

Registered pharmacy inspection report

Pharmacy Name: Homeground Care Pharmacy, 75 B S S House,
Cheney Manor Industrial Estate, SWINDON, SN2 2PJ

Pharmacy reference: 1110030

Type of pharmacy: Community

Date of inspection: 18/12/2023

Pharmacy context

This is a pharmacy which is based on an industrial estate in Swindon. It serves its local population which is mixed in age range and background but includes a significant number of elderly people. The pharmacy opens five days a week. The pharmacy mainly provides medicines in multi-compartment compliance aids for people to use while living in their own homes and in care homes. Most of these compliance packs are prepared with the assistance of a dispensing robot. It also offers treatment for a range of minor ailments using the NHS Community Pharmacist Consultation Service. The premises are normally not open to the public to visit in person.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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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 did not have adequate procedures in place to ensure that risks were identified and managed.
		1.2	Standard not met	The pharmacy team did not have any processes in place to monitor the safety and quality of their services.
		1.6	Standard not met	The pharmacy team do not keep and adequately maintain all of the records necessary for the safe provision of pharmacy services.
		1.7	Standard not met	The pharmacy team were not trained to protect people's confidential information.
		1.8	Standard not met	The pharmacy team could not show that they safeguard vulnerable adults and children adequately.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy team have many staff members who were not appropriately trained and not on an accredited training course.
		2.4	Standard not met	The pharmacy team did not regularly undergo any ongoing training and development.
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy premises are not clean and adequately maintained.
		3.2	Standard not met	The pharmacy does not adequately safeguard people's private information.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy team manage services in such a way that presents risks to people.
		4.3	Standard not met	The pharmacy team stored medicines in a disorganised way, and there are inadequate procedures in place to ensure that they are supplied safely to people.
5. Equipment and	Standards	5.3	Standard	The pharmacy team used facilities

Principle	Principle finding	Exception standard reference	Notable practice	Why
facilities	not all met		not met	that could compromise people's private information.

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy does not have satisfactory written procedures for its services to help make sure the team works safely. Pharmacy team members do not have up-to-date procedures in place to record and review mistakes when they happen. The pharmacy asks its customers and staff for their views and uses this to help improve services. The pharmacy has given inadequate assurances that it appropriately manages and protects people's confidential information, and it tells people how their private information will be used. The pharmacy has appropriate insurance to protect people when things do go wrong.

Inspector's evidence

The pharmacy did not have adequate processes for identifying and managing risks. The superintendent pharmacist had no up-to-date procedures in place to record near miss mistakes or dispensing errors. Most of the multi-compartment compliance aid dispensing activity was carried out by an automated dispensing robot. The superintendent pharmacist explained how bar-code technology was used to so that medicines were scanned when they were de-blistered into canisters that were then placed into the dispensing robot. The compliance aids were then prepared by the dispensing robot and clinically and accuracy checked by a pharmacist and assembled for delivery. The pharmacist explained that the barcode system helped mitigate the risk of selection errors as error messages would appear if the incorrect medicine was scanned when de-blistering into each canister. A member of the pharmacy team explained that sometimes mistakes do happen, such as when individual capsules or tablets can become misplaced rather than entering the specific dosing slot on the compliance aid. These were manually corrected. But the pharmacy kept no records of when errors happened and did not have a system in place to review these.

There was a workflow in the pharmacy where labelling, dispensing and checking activities were carried out at dedicated areas of the dispensary. The team used stackable containers to hold dispensed medicines to prevent the mixing up different prescriptions. Each compliance aid examined had been signed by the pharmacist who checked it.

The pharmacy did not complete any risk assessments for the clinical services it provides, including for the prescribing activity it undertook. There were no standard operating procedures (SOPs) or policies relating to the prescribing service or how Community Pharmacy Consultation Service (CPCS) referrals were managed. The scope of the prescribing service was not clearly defined, such as the types of conditions treated, or the types of medications prescribed (see principle 4).

There was no monitoring of the prescribing activity of the pharmacist independent prescribers (PIPs) in relation to the prescribing service, such as clinical audits or reviews. The pharmacy did not have a system in place to identify and investigate patient safety incidents relating to the prescribing service. And the Superintendent Pharmacist (SI) did not fully understand the extent of the prescribing service or have oversight of prescribing activity.

