General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Tout's Pharmacy, Roynon Way, CHEDDAR, Somerset, BS27 3RB

Pharmacy reference: 1109089

Type of pharmacy: Community

Date of inspection: 01/05/2019

Pharmacy context

This is a community pharmacy located within a supermarket in the village of Cheddar in Somerset. A range of people from the local area use the pharmacy. The pharmacy dispenses NHS and private prescriptions. It also offers a few services such as Medicines Use Reviews (MURs) and the New Medicines Service (NMS). And, it supplies some people with their medicines inside multi-compartment compliance aids if they find it difficult to take their medicines on time.

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 has not identified or managed several risks associated with its services. The team are not recording or reviewing mistakes that occur during the dispensing process, there is little evidence of remedial activity or learning occurring in response to incidents and there is no information on display about the pharmacy's complaints process. Pharmacy staff are not trained on recent developments in data protection laws, people are not informed how their private information is maintained and their confidential information is at risk from the way the consultation room is used as well as from the delivery service. Team members are not trained on safeguarding the welfare of vulnerable people and they are not segregating date-expired Controlled Drugs clearly from those that have been returned by the public for disposal. People prescribed higher risk medicines are not identified, they are not counselled, relevant parameters are not checked or details documented
		1.2	Standard not met	There is not enough assurance that the pharmacy has up-to-date written Standard Operating Procedures in place to cover services and to maintain people's privacy. There are two sets of operating procedures present and neither fully reflect the pharmacy's current services. Staff have not read or signed these and there are details missing from the pharmacy's written Information Governance procedures
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 met	N/A	N/A	N/A
5. Equipment	Standards	N/A	N/A	N/A

Principle	Principle finding	Exception standard reference	Notable practice	Why
and facilities	met			

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

Summary findings

The pharmacy does not identify or manage several risks associated with its services effectively. It has written instructions to help with this. But, there are two different sets in place. And, members of the pharmacy team have not read them. This could mean that they are unclear on the pharmacy's current processes. Pharmacy team members deal with their mistakes responsibly. But, they are not recording or reviewing all of them. This could mean that they may be missing opportunities to spot patterns and prevent similar mistakes happening in future. Team members know to protect people's private information, but they have not been trained on recent updates in the law. And, the pharmacy doesn't tell people what it does with their personal information, as required by law. Not all the pharmacy's team members understand how to protect the welfare of vulnerable people. So, they may not know how to respond to concerns appropriately. The pharmacy is maintaining its records that must be kept. But, these are not always made in accordance with the law. This means that team members may not have all the information they need if problems or queries arise.

Inspector's evidence

The pharmacy was small (see Principle 3) and most of the available bench space was taken up with baskets of prescriptions awaiting checks or requiring assembly. There was a small segregated space for the Responsible Pharmacist (RP) to carry out the final check.

Staff were not routinely recording their near misses. Details about near misses were last seen recorded in July 2018 and then from January until March 2019 but not since then. The pharmacist manager stated that they discussed near misses with staff at the time and separated medicines involved. Specific examples could not be provided. There were no details about the action taken in response to these or review of these recorded. Staff were unable to provide examples of trends, patterns or remedial activity taken in response to near misses to help prevent mistakes occurring in the future. They stated that the superintendent pharmacist was responsible for this.

There was no information on display about the pharmacy's complaints procedure. Pharmacists handled incidents. This process was described as checking relevant details, speaking to everyone involved, identifying the root cause, to inform the person's GP if anything was taken incorrectly and to record details on the person's medication record. Documented details of previous incidents could not be recalled or brought up from these records. The pharmacist manager explained that a new pharmacy system had been implemented since March 2019. However, on further probing, they admitted that minor incidents where for example, tablets and capsules had been interchanged, may not have been recorded on the system.

There were two sets of documented Standard Operating Procedures (SOPs) present on site. The first set were dated. There were no details on these to indicate when they were last reviewed. Some members of staff had read and signed these in the past. The second set were recent and from the National Pharmacy Association (NPA). These were not filled in with relevant details and staff declarations were incomplete. Newer team members (such as the dispensing assistant in training) as well as the delivery driver (see Principle 4) had not read any SOPs.

Staff were not trained to identify signs of concern to safeguard vulnerable people. Pharmacists were trained to level 2 via the Centre for Pharmacy Postgraduate Education (CPPE). There were local contact

details present for the team to use if needed. Confidential details on bagged prescriptions awaiting collection could not be seen from the retail space. The inspector was told that staff had not received any training on the EU General Data Protection Regulation (GDPR). A set of Information Governance SOPs were present that were dated from February 2019 but these had not been signed by any members of staff. There was no information on display at the point of inspection to inform people about how their privacy was maintained.

The correct RP notice was on display. This provided details of the pharmacist in charge. Staff maintained daily records of the minimum and maximum temperature of the pharmacy fridge. This helped demonstrate that medicines stored here, were held under appropriate conditions. There were odd gaps in the electronic RP record where pharmacists had failed to record the time that their responsibility ceased.

