General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: The Feel Good Pharmacy, Unit 5, Oakwood Business Park, Standard Road, London, NW10 6EX

Pharmacy reference: 9011329

Type of pharmacy: Internet / distance selling

Date of inspection: 28/10/2021

Pharmacy context

This is a distance selling pharmacy located in a business park in north west London. The pharmacy dispenses specially made medicines prescribed by pharmacist independent prescribers (PIPs) to treat skin conditions. The inspection took place during the COVID-19 pandemic. All aspects of the pharmacy may not have been inspected.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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 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's working practices are generally safe and effective. It has up-to-date written procedures which tell team members how to manage risks and work safely. The pharmacy enables people to give their views on how it can improve its services. The pharmacy's team members keep satisfactory records they need to by law so they can show the pharmacy is providing safe services. They have introduced new ways of working to help protect people against COVID-19 infection. The pharmacy's team members understand their role in protecting vulnerable people. And they keep people's private information safe.

Inspector's evidence

The pharmacy only compounded and supplied creams against prescriptions issued by the pharmacist independent prescribers (PIPs) at the online prescribing service which people contacted via its website www.skinandme.com. The PIPs were all UK based and they only provided prescribing services for UK customers. The pharmacy did not supply any creams via a pharmacy website. And it did not supply other medicines such as those medicines needing to be kept in a fridge or controlled drugs.

The pharmacy had systems to review dispensing errors and near misses. Members of the pharmacy team and the PIPs team attended regular clinical governance meetings. They reviewed the mistakes they made to learn from them and reduce the chances of them happening again. The pharmacy team was able to track individual ingredients which were used in production of specific batches and quarantine any remaining at the pharmacy. And they could contact any people who may have been supplied a particular batch of a cream. The responsible pharmacist (RP) described an incident regarding the quality of one of the creams. The pharmacy team reviewed and adjusted the method of production and arranged for the equipment used to be serviced. They reviewed and adjusted the quality control process post-production to ensure early detection of any future similar issues. An issue was identified with the dispensing container mechanism, the pharmacy changed the design of one of the components to correct the problem. The prescribing service had procedures to identify, record and report an adverse incident, including near miss and serious untoward incidents and the outcome. A PIP described changing the formulation of a cream in response to feedback about reactions to the cream. This resulted in a statistically significant reduction in reactions. The prescribing service implemented a change management plan if they identified error trends in prescribing.

The pharmacy had up-to-date standard operating procedures (SOPs) for the services it provided. SOPs stated information such as the author’s name, who approved the SOP, dates of preparation and review. They included procedures for production, quality control, hygiene control and product recall. The SOPs were based on good manufacturing practice (GMP). Members of the pharmacy team were required to read and sign the SOPs relevant to their roles to show they understood them. They knew what they could and couldn’t do, what they were responsible for and when they should refer to the RP for help. And their roles and responsibilities were described within the SOPs. The RP explained that they would not dispatch medicines from the pharmacy with the courier for delivery to people if a pharmacist was

not present.

The pharmacy had a complaints procedure detailed in the SOP for dealing with incidents, near-misses and complaints. People wishing to report a concern or complain could contact the customer service team via an email address on the prescriber website. Customer services forwarded the complaints information to the pharmacy. The superintendent pharmacist (SI) reviewed complaints on a regular basis. The pharmacy received service user feedback through customer service. Feedback was generally about skin treatment. People posted online feedback via Trustpilot on the prescribing service website.

The pharmacy had risk assessed the impact of COVID-19 upon its premises and the employees. There was a COVID-19 policy for the pharmacy. The pharmacy team members self-tested for COVID-19 twice weekly. Members of the pharmacy team knew that any work-related infections needed to be reported to the appropriate authority. They wore fluid resistant face masks, and their desks were socially distanced to help reduce the risks associated with the virus. They washed their hands regularly and used hand sanitising gel when they needed to.

Staff members in the production room wore protective gear to help reduce the risk of contamination of the production room and the creams which were compounded there. Pharmacy team members first entered a changing room and put on protective gear which covered hair, footwear and clothing before washing their hands with knee-operated taps. Upon entering the production room, team members wore protective single-use gloves. The pharmacy was distance selling so it was closed to the general public and there was no face-to-face contact with people who used the pharmacy's services.