Up-to-date standard operating procedures (SOPs) were not in place for the services provided. Those examined did not reflect current dispensing practice in the pharmacy and had not been reviewed since 2017. There were no responsible pharmacist SOPs in place. There was a complaints procedure in place

and there were details about how to raise a complaint on the website. The pharmacy team gathered feedback by liaising with care homes and directing people to the company website. A certificate of public liability and indemnity insurance was held from Numark and was valid and in date until 31st December 2024. The PIPs reported that had their own professional indemnity insurance and the SI stated that the pharmacy's insurance covered independent prescribing activity.

Inspectors reviewed consultation records from May 2023 to December 2023 following the inspection. A theme identified was minimal detail around the persons presenting complaint and inconsistencies with how serious possible diagnoses were excluded. Several consultations appeared to have been processed but had no consultation notes recorded. The pharmacy's record keeping system did not include details of medication prescribed so the safety of this element of the service could not be established. Key pieces of information were regularly missing from records, such as how the PIP excluded symptoms which could indicate serious medical conditions (so called 'red flag' symptoms), information provided to people about what to do if their condition worsened or did not resolve or information on the urgency of referrals to other services.

Records of controlled drugs (CD) and patient-returned CDs were kept. CD balances had not been checked since February at the time of the inspection. A responsible pharmacist (RP) record was kept, and the RP notice was displayed in pharmacy. The fridge temperatures were recorded daily and were within the two to eight degrees Celsius range. But only one fridge was used to store medicine was monitored. The pharmacist said that date checking was carried out regularly but there were no records to support this. The private prescription records were in place but often missed the date on the prescription. The pharmacist reported that he did not often do emergency supplies and these records were not demonstrated. The specials records were retained but often missed the prescriber's name and address.

Confidential waste was collected in confidential waste bins and this was removed for destruction. There was no clear information governance policy (IG) was in place and it was unclear what training staff had undertaken to ensure that people's private information was adequately safeguarded.

The locum pharmacist was not aware of any safeguarding children and vulnerable adults procedure when questioned. The pharmacy team could not readily locate local contact details to raise safeguarding concerns or ask for advice about them.

Principle 2 - Staffing Standards not all met

Summary findings

The pharmacy's team members did not have the appropriate skills, qualifications and training to deliver services safely and effectively. The pharmacy team members appear to work well together. They are comfortable about providing feedback and raising concerns to the superintendent pharmacist.

Inspector's evidence

There were three pharmacists, one trained dispensing assistant and four untrained members of staff at the time of the inspection. The pharmacy team had two delivery drivers. The staff were observed to be working well together and providing support to one another when required.

The pharmacist explained that performance was reviewed on an ad-hoc basis. But there were at least five untrained members of staff that were dispensing medicines who had not been put on an appropriate accredited training course. These pharmacy staff had been at the pharmacy for over three months. There was no evidence the pharmacy team completed any training or kept up to date with their knowledge and understanding of the services and medicinal products provided.

The superintendent pharmacist reported that the pharmacy team would hold meetings on an ad-hoc basis to update all staff about patient safety issues. The pharmacy team explained that they felt comfortable with raising any concerns they had with the superintendent pharmacist. There were no formalised targets in place at the pharmacy.

Principle 3 - Premises Standards not all met

Summary findings

The pharmacy does not provide a safe and appropriate environment for the provision of pharmacy services. The pharmacy team is unable to give assurances that it adequately protects people's private information. The pharmacy is secure and protected from unauthorised access.

Inspector's evidence

The pharmacy was based in room on an industrial estate and was not open to the public. The pharmacy was secured from unauthorised access. It had two levels and the dispensary was on the ground level. Although the pharmacy appeared spacious, it was unprofessional in appearance. It was not clean, organised or well maintained. There were boxes of stock, cardboard and assembled prescriptions that were stored on the floor in the dispensary. This may mean that the pharmacy team are at an increased risk of trip hazards.

