General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Badham Pharmacy Ltd, 45 - 47 Filwood Broadway, Knowle, Bristol, Somerset, BS4 1JL

Pharmacy reference: 9010874

Type of pharmacy: Community

Date of inspection: 05/07/2019

Pharmacy context

This is a community pharmacy located along a parade of shops in a residential area of Bristol in Somerset. The pharmacy dispenses NHS and private prescriptions. It provides some services such as Medicines Use Reviews (MURs) and the New Medicine Service (NMS). And, it supplies some people with their medicines inside multi-compartment compliance packs, if they find it difficult to manage their medicines.

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 is not identifying and managing several risks associated with the provision of its services as failed under the relevant principles. Some of the pharmacy's standard operating procedures (SOPs) are missing or are outdated, they do not reflect current practice and staff are not always working in line with them. There are issues with Controlled Drugs and there is limited evidence that an appropriate investigation has been undertaken. The pharmacy must ensure that any remedial activity subsequently implemented is robust enough to ensure improvements will be maintained
		1.2	Standard not met	There is not enough assurance that the pharmacy has a robust process to manage and learn from dispensing incidents and it has not ensured that these processes are sustained. Staff are still not routinely recording near misses, there are high levels of dispensing incidents occurring, full details are still not being documented and there is limited evidence of remedial activity or learning occurring in response
		1.6	Standard not met	The pharmacy is not maintaining all of its records in accordance with the law and must ensure ongoing compliance with legal requirements occurs. This includes the management and record keeping for Controlled Drugs.
2. Staff	Standards not all met	2.1	Standard not met	The current staffing arrangements are insufficient to cope with the workload. The pharmacy does not have enough staff to provide pharmacy services safely and effectively as routine tasks were not being completed at the point of inspection. The pharmacy must ensure that a suitable number of staff are in place to routinely manage the workload and that compliance with this standard is maintained
		2.4	Standard not met	There is no evidence of training resources or ongoing learning provided to the team to improve their knowledge. The pharmacy

Principle	Principle finding	Exception standard reference	Notable practice	Why
				needs to ensure that any activity to remediate the situation is sustained
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	Staff are assembling some multi-compartment compliance packs without prescriptions and supplying some medicines inside packs that are not suitable to be packaged in this way without making any of the necessary checks. Patient Information Leaflets are not routinely supplied to people with their medicines and date-expired prescriptions are present in the retrieval system. Controlled Drugs have been supplied as instalments against prescriptions that are not permitted for this purpose, in accordance with the law, the prescriptions do not contain directions to enable instalments to be made, the amount which should be supplied or the interval that should occur between dispensing. People prescribed higher-risk medicines are still not being routinely identified, counselled, relevant parameters checked, or details documented
		4.3	Standard not met	There is insufficient assurance that stock is stored and managed appropriately. There are mixed batches of medicines and loose blister strips present. There is also a lack of verifiable processes to routinely identify and remove date-expired medicines. The pharmacy should ensure that any action taken to redress this is robust enough to be maintained
5. Equipment and facilities	Standards not all met	5.3	Standard not met	The privacy and dignity of people who use the supervised consumption service is compromised by the position of the automated software system, used for recording and dispensing their medication

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

Summary findings

The pharmacy doesn't always effectively manage risks associated with the provision of its services. It has written instructions to help with this. But some of these are out of date or missing altogether. This could mean that members of the pharmacy team are unclear about the pharmacy's current processes. Pharmacy team members deal with their mistakes responsibly. But, they are not always recording or formally reviewing 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 is not maintaining all of its records, 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 struggling with its workload at the point of inspection. The responsible pharmacist (RP) was relatively new to the company and was visibly finding it difficult to ensure the pharmacy's governance arrangements were in place. The staff present were also under pressure with the workload (see Principle 2). The pharmacy was a few days behind with the current workload, staff were observed looking in several different places to locate people's repeat prescriptions as they were not ready when they arrived to collect them. Routine tasks such as date-checking (see principle 4) were not occurring.

