General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Acre Pharmacy, Unit 7B, Unit 5-7 Tintagel Way, Walsall, West Midlands, WS9 8ER

Pharmacy reference: 9011661

Type of pharmacy: Internet / distance selling

Date of inspection: 24/11/2021

Pharmacy context

This internet pharmacy is closed to the public. It is located on an industrial estate in Aldridge, West Midlands. The pharmacy does not have an NHS contract. It specialises in providing aesthetic products and consumables via its website; www.acrepharmacy.co.uk. It mainly supplies products used for non-surgical cosmetic procedures against private prescriptions directly to healthcare professionals and aesthetic practitioners that are based in the UK. The inspection was undertaken during the Covid-19 pandemic. This was an intelligence-led inspection after information was received by the GPhC regarding inappropriate supplies of aesthetic medicines.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; Statutory Enforcement

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy has not completed robust risk assessments for all of its services. And it is not able to show that the risks associated with supplying aesthetics treatments are being effectively managed.
		1.1	Standard not met	The pharmacy does not make enough checks to provide assurance that the medicines it supplies to non-medical aesthetic practitioners are being used appropriately. This matter is addressed through the imposition of an Improvement Notice.
		1.2	Standard not met	The pharmacy does not proactively audit or review the quality and safety of its services. And it does not carry out enough checks to provide assurance that the prescribers it works with are appropriately registered and authorised to prescribe. This matter is addressed through the imposition of an Improvement Notice.
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 not all met	4.2	Standard not met	The pharmacy does not carry out appropriate clinical checks to provide assurance that all of the medicines it supplies are being used safely and appropriately. This matter is addressed through the imposition of an Improvement Notice.
		4.3	Standard not met	Medicines that require cold chain delivery are not always handled appropriately to make sure they are suitable to supply. This matter is addressed through the imposition of an Improvement Notice.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

There is a lack of meaningful risk assessments and the pharmacy does not proactively review or monitor its services. This means that the risks associated with providing the pharmacy services are not always identified or managed. The pharmacy relies on the people using its services following its terms and conditions. But its processes are not robust enough to identify and challenge when these are not followed. Which means that people can sometimes obtain medicines that may not be suitable.

Inspector's evidence

This pharmacy first started operating in March 2019 from a smaller premises in the same business unit but relocated in July 2021 as the pharmacy required more space due to business growth.

The pharmacy provided most of its services through its website; www.acrepharmacy.co.uk. It had also provided services for a third-party website, but these had been suspended prior to the inspection after concerns had been raised. A range of non-surgical cosmetic treatments including medicines and associated products, such as syringes, were available on the website and supplied to prescribers and non-medical aesthetic practitioners based in the UK. The prescribers and aesthetic practitioners were required to register an account through the website; they were required to supply proof of their identity, and some other documents depending on whether they were registering as a prescriber or practitioner. Once the registration had been approved by the pharmacy; the person was authorised to use the website. The website could be used to order products or generate electronic prescriptions if people had successfully registered as a prescriber, and these prescriptions were then supplied by the pharmacy.

Prescribers provided proof of their identity when they registered to use the website and the customer services team checked their professional registration and confirmed they had the necessary authority to prescribe. A recent newspaper article highlighted some underlying issues with the due diligence checks, and this had led to a reactive review of the service by the pharmacy team. The team members were in the process of re-checking all prescriber registrations and their prescribing authority, and they had created a spreadsheet to record this. Further issues with some of the registrations had been identified and some prescriptions had been rejected as a result. It was noted that one of the GMC registered prescribers who had been blocked during the checking process, had issued three prescriptions in 2021 and these had been supplied by the pharmacy. This prescriber had conditions on their practice which had been in place since December 2020, but this had not been identified by the pharmacy at the time and so these prescriptions were not legally valid. Prescribers were not asked to provide evidence of their training or competence to prescribe for aesthetics or weight management.

Non-medical aesthetic practitioners were required to provide proof of their identity when they first registered. In addition, they were required to provide proof of their training and a copy of their indemnity insurance details. These were saved to the practitioner's individual page of the computer system. A sample of records were checked and appeared to be in order. The pharmacy did not check the validity or quality of the training completed by the practitioners. And the pharmacy did not appear to check that the practitioner had undertaken specific training for the products that they were being supplied with.

