General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Boots, Dispensing Support Pharmacy, c/o AHDL Preston SC, Dodd Way Walton Summit, PRESTON, PR5 8AW

Pharmacy reference: 1121765

Type of pharmacy: Dispensing hub

Date of inspection: 30/09/2022

Pharmacy context

This is a large dispensing hub pharmacy. Its sole activity is dispensing medicines for the company's community pharmacies across Great Britain. People do not visit this pharmacy, as their medicines are sent to their chosen Boots Pharmacy for supply. The pharmacy is located on a purpose-built mezzanine above a large pharmaceutical wholesaler on an industrial estate, near Preston. The medicines they dispense are distributed to the branch pharmacies using the wholesaler's logistical network. The pharmacy's usual turnaround time from receipt of a request to patient collection is next working day plus one.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Good practice	1.1	Good practice	The pharmacy has robust governance arrangements in place to help ensure risks are identified and managed.
		1.2	Excellent practice	The pharmacy utilises technology to monitor each stage of the dispensing process to be monitored. And it uses this information to deliver improvements in safety and effectiveness.
		1.7	Good practice	The pharmacy has effective controls in place to protect confidential information.
2. Staff	Good practice	2.1	Good practice	The pharmacy actively manages staffing levels to effectively deal with variations in workload.
		2.2	Good practice	Members of the team complete an ongoing structured training programme to help keep their skills up to date.
		2.4	Good practice	Error reporting and review, support by senior staff, appraisals and regular team meetings are indicative of a culture of openness and learning.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Good practice	4.2	Good practice	The pharmacy uses automation to provide its services effectively and efficiently. There are in-built systems to safeguard against errors and to help ensure accuracy.
5. Equipment and facilities	Good practice	5.2	Good practice	The pharmacy has an on-site maintenance crew, who have access to a full range of replacement parts to use in the event of equipment failure.

Principle 1 - Governance ✔ Good practice

Summary findings

The pharmacy has robust governance arrangements in place to help ensure risks are identified and managed. It keeps the records it needs to by law, and it has effective controls to protect confidential information. The pharmacy uses technology to monitor the dispensing process at every stage. And it uses this information to continuously improve its safety and effectiveness.

Inspector's evidence

A set of Standard Operating Procedures (SOPs) were available and were specific to the operations within the hub. Members of the team had signed to say they had read and understood the SOPs. Team members had access to a business continuity plan in case of an event which would drastically affect the level of service provided by the pharmacy. The plan addressed a range of possible occurrences, from those with minor impact, such as local failings in label printers or machinery, to large scale fire or destructive events. The action to take following an event was detailed to mitigate the impact to the service users.

The pharmacy dispensed a very large volume of medicines each day for approximately 500 pharmacies within the company. It used automated machinery which enabled it to process and dispense such a volume. Five machine lines were in operation, and each line contained sensors and cameras to monitor the dispensing using barcode and optical technology. If the sensors detected an irregularity, a 'system flag' was logged on a database record, and the medicine was diverted to an 'exceptions station' for a manual accuracy check. A digital counter was on display and showed the number of interventions which had been actioned by the exceptions station throughout each day.

The pharmacy used the medicines diverted to the exceptions station to quality assure and monitor how well the system was performing. Totes were used as containers to store either medicines or dispensed and bagged medicines for up to five patients at the same pharmacy. Most totes directed to the exception station did not contain an incorrect medicine. A manual check was completed as due diligence following a mechanical issue, human interference or abnormality in the system. If a tote was found to have a mistake inside, the pharmacist would investigate and inform the senior leadership team (SLT). Part of the investigation involved using records which showed the number and the types of system flags being created each hour causing totes to be diverted to the exception area. If there was a spike in exceptions, or a number of consistent exception types, on-site engineers would attempt to pinpoint the problem and investigate. The data provided real-time information of the number of flags the system was creating for each line, and each process.

A risk register had been created and was used by the SLT to identify any parts of the process which they considered to involve a potential risk to the operation of the pharmacy. A risk could be something that affected the system's safeguards, the pharmacy's efficiency, or human factors, such as team members. There were details of the actions taken to help mitigate risks. An example seen within the risk register involved team members not completely emptying the totes boxes to fill the automated machinery. This meant a box of medicine was sometimes left in the tote, and when a pharmacy branch received the medicine, they would have to re-check all of the dispensed medicines in case there was a problem. To help prevent this occurring again, team members were informed and trained on how to use the automated machinery to tilt the tote so they could check it had been completely emptied. There was a current action point in place to review how some medicines were being manually labelled by team

members. If the pharmacist identified a concern after medicines had been dispensed and bagged, and were destined for pharmacy branches, they could send an alert for the branch to perform additional checks on specific totes or a bag of dispensed medicines for an individual, for further assurance.

