General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Dermatica, Unit 7, Datapoint, Cody Road, London, E16 4TL

Pharmacy reference: 9011448

Type of pharmacy: Internet / distance selling

Date of inspection: 17/04/2024

Pharmacy context

This is a distance-selling pharmacy located within a large industrial unit in East London. The pharmacy dispenses unlicensed topical medicines which it prepares on site for various skin conditions. The pharmacy uses pharmacist independent prescribers (PIP) to prescribe these preparations. The prescribing service is not registered with the Care Quality Commission (CQC). This was a reinspection of the pharmacy, as it was last inspected in September 2023 and at that time was not meeting all the Standards. The pharmacy subsequently addressed this by way of an improvement action plan.

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	2.2	Good practice	The pharmacy provides structured ongoing training for its team members and gives them protected time to complete it.
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 identifies and manages the risks associated with its services. It has written procedures that the pharmacy team follows, and it protects people's private information correctly. The pharmacy audits and reviews its prescribing service to make sure its processes are safe and effective. And team members are provided with training about how they can help to protect the welfare of vulnerable people. But the pharmacy could do more to make sure that people using its services are who they say they are. And that they clearly understand that the preparations they are receiving are unlicensed medicines.

Inspector's evidence

The pharmacy compounded and supplied a range of topical medicines mainly for the treatment of acne, ageing, melasma, hyperpigmentation and rosacea. The medicines were prepared under section 10 of the Medicines Act 1968 which meant the medicines did not hold a UK marketing authorisation or registration and were unlicensed. Therefore, the medicines had not been formally assessed through the licensing process for safety, quality, and efficacy. The unlicensed nature of medications was only explained to patients in the 'frequently asked questions' on the pharmacy's website. So, it ws possible that people may not see this section and understand that they had been prescribed an unlicensed medicine, or the potential risks associated with this.

Up-to-date standard operating procedures (SOPs) were available at the pharmacy. Current members of the team had signed the relevant procedures to confirm they had read and understood them. Responsibilities of team members were listed on individual SOPs, so it was clear who was responsible for which tasks. The pharmacy was laid out such that each task was assigned an area.

Most of the medicines supplied were against prescriptions issued by pharmacist independent prescribers (PIPs) at the pharmacy's online prescribing service. People accessed this service via the pharmacy's website www.dermatica.co.uk. This was a remote prescribing service and people were not seen face-to-face. The medicines contained combinations of ingredients some of which were prescription only medicines (POMs) such as tretinoin, adapalene, clindamycin and metronidazole. People were generally asked to select their condition, and then complete an online consultation and upload at least three photographs of themselves which showed the condition to be treated. Some over-the-counter products were supplied for example moisturizers and cleansers. People could select these and go straight to the checkout without a consultation. Medicines were delivered to people living in the UK and some European countries using a Royal Mail service which could be tracked.

Dispensing errors and near misses were reported and reviewed at monthly patient safety meetings by senior members of the pharmacy team. Learnings were shared with relevant team members. All the medicines supplied by the pharmacy were in very similar packaging which could increase the risk of mistakes. However, the pharmacy lead stated that errors were minimal as there were four stages in the dispensing process, which were printing labels, picking, dispensing and checking, and each were carried out by a different member of the team. Any mistakes identified during these stages were recorded as near misses, so the team could learn from them. The pharmacy lead explained that the pharmacy always had at least one core member of the team working on any day to support locum dispensers. A double check had also been introduced for over-the-counter skincare products to help reduce order

errors.

The pharmacy had risk assessments for all products that the pharmacy prescribed. The risk assessments included consideration of the risks associated with prescribing remotely. The clinical risk assessments were developed by the clinical lead with input from other members of the clinical team. Prescribers read and signed these risk assessments and added them to their personal declarations of competence. The risk assessment for tretinoin assessed the risk in pregnancy as 'very low.' The online consultation asked people if they were pregnant. If they answered yes, the prescribing system did not offer treatment options such as those containing tretinoin. So, prescribers were not able to prescribe medicines which the pharmacy assessed as unsafe in pregnancy if a person had indicated they were pregnant. However, the responsibility was placed on the person ordering treatments to advise if they were pregnant or breastfeeding for any subsequent order. This could create a risk of pregnancy not being highlighted before supply of medicines which are potentially unsafe in pregnancy. For example, tretinoin. However, the pharmacy had taken steps to help mitigate this risk, for example by providing treatment guides and giving people regular notifications to remind them to update their medical information. There was a risk assessment for staff members, and those who were pregnant or trying to become pregnant were not allowed to come into contact with tretinoin, to reduce the risk of any teratogenic effects.

