General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Badham Pharmacy Ltd, 23 Church Road, Bishops Cleeve, CHELTENHAM, Gloucestershire, GL52 8LR

Pharmacy reference: 1031484

Type of pharmacy: Community

Date of inspection: 14/08/2024

Pharmacy context

This is a community pharmacy in the centre of the village of Bishops Cleeve, near Cheltenham in Gloucestershire. The pharmacy's team members dispense NHS and private prescriptions. They sell a range of over-the-counter medicines and offer local deliveries, the New Medicine Service (NMS), seasonal flu, COVID-19 and travel vaccinations, blood pressure testing as well as the Pharmacy First Service. In addition, the pharmacy supplies many people with their medicines inside multi-compartment compliance packs if they find it difficult to take them.

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 its services as indicated under the relevant failed standards and Principles below. The pharmacy team are not routinely working in line with all of the pharmacy's standard operating procedures (SOPs). And there is evidence that things have gone wrong because of this. This is creating significant risks.
		1.2	Standard not met	The pharmacy does not have a robust process in place to manage and learn from incidents. There is no evidence that staff are routinely recording details about incidents and complaints, there are large gaps in the near miss mistake records, and there is limited evidence of remedial activity or learning occurring in response to mistakes.
		1.3	Standard not met	There are no audit trails in place for the pharmacy to identify who was responsible for professional activities such as clinical checks made or accuracy checking when this has been undertaken by a non-pharmacist accuracy-checker.
		1.6	Standard not met	The pharmacy records for assuring the safety of services are incomplete, inaccurate, or not available. All necessary records to verify that pharmacy services are provided safely should be readily available for inspection. At the point of inspection, the pharmacy was unable to provide records to verify that it had been recording fridge temperatures regularly. And the pharmacy has consistently failed to ensure details within other necessary records required for the safe provision of pharmacy services are kept in accordance with legal requirements.
		1.8	Standard not met	The pharmacy has evidently failed to appropriately safeguard the welfare of vulnerable people. They have not always ensured that people receive the correct medicine(s) within multi-compliance packs.

Principle	Principle finding	Exception standard reference	Notable practice	Why
2. Staff	Standards not all met	2.4	Standard not met	The pharmacy does not have a culture of openness, honesty and learning. There are gaps in the team's knowledge. And no evidence that regular updates are shared with the team, or resources provided to help them with ongoing learning.
		2.5	Standard not met	Members of the pharmacy team are inadequately supported. They are not provided with opportunities to discuss feedback or concerns due to the lack of regular performance reviews, updates or team meetings.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy's services are not managed or delivered safely and effectively. There are risks associated with the preparation and assembly of multi-compartment compliance packs.
		4.3	Standard not met	The pharmacy has compromised the safety of medicines and medical devices due to inadequate management of its medicines. The team has not consistently been checking medicines for expiry. The pharmacy has large quantities of date-expired medicines in amongst its stock, short-dated medicines are not always identified and the staff cannot show that they have been storing medicines requiring refrigeration at the appropriate temperatures.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy is not operating safely. It does not effectively identify and manage the risks associated with its services. And it's working environment is extremely unsafe. The company has set procedures to help manage risks. But members of the pharmacy team are not working in line with them. The pharmacy does not effectively safeguard vulnerable people. It is unable to demonstrate that it records all its mistakes or learns from them. And, it has not maintained its records, in accordance with the law or best practice.

Inspector's evidence

The pharmacy was inspected because of a complaint made to the GPhC about the pharmacy supplying medicines without legally valid prescriptions. An inspection was subsequently carried out to assess the situation and several concerns were identified during the inspection. The pharmacy's volume of workload was high but limited staff were present, there were gaps in their knowledge, inappropriate, and unsafe behaviour was also seen (see below and Principle 2). The team was also behind with some routine tasks and there were issues with the pharmacy's management of medicines (see Principle 4). Health and safety risks were noted with the premises (see Principle 3), and the pharmacy's team members were often observed to work outside of the pharmacy's standard operating procedures (see below).

