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: 21/07/2021

Pharmacy context

This is a distance-selling pharmacy located within a large industrial unit in East London. The pharmacy dispenses unlicensed topical medications which it prepares on site for various skin conditions. The pharmacy uses pharmacist independent prescribers, as well as doctors, to prescribe these preparations. This inspection was undertaken 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's website allows people to select prescription-only medicines before they have a consultation with a prescriber.
		3.4	Standard not met	Members of staff working at another pharmacy can access this pharmacy's premises.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy doesn't always prescribe all of its medicines safely. When it prescribes antibiotics, it doesn't consider antimicrobial stewardship guidelines relevant for the person and their location. Most people do not give consent for their GP to be contacted about any medicines prescribed. And in the case of antibiotics, in the absence of this consent, the pharmacy does not always make a clear record setting out the justification for prescribing. The pharmacy does not use a robust process to check the identity of people who are prescribed antibiotics.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy generally identifies and manages the risks associated with the services it provides. It records and reviews near misses and dispensing mistakes to identify patterns or trends, and takes remedial actions to help avoid a reoccurrence. People can raise concerns and provide feedback about the pharmacy. The pharmacy generally maintains its records appropriately. But it could do more to ensure that relevant clinical information is consistently recorded (see Principle 4).

Inspector's evidence

The inspection was conducted by an inspector and a clinical advisor, with the superintendent pharmacist (SI) and pharmacy manager present.

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. The SOPs had recently been reviewed and were being held electronically pending authorisation. Members of the team would be asked to read these once they were authorised. 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.

A staff risk assessment had been carried out in response to the COVID-19 pandemic. Members of the team were also provided with an option to complete an individual risk assessment. Personal protective equipment (PPE) and hand gel were available for the team. Disinfectant wipes were available at all workstations to wipe down surfaces. There was an outdoor area for staff breaks and lunch breaks were staggered to support safe distancing measures. Lateral flow tests were done twice a week by all members of the team.

Dispensing mistakes which were identified before the medicine was handed to a person (near misses) were seen to be routinely documented in a logbook. A meeting was held every month with the pharmacy manager, pharmacist, SI and supervisor to review mistakes and discuss action required. Another meeting was then held with the rest of the team. A report of near misses, incidents and complaints was generated and shared with the team. This was also used to document any action to be taken, for example, the pharmacy had separated dispensing desks to reduce contamination between batches. It had also introduced a new step in the workflow where a designated person counted the number of baskets against the number of treatments before they were sent to the assembly section. The SI said that batches were never left half done.

Dispensing mistakes which reached people (dispensing errors) were also documented. The SI described a dispensing error where two patients' preparations were swapped as the baskets had been dropped at the packing stage. The SI said that baskets were now stacked a maximum ten high. Team huddles were held every Monday morning to discuss mistakes and members of the team had been made aware of this mistake and were briefed to double check dropped baskets. Products were seen to be packed in similar packaging which could increase the risk of picking errors.

Complaints and uncommon adverse events were documented in the relevant logs. The SI described a 'non serious' complaint where a preparation had been provided in a bottle with a faulty pump. He said the medicines were replaced. Another person was unhappy with their treatment. They were referred to

a doctor for review who advised them to see their GP for oral treatment.

The SI explained that the prescribers based their prescribing of the unlicensed preparations on clinical trials and information available on licensed combinations. The SI said that the pharmacy was not fully complying with guidance from the British Association of Dermatologists (BAD) or National Institute for Health and Care Excellence (NICE) but the products aligned with BAD guidance. He added that global clinical trials were reviewed by a clinical team which was led by one of the doctors. Prescribers had prescribing reviews and the team held monthly meetings where they conducted case reviews to learn from specific case scenarios. New prescribers had to complete 50 cases on a learning platform and had those consultations reviewed by the medical team. A prescribing risk assessment had been completed and signed by the SI, but he had not checked the clinical trial data referenced in the risk assessment. The SI said that monthly meetings were previously held with the clinical team, but he had not discussed guidance for some time with them. Risk assessments had also been carried out for each preparation of unlicensed medicine. These covered contraindications, potential adverse events, and risks of overuse or misuse. Links to the relevant references, such as the MHRA, were included within each risk assessment for easy access by the pharmacy team.

