General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Batley Pharmacy, 157 Upper Commercial Street, BATLEY, West Yorkshire, WF17 5DH

Pharmacy reference: 1090774

Type of pharmacy: Community

Date of inspection: 16/01/2020

Pharmacy context

The pharmacy is in the suburbs of Batley town centre. It is open 100 hours per week over seven days. Pharmacy team members dispense NHS prescriptions and sell a range of over-the-counter medicines. They offer services including a private prescribing service. And seasonal flu vaccinations. The pharmacy provides medicines to people in multi-compartment compliance packs. And it delivers medicines to people's homes. It provides a substance misuse service, including supervised consumption and needle exchange.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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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 does not routinely assess the key risks associated with its private prescribing service and does not have proper governance arrangements in place for the service. The main prescriber, who is also the superintendent pharmacist of the pharmacy, has shown insufficient understanding of the risks associated with his wide areas of prescribing. The pharmacy does not have complete risk assessments for all areas of the prescribing service, including the wide clinical areas being prescribed for. Or for any recommended necessary monitoring and diagnostics.
		1.2	Standard not met	The prescribing service does not have a robust audit process, with reviews and actions identified to establish whether people are receiving medicines appropriate for their condition.
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	Pharmacy team members do not have an insight into the end-to-end prescribing service. So, it is difficult for them to establish whether medicines are being prescribed safely and appropriately. The superintendent pharmacist regularly works in the capacity as independent prescriber whilst simultaneously acting as the pharmacy's responsible pharmacist. He has not addressed the risks associated with this. The prescribing service does not keep complete and robust records of all consultations.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy has procedures to identify and manage risks to most of its services. But it has not identified or managed the risks associated with providing a private prescribing service. It does not have a complete risk assessment for the wide range of clinical areas covered. And the prescribers do not have access to all monitoring and diagnostic information required to support safe prescribing. Pharmacy team members dispense prescriptions for people accessing the private prescribing service with little knowledge of how the service operates. The pharmacy has written procedures to follow, which they mostly follow to complete the required tasks. But the procedure relating to the private prescribing service is not always followed. Pharmacy team members discuss their mistakes. And record some details of why these mistakes happen. But they may miss opportunities to learn and improve the pharmacy's services. Pharmacy team members know how to safeguard the welfare of children and vulnerable adults and they protect people's confidential information. They keep the records they must by law.

Inspector's evidence

The pharmacy provided a private prescribing service for people. The pharmacy team members present during the inspection were unable to provide any information about the service. They said it was operated by the pharmacy's superintendent pharmacist (SI). And he usually provided the service when he worked at the pharmacy on a Saturday. The pharmacy did not advertise the service to people. Subsequent to the inspection, the inspector questioned the SI about the pharmacy's prescribing service. The SI explained that he usually provided the service on a Saturday, where he carried out the role of independent prescriber and responsible pharmacist (RP) at the same time. The pharmacy had a standard operating procedure (SOP) in place for the private prescribing service. But it was not being followed by the SI. And there were no records that the SOP had been read or signed by other pharmacy team members. The inspector asked the SI for any risk assessments that had been carried out for the service. The SI provided a risk assessment that had been completed in 2018 and 2019. The assessment was brief. And it did not consider all aspects of the prescribing service, for example prescribing to people from overseas. Or for the wide variety of clinical areas being presented. The inspector asked the SI if he shared information about his prescribing decisions with people's GP. The SI explained that it was not a legal requirement to share information with a patient's GP. He said he did not routinely share information with GPs because he did not have the resources to do so. This means people may obtain medicines from a variety of sources without the proper controls in place.

The inspector asked the SI to provide any audits that had been carried out about the pharmacy's prescribing service. The SI provided two documents that contained tallies of the medicines that had been prescribed for certain presenting complaints. And the number of medicines prescribed in various clinical areas over a period. The documents did not contain any information about the scope of the audits. Or any information about the outcomes from the data collected and any changes the pharmacy had made to improve its services. This was discussed. And the SI said that the tallies provided evidence of prescribing habits at the pharmacy. He said they were simple audits to satisfy him there was no overprescribing.

