General Pharmaceutical Council

# Registered pharmacy inspection report

**Pharmacy Name:** Tongwynlais Pharmacy, 17 Merthyr Road, Tongwynlais, CARDIFF, South Glamorgan, CF15 7LF

**Pharmacy reference:** 1043718

**Type of pharmacy:** Community

**Date of inspection:** 29/10/2019

## Pharmacy context

This is a village pharmacy on the outskirts of Cardiff. It sells a range of over-the-counter medicines and dispenses NHS and private prescriptions. It offers a range of services including emergency hormonal contraception and treatment for minor ailments.

## 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 | Records of controlled drugs are not properly maintained |
| | | 1.8 | Good practice | Safeguarding is an integral part of the culture within the pharmacy |
| **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 | Prescriptions are not kept for dispensed items and patient information leaflets are not supplied with compliance aids |
| **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 record some of their mistakes. But they do not always review everything that goes wrong. So they may miss some opportunities to learn. The pharmacy asks people to give their views about the services it provides. And it keeps people's private information safe. But it does not always keep the records it needs to. And details are sometimes incorrect or missing, so it may not always be able to show exactly what has happened if any problems arise. The pharmacy's team members are good at recognising and reporting concerns about vulnerable people to help keep them safe.

### Inspector's evidence

The pharmacy had some systems in place to identify and manage risk, including the recording of dispensing errors. Near misses had not been recorded during 2019 and very few had been recorded in 2018. Staff said that the pharmacists tended to discuss near misses with them at the time of each occurrence rather than analyse all patient safety incidents on a regular basis to identify patterns and trends. Some action had been taken to reduce risks that had been identified: for example, caution stickers had been used to alert staff to the risks of picking errors with imipramine, indapamide, amlodipine and amitriptyline following dispensing incidents. A range of written standard operating procedures (SOPs) underpinned the services provided and these were regularly reviewed. The Responsible Pharmacist notice displayed was incorrect but the locum pharmacist remedied this as soon as it was pointed out to her.

The pharmacy received regular customer feedback from annual patient satisfaction surveys. Staff said that the results of the most recent survey showed that this was mostly positive. The pharmacy used the NHS complaints procedure 'Putting Things Right' to deal with complaints and staff had read and signed a copy of this. A poster advertising the complaints procedure was displayed on the consultation room door, although this was not visible from the retail area. Information about how to make complaints was included in the practice leaflet.

A current certificate of professional indemnity insurance was on display. Responsible pharmacist (RP), p rivate prescription and unlicensed specials records were kept and generally properly maintained. The RP register had not been completed that day, but the locum pharmacist remedied this immediately. No records of emergency supplies were available, but staff said that they could not remember the last time such a supply was made, as they were always able to signpost patients to the local surgery. Controlled drug (CD) records were not always well-maintained. Some headings in the CD register had been altered by obliteration, with no audit trail to show who had been responsible for the amendment. This meant that it might be difficult for the pharmacy team to fully resolve queries or deal with errors effectively. CD running balances were initialled after each entry, but it was not clear if this indicated that they had been checked. Several random balances were checked and some discrepancies were identified. The last entry in the register for patient-returned CDs was dated 2011 and there was no record of the medicines currently held. This increased the risk that instances of diversion might be missed.

Staff said that they had signed confidentiality agreements but they could not locate these. They understood the importance of confidentiality and were aware of the need to protect confidential information. They were able to identify confidential waste and demonstrated that it was disposed of

appropriately. The pharmacist and the two dispensing assistants had individual passwords to access the pharmacy computer system. A poster at the pharmacy entrance explained how NHS Wales used prescription information to help them make better informed decisions about medicines and patient services.

The pharmacist had undertaken level two safeguarding training and had access to guidance and local contact details via the internet. Staff had received in-house training and were able to identify different types of safeguarding concerns. They said that after having concerns about an elderly patient who lived alone and was becoming very confused they had contacted her GP, who had carried out a home visit. Staff said that arrangements had subsequently been made for the patient to be placed in a retirement home close to her family. During the inspection, staff helped a vulnerable person who could not read or write and had run out of medication by contacting the surgery on his behalf and arranging for a prescription to be generated so that they could make a supply. A chaperone policy was advertised in a poster displayed on the consultation room door and inside the room itself. Information about support groups and services for carers was displayed in the consultation room.