Routine batch audits were carried out. These involved reviewing documents, such as the batch number sheets, batch release sheets and bottle release (fill volume) records. The pharmacy was keeping records of any issues, for example, information missing on batch sheets, or incorrect expiry date. Temperature and humidity logs were in place and external companies were used for pest control and to maintain CCTV and alarm systems. The SI added that formal audits would be carried out in the future.

The electronic prescribing system held prescriptions, diagnosis, communication, photographs and consultation information. Consultation documentation and prescriptions could not be erased or changed. Members of the team understood their roles and responsibilities and were aware of the tasks they could and could not carry out in the absence of the responsible pharmacist (RP). The correct RP notice was displayed, and the RP record was well maintained. Controlled drugs and emergency supplies were not provided from the pharmacy. The private prescription register was held electronically. Samples of the register examined were complete and included a link to the original prescription. Records for unlicensed medicines were completed in line with requirements and included compounding steps, and calculations and formulas used. The pharmacy had current professional indemnity and public liability insurance which covered independent prescribing, overseas supply and compounding (preparation of unlicensed medicines).

A complaints procedure was in place and people were able to contact the pharmacy by telephone, email or via the website. People were also able to review and rate the pharmacy on various platforms, such as Trustpilot. People were emailed 24 hours after consultation to obtain feedback about the service they received. A complaints log was filled in with details of the complaint and any action taken by the pharmacy. A complaint was discussed where a group of people had completed questionnaires for different skin concerns but were prescribed the same treatments. One of the people was concerned that it was not a unique product and the pharmacy team had explained that some treatments had a wide range of benefits and could be used for multiple conditions.

Members of the team had completed online training on the General Data Protection Regulation. Computers were password protected and members of the team were not provided with access until they had completed the relevant training. Confidential information was obscured with a roller stamp or shredded. The pharmacy premises were not accessible to members of the public.

Team members had completed an online safeguarding course. The contact details of the local safeguarding team were displayed at the pharmacy and members of the team said they would search

for the contact details of the relevant team online, if they were concerned about a person who did not live locally.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members to manage its workload. Team members have clearly defined responsibilities and they do the right training for their roles. And they complete some ongoing training to help keep their knowledge up to date, although the pharmacy does not always document this.

Inspector's evidence

Members of the team were arranged in workstations, depending on their role and their responsibilities for the day. A rota was generated for the week and all members were aware of their responsibilities and what they could and could not do, including in the absence of the RP.

At the time of inspection, the main pharmacy was staffed by the floor manager (who was also a dispenser), two accuracy checking technicians (ACTs), two trained dispensers, three trainee dispensers and three assistants. The assistants were not enrolled onto a course but were only involved in packing and dispatch tasks. The compounding unit was staffed by two pharmacists and six qualified dispensers. Four dispensers were involved in preparing the unlicensed product and two operated the filling machines. One of the compounding pharmacists had been working at the pharmacy for over a year and a half and held a Masters in Pharmaceutics in addition to a pharmacy degree.

The pharmacy used 11 pharmacist independent prescribers (PIPs) to carry out consultations and to prescribe. PIPs were provided with in house training which included protocols and flowcharts. Prescribers were trained on how to conduct consultations and asked to complete 50 cases. They were provided with feedback and areas for improvements. The training did not include local or national guidance. Audits were conducted two weeks after a prescriber started live consultations, in order to review their consultations and prescribing patters. Monthly clinical meetings were held to discuss case examples and give feedback from audits anonymously. Supervision of PIPs was conducted by the clinical pharmacy lead who was a pharmacist. She had no dermatology experience in the past but had completed a Master's degree project focusing on a skincare lab-based microneedling product. PIPs were trained by a doctor.

The SI held a PhD in skin formulation and had worked in an aseptic unit at hospital and in production at a pharmaceutical company. He said that ongoing training was provided for the team though this was not always documented. Records were maintained for training completed at the start of employment. All members of the compounding team had completed a manufacturing course and an American-led compounding course. The manufacturer of the mixing machines also provided training to the team. The SI said that staff involved in compounding had read the formula documents and had been provided with in house training, for example, on measuring, calibrating, using machines and devices. He added that most members of the compounding team had previously worked in laboratories and had experience in the field. The SI kept up to date by reading a compounding journal. He had also completed training in quality assurance procedures.

