Registered pharmacy inspection report

Pharmacy Name: Numan Operations Limited, W2, Capital Business Park, Parkway, Cardiff, Caerdydd, CF3 2PZ

Pharmacy reference: 9011408

Type of pharmacy: Internet / distance selling

Date of inspection: 15/09/2023

Pharmacy context

The pharmacy is located in a business centre unit on the outskirts of Cardiff. It is associated with Numan, a CQC-registered online prescribing service owned by Vir Health Ltd. The pharmacy's only service is dispensing private prescriptions written by prescribers employed by the prescribing service. The pharmacy supplies prescription medicines for hair loss, erectile dysfunction, premature ejaculation, weight loss, low testosterone levels and sleep problems. People do not visit the pharmacy in person and medicines are sent by post or courier.

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 has written procedures to help make sure the team works safely. And its team members record and review their mistakes so they can learn from them. The pharmacy keeps the records it needs to by law. Its team members understand how to keep people's private information safe. And they receive training so that they know how to report concerns about vulnerable people to help keep them safe.

Inspector's evidence

The pharmacy supplied a small range of GSL (general sales list) medicines, P (pharmacy) medicines and POMs (prescription only medicines) to people in the UK through its associated prescribing service, Numan (www.numan.com). All medicines were supplied against private prescriptions issued by prescribers who were employed by Numan and registered and based in the UK. The prescribing service was registered and inspected by the Care Quality Commission (CQC), a UK health regulator. A recent CQC inspection carried out in 2023 had rated the prescribing service as performing well and meeting their expectations. Patients using the prescribing service needed to register via the prescribing service website. During registration, patient details such as date of birth, gender, address, email address and telephone number were recorded. Identity checks were carried out using a third-party provider, LexisNexis, to help prevent fraudulent requests for medicines. If a person provided information that was fraudulent or in breach of the website's terms and conditions, they were prevented from ordering again or from setting up a new account using the same information.

The pharmacy had completed risk assessments to identify and manage risks associated with the services they provided and the products they supplied. The superintendent pharmacist attended monthly clinical governance meetings with the Numan clinical team to review risks and to discuss prescribing and other clinical issues. Prescribing decisions were subject to regular audit and the prescribing team had recently conducted an audit of medicines prescribed for weight loss. The superintendent pharmacist held monthly meetings with the pharmacy team to discuss issues that directly involved them before taking these to the wider Numan team meeting. Topics discussed included learning points from patient safety incidents and training and development needs.

The pharmacy team recorded and reviewed dispensing errors and near misses. The pharmacist said that error and near miss rates were very low, with most incidents involving incorrect quantities or missing patient information leaflets. Some action had been taken to reduce risks that had been identified. For example, team members demonstrated that they highlighted a different pack size of Priligy 30mg tablets that were being ordered from the wholesaler due to a shortage of the pack size they would normally stock. This helped team members carry out additional checks to reduce the risk of the incorrect quantity being dispensed. A range of up-to-date electronic standard operating procedures (SOPs) underpinned the services provided. Training records were available to indicate that the pharmacy team had read and accepted the SOPs. Three responsible pharmacist (RP) notices were displayed in the pharmacy, which was misleading. The pharmacist removed the incorrect notices as soon as this was pointed out.

The pharmacy's associated prescribing service asked people receiving medicines via their website to complete feedback surveys. They also used Trustpilot to monitor customer service. People were able to

give feedback about the pharmacy via both platforms. Most customer feedback was positive, although there were occasional negative comments about the prescribing service's subscription model. The pharmacy address and customer care helpline number were printed on dispensing labels for reference. A formal complaints procedure was in place and information about how to make complaints was available on the Numan website.

A current certificate of professional indemnity insurance was available. Responsible Pharmacist (RP) records were kept and generally well maintained. Supplies against private prescriptions were recorded electronically. Private prescriptions were received in electronic format. The pharmacist confirmed that the prescriptions were authorised with an advanced electronic signature.

Pharmacy team members were aware of the need to protect confidential information, for example by being able to identify confidential waste and dispose of it appropriately. They had received training on information governance, including the General Data Protection Regulations (GDPR), as part of their induction programme. Individual team members had unique passwords as part of a two-step login to access the pharmacy software. Staff with administrative privileges were required to log in to the administrative software platform using touch identification via a portable 'fingerprint key' USB stick. Pharmacy team members were not permitted to take mobile telephones into the dispensing area to reduce the risk of unauthorised copying or sharing of information. The office manager explained that when a team member left the business, all passwords and email accounts were deleted, and fingerprint keys and key fobs were deactivated.