A sample of registers for Controlled Drugs (CD) were checked. Balances for CDs were last seen documented in June 2018. On checking a random selection of CDs (Longtec, Zomorph), only the quantity of the former CD matched the balance entry in the register. The RP admitted that when she had worked as a locum pharmacist at the pharmacy last year, a discrepancy was raised with the pharmacist manager at the time. There were no details documented to support whether this had been resolved at the time.

The superintendent pharmacist provided email confirmation following the inspection that this had been reconciled. This was described as due to errors in calculating the balance that had been carried forward and from a supply that had been entered twice in January 2019. There was a register to record details about CDs brought back by the public for destruction. According to the audit trail, returned CDs from September 2018 had not been destroyed. It was difficult to locate some of these returned CDs from the CD cabinet (see Principle 4) and some of these, had not been recorded in the register at the point of receipt.

Most records of emergency supplies were documented as “script to follow” and some that were marked as “patient request/sale” did not include the nature of the emergency. Only a few recorded the nature of the emergency. Prescriber details were missing from records of unlicensed medicines and from electronic records of private prescriptions. In some instances for the latter, prescriber details were only seen recorded as “dentist”.

A faxed prescription from an online provider (Push Doctor) was present from 23/02/19. There was no original seen for this. The superintendent pharmacist confirmed after the inspection that this had been requested from the prescriber. The pharmacy’s professional indemnity insurance was through the NPA. This was due for renewal after 09/11/19.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has an adequate number of staff to manage its workload. But, its services could be affected if the pharmacy's workload continues to increase. In general, team members understand their roles and responsibilities. But, once they have completed their basic training, they are not provided with many resources or opportunities for ongoing training. This means that they may not be keeping their skills and knowledge up to date. And, the team do not have regular performance reviews. This could mean that gaps in their skills and knowledge are not identified.

Inspector's evidence

The pharmacy dispensed 10,000 prescription items every month with three to four people receiving their medicines through instalment prescriptions and 80 people supplied Monitored Dosage Systems (MDS).

Staff present included the RP, the pharmacist manager and two dispensing assistants, one of whom was trained and the other was undertaking accredited training with Buttercups. The delivery driver was also briefly seen. Other staff included another trained dispensing assistant and three Medicines Counter Assistants (MCAs). The latter included one trained MCA, another MCA was in training with Buttercups and the third was described as a new starter who would eventually be undertaking dispenser training. Certificates for staff qualifications obtained were not seen.

In the absence of the RP, the team knew which activities were permissible and the process involved if the pharmacist failed to arrive. Before selling medicines over-the-counter (OTC), team members asked a range of questions to determine suitability and used an established sales of medicines protocol. They referred to the RP when unsure or when required and demonstrated knowledge of OTC medicines.

Staff in training completed course material at home. To assist with training needs, staff described taking instruction from pharmacists, using their course material, workbooks provided by pharmaceutical company sales representatives or reading the details on the packaging of medicines themselves. Some team members stated that they had not received any appraisals recently. Some dated information about previous performance reviews for some of the team were seen.

In addition to MURs and the NMS, the pharmacy provided influenza vaccinations against Patient Group Directions (PGDs) and a locally commissioned minor ailments service. Pharmacists described a formal target to achieve 20 MURs per month. This was described as currently not manageable. The inspector was told that the pharmacy was now the only one in the village as another local pharmacy had recently closed and the team's workload had subsequently increased. In addition, two weeks prior to the inspection, the team were re-instated with dispensing their MDS trays back on site. The latter had previously been sent to another branch for assembly but had since been moved back to them.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are adequate to ensure the effective delivery of its services. But, the pharmacy is small and there is limited space to store dispensed medicines and stock safely. And, people might see confidential information in the consultation room. This means that the team may not always be keeping other people's private information safe.

Inspector's evidence

The pharmacy was located inside a local supermarket. Its premises consisted of a small retail space and a small dispensary located behind. There was very little bench space available for dispensing. The pharmacy was appropriately ventilated, sufficiently lit and well-presented. Pharmacy only (P) medicines were stored behind the front counter. Staff were always within the vicinity. This helped reduce the self-selection of P medicines.

A signposted consultation room was available to provide services and private conversations. The door was kept locked. The space was of a suitable size for the services provided but was cluttered at the point of inspection. The room was being used to dispense MDS trays because of the lack of space in the dispensary. Hence there were prescription-only medicines (POMs) present. There was also confidential information present (from folders that were kept in the room, records for people supplied MDS trays and a pile of prescriptions).

