General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Heald Green Pharmacy, 208 Finney Lane, Heald

Green, CHEADLE, Cheshire, SK8 3QA

Pharmacy reference: 1117667

Type of pharmacy: Community

Date of inspection: 04/12/2024

Pharmacy context

This pharmacy is situated in a residential of Heald Green, Cheadle. The pharmacy premises are accessible for people, with adequate space in the retail area. The pharmacy sells a range of over-the-counter medicines and dispenses both private and NHS prescriptions. The pharmacy provides treatment under patient group directions (PGDs) face to face and online for different conditions, including, hair loss, acne, erectile dysfunction, period delay, nausea, and others. And it has a consultation room available for private conversations. This was a targeted inspection which focussed on the online operation of the pharmacy, involving the supply of medicines for various health conditions under PGDs. The inspection primarily covered standards 1.1, 1.2, 1.6, 1.8, 2.2, 3.1, 4.2 and 5.1.

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 not all met	1.1	Standard not met	The pharmacy does not demonstrate that it effectively identifies or manages the risks associated with its services. The pharmacy provides access to medicines and treatments online for a number of different health conditions under patient group directions (PGD), but this falls outside the scope of the PGDs, so the supplies of medication are not legal, and may compromise patient safety.
		1.5	Standard not met	The pharmacy cannot demonstrate that the current indemnity insurance in place covers the remote provision of treatment, as this falls outside the scope of the patient group directions (PGDs).
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 not all met	4.2	Standard not met	The pharmacy does not have a robust process to verify people's identification when supplying medcines online, and may increase the possibility of supplying medicines or treatment which are not appropriate or safe to use.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy provides access to treatment online for a number of different conditions under patient group directions (PGD). But this falls outside the scope of those PGDs, which means the supplies of medication are not legal and may compromise patient safety. The pharmacy has most of its up-to-date standard operating procedures (SOP) for the services provided available for team members to refer to. But some important SOPs are not always accessible which may make it harder for its team members to understand the correct process to follow if an incident were to occur.

Inspector's evidence

There were largely up-to-date standard operating procedures (SOPs) for the services provided, with sign off records showing that members of the pharmacy team had read and accepted them. Roles and responsibilities of staff were set out in SOPs. A member of the pharmacy team clearly described her duties. The SOP for the treatment of conditions under a patient group direction (PGD) was not available. The superintendent (SI) stated that there was a SOP for the treatment of conditions under a PGD and he would provide a copy as soon as he was able to. This meant that the pharmacist involved in the supply of treatment under PGD may not be able to refer to the written procedures if needed.

The pharmacy had up-to-date, signed PGDs for the conditions and treatments provided. The PGDs had been signed off and approved by the SI as the Clinical Lead. And a regular pharmacist at the pharmacy was the sole person who had been named and approved for the PGDs. There were risk assessments documented for each patient consultation carried out. The information obtained from the patient during their consultation either face to face or online, formed the basis of the risk assessment, with written and signed consent from patients for any treatment suitable for the supply under a PGD routinely obtained. Prior to the inspection, the PGD provider clarified that the PGDs only permitted face-to-face consultations in a registered healthcare setting such as a pharmacy premises. This meant that the remote provision of supply of treatment for the conditions listed on the pharmacy website, including acid reflux, acne, back pain, emergency hormonal contraception, erectile dysfunction, hair loss, hives, migraine, nausea, period delay, premature ejaculation, quit smoking, urinary tract infection and weight loss was outside the scope of the PGDs and therefore not legal supplies of medication. The SI and the second pharmacist who was approved for the PGDs were made aware of this fact and they both stated they were unaware this was the case, but understood the PGD provider had led them to believe that the PGDs could be used online. They both stated this was further reinforced when the website developer had liaised with the PGD provider to set up the online service. The SI said he was going to immediately cease the online PGD service, and he deactivated this functionality from the pharmacy website. He provided verbal assurance that under no circumstances would the pharmacy be providing remote provision for treatment of conditions under PGD online again.

Dispensing errors were recorded on the computer system and learning points were included. Near miss incidents were recorded on a log and were discussed with the pharmacy team member involved in the dispensing process at the time they occurred. The near miss records were regularly reviewed for trends and patterns, with the outcome of the review shared with the pharmacy team, to help prevent the same errors from occurring.

The correct responsible pharmacist notice was displayed. The responsible pharmacist (RP) record,

emergency supply record, private prescription record, unlicensed 'specials' record, and the controlled drugs (CD) register were in order. CD running balances were kept but not audited regularly. For example, Morphine Sulphate (MST) 60mg tablets were audited on 5 May 2024 and 5 November 2023. This meant it was more difficult if a discrepancy arose for auditing and may not identify potential diversion at the earliest opportunity. Patient returned CDs were recorded appropriately.

