General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Holden's Chemist Express, Unit 3, The Old Police Station, Shrewsbury Road, Bircotes, Doncaster, Nottinghamshire, DN11 8DE

Pharmacy reference: 9012059

Type of pharmacy: Internet / distance selling

Date of inspection: 07/08/2023

Pharmacy context

This pharmacy is located in a closed unit in a residential area. Members of the public do not visit the pharmacy in person unless they have an appointment for a private service. The pharmacy dispenses NHS prescriptions, and it delivers medicines to people in the local area. It supplies some medicines in multi-compartment compliance aid packs to help people take their medicines at the right time. The pharmacy has a private prescribing service and provides treatments for hayfever.

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 team members do not always read and follow the pharmacy's standard operating procedures. And the pharmacy supplies medicines for off license use without properly considering or informing people of the risks.
		1.6	Standard not met	The pharmacy's responsible pharmacist log and private prescriptions records are incomplete or inaccurate. And the pharmacy does not maintain appropriate records for deliveries or patient returned controlled drugs.
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 contains some misleading information. And it advertises a medicine for the treatment of hayfever which is outside the terms of its marketing authorisation.
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 not all met**

Summary findings

The pharmacy does not adequately identify and manage all of the risks involved with its services. It does not keep accurate records as required by law and some important details are missing. This could make it harder to understand what has happened if queries arise. And it could do more to monitor compliance with policies to make sure its services are safe, and prescribing is appropriate. The pharmacy team members have not confirmed their understanding of the pharmacy's written procedures, so they may not always work effectively or fully understand their roles and responsibilities. The team understands how to keep people's private information safe and protect the welfare of vulnerable people.

Inspector's evidence

The pharmacy had been operating for around three months and had standard operating procedures (SOPs) for the services it provided. Team members had not indicated that they had read and accepted the SOPs, so there was a risk that they might not fully understand the pharmacy's procedures or complete tasks in the right way. The superintendent pharmacist (SI) explained that he had prepared the SOPs, so he was aware of the contents, but some SOPs were not being closely followed. For example, the delivery SOP. The dispenser, who was new to the pharmacy, had not read the SOPs but said that the SI had explained the procedures to her, and she agreed to read the SOPs as soon as possible. Roles and responsibilities were set out in SOPs and the dispenser was performing duties which were in line with her role. She was clear what activities she could and couldn't carry out if the pharmacist was absent.

The SI was a director of the company that owned the pharmacy. He also worked as the regular responsible pharmacist (RP), and his name was displayed on an RP notice in the pharmacy. He supervised the dispensing activity and was a pharmacist independent prescriber (PIP), and he prescribed in the pharmacy. This meant he undertook the roles of prescriber and supplying pharmacist. The pharmacy had not yet completed formal audits of prescribing activity due to the low levels of prescribing so far. And the SI had not considered appointing anyone to carry out audits to monitor prescribing and compliance with prescribing policies, which could help to mitigate some of the risks of working in clinical isolation.

The pharmacy had written risk assessments to identify and manage risks with the prescribing and dispensing services. But the risk assessments for the prescribing service didn't cover all of the services and medicines provided. The pharmacy provided a hayfever injection service. The SI explained that people attended the pharmacy for a face-to-face consultation for this. And he prescribed and administered Kenalog injections for people following an assessment. The pharmacy had clinical guidelines for this medication and a risk assessment. The SI informed people that it was not recommended by the National Institute of Health and Care excellence (NICE) or the NHS for hayfever, but he was not aware that the use of Kenalog was outside of the manufacture's product license for the treatment of hayfever. And the pharmacy did not have a policy for prescribing off licensed medicines. This meant that the SI had not informed people that the medicine was being prescribed off label or what this meant to allow people to make an informed decision. And the patient information leaflet did not explain the medicine's off-label use so people might be confused by this. The pharmacy requested permission to inform people's regular doctor (GP) when medication was

prescribed, and the SI explained that a letter would be sent the patient's GP if they consented to sharing this information. That was stated as a mandatory requirement in the clinical guidelines for Kenalog, but the person's GP had not been informed according to some of the consultation records seen.

The pharmacy had an SOP for dealing with incidents. The SI said there had not been any near misses or dispensing errors, but that any errors would be recorded, and any learnings shared with the team. The complaint procedure and the details of who to complain to was available on the pharmacy's website. The SI was not aware of any customer complaints. Professional indemnity insurance arrangements were in place. The SI confirmed that these covered all the services provided by the pharmacy including the prescribing service.

