General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: The Family Chemist, 6B Wilford Lane, West Bridgford, Nottingham, Nottinghamshire, NG2 7QX

Pharmacy reference: 9011964

Type of pharmacy: Internet

Date of inspection: 05/06/2023

Pharmacy context

This family-owned distance selling pharmacy is in a shared office building in West Bridgford, Nottingham. It provides private prescribing and dispensing services to people through its website www.thefamilychemist.co.uk. It also sells a small range of medicines and devices through its website. The prescriptions for its services are issued by a Pharmacist Independent Prescriber (PIP). The pharmacy does not offer any NHS funded services and its premises are not accessible to members of the public.

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 adequately manages the risks associated with providing its services. It keeps its legal records in order, and it manages confidential information appropriately. The pharmacy uses findings from its audits and feedback it receives from people to help inform the way it provides its services. Pharmacy team members regularly share learning following mistakes made during the dispensing process. And they have the necessary knowledge to recognise and raise safeguarding concerns.

Inspector's evidence

The pharmacy provided all its services at a distance through its website. Its superintendent pharmacist (SI) was the sole PIP and prescribed medicines for a range of conditions. The pharmacy had up-to-date standard operating procedures (SOPs) relevant to its services. SOPs covered responsible pharmacist (RP) requirements, clinical governance arrangements, information governance arrangements and safeguarding. They contained clear review dates and were signed by both members of the pharmacy team to confirm they had read and understood them.

The pharmacy had a risk assessment that covered a range of conditions including erectile dysfunction, hair loss, period delay, cystitis, migraine, weight loss, anti-malaria medicines and emergency hormonal contraception (EHC). The risk assessment provided a description of the activity, hazards identified and controls in place. It also provided details of required training and supporting information to help with prescribing decisions, such as local and national guidelines to refer to. It took into consideration the need to refer a person to their regular prescriber if there were any concerns raised from the questionnaire or telephone conversation with the person. For example, The SI had referred a person to their GP when they felt it was not appropriate to supply hormone replacement therapy (HRT) based on the response from the questionnaire and subsequent telephone review with the person. The risk of each condition prescribed for was scored as either low, moderate, or high. The risk assessment was version controlled with changes clearly documented. Additional information available to the prescriber included safeguards to prevent overprescribing. For example, it was policy to not prescribe antibiotics to a person for cystitis more than twice in a six-month period. And records seen confirmed the SI was following this policy. The pharmacy had recently introduced other conditions to its website. But it had not updated its written risk assessment to include these conditions. These conditions and treatments included HRT, acne, contraception, rosacea, and hay fever. The SI was able to verbally describe what they would be assessing when undertaking a consultation for these conditions. And an updated written risk assessment was made available following the inspection.

People accessing the pharmacy's services completed an online questionnaire which covered key areas such as medical history and any risk factors that may mean treatment wasn't suitable for the person. For people accessing the weight loss service, they were asked about their height and weight so that their body mass index (BMI) could be calculated. Generally, people with a BMI greater than 30 or a BMI between 27-30 with at least one weight-related co-morbidity such as a high blood pressure or high cholesterol would have the option to receive treatment. The questionnaire asked people to submit a photograph of themselves standing on scales as part of the consultation process to independently validate the questionnaire answers. And the majority of people did this, but the pharmacy had not made it mandatory for treatment. So, not all people had their submissions validated in this way. There

were additional steps after the SI had reviewed the questionnaires as people received a telephone call as part of the follow up to the consultation process. But the SI did not routinely make a record of these calls within the person's clinical record. The prescriber was able to demonstrate in depth knowledge of individual people using the pharmacy's services, including interventions and outcomes of conversations that had taken place. Some of these were supported by follow-up email correspondence which was demonstrated. The SI issued a private prescription if treatment was appropriate. Prescribing records inspected confirmed that prescribing followed the pharmacy's protocols in the majority of cases. One record associated with a person receiving Saxenda for weight loss found the BMI to be below the recommended guidelines for initiation. The rationale for prescribing in this case was not recorded. This record was discussed and found to be an isolated incident.