Dispensing staff explained that they used a ticking system to ensure that the right medicines were selected and the correct details were generated when they assembled prescriptions. The RP recorded their near misses, there were eight near misses seen recorded in June 2019, the action taken, and learning seen was not routinely documented in these. Prior to this, near misses were last recorded in November 2018, there were several gaps and no evidence of their review seen recorded. There were sheets available to capture this information, but these had not been utilised. The lack of recording and reviewing near misses was identified at the last GPhC inspection and there was insufficient evidence to show that the resulting action plan had been implemented and sustained after the follow-up inspection.

There was no information on display about the pharmacy's complaints procedure and the pharmacy did not have a documented complaints procedure. Previous records for incidents were present, in the past year, this included 21 dispensing incidents, seven of which involved Controlled Drugs. Apart from one for the latter, that the RP had notified, the pharmacy had not informed the Controlled Drugs Accountable Officer of these or NHS England. For the remaining, some incidents were seen recorded with no details about the root cause documented or next steps identified.

When details about the root cause for errors were documented in the incident reports, these reflected that mistakes routinely occurred due to the pharmacy being short-staffed. There was no evidence that the staffing situation had subsequently been reviewed and changes implemented in response to this.

Some documented standard operating procedures (SOPs) were present to support the services provided. However, some were not up-to-date, as they were from 2014 or 2010 and staff were not always following them (such as the date-checking process). There was no SOP to cover the Accuracy Checking Technician's (ACT) procedure, the ACT had not read this, and the inspector was told by the

ACT that she had asked the company's head office on three separate occasions to provide the pharmacy with this and it had still not been provided. The ACT had worked at the pharmacy for the past three years. Staff knew when to refer to the RP and knew which activities were permissible in the absence of the RP. The correct RP notice was on display and this provided details of the pharmacist in charge on the day.

Staff were trained to identify groups of vulnerable people to safeguard, The RP was trained to level two via the Centre for Pharmacy Postgraduate Education (CPPE) to safeguard vulnerable people. An SOP to safeguard vulnerable people was present, this included local contact details for the safeguarding agencies. There was no chaperone policy seen.

The team segregated confidential waste and sent this to their head office for disposal. Dispensed prescriptions awaiting collection were stored in a location that prevented sensitive information being visible from the retail area. There was no confidential material left within areas that faced the public and there was information on display to inform people about how their privacy was maintained. Not all staff were trained on the EU General Data Protection Regulation (GDPR) and there was no Information Governance policy to provide guidance to the team.

The team checked the minimum and maximum temperatures of the fridge to ensure medicines were appropriately stored here. Daily records were kept verifying this. A complete record documenting details for the receipt and destruction of Controlled Drugs that were returned by people for disposal was present. Emergency supplies were recorded in line with statutory requirements.

There were several missing gaps in the RP record where pharmacists had not recorded the time that their responsibility finished. Prescriber details were missing from records for unlicensed medicines. Professional indemnity insurance for the pharmacy was through the National Pharmacy Association (NPA), this was due for renewal after 30 November 2019.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy does not have enough staff to manage its workload safely at all times. It does not provide its team members with resources or training materials once they have completed basic training and it does not monitor their ongoing performance. This can affect how well the pharmacy cares for people and the advice that it gives.

Inspector's evidence

The pharmacy dispensed 14,000 prescription items every month with around 220 people receiving their medicines inside multi-compartment compliance packs and between 80-100 people receiving medicines via instalment prescriptions.

The staffing profile included a newly employed regular pharmacist who had worked at the branch for the past five weeks, two delivery drivers, two medicines counter assistants (MCAs), a full-time ACT, two full-time dispensing assistants, and two part-time dispensing assistants, one of whom was undertaking accredited training with the NPA and had only started working at the pharmacy within the previous four weeks. Staff wore name badges, their certificates of qualifications obtained were not seen.

