Registered pharmacy inspection report

Pharmacy Name: Tait's Pharmacy, 45 Saltaire Road, SHIPLEY, West

Yorkshire, BD18 3HZ

Pharmacy reference: 1109439

Type of pharmacy: Internet / distance selling

Date of inspection: 29/08/2019

Pharmacy context

The pharmacy is above a business premises in Shipley. It is a distance selling pharmacy and the premises are not open to the public. The pharmacy mainly dispenses NHS prescriptions and delivers medicines to people's homes. It also supplies medicines in multi-compartmental compliance packs to a small number of people.

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	The pharmacy has some historical standard operating procedures. And it chooses not to review them regularly. Some of these procedures don't reflect current practice. And some procedures are not documented at all. The pharmacy doesn't use them to help manage the risks to its services. The pharmacy is cluttered and untidy. It doesn't have appropriate date checking procedures. And it removes medicines from the manufacturer's packaging and doesn't store these appropriately. So, the pharmacy misses opportunities to manage the risks to its services.
		1.2	Standard not met	The pharmacist does not make records of near miss errors. So, may miss opportunities to learn and to make services safer. And, there is little evidence of any changes being made to prevent mistakes happening again.
		1.6	Standard not met	The pharmacist consistently fails to properly maintain the responsible pharmacist log. And, she regularly does not record her absences from the pharmacy. So, she is consistently not maintaining the record in accordance with the law.
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 does not have a robust process for managing the storage of its medicines and for checking the expiry dates. And there is evidence of out-of-date medicines on the shelves. The pharmacy does not always keep its medicines in the original packs. And it doesn't label these medicines with the required details. So there is a risk the pharmacy can supply medicines that may have expired or been subject to a drug recall.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy has some historical standard operating procedures available. But these don't reflect current practice. Some procedures are not documented at all. And the pharmacist doesn't use them to help manage the risks to the pharmacy's services. The pharmacist doesn't record mistakes that happen whilst dispensing. And she doesn't routinely make changes to help prevent mistakes happening again. So, she may miss opportunities to improve services and make things safer. The pharmacy keeps some records required by law. But, the responsible pharmacist record is incomplete. And, the pharmacist consistently does not record her absences from the pharmacy. The pharmacy adequately protects people's privacy and confidentiality. And, the pharmacist generally knows how to safeguard the welfare of children and vulnerable adults.

Inspector's evidence

The pharmacy had a set of standard operating procedures (SOPs) in place. But, the pharmacist owner did not review them regularly. She had reviewed some procedures in 2016. But, she had not reviewed some since 2012. She said she did not feel it was necessary to review the procedures as only she worked at the pharmacy and she rarely used them. Some procedures seen contained out of date information. And some had not been updated to reflect changes in the law, such as the General Data Protection Regulations in 2018 or the Falsified Medicines Directive in 2019. The inspector discussed the impact of disregarding the SOPs with the pharmacist.

The pharmacist did not record any near miss errors she made. And, she admitted that she had made mistakes in the past. She could not give any examples of any changes she had made to prevent the same or similar mistakes happening again. The pharmacy had a procedure for recording and responding to dispensing errors that had reached the patient. It had one record of an error from June 2017. The pharmacist said there had not been any error since. The record gave a brief account of what had happened. But, there was no information about why the mistake had occurred and what had been done to prevent it happening again. This was discussed with the pharmacist. She said that other than making a mental note about the two strengths of the medicine involved in the error, she had not changed anything further to prevent it happening again.

The pharmacy had a procedure to deal with complaints handling and reporting. But, it was out of date and had last been reviewed in 2012. The pharmacy did not have a practice leaflet. The pharmacist said the few people who used the pharmacy were mostly family and friends. And, all these people knew her phone number to get in touch. The pharmacy did not advertise its complaints procedure to people. And, it did not collect regular feedback from people. The pharmacist said any feedback was received verbally. And, she had not received any complaints.