People were asked their age as part of the process, but their age and identity (ID) were not verified, so this there was a risk people could provide false information to obtain medicines. The prescriber compared the person's name, sex, and date of birth to the photographs that the person had uploaded. If the prescriber felt the need to confirm anything, such as their age, they contacted the person and requested proof of their ID. The pharmacy had carried out an internal review of their ID policy and felt that the risk of somebody not providing genuine ID details such as the correct age was very low, as none of the medicines were liable to abuse or misuse. And the pharmacy lead explained that a person was placed on only one pathway as their skin could not tolerate multiple products or excess use of products.

Clinical protocols for all treatment pathways were in place. And these outlined what treatments were available for each condition treated. The protocols were developed with reference to national guidance, including that published by the British Association of Dermatologists (BAD) and the National Institute for Health and Care Excellence (NICE), and were approved by the medical lead for the pharmacy, who was a registered medical dermatologist. The pharmacy had a process to audit every prescriber's consultation notes monthly. Each prescriber had random consultations audited against set standards and a quality score was generated. The pharmacy's clinical lead had access to a dashboard and checked this on a weekly basis. The dashboard highlighted each prescriber's approval and prescribing rate. A high approval and prescribing rate were flagged for investigation as the pharmacy expected that not all requests for treatment were clinically appropriate, therefore there should be a percentage of rejected requests. The clinical lead discussed audit results with team leads and highlighted trends and areas for improvement, and these insights sometimes triggered training sessions. Feedback was also provided individually to each prescriber.

The pharmacy's website included details about how to make a complaint. People could contact the customer care team by completing a form in the 'contact us' section on the website. People were able to review and rate the pharmacy on various platforms, such as Google and Trustpilot. A customer complaint SOP was in place and complaints or significant adverse events were documented on an electronic log. People were asked to send the product back to the pharmacy for testing if the complaint was about a compounded preparation. If batch errors were identified, then the customer care team contacted other people who had received a medicine from the same batch. Serious drug reactions were reported through the Yellow Card Scheme but if the reported reaction was a normal side effect, such as

mild stinging or burning, then these were documented on an 'issues log'. Queries and concerns of a clinical nature were escalated to the clinical team for investigation. The pharmacy had changed the formula of a product to prolong its use-by date following some complaints about its short expiry dates.

The responsible pharmacist (RP) record was in order and the correct RP sign was displayed at the pharmacy. The pharmacy did not supply any controlled drugs (CDs). Each prescriber had an individual login to the prescribing system. And prescriptions could only be generated and authorised by the pharmacy's prescribers as only prescribers had the functionality to prescribe. And changes or additions to a person's clinical record were logged by the individual prescriber's login details. Each prescription was signed by a prescriber using an advanced electronic signature. The prescriptions were sent electronically to the pharmacy and the prescriptions could not be edited after the point of prescribing. The private prescription register was electronic and was in order. The pharmacy maintained electronic consultation notes for people it prescribed treatment to. The online consultation as well as all prescriptions, photographs, comments, and queries were logged on the person's record. The RP, superintendent pharmacist (SI) and other prescribers had visibility of the prescriptions and patient record. So clinical information relating to the persons prescription was visible to those who needed access to it. The pharmacy had regular backups of servers. There were Control of Substances Hazardous to Health (COSSH) records available. The pharmacy had current professional indemnity and public liability insurance and that it covered all the activities carried out at the pharmacy, including independent prescribing, and compounding unlicensed medicines.

Members of the team completed training on the General Data Protection Regulation (GDPR), handling patient information and record keeping, as part of their induction. The premises were not accessible to members of the public. Computers were password protected and confidential waste was shredded. The pharmacy's privacy policy was available on the website.

Team members had completed training on safeguarding according to their role. The prescribers, pharmacists and pharmacy technicians had completed level three training. The contact details of the local safeguarding team were displayed in the pharmacy. The SI explained that if a safeguarding concern was outside for a person outside the local
area, a team member would look up the relevant details.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload. Team members have opportunities to discuss issues and they communicate well. They are encouraged to keep their skills up to date and are supported in their development. And they get protected training time at work.