The pharmacy had a process to record near misses. These were analysed each month by the lead pharmacist as part of a patient safety review. The review identified any actions to be taken from the data obtained from near miss records, dispensing incidents reports, professional standards and feedback from user pharmacies. The review was printed and put on display in the pharmacy. Displayed alongside the patient safety review was a 'key actions' document which identified key messages collated from the four areas reviewed within the patient safety review. For example, there was an action of asking team members to ensure they are following SOPs at the exceptions station, due to an increased number of people taking a shortcut in the process, leading to errors. If a team member was found to not have followed a process correctly, they would be required to complete a refresher training programme.

Each Friday morning, there was a dispensing incident meeting involving a number of stakeholders, including members of the pharmacy team, senior management, superintendent pharmacist's team, and a technician. The meeting was used to investigate and discuss any alleged dispensing incidents so they could identify whether there were any improvements which needed to be made to the dispensing process. The investigation used CCTV at key areas of the dispensing process to help to identify what had gone wrong. An example of an investigation was seen, involving an incident where a branch had reported that the wrong medicines had been placed in the wrong bag. CCTV had shown that the medicines had in fact been dispensed and bagged correctly. Data from the automated machine also helped to show the two patients medicines had not been dispensed on the same day. As no dispensed medicines were left at the hub overnight, it was concluded that the pharmacy was not at fault, and it was likely to be an error by a team member at the branch pharmacy. These findings were reported back to the branch pharmacy, and they were requested to complete an investigation to find the source of the error.

Roles and responsibilities of staff were described in individual SOPs. When questioned, various members of the team were able to describe what their responsibilities were and when they would refer to another member of the pharmacy team. Staff wore lanyards identifying their names and roles. Computer access was via a user log on with restrictions limited to the user's role. Branch pharmacies were able to log feedback or complaints by a similar mechanism as reporting errors. An example of a complaint received from pharmacy branches was when the branch received a tote containing a bag that had split. This resulted in additional workload for the branch as they had to check all the medicines within the bags in the tote. To help prevent similar issues, the engineers installed additional sensors where medicines were bagged, so that any problems could be resolved at the exception station.

The pharmacy provided evidence that professional indemnity insurance was in place. A responsible pharmacist (RP) notice was prominently displayed. The RP records appeared to be in order. Information governance (IG) procedures were in place. Staff received annual IG training and had signed confidentiality agreements in their contracts. Confidential waste was segregated to be removed by a waste carrier. Members of the pharmacy team did not have access to people's patient medical record or data. In order for a pharmacist to obtain people's medication records, they had to submit a request to the central team for the information to be released.

The pharmacy had safeguarding procedures available. Although the pharmacy had limited scope for safeguarding activity, the management felt it was an important skillset to have. Pharmacy professionals had completed level 2 safeguarding training, and other members of the pharmacy team had completed level 1 safeguarding training. Contact details to raise a safeguarding concern were displayed in the

communications area.

Principle 2 - Staffing ✔ Good practice

Summary findings

The pharmacy continuously adjusts its workload and staffing levels throughout the day. This means increases in workload can be effectively managed without members of the team being under additional pressure. Each member of the team regularly completes training modules to keep their knowledge up to date. And they receive regular feedback to help them improve and develop.

Inspector's evidence

The pharmacy employed a senior leadership team (SLT), which consisted of a senior operations manager, who was also a pharmacist, a lead pharmacist and an operations manager. There were also four pharmacists, four accuracy checking pharmacy technicians (ACPT), a trainee ACPT, and 107 full-time-equivalent operators. Operators undertook various activities to support the automated dispensing processes of the pharmacy, such as completing semi-automated labelling processes and managing stock. Eight of the operators were assistant mangers who were responsible for a team of 15-19 operators, some of whom had a more senior operator position as a task co-ordinator. All operators had been in their roles for more than 12 months, providing some degree of consistency in the team's turnover. To help achieve this, the company had invested in advertisement to ensure people understood what the roles entailed before they applied for the positions.