The pharmacy safeguarding SOP was not available and there were no details of local safeguarding contacts. The SI explained that the pharmacy had been refitted and some SOPs had been stored away from the pharmacy during this time. He said he would return the safeguarding SOP to the pharmacy and provide a copy at the earliest opportunity. This meant that team members may not be aware of the correct procedure to follow in the event of a safeguarding concern arising. The SI and second pharmacist had both completed level 2 safeguarding training.

Principle 2 - Staffing ✓ Standards met

Summary findings

There are enough staff to manage the pharmacy's workload. But there are no additional training packages provided to members of the team. And there is no formal appraisal programme. So, the learning and development needs for members of the team may not be fully met.

Inspector's evidence

There was the superintendent (SI) pharmacist who was signed in as responsible pharmacist (RP), a second pharmacist who was approved to supply treatments under PGD, an accuracy checking pharmacy technician, three dispensers, three medicines counter assistants and a delivery driver on duty. They worked well together and managed the workload adequately. The pharmacy team kept up to date by reading any updated information in SOPs, including new services that were relevant to their roles. There was no ongoing training or formal appraisal. This meant opportunities for the pharmacy team to learn, and progress may be missed. The SI and pharmacy manager provided the team with informal feedback on a regular basis and addressed any issues when they arose.

The second pharmacist had completed additional training for some of the health conditions treated under PGD, but not all, as he had felt competent in his role to follow the PGD and complete a patient risk assessment, accordingly, referring to the inclusion and exclusion criteria and reviewing the information provided.

The pharmacy team were aware of the whistle blowing policy that was in place and knew how to report concerns. Details outlining the policy were available for the team to refer to. They said that the SI and second pharmacist were both approachable, supportive and they were more than happy to ask them questions when needed.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is clean and tidy. It is a suitable place to provide the services that it offers. It has a consultation room so that people can have a conversation in private with members of the team.

Inspector's evidence

The pharmacy was clean and tidy and had a waiting area. The temperature in the pharmacy was controlled by air conditioning units. Lighting was good. The pharmacy team cleaned the floor, dispensing benches and sinks regularly. The consultation rooms were uncluttered and clean in appearance.

The pharmacy website included information on how people were able to access pharmacy services and what services were available at the pharmacy and online. The website displayed contact details of the pharmacy and had a section for health conditions. People were able to see a number of health conditions and the medicines or treatments available. A number of health conditions were available online and required people to register for an online account, complete an online questionnaire and submit this information to the pharmacy, which was then assessed by a pharmacist.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy's services are easy to access. And it uses electronic software to help provide them effectively. However, it does not adequately verify the identification of people accessing treatment or medicines online which means there is an increased risk of supplying a medicine that is not appropriate or safe to use. The pharmacy attempts to speak with people who request an online consultation. But the process is not robust, and treatments are sometimes provided whether they speak to a pharmacist or not. This may further increase the risk of medicines being supplied in an unsafe manner.

Inspector's evidence

The second pharmacist who had been approved to provide treatments and medicines under PGDs for different health conditions explained how the online service was carried out. Each patient was required to register and set up an online account. As part of the online registration process, all patients were required to upload a copy of their driving license or passport for ID verification purposes. Several online consultations were reviewed, that had taken place over the last six months, and only those approved had a copy of their driving license or passport uploaded. As a result of a previous incident, where a person had been supplied a medicine after entering an incorrect date of birth and reason for requesting the treatment, the SI and second pharamcist had spoken to the website developers and made it a mandatory requirement for ID to be uploaded and cross-checked against the registration details for each patient accessing the service. However, prior to this incident, ID verification was not routinely being completed, which increased the risk of medicines and treatments being supplied inappropriately.

The second pharmacist explained the online consultation form was completed by the patient and was then reviewed by a pharmacist. He said an attempt was made to telephone the patient to discuss the information contained within the consultation form. The nature of the telephone calls was not documented, which would be a useful audit trail to maintain in the event of a query or incident. If he was unable to speak with the patient, but was satisfied the information provided in the online consultation questionnaire was clinically appropriate, a supply of treatment was made. He explained that any treatments supplied online were posted to the patient using Royal Mail 24 Tracked and Signed for.

The workflow in the pharmacy was organised into separate areas and a designated checking area for the pharmacist. An audit trail of dispensing, accuracy check, clinical check, and hand out was present on the PMR. Baskets were used to separate prescriptions, to reduce the risk of medicines becoming mixed up during dispensing.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment it needs to provide services safely. It is used in a way that protects people's privacy. And the electrical equipment is in working order.

Inspector's evidence

The pharmacy team used the internet to access websites for up-to-date information. For example, Medicines Complete, BNF and BNFc. Any problems with equipment were reported to the SI. All electrical equipment appeared to be in working order. Computers were password protected and screens were positioned so that they weren't visible from the public areas. Cordless telephones were present and were used to have private conversations with people when needed.

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.