General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Williams; J.R.G., 31 High Street, Llandybie, AMMANFORD, Dyfed, SA18 3HX

Pharmacy reference: 1043214

Type of pharmacy: Community

Date of inspection: 17/08/2021

Pharmacy context

This is a rural village pharmacy. It sells a range of over-the-counter medicines and dispenses NHS and private prescriptions. It offers a limited range of services including treatment for minor ailments and a basic smoking cessation service. Substance misuse services are also available. This inspection was carried out during the COVID-19 pandemic.

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	1.6	Standard not met	Responsible Pharmacist records, records of unlicensed specials and records of controlled drugs are not well-maintained.
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 does not have a robust system in place to deal with prescription items that are owed to people.
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 procedures to help make sure the team works safely. Its team members talk about things that go wrong and take action to help stop them from happening again. The pharmacy generally keeps the records it needs to by law. But some details are missing, so it may not always be able to show exactly what has happened if any problems arise. It asks people to give their views about the services it provides. And its staff know how to keep people's private information safe. The pharmacy's team members understand how to recognise and report concerns about vulnerable people to help keep them safe.

Inspector's evidence

The pharmacy had systems in place to identify and manage risk, including the recording of dispensing incidents. It was not always clear from the records which incidents had reached the patient and which were near misses, although the pharmacist was able to distinguish these. Staff said that the pharmacist discussed near misses with them at the time of each occurrence. They said that they often shared examples of similar packaging that they thought might lead to selection errors and had recently separated different forms of metformin tablets on dispensary shelves for this reason. A range of written Standard Operating Procedures (SOPs) had been signed by all staff, although these were overdue for review. There were many slightly different versions of SOPs which was confusing. It was difficult to tell which SOPs were current and if they accurately reflected the activities carried out in the pharmacy. However, the pharmacy team were able to give detailed and appropriate descriptions of their roles and responsibilities.The pharmacy usually received regular customer feedback from annual patient satisfaction surveys, but this process had been paused during the pandemic. The pharmacist said that verbal feedback was mostly positive. The pharmacy used the NHS formal complaints procedure 'Putting Things Right' to manage complaints. Information about how to make complaints was included in the practice leaflet, although this was not displayed in the retail area. Evidence of current professional indemnity insurance was available. All necessary records were kept, including Responsible Pharmacist (RP), unlicensed specials, private prescription and emergency supply records. However, there were occasions on which the pharmacist had not signed out of the RP register to show the time at which he had relinquished responsibility for the safe and effective running of the pharmacy. There was a risk that there would not be enough information available to provide a clear audit trail in the event of queries or errors. Some electronic emergency supply records stated that they had been made at a prescriber's request when in fact they had been made at the request of a patient. Records of unlicensed specials did not include patient details as required by law. Some headings were missing from CD registers. There had been no entries made in the patient-returned controlled drug (CD) register since February 2017. The pharmacist said that he did not remember having received any patient-returned CDs after this date and there were none present in the CD cabinet.Staff had signed confidentiality agreements. They were aware of the need to protect confidential information, for example by being able to identify confidential waste and dispose of it appropriately. The pharmacist and staff had undertaken formal safeguarding training and had access to local guidance and contact details via the internet.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload. They are properly trained for the jobs they do. And they feel comfortable speaking up about any concerns they have.

Inspector's evidence

The pharmacist owner worked at the pharmacy from Monday to Friday each week. The pharmacy was very quiet at the time of the inspection and there were enough suitably qualified and skilled staff present to comfortably manage the workload. The staffing level appeared adequate for the services provided. The support team consisted of two dispensing assistants and a medicines counter assistant (MCA). Staff had the necessary training and qualifications for their roles. Part of the MCA's role was to check dispensary stock against wholesaler invoices before putting it away and she had successfully completed an appropriate training course to allow her to do this. One dispensing assistant had been declared competent under the grandparent clause. She had trained as an accuracy checker but did not currently use this qualification. There were no specific targets or incentives set for the services provided. Staff worked well together and had an obvious rapport with customers since they served a small and close-knit community. They said that they were happy to make suggestions within the team and felt comfortable raising concerns with the pharmacist owner. A whistleblowing policy in the Information Governance file advertised a confidential helpline for reporting concerns outside the organisation.

