General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: A.H. Hale Ltd., The Bathwick Pharmacy, 8 Argyle Street, Laura Place, BATH, Avon, BA2 4BQ

Pharmacy reference: 1028531

Type of pharmacy: Community

Date of inspection: 08/04/2019

Pharmacy context

This is a community pharmacy located in an affluent area in the centre of Bath. It serves its local population which is varied and includes tourists. The pharmacy opens six days a week. The pharmacy sells a range of over-the-counter medicines, dispenses NHS prescriptions and supplies medicines in multi-compartment medicine devices for people to use living in their own homes.

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 does not identify and manage risk well. There are no procedures in place to learn from mistakes.
		1.6	Standard not met	The pharmacy does not maintain the necessary records it needs to by law.
		1.7	Standard not met	The pharmacy does not manage information to protect the privacy of its patients.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	Some areas in the pharmacy are very untidy and represent a trip hazard to staff.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	Pharmacy services are not managed and delivered safely and effectively. The pharmacy does not routinely use audit trails to show who has dispensed and checked the medicines that they dispense. Monitored dosage system trays are filled in advance and then labelled at a later stage which may increase the risk of mistakes.
		4.3	Standard not met	The pharmacy does not store medicines in accordance with the law. Unlabeled monitored dosage system trays are stored prior to the prescription arriving in the pharmacy.
5. Equipment and facilities	Standards not all met	5.1	Standard not met	The pharmacy does not have the appropriate equipment to provide the services offered.

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

Summary findings

The pharmacy does not identify and manage risk well. The pharmacy does not have adequate procedures to help them learn from mistakes that happen so that opportunities for learning could be missed. The pharmacy does not routinely use audit trails to show who has dispensed and checked medicines. The pharmacy does not have responsible pharmacist procedures in place which are required by law. The pharmacy does not maintain all of its records correctly as required by law. The pharmacy does not dispose of people's confidential information securely. Pharmacy team members are clear about their roles and responsibilities. The pharmacy asks its customers and staff for their views and uses this to improve services. The pharmacy has appropriate insurance to protect people when things go wrong.

Inspector's evidence

Insufficient processes were in place for identifying and managing risks. Near misses were incorrectly recorded as dispensing errors on the patient medical record system and these were recorded infrequently. There was no procedure in place for dealing with dispensing errors. The superintendent pharmacist could not demonstrate that any dispensing errors had been recorded.

There was an established workflow in the pharmacy where labelling, dispensing and checking activities were carried out at dedicated areas of the work benches. Three assembled prescriptions were examined and neither had initials to indicate which pharmacist had checked the medicines.

Standard operating procedures (SOPs) were in place but staff were not routinely following these as they were pre-assembling monitored dosage system trays. (see also principle 4). Responsible pharmacist SOPs were not in place. The superintendent pharmacist reported that SOPs were reviewed every two years. On questioning, staff were all able to explain their roles and responsibilities.

A complaints procedure was in place and the staff were all aware of the complaints procedure. The pharmacy carried out a Community Pharmacy Patient Questionnaire (CPPQ) annually as part of their NHS contract. Indemnity insurance and public liability certificate from Pharmacy Guard was in place and was valid and in date until 3rd June 2019.

Records of controlled drugs (CD) and patient returned CDs were seen as being kept. Obliterations were present in the CD registers examined. The address that a CD was received from was often omitted from the examined records. A sample of Ritalin 10mg tablets was checked for record accuracy and was seen to be correct. Not all of the out-of-date CD stock was clearly labelled as such.

The pharmacy team reported that date checking was carried out regularly but no record were kept to demonstrate this. The fridge temperatures were recorded daily and were always in the 2 to 8 degrees Celsius range. An electronic responsible pharmacist (RP) record was retained and the responsible pharmacist notice was displayed in pharmacy where patients could see it. The time that the RP ceased responsibility was often omitted. The pharmacist was not in the pharmacy at the time of the inspection and did not sign out as absent on the RP log. The inspector proffered advice about this.

There was a general lack of understanding about how private prescriptions were recorded in the

pharmacy. Private prescription records were retained in an inconsistent manner – some had been written in a book and others were put on the computer. The pharmacist could not demonstrate any emergency supply records as he was unfamiliar with the patient medical record system. Specials records could not be demonstrated and the pharmacist could not immediately find them.

Staff were seen to be following the company information governance policy. The computer screens were all facing away from the public and access to patient confidential records was password protected. Staff explained that they were aware what signs to look out for that may indicate safeguarding issues in children and vulnerable adults. Contact details were available for safeguarding referrals, advice and support.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy staff have the appropriate skills, qualifications and training to deliver services safely and effectively. The pharmacy team members work well together. They are comfortable about providing feedback and raising concerns and are involved in improving pharmacy services.

Inspector's evidence

There was one pharmacist, one dispensing assistant and one medicine counter assistant present during the inspection. They were all seen to be working well together. Staffing levels were seen to be sufficient for the level of the services provided during the inspection.

Staff meetings would take place on an ad-hoc where any significant errors and learning would be discussed with the team. The staff reported that they kept their knowledge up to date by reading third party materials and would ask the pharmacist if they had any queries. A dispensing assistant reported that he had recently been learning about the new requirements for the recently rescheduled gabapentin and pregabalin.