A small number of private prescriptions had been supplied. Most of the prescriptions were for Kenalog injections which had been issued by the SI. Private prescriptions were recorded electronically, but the records were sometimes inaccurate. Four private prescriptions were seen which had been incorrectly recorded as NHS prescriptions and they had not been recorded in the private prescription register. The date of prescribing had been incorrectly recorded on another private prescription entry. One patient had two separate accounts on the patient medication record (PMR) system which could cause confusion. The SI explained that he would merge the two accounts together. The RP log was electronic. The SI had been recorded as the RP on every entry since 5 May 2023. There was no record of what time the RP ceased their duties on most of the entries and the SI admitted that he had not signed in as RP on some days. The SI was absent at the start of the inspection. He had not recorded this, or any absence in the RP record so there was an incomplete audit trail. There was a controlled drug (CD) register. It contained one entry for the receipt of Zomorph capsules. The SI confirmed that this was the only entry in the register, and it had been the only schedule 2 CD received. There were some patient-returned CDs in the CD cabinet. Their return had not been recorded. The SI said that he had obtained a designated book to record the return and destruction of patient-returned CDs, but he was not able to locate it. The SI kept paper prescribing records for the consultations he had completed.

There was an information governance (IG) SOP and a guide to confidentiality. Confidential waste was collected in a designated place. The SI said he took it home to shred. He confirmed that it was kept secure until it was disposed of to reduce the risk of accidentally breaching people's confidentiality. The dispenser hadn't received any training on IG in the pharmacy and she couldn't remember if she had read and signed a confidentiality clause when she started working at the pharmacy. She had a good understanding of patient confidentiality from working in another pharmacy and a GP practice. A privacy policy and cookies policy were available on the pharmacy's website. The SI confirmed that consent was received when people's Summary Care Records (SCR) were accessed.

There was a child and vulnerable adult protection policy. The SI had completed level two and level three training on safeguarding. The dispenser said she knew to voice any concerns regarding children and vulnerable adults to the pharmacist working at the time. The team knew to contact the area safeguarding leads or emergency services if necessary. The SI confirmed that he usually asked people if they would like a chaperone when they were using the consultation room, but there was nothing on display highlighting this, so people might not realise this was an option.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has a small team and the workload is manageable. Team members have the right qualifications for the jobs they do. And they have opportunities to discuss issues informally together.

Inspector's evidence

The SI and an NVQ2 qualified dispenser (or equivalent) were on duty at the time of the inspection. The staffing level was adequate for the volume of work during the inspection. The dispenser had been recently recruited because the pharmacy's workload had increased, and the SI was considering recruiting a part time delivery driver. At certain times of the day, the SI worked alone in the pharmacy which meant he dispensed and self-checked prescriptions. He explained he only dispensed urgent prescriptions at this time and gave himself a mental break between the two processes to minimise the risk of mistakes happening.

The SI qualified as a PIP several years ago. He explained that he had completed some self-directed learning and was competent to prescribe for the hayfever service. He provided a certificate for a training course 'Treating hay fever and allergy with triamcinolone' which he had completed in June 2023. The website also offered a vitamin B12 injection service but the SI said he had not prescribed or administered any as he had not completed appropriate training for this. And said he would stop offering it on the website.

The dispenser and SI discussed issues on a daily basis. The dispenser said she would feel comfortable talking to the SI about any concerns she might have. There was a whistleblowing policy. The SI explained that he was going to introduce a formal appraisal process for team members so their performance and development could be discussed.

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

Summary findings

The premises provide a professional environment for people to receive healthcare services from. The pharmacy's website has some useful information about the pharmacy and its services, but some of the information is inaccurate and could be misleading. And it promotes a prescription only medicine for use outside of its terms of marketing authorisation which does not comply with advertising regulations.

Inspector's evidence

The pharmacy was situated in a secure, closed unit on the first floor of a commercial building. The pharmacy premises were well maintained, and the fixtures and fittings were in good order. The pharmacy was clean. The temperature and lighting were adequately controlled. There was a stockroom where excess stock was stored and a separate room for the assembly and storage of compliance aid packs. The consultation room was clean and professional in appearance. This room was used when carrying out private services such as hayfever consultations.

Staff facilities included a kitchen area and a WC, with a wash hand basin, hand wash and hot and cold running water. Access into the premises was via a locked gate and a front door on the ground floor. People needing access such as wholesale drivers were required to ring the doorbell to request entry.

The pharmacy's website (www.holdenschemistexpress.co.uk) contained some information about the pharmacy and its services. The pharmacy's address and GPhC registration number was displayed on the website, and the SI's name and registration number. The website advertised a 'hayfever injection' service and promoted a specific prescription only medicine (POM) (Kenalog injection) which was not licensed for treatment of hayfever. Some of the services advertised on the website were not currently provided. For example, a vitamin B12 injection service and a minor ailment clinic, which could cause confusion for people.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy offers a small range of healthcare services which are reasonably well managed. But the lack of audit trails when delivering medicines to people's homes, may make it harder for the team to deal with any queries or problems that arise. And the pharmacy could manage its compliance aid packs service more effectively, to make sure people receive all the information they need to take their medicines safely. The pharmacy gets its medicines from licensed suppliers, and it carries out some checks to ensure medicines are in good condition and suitable to supply.