A contingency plan was in place. The SI said that the pharmacy tried to keep the dispensing and compounding team as separate as possible. The clinical team was also trained in compounding and on IT systems, and all were currently working from home so could cover the pharmacy in an emergency. Several locum pharmacists and ACTs also worked for pharmacy and were familiar with its processes.

They were provided with training specific to their job role though not many were trained on the computer system, except the current full-time staff working on site and the clinical leads working from home. Staff always wore PPE, including face masks. Hand gel and disinfectant wipes were available at the workstations.

Performance reviews were conducted with all permanent members of the team. These were now being held every six months, rather than annually. Prescribers felt that the pharmacy had an open culture of sharing and that they could review each other and share feedback. Targets were not set for the team.

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

Summary findings

The pharmacy's website allows people to choose a prescription only medicine before beginning a consultation with a prescriber. This could mean that they may not receive the most suitable treatment option for their needs. The pharmacy does not sufficiently secure its premises from unauthorised access, as staff working at another pharmacy can access them. Otherwise, the premises are suitable for the services offered and are well maintained. The pharmacy could do more to ensure that the information on its website is accurate and provides the right information for people using it. And the pharmacy needs to comply with any guidance or advice provided by any other healthcare regulators.

Inspector's evidence

The pharmacy, which was not accessible to members of the public, was located within a large warehouse and comprised of two floors. The warehouse was split into two units, housing two pharmacies. The storage area, which was part of this pharmacy's registered premises, and located on the ground floor, was also accessed by members of the team of the second pharmacy. This was discussed with the SI who said that the storage area could be deregistered and separated from this pharmacy so that both pharmacies could access it. An office was also located on the ground floor.

The pharmacy was well organised. There were separate stations for processing and labelling prescriptions, packing and assembling preparations, checking, and dispatch. Two spacious laboratories were located on the mezzanine floor of the unit. PPE, including goggles, hair nets, shoe covers and lab coats, was stored in the corridor just outside of the rooms. A sink and laboratory safety shower were also fitted in the corridor.

The premises were cleaned daily by a cleaner. Surfaces were disinfected at least once a day and the laboratories were cleaned multiple times, between each block of treatment/preparations. Areas were decontaminated with various agents, including 70% and 100% isopropyl alcohol. All utensils were rinsed with distilled water. A deep clean of the laboratories was done every month.

The pharmacy's website generally displayed the required information. However, people accessing the website were able to select a prescription only medicine before having a consultation. The website also provided two pharmacy addresses, one of which was no longer in use according to the pharmacy manager. This could cause confusion as to where the preparations were being provided from. It was also unclear who was prescribing the preparations as the list of UK registered prescribers included only pharmacist independent prescribers (PIPs), whereas the 'meet the team' section of the website included dermatologists, doctors and nurses. The website also promoted the pharmacy's preparations as 'custom made' which could be misleading to members of the public as preparations were made in large batches. The pharmacy was promoting its unlicensed, prescription only preparations on its website. And it was offering these via a free trial, where people only paid the postage fee. This was discussed with the SI during the inspection. And the MHRA is considering these matters.

The ambient temperature and lighting were adequate for the provision of pharmacy services.
The building itself was secure from unauthorised access.

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

Summary findings

The pharmacy doesn't always prescribe all of its medicines safely. When it prescribes antibiotics, it doesn't consider antimicrobial stewardship guidelines relevant for the person and their location. Most people do not give consent for their GP to be contacted about any medicines prescribed. So, the pharmacy does not always proactively share information about prescribed treatments with other people responsible for a person's care. And in the case of antibiotics, in the absence of this consent, the pharmacy does not always make a clear record setting out the justification for prescribing. And the pharmacy does not use a robust process to check the identity of people who are prescribed antibiotics. However, people can access the pharmacy's services easily. The pharmacy obtains medicines and raw materials from reputable sources.

