's care. The pharmacy obtains its medicines from reputable sources and stores its medicines stock securely at the right temperature. It makes sure people have all the information such as patient information leaflets and treatment plans that will help them to use their medicines safely. The pharmacy team members know what to do if any stock needs to be returned to the suppliers.

Inspector's evidence

The customer care team helped people to navigate the website and set up an account if it was their first time. The pharmacy's prescribing service was accessed via their websites. People could telephone or email the pharmacy if they wanted advice. And people who had an account with the pharmacy's prescribing service could use messaging functionality to seek advice.

The pharmacy had processes in place to confirm the identity of people who used the online prescribing service. When they placed an order, a third-party provider used bank card details to perform the identity checks. And the pharmacy's computer system automatically identified duplicate accounts and highlighted these for further investigation. The pharmacy's processes were designed so that orders could not be approved until a satisfactory identity check had been confirmed. People who were treated for weight loss were required to provide a form of photographic identification before their initial supply was made. This was in addition to the identity checks outlined above.

People completed online questionnaires for the conditions they wished to be treated for. These were stored on the person's record on the pharmacy computer system and were available to both PIPs and the pharmacy team for review. It was possible to see when people changed their responses to questions. And the SI explained that PIPs were required to perform a risk assessment when they reviewed questionnaires with amended answers. Certain responses to questions were highlighted if they indicated treatment may not be clinically appropriate. For example, if the person answered 'yes' to the question about diagnosed medical conditions in the weight loss questionnaire, this was highlighted.

The weight loss service consisted of medicine alongside optional coaching support, and a treatment plan was sent to people via email. The pharmacy identified weight loss treatment as medium risk due to the coaching support available. But this was not mandatory, and people could choose to only use the medicine to lose weight. Full-length photographs were required before the initial supply of medicine for weight loss. And people could log their weight on their online account. PIPs were able to review these when approving repeat orders. The service outline document for weight loss stated that a weight reading was a requirement for further supplies after the initial six-month period. But this information was not always verified as people did not have to upload a new full-length photograph and the

pharmacy did not have access to people's medical records. There was evidence that some people had obtained more than six months treatment without a second full-length photograph being provided. PIPs were unable to verify information people provided about their medical history and other prescribed medicines. And it was not mandatory for people to provide details of their regular prescriber, such as their GP, before obtaining medicines for weight loss. So there was a risk that people could be prescribed medicines for weight loss when it was not clinically appropriate to do so. This contradicted the pharmacy's policy for prescribing which said: 'They [clinicians] are responsible for understanding the person's medical background, including other treatments they are under and medicines they are using. The prescriber should check if the patient has any allergies, intolerances or sensitivities to medicines.' The Approval SOP, used by PIPs when approving orders, stated 'If there's no mention of any issues/side effects on the above-mentioned areas then we should up titrate the medicine as per the treatment plan.' So from the documents seen there was no proactive assessment of how people tolerated the treatment. The prescriber made an assumption that a higher dose was appropriate if the person did not highlight any side effects or concerns.

Consultation notes were randomly selected and reviewed during the inspection visit and photographic evidence taken at the time. The SI provided complete records for these patients following the inspection. These records related to the prescribing of the following GLP-1 medications off-label for the management of weight:

- Ozempic
- Rybelsus
- Trulicity

The consultation records reviewed for some people prescribed Rybelsus off-label for weight management were found to contain a photograph uploaded by the person at the beginning of treatment for monitoring purposes. But they had not provided their GP details for the pharmacy to share information with their GP. And there were no follow up consultations or coaching sessions recorded on the person's record by the pharmacy. So the pharmacy had supplied at least six months of treatment with no monitoring in place and no independent verification of medical history or biometrics.

The pharmacy's records of messages to one person showed that PIPs offered Ozempic at a discounted rate to this person when they enquired about switching from Rybelsus to Ozempic.

Consultation records were reviewed for some people prescribed Trulicity off-label for weight management. Those records examined showed that people had uploaded one photograph at the beginning of treatment. But either the photograph was not the required full body size or no further photographs were uploaded for any subsequent supplies. These people had not provided their GP details for the pharmacy to share treatment information with the GP. And the pharmacy had not recorded follow up consultations or coaching sessions on the person's record at the pharmacy. This indicates that the pharmacy had supplied people with around five months of treatment with no monitoring in place and no independent verification of medical history or biometrics.

