General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Monderma, Unit 2C, Gazelle Buildings, Wallingford Road, Uxbridge, UB8 2RW

Pharmacy reference: 9012305

Type of pharmacy: Internet / distance selling

Date of inspection: 03/10/2024

Pharmacy context

This is a distance selling pharmacy located in a business park on the outskirts of Uxbridge. The pharmacy specialises in the preparation and supply of specially made medicines to treat skin conditions. And the medicines are prescribed by pharmacist independent prescribers (PIPs). The pharmacy offers its services via its website www.monderma.co.uk. And it is not open to the public. Medicines are delivered to people using a tracked postal service. The pharmacy first registered in January 2024, but it had only recently started trading.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy has documented risk assessments, prescribing policies and operating procedures, so it can demonstrate that it supplies medicines safely. And it generally keeps appropriate records as required by law and for good governance. For its current level of business, the pharmacy identifies and the manages risks associated with its services adequately. But as the service continues, the pharmacy needs to do more to measure and monitor the safety, effectiveness and appropriateness of the medicines it supplies. And it must ensure that it keeps all the records required by law.

Inspector's evidence

The pharmacy specialised in compounding and supplying creams against prescriptions issued by a pharmacist independent prescriber (PIP). And it provided the service through its website www.monderma.co.uk. The PIP was UK based and provided prescribing services for UK customers only. The pharmacy did not supply other medicines such as fridge items or controlled drugs.

At the time of the inspection the pharmacy had dispensed and supplied medicines against a small number of prescriptions only. And so, it operated on an occasional basis. The business was managed by the sole director of the company which owned the pharmacy. The superintendent pharmacist (SI) worked as the responsible pharmacist (RP). And he worked separate to but closely with the pharmacy's pharmacist independent prescriber (PIP). The PIP worked remotely from the pharmacy. The SI had taken over the role from the previous SI in February 2024, six weeks after the pharmacy had opened. The pharmacy kept an RP log as required by law. And RPs completed the log on arrival at the pharmacy when they were required to make a supply against a prescription, or when any pharmacy activity including the compounding of medicines took place. The director confirmed that the pharmacy had professional indemnity insurance and that this covered all aspects of the service. The PIP had his own personal insurance which covered his prescribing role. The pharmacy's complaints procedure was explained on its website, and the pharmacy sought feedback from people accessing the service using various online messaging and social media platforms. The team also encouraged people to let them know about any unusual reactions to any of the products prescribed. The director described how they had reviewed their formulations when people reported having unusual or unexpected skin irritations from using the creams.

The pharmacy compounded topical unlicensed medicines for four skin conditions. Conditions treated were acne, rosacea, ageing skin and hyperpigmentation. The preparations all contained prescription only medicines. The pharmacy had developed several different formulas tailored to different needs. People accessing the pharmacy's services completed an online questionnaire to request a treatment. Alongside the questionnaire they were required to provide photographic images of their condition. And if required prescribers made a video call to people to ensure that they could ask any additional questions and view their skin condition.

People were required to register an account when purchasing a medicine. This meant their ordering history was retained with their account when they made further requests. The formulations and the online questionnaire had been developed on the advice of a dermatology consultant, the pharmacy's PIP and the SI, who had experience in the preparation and compounding of topical medicines. The pharmacy had produced basic monographs for each active pharmaceutical ingredient. And these were

being reviewed to improve them. The monographs had been produced from reference to prescribing guidelines and scientific articles from recognised organisations specialising in treating skin conditions such as the British Association of Dermatologists, the NHS, NICE guidlines and the Journal of American Academy of Dermatology. The SI explained that he had a professional background in pharmaceutical manufacturing. And he was aware of industry standard reference materials. He also had experience of using similar unlicensed preparations whilst working as a quality director for Imperial College NHS Healthcare Trust in north-west London.

Completed online questionnaires were reviewed by the prescriber who approved or refused to supply based on the person's responses. The managing director explained circumstances where a person may be refused a prescription. For example, if someone had made too many requests for the same product. Or if someone was breastfeeding, trying to conceive or pregnant. The pharmacy had a documented prescribing policy explaining the inclusion and exclusion criteria or treatment plans associated with each condition and for each active pharmaceutical ingredient. And within its governance procedures and prescribing policies it had included documented risk assessments. This showed that it had considered the risks prior to commencing the service. And how it proposed to manage them on an ongoing basis. The pharmacy had not yet completed any audits to confirm prescribing was appropriate. But it proposed to do so on a six-monthly basis and when a risk assessment deemed it appropriate.

The pharmacy had standard operating procedures which had been developed by the SI and the current PIP. The SOPs covered the pharmacy's operational activities. And included the consultation process, the screening process, the compounding and dispensing process, the process for releasing the product and delivering it. And a follow up process where the prescriber would assess whether the product was suitable and effective for a person . And whether a repeat supply was required. Processes still to be covered by an SOP included, pharmaceutical stock management, safeguarding and security. The pharmacy used a bespoke software system and records were integral to the pharmacy's website. The website provided a prescription form which prescribers completed and printed out before adding a wet signature.