The dispensary in the pharmacy had a small room that the superintendent pharmacist had suggested could be used as a consultation room in future. But it was small, cluttered, and unprofessional in appearance. It was also located inside the dispensary with medicines and patient confidential details surrounding it. One of the pharmacists reported that they used a conference room in the building to have face-to-face consultations with people if it was deemed clinically appropriate. This was not part of the registered pharmacy premises and was located on a corridor beside the building reception. It was not appropriately soundproofed as conversations could be clearly heard from the corridor outside. This room did not have handwashing facilities or anywhere to safely dispose of clinical waste. The PIP present at the inspection said that he brought his own clinical equipment to this room when he saw people face-to-face. The software used for managing the Community Pharmacy Consultation service and prescribing service was bespoke to this pharmacy and maintained by the lead PIP, but the pharmacist was unable to explain how this system protected people's private information.

The pharmacy website included contact information for the pharmacy. The ambient temperature and lighting throughout the pharmacy was appropriate for the delivery of pharmaceutical services. There were hand washing facilities available in the dispensary area.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy's services are not easily accessible or effectively managed and delivered safely. The pharmacy obtains medicines from reputable suppliers but stores and manages them in a way which may increase risk to people using the service. The pharmacy team takes appropriate action where a medicine is not fit for purpose.

Inspector's evidence

Information about the services provided was displayed on the pharmacy website. The pharmacy was closed to the public. The pharmacy team liaised with care homes to generate business. Referrals for consultations for minor ailments were received via various GP surgeries.

The pharmacy was in an industrial park which was difficult to locate during the inspection. It was a closed pharmacy, but people using the Community Pharmacy Consultation Service (CPCS) were permitted to collect medicines instead of having them delivered. It was not signposted and it was not clear how or where people collected these medicines. So, it was not easy for people to access the service.

The pharmacy provided a prescribing service which was linked to the NHS CPCS service since December 2022. But the prescribing that was outside the scope of the CPCS was not commissioned by the NHS and was established via arrangements with local GP surgeries. The pharmacist explained that the CPCS and prescribing service was run by two PIPs, one who completed approximately 10 referrals per day and one who completed approximately 80 referrals a day. Referrals were received via the pharmacy's NHS email from local GP surgeries and then forwarded to the PIPs email. Examples of GP referrals were seen during the inspection and contained information such as the patients details and the nature of the presenting complaint. They did not contain any triage details or an assessment of the severity of the condition. The PIP made triage decisions based on the presenting complaint and determined which referrals required a consultation with the patient either remote or in-person. The PIP present during the inspection explained that many of the referrals resulted in simple self-care advice or referral to another pharmacy to buy over-the-counter products and that approximately 30 per day required more detailed discussion with the patient.

Once the referral has been imported into the pharmacy's software, a text notification is sent to the patient to explain that they were in a queue. It was not clear how this was communicated to people who did not have a mobile phone. The PIP stated that approximately 70% of cases resulted in a video consultation. If someone needed to be seen in-person, the PIP invited them to the conference room in with same building of the pharmacy. The PIP explained that they conducted in-person consultations on most days for approximately 5 or 6 people. The PIP had their own equipment to support in-person examinations such as a stethoscope, blood pressure machine, pulse oximeter and otoscope.

It was not possible to determine the safety of prescribed medicines as these were not recorded on the pharmacy's computer system alongside consultation records. Several examples were seen where in-person clinical assessments were not completed so it was unclear how the PIP confirmed certain diagnoses or ruled out potentially serious conditions. Examples included people treated for suspected ear infections and chest infections, and some people with suspected urinary tract infections who showed

signs of potential complications. For several referrals it was not clear if the person had been assessed by the PIP as no records were made. So, there was a risk of people's conditions worsening or their treatment being delayed. The PIP regularly referred people to the NHS 111 service, but it was not clear with what urgency, as key red flag symptoms were not excluded. So, there was a risk that people may not have understood the seriousness of their condition. One person was referred to the deep vein thrombosis (DVT) clinic, but the records did not outline what assessments the PIP made or what information was given to the person regarding the urgency of the referral.