The pharmacy undertook regular reviews and audits of the prescribing service. For example, a recent prescribing audit for Saxenda had identified that BMIs were checked but not documented. This had informed a change in practice to ensure the BMI was documented on the person's record at each prescribing. The SI had completed an audit of cystitis prescribing to check they were prescribing in accordance with NICE and local guidelines. They identified that for those people who may not need an antibiotic a telephone consultation was used to assess whether they required delayed antibiotics. The pharmacy was now providing a urine sample bottle to people in these cases with a recommendation that they take a sample to their GP to rule out cystitis.

The pharmacy team regularly recorded mistakes made and identified during the dispensing process, known as near misses. These mistakes were reviewed during wider clinical governance meetings and acted upon to reduce risk. For example, it had separated different pack sizes of sildenafil tablets to reduce the risk of a quantity error occurring. The pharmacy had a documented process for managing mistakes identified after the supply of a medicine to a person, known as dispensing errors. The SI confirmed there had been no reported dispensing errors to date. The pharmacy had a complaints process, and this was clearly advertised on its website. It also invited people to leave a review through an independent digital review service and it shared these reviews on its website. Feedback through the review service was positive. The team regularly reviewed and responded to the feedback it received. And it used this feedback to inform the way it provided its services. For example, it had changed the way it packed Saxenda to reduce any moisture caused by the cold packs included within the parcel. And it had updated its packaging for all medicines to ensure it was robust following some feedback relating to some medicine boxes being damaged in transit.

The pharmacy team had completed safeguarding learning, with the SI completing level three learning. The SI had experience of referring concerns about vulnerable people to safeguarding authorities from their NHS roles. Team members understood the risks associated with supplying medicines online. And some of these risks were identified within the pharmacy's risk assessment. For example, the need to confirm that a person requesting period delay treatment was female. And there was evidence of refusals when a male had completed the questionnaire. But specific safeguarding risks associated with the supply of weight loss medicines were not highlighted within the risk assessment. The pharmacy had recently strengthened procedures to help protect potentially vulnerable people. This included having visibility of how many changes people made to the answers they provided within the online questionnaires. The pharmacy was in the process of strengthening these procedures further by introducing a flag system based on different parameters within the questionnaire. This would prompt extra checks to help ensure a treatment was suitable.

The pharmacy had current professional indemnity insurance. It held its private prescription record electronically and a sample of entries confirmed they were made in accordance with legal requirements. It retained original prescriptions onsite in clearly labelled folders. This supported the team in ensuring it held records for the necessary period and could dispose of them safely when this

period expired. The RP notice displayed contained the correct details of the RP, and the RP record was seen to be completed accurately. A number of clinical records were inspected and necessary records were kept from the questionnaire and treatment plan. There were examples of follow-up correspondence with people via email after telephone calls. For example, when a supply of antibiotics was refused. A discussion highlighted the risks associated with not recording either telephone or email consultation notes within the clinical record. The SI provided assurances of improvements to clinical record keeping following the inspection. The pharmacy had full oversight of correspondence relating to the consultation process. It was registered with the Information Commissioner's Office. And it held its records securely and disposed of confidential waste through a secure shredding service.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has a small, dedicated team of people providing its services. Team members engage in continual learning associated with their roles. And they regularly share information and learning to help improve services and to reduce the risk of mistakes.

Inspector's evidence

The company directors were the only members of the pharmacy team. One was the SI and the other was a qualified dispenser. The pharmacy was planning to expand and recruit a regular pharmacist to work within the dispensing side of the business. But currently the SI undertook both the PIP and RP role. Currently the SI undertook the prescribing role offsite to separate the prescribing and dispensing functions. This meant the SI was not clinically checking a prescription they had issued straight away. People were asked appropriate questions as part of a questionnaire consultation and the SI used their own professional judgement when prescribing. There were no incentives to prescribe and there were examples of orders being rejected when a supply of medicine was not deemed to be appropriate. The prescribing system provided the SI with sight of historical orders to inform their prescribing decision. The dispenser was encouraged to make interventions when completing labelling tasks. A document next to the pharmacy's desktop computer prompted checks of people's medication history. It contained safety information that prompted a referral to the SI. For example, a referral to the SI was required if checks revealed a person prescribed period delay treatment had placed more than three orders within the last twelve months or had multiple orders in a short space of time for large quantities. The pharmacy's operational hours occasionally varied due to leave. When this had happened, it had appropriately notified people and there was an option to switch off the prescribing service on the website should the SI be in a position where they were not able to provide the service.