One full-time and one part-time dispensing assistant alongside the ACT, worked in the dispensary to prepare multi-compartment compliance packs. The part-time dispensing assistant was employed for 16 hours/week and was required to prepare 90 packs in this time frame, the former described being told by the superintendent pharmacist (SI) to work in the main dispensary all day on Mondays, and until 12pm for the rest of the week, this left her with 20 hours to complete 140 packs.

Out of the remaining staff, this left one full-time and one part-time dispensing assistant to cover the main dispensary's workload. The former was responsible for pre-assembling that week's supplies of medicines for those people using the substance misuse service. This took most of one day and she was also responsible for preparing supplies for the supervised consumption service, alongside the pharmacist.

Before the appointment of the regular pharmacist, the pharmacy had been managed by locum pharmacists for a period of six to seven months. Staff were currently running behind with assembling the compliance packs and described working on them the day before they were required. The team was also a few days behind in the main dispensary with people's repeat prescriptions. Staff were observed looking in several different places to locate people's prescriptions as they were not ready when they arrived to collect them.

There were not enough staff available at the point of inspection to safely manage the pharmacy's workload. Staff explained that they had frequently informed the superintendent pharmacist that they did not have enough staff and that they were struggling. The inspector was told that his response was, that one of his branches dispensed 20,000 prescription items per month and that they managed with two members of staff.

There were inadequate contingency measures in place for planned or unplanned absences at the last inspection. The superintendent had previously provided assurances that cover could be arranged if

necessary and an ACT was in place to cover unplanned absences. The latter had not occurred according to the branch and the ACT at the pharmacy was unaware that her role required her to do this. Team members explained that they were expected to cover one another, and over-time required authorisation from head office.

Counter staff asked people some questions before over-the-counter (OTC) medicines were sold. This included asking people who the medicine was for, if they were taking any medicines, about symptoms, and how long these had been experienced for. If staff were unsure, they ran details past the RP. Some knowledge of OTC medicines was demonstrated, but refresher training was required for some medicines.

Members of the pharmacy team who had worked at the pharmacy for several years had only received a performance appraisal once. Staff explained that no-one had monitored or checked their progress since then. There were no team meetings held, the inspector was told by more than one member of staff that they were not provided with any updates, no literature/resources were supplied to assist with their training needs and they were only told about new products from the pharmacists. It was identified at the last GPhC inspection that the pharmacy team were not receiving appropriate ongoing training. Previous information provided by the superintendent in the action plan issued at that time, stated that ongoing training would occur through an online platform. There was no evidence that this had occurred.

There were no formal targets set to complete services at the point of inspection.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises provide a suitable space to deliver its services. But, it keeps its consultation rooms unlocked, and stores sharps bins in here. So, there is a chance of unauthorised people gaining access to them.

Inspector's evidence

The premises consisted of a medium sized retail area and two dispensaries, one of which was located in the adjacent premises but was still linked to the main dispensary. There were staff areas at the back of the second dispensary which was used to store and assemble compliance packs. A door separated the front retail section of the adjacent premises, this section was used to store/sell mobility aids and the pharmacy's two consultation rooms were also located here. The front counter also consisted of a separate section to one side, where people could access the supervised consumption service.

There was enough space to store and assemble prescriptions safely. In the main dispensary, this included bench space, the RP's segregated area for accuracy-checking and two further units where dispensing assistants worked. Except for the men's WC and the sink in one of the consultation rooms, which could have been cleaner, all other areas were clean. One area behind the second dispensary was cluttered with unused shelving and yellow bags containing returned medicines awaiting disposal.

The pharmacy was adequately presented, suitably bright and well-ventilated with an air conditioning system. Pharmacy (P) medicines were stored behind the front counter and there was gated access into this area. Staff were always within the vicinity, which helped to prevent the self-selection of these medicines.