The pharmacy team had completed risk assessments to identify and mitigate risks in the pharmacy procedures such as pharmacy review which assessed the risks identified when clinically screening prescriptions, and the mixing process for the formulations of cream. A Control of Substances Hazardous to Health (COSSH) risk assessment had been completed for substances used in the pharmacy such as excipients, active pharmaceutical ingredients (APIs), chemicals used with quality assurance equipment and cleaning materials. The prescribing team had recently risk assessed the prescribing process to identify risks associated with consultation and diagnosis leading to prescribing a cream. The risk assessment included the active ingredients rather than each formulation.

The pharmacy team undertook ongoing audits to monitor the safety and quality of the services it provided. These included traceability of active pharmaceutical ingredient (API), compliance with expiry dates and filing certificates of analysis (CoAs) in line with GMP requirements. The team concluded from the results that they were confident in the system for tracing APIs. The pharmacy review audit monitored the initial screening process when the prescriptions were received each day. And all prescribers were audited every month by looking at a random sample of prescriptions and follow-up consultations. Prescribing audits highlighted when prescribers didn't follow a designated process.

The pharmacy dispensed prescriptions issued by a team of PIPs who were based at 'Skin and Me'. There was an audit trail on the computer system of who prescribed each item and all the prescribers had electronic signatures. They prescribed in line with National Institute for Health and Care Excellence (NICE) guidance and had an in-house formulary of products compounded by this pharmacy listing indications, strengths, contraindications and side-effects. And they had prescribing guidelines (or algorithms) to use in conjunction with a prescribing handbook. The team had a prescribing policy for the different conditions they treated, and they used the algorithms to decide on treatment options and when to refer the person. The PIP team members would prescribe treatment for certain skin conditions but if the condition became more severe or was not improving, the PIPs knew to refer the person for different treatment options.

Regarding prescribing of antibiotics, the PIPs followed NICE antibiotic resistance guidance and stewardship guidance. The antimicrobial guideline was written in Nov 2021 and did follow NICE guidance where guidance was available. But the consultation questionnaire did not ask for information about prior antibiotic use or gain consent to share information about the prescriptions for antimicrobials with other healthcare professionals involved in their care such as the person's doctor. The PIPs did not prescribe antibiotics for someone already being treated with antibiotics due to the risk of developing resistance.

The prescribing dashboard contained a file for each individual person. The PIPs documented all communications, consultation and photos on the prescribing dashboard which required login. And the PIPs kept records on the prescribing dashboard of diagnoses, treatment and also when they referred the person or were unable to treat them. The PIPs checked patient identity and age during the initial signing up process with a new person and they obtained consent to share the person's information with this pharmacy. So, pharmacists at the Feel Good Pharmacy could see all the consultation information recorded by the PIP. The RP did occasionally contact PIPs to recommend patch tests or query prescriptions. All people were asked to consent to share information on all prescribed oral and topical treatments from their doctor, but the service did not have consent of people to share information with their doctor. The pharmacy stored non-identifiable patient reaction data.

Patient information leaflets (PILs) on the prescriber website provided comprehensive information and were patient focused. They informed people that the topical medications supplied were unlicensed. The risk of using tretinoin, clindamycin and metronidazole products during pregnancy, breastfeeding or when trying to conceive was emphasised during the consultation, on packaging, within PILs, and through the person's account and email communications every month. And the PIPs reiterated this information and asked about changes to medical eligibility: pregnancy, breastfeeding and conception every month with the person's new supply of medicines. They assessed patients at a follow-up consultation to deal with any reaction concerns at that point. When people were reviewed their treatment may be adjusted or stopped. They were advised on managing their condition.

Upon receipt, the RP screened prescriptions to identify people with allergies, certain medical conditions or who were pregnant or breast feeding. Following the clinical check by the RP, the prescription was transferred to the dispensing area. The RP had oversight of the production process. The pharmacy team created a proforma containing the information on the required formulation of skin cream to be compounded. The ingredients and % ingredients in the requested formulation were checked. The proforma was sent to the production room to be mixed. Stock batches of creams were made up under S10 of the Medicines Act.

Each ingredient was supplied to the pharmacy with a certificate of analysis (CoA) which provided an assurance of the quality of that ingredient. The pharmacy could refer to the manufacturer for information on stability. The pharmacy team created a unique audit trail for each ingredient on receipt from suppliers. So, an individual ingredient could be tracked from arrival from the supplier to the finished batch of cream. And to whom it was supplied. The pharmacy recorded all information regarding unlicensed preparation in the Extemporaneous Compounding Log which included the formula, the mixing process, the ingredients (CoAs, BSE/TSE (Bovine/Transmissible Spongiform Encephalopathies (TSE)) statement and batch number), patient details, prescription details and concerns.