Two pharmacists worked at the pharmacy regularly and one of them was working as the responsible pharmacist (RP) during the inspection. The superintendent pharmacist (SI) also occasionally worked at the pharmacy. All three pharmacists had only recently started working at the pharmacy in their curent roles. The RP explained that he had been in his role for six-weeks and had previously worked in a traditional community pharmacy, so this area of practice was new to him. The RP confirmed that the pharmacy had not undertaken any risk assessments or audits that he was aware of other than the review of prescribers that was being carried out following the newspaper article.

A range of standard operating procedures (SOPs) were in place which covered the operational activities of the pharmacy and the services provided. The SOPs had been prepared by one of the regular pharmacists in October 2021. Roles and responsibilities of staff were highlighted within the SOPs.

Some of the risks involved in the business model had not been suitably identified by the pharmacy and various issues were identified. For example, there was evidence that the pharmacy dispensed prescriptions for prescription only medicines (POMs) issued in the names of aesthetic practitioners. These prescriptions were often for unusually large quantities of aesthetic treatments, so it was highly unlikely that the medicines were intended for their own treatment, but rather for them to use as stock to treat their patients. This was not appropriate as non-medical practitioners should only administer POMs if they have been prescribed for the named patient. These prescriptions were dispensed and supplied without any intervention being made by the pharmacy team to challenge why the medicine or treatment had been ordered in the name of the practitioner rather than a named patient. This meant that non-medical aesthetic practitioners could be administering POMs to people without the correct legal authority to do so, and without the pharmacy being assured that people were old enough for the treatment or that they had been physically examined by the prescriber. The RP was aware of new legislation that prevented the prescribing of aesthetic treatments to minors and prescriptions contained the patient's date of birth. But as prescriptions were not always being written in the name of the actual patient, the pharmacy could not check if the medication was being administered to someone underage. There were multiple examples of supplies being made in the name of the practitioner, including prescriptions for weight loss injections, emergency kits containing multiple POMs, and botulinum toxins. The terms and conditions on the website stated "The products are for use by the named patient only and are not for onward sale under any circumstances" so this demonstrated a disregard for the terms and conditions by the people using the pharmacy, but also by the pharmacy team.

Another problem that was identified in the newspaper article was that prescribers were issuing prescriptions for practitioners without the prescriber undertaking a physical examination of the patient. The RP was asked about this and he believed that a face-to-face examination could take place over a video call. This was not in line with guidance issued by UK healthcare regulators, including the General Pharmaceutical Council (GPhC) and the General Medical Council (GMC), which specifically states that remote prescribing for non-surgical cosmetic procedures is not appropriate. In addition, one of the voluntary UK regulators for cosmetic practice states that repeat prescribing is not appropriate if it has been more than six-months since the prescriber last physically examined the patient. There was a standard statement on the prescription form, and in the terms and conditions, stating that a face-to-face consultation had taken place. However, there was no further assurance to show that the pharmacy was checking that this had happened, and it was noted that on some prescriptions the patient address and the prescribers address were hundreds of miles apart.

Dispensing near miss logs were used and they were reviewed at the end of the month. A near miss improvement form was completed which was used to identify patterns and trends. The pharmacy team dispensed from a limited formulary and many of the products had very similar packaging. The dispenser explained that she had identified a problem with dispensing part packs so had suggested a change to the stock layout which had been implemented and she said that she had noticed a reduction in picking

errors since. Members of the pharmacy team were knowledgeable about their roles and discussed these during the inspection.

People could contact the pharmacy in various ways, such as, telephone, email and by using an online form. Contact details were advertised on the website. The customer service team was in a different location and any queries that required pharmacy input or pharmacist support were transferred across to the pharmacy. A CCTV camera was positioned above the packing area so that complaints related to incorrect quantities could be investigated.

The pharmacy had up-to-date indemnity insurance arrangements in place. The Responsible Pharmacist notice was clearly displayed, and the RP log complied with requirements. Records of prescription queries and interventions were made on the computer system and records of messages sent to and from the customer services team were stored. The private prescription register was integrated into the computer system and appeared to be accurate and complete.