## Principle 2 - Staffing ✔ Standards met

### Summary findings

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

### Inspector's evidence

One of the pharmacist owners worked at the pharmacy on a regular basis. He was not present during the inspection and a locum pharmacist was covering his role. She was assisted by a dispensing assistant and a trainee dispensing assistant. Another dispensing assistant and a qualified medicines counter assistant were absent. Certificates were displayed as evidence that staff members had the necessary training and qualifications for their roles. The trainee dispensing assistant worked under the pharmacist's close supervision.

The pharmacy was quiet and staff present worked well together to manage the workload effectively. The pharmacy served a small and close-knit community and staff had an obvious rapport with customers. There were no specific targets or incentives set for the services provided. Staff said that they were happy to make suggestions within the team and felt comfortable raising concerns with the two pharmacist owners. A whistleblowing policy in the SOP file had been signed by all staff and included details of a confidential helpline for reporting concerns outside the company. The GPhC's Guidance on Raising Concerns was also available in the SOP file.

A member of staff working on the medicines counter was observed to use appropriate questions when selling over-the-counter medicines to patients and referred to the pharmacist on several occasions for further advice on how to deal with a transaction. Staff had access to informal training materials such as articles in trade magazines, training modules on counter skills provided by suppliers and information about new products from manufacturers. They said that much of their learning was via informal discussions with the pharmacist. There was no formal appraisal system in place, but all staff could informally discuss performance and development issues 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 clean, tidy and well-organised, with enough space to allow safe working. The sink had hot and cold running water and soap and cleaning materials were available. A consultation room was available for private consultations and counselling and its availability was clearly advertised. The room doubled as an office and access was at the entrance to the dispensary. Staff said that patients were escorted into the room and they made sure that no confidential information was visible. The lighting and temperature in the pharmacy were generally appropriate, although the area in which the CD cabinet was located was not well lit, increasing the risk of errors.

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

### Summary findings

The pharmacy's services are accessible to most people but some, such as wheelchair users, may have difficulty accessing them. If it can't provide a service, it directs people to somewhere that can help. It stores most medicines appropriately and carries out some checks to make sure they are in good condition and suitable to supply. But its working practices are not always managed effectively. It doesn't always keep prescription forms with dispensed medicines. This means that the pharmacy's team members may not always have all the information they need when they hand out the medicines. And they do not always know when higher-risk medicines are being handed out. So they might not always check that medicines are still suitable, or give people advice about taking them.

### Inspector's evidence

The pharmacy offered a range of services that were advertised in the practice leaflet, although this was not on display in the retail area. Staff located copies of the leaflet and displayed them as soon as this was pointed out. The entrance to the pharmacy was not flat, but staff said that people in wheelchairs were able to access it easily. There was no wheelchair access to the consultation room, but the pharmacist said that she could make out-of-hours appointments for people, speak to them by telephone or visit them at their home address if necessary. The locum pharmacist was not accredited to provide advanced or enhanced services and staff said that they would signpost people requesting these to other nearby pharmacies. Lists of pharmacies participating in the local health board's palliative care and needle exchange schemes were displayed in the dispensary. Some health promotional material and details of local community support groups were on display in the retail area.

Baskets were not used to assemble prescriptions. There were very few walk-in prescriptions, and these were dispensed and bagged in the order that they were presented to avoid the risk of transposition of medicines. Repeat prescriptions were assembled and lined up on the dispensary bench. Space was left between individual prescriptions to reduce the risk of medicines becoming mixed up. This was achievable at the time of the inspection as there was ample workbench space and the pharmacy was quiet. However, it was unclear if it was still the case during busy periods. Dispensing labels were usually initialled by the dispenser and checker to provide an audit trail. However, some labels were found that did not bear the dispenser's initial. There were no initials at all on some multi-compartment compliance aids and the bulk medicines that accompanied them. This lack of a clear audit trail might prevent a full analysis of dispensing incidents.

Prescriptions were not retained for most dispensed items awaiting collection. This meant that prescriptions for some Schedule 3 CDs might not be marked with the date of supply at the time the supply was made, as required by legislation. Staff said that prescriptions were scanned wherever possible, but they were unable to retrieve the scanned images for reference. One prescription awaiting collection was over six months old and so no longer valid. The pharmacist removed this from the retrieval area as soon as this was pointed out. There was no strategy in place to ensure that Schedule 3 or 4 CDs were not supplied to the patient or their representative more than 28 days after the date on the prescription. One prescription for gabapentin was found present that was over 28 days old, so no longer valid. The pharmacist said this was an oversight and removed it from the retrieval area. Prescriptions that included CDs requiring safe custody or fridge lines were stored in a dedicated area of the dispensary. Staff said that these items were usually only added when the patient or their

representative attended to collect the prescription. However, one prescription bag contained a dispensed box of MST Continus tablets. Staff said that this had been added that morning as the representative of a terminally-ill patient had telephoned to say that they were on their way to collect it. When it was pointed out the pharmacist secured it in the CD cabinet until the patient's representative arrived.