Throughout the inspection, it was clear that the pharmacy was not operating in a safe and effective manner. There were limited systems in place to identify or monitor the safety of the services being provided. Staff were not always working in accordance with the pharmacy's standard operating procedures (SOPs).

The correct notice to identify the pharmacist responsible for the pharmacy's activities was on display. The inspector was aware that the company had a range of current electronic SOPs to provide its team with guidance on how to complete tasks appropriately. Staff said that they had seen and read them. However, team members who prepared and checked compliance packs admitted to the inspector that for people requiring any controlled drug (CD) inside compliance packs, they were prepared ahead of and without prescriptions. The pharmacy technician was one of these members of staff. This practice was not in accordance with the pharmacy's SOPs for this task (SOP 15) which stated, 'CDs are not to be added to the box, until the day of the supply, and a CD label must be put on every box, to ensure the CD is not omitted' But Pregabalin and Gabapentin were specified that they could be added in advance. This process had not been changed considering the recent incident and complaint made to the GPhC and staff were continuing to prepare compliance packs in this way.

The responsible pharmacist (RP) also admitted to the inspector that he caried out the final accuracy check for compliance packs containing CDs without legally valid prescriptions. He said that he checked the person's medication record (PMR) and summary care record (SCR) before doing so. However, this practice was also not in accordance with the pharmacy's SOP. The PMR showed what had been processed by staff, so this was not indicative of what had been prescribed. SCR showed repeat medicines and when prescriptions were last issued. But there is no evidence that these checks routinely occurred or were consistently checked because it would have highlighted those prescriptions that had not been issued and where those medicine(s) had been taken off repeat. The Pharmacy's SOP (SOP 31)

for this also stated that prior to viewing SCR, explicit written consent from the patient would be obtained. There was no evidence that this had been obtained for the sustained period that this practice had been undertaken. In addition, the same SOP stated that contemporaneous notes would be made in the PMR to record that SCR had been accessed. The inspector checked PMRs for people prescribed CDs and no notes were seen to have been recorded. There was no reference in any of the company's SOPs that SCR could be used instead of valid prescriptions to accuracy-check medicines. Furthermore, supplying CDs without legally valid prescriptions is unlawful and not in line with the Misuse of Drugs Legislation.

Once prescriptions had been assembled, the RP usually carried out the final accuracy-check, but the ACT could also assist with this. The ACT said that she did not accuracy check compliance packs containing CDs. There was an SOP (SOP 11) to cover this process, but this was also not being adhered to by the RP or ACT. The SOP stated that 'The pharmacist must sign the "CA" or other Clinically Checked section on the prescription, after it has been stamped (usually in the top right corner to confirm patient details) when they have completed the clinical check to allow the ACT to perform the final accuracy check. The pharmacist may wish to sign the "Clinically checked" box before or after the ACT, but always before the prescription is handed to the patient or put out for delivery.' Staff confirmed and the inspector saw that there was no stamp and no audit trail being used to help identify or verify this process. Since the incident that had been brought to the attention of the GPhC, the SI had brought in an additional record or audit trail to help verify who had processed, prepared, clinically and accuracy checked prescriptions. But despite the pharmacy giving documented assurances that this would be implemented, at the point of inspection, this was still not being used. There was therefore no indication and no verification that appropriate clinical checks were taking place. The ACT also admitted to the inspector that she assumed that the clinical check had taken place when assembled prescriptions were passed to her to accuracy check without this being verified.

