General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Village Pharmacy, 7 Village Centre, Leverstock Green, HEMEL HEMPSTEAD, Hertfordshire, HP3 8QG

Pharmacy reference: 1032211

Type of pharmacy: Community

Date of inspection: 13/06/2019

Pharmacy context

The pharmacy is located in a small shopping precinct. It dispenses NHS and private prescriptions, sells over-the-counter medicines and provides health advice. The pharmacy dispenses medicines in multi-compartment compliance packs (MDS blister packs) for people who have difficulty managing their medicines. Services include prescription collection and delivery, stop smoking and supervised consumption.

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 lacks systems to review and manage the safety and quality of its services.
		1.7	Standard not met	The pharmacy does not always keep people's private information securely.
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 team does not assemble blister packs in a way that provides an assurance that this service is undertaken safely and effectively.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy team members aim to minimise risks associated with providing services. But they do not routinely record and review mistakes that are found during the dispensing process. So they may be missing opportunities to improve safety and quality of the services. The pharmacy has written procedures which tell staff how to complete tasks safely. But these do not always reflect current practice and team members do not always follow them. The pharmacy does not always keep people's private information securely. The pharmacy team's members have not received appropriate training and have not signed their own confidentiality agreements. The pharmacy generally keeps the records it needs to so that medicines are supplied safely and legally. The pharmacy team members understand their role in protecting vulnerable people.

Inspector's evidence

Near misses were recorded and reviewed but there were nine records dated from Jan 2019. A patient safety review was not completed. There was no evidence to show the pharmacy team members had taken any action to minimise future risk as a result of mistakes.

Workflow: the pharmacist said the legal check was performed on receipt of the prescription. Labels were generated from scanning the bar code on the prescription or manually from reading the prescription. Medicines were picked from reading the prescription. In a random check the dispensing audit trail was not fully completed identifying who dispensed and checked the prescription. Medicines, labels and the prescription were retained in an unsealed bag in a cardboard box which staff said were waiting final check by the pharmacist.

There was a procedure for dealing with outstanding medication. The original prescription was retained until stock was received and an owing slip was issued to the patient. Multi-compartment compliance packs (blister packs) were prepared for four people in a care home and 70-80 patients who live in their own home. The pharmacy managed prescription re-ordering on behalf of patients except for the care home who ordered their own prescriptions.

The backing sheet providing information on how and when the patient should take the medicines was very faint and difficult to read. There was a description to identify individual tablets/capsules but patient information leaflets (PILs) were not routinely supplied with all medicines in the blister pack. Staff said that blister packs were assembled from a screen print which was checked against the prescription before the blister pack was supplied. When discharge summaries were sent the prescription was changed. The pharmacist said notes were not kept once medicines were changed. Blister packs were made up following the current prescription, but a record of notes was not maintained on the patient medication record (PMR). There was a cardboard box containing original dispensing containers which were filled with loose, de-blistered tablets to be supplied in blister packs. (See principle 4)

Sodium valproate was not supplied in a blister pack. A controlled drug (CD) was included in the blister pack at the time of delivery and the date of the prescription was managed to ensure supply within 28-day validity from date of issue. The pharmacist said he risk assessed new patients identified who would manage taking their medicines more effectively via a blister pack and arranged for supply of a weekly blister pack or all four blister packs together. The pharmacist liaised with a relative if appropriate

regarding how best to manage blister packs on behalf of the patient.

There was a set of standard operating procedures (SOPs) reviewed by the pharmacist in Jan 2019 and which included a complaints procedure. The CD SOPs did not include details of the current accountable officer. The delivery SOP referred to obtaining a patient signature to accept the delivery but the patient did not sign indicating a safe delivery. The CD delivery SOP referred to written patient consent but patient consent was now recorded on the PMR and then showed on the bag label if it was a 'delivery' patient. Both delivery drivers had not signed the training record for the CD delivery SOP. The staff member who served at the medicines counter said she would not give out a prescription or sell a P medicine if the pharmacist were not on the premises. Diabetics were generally referred to the pharmacist or doctor when they requested a remedy for a foot condition. Purchase of Viagra Connect was referred to the pharmacist.

The practice leaflet was on display and included details of how to comment or complain. The annual patient questionnaire had been conducted and people had commented that they would like more health-related advice. To protect patients receiving services, there was professional indemnity insurance in place provided by NPA expiring 30 April 2020. The responsible pharmacist (RP) notice was on display and the responsible pharmacist log was completed although the RP did not always sign out at the end of the session. The responsible pharmacist notice was on display and the responsible pharmacist log was completed.