The pharmacy could view what had been prescribed. So that it could begin the compounding process. Compounded preparations were not dispatched until the pharmacy had received the original prescription. Records of supplies contained the person's details including their name, address, email, telephone number and date of birth, the completed questionnaire, details of any previous supplies and any feedback or responses. This meant the SI could review this information when considering whether to authorise a supply. The records identified the prescriber and the date they had authorised the supply. Records contained a prescribing notes section, but this was not always completed to show what additional checks the prescriber had completed or how they had made their decision whether to prescribe or not. However, while the pharmacy held records of supplies for each person. It did not keep a dedicated private prescription register. The director, the SI and the inspector agreed that it was important that the pharmacy kept all the records required by law.

The pharmacy was registered with the Information Commissioner's Office. Its privacy policy was displayed on the website. And team members had read and signed a confidentiality agreement. Confidential material was stored securely, and the computer system was password protected. The pharmacy used a recognised system for checking people's identity including their age. And the managing director, pharmacists and prescribers had completed appropriate safeguarding training. But the pharmacy did not have a formal safeguarding policy explaining how potential concerns should be managed. And it did not always seek to verify people's healthcare information or inform their usual doctor about the additional medication they had been prescribed.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage the current workload. And its team members have the appropriate skills and training for their roles. The pharmacy effectively supports its team members to communicate with each other. So, they can discuss concerns and help the pharmacy make improvements.

Inspector's evidence

The pharmacy's workload was very low, and it could be easily managed by the team, who all worked on an ad hoc basis. During the inspection the team consisted of the managing director and the SI. The pharmacy also had part time pharmacist and a technician on its team who worked at the pharmacy when required. The SI worked as the RP currently. But the pharmacy had recently recruited an additional part-time pharmacist and a technician. Both new team members had a background in compounding medicines. The current technician also had a background in compounding topical skin preparations. And she worked under the supervision of the RP when preparing batches of medicines. And she did not do any compounding in the absence of the RP.

The managing director coordinated the team and administrated the business. He had not completed any clinical or pharmacy related training. Instead, he handled general queries and sometimes helped to dispatch prescriptions. The SI, PIP, pharmacist and technician provided advice and support to the director when required.

The SI had completed his training in dermatology. He also worked regularly at the Imperial College NHS trust. The pharmacy's PIP had also completed training in dermatology. The training had been provided by The British Association of Dermatologists. And he also worked closely with a consultant dermatologist working in a hospital setting, who was available to support and advise him with his prescribing. And refer him to up-to-date prescribing practices. Team members appeared to work supportively with one another. And the director acted as their main point of contact. Team members described being able to easily discuss any issues and concerns. And being supported to find solutions to any problems they encountered.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy’s premises are suitable for the service it provides. Its website provides useful information about the pharmacy and the service it offers.

Inspector's evidence

The pharmacy was in a large business unit on a business park. It occupied two main floors. The ground floor had a reception area with office space and a staff area. And it had a bay for receiving deliveries and dispatching dispensed medicines. It had a doorway for team members to enter and exit. And it had a shuttered opening for receiving and dispatching goods. Its upper floor had a small storage room. And a large dispensary. The dispensary was designed to provide an efficient workflow with work benches on three sides. Its work benches had been assigned to different activities. One run of work bench was used for weighing and measuring out raw ingredients and compounding them. And another for dispensing, labelling and accuracy checking each formulation against its prescription.

The pharmacy was well lit, bright and modern. And it was clean, tidy and well laid out. It was secured when not in use. And it had air conditioning and temperature controls in place. And it was suitable for the preparation and storage of medicines. The pharmacy’s website contained information about the service. It provided information about the company and the products it prescribed. It also had information about the managing director, the SI, the PIP, the pharmacist and the technician, as well as contact details.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy generally manages its service safely. It sources its pharmaceutical ingredients through approved UK suppliers. The pharmacy follows appropriate procedures when compounding unlicensed medicines to make sure these are safe to use. And it provides people with enough information about their medicines to make sure they understand the risks.

Inspector's evidence

The pharmacy promoted its services through its website. And people could contact the team by email, telephone or through the online form on the website. The managing director generally managed most communications of a non-clinical nature. And he was usually contactable when the pharmacy was closed.

To date the pharmacy had compounded and dispensed medicines for a low volume of prescriptions. And the managing director was actively promoting the business whilst observing the MHRA restrictions around advertising prescription only products. But while the business was growing the team had taken time to try to develop and improve the quality of its skin product formulations. And so, the pharmacist, technician and SI assessed formulations for consistency, smoothness and stability whilst taking feedback from people on their opinion about the effectiveness and quality of each product from a user's point of view.