The team members worked well together. Evidence of the dispenser's qualification and ongoing learning was available. The SI was experienced and worked in roles within the NHS where they prescribed regularly. They explained how they shared learning from these roles to support safety and their role within the pharmacy as the sole prescriber. Evidence of shared learning included a prominent display of safety information designed to reduce risk when dispensing medicines that looked similar and sounded alike. Training certificates belonging to the SI covered a range of clinical practice, including learning associated with the conditions on the pharmacy's website. There was evidence of ongoing continuing professional development and a portfolio of ongoing learning. And a scope of practice document identified the range of conditions the PIP had declared competence in. This document included evidence of a supervised prescribing session completed within a primary care setting. Regular discussions about workload and the management of services took place. These discussions included some documented clinical governance meetings where topics such as safeguarding, near misses and outcomes from clinical audits were documented.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are clean, hygienic, and secure. The pharmacy's website is professionally laid out and is set up in a way which enables the pharmacy and its prescriber to make decisions about the suitability of its treatments.

Inspector's evidence

The pharmacy premises were secure from unauthorised access. They were clean, well maintained, and tidy. The pharmacy monitored its room temperatures to ensure it kept medicines in an ambient environment. It had suitable heating and ventilation systems. Lighting throughout the premises was bright. The premises consisted of one large room split into an administration area and a designated dispensing area. This layout effectively supported a safe workflow.

People accessed the pharmacy's services through its website. The website was professionally laid out with relevant information about the different health conditions and the treatments offered through the service. People could look at the treatments provided by the pharmacy and were appropriately signposted back to the page detailing information on the conditions to be treated, to begin the consultation process. People using the website were taken to the GPhC's register when clicking on the registration number of the pharmacy, SI, and prescriber.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy sources and stores its medicines appropriately. And it uses effective audit trails to ensure people receive their medicines in a timely manner. It takes suitable action to ensure its medicines remain fit for purpose. Overall, the pharmacy manages its prescribing services appropriately. And it makes some records of the information it obtains during the consultation process. But these records are not always complete and this may make it more difficult to monitor people's treatment and answer queries about prescribing decisions.

Inspector's evidence

People accessed the pharmacy's services by completing a consultation questionnaire on its website. They could also contact the pharmacy by telephone and email for queries and for support when completing the form. The dispenser was observed providing telephone support to a person wishing to access the service. The website contained video guides for the service and in some cases for individual treatments as well as a pictorial guide. And the website clearly informed people they could speak directly to the prescriber. The website contained brief information about each condition it prescribed treatment for. And people could read detailed Information about each treatment option. The baby and child conditions page consisted of General Sales List (GSL) medicines available for people to purchase without a prescription. The website also signposted people to other helpful information and video guides, such as a guide to using Saxenda injection pens. A video associated with the weight loss service offered people healthy eating advice and the option of regular video calls with a member of the team. The SI provided details of a video call which had involved additional support to help a person in self-administering the Saxenda injection safely.

The pharmacy confirmed the identity of people using the prescribing service via a third-party identification checking service. It provided details of the service it used on its website. The SI demonstrated how further checks and assurances were made to confirm a person's identity should an initial check fail. And there were examples of prescriptions not being processed due to failed identity checks. The pharmacy had a process for identifying and flagging multiple accounts at both the prescribing and dispensing stage of the process.