Records for private prescriptions, emergency and special supplies were generally complete although the nature of the emergency was not always recorded. The CD and methadone registers were generally complete. The frequency of audit of CDs was not specified in the CD SOPs but the pharmacist described audit as being 'as and when'. A random check of actual stock of three strengths of MST reconciled with the recorded balance in the CD registers. Footnotes correcting entries were mostly signed and dated. Invoice details for receipt of CDs were complete.

Patient returned CDs were recorded in the destruction register for patient returned CDs but not until the point of destruction. There was a discussion about more frequent routine of audit of CDs to provide an earlier opportunity to detect discrepancies and diversion and listing patient returned CDs on receipt to provide a more robust audit trail.

There was a code of conduct for employees in respect of confidentiality on display in the consultation room which staff had signed but this had been on display during previous visits. Individual confidentiality agreements were not seen. There was no evidence of training or briefing of staff in General Data Protection Regulation (GDPR) although the pharmacist said staff had been briefed on data protection. There was a shredder to deal with confidential waste paper and a cordless phone to enable a private conversation. No confidential waste paper was found in the ordinary rubbish. The doors to the consultation room were open at the time of the visit so documentation and blister packs with patient sensitive information visible to anyone entering the consultation room. It may have been possible to see the contents of the pharmacy computer screen in the consultation room from the door.

Staff had undertaken safeguarding and dementia friends training and the pharmacist was accredited at level 2 in safeguarding training. Safeguarding contact details to report concerns were displayed and ensuring these were current was discussed.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy team manages the workload within the pharmacy. The team members can provide feedback but there is no formal procedure to report concerns. And more could be done to support team members keeping their knowledge up to date.

Inspector's evidence

Staff comprised: one full-time pharmacist, one pre-registration pharmacist, one full-time medicines counter assistant (MCA), one part-time MCA and two part-time delivery drivers. A new staff member had been recruited. There was one student whom the pharmacist said worked ‘as and when’ but had not undertaken any accredited training but was leaving employment.

The pharmacist was the pre-registration tutor. The pre-registration pharmacist had been enrolled on ProPharmace training course and attended regular training days. There was no set aside time at work apart from lunch break to study. Study topics included chapters of the BNF and calculation. There had been 13 weekly appraisals which were documented. The other staff were provided with Counter Skills which included product information and topics such as family planning. Staff had attended a training evening in May on lifestyle changes.

Staff had no formal appraisal to monitor performance. Staff provided feedback on retail stock and what would sell at the counter. There was no whistleblowing policy in writing, but the pre-registration pharmacist explained it was a procedure to protect staff where concerns could be reported to head office or the GPhC. Targets and incentives were not set.

Principle 3 - Premises ✔ Standards met

Summary findings

The public area of the premises is clean and secure. But medicines stock, equipment and information in the consultation room is not adequately secured and protected.

Inspector's evidence

The premises were generally clean although there were older fixtures and fittings. Dispensary benches were cluttered which limited space. The dispensary and consultation room sinks required treatment to remove lime scale. Lavatory facilities required some additional cleaning although handwashing equipment was provided.

The consultation room was not locked at the time of the visit. The door from the retail area was open. In the consultation room there was documentation and blister packs with patient sensitive information visible to anyone entering the consultation room. There was sufficient lighting and ventilation.

Principle 4 - Services **Standards not all met**

Summary findings

The pharmacy's services are accessible to most people. The pharmacy gets its medicines from reliable sources. But it does not routinely mark prescriptions for higher risk medicines. This may mean that people do not receive all the necessary information they need to take their medicines safely and CDs may be supplied when the prescription is no longer valid. The pharmacy does not always keep a record of therapeutic monitoring checks so it may not be able to show that appropriate counselling was provided to protect patient safety. The pharmacy does not always store medicines in their original packaging. This could affect the stability of the medicines and may mean the pharmacy cannot be sure that medicines are safe to use. The pharmacy does not keep records of the checks it makes in response to safety recalls. So it may not be able to show it has taken the right steps to keep people safe in the event of a future query.The pharmacy does not always provide medicine leaflets to people who receive medicines in blister packs. This means the patient may not have all the information they need to take their medicines safely. The pharmacy provides printed instructions for blister packs, but the ink is very faint which means people may not be able to read how to take their medicines. The absence of supporting notes for previous blister packs may make it difficult to deal with any queries relating to changes in medication. The pharmacy team does not always follow the written procedures for recording prescription deliveries. This may make it difficult to investigate when people query a failed delivery of their medicines.

