General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: WELL, 6 Ardwell Lane, Greenleys, MILTON KEYNES, Buckinghamshire, MK12 6AX

Pharmacy reference: 1029149

Type of pharmacy: Community

Date of inspection: 17/10/2019

Pharmacy context

This community pharmacy is located within a parade of shops in a residential area of Milton Keynes. It sells a range of over-the-counter medicines and dispenses prescriptions. It offers Medicines Use Reviews (MURs), New Medicine Service (NMS) checks and a prescription delivery service. It supplies medicines in multi-compartment compliance packs to people who need assistance in managing their medications. It also provides seasonal flu vaccination service and it has a small number of people who receive instalment supplies for substance misuse treatment.

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 is not identifying and managing risks associated with the services it provides.
2. Staff	Standards not all met	2.1	Standard not met	The pharmacy does not have enough team members to operate its services safely and effectively.
		2.5	Standard not met	There is insufficient evidence that appropriate action has been taken to address the concerns raised by members of the pharmacy team.
3. Premises	Standards not all met	3.1	Standard not met	The dispensary is untidy and cluttered. And this may increase the risk of dispensing errors or accidents.
4. Services, including medicines management	Standards not all met	4.3	Standard not met	Pharmacy medicines are not stored tidily or in an organised fashion and this may increase the risk of dispensing errors.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy has written instructions which describe how tasks should be done safely. But the team is not always able to work in an organised way. And the pharmacy's team members do not consistently record or review their mistakes. This may mean that they miss opportunities to learn and improve from these events. The pharmacy keeps people's private information securely. And it generally keeps the records it needs to by law. Members of the pharmacy understand how they can help protect vulnerable people.

Inspector's evidence

At the time of the inspection, the pharmacy was very busy. There was a constant flow of people in the pharmacy and there were queues of people waiting to be served. The pharmacist on duty was busy acknowledging people on the counter and trying to check prescriptions. The workflow in the dispensary was not organised. Members of the pharmacy team were struggling to locate people's prescriptions. The workbenches were congested with multiple dispensed items awaiting final accuracy check. Members of the pharmacy team had a backlog of prescriptions yet to be dispensed and this was causing frustration for people visiting the pharmacy to collect their prescriptions.

The pharmacy had a range of standard operating procedures (SOPs). And these were held electronically. The SOPs were reviewed every two years by the superintendent pharmacist (SI) and members of the pharmacy team were made aware of any changes on the online system. Members of the pharmacy team signed in using individual usernames. It was not possible to check the system to see if all current members of the pharmacy team had read the SOPs. But all staff present confirmed that they had read and signed the SOPs. And they were aware of the tasks they could or could not undertake in the absence of a pharmacist.

The pharmacy had SOPs about dealing with dispensing errors and near misses. The pharmacist said that dispensing errors were reported on an electronic reporting system called Datix. The pharmacist was yet to report an incident that took place in September 2019 involving a supply of medicines to a wrong patient. The medicines had been brought back to the pharmacy and the pharmacist said she had discussed the incident with the rest of the team.

There were some records of near misses kept but it appeared these were currently not being recorded consistently. There were some records had been made in February 2019 and one near miss reported in September 2019. There were no records made in August or in October 2019. The incidents had not been reviewed to identify any learning points and the information written down on some of the near miss logs was too brief to allow any meaningful analysis or identify any emerging trends.

The pharmacy’s complaints procedure was included in its practice leaflet. Members of the pharmacy team undertook an annual survey of the people who used the pharmacy but said they hadn’t received the results of the most recent survey. The results of the survey conducted in 2018 were posted on the NHS website and were largely positive. Approximately 4% of respondents had commented on the time it took to be served.

The pharmacy's computers were password protected and the pharmacist used her own NHS smartcard to download electronic prescriptions. Prescriptions awaiting collection were stored securely and private information on them was not visible to people visiting the pharmacy. Confidential waste was separated and collected by a specialist waste contractor for secure disposal. Prescriptions awaiting collection were stored securely and people's personal details were not visible to members of the public. Members of the pharmacy team confirmed that they had all signed confidentiality agreements and had undertaken mandatory Information Governance some time ago.

The pharmacy had appropriate indemnity insurance arrangements in place. The Responsible Pharmacist (RP) notice on display was not of the pharmacist on duty at the time of the inspection. The pharmacist realised this and rectified the situation immediately. The RP records were complete.