Patients prescribed 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. The pharmacist said she would ask walk-in patients prescribed these medicines for relevant information about blood tests and dose changes. The pharmacy team were aware of the risks of valproate use during pregnancy. Staff said that any patients prescribed valproate who met the risk criteria would be counselled and provided with appropriate information. The information pack for valproate patients was available in the dispensary office. Staff said that the pharmacy carried out regular high-risk medicines audits 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 prescription delivery service was managed by members of staff. Signatures were not routinely obtained for prescription deliveries, which meant that the pharmacy might have difficulty dealing with any complaints or queries. Staff said that signatures would be obtained for controlled drugs but that these were rarely delivered. There were no recent examples of CD signature sheets available. Staff said that they would write the name of the delivery driver in the CD register as an audit trail if an entry was required. If a patient or their representative was not at home to receive a delivery, the delivery driver put a notification card though the door and brought the prescription back to the pharmacy.

The pharmacy provided medicines in disposable multi-compartment compliance aids to a number of patients. The trays were labelled with descriptions to enable identification of individual medicines. The pharmacist said that patient information leaflets were not routinely supplied. This did not comply with legislation, and there was a risk that patients might not always have all the information they need for them to make informed decisions about their own treatment. A list of patients was displayed in the dispensary for reference. Each patient had a labelled drawer that contained their stock medicines.

Medicines were obtained from licensed wholesalers and generally stored appropriately. Some bottles and boxes containing loose tablets or blister strips that had been removed from their original packaging were not adequately labelled either as stock or named-patient medication. This increased the risk of error and did not comply with legislative requirements. Controlled drugs were stored in a safe that was securely bolted to the floor. Two boxes of patient-returned 10mg and 30mg MST Continus tablets had been segregated from usable stock but were not clearly marked to show that they were obsolete. There was a risk they could be confused with stock medicines, as they were in date and the dispensing labels had been removed. However, staff said that they could identify the boxes as patient returns because they were stored on a shelf they knew should only be used for obsolete CDs.

Medicines requiring cold storage were stored in a small, well-organised drug fridge. There was ice in the freezer compartment and staff said that the fridge was due to be defrosted. Maximum and minimum temperatures were usually recorded daily although there were some gaps in the records. Minimum temperatures below two degrees Celsius had been recorded on several occasions. Staff could demonstrate how they read and reset the drug fridge thermometer, but they did not know what the recommended temperature range was. This made it difficult for them to be assured that medicines were always stored properly and were safe and fit for purpose. On discussion, they understood that if the temperature fell outside the range of two and eight degrees Celsius the pharmacist should be

informed, and remedial action taken if necessary.

Stock was date-checked regularly, and a sticker was placed on each shelf to record the date on which stock was last checked. However, one pot of Persantin Retard was found to be out of date. The pharmacist said that she would identify any expired medicines during her final accuracy check as she included a date check as part of this procedure. Date-expired medicines were disposed of appropriately, as were patient returns. There was no separate bin for disposing of cytotoxic waste but staff said that they would order a cytotoxics bin from their waste contractor and segregate any cytotoxic waste they received in the meantime. The pharmacy received drug alerts and recalls via its NHS email account. Neither the staff present, nor the locum pharmacist were able to access this account, saying that only the two pharmacist owners could do so. However, staff said that when their regular pharmacist was absent, the other pharmacist owner would always inform them of any recalls that needed to be actioned. Staff were able to describe how they would deal with drug recalls by quarantining affected stock and returning it to the relevant supplier. There was a concern that failure to receive drug alerts or recalls promptly might delay any action required to reduce risk to patients. The pharmacy had the necessary hardware to work in accordance with the Falsified Medicines Directive, but the software had not been installed and so the pharmacy was not yet able to comply with legal requirements

## Principle 5 - Equipment and facilities ✔ Standards met

### Summary findings

The pharmacy has the equipment and facilities it needs to provide its services. Its 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. One 10ml measure was not validated, but 10ml water measured in this also measured 10ml in a validated measure. Triangles and a tablet counter were used to count tablets and a separate triangle was available for use with loose cytotoxics. The pharmacy had a range of up-to-date reference sources. Equipment was clean and most was in good working order, although there was no evidence to show it had recently been tested. Staff said that a printer was not currently working but they were able to use the fax machine to copy documents if necessary. They had reported this to the pharmacist owner. 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. |