Inspector's evidence

During the inspection, the dispensing side of the pharmacy was staffed by the SI (who was the RP for the day), an accuracy checking technician (ACT), seven dispensers and four locum dispensers. The dispensers had either completed or were enrolled onto an accredited course. The compounding team comprised of one ACT, two dispensers and five compounding operatives. The staffing level was adequate for the volume of work during the inspection. Absences were covered by re-arranging the staff rota and locum pharmacists, ACTs and dispensers were used when necessary. A pharmacy lead was present for the inspection and worked between the two pharmacies in the building. There was a warehouse team which worked between both pharmacies. All members of the compounding team had completed a manufacturing course and a compounding course. The manufacturer of the mixing machines also provided training to the team. The operators all had degrees in a scientific field, such as biomedical science, and had been provided with in house training. The SI had a PhD in skin formulation and had worked in an aseptic unit at a hospital and in production at a pharmaceutical company. He kept up to date by reading a compounding journal. He had also completed training in quality assurance procedures.

The clinical team consisted of pharmacists, dermatologists, doctors, and nurses. A new clinical lead, who was a nurse, had started three months ago. There were contingency plans in place in case of a surge in demand, and this included asking some prescribers who worked part-time to work additional hours if needed. The pharmacy carried out annual appraisals for prescribers. And there were mid-year performance checks. There was a bespoke competency framework for prescribers which outlined the skills, knowledge and behaviours expected of prescribers who worked for the pharmacy. And it outlined how competency was measured and checked through audits and assessment. The pharmacy's Human Resources team checked the professional registration and prescribing qualification of all prescribers on appointment. And prescribers maintained a declaration of competence statement which outlined what clinical areas they were competent to prescribe in.

Prescribers were able to escalate consultations to a more senior prescriber if needed. This was at the professional discretion of prescribers if they identified a case outside their scope of competence. There was a senior prescriber on-call during shifts for prescribers to seek support from. Prescribers also had access to a knowledge base of information that the pharmacy had developed which prescribers could search if they needed to refer to guidance. And the pharmacy had a dedicated messaging channel for prescribers to seek advice from each other.

The pharmacy's staff were in separate teams which included the dispensary team, the clinical team, the compounding team, and the customer care team. The clinical team and customer care team worked remotely, and the dispensary and compounding team worked on the pharmacy premises. The pharmacy used an electronic messenger system to communicate between the teams. The dispensary team was managed by a qualified dispenser and there was a regular pharmacist based in the

dispensary.

Ongoing training was provided for the dispensary team and training records were maintained including new team member's induction. The induction training covered a range of areas including stock ordering, deliveries, the dispensing system, near miss log, packaging, security of email accounts, health and safety, confidentiality, and the pharmacy's SOPs. Certificates were on display of the dispenser's qualifications. Members of the team on dispensing courses were given half an hour protected training time each week. Performance reviews were conducted with all permanent members of the team every six months and informal meetings were also held to discuss any issues or changes. A locum folder was available in the dispensary, and this contained condensed SOPs which were relevant to locum staff. This enabled easy access to the pharmacy's procedures.

The SI said he was empowered to exercise his professional judgement and could comply with his own professional and legal obligations. He said he raised any clinical issues which he had with the prescribers and could refuse to supply a medicine if he felt it was inappropriate. He said in these cases he would refer the person to their own GP or the clinical team. The pharmacy did not impose any financial targets on prescribers and prescribers were not paid based on the volume of prescriptions they issued.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean, well-organised, and provides a safe and appropriate environment for people to access its services. The pharmacy's website provides the relevant information to people. But the pharmacy could do more to ensure that information on its website about its prescribers and unlicensed preparations is clearer so people using the service are better able to make an informed decision about their care. And the pharmacy needs to comply with any guidance or advice provided by any other healthcare regulators.

Inspector's evidence

The pharmacy was located within a large industrial unit which also contained a warehouse and another pharmacy. The premises were clean, spacious and in a good state of repair. The temperature and lighting were adequately controlled. The premises were cleaned daily by a cleaner. The pharmacy was not accessible to members of the public. There was a steel mesh door between the pharmacy and the warehouse, and entry was restricted by a lock which required an access code. This had been installed to prevent access by people from the other pharmacy via the warehouse. Some of the pharmacy's stock including POMs were stored in the warehouse and some members of the warehouse team were authorised to access to the pharmacy. The pharmacy was on two floors. There was a compounding room, laboratory and sink on the second floor. The compounding room was cleaned around three to four times a day. Areas were decontaminated with various agents, including industrial methylated spirit, isopropyl alcohol, and distilled water. Staff had access to a tea-room with a kitchen area, and two WCs, with wash hand basins and hand wash. There was hot and cold running water.