Inspector's evidence

The pharmacy premises were not accessible to members of the public. Medicines were delivered to people living in the UK and some European countries using Royal Mail. The pharmacy's website was user-friendly and provided clear information about the ingredients used in the pharmacy's preparations.

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. The pharmacy team would email the person to obtain further information or block the account.

Dispensing audit trails to identify who prepared, packed and checked medicines were completed. This helped identify who was involved in these processes. There were designated stations for each tasks and baskets were used to separate prescriptions and prevent transfer between people.

The pharmacy prepared 36 unlicensed, prescription only preparations, mainly for the treatment of acne, melasma, hyperpigmentation, rosacea and ageing. Approximately 15-20 batches were made each day. Formulations were obtained from an external pharmaceutical compounding company and reviewed by the clinical team. Some treatments were based on licensed products with additional ingredients.

The pharmacy lead explained that there were numerous reasons why the pharmacy used particular unlicensed products. These included better patient compliance with combination therapy, ability to use excipients that were more effective for patient skin conditions and the ability to titrate doses more finely. Also, there were currently no licensed options for hydroquinone. Risk assessments had been carried out on all of the treatments the pharmacy offered.

People were asked to select their condition, such as acne, rosacea or pigmentation, before being directed to a registration form. Once registered, they could complete an online consultation and upload photographs. People had the option to provide consent to share their treatment information with their GP. Only 4% of people provided their GP details to the pharmacy which could mean that most people's GPs were not aware of treatments they were receiving from the pharmacy.

Routine queries were referred to a clinical lead who was based in the USA. And the SI added that the

clinical lead was accessible all the time. The SI was not entirely sure what guidance the prescriber in the USA referred to and said that local guidance was not taken in account when prescribing antibiotics in the UK. If antibiotics were prescribed in the absence of consent to contact a person's GP, the pharmacy did not always make a clear record of the clinical justification for prescribing. Following the inspection, the clinical lead said that the pharmacy followed national guidelines when prescribing antibiotics, specifically NICE guidelines, and that topical antibiotics were only prescribed when clinically necessary in acne and rosacea. Oral antibiotics were not prescribed.

The pharmacy did not carry out identification (ID) checks for all people accessing its services. A person's age was asked for as part of the clinical assessment process by the prescriber. The prescriber checked the person's name, sex and date of birth against the three photographs that the person was asked to upload as part of their consultation. If the prescriber felt the need to confirm the person's age they contacted the person and requested proof of their ID. This may not be the most robust way of confirming a person's age.

Approximately 4% of consultations were rejected and people referred to their GP for treatment. A 'refusals log' was maintained which included reasons for refusal, for example, previous allergic reaction, skin concerns not affecting the face, or a skin condition not currently treated by the pharmacy. The clinical pharmacy lead sent a 'referral to GP' list following the inspection. This was relatively vague, for example, it stated 'suspicious lesion' but did not clarify how the pharmacy differentiated between suspicious and non-suspicious lesions. Following the inspection, the pharmacy sent a copy of the GP referral and triage SOPs. But these did not cover some exclusions in detail, for example, how a prescriber could differentiate between a suspicious and non-suspicious lesion.

Online questionnaires were sent to the clinical team who issued a prescription if appropriate. The prescription was sent electronically to the pharmacy and could not be amended. The clinical team was predominately made up of pharmacists and dermatologists. Prescriptions were triaged by a pharmacist. Patient questionnaires which were relatively straightforward were sent to a PIP to review and prescribe a preparation. The PIPs had access to a team of dermatologists who were involved in developing the prescribing hierarchy and treatment algorithm. All prescribers had access to the dashboard platform where patient information, treatment plan, patient communication and records of all clinical team correspondence were stored. The dashboard could also be accessed by people wanting to find out about the treatments they have received. A sample of clinical notes were sent following the inspection. These did not always include all the relevant details. For example, one patient had breakouts in the chin and the prescriber had recommended the addition of clindamycin to the treatment, but did not clarify the rationale behind this decision.