There was no evidence that the pharmacy was routinely identifying its mistakes or learning from them. A near miss record for August 2024 was on display which had a few entries on it. However, prior to this, records were seen from March 2024 and then in April 2024 but not after this and not for a few years before this time. There had been no details recorded to verify that they had been reviewed, about the contributory factors, or the learning and action taken. Staff, including the RP could not provide the inspector with specific examples of any action taken in response. The RP described an appropriate response to managing incidents, he said that incident reports were completed electronically and sent by email to the superintendent pharmacist. However, at the point of inspection, he could not locate any other incidents on the pharmacy's emails aside from the recent incident which had been brought to the GPhC's attention. In a subsequent phone call with the SI, he confirmed that dispensing incidents were not being reported to him. The inspector was told that when the SI had worked at the pharmacy, he was made aware of three dispensing incidents but depsite telling the team to report this to him, this did not happen. This meant that neither near misses nor incidents had been regularly recorded, reviewed or any trends or patterns identified, and there was no evidence that any remedial action had been taken in response.

The pharmacy team ensured people's confidential Information was protected. The pharmacy's confidential waste was separated and removed for disposal. There was no sensitive information visible from or left in the retail space and the pharmacy's computer systems were password protected. However, the inspector noted that a member of staff's NHS smart card had been left within one computer terminal and was being used during the inspection. This person was not on the premises at the time and their password was known. This limits the pharmacy's ability to control access to people's confidential information.

The RP said that he was trained to level two to safeguard the welfare of vulnerable people. Experienced staff members had also been trained on this. They would refer to the RP if concerns were seen but did not know where they could locate relevant contact details for the relevant agencies. This could mean that the team may not know how to respond to concerns appropriately. There was, however, evidence that mistakes had happened with vulnerable people's medicines. People receiving compliance packs are vulnerable and the pharmacy's processes for preparing compliance packs as described above and under Principle 4 were unsafe.

There were also concerns noted with all the pharmacy's records. This included a sample of registers seen for controlled drugs (CDs) and the odd record of CDs that had been returned by people and destroyed at the pharmacy where no details about the destruction had been recorded. The former had some crossed-out entries without appropriate footnotes. On randomly selecting CDs held in the cabinet, their quantities did not match the stock balances recorded in the corresponding registers. The RP was asked to provide the inspector with an update about this once he had investigated the discrepancy. The SI subsequently informed the inspector that branded and generic CDs had been recorded in the same register, so there was no discrepancy. However, there was no indication in the register about this, nor was the team consistently identifying which brand or generic CD had been supplied or obtained. There were gaps in the RP register where pharmacists had consistently not recorded the time that their responsibility ceased. Records of supplies made against private prescriptions consistently had missing prescriber information or incorrect details recorded and no records for emergency supplies made at the request of people, were seen to have details about the nature of the emergency recorded. There were also no records verifying that fridge temperatures had remained within the required range kept at the pharmacy (see Principle 4).

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

Summary findings

The pharmacy does not have a culture of honesty, openness or learning. Staff do not have the necessary knowledge required of them, they cannot up-skill or keep their learning up to date easily because the pharmacy does not provide them with additional resources, updates or support. And there is no evidence that staff are provided with regular opportunities to discuss their performance. But the pharmacy employs a team of staff with various levels of skills and qualifications.

Inspector's evidence

Staff present during the inspection included the regular RP who was also the manager, a pre-registration trainee pharmacist, the ACT, a pharmacy technician, two dispensing assistants one of whom was trained, the other was undertaking accredited training in accordance with his role, and a medicines counter assistant (MCA). The pharmacy's volume of workload was very high. Another trainee dispensing assistant was present who had come from a different pharmacy under the same company to gain experience. There was also a second, part-time pharmacist, another MCA, two trained dispensing assistants, and two evening staff who were said to be on accredited training courses relevant to their role(s).

Staff wore unforms and name badges. The team was said to be up to date with dispensing prescriptions and preparing compliance packs, but they were behind with other routine tasks such as date-checking. The pharmacy's current workload was seen to be stretching for the number of staff available on the day of the inspection. The ACT and RP were adamant however, that they had enough staff to manage, they said that more staff were not required, locum dispensers could be used for contingency, but the inspector was told that they did not work as effectively as existing staff. However, the inspector was also told that the latter was untrue. Staff said that the trainee dispenser and another dispenser routinely worked at other pharmacies owned by the same company when they required cover which left the pharmacy team short and that it could be stressful working here.