Since the previous inspection, the pharmacy had changed its website so that people using the website were not able to select a POM before having a consultation with a prescriber. The pharmacy's website contained some information about the pharmacy, but the pharmacy's phone number and email address were not displayed, so people might find it difficult to contact the pharmacy by these methods. People were able to send a message via the website. There was a list of 25 UK registered prescribers on the website, who were all PIPs. The 'meet the team' section of the website included dermatologists and GMC registered doctors, so people might think they also prescribed for the service. People were informed that preparations were unlicensed in the FAQ section, which may not necessarily always be checked by people.

There were references to discounts on the pharmacy's website. The pharmacy was made aware that this was not in accordance with GPhC guidance. There was also an option to 'upgrade your routine with oral antibiotics'. The pharmacy lead said that people would have to complete the questionnaire as usual and upload videos, and it was up to the PIP to prescribe antibiotics or not. There was no evidence found on the inspection that medicines had been prescribed inappropriately. Following the inspection, the pharmacy lead confirmed that the option on the website to 'upgrade your routine with oral antibiotics' had been changed. These matters were discussed with the pharmacy during the inspection and referred to the MHRA for consideration.

Principle 4 - Services ✔ Standards met

Summary findings

Overall, the pharmacy manages and delivers its services safely. The pharmacy obtains its medicines and raw materials from reputable sources. And it carries out checks to ensure medicines are prepared safely and suitable to supply.

Inspector's evidence

Details about the pharmacy's services were stated on the website. Information about the ingredients and links to studies were available on the website as well as information on skin conditions and people's treatment journeys. People communicated with the pharmacy via the customer service team and could ask to speak to a pharmacist or prescriber.

People were required to set up an account when they started using the pharmacy's online services. The pharmacy operated a subscription model so people received monthly supplies once they had signed up. The pharmacy's IT system had multiple-account recognition and automatically flagged up duplicated information, such as post codes or telephone numbers. This helped prevent people creating multiple accounts and a team member would email the person to obtain further information or block the account if necessary. A person's previous order history was checked when reviewing a consultation to make sure any inappropriate requests were identified.

Responses in the online consultation could not be edited once submitted to the clinical team for review. Once the person using the prescribing service completed their online consultation and uploaded photographs of themselves, the prescribers reviewed these with reference to previous consultations where applicable. A new consultation was triggered if there was any change to the person's condition. Every request for treatment required photographs to be uploaded. The prescribing system highlighted people's responses to the online consultation in a colour-coded format. This drew attention of the prescribers to answers which required consideration such as pregnancy status and helped flag clinically relevant information easily. The pharmacy had a process in place for prescribers to escalate clinical queries to one of the clinical team leads.

Prescribers treated a limited number of conditions, and each condition had its own formulary. The prescribing system was able to remove formulations of medicines unsafe in pregnancy if a person stated they were pregnant when completing the online questionnaire. Although people could select any condition, the prescribers assessed the information provided against all conditions and decided the diagnosis themselves. People had the option to provide consent to share their treatment information with their GP. Letters were printed out and posted to the person's usual prescriber when consent was received, although confirmation of this did not appear to be recorded on the persons consultation records. Only a small percentage of people provided their GP details which could mean that most people's usual prescriber was not aware of treatments that they were receiving from the pharmacy. The pharmacy showed clear records where it had refused supplied, and these sometimes included antibiotics.

A sample of consultation records were reviewed during the inspection. Photographs, online questionnaire responses and previous clinical notes were visible on each person's consultation record. There was a visible audit trail of previous orders. And of who made comments and additions to the

record, including details of who prescribed the medicine(s).

The pharmacy prepared a range of unlicensed POMs, some of these were different forms of the same formulations such as creams and lotions. Several different batches were made each day. Some treatments were based on licensed products with additional ingredients. The medicines were prepared in the compounding room and labelled at a labelling station on the ground floor. The SI said that the pharmacy was following the principles of Good Manufacturing Practice (GMP), but the team did not make all the records required by the MHRA, as it wasn't necessary because they weren't regulated by them. Members of the team working in the laboratory wore full Personal Protective Equipment (PPE), including disposable gowns, hair nets, face masks, gloves, shoe covers and goggles.