The pharmacy had a set of SOPs in place for other services it provided. The sample checked were last reviewed in May 2018. And the next review was scheduled for May 2020. There were no records that

staff had read and understood the SOPs. A dispenser and the pharmacist stated they had read the SOPs last in 2019. The pharmacy defined the roles of the pharmacy team members in each SOP.

The pharmacist highlighted near miss errors made by pharmacy team members when dispensing. Pharmacy team members sometimes recorded their own mistakes. They discussed the errors made. From the records seen, there were a low number of incidents recorded. For example, one near miss had been recorded in January 2020, one in December 2019, two in November 2019 and one in October 2019. Pharmacy team members said it was likely that not all mistakes were recorded. Pharmacy team members did not discuss or record much detail about why a mistake had happened. Sometimes no information about causes was recorded or was basic, for example, stating not reading the prescription properly had caused the mistakes. Their most common change after a mistake was to double check next time. The pharmacist analysed the data collected about mistakes after ten records were made. And records of the analysis were kept. The pharmacist based their analysis on quantitative information. These included the number of different types of errors occurring, such as wrong strength or wrong quantity errors. They did not reflect on the causes of mistakes to help inform the changes they made. The last four records of analysis, January 2019 to May 2019, highlighted patterns of wrong strength errors in each report. The report stated that this had been discussed with the team. And pharmacy team members confirmed this. There were no records of any near-miss analysis after May 2019. They gave examples of recent near miss errors after they had made picking errors with sertraline and sildenafil. And with amlodipine and amitriptyline. In response, they had separated the products on the shelves. And they had attached alert stickers to the shelves where the products were kept highlighting the risks when dispensing. The pharmacy had a process for dealing with dispensing errors that had been given out to people. It recorded incidents using a template reporting form. Pharmacy team members discussed errors and sometimes made changes to prevent recurrence. One recent example, from June 2019, was an error where someone had been provided with the incorrect formulation of salbutamol inhaler. The report gave information about what had happened. But there was very little information about what had caused the error. The report stated that warning labels had been attached to the edges of shelves to help highlight the risks. But there were no stickers on the shelves where the salbutamol inhalers were kept. And the two different formulations of salbutamol inhalers were kept next to each other and were in very similar packaging.

The pharmacy had a procedure to deal with complaints handling and reporting. It had a poster available for customers in the retail area which clearly explained the company's complaints procedure. It collected feedback from people by using questionnaires. One example of feedback was about the smell of drains in the pharmacy. A team member explained that the building was old. And they had responded to the feedback by having the drains assessed and repairs made as much as possible.

The pharmacy had up-to-date professional indemnity insurance in place. The pharmacy kept controlled drug (CD) registers complete and in order. It kept running balances in all registers. And pharmacy team members audited these against the physical stock quantity at least monthly, including methadone. The pharmacy kept and maintained a register of CDs returned by people for destruction. And this was complete and up to date. The pharmacy maintained a responsible pharmacist record on paper. And this was complete and up to date. The pharmacist displayed their responsible pharmacist notice to people. Pharmacy team members monitored and recorded fridge temperatures daily in two fridges. They kept private prescription records in a paper register, which was complete and in order. And they recorded emergency supplies of medicines in the private prescription register. They recorded any unlicensed medicines supplied, which included the necessary information in the samples seen.

The pharmacy kept sensitive information and materials in restricted areas. It shredded confidential waste. Pharmacy team members had been trained to protect privacy and confidentiality by reading a

folder of information. But there were no records of when they had last read the information. The pharmacy had appointed a dispenser to oversee information governance (IG) in the pharmacy. She said that everyone had read the information in the folder approximately six months ago. Pharmacy team members were clear about how important it was to protect confidentiality.

A pharmacy team member gave a clear explanation of how they would raise concerns about vulnerable children and adults. The pharmacy had a procedure and a folder of supporting information in place instructing pharmacy team members where to raise their concerns and how to obtain advice. And it had up-to-date contact information for local safeguarding teams displayed. The pharmacist had completed training about safeguarding in 2019. Other pharmacy team members had not completed any formal training.