The staffing level varied throughout the day in order to match with the varied workload to meet logistical deadlines. From 6am until 2pm the highest number of staff was present. This number reduced in the afternoon, and again in the evening until all of the work was complete. The operations manager would routinely assess each day how well the pharmacy was completing its workload. Because the work was submitted by pharmacy branches on the day before, the operations manager would know how many members of the team were required throughout the day to ensure the work was kept up to date. If there was a problem, the operations manager could 'flex' the arrangement of the team and ask people to continue to work past their scheduled hours, bring people in, or extend the operating hours of the pharmacy until the work had been completed.

Members of the team had all completed bespoke training relevant to their roles. Pharmacy professionals were required to complete an induction process, and pharmacists were required to complete a 3-day induction programme before being able to act as the RP. Newly inducted pharmacists would not be able to act as the RP unless a more experienced pharmacist was also on-site. Operators had completed training specific to their roles within the pharmacy, and the training courses had been approved by the GPhC education team. A buddy system was used for all newer staff to help provide additional support. Team members completed a structured e-learning training programme and the training topics appeared relevant to the services provided and the members of staff completing the e-learning. Managers of team members were able to monitor training records to ensure ongoing training was up to date. Team members were allowed learning time to complete training. They received a professional standards bulletin every month that included learning points identified from across the branch network. Amongst other topics it covered common errors and professional related issues. Team managers would identify any areas of the professional standards bulletin which might be useful for their team and highlighted these during team discussions. They particularly liked to share examples which involved a person's 'journey' in order to help remind team members that real people would be receiving the medicines they dispensed.

Team members were seen to be working well together. This included both operators and pharmacy professionals. A number of pharmacists said they found working at the pharmacy enjoyable due to the uniqueness of the service. A structured appraisal programme was in place for members of the team, with reviews taking place at least once every 3 months. Assistant managers and task leaders also provided 'in the moment' feedback from various audits they completed throughout the day.

A communications area had been set up at a prominent entrance. This contained a lot of information for the team to refer to, including patient safety issues and company communications. During the COVID pandemic a public address system had been installed in order to allow people to continue working at a safe distance whilst listening to the regular weekly updates. They found it had worked well and so continued to use it for the weekly update, three times a day on two days a week. The pharmacy had a whistle blowing policy in place. Targets were set to help meet key logistical deadlines, but the workload could be flexed if a deadline was missed.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and tidy and well maintained. It is located in a purpose-built area which is suitable for the services provided.

Inspector's evidence

The pharmacy was located on a purpose-built mezzanine floor in a warehouse. There was a separate entrance to the pharmacy's operations. The premises appeared clean and tidy, and adequately maintained. On-site cleaners were responsible for cleaning office areas, and team members and engineers kept the areas containing automated technology clean and tidy. A maintenance management system was in place, and issues could be raised by members of the SLT. There was sufficient space for the workload. Lighting and heating arrangements were suitable. Members of the team had access to a canteen and WC facilities.

The pharmacy was closed to the public and staff entered via one controlled entrance. Access throughout the building was controlled by swipe card, with restrictions according to staff roles. The perimeter of the site was protected by a high metal fence and access via vehicle was controlled by a barrier gate.

Principle 4 - Services ✔ Good practice

Summary findings

The pharmacy uses automated dispensing systems to provide its services effectively and efficiently. And there are in-built safeguards to help ensure accuracy and minimise the risk of errors. The pharmacy gets its medicines from recognised sources and carries out regular checks to ensure they remain safe to use.

Inspector's evidence

The pharmacy was closed to the public and did not deal directly with patients. Information packs were sent to pharmacy branches using the service, which included information about roles and accountability, a service guide, and details of what to do in the event of an error. Clinical checks and data accuracy checks were conducted at the branch pharmacy and SOPs defined this responsibility.

Branch pharmacies would process a person's prescription to be dispensed by the hub if it was repeat medication which was not urgently required that day. The branch pharmacy uploaded data onto the Boots server which enabled the hub to acquire the stock from the wholesaler that was located in the same building, and later print a dispensing label. No patient data was transmitted to the wholesaler. Stock was received from the wholesaler packed inside trackable totes via a conveyor belt. The totes contained medicines which were matched to barcodes on the totes. Conveyor belts were used throughout the facility to direct the tote to the correct area for processing. Some totes contained medicines which were suitable to be fully processed by automation. Whilst others required some intervention for either labelling or the addition of stock to a bag. If stock was obtained from other wholesalers or directly from the manufacturer, it was stored in a specific barcoded areas for picking. Operators used electronic devices which instructed them what was required and where it was to be placed. Stock was picked and checked one box at a time using barcode-led picking technology. To help keep members of the team alert, team members were rotated across different workstations each hour.

