General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Waterloo Pharmacy, 159 Waterloo Road, Cobridge, STOKE-ON-TRENT, Staffordshire, ST6 2ER

Pharmacy reference: 1092737

Type of pharmacy: Community

Date of inspection: 25/07/2019

Pharmacy context

This 100-hour community pharmacy is located on a busy main road in a residential area. There are a limited number of other retail units in the vicinity. The pharmacy offers essential NHS services and sells over-the-counter medicines. A substance misuse treatment service is also available.

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	Pharmacy team members do not always follow written procedures, so tasks are not always completed effectively and some risks associated with pharmacy services are not adequately managed.
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	4.3	Standard not met	The pharmacy's stock management procedures are lacking. It does not complete regular date checks, fridge temperature monitoring is sporadic and waste medicines are not segregated and dealt with promptly.
		4.4	Standard not met	The pharmacy cannot demonstrate that it receives and actions drug recalls effectively.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

Written procedures are not always followed so tasks are not completed effectively. This introduces unnecessary risks to service delivery. The pharmacy keeps the records required by law and protects people's private information. But it is not always clear how it meets some data protection requirements to show how it uses and processes people's data. The pharmacy's team members are clear on their roles and they understand how to raise concerns to help protect vulnerable people.

Inspector's evidence

The pharmacy had written standard operating procedures (SOPs) covering operational tasks and activities. They defined staff responsibilities and had been updated in January 2018. But the procedures were not always followed, so the team may not always work effectively. For example, date checking procedures were not followed and several expired medicines were found. The team members present were clear on their roles, a medicine counter assistant (MCA) discussed the tasks that he would complete during the day and demonstrated an understanding of the activities which could and could not take place in the absence of a responsible pharmacist (RP). Professional indemnity insurance covering pharmacy services was provided through the NPA.

A near miss log was available. Records were limited with single entries in April, May and June and none to date in July. No records of a near miss reviews were maintained, so the team may not always be able to show what they had learnt. The team reported previously using shelf-edge labels to highlight medicines and encourage care with selection but stated that these had now faded or been removed and had not been replaced. The pharmacy had an incident reporting procedure and report forms were available for completion. The team were unable to recall any recent incidents.

People using pharmacy services were able to provide feedback verbally and the details of a complaint procedure were displayed in a pharmacy practice leaflet. People were also able to complete reviews online and the pharmacy participated in an annual community pharmacy patient questionnaire (CPPQ).

On arrival the incorrect RP notice was displayed. This was immediately amended when highlighted by the inspector. The pharmacist on duty had signed in to assume RP duties and a sample portion of the RP log appeared compliant. As did specials procurement records which provided an audit trail from source to supply. The pharmacy recorded the details of emergency supplies and private prescriptions electronically. But on occasion the details of the prescriber were inaccurate, so the team may not always be able to clearly show what has happened in the event of a query. Controlled drugs (CD) registers kept a running balance and some balance checks were carried out. A patient returns CD register was also available and previous destructions were signed and witnessed.

Pharmacy team members had a general understanding of confidentiality but compliance with some requirements of the General Data Protection Regulations (GDPR) were not always clear. The pharmacist was unsure as to the current registration status with the Information Commissioner’s Office (ICO) and a privacy policy was not available in line with GDPR requirements. The pharmacy segregated confidential waste into a designated bin, which was removed by an external contractor and completed prescriptions

were stored out of public view. No other confidential information was visible on the day and the appropriate use of NHS Smartcards was seen.

The pharmacist had completed safeguarding training through the Centre for Pharmacy Postgraduate Education (CPPE). Other team members had not completed training, but a dispenser was able to discuss some concerning behaviours that might be identified and stated that concerns regarding some local vulnerable adults had previously been raised when they had failed to collect their regular medicines. A chaperone policy was displayed on the table in the consultation room.

Principle 2 - Staffing ✔ Standards met

Summary findings

Pharmacy team members work within their competence and generally manage the workload effectively. They can raise concerns directly to the superintendent pharmacist, and they complete some ongoing training. But records of this are not always kept and they are not provided with regular or structured feedback on their development. So, they may not always be able to show how they learn and make improvements to address gaps in their knowledge.

Inspector's evidence

On the day of the inspection the regular pharmacist, who was also the superintendent pharmacist (SI) was working alongside a qualified dispenser. A third member of staff was working as an MCA and was present for part of the inspection. Both the pharmacist and MCA independently confirmed that the MCA had been in post for approximately three weeks, providing cover on an ad hoc basis for staff sickness. The MCA was untrained and the GPhC requirements for team members to be enrolled on an accredited training course within three months of employment were discussed and reinforced. The team were below the usual staffing level on the day due to leave and other unplanned absences. Pharmacy team members worked overtime or amended their regular hours when cover was required, and leave was usually restricted to help maintain sufficient staffing levels. The workload was adequately maintained during the inspection and there was no backlog to dispensing or other service delays, but staff said managing the workload had been more challenging recently due to staff absences.

The dispenser had completed an accredited training programme provided by Buttercups and the untrained MCA worked under supervision. The MCA discussed the questions that he would ask to ensure that sales of medicines were safe and appropriate, and concerns were referred to the pharmacist. Examples of this were seen on the day. Staff read training magazines and mail shot materials which were received through the post and a dispenser had recently completed a child oral health training module through CPPE. But there was limited pre-planned and structured training and no formal training records were maintained. The team were encouraged to ask questions on an ongoing basis and their learning and development needs were reviewed in response to this.