The two consultation rooms were signposted but as they were in the extended section, and there was no sign in the main retail space to indicate the use of rooms where services or private conversations could occur, this was not readily obvious. The doors to both, opened inwards. One could be accessed from the second dispensary and contained a sink as well as a sharps bin on the floor. Both rooms were unlocked.

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

Summary findings

The pharmacy obtains its medicines from reputable suppliers. But, it does not always store its medicines appropriately. The pharmacy's team members are not always making enough checks to ensure that stock is safe to supply. And, the pharmacy has no up-to-date written details to verify this. The pharmacy does not always provide its services in a safe and effective way. Team members sometimes prepare medicines inside compliance packs without prescriptions. There is a risk that the wrong medicine could be supplied. And, the pharmacy does not always provide patient information leaflets. This means that people may not have all the information they need to take their medicines safely. The pharmacy delivers prescription medicines safely to people's homes and it keeps records to show this. But, team members 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. And, they are not removing date-expired prescriptions in time. This increases the chance of them supplying these medicines unlawfully.

Inspector's evidence

The pharmacy's front entrance was accessed from the street through a wide front door. This, along with the clear, open space inside the premises meant that people needing wheelchair access could easily use the pharmacy's services. There were two seats available for people to wait for their prescriptions if needed and car parking spaces available outside. The pharmacy's opening hours were listed on the door.

The pharmacy staff provided people with relevant information verbally if they required supervised consumption or received medicines from instalment prescriptions. Staff did not always hold contact numbers for people or details of their key workers and the RP was unaware of local prescribing or policy guidelines for the management of drug misusers. This was discussed with the pharmacist during the inspection and she was instructed to seek further information on the subject.

The pharmacy team used baskets to hold medicines once they were dispensed. This helped to prevent any inadvertent transfer. Staff were maintaining dispensing audit trails through a facility on generated labels and this helped identify their involvement in the process. The ACT explained that other staff were involved in assembling trays, the pharmacist clinically checked prescriptions before they were accuracy-checked by her. They used a stamp on prescriptions to confirm that each of these stages had been completed.

The inspector was told that the SI had instructed staff that the pharmacy could provide anyone with their medicines inside compliance packs, regardless of whether there was a need. There was no evidence that an assessment had occurred before packs were issued and staff described being told not to take on any more people for compliance packs if the surgery only issued monthly scripts. After discussing the situation with them, staff described a representative from the Local Pharmaceutical Committee also advising them that compliance packs should only be supplied to people who found it difficult to manage their medicines after an assessment occurred.

The pharmacy ordered prescriptions on behalf of people using compliance packs, in general they were

issued as Repeat Dispensing and in batches, when they were received, details on prescriptions were cross-referenced against individual records to help identify changes or missing items. Queries were checked with the prescriber and audit trails were maintained to demonstrate this. The ACT maintained her own records of checks, the team used progress logs to track when prescriptions were due and kept a communication book. Some trays were also prepared ahead of prescriptions; staff explained that this was to help them get ahead and this was before the new batch of prescriptions were issued.

All medicines included inside packs were de-blistered and removed from their outer packaging. Descriptions of medicines within packs were provided and the packs were not left unsealed overnight. Backing sheets were supplied loose inside packs, this meant that people could easily lose this information. After discussing the risks, the team immediately changed their practice to stick this information down going forward.

Patient Information Leaflets (PILs) were not routinely supplied. One elderly person received valproate inside packs, four weeks at a time were prepared. Nicorandil was also supplied inside packs due to historical practice. The ACT knew about the stability concerns with both. There was no information documented to verify whether the prescriber was aware of this activity, if the pharmacy had made any suitable checks or if risk assessments for this situation were carried out. The team was instructed to seek further guidance and information about this. During the inspection, staff decided to supply these medicines separately provided the person had the ability and mental capacity to take their medicines in this way.