There was a privacy policy on the pharmacy website. It was unclear whether the prescribers or practitioners gained consent from the patient to pass on their personal details to the pharmacy for the prescription to be dispensed. This was written into the privacy policy; however, patient consent was not confirmed when the prescriber issued a prescription using the pharmacy's online system. Confidential waste was stored separately and destroyed securely.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to manage the current workload and the services that it provides. The pharmacy's team members can provide feedback about the service. But team members lack experience in the specialist area of practice in which they are working, which means they might have gaps in their knowledge and skills.

Inspector's evidence

The pharmacy team comprised of two regular pharmacists, an operations manager (a non-dispensing role), two dispensing assistants and two trainee dispensing assistants. The pharmacy business was a 'sister-company' of a large pharmaceutical wholesaler. The pharmacy team was supported by a customer service team which was in a different location. Three of the dispensing assistants were new to working at the pharmacy and had been recruited due to the growth in pharmacy business.

A dispensing assistant was enrolled on a NVQ3 course and was on track to complete it within the course provider's recommended time frame. She had a placement at a community pharmacy planned to broaden her experience in other areas of pharmacy. A member of the team was enrolled on the NVQ2 course, and the newest member of the team was receiving on the job training but was still within her induction period so had not yet enrolled on a training course.

The pharmacists had only recently started working at the pharmacy and they had no previous experience in aesthetics, and they did not have access to support from anyone with experience or expertise in this area of practice. This lack of experience and relevant clinical knowledge meant they might overlook potential patient safety issues.

The pharmacy team appeared to work well together during the inspection and were observed helping each other. The team had meetings and discussions within the dispensary and said that they could raise any concerns or suggestions with the operations manager, the pharmacists, the SI or the company directors, and felt that they were all responsive to feedback.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is well maintained, secure and provides an environment that is suitable for the provision of healthcare. The pharmacy's website generally provides accurate information about the pharmacy and its services.

Inspector's evidence

The pharmacy's website www.acrepharmacy.co.uk was used by prescribers and practitioners to order private prescriptions for non-surgical cosmetic treatments such as, toxins, fillers, threads, medicines and ancillary items. Medicines and treatments could only be requested by people who were registered with the pharmacy.

The pharmacy website included information about the pharmacy in the contact us section, at the bottom of each web page and in the FAQ section. The website prominently displayed relevant information about the pharmacy such as, GPhC premises registration number, name of the SI and information on how to check whether the pharmacy is registered. The website also displayed the MHRA distance selling logo which is no longer in use, and this was incorrectly linked to the GPhC website, which could be confusing for people accessing the website.

The pharmacy was part of a much larger wholesale premises. It was smart in appearance and appeared to be well maintained. Any maintenance issues within the dispensary were reported to the building maintenance department. The dispensary was large, and an efficient workflow was seen to be in place. Dispensing, checking and packaging took place in separate areas of the dispensary.

The dispensary was clean and tidy with no slip or trip hazards evident. Hot and cold running water, hand towels and hand soap were available. Restroom and bathroom facilities for staff were available within the main building. The pharmacy had air conditioning and the ambient room temperature was monitored. Lighting was adequate for the pharmacy services offered. Prepared medicines were held securely within the pharmacy premises until they were dispatched.

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

Summary findings

The pharmacy does not make enough checks to ensure the medicines it supplies are clinically appropriate for the person receiving the treatment. It cannot provide assurance that prescription supplies of non-surgical cosmetic medicines are for the treatment of the named patient. And there are clear indications these are more likely to be used to treat other people. This means the non-medical practitioners may be administering the medicines inappropriately and without the correct authority to do so. Medicines that require cold chain storage are not always handled properly so they may not always be fit for purpose.

Inspector's evidence

Dispensing baskets were used to keep medication separate and coloured baskets were used to prioritise the accuracy checking and packing of cold-chain products. A dispensing audit trail was seen to be in place for prescriptions through the practice of staff signing their initials on the dispensed and checked by boxes provided on medicine labels. The computer system also recorded which member of the team had completed certain processes.