Ingredients were purchased from reputable suppliers. The pharmacy requested Certificates of Assurance (CoA), conformity and GMP records for every batch ordered. Raw materials were either sent to a third party to carry out checks or tested in house using the pharmacy's own equipment before a supplier was used. Stock sheets were used to log the amount of stock prepared and their expiry date.

Worksheets were prepared by a team member and double checked by a pharmacist or ACT when compounding a product. The required ingredients were collected and placed in tubs which were used to mix the ingredients. The tubs were pre-labelled with the formulation, batch number, strength, and batch size. The ingredients were weighed by the compounding staff and double checked by a pharmacist or ACT. Ingredients were added according to the formula and specific mixing programmes were used depending on the formulation. The preparation was checked and signed by a pharmacist or ACT. A member of the production team carried out pH and density checks. A pharmacist or ACT carried out quality and texture checks, including colour and odour. Duplicate medicine labels were attached to batch sheets so that people could be contacted if there was an issue with a particular batch. The pharmacy kept records of any issues in the compounding process. For example, information missing on batch sheets, or incorrect expiry date and these issues were formally reviewed 6-12 monthly.

During development of new products preparations were tested to confirm that expiry dates generated by the pharmacy were appropriate. The pharmacy had equipment which it used for quality assurance, and this was used when formulating new products. The texture and pH of a samples were checked for stability over time. An oven and a fridge were available for stability testing. Assay checks to test concentration were not carried out.

Designated team members were responsible for labelling the filled plastic bottles and they had access to the production record spreadsheet. The spreadsheet detailed which preparation had been made, the amount, and the date it was made. There was a colour-coded system on the spreadsheet to help members of the team identify the stage of the process. The bottles were then labelled using a laser printer before being stored on designated shelves in the dispensary.

There were designated stations for processing and labelling prescriptions, packing, and assembling preparations, checking, and dispatch. Different coloured baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. Red baskets were used for people who were pregnant, so that additional checks would be carried out.

When dispensing the preparations, a dispenser placed the filled plastic bottle in an outer box and checked the label and medicine against the worksheet. Another dispenser labelled the outer box with the medicine label and carried out a second check. A final accuracy check was then conducted by an ACT or pharmacist. A worksheet and medication labels were used to dispense and check against during the dispensing process. Prescriptions were not routinely printed out, but the prescription could be

viewed and printed out if necessary. The pharmacy lead explained that the medication label was generated directly from the prescription, so there was no possibility of an error occurring when the medication label was produced. Dispensed by and checked by boxes were initialled on the medication labels to provide an audit trail. There was no clinical check by a pharmacist as part of the checking process. The pharmacy lead explained that it was not deemed necessarily as a clinical check had been carried out by the clinical team before the prescription was authorised and by the prescribing pharmacist.

A 'QR code' containing a link to a patient information page was printed on the outer box. This meant that people had access to up-to-date information about their treatment. Treatment guides were sent with initial supplies of a preparation. And people were advised that pregnancy needed to be reported to the pharmacy and treatment reviewed. There were regular notifications sent to people to remind them to update their medical information.

Medicines were sent using Royal Mail 48-hour service which could be tracked by the pharmacy and could be posted through people's letter boxes. People were notified once their treatment was dispatched. A returns log was maintained if an order was returned to the pharmacy. People were refunded if their orders were not delivered. Medicines which were returned were not re-used and were destroyed.

Alerts and recalls were received via email messages from the MHRA. These were read and acted on by a member of the pharmacy team. A copy was retained in the pharmacy with a record of the action taken so the team were able to respond to queries and provide assurance that the appropriate action had been taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

Members of the pharmacy team have access to the equipment and facilities they need for the services they provide. The team maintains and monitors the equipment it uses so that it is accurate and fit for purpose.

Inspector's evidence

A maintenance log was kept for all the equipment and machines used at the pharmacy. Balances used for measuring weight were tested regularly and calibrated annually by an external company. The pH meter was calibrated at least once a week. The filling and mixing machines were serviced annually and kept in good repair. There was a fume hood in the laboratory which was serviced yearly. Scoops, spoons, and spatulas were cleaned with soap and water, and alcohol. An ultrasonic cleaner was used for some items. Medicine bins were used to dispose of waste medicines. Members of the team had access to the internet and several up-to-date reference sources.

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.