Principle 2 - Staffing ✔ Standards met

Summary findings

Pharmacy team members are suitably qualified and have the right skills for their roles. Pharmacy team members complete training ad-hoc. They reflect on their own performance, discussing any training needs with the pharmacist and other team members. And they support each other to reach their learning goals. Pharmacy team members feel able to raise concerns and use their professional judgement.

Inspector's evidence

At the time of the inspection, the pharmacy team members present were a locum pharmacist and three dispensers. Pharmacy team members completed training ad-hoc by reading various trade press materials. And by attending local training events. The pharmacy had an appraisal process. Pharmacy team members received an appraisal with their manager every three months. They discussed their performance and identified any learning needs. They set objectives to help them achieve their goals. One recent example of an objective was a dispenser improving their knowledge of good customer service. They had planned to do some training on customer service skills. But they had not yet had the chance because of staffing shortages in the pharmacy.

A dispenser explained that he would raise professional concerns with any of the pharmacy's three managers or the superintendent pharmacist (SI). He said he felt comfortable raising a concern. And confident that his concerns would be considered, and changes would be made where they were needed. The pharmacy had a whistleblowing policy. And pharmacy team members were aware of how to access the procedure. The pharmacy team communicated with an open working dialogue during the inspection. Pharmacy team members explained a change they had made after they had identified an area for improvement. They had identified issues with some stock not being sorted and put away by team members at the beginning of the week. This increased the amount of work and pressure on pharmacy team members working at the end of the week. They had discussed their concerns and now team members made sure that all stock is processed and put away as soon as possible after the delivery arrives. This meant that team members could start each day with minimal backlog. Pharmacy team members explained the company asked them to reach targets in some general areas, such as the number of MUR and NMS consultations provided. They said that targets were not closely monitored. And there were no consequences when a target was not met, except some discussion about how they could improve.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and properly maintained. It provides a suitable space for the health services provided. And it has a suitable room where people can speak to pharmacy team members privately.

Inspector's evidence

The pharmacy was clean and well maintained. All areas of the pharmacy were tidy and well organised. And the floors and passageways were free from clutter and obstruction. The pharmacy had a safe and effective workflow in operation. And clearly defined dispensing and checking areas. It kept equipment and stock on shelves throughout the premises. The pharmacy had a private consultation room available. Pharmacy team members used the room to have private conversations with people.

The pharmacy had a clean, well maintained sink in the dispensary used for medicines preparation. It had a toilet, with a sink which provided hot and cold running water and other facilities for hand washing. Heat and light in the pharmacy were maintained to acceptable levels. The pharmacy's overall appearance was professional, including the exterior which portrayed a professional healthcare setting. The professional areas of the premises were well defined by the layout and well signposted from the retail area.

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

Summary findings

The pharmacy's private prescribing service doesn't have adequate safeguards in place to reassure people that medicines are being prescribed safely and appropriately. The pharmacy doesn't always make independent checks on the clinical appropriateness of prescriptions written as part of the private prescribing service. Pharmacy team members do not have adequate knowledge of the service to be able to manage the dispensing of these private prescriptions safely and effectively. The pharmacy provides its other services safely and has procedures in place to manage the risks. The pharmacy's services are easily accessible, and members of the team can speak languages other than English to help people.

Inspector's evidence

The pharmacy provided a private prescribing service and most of the prescriptions written by the prescriber were dispensed in the pharmacy. The superintendent pharmacist was the main prescriber. And he often completed the clinical and accuracy check during the process to dispense the prescriptions he had written. This is not good practice as described in the GPhC In Practice: Guidance for Pharmacist Prescribers (November 2019). And the superintendent pharmacist had not assessed the risk of this practice. The pharmacy received prescriptions from this service for a wide range of clinical conditions and medicines, such as various anti-hypertensives, high-risk antibiotics such as rifaximin, isotretinoin, proton pump inhibitors and prescribing for a patient with adrenal insufficiency and a renal transplant patient. The prescriber had access to the person's summary care records (SCR) but generally no other medical records. He described how he would ask if someone had had a chest X-Ray. And would accept their word about whether it had been normal. He didn't have access to provide monitoring, such as blood tests, X-rays or other recommended tests. The prescriber didn't always make records of these consultations and some of the consultation notes provided lacked detail. The pharmacy especially did not keep any records of consultations if no prescription was generated. And where the patient chose to take the prescriptions elsewhere to be dispensed. Pharmacy team members said they had little knowledge of the private prescribing service but did dispense the prescriptions at the pharmacy.