Inspector's evidence

There was wheelchair access and large font labels could be printed to assist visually impaired patients. Staff could converse in Shona, Hindi and Gujarati to assist patients whose first language was not English. The pharmacy team had not participated in the quality payments scheme. Patients were signposted to other local services via NHS website and information contained in a signposting document although it was not clear how up to date the information was.

Regarding the campaign to raise awareness of sodium valproate, there did not appear to be any information to distribute to patients of child bearing potential regarding pregnancy prevention programme (PPP). There were no patients of child bearing potential being supplied sodium valproate. The pharmacist was signposted to MHRA website for information. No patient was identified for referral for prescription of proton pump inhibitor for gastric protection during the non-steroidal anti-inflammatory drug (NSAID) audit. There was information displayed for the 'Smile 4life' campaign.

Blister packs were prepared for patients. PILs were not routinely supplied to patients with each set of blister packs. The backing sheet was very faint and difficult to read. Replacing the printer cartridge to increase the definition of print was discussed. There was a cardboard box containing original dispensing containers which were filled with loose, de-blistered tablets to be supplied in blister packs. (See principle 1)

Although stickers were not seen highlighting prescriptions for high risk medicines there were SOPs for their supply. The pharmacist and pre-registration pharmacist said patients taking warfarin would be asked for evidence of INR. The INR was not recorded on the PMR in line with the SOP. Advice was given regarding blood tests, interactions with over-the-counter medicines and side effects of bruising. The pre-registration pharmacist explained that isotretinoin prescriptions should be dispensed within 7 days

of issue and confirmation that there has been a negative pregnancy test. Advice would be given on PPP and noted on the PMR. Patients taking lithium would be advised about blood tests and not switching brand.

Falsified medicines directive (FMD) hardware and software had not been installed at the time of the visit. Prescriptions awaiting collection on shelving in the store had prescriptions dating from Feb 2019 in a random check. CD prescriptions were not highlighted to ensure supply within 28-day validity and there was an uncollected prescription for zopiclone tablets which was dated Feb 2019 which was at risk of supply. Stickers were not seen to alert the pharmacist to counsel patients on other high-risk medicines.

Medicines and medical devices were outside the pharmacy, but the delivery drivers did not follow the written procedure and obtain a patient signature indicating a safe delivery. Medicines and medical devices were obtained from Alliance, AAH, Phoenix, Colorama and Sigma. Floor areas were clear. Stock on the dispensary shelves was not stored in a very tidy way. Stock was date checked and recorded. No date expired medicines were found in a random check. Liquid medicines were marked with the date of opening. Medicines were generally stored in original manufacturer's packaging apart from tablets de-blistered for supply in blister packs. Cold chain items were stored in the medical fridge. Waste medicines were stored separately from other stock.

Three or four patients accessed supervised consumption service. There were no clients for stop smoking service at the time of the visit. The pharmacist said drug alerts were checked but no record was maintained of actions taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy generally has the equipment and facilities it needs to provide its services. The pharmacy supplies liquid medicine in the same container with a new label each day and this may lead to contamination of the container.

Inspector's evidence

Current reference sources included BNF and Drug Tariff. The medical fridge was clean and tidy. Minimum and maximum temperatures were monitored daily and found to be within range 2□-8□. Both CD cabinets were fixed with bolts.

There were two British standard glass measures to measure liquids including one separate marked measure for methadone. For blister packs, the printed backing sheet which included when to take medicines and any special instructions was very faint and difficult to read. Replacing the printer cartridge would improve the definition of print.

There was a code of conduct for employees in respect of confidentiality on display in the consultation room which staff had signed but individual confidentiality agreements were not seen. There was no evidence of training or briefing of staff in General Data Protection Regulation (GDPR) although the pharmacist said staff had been briefed on data protection. There was a shredder to deal with confidential waste paper and a cordless phone to enable a private conversation. No confidential waste paper was found in the ordinary rubbish. The doors to the consultation room were open at the time of the visit so documentation and blister packs with patient sensitive information visible to anyone entering the consultation room. It may have been possible to see the contents of the pharmacy computer screen in the consultation room from the door.

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.