There were other concerns noted with members of the pharmacy team and their knowledge or practice. The pharmacy technician did not know and could not tell the inspector about the safety concerns or recent alerts associated with sodium valproate. The MCA did not ask the full range of questions before selling medicines to people over the counter, very few details were checked. She did not know that pseudoephedrine could be abused to make an illicit substance, nor that codeine linctus was now prescription-only. The trainee dispensing assistant said that people could be given their assembled medicines when the RP was absent and away from the premises, despite them reading SOPs, this being unlawful and their working at the pharmacy for over four months. The RP told the inspector some things which every other member of staff present confirmed to be untrue. As an example, he stated that team meetings took place regularly, but staff stated that they had not had any for years. The RP was also unable to inform the inspector about the most recent drug alert, nor he could tell the inspector about the outcome from an audit said to be completed for people prescribed sodium valproate (see Principle 4). In addition, when some issues were brought to the attention of the RP by the inspector, his consistent response was that 'it wasn't me.' This included record keeping of CDs. The RP was informed during the inspection that this was an unacceptable response from a pharmacist, from the RP, pharmacy manager and company director.

The inspector was told that no formal appraisals had been undertaken for years, and team members were not provided with any training materials or resources for ongoing training. Staff said that they heard about updates from informal discussions between the team. The RP did not provide staff with updates on recent changes, processes, products, or updated guidance.

The foundation trainee pharmacist was undertaking a split training placement with Gloucestershire Hospitals. She said that protected training time was given provided this was undertaken at the pharmacy or at the company's head office. The RP was her designated supervisor at the pharmacy. However, she was unaware of a training plan and said that no regular or consistent time was spent with the RP. This was also observed at the inspection. The inspector was also told that the trainee pharmacist's role at the pharmacy consisted of cleaning, dispensing, and serving customers. Reviews at the various stages for her training were said to have been very quick with no formal 'sit down' process taking place. The inspector was further aware that a concern had been raised with the RP to discuss this situation by the South-West regional training programme, but no response had been received by them. Following the inspection, the GPhC could confirm, from its records, that in 2023, a training plan was in existence and issued by the company for foundation-year trainees. This was quite comprehensive although, from the inspection, from observing the trainee pharmacist's activities and lack of interaction or input seen from the RP towards her as well as her role, this did not appear to have been implemented at this pharmacy.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy has separate areas where confidential conversations or services can take place. But parts of the pharmacy are not kept sufficiently clear of clutter. And the pharmacy does not effectively manage some additional risks associated with its consultation rooms.

Inspector's evidence

The pharmacy premises were large. They consisted of ample space in both the dispensary and retail area with additional staff and storage areas at the rear. There were some indications that the pharmacy was being re-designed or re-fitted as excess building material was present in the back sections. Fixtures and fittings in the pharmacy were dated but functional. The retail area was presented appropriately but some of the back areas including the stock room were cluttered. The pharmacy had ample space to dispense medicines safely. There were different areas for certain activities to take place such as a designated section to prepare compliance packs and the dispensary was observed to be clear of clutter during the inspection. The premises were bright and suitably ventilated. The ambient temperature was suitable for the storage of medicines. The pharmacy was also secured against unauthorised access.

The consultation rooms were very professional in their appearance. They were signposted to indicate their presence and could be locked when not in use. However, one room which was used most often, was open at the point of inspection and contained two open sharps bins as well as a fridge containing vaccines. This situation created risks and permitted potential access to prescription only medicines. The RP was advised to lock this room during the inspection, but he did not do this. In addition, the pharmacy had no hot water in the staff WC at the point of inspection. It was subsequently confirmed that the pharmacy has hot water but it takes some time for the water to heat up in this area.