Consultation records were reviewed for some people prescribed Ozempic off-label for weight management around five times up to the beginning of November 2023. The person being treated uploaded one photograph at the beginning of treatment. But no further photographs were uploaded for any subsequent supplies and there were no GP details to share information. The pharmacy's records did not show any follow up consultations or coaching sessions which suggested that people obtained five months of treatment with no monitoring in place and no independent verification of medical history or biometrics. One person's original responses to the online questionnaire stated that they were prescribed other medicines. But the person's record did not contain any documented discussion

regarding the medicines, what they treated and the effect on medicines for weight loss.

The SI explained that the pharmacy had considered the National Patient Safety Alert (NPSA) issued by the Department of Health and Social Care on 18 July 2023 regarding off-label use of GLP-1 medicines for weight loss. As a result, they had decided not to prescribe these medicines for people new customers seeking weight loss treatment but to continue to prescribe for existing customers. The rationale for this was the risk that people on existing treatment with GLP-1 medicines for weight loss could experience worsening in their other medical conditions and could be at increased risk of worsening mental health if treatment was stopped completely. The pharmacy documented their consideration of the NPSA and this was reviewed as evidence following the inspection visit. This documentation stated that 'Prescribers may continue to make prescribing decisions based on professional judgement and regulators joint statement'. But these decisions were not documented in consultation records seen during the inspection. And there was evidence that GLP-1 medicines were routinely prescribed off-label for weight loss on a large scale for people with existing treatment plans. So the pharmacy had not met the actions set out in the NPSA by the required deadline of 18 October 2023. The SI stated that no new orders for GLP-1 medicines to wholesalers had been placed, and that the pharmacy only obtained supplies from historic orders placed before the NPSA (18 July 2023), which were issued on a delayed basis due to ongoing shortages of these products.

The pharmacy had safeguards in place to minimise the risk of overuse of a medicine to treat insomnia. The pharmacy limited the strength and number of tablets it would supply. When a PIP issued a prescription, the person being treated also received a written Treatment Plan and a manufacturer's patient information leaflet.

The pharmacy's customer base was in the UK and it used a 24 hour or 48 hour tracked delivery service to deliver medicines to people's homes. And the RP was present when the courier collected packages for dispatch. Members of the team packed the items into strong, plain cardboard boxes which protected the contents and the recipient's privacy. Medicines requiring refrigeration during transportation for storage were packed in insulated packaging and delivered with ice packs. The SI had calculated the number of ice packs required for each package by sending out test packages with data loggers to check if the package stayed within the required temperature range. The effects of ice packs being in direct contact with the packaging or the medicines was highlighted and it was concluded that the medicine should not be in direct contact with the ice pack. If a delivery containing a medicine requiring refrigeration had failed, a new supply was issued for re-delivery which helped to minimise the risk of medicines being supplied which were not maintained within the manufacturer's recommended temperature range.

The pharmacy used recognised wholesalers to obtain its pharmaceutical stock. It kept most of its medicines and medical devices in their original manufacturer's packaging. The pharmacy team checked the expiry dates of medicines and rotated stock. The pharmacy stored its stock, which needed to be refrigerated, between two and eight degrees Celsius. The pharmacy had procedures for handling obsolete medicines. And these medicines were kept separate from stock in pharmaceutical waste bins. The pharmacy had a procedure for dealing with alerts and recalls about medicines and medical devices. And the RP described the actions they took and what records they kept when the pharmacy received a concern about a product.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the facilities and equipment it needs for the services provided. The pharmacy uses its equipment appropriately to keep people's private information safe.

Inspector's evidence

The PIPs had access to a range of online reference sources such as the electronic BNF, manufacturers Summary of Product Characteristics and the Medicines Ethics and Practice guide. The warehouse team had the personal protective equipment its team members required. The pharmacy had several refrigerators to store pharmaceutical stock requiring refrigeration. And its team regularly checked the maximum and minimum temperatures of each refrigerator.

The pharmacy's equipment was portable appliance tested (PAT). The pharmacy had two robots which de-blistered and repackaged tablets. A member of the team explained the process which had been risk-assessed and there was an SOP. The robots were serviced every six months and cleaned daily between de-blistering different drugs. The pharmacy used separate colour-coded utensils for different drugs to avoid cross-contamination. The team member explained that the pharmacy maintained records of what medicines were processed and their batch numbers and expiry dates to be able to trace medicines in the event of a recall.

The team could dispose of confidential waste appropriately. The pharmacy restricted access to its computers and patient medication record system. And only authorised team members could use them when they put in their own password. The pharmacy positioned its computer screens so they could only be seen by a member of the pharmacy team.

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.