The pharmacy did not have professional indemnity insurance in place for the premises. But, the pharmacist had personal professional indemnity insurance, and a current certificate was seen. She gave an assurance that she had checked to make sure that her personal insurance provided the right level of cover for the services being provided. The pharmacy maintained a responsible pharmacist record on paper. But, the pharmacist regularly did not record their sign out time or absences from the pharmacy when she regularly went out to do deliveries or to collect prescriptions from the surgery. The pharmacist displayed their responsible pharmacist notice. The pharmacy kept controlled drug (CD)

registers complete and in order. It kept running balances in all registers. And they were audited against the physical stock quantity after each entry was made. It kept and maintained a register of CDs returned by people for destruction. And it was complete and up to date. The pharmacist monitored and recorded fridge temperatures every two to three days. This was discussed, and the pharmacist gave assurance that she would monitor minimum and maximum temperatures every day. The pharmacy kept private prescription records in a paper register, which was complete and in order. And, they recorded emergency supplies of medicines electronically. The pharmacy rarely dispensed private prescriptions and emergency supplies.

The pharmacy could not be accessed by the public because of its type of NHS contract. It shredded confidential waste. The pharmacist said there was a procedure about how to protect confidential information. But, it was not available in the pharmacy. And, the pharmacist said it had not been updated to reflect the General Data Protection Regulations (GDPR). And, there was no evidence that the pharmacist had completed any training about the requirements of GDPR. The pharmacist gave a satisfactory explanation about how she maintained people's privacy.

The pharmacist provided evidence that she had completed distance learning on safeguarding in 2017. The pharmacist gave brief examples of symptoms that would raise her concerns. She said that if she had a concern, she would use Google to find out who to contact. But, the pharmacy did not have a procedure for dealing with a safeguarding concern about a vulnerable child or adult.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy primarily offers a dispensing service which the pharmacist owner manages. She has the skills and knowledge to operate the pharmacy safely. She completes on-going training to maintain her professional registration. And, she knows how to raise a professional concern. But she doesn't have formal plans for pharmacist cover in case of unplanned periods of absence.

Inspector's evidence

The pharmacist was subject to mandatory revalidation as part of her professional registration. She explained there were no other parties involved in operating the pharmacy. And, she was solely responsible for running the business. But, the pharmacy did not have any plans in place to deal with the unplanned pharmacist's incapacity. And had neo assessed the impact this may have on the continuity of care to people receiving pharmacy services. The pharmacist said she would raise any professional concerns with the GPhC.

Principle 3 - Premises Standards met

Summary findings

The pharmacy provides an adequate space for the services being provided. And, it is adequately maintained. But, the pharmacy has untidy benches, which may increase the risks of mistakes.

Inspector's evidence

The pharmacy was in a business unit and it could not be accessed by the public due to the contract it held. It provided a small room used for dispensing. The pharmacy was generally untidy. The benches were cluttered with paperwork and medicines waiting to be put away. The floors and passage ways were generally free from clutter and obstruction. There was a defined workflow in operation. And clearly defined dispensing and checking areas. There was a clean, well maintained sink in the corridor outside the pharmacy used for medicines preparation. The sink was shared with other occupants of the building. The pharmacists said she rarely had to use the sink to prepare medicines. There was a toilet, with a sink with hot and cold running water and other facilities for hand washing. Heat and light in the pharmacy was maintained to acceptable levels. The overall appearance of the premises was adequate for the services being provided

Principle 4 - Services Standards not all met

Summary findings

The pharmacy sources its medicines from reputable suppliers. But, it does not always manage its medicines appropriately. The pharmacy does not have a robust process for checking the expiry date on medicines. And, there is evidence of out-of-date medicines on the shelves. The pharmacy does not always keep its medicines in the original packs. And, it doesn't label these medicines with the required details to ensure it knows when these medicines expire or are subject to a drug recall. The pharmacy has some processes to manage the risks associated with its services. The pharmacist is adequately equipped to provide advice for people taking high-risk medicines. But, they do not always have the written information to share with these people.

Inspector's evidence

The pharmacist explained that most people who used the pharmacy were family or friends of her family. So, they knew how to contact her if necessary. The pharmacy was able to produce large-print labels for people who had a visual impairment. And, the pharmacist said she would written communication with someone with a hearing impairment. But, she currently did not have anyone who required such adjustments.