Members of staff were observed to use appropriate questions when selling over-the-counter medicines to patients. They referred to the pharmacist on several occasions for further advice on how to deal with transactions. Staff had access to informal training materials such as articles in trade magazines and information about new products from pharmaceutical representatives. There was no formal appraisal system in place, but all staff could discuss performance and development issues informally with the pharmacist whenever the need arose. The lack of a structured training and development programme increased the risk that individuals might not keep up to date with current pharmacy practice and that opportunities to identify training needs could be missed.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean, tidy and secure. It has enough space to allow safe working and its layout protects people’s privacy.

Inspector's evidence

The pharmacy was housed in an old building but was clean, generally tidy and well-organised. The dispensary was small but had sufficient space to allow safe working. Some stock was being stored on the floor but it did not pose a trip hazard. The sink had hot and cold running water and soap and cleaning materials were available. A plastic screen had been installed at the medicines counter to reduce the risk of viral transmission between staff and customers. A consultation room was available for private consultations and counselling. But it was not visible from the retail area and it was not clearly advertised, so people may not have known it was available. The lighting and temperature in the pharmacy were adequate. One prescription retrieval area was not well-lit, which increased the risk of pharmacy team members picking up the wrong bag, but a torch was available for use if necessary.

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

Summary findings

The pharmacy's services are easy for people to access. If it can't provide a service, it directs people to somewhere that can help. The pharmacy's working practices are generally safe and effective and it stores medicines appropriately. But it does not have good systems in place to deal with items that are owed to people, which might lead to mistakes being made. And there is a risk that the pharmacy team will not have all the information they need to investigate properly if something goes wrong.

Inspector's evidence

The pharmacy offered a limited range of services, some of which were advertised in the pharmacy window and in the practice leaflet, although this was not displayed in the retail area. Information about coronavirus and related safety procedures was displayed on the pharmacy entrance door and at the medicines counter. There was wheelchair access into the pharmacy and consultation room. A signposting file provided by the local health board was available and staff said that they would signpost people requesting services they could not provide to nearby pharmacies or other providers such as the local surgery. Some health promotional material was available in the retail area. The pharmacy was located in a Welsh-speaking area. The pharmacist was a fluent Welsh-speaker and several transactions were observed to take place in Welsh.

The pharmacist said that the dispensing workload was easy to manage as most of it consisted of repeat prescriptions with very few walk-ins. The pharmacy offered a repeat prescription collection service from four local surgeries.

Dispensing staff used a basket system for assembling repeat prescriptions to help ensure that medicines did not get mixed up during dispensing. Baskets were not used for walk-in prescriptions, but these were dispensed and bagged in the order that they were presented to reduce the risk of transposition of medicines. Dispensing labels were initialled by the dispenser to provide an audit trail. However, the pharmacist did not routinely initial labels to show that he had performed an accuracy check. This prevented a full analysis of dispensing incidents, and there was a risk that items that had not been checked by the pharmacist might be handed out in error.

The system in place for dealing with prescription items owed to people was not robust. If there was not enough stock of a product available to fulfil a prescription, a label was generated for the full quantity of the product and attached to the part pack. The prescription was then annotated with the quantity to follow and the prescription bag placed in the retrieval area for collection. If more stock of the product arrived before the patient came in to collect their prescription, staff added the outstanding quantity to the part pack before handout. However, if this was not the case, a staff member or the pharmacist simply informed the person of the quantity that was to follow, without giving them an owing slip. The patient medication record (PMR) was not subsequently altered to show the actual quantity that had been supplied. This system relied on the person collecting the prescription to understand and remember that they had only received a part supply, and to relay this information to the patient if they were a representative. The accuracy of the PMR could not be relied upon and the part product was not labelled with the correct quantity according to legal requirements. It was also unclear if the annotated prescription was always available for reference when the owing quantity was collected. There was a risk that this system might lead to confusion and that people could run out of their medicines or

that incorrect supplies might be made.