Staff reported that they felt comfortable to approach the superintendent pharmacist with any issues regarding service provision. There superintendent pharmacist reported that there were no targets in place at the pharmacy.

Principle 3 - Premises **Standards not all met**

Summary findings

The premises provide adequate space for delivering pharmacy services. But the pharmacy has areas which are disorganised and untidy. The premises can be secured and safeguarded from unauthorised access.

Inspector's evidence

The pharmacy was based in a Grade 2* listed building. There was a sink available in the dispensary with hot and cold running water with hand sanitiser to allow for hand washing. Medicines were organised in a generic and alphabetical manner. Some stock was stored on the floor in the dispensary which may increase the risk of trip hazards.

The pharmacy did not have a consultation room but the pharmacist reported that he would wait until the pharmacy was quiet and use the corner of the room if patients wanted a private conversation. A back room where some assembled monitored dosage system trays were kept was extremely untidy with many boxes of stock, paperwork and other items were kept which represented a trip hazard to staff.

Open bags of assembled medicines were stored below the dispensary shelves which may increase the risk of medicines falling into these bags. The pharmacist agreed to address this. The ambient temperature and lighting throughout the pharmacy was appropriate for the delivery of pharmaceutical services.

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

Summary findings

The pharmacy's services are accessible but not effectively managed and safely delivered. Pharmaceutical stock is appropriately obtained, but monitored dosage system trays are not stored in accordance with the law and they are not supplied in accordance with the pharmacy's own procedures and this increases the risk of errors. Where a medicinal product is not fit for purpose, the team take appropriate action but audit trails are not kept to demonstrate this. The pharmacy does not currently have a hazardous waste bin to dispose of hazardous waste medicines and this may increase the risk to staff and the environment.

Inspector's evidence

Leaflets were available in the pharmacy detailing some services. Access to the pharmacy was via a step but staff reported that they could help people if necessary. There was space for the movement of a wheelchair or pushchair in the pharmacy and seating for patients and customers who were waiting. Large print labels were available for patients with sight difficulties.

The pharmacy team dispensed monitored dosage system (MDS) trays for 53 patients. Trays were pre-assembled without prescriptions and stored unlabelled in the pharmacy. Trays were later labelled when the prescription arrived in the pharmacy and the pharmacist said he would check for any changes at this point. Trays were handed out without reference to the prescription which was contrary to the pharmacy's own procedures. Audit trails to show who had dispensed and checked the trays were not routinely used. Complete descriptions were provided for the medicines contained within the MDS trays. The pharmacist reported that patient information leaflets were supplied once a month.

The pharmacy team had an awareness of the strengthened warnings and measures to prevent against valproate exposure during pregnancy. But valproate patient cards and leaflets were not available for use during dispensing to valproate to female patients. The pharmacist agreed to address this. The pharmacist reported that he would check that that the patient's prescriber had discussed the risks of exposure in pregnancy with them and they are aware of these and query if they were taking effective contraception.

There were destruction kits available for the destruction of controlled drugs and doop bins were available and being used for the disposal of medicines returned by patients. A hazardous medicines waste bin was not available for use during the inspection. Waste collection was regular and the team explained they would contact the contractors if they required more frequent waste collection.

The pharmacy was in the process of complying with the European Falsified Medicines Directive (FMD). The relevant equipment was in place and the superintendent pharmacist reported that he intends to source software from 'Spider FMD'.

Medicines were obtained from suppliers such as AAH, Alliance, Trident, Sigma and Colorama. Specials were obtained via suppliers such as the DE Midlands specials. The majority of medicines and medical devices were stored within their original manufacturer's packaging. The following medicines were stored without a container as loose strips on the dispensary shelf: Ibuprofen 200mg tablets and Co-codamol 30/500 effervescent tablets

Staff reported that pharmaceutical stock was subject to date checks but these were not documented. The fridge was in good working order and the stock inside was stored in an orderly manner. MHRA drug alerts and recalls came to the pharmacy electronically and the pharmacist explained that these were actioned appropriately. Audit trails were not kept to demonstrate this.

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

Summary findings

The pharmacy does not have the appropriate equipment to provide the services offered. The pharmacy's facilities are appropriate to provide the services offered and they generally protect patient privacy.

Inspector's evidence

There was only one 100ml crown stamped measure available for use and the pharmacist reported that this was used to reconstitute all antibiotic suspensions. Measures were seen to be clean. Amber medicines bottles were seen to be capped when stored and there were counting triangles available for use. Electrical equipment appeared to be in good working order and was PAT tested annually. Pharmacy equipment was seen to be stored securely from public access.

Up-to-date reference sources were available in the dispensary and the consultation room and included a BNF, a BNF for Children and a Drug Tariff. Internet access was also available should the staff require further information sources. There was one fridge in use which was in good working order and the maximum and minimum temperatures were recorded daily and were seen to always be within the correct range.

Doop bins were available for use and there was sufficient storage for medicines. Confidential waste was separated and shredded using a strip shredder which meant that some confidential details could potentially still be seen. The computers were all password protected and patient information was safeguarded.

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.