Records about controlled drugs (CDs) were generally maintained in line with requirements. Running balances were audited periodically. A random balance check of a CD during the inspection did not match the recorded balance in the register. The reasons for this and remedial actions were later confirmed to the inspector by the RP. CDs returned by people for disposal were recorded and denaturing kits were used for safe disposal. A sample of records checked about unlicensed specials and private prescriptions were in order.

The SOPs for protecting children and vulnerable adults were available and the pharmacist had completed Level 2 safeguarding training. The details of local safeguarding agencies for escalating safeguarding concerns were available in the pharmacy. And members of the pharmacy team could explain what to do or who they would make aware if they had any concerns about the safety of a child or a vulnerable person.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy's current staffing arrangements are not sufficient to manage all of its activities effectively. And there is no capacity to cope with any unplanned absence or increase in workload. Members of the pharmacy team are not coping with their current workload. And they do not always complete other routine tasks such as housekeeping duties, record-keeping or managing stock effectively. This could increase the risk of errors and means that some parts of the premises do not look professional.

Inspector's evidence

A regular part-time pharmacist, a qualified dispenser, a qualified locum dispenser and a trainee dispenser were on duty at the time of the inspection. The branch did not have a manager and was currently being managed by relief or locum pharmacists. After the inspection, the head office provided an email confirmation that a non-pharmacist branch manager was in place, but he was on annual leave at the time of the inspection. Although members of the pharmacy team were working well together and supportive of each other they were struggling to cope with the workload.

The pharmacy was in disarray. The pharmacist was trying to dispense prescriptions but was constantly being interrupted to address people's queries and attend to people on the counter wanting advice and recommendations for their ailments. There was a constant flow of people in the pharmacy and staff at times were struggling to locate people's prescriptions. Several people chose to call back and some were complaining about waiting times. The workflow in the dispensary was chaotic. And the workbenches were very cluttered, untidy and congested with stacks of baskets with dispensed medicines awaiting checking. There were approximately 500 items awaiting final check. The team had a backlog of prescriptions yet to be dispensed and a pile of prescriptions collected from the surgery couple of days had been buried under a stack of baskets.

Members of the pharmacy team said that they had been short staffed for quite some time. And they hadn't been able to book annual leave as there was nobody available to cover their leave. They also said that an experienced member of the team had walked out as she couldn't cope with stress levels in the pharmacy. They said they had raised concerns on many occasions about staffing levels with their area manager. Additional support had been sent for a few day for staff to catch up. But the situation had reverted back once this additional support was withdrawn. The pharmacist who worked on two days a week said that she was constantly being contacted on her days off about general queries. On quite a few days, it was noted on the RP records that comments such as 'no staff to open up', 'no keys to open up' and 'no other staff members to open up' had been made.

A whistle blowing policy was in place and members of the pharmacy team were aware about raising concerns. And said that they had raised concerns on many occasions but nothing was being done to help address their concerns. The company provided training resources to support staff in keeping their skills and knowledge up to date. But members of the pharmacy team were not able to make use of this because there was not time to do training whilst at work.

The pharmacist said that the company had set MUR targets but she was not under any undue pressure to achieve targets due to staff shortages.

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

Summary findings

The pharmacy's premises are secure and adequate for the services it provides. But work benches are cluttered and untidy. This reduces the efficiency of the dispensing process and may increase the risk of errors.

Inspector's evidence

The front fascia of the pharmacy was well maintained and projected a professional image. The retail area of the pharmacy was spacious and there was seating available for people waiting for services. The flooring in the retail area, consultation room and the dispensary was covered in litter, dusty and not clean. The dispensary comprised of three workbenches; all of which were very cluttered and untidy. Prescriptions were left lying around various parts of the dispensary. Floor spaces in the dispensary were obstructed with baskets of assembled prescriptions and bulky items. This could increase the risk of slips or trips.

There was a clean sink with hot and cold running water in the dispensary which was used for the preparation of medicines. The temperature was appropriate for the storage of medicines and the lighting throughout the premises was adequate. The dispensary was clearly separated from the retail area and afforded good privacy for the dispensing operation and any associated conversations or telephone calls.

A spacious consultation room was available. The room was suitable for private consultations, but it was untidy and not kept locked when not in use. This meant that a sharps bin and some equipment was not safeguarded against unauthorised access.

Members of the pharmacy team had access to adequate hygiene facilities. And the premises could be secured against unauthorised access.