The pharmacy had level access from the street into a large retail area via automatic doors. Its services were advertised on a banner attached to the wall outside the pharmacy, which could be seen when the pharmacy was closed. Pharmacy team members prepared prescriptions in the dispensary at the back of the pharmacy. They used written communication to help people with a hearing impairment. And there was a hearing induction loop available. Pharmacy team members were unsure about how they would help people with a visual impairment. Some pharmacy team members could speak other languages spoken by people in the local community. These included Punjabi, Urdu, Gujrati and Russian.

Pharmacy team members signed the dispensed by and checked by boxes on dispensing labels during dispensing. This was to maintain an audit trail of the people involved in the dispensing process. They used dispensing baskets throughout the dispensing process to help prevent prescriptions being mixed up. The pharmacist counselled people receiving prescriptions for valproate if appropriate. And she said she would check if the person was aware of the risks if they became pregnant while taking the medicine. She advised she would also check if they were on a pregnancy prevention programme. The pharmacy had a stock of printed information material to give to people and to help them manage the

risks. The pharmacy supplied medicines to people in multi-compartment compliance packs when requested. It attached backing sheets to the packs, so people had written instructions of how to take their medicines. Pharmacy team members included descriptions of what the medicines looked like, so they could be identified in the pack. And they provided people with patient information leaflets about their medicines each month. Pharmacy team members documented any changes to medicines provided in packs on the patient's master record sheet. The pharmacy delivered medicines to people. It recorded the deliveries made. And it asked people to sign to confirm they had received their medicines. People signed to confirm they had received a controlled drug (CD) using a separate itemised delivery docket. Pharmacy team members highlighted bags containing CDs to the delivery driver. The delivery driver left a card through the letterbox if someone was not at home when they delivered. The card asked people to contact the pharmacy.

The pharmacy obtained medicines from licensed wholesalers. It stored medicines tidily on shelves. And it kept all stock in restricted areas of the premises where necessary. Pharmacy team members were aware of the requirements of the Falsified Medicines Directive (FMD). The pharmacy had some equipment in place to scan compliant packs of medicines. But not all the necessary equipment or software was available. Pharmacy team members had not been trained about the new requirements. And the pharmacy did not have any updated procedures available to incorporate the requirements of FMD into the dispensing process. Pharmacy team members said they did not know the company's plans for further implementation of FMD. The pharmacy had adequate disposal facilities available for unwanted medicines, including CDs. Pharmacy team members kept the CD cabinet tidy and well organised. And they segregated out-of-date and patient-returned CDs. The inspector checked the physical stock against the register running balance for three products. And these were correct. Pharmacy team members kept the contents of the pharmacy fridge tidy and well organised. They monitored the minimum and maximum temperatures in the fridge every day. And they recorded their findings. The temperature records seen were within acceptable limits.

Pharmacy team members checked medicine expiry dates every 12 weeks. And some records were seen. But not all records of their checks were available. Each pharmacy team member was responsible for various sections where medicines were stored. But not all pharmacy team members had returned their records to the same file. This was discussed and pharmacy team members agreed that it would be useful to keep all records of expiry date checks in the same place. Pharmacy team members highlighted any short-dated items with a sticker on the pack up to six months in advance of its expiry. And they removed items from the shelves if they expired before the next date check. Pharmacy team members also used packs with stickers attached first to help prevent wastage. The pharmacy responded to drug alerts and recalls. It quarantined any affected stock found for destruction or return to the wholesaler. It recorded any action taken. And records included details of any affected products removed.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment available for its services, 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. It positioned computer terminals away from public view. And these were password protected. The pharmacy stored medicines waiting to be collected in the dispensary, also away from public view. It had a dispensary fridge that was in good working order. And pharmacy team members used it to store medicines only. They restricted access to all equipment. And they stored all items 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.