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy opens early and stays open later than is usual. It sources and stores its medicines appropriately. The team makes some checks to ensure that medicines are not supplied beyond their expiry date. But, the pharmacy has no up-to-date written details to demonstrate this. So, it may not always be able to show that all stock is safe to use. And, the pharmacy doesn't always keep records of the checks it makes in response to safety recalls. So, team members may not be able to show that they have taken the right steps to keep people safe in the event of a future query. The pharmacy provides most of its services safely and effectively. But, members of the pharmacy team don't always highlight prescriptions that require extra advice or record information when people receive some medicines. This makes it difficult for them to show that appropriate advice has been provided when these medicines are supplied. The pharmacy delivers prescription medicines safely to people's homes and keeps records of this. But, people can see other people's private information when they sign to receive their medicines.

Inspector's evidence

The pharmacy was open for 100 hours every week. People entered the pharmacy through the supermarket's wide front door and after it closed, its services were accessible via a hatch. The clear, open space inside the retail area helped people requiring wheelchair access to use the pharmacy's services. There were three seats available for people waiting for prescriptions and some car parking spaces available outside the premises. Staff physically assisted people who were visually impaired, they used written communication for people who were partially deaf and used gestures to assist tourists,, if their first language was not English.

Pharmacists assessed suitability for MDS trays. The pharmacy was currently operating a waiting list for new people. Staff ordered prescriptions on behalf of people receiving trays and when these were received, they checked details against individual records to help identify changes or missing items. Queries were checked with the prescriber and audit trails were maintained to verify this. Trays were not left unsealed overnight. Descriptions of medicines within trays were provided. Patient Information Leaflets (PILs) were routinely supplied. All medicines included in trays were de-blistered and removed from their outer packaging. Staff in training were unaware about risks associated with finasteride. Mid-cycle changes involved trays being retrieved, amended, re-checked and re-supplied.

Medicines were delivered. The delivery driver was seen. He explained that his initial training involved shadowing another experienced driver. The inspector was told that he had not read and signed the relevant SOP. There were records to demonstrate when and where medicines were delivered. The driver obtained signatures from people when they were in receipt of their medicines. However, there was a risk of access to confidential information from the way people's details were laid out when signing. Failed deliveries were brought back to the pharmacy and notes were left to inform people of the attempt made to deliver. The driver explained that medicines were only left with neighbours (and not unattended) if prior consent was obtained.

The team used a dispensing audit trail through a facility on generated labels. This identified their involvement in processes. They used baskets to hold prescriptions and associated medicines. This helped prevent any inadvertent transfer. Baskets were colour co-ordinated to help highlight priority. Staff were aware of risks associated with valproate. The team at the inspection had not completed an

audit to identify females of child bearing potential. They stated that they had not seen any prescriptions for this medicine.

Prescriptions for higher risk medicines were not marked in any way to counsel or to ask people about relevant parameters. This included asking about the International Normalised Ratio (INR) level, for people prescribed warfarin. Some people's records were checked. There were no details seen documented about this. Assembled prescriptions awaiting collection were held in an alphabetical retrieval system. Fridge items and CDs (Schedules 2-3) were identified with stickers or details were written onto prescriptions. Assembled fridge items were stored within clear bags. Uncollected prescriptions were removed every three months. Schedule 4 CDs were not identified. Trained staff could not recognise some of these or their 28-day prescription expiry.

The pharmacy obtained its medicines and medical devices from licensed wholesalers such as AAH, Colorama, Phoenix, Bestway and Alliance Healthcare. Unlicensed medicines were obtained through Alliance Healthcare. Staff were unaware of the process involved for the European Falsified Medicines Directive (FMD). The pharmacy was registered with SecurMed. Relevant equipment was present. This was not connected at the point of inspection to enable compliance with the process. There was no guidance information present for the team.

Medicines were generally stored in an ordered manner in the dispensary. The team described date-checking medicines for expiry every month. Short dated medicines were identified. However, there was no schedule in place to demonstrate the process. The inspector was shown a laminated matrix where details could be wiped off, but this was blank at the inspection. There was no date expired or mixed batches seen. CDs were stored under safe custody. Keys to the cabinet were maintained in a manner that prevented unauthorised access during the day and overnight.

Medicines returned by people for disposal were held within appropriate containers prior to collection. People bringing back sharps for disposal, were referred to the GP surgery or to the local council. Returned CDs were brought to the attention of the RP. Drug alerts were received by email. The process involved checking for stock and acting as necessary. There was no audit trail seen to verify the process.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely.

Inspector's evidence

The pharmacy was equipped with current versions of reference sources. There were crown-stamped conical measures available for liquid medicines. This included designated ones for measuring methadone. Some lime scale was observed on one conical measure. The fridge used for medicines that required cold storage was appropriate. The CD cabinet was secured in line with legal requirements.

Computer terminals were positioned in a manner that prevented unauthorised access. The team used their own NHS smart cards to access electronic prescriptions. These were stored securely overnight. There were counting triangles present. The dispensary sink used to reconstitute medicines was relatively clean but stained. There was hot and cold running water with hand wash available.

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.