General Pharmaceutical Council

Registered pharmacy inspection report

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

Pharmacy reference: 9011408

Type of pharmacy: Closed

Date of inspection: 18/02/2022

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 men's health prescribing service owned by Vir Health Ltd. The pharmacy's only service is dispensing private prescriptions written by pharmacist independent prescribers employed by the prescribing service. People can request a prescription via the prescribing service website by filling in an online questionnaire which is then assessed by the prescriber before the pharmacy supplies the medicine. The pharmacy supplies prescription medicines for hair loss, erectile dysfunction and premature ejaculation. People do not visit the pharmacy in person and medicines are sent by post. This inspection was carried out during the COVID-19 pandemic.

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 met	N/A	N/A	N/A
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy is associated with a prescribing service whose website is arranged so that a person can choose medicines before there has been an appropriate consultation with a prescriber.
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. Its team members record and review their mistakes so they can learn from them. And they take action to help stop similar mistakes from happening again. The pharmacy generally maintains the records that it must keep by law. But some details are missing, so it may not always be able to show exactly what has happened if any problems arise. It asks people to give their views about the services it provides. And it keeps people's private information safe. The pharmacy's team members 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 men in the UK through its associated prescribing service, Numan (www.numan.com). All medicines were supplied against private prescriptions issued by pharmacist independent prescribers (PIPs) 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 2021 had rated the prescribing service as performing well and meeting their expectations.

The pharmacy's website could not be used to access its services. The pharmacy dispensed prescriptions for patients of the associated prescribing service. 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 medication. 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 prescribing service's clinical team, including pharmacists and GPs, to discuss prescribing and other clinical issues. She demonstrated that prescribing decisions were subject to regular audit by clinical pharmacists employed by the prescribing service. Scheduled audits for the coming year included audits of declined prescription requests and repeat prescription length.

The pharmacy recorded and reviewed dispensing errors and near misses. Some action had been taken to reduce risks that had been identified: for example, after a recent error involving the incorrect supply of sildenafil 100mg tablets against a prescription for sildenafil 50mg tablets, the two strengths were now dispensed in separate areas of the pharmacy to help reduce the risk of a similar incident occurring in future. Error logs did not include details of which pharmacy team members had been involved, which might prevent a full analysis of dispensing incidents and limit learning opportunities. The pharmacist agreed that she would arrange for this field to be added to the log, but said that learning points from errors were shared with all pharmacy staff. Staff whiteboards were used to display internal messages for staff information. For example, the dispensary and warehouse areas were used to process different items and the whiteboards listed the different treatments being processed in those areas that day.

A range of written standard operating procedures (SOPs) underpinned the services provided. Training records were available to indicate that the pharmacy team had read and accepted the SOPs. Staff present were able to competently describe their roles and responsibilities and demonstrated that they followed SOPs relevant to their role. Two responsible pharmacist (RP) notices were displayed in the pharmacy, which was misleading. The pharmacist removed the incorrect notice as soon as this was pointed out. Information about the superintendent pharmacist was available on the pharmacy's website.

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 delayed orders or the prescribing service's subscription model. The pharmacy could be contacted directly via an e-mail address or telephone number displayed on the pharmacy's website. The telephone number was also printed on dispensing labels for reference, although on some labels it was listed as '0000000'. A formal complaints procedure was in place and information about how to make complaints was available on the pharmacy website.

A current certificate of professional indemnity insurance was available. Responsible Pharmacist (RP) records were kept and generally well maintained. However, there were some gaps in the records, which meant that it might not always be possible to identify the RP working at a particular time. 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.

Staff had signed confidentiality agreements as part of their contract. They 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). Individual staff members had unique passwords to access the pharmacy software. They were observed to log out of the system if they left their workstation for a prolonged period. Comprehensive information about how and when patient information was recorded and shared was included a privacy policy that was accessible on the prescribing service website. 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. A safeguarding file was available which included both local and national guidance and contact details.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload. Support staff 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 worked at the pharmacy on most days, checking prescriptions and overseeing any other professional activities. She was assisted between Monday and Friday by one of two part-time locum pharmacists. Other locum pharmacists were used to cover any absences. The pharmacy support team consisted of 20 trainee dispensing assistants, five 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. Two 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.