The pharmacy displayed a notice that told people who the RP was and kept a record to show which pharmacist was the RP and when. The SI confirmed that the pharmacy had insurance arrangements in place, including professional indemnity, for the services it and the PIPs provided. The pharmacy did not maintain a controlled drug (CD) register as no CDs were supplied. The pharmacy recorded the private

prescriptions it dispensed electronically although not in a single private prescription register. Following the visit, the SI gave an assurance that going forward prescriptions would be recorded in line with requirements and an updated version of the private prescription register was devised. An intervention record was maintained for rejected prescriptions and reasons they were rejected. The pharmacy maintained records for preparing unlicensed medicines as the 'Extemporaneous Compounding Log'. So documents and information associated with preparing a specific batch of a cream could be easily viewed or located.

The pharmacy team had completed General Data Protection Regulation (GDPR) training and there was a GDPR manual. The pharmacy was registered with the Information Commissioner's Office and a privacy notice was displayed on the prescriber's website. Team members disposed of confidential wastepaper securely. The pharmacy's computer was password protected and members of the pharmacy team had appropriate access specific to their roles. All patient information on the prescribing service computer system was protected by VPN access.

The pharmacy had a safeguarding SOP and an appointed safeguarding lead person. The pharmacists had completed level 2 safeguarding training. Members of the pharmacy team knew what to do or who they would make aware if they had concerns about the safety of a vulnerable person. The PIPs team and Customer Services team were trained in safeguarding. Common safeguarding issues which may be identified in people accessing the treatment included: age being inappropriate, unclear photographs supplied so the PIP was unable to assess the skin, presenting with a condition which was contra-indicated with the treatments available and signs of mental health issues such as picking skin which would result in a referral to their doctor.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough suitably trained team members to deliver its services safely. They work well together to manage the workload. And they keep their knowledge and skills up to date so they work within their level of competence. Team members can make suggestions to improve services.

Inspector's evidence

The pharmacy team comprised: the superintendent pharmacist, two full-time quality assurance pharmacists, a locum pharmacist and several full-time dispensing assistants who were enrolled on accredited training or were on probation and pending enrolment on accredited training relevant to their roles. In addition, there was a person who cleaned the pharmacy daily and a person who was employed for warehouse duties. The pharmacy team was divided into smaller teams – to cover day and night shifts as the pharmacy was operational 24 hours per day on certain days of the week and 12 hours per day for the remaining days. The rota was split into 12 hour shifts and the pharmacists worked four days on and four days off. The pharmacy had a capacity plan which was updated regularly at the end of each month to help determine the capacity needed for the remainder of the year and plan recruitment of more staff.

Team members had protected learning time with the pharmacist for an hour twice a week. The pharmacy maintained staff training and development records and apart from accredited training in line with their roles, the pharmacy also provided in-house training such as SOPs, health and safety and clean room cleaning. There were regular meetings with the superintendent pharmacist, pharmacists and the dispensing assistants to plan pharmacy activities.

The team of full-time PIPs worked daily with a weekend rotation and were headed up by a lead training pharmacist. PIP qualifications and experience ranged from one year to five years qualified. PIPs were trained to meet the standards in the Prescriber Quality Assurance Framework to conduct the initial consultations, with additional training being required for follow-up consultations. The training was phased using competencies and lasted for a minimum of four to six weeks for all new prescribers and the competency framework was reviewed regularly. Clinical training topics included skin and dermatology, acne, anti-aging, pigmentation and what to observe on the skin. The PIPs team members learned to use the prescribing system, complete a consultation, refer to photographs, review skin by teledermatology, prescribe and follow the decision-making matrices. (The British Teledermatology subcommittee was part of the British Association of Dermatologists (BAD) Clinical Services Unit, providing support for prescribers to improve patient care). Training was provided on new formulations but the source of training information was not seen. With training, PIPs could discuss alternative differential diagnosis and knew when to refer people they were unable to treat. The team attended external teaching sessions and shared learnings.

PIPs were observed prescribing for the first day and a set number of prescription items were audited to ensure PIPs were prescribing to the expected competency level. They were closely reviewed until they

passed the competency check. They undertook weekly training which may be challenging situations with patients, case-based learning or any new information from dermatologists. A presentation on seborrheic dermatitis was seen although it wasn’t clear which guidance it followed. The PIPs had regular appraisals and 'one to one' meetings to monitor performance via personal development plans. PIPs could seek guidance on difficult cases with the lead pharmacists. They attended regular team meetings to address any problems and check in with everyone. And a team member described there being a very open culture of speaking up but there were also anonymous channels to provide feedback or raise concerns. The PIPs had a record of their feedback and actions taken in response. There were contingency plans for dealing with staff absence and prioritising patient care.