Comprehensive information about how and when patient information was recorded and shared was included in a privacy policy that was accessible on the prescribing service website. The policy explained that Numan shared information with the pharmacy to allow them to supply prescribed medicines to people. However, the pharmacy's GPhC registration number was incorrect, which might be confusing for people. The pharmacy used remote servers to store patient-sensitive data, and this also allowed them to wirelessly back up electronic devices. Patient-sensitive data stored in the server was encrypted and password-protected. Medicines were delivered in discreet packaging which did not disclose any confidential details, other than the patient's name and address. The pharmacist and staff had undertaken formal safeguarding training. All pharmacy team members were subject to basic disclosure and barring service (DBS) checks. Prescribers and pharmacists were required to undergo advanced DBS checks.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to manage its workload. Pharmacy team members are properly trained for the jobs they do. And they feel comfortable speaking up about any concerns they have.

Inspector's evidence

The superintendent pharmacist was present at the pharmacy on most days, checking prescriptions and overseeing professional activities. She was assisted by one of four part-time locum pharmacists from Monday to Friday. Other locum pharmacists were used to cover absences. The pharmacy support team consisted of around 38 dispensing assistants, seven warehouse operatives and a full-time office manager. Staff could comfortably manage the workload and the staffing level appeared adequate for the services provided. Staff had the necessary training and qualifications for their roles. Four warehouse operatives held forklift truck licences. The trainee dispensing assistants and warehouse operatives worked under the supervision of the pharmacists and were able to refer to them throughout the day for help and advice.

Pharmacy team members worked well together. They were happy to make suggestions, either directly to the pharmacists and team leaders, or using a suggestion box that was in the staff room. They felt comfortable raising concerns with the pharmacists or office manager. There was a quarterly bonus scheme for productivity and error rates. Each team member was required to dispense an average of 30 items per hour, which was achievable. They were also required to ensure that the error rate for the team remained under 0.02% and that all items were dispatched on time. Team members were removed from the bonus scheme if they were involved in a dispensing error. The pharmacist said that the targets had been based on staff input and encouraged the team to dispense efficiently but safely.

Pharmacy team members received training on the different conditions treated by Numan and only dispensed medicines related to the conditions for which they had completed training. As part of their training, each member of the team shadowed a trained member of staff, then undertook the dispensing process themselves under supervision. They were finally required to successfully demonstrate the dispensing process to a senior team member and could then undertake the dispensing role unsupervised.

In addition to any mandatory training needed for their roles, all pharmacy team members received formal ongoing training through a private healthcare training provider. The provider's training modules were verified by the Royal College of General Practice. Team members were allowed protected time to complete these modules, which included safeguarding, whistleblowing, health & safety, autism and equality, diversity & inclusion training. They were subject to a probationary appraisal after three months followed by annual performance and development reviews. They could discuss issues informally with the pharmacists, team leaders or office manager whenever the need arose.

Principle 3 - Premises Standards met

Summary findings

The pharmacy is clean, tidy and secure. There is enough space to allow safe working. And the pharmacy layout has been designed to provide services effectively.

Inspector's evidence

The premises was closed to the public. It was located in a suite of rooms in a business centre. The pharmacy office occupied an unregistered area on the first floor. The dispensary was located on a mezzanine floor and fire escapes at either side led to ground floor exits. The pharmacy was spacious, clean and well-organised. The sinks had hot and cold running water and soap and cleaning materials were available. Antibacterial wipes, cleaning products and hand sanitiser gel were available on each dispensary workstation. The lighting was appropriate. The pharmacy was temperature-controlled, with the ambient temperature set to 18 degrees Celsius in spring and summer and 20 degrees Celsius in autumn and winter. If the temperature went out of range, the electronic control system displayed a warning in red, and the superintendent pharmacist and warehouse manager were alerted by email. The pharmacy had a basic website, but this was not operational at the time of the inspection. The associated prescribing service operated a website, but this did not include up-to-date information about the pharmacy it used to supply medication, which might be confusing for people.

Principle 4 - Services Standards met

Summary findings

The pharmacy's working practices are safe and effective. The pharmacy gets its medicines from licensed suppliers and its team members carry out checks to make sure they are in an appropriate condition to supply.

Inspector's evidence

The pharmacy supplied a small range of medicines for the treatment of hair loss, erectile dysfunction, premature ejaculation, weight loss, low testosterone levels and sleep problems. All medicines were supplied against private prescriptions written by prescribers employed by the pharmacy's associated prescribing service. People were asked for permission for the prescribing service to contact and share information with their GP. People wanting treatment were required to complete a consultation questionnaire which was tailored to a specific indication. Some people were required to provide blood samples, or undergo an additional telephone and/or video consultation with a clinician before a prescription was issued. The prescriber decided whether to write a prescription based on the information provided. The pharmacist had been told that the prescribing refusal rate was between 20% and 35% depending on the condition being treated. They said that if a person's order was refused, they were signposted to the prescribing service's customer care for further information and their GP was informed if they had given consent for GP contact.