The pharmacy did not have a procedure for regularly checking stock for short-dated or expired medicines. The pharmacist also said she did not regularly check all stock expiry dates. But, she checked expiry dates on packs when dispensing. After a search of a sample of the pharmacy's shelves, the inspector found 25 items on the shelves that were out-of-date. The packs found showed various expiry dates between August 2016 and August 2019. The pharmacist said she responded to drug alerts and recalls. And, any affected stock found was quarantined for destruction or return to the wholesaler. But, the pharmacy did not keep records of recalls or any action it took. Several amber bottles were found on the shelves containing medicines that had been removed from their original container. The pharmacist had attached labels to the bottles to identify what the medicines were. But, she had not recorded on the labels the batch number or expiry dates of the medicines. The inspector found a carton of amitriptyline 10mg tablets containing loose medicines that had been removed from the blister strips. The inspector also found packs on the shelves containing mixed batches of medicines. Some of the medicines in these containers did not match the batch number or expiry date on the pack. And, some did not show a batch number or expiry date. An opened bottle of vitamin E liquid was found on the shelves. The pharmacist had written the date it had been opened on the bottle, which was 21 December 2016. The manufacturer's instructions stated that opened bottle should be discarded one month after opening.

The pharmacist signed the checked by box on dispensing labels. She said she tried to have a break between dispensing and checking her own work. But, she didn't sign the dispensed by box and so couldn't evidence the two processes were completed separately. She used dispensing baskets during the dispensing process to help prevent prescriptions being mixed up. The pharmacy supplied medicines in multi-compartmental compliance packs when requested. The pharmacy attached backing sheets to the pack, so people had written instructions of how to take the medicines. And it included the descriptions of what the medicines looked like, so they could be identified in the pack. But, the pharmacist did not routinely provide people with information leaflets about their medicines. She documented changes to medicines provided in packs on the patient's electronic record. The pharmacy obtained medicines from three licensed wholesalers. It generally stored medicines on shelves. And, all stock was kept in restricted areas of the premises where necessary. It had adequate disposal facilities available for unwanted medicines, including controlled drugs (CDs). The pharmacist kept the CD cabinet tidy and well organised. And, out of date and patient returned CDs were segregated. The inspector checked the physical stock against the register running balance for two products. And they were found to be correct. The pharmacy did not stock many CDs. The pharmacist said she usually only ordered stock of CDs when she received a prescription for them. The pharmacy kept the contents of the pharmacy fridge tidy and well organised. The pharmacist monitored minimum and maximum temperatures in the fridge two to three days. And, she recorded her findings. The temperature records seen were mostly within acceptable limits. The inspector discussed with the pharmacist about monitoring fridge temperatures every day. The pharmacist gave an assurance she would start monitoring and recording minimum and maximum fridge temperatures every day. The pharmacist said she had one person who regularly received prescriptions for valproate. And, the person was not at risk of becoming pregnant. She said she would discuss the risks of valproate with anyone receiving a prescription for the medicine that could become pregnant. And, she would check if they were using adequate contraception. But, the pharmacy did not have any printed material to give to people to help explain the risks. The pharmacist gave an assurance that a pack of materials would be ordered. The pharmacist was aware of the requirements of the Falsified Medicines Directive (FMD). The pharmacy had the right scanners and software in place to scan compliant medicines packaging. But, the software was not working. The pharmacist said she had contacted the software supplier and was in the process of having the issues resolved. There were no procedures to incorporate the requirements in to the dispensing process. The pharmacy was not complying with the current law.

The pharmacist delivered medicines to people. She recorded the deliveries made in a diary. But, she did not ask people to sign for any deliveries made, including deliveries of CDs. So, there was no complete audit trail of whether people had received their medicines.

Principle 5 - Equipment and facilities Standards met

Summary findings

The pharmacy has the necessary equipment available, which it properly maintains. And, it manages and uses the equipment in ways that protect people's confidentiality.

Inspector's evidence

The pharmacy had the equipment it needed to provide the services offered. The resources available included the British National Formulary (BNF), the BNF for Children, various pharmacy reference texts and use of the internet. The pharmacy had a set of clean, well maintained measures available for medicines preparation. Computer terminals were kept in the secure pharmacy premises. And they were password protected. The dispensary fridge was in good working order. Access to all equipment was restricted and all items were stored securely.

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.