Warfarin and methotrexate were provided separately. There were no questions asked about blood test results, or relevant parameters and no details documented. This included no checks to ask people prescribed warfarin about their International Normalised Ratio (INR) level. Mid-cycle changes involved trays being retrieved and new trays supplied.

Staff had also dispensed prescriptions for CDs as instalments for people receiving MDS trays, against FP10 prescriptions. There was no instruction on the prescriptions to permit instalments to occur and this type of prescription should not be used for this purpose.

The pharmacy provided a delivery service and kept records for each delivery. Fridge items and CDs were highlighted, the drivers obtained people's signatures when they were in receipt of their medicines, they used a handheld device to assist with this. Failed deliveries were brought back to the branch, notes were left to inform people about the attempt made and medicines were not left unattended.

Staff were aware of risks associated with valproate. There was literature present to provide to people and a poster on display to highlight the risks. Staff explained that they had not seen prescriptions for females at risk. Prescriptions for higher-risk medicines were not identified to enable pharmacist intervention, counselling or checking of relevant parameters to routinely occur. This had been identified at the previous GPhC inspection and there was insufficient evidence to show that the resulting action plan had been implemented and sustained after the follow-up inspection.

Dispensed prescriptions awaiting collection were stored in an alphabetical retrieval system. Fridge items and CDs (Schedules 2-3) were mostly highlighted with details written on or stickers used. Clear bags were used to hold these medicines once they were dispensed. Schedule 4 CDs were not identified, and counter staff could not recognise them or their 28-day prescription expiry.

There were also several date-expired prescriptions for CDs present (tramadol, dated 02 April 19, Bupeaze dated 30 April 19, pregabalin dated 18 April 2019 and 02 May 2019). Staff did not look at the

date on the prescription when some of these prescriptions were shown to them.

The pharmacy obtained its medicines and medical devices from its company's warehouse as well as from licensed wholesalers such as Alliance Healthcare, AAH, Colorama and Phoenix. Unlicensed medicines were obtained through the Specials Laboratory. Staff explained that invoices for CDs were sent to their head office, one member of staff photocopied invoices for methadone liquid and retained them on site, the RP had also started to photocopy the pharmacy's invoices for CDs because of the discrepancies seen. The team was not yet complying with the European Falsified Medicines Directive (FMD). The pharmacy was not registered with SecurMed, there was no guidance information present, software or relevant equipment. Staff were unaware of the processes involved with this.

Medicines were stored in a disorganised manner in some places. There were no routine checks being made by staff to date-check medicines for expiry. There was no up-to-date schedule in place. Loose blisters and mixed batches were seen on shelves, medicines approaching expiry were not highlighted using any means and date-expired medicines were present. Some staff stated that they did not always have time to incorporate a date-check into their processes. Some CDs were stored under safe custody and medicines in the fridge were stored appropriately. Staff received drug alerts by email, they took the appropriate action and kept records to demonstrate this.

Once accepted, the team stored returned medicines requiring disposal within appropriate receptacles. People bringing back sharps for disposal, were referred to the local council. Returned CDs were brought to the attention of the RP before being segregated in the CD cabinet.

Principle 5 - Equipment and facilities **Standards not all met**

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services appropriately. But, it has not installed all of them in locations where people's privacy can be protected.

Inspector's evidence

Current versions of reference sources and relevant equipment were seen. This included clean, crown stamped conical measures for liquid medicines, as well as designated measures for methadone, counting triangles and a separate one for cytotoxic medicines. The dispensary sink used to reconstitute medicines was clean and there was hot and cold running water available. The fridge appeared to be operating appropriately and the CD cabinet was secured in line with legal requirements.

Computer terminals were positioned in a way that prevented unauthorised access. Staff used their own NHS smart cards to access electronic prescriptions and took them home overnight. The pharmacy team used cordless phones, and this helped conversations to take place away from the retail space, if required.

The pharmacy used an automated software system (Methasoft) to dispense methadone for people. This was calibrated and cleaned daily and staff, maintained records to demonstrate this.

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.