The pharmacy was well organised. There were separate stations in the dispensary for labelling and assembling prescriptions, accuracy checking, and dispatch. Information on the dispensary whiteboard showed which team members were present that day and a diagram showed which products were being dispensed at each workstation. The pharmacy used two different dispensing software systems in parallel. One was an internal bespoke system designed by Numan and the other, Titan, was provided by an external company. An application programming interface connected Titan with Numan's software system to share prescription information between the two. The pharmacist said that eventually all operations would be moved to the Numan system. Dispensing labels were usually initialled by the dispenser. However, this was not always the case. The checker did not routinely initial dispensing labels. The pharmacist said that records were kept showing the days and times at which a particular pharmacist worked as an accuracy checker. However, it was not clear whether this took into account the fact that an urgent prescription might be checked by a different person on days when more than one checker was present. The lack of a robust audit trail might prevent a full analysis of dispensing incidents.

An alert was displayed on the Titan dispensing software system if a person whose prescription was being processed had placed an order for any similar medicines in the previous seven days. A 'duplicate therapy' flag was also displayed. The pharmacy's internal bespoke system displayed similar alerts if any medicine had been prescribed for the same person in the previous 14 days. In both cases, the pharmacy team checked whether the prescription was appropriate for dispensing and referred any queries to the prescribing service. An alert was also displayed on the system if any part of the person's details were the same as those of another registered user. This allowed the pharmacy team to flag up possible duplicate accounts and refer instances of these to the prescribing service for further checks before the prescription was dispensed. The pharmacists also picked up anomalies at the accuracy checking stage, such as a person with an obviously female name who had been prescribed a male treatment, or a date of birth that did not fit the usual age policy. They would refer any such concerns to the prescribing service for them to make further checks before a supply was made.

The pharmacy ordered large quantities of the limited range of medicines that were supplied, and these were delivered to the pharmacy on pallets that were transported around the warehouse using a small forklift truck. Each outer box on a pallet contained original packs of medicines from the same batch and was labelled with a batch number and expiry date. Warehouse operatives 'deboxed' one outer of medicines at a time for immediate dispensing purposes. They did this by removing blister strips from original packs and placing them into large tote boxes which were then labelled with the product name, strength, quantity of strips, number of tablets in each strip, batch number, expiry date and manufacturer. The tote box was also marked with the initials of the pharmacy team members who had 'deboxed' the strips and the date on which the 'deboxing' occurred. The labelled tote box was then moved into the dispensary. Some labels had been used more than once and included old information that had been crossed out. There was a possibility that this might increase the risk of errors. Patient information leaflets were put into a separate box and were also taken to the dispensing areas. Each dispenser had a plastic tub at their workstation and filled this with strips from a labelled tote box to use as stock for filling prescriptions. All team members carried a radio, and this enabled them to contact warehouse operatives and ask for more stock to be brought up to the dispensary when necessary.

The pharmacy workload was organised so that all prescriptions for a particular drug, form and strength were dispensed before moving on to the next product. This meant that the risk of an incorrect medicine being dispensed was low. Pharmacy team members assigned to a product that was dispensed using the Titan system generated dispensing labels directly from electronic prescriptions written by the prescriber. A 'batch' of prescriptions was downloaded to the pharmacy's software system from the prescribing service and dispensers were able to generate all dispensing and shipping labels directly from the electronic information on these prescriptions. If a specific prescription was selected by the dispenser for information, the system brought up a corresponding image which included patient details, medication details and the prescriber's name. This image appeared to be based on an NHS-style electronic dispensing token and carried the NHS logo. This was inappropriate as the prescribing service was not associated with the NHS. Dispensers put the required number of blister strips of the product and a patient information leaflet into boxes branded with the prescribing service livery. If a person was receiving the medicine for the first time, a prescribing service branded information leaflet was also included, giving information about their treatment. The dispenser then attached the dispensing label to the inside of the box so that it was clearly visible when the box was opened. A 'QR code' containing a link to a patient information page was also printed on each box. This meant that people had access to up-to-date information about their treatment. The dispenser generated the shipping label by scanning a QR code on the dispensing label and included this in the box, which was then assembled ready for checking and placed into a tote box. When the tote box was full it was moved to the checking area. The pharmacist checked that the dispensed medicines matched the details on the dispensing label and that the patient details on the dispensing label matched those on the postal label. Checked items were packaged appropriately, the postal label was attached, and parcels were put into Royal Mail sacks for dispatch.