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

Summary findings

The pharmacy does not always provide its services, prepare, or store its medicines in a safe and effective way. The pharmacy is assembling its compliance packs in an unsafe manner. The pharmacy manages its medicines inadequately. The team does not make any checks to ensure that medicines are not supplied beyond their expiry date, and there are no records available to help verify this. The pharmacy cannot show that temperature sensitive medicines are stored appropriately. And the pharmacy's team members are not making any checks to help people with higher-risk medicines take their medicines safely. But the pharmacy obtains its medicines from reputable sources.

Inspector's evidence

People's medicines were delivered to them, and the team kept records about this service. However, the records were stored in an extremely disorganised way. Failed deliveries were brought back to the pharmacy, notes were left to inform people about the attempt made and no medicines were said to be left unattended. A driver for the company confirmed that occasionally people requested for their medicines to be left with a neighbour.

The pharmacy prepared and supplied many people with their medicines inside compliance packs. The inspector was told that there was no specific assessment prior to setting this up, so anyone could have a compliance pack. They were usually supplied for elderly people provided the person's GP supplied weekly prescriptions for this. The pharmacy ordered prescriptions on behalf of people using this service. Queries were said to be checked with the prescriber and notes made about the situation, but the inspector did not see any specific details recorded about this for the incident with the complaint that had been made to the GPhC. Backing sheets were kept as individual records for people, they held details about the medicines prescribed, and their timings within the compliance packs. Any changes resulted in the backing sheet being updated, the new backing sheet was then printed and retained as a record for this purpose alongside previous ones. However, for the situation where the complaint had been made to the GPhC, every updated backing sheet contained the medicine which was no longer prescribed. So, the records being made or retained were inaccurate. Staff used the backing sheets to manually dispense medicines into the compliance packs or the automated system (robot) was used for this.

When prescriptions were received, the ACT was said to match the backing sheet to the received prescription(s) and checked that the pharmacy had received all four weeks of prescriptions for each person. However, she said that she did not do this for compliance packs containing CDs. The inspector could not see that any member of staff was responsible for ensuring that prescriptions for CDs were matched to the backing sheet. This step therefore did not appear to have been routinely taking place. There were also no audit trails (as described under Principle 1) to help verify that this stage had occurred. Following the incident and complaint made to the GPhC, an additional stage was due to be implemented where staff used a colour coded system. Distinct colours were to be added to the backing sheet, pink indicated that additional medicines needed to be added (such as sodium valproate which was supplied weekly but left unsealed until this was added), orange was for CDs and green indicated that CDs were to be added, which were again left unsealed for periods. The ACT said that this system had only just started but the inspector did not see this being used on any compliance packs at the point of inspection. This system further also complicated the pharmacy's processes for compliance packs

which in turn, created more risks.

Unstable medicines such as sodium valproate were supplied every week. The inspector was told that relevant checks had been made with people to help justify this practice, but no details had been documented to help verify this. In addition, some people received methotrexate in a separate slot in the compliance pack, others had this mixed in with other medicines without being provided with any specific information about this medicine.

All the medicines were de-blistered into the packs with none currently supplied within their outer packaging and patient information leaflets were supplied routinely. However, compliance packs were routinely left unsealed overnight as described above. The compliance packs had some generated descriptions of the medicines included on them, but they were not always accurate, or changed during the dispensing process and when the robot had been used, some of this information was missing. In addition, the inspector saw prepared compliance packs stored on the dispensary shelves without prescriptions. When this was highlighted, the pharmacy technician confirmed that there were electronic prescriptions, but the tokens had not been printed. They were attached only when the inspector highlighted this. In view of the incident that had already occurred where compliance packs had been issued without legally valid prescriptions, it was visibly clear that the pharmacy had not learnt from this situation nor implemented any of the necessary changes to help prevent it recurring.