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

Summary findings

The pharmacy's services are accessible to most people. But the overall workflow in the pharmacy and storage of medicines could be improved. The pharmacy obtains its medicines and medical devices from reputable suppliers. And it takes the right action in response to safety alerts, so that people are supplied with medicine and medical devices that are fit for purpose. But it does not always highlight prescriptions for higher-risk medicines. And this may mean that it misses the opportunities to speak with people when they collect these medicines.

Inspector's evidence

The entrance of the pharmacy had a small step and a power assisted door. A portable ramp was available to assist people with mobility difficulties to access the pharmacy. The pharmacy's opening hours and a list of services offered by the pharmacy were advertised within the store. And there was a range of healthcare leaflets on display. A prescription delivery service was offered to people who couldn't come to the pharmacy to collect their medicines. And the audit trail for this was complete.

The pharmacy's dispensing process on the day of the inspection was chaotic. The bench spaces were congested and there was very little clear bench space available to allow safe working. Baskets were used during the dispensing process to prioritise workload and minimise the risk of prescriptions getting mixed up. But these were stacked on top of each other, increasing the risk of medicines falling out and getting mixed up with other prescription items awaiting a final accuracy check.

The pharmacy supplied medicines in disposable multi-compartment compliance packs to people who had difficulties in managing their medications. The packs were supplied either weekly or monthly depending on the person's needs. Prescriptions were cross-checked with individual record sheets to ensure all items were prescribed and any changes to the person's medication were documented. An unsealed compliance pack was seen on the bench. It appeared that the trainee dispenser was in the process of assembling the pack but was called upon to attend to another task. A pack checked during the inspection included descriptions of medicines contained within it and dispensing labels were initialled. But patient information leaflets were not supplied.

The pharmacy had begun its winter flu vaccination service in the latter part of September. The pharmacist on duty at the time of the inspection had completed her training but the availability of the service on other days was very much dependent on whether the duty pharmacists had completed their accredited training. The anaphylaxis algorithm was on display in the consultation room and three adrenaline injections (Emerade 300) were available. Two of the three injections were due to expire end of 11/2019. But the pharmacist said she was aware that the injections were expiring the next month.

The pharmacist was aware of the valproate Pregnancy Prevention Programme (PPP) and knew which patient groups need to be provided with advice about the medicines contraindications and precautions. Patient information leaflets and cards were available in the pharmacy. The pharmacy did not currently have any people in the at-risk group taking valproate. Prescriptions for diazepam, tramadol, zopiclone, pregabalin and gabapentin were found in the retrieval system which had not been highlighted or marked in any way with their validity period. The pharmacist said that members of the pharmacy team were aware that prescriptions for CDs were valid for 28 days. Prescriptions for higher-risk medicines such as methotrexate were not highlighted to ensure people could be provided with advice when these

were handed out to people.

Medicines were obtained from licensed wholesalers and specials were obtained from specials manufacturers. No extemporaneous dispensing was carried out. Pharmacy-only (P) medicines were stored out of reach of the public. At the time of the inspection, the pharmacy was not fully compliant with the Falsified Medicines Directive (FMD). Members of the pharmacy team had some knowledge about the directive but were awaiting further guidance from the head office. The pharmacist was aware about the serious shortage protocol but had not had the need to use it yet.

Members of the pharmacy team had date checked stock medicines in September and short-dated items had been marked for removal at an appropriate time. Medicines were checked at random and no expired stock was found. But medicines were not stored tidily on the shelves. Medicines requiring refrigeration were stored between 2 and 8 degrees Celsius. Fridge temperatures were checked and recorded daily. But these were stored haphazardly in the fridge. All CDs were stored appropriately in the cabinet. The pharmacy kept a folder of alerts and recalls. But the file was very full and the records were somewhat cumbersome to access. Members of the pharmacy team had recently removed ranitidine from stock medicines but were not sure where they had kept the recall document.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy generally has the equipment and facilities it needs to provide pharmacy services safely. And its equipment is adequately maintained.

Inspector's evidence

Members of the pharmacy team had access to the internet and a range of reference sources. Pharmacy computers were password protected and computer terminals were not visible to customers visiting the pharmacy. A consultation room was available for private conversations and counselling. Equipment for counting loose tablets and capsules was clean. And a range of clean, crown-stamped, glass measures were available. All electrical equipment appeared to be in good working order. But members of the pharmacy team said that they had reported to head office about faulty telephone lines and it took three weeks for the matter to be resolved. Meanwhile members of the public could not get in touch with the pharmacy. The pharmacy's telephone lines were now in good working order.

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.