Weight loss medicines were assembled at a dedicated workstation and processed using the pharmacy's internal bespoke software system. The pharmacist explained that the software system incorporated bar-code scanning for all medicines supplied to reduce the risk of dispensing errors. If the wrong product was selected and scanned, the system would not allow a label to be generated. Pharmacy team members who were trained to dispense weight loss medicines assembled one prescription at a time and used baskets to ensure that associated paperwork did not get mixed up during the dispensing process. Each dispensing label was marked with unique initials that corresponded to the person logged

in to the software system. The system could be interrogated to show who was recorded as having dispensed a specific prescription at any given time. Each workstation was covered with CCTV to allow team members to be identified if there was any dispute about who had dispensed a particular prescription. When a prescription had been assembled, temperature-sensitive medicines were stored in a drug fridge. Numbers of weight loss prescriptions were low, and the pharmacist checked these at the dispensing workstation at the end of each day. They were then packaged appropriately for dispatch and collected by a courier soon afterwards. This reduced any risks associated with moving the medicines away from their temperature-controlled environment for long periods. People prescribed medicines for weight loss had access to a treatment plan that included lifestyle advice and counselling. They were supplied with needles (if these were not included with the product), alcohol wipes and sharps bins at regular intervals. The customer care team signposted people to regional sharps collection services for disposal of sharps.

Any prescriptions deemed to be 'urgent' were flagged up to the team leader who prioritised them to the relevant workstation and took them straight to the pharmacist for an accuracy check as soon as they were complete. They were then dispatched as soon as possible.

Medicines were only delivered within the UK and the delivery service was free to all patients. It was managed using Royal Mail and next-day courier services. Royal Mail delivery drivers made two collections from the pharmacy each day at 4pm and 5.15pm. Courier delivery drivers made a collection from the pharmacy each day at 5pm. A small number of customers chose to have a delivery from a different courier, and these parcels were taken to that courier's depot by a member of the pharmacy team. Each prescription was scanned to create a tracking number and could be tracked from the pharmacy to its destination. Most prescriptions were delivered via the Royal Mail tracked 48-hour service, but a tracked 24-hour service was also available. The pharmacist explained that if a person contacted them to report that they had not received an order then this was referred to the prescribing customer service team. Failed deliveries were usually returned to the pharmacy. The pharmacy kept a log of returned orders and shared this with the prescribing service's customer services team for follow-up purposes.

Medicines were obtained from licensed wholesalers and were stored appropriately. Some medicines supplied for weight loss required cold storage, and these were stored in two large well-organised lockable pharmacy fridges and a cold room. Daily maximum and minimum temperatures for the fridges and cold room were not always recorded. The pharmacist said that this was an oversight and gave assurances that temperatures were checked every day. Recorded temperatures were consistently within the required range. Maximum and minimum temperatures were also within range at the time of the inspection.

One medicine used for treating low testosterone levels, Testogel, was stored in a double-padlocked cage in the pharmacy warehouse. The pharmacist explained that it was stored securely as a precautionary measure because it was a controlled drug that was liable to misuse. Keys to the padlocks were stored in the pharmacy office and could only be provided to authorised team members on request. A paper record of Testogel receipt and supply was kept in the warehouse and regular balance checks were carried out. No discrepancies had been reported.

Stock was subject to regular expiry date checks. A team member generated a monthly report listing stock items that would expire within the next three months. Stock medicines were removed from shelves a month before their expiry date unless the medicine was usually prescribed as a prn ('when required') item, in which case it would be removed three months before its expiry date. Date-expired medicines and patient returns were disposed of appropriately and pharmaceutical waste was collected

monthly by an external company. The pharmacy and prescribing service received drug alerts and recalls via MHRA e-mails. The pharmacist was able to describe how she had appropriately dealt with medicines that had been recalled as unfit for purpose. This included identifying patients who had been supplied medicine from an affected batch, contacting them where necessary and returning quarantined stock to the relevant supplier.

Principle 5 - Equipment and facilities Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide services. It makes sure that these are always safe and suitable for use.

Inspector's evidence

The pharmacy's equipment was clean and in good working order. There was evidence to show that it had recently been tested. A small amount of replacement computer hardware was available in the pharmacy office in case of equipment failure. The pharmacy had access to a range of up-to-date reference sources. The computers were password-protected. A backup 4G modem provided the pharmacy with an internet connection in the event of broadband failure. The pharmacist said that this worked well and that there was negligible downtime on the rare occasions that it needed to be used.

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.	