Prescriptions for controlled drugs requiring safe custody and fridge lines were not dispensed until the point of handout. Dispensing labels were attached to alert staff to the fact that these items were outstanding. Prescriptions for Schedule 3 and 4 CDs awaiting collection were marked with an asterisk to remind staff that these should not be supplied more than 28 days after the date on the prescription. Patients on high-risk medicines such as warfarin, lithium and methotrexate were not routinely identified and there was a risk that opportunities for counselling might be missed. However, staff referred all prescriptions to the pharmacist before handout. The pharmacy team were aware of the risks of valproate use during pregnancy. The pharmacist said that any patients prescribed valproate who met the risk criteria would be counselled appropriately and provided with information. The pharmacy carried out regular audits of high-risk medicines, which were commissioned by the local health board. These audits were used to collect data about the prescribing, supply and record-keeping associated with high-risk medicines to flag up areas where risk reduction could be improved within primary care.

The pharmacy did not provide a routine delivery service, but the pharmacist delivered about ten prescriptions to vulnerable and housebound patients each week. He asked patients to sign the back of their prescription if a controlled drug was supplied.

Disposable compliance aid trays were used to supply medicines to a number of patients. Trays were labelled with descriptions to enable identification of individual medicines and patient information leaflets were routinely supplied. Each patient had a section in a dedicated file that included their personal and medication details, details of any messages or changes and relevant documents, such as discharge summaries. A list of patients was available for reference in the front of the file. A record of the date on which each patient's compliance aid had been collected was also kept for reference.

The pharmacy was not currently providing medicines use reviews, as this service had been suspended by Welsh Government in light of the COVID-19 pandemic. Very few discharge medicines reviews had been carried out in recent months. The pharmacy continued to provide the Just in Case palliative care service, the level two (supply only) smoking cessation service and the Choose Pharmacy common ailments service. The pharmacist was hoping to start providing the influenza vaccination service in the autumn but had not yet completed the necessary annual training and did not currently have any stock of vaccines. He had also applied to provide the Welsh Government's COVID-19 lateral flow test supply service but had not yet been able to obtain any tests from the designated wholesaler.

Stock medicines were obtained from licensed wholesalers and were stored appropriately. Medicines requiring cold storage were stored in a drug fridge. Maximum and minimum temperatures were recorded daily and were consistently within the required range. CDs were stored in a safe that was secured to the fabric of the building. There was not a great deal of stock, but different products were stored in piles on top of one another and some out-of-date CDs had not been segregated from usable stock, increasing the risk of errors. Some poisons were stored appropriately in a locked cupboard in the dispensary away from other medicines. The pharmacist gave assurances that he would contact the appropriate authority for collection and disposal of these in the near future.

Staff said that stock was regularly date-checked, but the frequency and scope of these checks were not documented. This created a risk that out-of-date medicines might be overlooked. Four packs of CDs were found to be out of date. However, the pharmacist and dispensing assistants said that they always included an expiry date check in their dispensing and checking processes. Date-expired medicines were disposed of appropriately, as were patient returns and waste sharps. The pharmacy received drug alerts and recalls via NHS email. The pharmacist was able to describe how he had dealt with recalls for

medicines by contacting patients where necessary and returning quarantined stock to the relevant supplier.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services. The pharmacy's team members use these in a way that protects people's privacy.

Inspector's evidence

The pharmacy used a range of validated measures to measure liquids. These were clean and the pharmacist said that they were washed after being used to measure methadone. Triangles were used to count tablets and staff said that these were washed after use with loose cytotoxics. The pharmacy had a range of up-to-date reference sources. Personal protective equipment was available for staff use and the pharmacy team were wearing face masks.

All equipment was clean and in good working order, although there was no evidence to show that it had recently been tested. Equipment and facilities were used to protect the privacy and dignity of patients and the public. For example, the pharmacy software system was protected with a password and the consultation room was used for private consultations and counselling.

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.