Most prescriptions were generated by the prescriber using the electronic prescribing function of the pharmacy's website. The electronic prescription, order details and payment were checked by the customer services team and then forwarded to the pharmacy to be dispensed. The prescriber, practitioner and patient's details were recorded on the invoice and the prescription contained the legally required information. The prescription was then dispensed and dispatched to the chosen delivery address. Some prescriptions were emailed to the pharmacy as a scanned copy of photograph and as part of the terms and conditions, the original prescription was then sent from the prescriber to the pharmacy within 72-hours and reconciled with the order. The prescription contained a space for the directions; however, this was not always completed. The lack of directions or information about administration made it more difficult for the pharmacists to determine if the supply was appropriate, and the lack of clear instructions increased the risk of inappropriate use.

Intra venous nutritional therapy (IVNT) kits, sterile sodium chloride bags, and vitamin injections were available on the website. Some of the vitamins were imported from Europe and the pharmacist did not have access to information about their stability if they were mixed with other vitamins in an IVNT. The RP checked the accuracy of the items against the prescription but said that he did not undertake a thorough clinical check of these items to make sure they were suitable to be administered together, despite these being written on the same prescription form. Some prescriptions contained multiple vitamins to be given, possibly in the same IV infusion, which had been supplied with no assurance that they would be stable when given together. A prescription for multiple 250ml sterile sodium chloride bags was seen. But the team had not checked whether this was all for the named patient, or whether it was for the practitioner's stock, meaning that an opportunity to make an intervention had been missed.

Some medicines were being prescribed for unlicensed indications. For example, patients at weight loss clinics were prescribed Ozempic. The RP was unsure whether these services were registered with the Care Quality Commission (CQC) or whether this had been checked. And the pharmacy did not seek any

further information to support the pharmacist's clinical check and make sure the prescribed medicine was suitable for the patient, such as their BMI, or whether ongoing monitoring was taking place.

Some products were supplied to aesthetic clinics for their own stock using a requisition form. These were technically a wholesale supplies and they occurred on a regular basis. But the company that owned the pharmacy did not hold a MHRA Wholesaler Dealer's Licence. Emergency kits, containing various medicines and ancillary items were available on the website. Some of the kits were supplied to practitioners using a private prescription in the name of the practitioner to be used as stock, which was not appropriate as non-medical practitioners should only be administering POMs to the person named on the prescription.

Prescriptions were delivered using a courier service. Cold-chain items were packed in boxes to ensure the contents were kept at the required temperature and sent using a tracked service. Cold-chain packaging was validated regularly so that adjustments to packaging materials due to seasonal weather changes could be made. The pharmacy team could track orders online and see evidence of delivery if required.

An undelivered cold-chain parcel was returned by the courier during the inspection and a dispensing assistant was observed unpacking the items, discarding one of the cold-chain medicines, and then preparing the other cold-chain medicines to be re-dispatched to the same practitioner. The dispensing assistant said that as the medicines had only been handled by the courier company and they were in cold-chain packaging, all but one of the medicines could be sent out and this was standard procedure. The RP confirmed that the medicines that were due to be re-dispatched had been held outside of the time period used for packaging validity checking, so he could not guarantee that the medicines had been stored at the appropriate temperature for their time in the delivery system. These items were not sent during the inspection and disposed of in the medicines waste container.

Medicines were stored in an organised manner on the dispensary shelves. Most medicines were observed being stored in their original packaging, some emergency kits had been pre-prepared, and part-packs of medicines were supplied in the kit. Date checking took place regularly and no out of date medication was seen during the inspection. Stock was obtained from a wide range of wholesalers. Returned medicines were stored separately from stock medicines in designated bins. The pharmacy was alerted to drug recalls via emails from gov.uk and from some wholesalers.

There were several medical fridges used to hold stock and assembled medicines. And freezers used to store ice packs for delivery packaging. The medicines in the fridge were stored in an organised manner. Fridge temperature records were maintained, and records showed that the pharmacy fridge was working within the required temperature range of 2°C and 8°Celsius.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely. The team uses this equipment in a way that keeps people's information safe.

Inspector's evidence

The pharmacy had a range of up-to-date reference sources, including online access to the BNF. Internet access was available. Patient records were stored electronically and there were enough terminals for the workload currently undertaken. Screens were not visible to the public as members of the public were excluded from the dispensary.

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.