There was an open dialogue amongst the team and any issues and concerns were raised with the regular pharmacist. A dispenser was not aware of how an anonymous concern could be raised and said the need for this had not previously occurred. This may restrict the ability of team members to raise a concern in this manner, should the need occur. The pharmacy did not have any formal targets in place for professional services.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is adequately maintained for the provision of healthcare services. But space is lacking in the dispensary and consultation room. This impacts on general organisation and could restrict some people's ability to access an area suitable for private and confidential discussions.

Inspector's evidence

The pharmacy's premises were old and although in an appropriate state of repair, some of the interior fixtures and fittings were dated which may detract from the overall professional appearance. The pharmacist was made aware of any maintenance issues and arranged for appropriate repairs. An example was provided, where changes had been made to the premises waste storage area in response to a previous issue. Pharmacy team members carried out daily cleaning duties, with support from an employed cleaner once a week. Some of the shelves used to store medicines were dusty. There was adequate lighting throughout the premises. The temperature could not be formally assessed but felt warm, despite the entrance door being propped open and several portable fans being used. This may not be appropriate for the storage of medicines. Outside temperatures on the day of the inspection were unseasonably hot and exceeded 30 degrees Celsius, so this was likely to be an isolated occurrence.

The retail area was small but generally tidy. A range of suitable products were available for sale and pharmacy medicines were secured from self-selection. Chairs were available for use by people less able to stand. The pharmacy had an enclosed consultation room which was very narrow and may not be suitably accessible to wheelchair users. The dispensary was compact and there was limited workbench space available, which may increase the likelihood of medicines being mixed up. A separate sink was available for medicines preparation and had hot and cold running water and hand sanitiser. Additional storage areas and WC facilities was reasonably well maintained.

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

Summary findings

The pharmacy's services are accessible to people with different needs and are suitably managed. But people on high-risk medications are not always identified, so they may not get all the information they need to take their medicines properly. The pharmacy obtains medicines from reputable sources, but it does not carry out sufficient checks to demonstrate that it stores medicines appropriately and make sure they are fit for supply.

Inspector's evidence

The pharmacy had a step-free access and a manual door. Additional adjustments could be made for those with disabilities, such as the use of large print labels from the dispensing system. A selection of health promotion literature was available near to the main entrance, along with a copy of the practice leaflet which listed the services available from the pharmacy. Pharmacy team members were observed to direct people to other healthcare providers and had an awareness of the services available in the local area. Further support for signposting was provided through internet resources.

Prescriptions were dispensed using baskets, to keep them separate and reduce the risk of medicines being mixed up. An audit trail for dispensing was maintained using ‘dispensed’ and ‘checked’ boxes. Stickers were available to highlight prescriptions for CDs, but these were not always used and an expired and unmarked prescription for diazepam was identified on the day. This may increase the risk that a prescription could be supplied after it has expired. People on high-risk medications were not usually identified for additional counselling and monitoring, so they may not always receive all the information they need to take their medicines properly. The team had a limited awareness of the risks of the use of valproate-based medicines in people who may become pregnant. But did not have access to the required safety literature and were not always clear on hat information should be provided at the time of supply. The Medicines and Healthcare products Regulatory Agency (MHRA) guidance was reinforced and the team were advised on how to obtain copies of the safety materials needed.

The pharmacy used a diary to track repeat prescription requests and medication orders for people who had their medicines in multi-compartment compliance aid packs. Basic records of medications were kept for compliance aid patients using the patient medication record (PMR) system. The record was updated each time a change was made to help make sure that it was accurate, but this did not record a running audit trail of previous amendments to show when medications had been stopped or changed. Completed packs had patient identifying details and descriptions of individual medicines, but patient leaflets were not being supplied as they should be.

Stock medications were sourced through reputable wholesalers and specials from a licensed manufacturer. Stock was arranged in an organised manner and was stored within the original packaging provided by the manufacturer. The team discussed date checking procedures but were unable to locate any records. They reported that recent checks had been carried out, but random checks identified several expired medicines on the shelves, some of which had expired more than three months prior to the inspection. Expired and returned medicines were placed in medicine waste bins and a cytotoxic

waste bin was available for hazardous materials. There was some returned waste which was still waiting to be sorted and placed for appropriate disposal. The pharmacist confirmed with another team member that the pharmacy had registered with SecurMed, with a view to becoming compliant with the European Falsified Medicine Directive (FMD) but the necessary hardware was not in place and the pharmacist could not provide a timescale on when the pharmacy would become compliant. There were some team members who were unfamiliar with FMD and its requirements. Alerts for the recall of faulty medicines and medical devices were received electronically. The pharmacist was unable to access the email system to demonstrate this and said that this was usually done by one of the regular dispensers. The dispenser was contacted and reported that he had not checked the system in 'a few weeks'. The pharmacy was unable to demonstrate that they had received or actioned any recent alerts.

CDs were stored appropriately. Patient-returned and expired CDs were segregated from stock and random balance checks were found to be correct. CD denaturing kits were available. The pharmacy fridge was fitted with a maximum and minimum thermometer. The temperature was within the recommended range and was checked daily, but there were multiple gaps in temperature records, so the pharmacy cannot always demonstrate that medications are stored appropriately to maintain the cold chain.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services. It maintains equipment to a reasonable standard and uses it in a way that protects privacy.

Inspector's evidence

The pharmacy had access to paper reference texts including the British National Formulary (BNF) and internet access supported additional research. Several glass crown-stamped and ISO approved conical measures were available for measuring liquids. Measures were marked to indicate which liquids they could be used with. A varispence device was also available and was calibrated using a conical measure prior to each use. The pharmacy had counting triangles for loose tablets, a separate triangle was used for cytotoxic medicines, with additional equipment including gloves also in place.

Electrical equipment was in working order. Computer systems were password protected and screens were located out of view. A cordless phone enabled conversations to take place in private, if required.

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.