The ‘Skin and Me’ (prescriber service) team and the Feel Good Pharmacy team attended monthly clinical governance meetings and discussed patient safety, complaints, concerns and reaction rates. The Customer Services team also contributed to the meeting and minutes were recorded. Customer services team members were all trained in safeguarding. The Customer Services team could raise concerns and feedback to senior staff. There was a whistleblowing policy.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are clean, secure and suitable for the provision of its services. The pharmacy does not supply any creams through a pharmacy website. The pharmacy's team members have introduced new ways to help protect people from COVID-19 infection. The pharmacy prevents people accessing its premises when it is closed so that it keeps its medicines and people's information safe.

Inspector's evidence

The pharmacy’s premises were in a unit in a business park. They were bright, clean and secure. The registered area was the mezzanine floor where the production room and dispensing areas were located. There was a large office with well-spaced desks to maintain social distancing and a large staff area with a catering facility. Lavatory facilities were clean and handwashing equipment and hand sanitiser were available for people to use.

The pharmacy didn’t have a consulting room as it was closed to the public so there was no face-to-face contact with service users. The pharmacy with its production and manufacturing facilities were in a different location to the PIPs team. The pharmacy did not supply any creams through a pharmacy website.

Pharmacy team members cleaned the production room according to a rota in line with the SOPs for cleaning, sanitation and contamination control. They deep cleaned the production room at the end of each rotation of four days, during allocated time and a record was maintained. They used GMP certified cleaning products. The air temperature in the production room was monitored in several places and recorded. The direction of airflow around doors into and out of the production room minimised the amount of contaminants entering the atmosphere of the production room. The pharmacy team monitored the level of microbial contamination with settle plates in the production room. Other areas of the pharmacy were cleaned regularly by the cleaner.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's working practices are mostly safe and effective. But the source of the cream formulations is unclear. It generally obtains and stores its stock appropriately. The pharmacy team members know what to do if any stock needs to be returned to the suppliers. The pharmacy makes appropriate checks to satisfy itself that the prescribers it works with are working within UK national prescribing guidelines and good practice guidance so it prescribes its medicines safely. And it makes sure people have all the information they need to use their medicines safely. The pharmacy and prescriber service do not always proactively share information about prescribed treatments with other people responsible for a person's care.

Inspector's evidence

The pharmacy's services were accessible to people signing up to a treatment plan through the prescriber website www.skinandme.com. The pharmacy could produce large print labels to assist people who had difficulty reading smaller print. There was a signposting SOP to other services which the pharmacy was unable to provide. When someone became a patient, they could access the resources on this website such as patient information leaflets and 'frequently asked questions' (FAQs). The prescribing and customer services team were available seven days per week. The staff called patients reporting a reaction to treatment to check they were adequately managed and seeking medical help. They signposted urgent cases to NHS 111 or Accident and Emergency (A&E) services and non-urgent cases to their doctor or a community pharmacy. PIPs referred patients to secondary care with their consent if necessary.

The RP recorded any interactions and interventions on the patient medication record (PMR) and these included the reason for rejecting a prescription. Sometimes the RP contacted the PIPs to recommend patch tests of cream on the skin or query prescriptions after completing the clinical check. The PIPs maintained a clinical intervention log and recorded all communications, consultation and photos on the prescribing dashboard in the person's file. When PIPs were completing the initial signing up process with a new person, they obtained consent to share the person's information with this pharmacy. And patient consent to provide information on their prior medical and medications history. The pharmacy did not ask people for consent to share information with their doctors during the initial consent process. So their doctors may be unaware they were receiving treatment from this service. The PIPs provided counselling on the prescribed creams during the consultation process and via the PILs.

The pharmacy sought assurance that the PIP would refer the person to their doctor if they were unlikely to benefit from topical treatment alone, and needed oral treatment too. And the PIPs could monitor multiple requests for treatment and past prescribing history via the prescribing dashboard. They checked pregnancy, breastfeeding and conception status for all high-risk medications at each consultation.

At the pharmacy, the RP screened the prescriptions before each supply. The PIPs made and recorded

clinical interventions such as if the person's use of the treatment was inappropriate and had been stopped. PIPs also required a mandatory follow up every six months and if the person did not check in or there was repeated non-delivery of creams, the pharmacy would refuse further supplies of cream. Customer services dealt with lost items and checked delivery status of items before replacements were made.