Inspector's evidence

The pharmacy was up a flight of stairs which meant it was not accessible for people with mobility difficulties and wheelchair users. There was a health promotion zone on the pharmacy's website with links to NHS health campaigns and information on conditions and medicines. Space was adequate in the dispensary. The dispensary shelves were well organised, neat and tidy. Dispensed by and checked by boxes were initialled on the medication labels to provide an audit trail. Baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. Stickers were put on assembled prescription bags to indicate when a fridge line or CD was prescribed. The SI explained that if counselling was required, he would telephone the patient or set up a video link. He was aware of the requirements for a Pregnancy Prevention Programme to be in place and that people who were prescribed valproate should have annual reviews with a specialist. He said that the pharmacy did not currently have any patients in the at-risk group.

The SI or dispenser usually delivered medicines to people's home after work. But they did not make records or get signatures for these deliveries so it may be difficult to work out what has gone wrong if problems arise, such as medicines going missing or being delivered to the wrong person.

The pharmacy provided medicines in multi-compartment compliance aid packs for people in the community and around twenty people in a care home. Staff at the care home provided the details of what medicines each patient was prescribed, and which medicines had been reordered each month. So, the pharmacy could check this when the prescriptions were received and follow up any missing prescriptions. The dispenser said she would always check any changes with the patient's GP practice. But these checks were not always recorded, so it might not be clear who had confirmed the change and what date it had been made, which could cause confusion when assembling packs. Medicine descriptions were usually included on the labelling sheets which were used for community patients, but the labels did not contain the cautionary and advisory warnings, so people might not know how to take their medicines safely. And packaging leaflets were not usually included so people might not be able to easily access additional information about their medicines. The SI said he would contact the labelling software provider to ask them to add the required cautionary and advisory labelling. Disposable equipment was used. The SI explained that most people whose medicine was supplied in a compliance pack had been referred to them by a healthcare professional, so he hadn't carried out any assessments as to the appropriateness of a compliance aid pack. But he was aware that other forms of adjustments were sometimes more appropriate to meet people's needs and he wouldn't automatically supply a pack without an assessment.

The pharmacy stocked a small range of over the counter (OTC) medicines such as paracetamol and antiseptics. The dispenser said she hadn't been involved in the sale of any OTC medicines and said they were stocked in case there was a request for something by telephone. The SI said the pharmacy had not sold any OTC medicines yet.

Consultations for prescribing services were made by appointment. The SI generally held face-to-face consultations with people. The SI explained not all consultations resulted in a prescription. He used a consultation template to fully document people's medical history, lifestyle factors and create a personalised treatment plan. The pharmacy offered a private minor ailments service for a limited range of common clinical conditions. But there were no documented policies for this prescribing service, and the SI explained that this service was not currently being provided due to lack of demand.

Patient returned CDs were segregated and stored securely. There were two denaturing kits and the SI confirmed that he would use them when carrying out CD destructions. Recognised licensed wholesalers were used to obtain stock medicines. Medicines were stored in their original containers at an appropriate temperature. Date checking was carried out, but it was not usually recorded, so some areas of the pharmacy might be missed. Dates were generally added to opened liquids with limited stability, but one bottle of morphine oral solution had not been dated when opened, so there was a risk it might not be suitable to use. The SI explained it had been an oversight and recalled it had only been opened in the last day or two. Expired and unwanted medicines were segregated and placed in a designated tote tray. The pharmacy didn't have a contract in place for collection by a suitable waste company, as they were still waiting for confirmation from NHSE about this.

The pharmacy received alerts and recalls via wholesalers, but the pharmacy had not signed up to receive the messages directly from the Medicines & Healthcare products Regulatory Agency (MHRA), and there was a risk some alerts might be missed. The pharmacy did not record the ones they received so team members might not be able to respond to queries and provide assurance that the appropriate action had been taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services, but it could do more to ensure that it always stores medicines requiring cold storage at the correct temperature.

Inspector's evidence

The pharmacist could access the internet for the most up-to-date information and the SI used an App on his mobile phone to access the electronic British National Formulary (BNF) and BNF for children. There was a large medical fridge for storing medicines. This had been obtained in the last few days to replace another medical fridge which had stopped working efficiently. The pharmacy team had not checked the maximum and minimum temperatures of the new fridge. This was because the SI thought the thermometer was not working correctly and he had ordered a new thermometer. When the thermometer was re-set it appeared to be working fine and it showed that the fridge was currently within the required temperature range. All electrical equipment appeared to be in good working order. There was a glass liquid measure with British standard and crown mark and a tablet triangle for counting loose tablets. The SI said he would use tweezers if he needed to count out any cytotoxics, but these were usually obtained in foil strips, so handling was not usually necessary. Medicine containers were appropriately capped to prevent contamination. PMRs were password protected.

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.