Once received, prescriptions were printed out and placed in baskets according to the treatment prescribed. The unlicensed product was prepared in the laboratory and labelled at the labelling station. The member of staff responsible for labelling the filled bottles had access to the production record spreadsheet which 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. For instance, once a batch was made, the spreadsheet was coloured yellow but once the bottles were filled it was changed to green. Failed batches were coloured red and the spreadsheet was updated with the reason, for example, if the formula was incorrect. Members of the team involved in labelling checked the batch sheets and the production record to create labels. The bottles were then labelled using a laser printer before being placed in bags or boxes, alongside the batch sheet. These bags and boxes were stored on designated shelves labelled with details of the preparation. The 'assembler' placed the filled bottles in an outer pack and checked the label, product and backing sheet. The dispenser labelled the outer pack with the medicine label. A final check was then conducted by an ACT or pharmacist.

A ‘QR code’ containing a link to a patient information page was printed on the outer pack. This meant that people had access to up-to-date information about their treatment. The pharmacy conducted reviews with people every three months to monitor their progress. People were referred to their GP if their symptoms did not improve.

Boxes were packed in mail bags at the dispatch station. The preparations were sent using Royal Mail 24-hour service and could be posted through the letter box. People were notified once their treatment was dispatched. A returns log was maintained if an order was returned to the pharmacy. Several orders were seen placed in a designated area. The SI explained that customs from some European countries had returned these as some were missing customs declarations. People were refunded if their orders were not delivered.

There was a clear workflow in the laboratory. The laboratory was clean and organised. The SI said that the pharmacy was following Good Manufacturing Practice but not documenting this. Members of the team working in the laboratory wore full PPE, including disposable lab coats, hair nets, face masks, gloves and goggles.

Worksheets were prepared by the compounding staff and double checked by the pharmacist. Stock was collected and empty tubs used to mix the ingredients were pre-labelled with the formulation, batch number, strength and batch size. Two to three batches could be made at the same time though designated areas were used for each batch. Material was weighed by the compounding staff and double checked by the pharmacist. Ingredients were added according to the formula and specific mixing programmes were used depending on the formulation. Once ingredients were mixed, the preparation was checked and signed by the pharmacist. Batches were stored in cupboards labelled with the formulation and were normally used within one to two days. The pharmacy carried out quality and texture checks (including pH, colour, odour and density), including on samples placed in an oven and a fridge. The pharmacy had recently purchased a quality assurance machine to analyse samples of their preparations.

Base ingredients were purchased from reputable suppliers. The pharmacy requested certificates of assurance, conformity and Good Manufacturing Process for every batch ordered. Raw materials were first sent to a third party to carry out checks before a supplier was used.

Preparations were currently sent to a third-party laboratory for testing and to confirm that expiry dates generated by the pharmacy were appropriate. In-house testing would be carried out in the future as the pharmacy had purchased a machine for this. Stock sheets were used to log the amount of stock prepared and their expiry date. This was reviewed every week and the stock checked.

Medicine labels were attached to batch number sheets so that people could be contacted if there was an issue with a particular batch. The SI described an incident were several people had reported texture changes to their preparations as their treatments had been left out in post boxes during cold weather. They were asked to send their preparations back to the pharmacy for testing. The pharmacy had carried out texture, smell and pH checks on the preparations and found these to be within the parameters set by the pharmacy. The pharmacy had based the parameters on in-house tests done on multiple batches and on quality checks made by other specials manufacturers. Serious drug reactions were reported through the Yellow Card Scheme. The pharmacy had reported one adverse reaction. Minor reactions, such as stinging and burning were not reported but documented on an ‘issues log’.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely. And it takes steps to ensure its equipment is appropriately maintained.

Inspector's evidence

A maintenance log was kept for the equipment and machines used at the pharmacy. Laboratory pressure checks were conducted daily. Balances used for measuring weight were calibrated annually by an external company and tested daily. The pH meter was calibrated at least once a week. The filling and mixing machines were serviced annually and fixed as and when needed. Scoops, spoons and spatulas were cleaned with soap and water and alcohol. The pestle and mortars were soaked in detergent and washed. An ultrasonic cleaner was available for some items. Fridges and ovens were available to help the team conduct stability checks. 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.