Some medicines needed to be labelled manually, for example, due to an awkward shaped box, a second label required on an internal container, or for certain high-risk medicines (such as valproate) where it was important not to place the label over the warnings on the box. These were completed by operators at a manual labelling station. Once medicines were labelled, they would be placed back into totes to be sent back into the automated process.

Totes to be processed by automation were sent on the conveyor belt to an assembly line manned by an operator. Medicines were taken out of the tote and placed onto a new conveyor belt system with the medicine facing a particular way in order for the dispensing label to be correctly and suitably applied. This conveyor would travel through a visual camera system (VCS) which used 8 cameras to check the barcode on the medicine box. It also used feature mapping to identify a product's characteristics, such as its name or strength. If there was a medicine which had a label pre-applied by operators, the VCS would read the 2D barcode on the dispensing label to identify and recognise it. Any medicines which could not be read were electronically 'flagged' and sent to the exception workstation. When dispensing labels were automatically applied to the box of the medicine the product was scanned again through a 2nd VCS to ensure the correct medicine had been picked, and the correct label attached appropriately attached. Any irregularities were electronically 'flagged' and sent to the exception workstation. Following labelling, medicines were then sorted by specific patient onto their individual conveyor. Medicines were sent in groups for one patient at a time through a 3rd and final VCS which contained a high frame rate per second camera. This would check accuracy for the final time using the

barcodes, and it counted and checked the number of boxes of medicine per patient. The medicines were then placed into bags and sealed using a tamper-evident method. Bags of dispensed medicines were placed into totes which were barcoded for specific stores. Any totes which contained medicines which could not be processed by automation due to their size or shape, were directed to the manual handling station. A barcode and visual-guided system helped operators to correctly select the additional medicine, open up the relevant bag, and place the item inside before sealing it.

When medicines were electronically 'flagged' as requiring a manual check, the tote was directed to an exception workstation which was manned by operators, ACPTs and pharmacists. A printed report was placed on top of the tote and provided details of why it had been directed to the workstation. This was scanned along with the tote by the accuracy checker to ensure they correctly matched. The bag was picked, and the team member performed a manual check and a semi-automated barcode check of the medicines. The outcome from the check was recorded on the system. Any actual errors were flagged to a pharmacist for investigation. If a medicine could not be supplied due to a stock shortage, an explanatory label was attached to the outside of the bag.

Once the process was completed, totes were sent to the wholesaler's Distribution area to be sent to pharmacy branches in the North-West, or to another wholesaler depot for national distribution. Operating hours were covered by the presence of a RP to oversee the manual and automated processes, and supply of completed totes for distribution. If a medicine became loose at any point and fell out of a bag or a tote, an intervention was required to be carried out by a pharmacy professional. Product data linked to barcodes were required to be assessed and checked by a pharmacist using a validation process before they came into use or were altered.

A date checking matrix was in place to check stock the hub held from third-party suppliers on a 3-month cycle. This was signed by staff and shelving was cleaned as part of the process. Short-dated stock was highlighted using a sticker. Any medicines which were not suitable for dispensing were segregated from current stock and placed into DOOP bins. Drug alerts were received from the central team by email. The barcodes for the relevant medicines were placed on a '100% check' and sent to the exception station for a manual accuracy check. These checks remained in place for 48 hours after the wholesaler confirmed they had quarantined any affected stock held.

Principle 5 - Equipment and facilities ✔ Good practice

Summary findings

The pharmacy uses automated dispensing systems to effectively dispense high volumes of prescriptions. It has a robust maintenance programme to keep the automated systems in good condition. And there are contingency arrangements in case of mechanical failure.

Inspector's evidence

The pharmacy used automated and semi-automated technology to dispense a very high volume of medicines. On-site engineers were available 24/7. The machines had thorough maintenance and servicing programmes, involving a number of checklists completed on a daily, weekly and ad hoc basis. Each of the five lines were serviced once per week, which involved a 'strip down' and clean of key parts, followed by testing to ensure it remained effective in its operation.

Each line had built in capacity for the number of medicines dispensed. This allowed the lines to run at higher speeds compared to their normal day-to-day operation and could be utilised if there were multiple line failures.

There was a large stores area, which contained replacement parts for a full line. This meant if there was a problem the on-site engineers were able to replace the part promptly without having to wait. This was particularly important due to current lead times on deliveries from Europe where the parts are manufactured. A bespoke automated "KNAPP" system was used to deliver the high volume of dispensed items and was in the process of being expanded.

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.