The majority of medicines supplied were for weight loss, hair loss and erectile dysfunction. Responses within the online questionnaires prompted people to enter information into a free-type box on some occasions and others were answered by selecting responses from a list. The information within questionnaires covered the main key points to help inform the prescribing decision and an additional telephone consultation with the person supported prescribing. The SI explained how they also telephoned people to make sure they understood the treatment they were receiving and to provide counselling about how to use their medicine. Requests from people who entered information that indicated they had a low BMI were automatically rejected. People were followed up after initiation of weight loss medicines as part of the pharmacy's ongoing monitoring prior to further new prescriptions being issued. This follow-up included monitoring their BMI to ensure treatment remained appropriate. People had the option to consent for information about the treatment to be shared with their regular prescriber. But most people did not consent for this information to be shared. And there were some examples of the pharmacy being unable to share information despite consent being obtained. This was because it had been unable to verify details of a person's regular prescriber through

the information provided. The SI explained in these cases the decision was made not to share to avoid the risk of breaching a person's confidentiality. This meant the pharmacy did not always have assurance that their regular prescriber was aware of any treatments prescribed through its services, especially medicines requiring ongoing monitoring such as those used for weight loss. The pharmacy made consent to share information with the regular prescriber mandatory for its weight loss service following the inspection. And it introduced additional safeguards to ensure it contacted people to verify details of their regular prescriber where this was needed.

The pharmacy provided dutasteride for treatment of hair loss which was an off-label indication for this medical condition. The hair loss consultation required a person to confirm they had read information about this. The pharmacy's risk assessment identified the risks associated with prescribing and supplying dutasteride, including the need to offer licensed treatments as a first line option. But the pharmacy did not provide a further information leaflet to people reminding them about this when supplying the medicine. The questionnaire for cystitis asked people how many times they had been treated with antibiotics in the last 12 months and the response was limited to once or twice. This could potentially have an impact on the limitation safeguards of the risk assessment for the service which stated the policy of two supplies in six months or three in 12 months.

The pharmacy only supplied medicines within the UK. It kept full records associated with dispensing medicines. It used baskets throughout the dispensing process to keep each person's medicine separate. And it had good checks to ensure details of the address label matched those on the prescription and dispensing record. Both the dispenser and SI completed a dispensing audit trail initialling medicine labels to identify their role within the dispensing process. Medicines supplied in non-original containers included details of their batch number and expiry date on the white boxes they were supplied in. The pharmacy provided patient information leaflets routinely. And people were provided with free needles and a storage case when the pharmacy supplied Saxenda. This reduced the risk of needles being re-used. The pharmacy also promoted the manufacturer's pen recycling scheme by encouraging people to return their used pens through the scheme.

The pharmacy used a national courier service, had procedures, and agreed timescales with the courier for the delivery of medicines. All deliveries were fully tracked, and the pharmacy required people to confirm that their medicine was safe to post if they were not at home. This included an insured returns policy in the event the courier did not deliver the medicines within the agreed timescales. People ordering medicines requiring cold chain storage such as Saxenda received morning deliveries the next working day. The pharmacy used cold packs in the packaging included with these medicines. The pharmacy had completed temperature mapping audits of its cold-chain supply since it had begun providing these medicines. Two separate audits in different weather conditions had been completed to date, both showed the cold-chain was maintained for 48-hours.

The pharmacy obtained its medicines from licensed wholesalers. It stored them in an orderly manner on shelves and within a medical fridge. It kept a record of fridge temperatures which were seen to be within the correct range. A date checking matrix supported regular checks of stock medicines. No out-of-date medicines were found during a random check of dispensary stock. Medicine waste receptacles and waste collection consignment notes confirmed how the pharmacy disposed of out-of-date and returned medicines. The pharmacy received details of medicine alerts by email. It kept an audit trail of any alerts and actions taken by the pharmacy. It took concerns about the safety of medicines seriously. For example, it had referred a concern about a device reported to be faulty to a manufacturer.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the required equipment for providing its services. Its team uses the equipment in a way which protects people's privacy.

Inspector's evidence

Pharmacy team members had access to appropriate reference sources and access to the internet for obtaining up-to-date information. Equipment to support the provision of services was readily available. For example, discreet robust packaging suitable for delivery by the courier service. Electrical equipment was in good working order and there was evidence of some monitoring checks to ensure it was safe to use. The pharmacy's computer systems were password protected and information. Access to the premises was restricted and as such people's personal information was protected from unauthorised access.

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.