Staff worked well together. They were happy to make suggestions within the team and felt comfortable raising concerns with the pharmacists or office manager. Targets were set for productivity: the dispensing target was currently 200 prescriptions per day for both the dispensary team and the warehouse dispensing team. Staff explained that in practice this meant that each team member was required to dispense between 30-50 prescriptions per day, which was achievable. The superintendent pharmacist said that the target had been based on input from staff.

In addition to any mandatory training needed for their roles, all staff received formal training through a private healthcare training provider. The provider’s training modules were verified by the Royal College of General Practice. Staff were allowed protected time to complete training, including safeguarding, whistleblowing, health & safety and equality, diversity & inclusion training. Whistleblowing information was stored in staff training files and included contact details for anonymously reporting concerns outside the organisation. Staff were subject to annual performance and development reviews and could discuss issues informally with the pharmacists or office manager whenever the need arose.

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

Summary findings

The pharmacy is clean, tidy and secure. There is enough space to allow safe working. But the associated prescribing service operates a website that lets people choose the medicines they want before there has been an appropriate consultation with a prescriber.

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 was in an unregistered area on the first floor. The pharmacy was clean, generally tidy and well-organised with sufficient space to allow safe working. The sinks had hot and cold running water and soap and cleaning materials were available. Alcohol wipes, cleaning products and hand sanitiser gel were available. Dispensing workstations were separated by Perspex screens to reduce the risk of viral transmission. The lighting and temperature were generally appropriate, although the warehouse felt cold, as external doors had been opened to receive deliveries. However, all staff were wearing warm clothing provided by the company, including fleeces, long-sleeved hooded tops, and trousers.

The pharmacy website included very little detail, but stated the name and physical address of the pharmacy and its GPhC registration number, as well as a contact telephone number and email address. The website for the pharmacy's associated prescribing service was arranged so that people could choose a prescription only medicine (POM) before completing a consultation questionnaire. This made the website appear transactional and it means that there may be more risk that people might not always receive the most suitable medicines for their needs. The consultation questionnaire included questions about symptoms, other conditions and other medicines being taken, with some free text boxes available for patients to input their answers.

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 some 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 erectile dysfunction, premature ejaculation and hair loss. All medicines were supplied against private prescriptions written by one of fourteen pharmacist independent prescribers (PIPs) employed by the pharmacy's associated prescribing service. People wanting treatment were required to complete a consultation questionnaire which was tailored to a specific indication. People were also asked for permission to contact and share information with their GP. The prescriber decided whether or not to write a prescription based on the information provided. The pharmacist had been told that the prescribing refusal rate was between 25% and 30% and said that if a person's order was refused, they were signposted to the prescribing service's clinical team for further information and their GP was informed if they had given consent for GP contact. If contacted directly, the pharmacy team signposted people requiring services they could not provide to their local pharmacy or to other appropriate healthcare providers.

The pharmacy was well organised. There were separate stations for processing and labelling prescriptions, assembling and packing medicines, accuracy checking, and dispatch. Most prescriptions were assembled and checked in the dispensary, but some were also assembled and checked in a section of the warehouse area which had been fitted for this purpose. The pharmacist said that there were plans to move this part of the dispensing operation up to a mezzanine floor, which was to be built over the coming months.

The pharmacy team used baskets to ensure that prescriptions did not get mixed up during dispensing. If any prescriptions were classed as 'urgent', they were placed in red baskets to highlight to staff that they were a priority. Dispensing labels were not initialled by the dispenser or checker, so the lack of a robust audit trail might prevent a full analysis of dispensing incidents.