The pharmacy prepared a number of unlicensed face creams to treat a variety of skin conditions such as skin ageing, melasma, rosacea, hyperpigmentation and acne. It had an in-house formulary. The pharmacy had checked that no licensed equivalent creams containing the same combination or concentration of ingredients were available. Depending on the ingredients, most of the creams were prescription only medicines (POM) but some were pharmacy (P) medicines.

The formulations of cream were devised and approved by the medical team at Skin and Me. Unlicensed formulations were approved for launch and there was stability information available but formulation information referenced to literature or articles was not seen. The origin of the formulations and training information for the PIPs was unclear. The SI did confirm that the mixing process for creams was risk assessed.

A PIP explained that the benefit of the formulations and preparing an unlicensed cream was that the dose of active ingredients could be tailored to start with a lower strength. So, licensed creams contained higher concentrations of tretinoin than Skin and Me's unlicensed cream containing tretinoin. Side effects and adverse reactions were reduced leading to better adherence to treatment and improved outcomes in the condition for the person using the cream.

The RP received prescriptions onto the computer system around 6pm and clinically checked them for any issues and contra-indications such as tretinoin prescribed for someone in the at-risk group or clindamycin prescribed for someone with bowel disease. The prescription was sent to the dispensing area. The pro-forma for the cream to be mixed was sent to the production room. The team member created an audit trail for each ingredient as it was added to the mix and recorded on the pro-forma. The required quantity of each ingredient was weighed and checked by weighing the remaining quantity in the stock container. When all the ingredients had been added to the mix, the container was secured in equipment which mechanically combined the mix into a consistently blended cream.

The pro-forma was attached to the container of blended cream and passed to the RP for quality control checks. The pharmacy had its own equipment to test stability of creams in different conditions such as temperature and humidity. So appropriate shelf-life could be attributed to the creams. Checks were carried out on each batch to assure the composition of the cream. After the quality control checks, the cream was placed in equipment to remove any air and then passed to the bottling station.

The finished cream was decanted into aluminium, plastic lined containers which had a mechanism to eject one dose at a time for application. The pharmacy team members weighed the filled containers to ensure they contained the right amount of cream. A QR code on the base of the filled container included information on date of preparation, batch numbers and expiry dates of ingredients and team members who prepared the cream. The finished cream was then placed in a designated location in the dispensing area.

The dispensing areas were outside the production room. The dispensing assistant referred to the prescription on the computer screen which showed the location of the item to be dispensed. The dispensing assistant scanned the QR code on the base of the container to check it matched what was requested on the prescription. The dispensing label details were printed onto the outside aluminium casing of the container. And included the formula for the cream, the patient first name, dosage

instructions and the pharmacy address. The dispensing label was printed onto the secondary packaging and included the patient's full name. The labelled container of cream was secured in packaging designed to protect its quality and minimise movement during delivery. The package was labelled for dispatch. The pharmacy provided a courier delivery service to people which could be tracked. And it confirmed the item was delivered to show that the right medicine was delivered to the right person.

The pharmacy used recognised suppliers to obtain its pharmaceutical stock. The pharmacy team had a procedure to identify each ingredient on receipt from suppliers and check its expiry date. So, an individual ingredient could be tracked from its arrival from the supplier to the finished batch of cream. The pharmaceutical stock was stored in the pharmacy area in the original containers. Stock batches of cream were stored in a designated location. Hazardous liquids were stored in a safety cabinet. Pharmaceutical waste was stored in pharmaceutical waste bins and removed by a contractor. The pharmacy had a procedure for dealing with alerts and recalls about medicines and medical devices at a national level and for an internal recall of an unlicensed cream.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the facilities it needs for the services provided and it can demonstrate that equipment is regularly cleaned, calibrated and serviced. The pharmacy uses its equipment appropriately to keep people's private information safe.

Inspector's evidence

Members of the pharmacy team had access to up-to-date reference sources. They cleaned the production room in line with the SOPs for cleaning, sanitation and contamination control. This included cleaning items to be brought into the production room and designated cleaning tasks to be completed before, during and after production. They deep cleaned the production room regularly during allocated time and a record was maintained. The pharmacy retained documents to show equipment used in the production of the creams was regularly cleaned, calibrated and serviced. The team disposed of confidential waste appropriately. The pharmacy restricted access to its computers and members of the pharmacy team had appropriate access specific to their roles. The prescriber service protected people's information on their computer system which was accessed by VPN password and password protected login.

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.