The RP was providing the Advanced NHS service, Pharmacy First. Suitable equipment was present which helped ensure that the service was provided safely and effectively (see Principle 5). The RP said that he had attended training on how to use relevant equipment such as the otoscope and told the inspector that he had read and signed the service specification as well as Patient Group Directions (PGDs) electronically. When he was asked to bring these records up, however, he could not locate them. The inspector was aware from other inspections of pharmacies owned by the same company that the PGDs were not available on the company's electronic portal. This meant that the RP could not show that he had the relevant legal frameworks in place to authorise supplies made under this service.

The team used baskets to hold prescriptions and medicines during the dispensing process. This helped prevent any inadvertent transfer between them. After the staff had generated the dispensing labels, there was a facility on them which helped identify who had been involved in the dispensing process. Team members routinely used these as an audit trail. CDs were generally stored under safe custody. The pharmacy used licensed wholesalers to obtain medicines and medical devices. Medicines returned for disposal, were accepted by staff, and stored appropriately in designated containers. This included sharps provided they were in sealed bins. Drug alerts and product recalls were received by email and the RP, despite not knowing what the last drug recall was, described taking appropriate action in response to them.

However, medicines could have been stored in a more organised way. In addition, there were numerous containers and bottles present in the section where compliance packs were prepared, which contained medicines that had been de-blistered into them. None, however, were labelled with the appropriate details such as the batch number, name of the product, the expiry date, manufacturer, or the date they had been de-blistered. Whilst most of the containers and bottles contained the original pack or had this attached to them, some were seen without this, and they had not been labelled appropriately either. Storing medicines in this way is unlawful and against current medicines legislation. Staff explained that they were for the robot. The pharmacy's use of this practice was therefore also discouraged. De-blistering medicines in this manner meant that the pharmacy was no longer storing the medicines inside its original packaging and under the optimal conditions. This could impact the medicine's overall stability and efficacy. There had also been no risk assessment conducted, or details

documented about this situation. A discussion was held about obtaining stability data, as far as possible and marking this information, directly onto the containers.

The team was not date-checking medicines for expiry regularly, there were no records seen to help demonstrate when this had happened, nor were any shelf-edge labels present to show when this had last been completed. In addition, the inspector found several date-expired medicines in amongst the pharmacy's stock. This included a few expired CDs which were not clearly segregated in the cabinets. Staff were aware of this situation, they confirmed that they had fallen behind with completing this task and were unsure when this had last been completed. However, the inspector had to also tell them to incorporate a date-check of each medicine into their final accuracy checks until they could catch up with this. There were also loose blisters present on the shelves which had not been stored inside appropriate packaging or labelled suitably with relevant details as described above. As mentioned in Principle 1, there were no records available to verify that the temperature of the fridges had remained within the required range. Data loggers were used but were said to be sent to another director's phone. This meant that the RP had no effective oversight of this situation. It was therefore not possible to verify that temperature sensitive medicines had been kept at the appropriate temperature during the inspection.

In addition, people prescribed higher-risk medicines were not routinely identified, asked relevant questions or details about their treatment recorded. Most staff were unaware of risks associated with valproates. When asked, team members did not ensure that the relevant warning details on the packaging of these medicines were not covered when they placed the dispensing label on them. As stated under Principle 2, there was limited evidence that the pharmacy had identified and continued to identify people at risk, who had been supplied this medicine, nor that people were counselled accordingly.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has an appropriate range of equipment available to provide its services.

Inspector's evidence

The pharmacy had the necessary equipment it needed to operate appropriately. The pharmacy's equipment included pharmacy fridges, a few standardised conical measures for liquid medicines and the dispensary sink that was used to reconstitute medicines. The latter could have been cleaner. The blood pressure machine was described as new. The pharmacy had relevant equipment to provide the Pharmacy First service such as an otoscope, torch, and tongue depressors. Cordless phones were available for private conversations to take place if required and the pharmacy's computer terminals were positioned in a way that prevented unauthorised access. Staff could store personal belongings in lockers.

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.