An alert was displayed on the pharmacy's dispensing software system if a person whose prescription was being processed had placed an order for any medicines in the previous seven days. 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 pharmacist said that she also picked up anomalies at the accuracy checking stage, such as a person with an obviously female name or a date of birth that did not fit the usual 20-70 years age policy, She would refer any such concerns to the prescribing service for them to make further checks before a supply would be 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. Staff members took turns, in pairs, to 'debox' one outer of medicines at a time for immediate dispensing purposes: they removed blister strips from the original packs and put these into a large plastic bin, which they labelled with the product name, strength, quantity of strips, number of tablets in each strip, batch number, expiry date and manufacturer. The bin was also marked with the initials of the pharmacy team members who had 'deboxed' the strips and the date on which the 'deboxing' occurred. When full, this labelled bin was moved into either the dispensary or the dispensing area in the warehouse and used as stock for assembling prescriptions. As an example. staff said that the stock from one full bin of sildenafil 50mg tablets would be used within two hours. 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. 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 the labelled bin to use as stock for filling prescriptions. One tub was labelled as tadalafil, which was misleading. The pharmacist admitted that in the past, when the workload was lower and smaller quantities of tablets had been required for dispensing, the box had been used as a 'stock' bin for tadalafil. She removed the label to avoid confusion.

The pharmacy used two different dispensing software systems, both supplied by Titan. The dispensary system was Titan Professional, a typical 'community pharmacy-style' software system that shared a server with other Titan users. It required manual input of prescription details to create a patient medication record (PMR) and generate labels. The system used in the warehouse dispensing area was Titan Enterprise. This used a server that was not shared by any other pharmacies and had the capacity to handle a much larger workload at speed. The Enterprise system allowed an application programming interface to connect it with the Numan software system and share prescription information between the two, so no manual input was necessary. The pharmacist said that eventually all operations would be moved to the Titan Enterprise system.

Prescriptions were transmitted to the dispensing team electronically and viewed on the pharmacy's computers. Staff manning the labelling workstations in the dispensary printed off a hard copy of each prescription, which they used to manually input patient details and generate dispensing labels and a postal label. These were placed into a basket and passed to a dispensing workstation. The pharmacist referred to the copy of the prescription to carry out the final accuracy check. Each prescription included a 'notes to pharmacy' section which the prescriber could use to relay a message to the pharmacy team. For example, one prescription had the message: 'no contraindications' written in this section. 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 patient's basket was then taken to the checking area. After the pharmacist had carried out a final accuracy check, the medicines were put into a plain cardboard box and a postal label was attached. The parcels were taken to the dispatch section of the warehouse and put into Royal Mail postal collection sacks for dispatch.

The dispensing process in the warehouse using the Titan Enterprise system was different to the process followed in the dispensary. Staff in the warehouse dispensing area generated dispensing labels and postal labels directly from electronic prescriptions written by the prescriber. A 'batch' of prescriptions was downloaded to Titan Enterprise from the prescribing service and a dispenser was able to generate all dispensing and postal 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. When the paperwork had been generated, each dispensing label was attached to a box branded with the prescribing service livery and placed into a basket with its corresponding postal label. The basket was sent to a dispensing workstation where a dispenser added the medication, then sent it on to a checking station. 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. The checked items were put into a plain outer box, a postal label was attached and the parcel was put into Royal Mail sacks for dispatch.

Medicines were only delivered within the UK and the delivery service was free to all patients. It was managed using Royal Mail, whose delivery drivers made two collections from the pharmacy each day at 3pm and 5.30pm. 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 and a special delivery service were also available. The pharmacist explained that if a person contacted them to report that they had not received an order this was referred to the prescribing service team. Royal Mail usually returned any failed deliveries 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. The pharmacy did not carry any temperature-sensitive medicines or controlled drugs. The pharmacist checked expiry dates as part of her accuracy checking process. Date-expired medicines and patient returns were disposed of appropriately. The pharmacy and prescribing service received drug alerts and recalls via MHRA e-mails and kept a log of these. The pharmacist was able to describe how she would deal with medicines if they were recalled as unfit for purpose by contacting patients 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 new and appeared to be in good working order. There was a small amount of replacement computer hardware available in the pharmacy office in case of equipment failure. Personal protective equipment and hand sanitiser were available for staff use. The pharmacy had access to a range of up-to-date reference sources. The computers were password-protected.

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.