The pharmacy did not stock or supply any conventional medicines. It sourced its raw ingredients for compounding from recognised producers registered with the MHRA. Raw ingredients were obtained directly from the UK or through a licensed importer in the UK, in line with requirements. Pharmaceutical ingredients were stored in original containers in the pharmacy with batch number and expiry dates. Certificates of conformity were available for pharmaceutical ingredients.

Unlicensed medicines were prepared in small batches. And team members used a formulation sheet to record each stage of the preparation. They gave each batch a number. And they used the sheet to record the batch number, the date of preparation, who had prepared it. And the percentage and weight of each pharmaceutical ingredient used. Team members also recorded the key steps of preparation. And they made notes about the perceived quality of the resulting product. This had led to the team to make small adjustments to formulations to improve the quality of each product for people using them. Each batch was given a 28-day expiry date. Which was in line with standardised practice for compounding other extemporaneously dispensed medicines in hospital trusts. But the pharmacy had not yet conducted any formal external assays to assure itself of the quality or stability of the unlicensed medicines to provide assurance about its compounding processes and the end products.

The PIP, pharmacists and technician could contact people requesting medicines by telephone or make further enquiries about their clinical need. The PIP based his prescribing decisions on the questionnaire. And people's purchasing history available on the system alongside any additional notes relating to adverse reactions or people's feedback. The team could recall incidents when supplies had been refused. The pharmacy did not have a clear process for follow up and monitoring which was relevant given the medicines were unlicensed, and the efficacy and side effects could not be assured in every case as products continued to be developed. Instead, the SI or PIP encouraged people to inform them if

they experienced any problems. Or if there had been any changes to their circumstances, such as becoming pregnant or breastfeeding. This was then taken into account on the issue of a repeat prescription 28 days later. And so, it was evident that a more formal process for monitoring and review was necessary. Prescriptions were generally issued as repeats, with a maximum of four supplies issued before a further assessment was carried out and the patient contacted. This was influenced by the pharmacy's risk assessment and clinical prescribing restrictions for any particular medicines, such as preparations containing antibiotics.

The pharmacy had implemented safeguards to ensure compliance with good practice guidance and antimicrobial stewardship. And antibiotic containing preparations were only prescribed when deemed appropriate and necessary. The team had carried out an additional risk assessment for products containing clindamycin. Where it would only be prescribed for cases of severe acne such as cystic acne. And only where someone had provided clear photographic evidence of microbial infection. When indicated, clindamycin would be prescribed on no more than 3 consecutive months and in line with current prescribing guidelines, to minimise the risk of antimicrobial resistance. Where someone with cystic or severe acne would not respond to clindamycin, the pharmacy would request their GP consent if they had not already provided it. And if the person chose not to provide consent, the pharmacy recommended that they contact their GP or local trust directly. And after a month, the pharmacy would check-in to see if they had done so. For counselling purposes, each person who was prescribed clindamycin would receive a clinical effectiveness call after their first week of treatment and another call upon completion of their treatment. But at the time of the inspection the pharmacy had not yet supplied any products containing clindamycin.

Compounded medicines were dispensed into containers with a pump to control the dosage amount. When a prescription was dispensed the container was placed inside a box and a dispensing label was applied. Medicines were then placed in discreet protective packaging and dispatched using a tracked 24-hour delivery service. The medicine container and its box were both labelled with ingredient details, an expiry date and warning labels to 'keep out of reach of children.' And the team had produced a patient information leaflet to accompany each supply. The leaflet identified the potential actions, uses , side effects and contraindications for each ingredient The batch details of the medicines supplied were documented on the person's record. And the pharmacy could search the system for people who had received a specific batch if one was found to be defective. The director said that substandard or expired batches were set aside to be discarded safely later. The pharmacy had a pharmaceutical waste contract. But the business had not had much waste yet. The director and SI agreed that it was essential to dispose of any pharmaceutical waste safely and appropriately.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for the services it provides. The team maintains and monitors the equipment so that it is accurate and safe to use.

Inspector's evidence

Team members had access to the internet and appropriate reference sources. Equipment included scales, mixing utensils and an Unguator. The Ungator is a machine which mixes and dispenses each individual preparation directly into its final pot. Each pot was designed to deliver a specified dose. And the pot could then be dispensed and labelled as usual. The system was designed in this way to reduce the risk of contamination. Individual pots could be disposed of by people the contents had been used up.

The pharmacy measured weighed and prepared its medicines in a laminar air flow cabinet. The cabinet had a high efficiency particulate air (HEPA) filter. Air drawn through the filter was blown in a way which separated the interior of the cabinet from the people using it and the environment around it. The cabinet was designed to have no gaps or joints where contaminants might collect. The team kept equipment clean. And it had cleaning materials available. Team members calibrated the pharmacy's scales regularly and proposed to have them calibrated periodically by an external company. Team members had access to appropriate personal protective equipment. And they wore this equipment when preparing medicines. The pharmacy used appropriate containers and packaging for dispensing and dispatch purposes.

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.