The service was organised in such a way that a large number of referrals were managed by a single PIP. The service received 12, 468 referrals between May 2023 and December 2023, with the majority managed by the lead PIP. This volume of referrals, combined with the lack of documentation regarding how conditions were safely managed and the lack of governance surrounding the service, created a risk that the service was not managed in a safe way.

The pharmacy team dispensed multi-compartment compliance aids (MCAs). The MCAs were organised and managed using the patient medical record system and the automated dispensing robot. One compliance aid was examined and audit trails to demonstrate who had checked it were present. Descriptions were provided for the medicines contained within the compliance aids. The pharmacist reported that Patient information leaflets (PILs) were also supplied to people regularly. The process for delivering MCAs was not clear as there was no up-to-date procedure in place.

The superintendent pharmacist said that if a compliance aid was to go to people's home addresses, two deliveries were attempted. The pharmacist was not able to provide an explanation around how he safeguards vulnerable people using this service.

The pharmacy team deblistered medicines and left these in canisters to be loaded in the automated dispensing robot. But there was no evidence that the team considered data on the stability of medicines to ensure that they were suitable for this type of storage or dispensing. The pharmacist was unable to give assurances that he had considered the timescale of their stability outside of their original packaging.

The pharmacy team had an awareness of the strengthened warnings and measures to prevent valproate exposure during pregnancy. Valproate patient cards were available for use during valproate dispensing to female patients. The pharmacist reported that he would check that the patient's prescriber had discussed the risks of exposure in pregnancy with them and that they were aware of these and query if they had effective contraception in place. The team were also aware of the new regulations requiring valproate medicines to be supplied in original packs.

The pharmacy used recognised wholesalers such as AAH, Phoenix and Alliance Healthcare to obtain medicines and medical devices. Specials were ordered via Colorama specials. Invoices from some of these wholesalers were seen. Destruction kits for the destruction of controlled drugs were available. Designated waste bins were available and being used for out-of-date medicines. A bin for the disposal of hazardous waste was not available at the time of the inspection. The pharmacist agreed to address this.

The pharmacy team stored medicines and medical devices in a disorganised manner. For example, containers of mirtazapine 45mg tablets, memantine 20mg tablets, midodrine 5mg tablets and melatonin 2mg prolonged release tablets had been mixed together which may increase the risk of selection errors. There were some examples of medicines being stored outside of their original manufacturer's packaging, but these were disposed of during the inspection. It was not clear if stock

was date checked regularly. The fridges were in good working order and the stock inside was stored in an orderly manner. MHRA alerts came to the pharmacy electronically and the pharmacist explained that these were actioned appropriately. But the pharmacy team did not keep audit trails to verify this.

Principle 5 - Equipment and facilities Standards not all met

Summary findings

The pharmacy has access to the appropriate equipment and facilities to provide the core services it offered. It is not clear that facilities are used in a way that suitably protects people's confidentiality and dignity.

Inspector's evidence

There was a satisfactory range of crown stamped measures available for use. There were two plastic 100ml measures that were not crown stamped and the superintendent pharmacist agreed to dispose of these. Amber medicines bottles were capped when stored. A counting triangle and a capsule counter were available for use. Electrical equipment appeared to be in good working order and was PAT tested annually. Pharmacy equipment was seen to be stored securely from public access. Up-to-date reference sources were available in the dispensary and the consultation room, including a BNF, a BNF for Children and a Drug Tariff. Internet access was also available should the staff require further information sources. The pharmacy automated dispensing robot had regular maintenance and the company support could be contacted to resolve any issues if necessary.

There were two fridges in use which were in good working order. The maximum and minimum temperatures were recorded daily and were seen to be within the correct range for one fridge, but the second fridge was not monitored. Designated bins for storing waste medicines were available for use and there appeared to be enough space to store medicines. The computers were all password protected.

It was not clear how the PIP who saw people in-person decontaminated equipment between consultations as the conference room used for consultations did not have handwashing facilities or cleaning equipment. And there were no facilities to dispose of clinical waste in this location. The PIP used a cloud-based online platform that he had modified to collect, store and process people's information. It was not clear that adequate processes were in place to safeguard people's information when this platform was used.

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.