General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Boots, 39 Four Seasons Shopping Centre, MANSFIELD, Nottinghamshire, NG18 1SU

Pharmacy reference: 1035539

Type of pharmacy: Community

Date of inspection: 10/03/2020

Pharmacy context

This pharmacy is in a shopping centre within the Mansfield town centre. The pharmacy is part of a larger health and beauty store. It sells over-the-counter medicines and dispenses NHS and private prescriptions. The pharmacy offers advice on the management of minor illnesses and long-term conditions. And it provides some private services including vaccination and travel health services. The pharmacy supplies medicines in multi-compartment compliance packs, designed to help people remember to take their medicines. It also supplies medicines to care homes. And it delivers medicines to people's homes for a fee.

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	Standards met	N/A	N/A	N/A
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy identifies and manages the risks associated with its services. It keeps people's private information secure. And it generally maintains all records it must by law. The pharmacy advertises how people can feedback about its services. And it responds appropriately to the feedback it receives. Pharmacy team members act openly and honestly by sharing information when mistakes happen. They discuss their learning and make changes to their practice to improve patient safety. Pharmacy team members are confident when responding to concerns about vulnerable people. And they recognise how further specialised learning could further support them in doing this. They act appropriately to help protect the safety and wellbeing of these people.

Inspector's evidence

The pharmacy had a set of standard operating procedures (SOPs) in place. The pharmacy superintendent’s team reviewed the SOPs on a two-year rolling rota. Roles and responsibilities of the pharmacy team were set out within SOPs. Pharmacy team members explained how updated and new SOPs were brought to their attention. And they were asked to read and sign SOPs periodically. A sample of training records confirmed that most members of the team had signed the SOPs. But some gaps in training records were seen. For example, a team member on duty had not signed a SOP relating to the sale of over-the-counter medicines. Team members explained that historically they signed a mix of photocopied and original SOPs due to the pharmacy having several dispensaries. They felt this could be one reason signatures were missing from copies in the main dispensary. Pharmacy team members on duty were seen working in accordance with SOPs. A member of the team clearly explained what tasks could not take place if the responsible pharmacist (RP) took absence from the premises. And an accuracy checking technician (ACT) discussed her role. And demonstrated how pharmacists physically marked prescription forms as they completed clinical checks of prescriptions. The ACT explained she was confident in referring to the pharmacist should she have any concerns when undertaking an accuracy check of a medicine.

The pharmacy had a business continuity plan in place. Pharmacy team members were aware of some information provided in an NHS SOP relating to pharmacies and the measures they should be taking in response to the COVID-19 outbreak. It had displayed a poster at the main entrance which advised people with symptoms to return home and contact NHS 111. But the pharmacy had yet to inform its team members of which room it would be using to isolate any people who presented with symptoms of COVID-19 which was a requirement of the SOP. A daily COVID-19 update was being received from the pharmacy’s head office. A discussion took place about the benefits of using available resources to ensure all team members were kept up-to-date with current information about the situation.

Managers undertook daily, weekly and monthly clinical governance checks of the pharmacy environment. This helped provide ongoing assurance that the pharmacy was operating safely and effectively. It had three dispensaries in operation. The main dispensary was situated alongside the healthcare counter. Pharmacy team members working in this dispensary managed acute workload and repeat prescriptions. The care home dispensary and Medisure dispensary were next to each other on the first floor level of the building. The Medisure dispensary was used to complete tasks associated with the supply of medicines in multi-compartment compliance packs to people living in the community.

Workflow in each dispensary was efficient and well managed.

The care home service had been without a service lead for some time. The ACT supported the management of the service. And a member of the team had been identified to step into the care home service partner role to support the ACT and other team members. Pharmacists attended the dispensary at least twice daily to complete clinical checks of prescriptions. And to provide any clinical interventions required. The dispensary used a red tray to alert pharmacists of queries. The pharmacist was required to check the contents of the tray and completed an audit sheet to confirm these checks and any outstanding actions had been completed. But there was some minor gaps in the audit record seen over the last few months. This meant it could be more difficult for the pharmacy to show that processes associated with managing queries were completed in accordance with its procedures.

The pharmacy team used 'Pharmacist information Forms' (PIFs) to communicate key messages to pharmacists and other team members, such as changes to medicine regimens, interactions and eligibility for services. The team retained PIFs with prescription forms to inform counselling required when handing-out medicines. A random check of the prescription retrieval filing system in the main dispensary found PIFs attached to most selected prescriptions. PIFs were not regularly attached to prescriptions relating to part-supplies of medicines (owings). Random checks of assembled medicines waiting to be checked in the care home dispensary and Medisure dispensary found specialist care service PIFs with all prescriptions. PIFs were completed in accordance with details within the SOPs. And a member of the care home team demonstrated where she was recording information relating to 'look-alike and sound-alike' (LASA) medicines on PIFs. This recording process was developed to prompt additional checks of some medicines identified as higher-risk of being involved in a near miss or dispensing incident.

There was a near-miss error reporting procedure in place. And pharmacy team members explained how they received feedback about their own mistakes from a pharmacist or ACT. The accuracy checkers recorded most near misses. The records contained full details of the mistakes which occurred. But they didn't often identify contributory factors. A discussion took place about how this information could support the team in identifying trends related to the cause of mistakes. Pharmacy team members reported dispensing incidents through an electronic reporting tool. The ACT reflected on a recent incident which had involved the wrong strength of medicine being supplied to a person in the care home. Team members had identified packaging associated with the two strengths had been very similar. And they had shared learning associated with the incident to help reduce the risk of a similar incident occurring.

Two patient safety reviews were held across the pharmacy each month. One focussed on the main dispensary. And the second review focussed on the care home and Medisure dispensary. The review was used to highlight trends in near misses and safety incidents. And it was designed to share learning. Pharmacy team members in both dispensaries explained how they had taken action to reduce near misses associated with quantity errors by highlighting information on prescriptions to prompt additional care during the dispensing process. Risk reduction actions were identified within patient safety reviews. Team members were asked to read the review templates. But the pharmacy didn't regularly encourage team members to discuss learning from reviews by holding structured meetings.

The pharmacy advertised its complaints procedure clearly within its practice leaflet. And pharmacy team members could explain how they would manage feedback or a complaint. A pharmacy team member discussed how she would manage a concern. And how she would escalate a concern to a pharmacist or manager if she was not able to resolve a concern herself. The team provided examples of how they listened to peoples feedback. For example, by putting flash notes on people's medication

records about preferred brands of medicine. And trying to obtain these brands whenever possible. The pharmacy invited feedback from people through its 'Community Pharmacy Patient Questionnaires'. And bags used to store assembled medicines provided people with details of an online survey they could complete. Feedback through these surveys was shared with team members periodically.

The pharmacy had up-to-date indemnity insurance arrangements in place. The RP notice displayed the correct details of the RP on duty. Entries in the RP record followed legal requirements. A sample of the controlled drug (CD) register found that it met legal requirements. The pharmacy kept running balances in the register. Balance checks of the register against physical stock took place weekly. Physical balance checks of Sevredol 50mg tablets and MST Continus 5mg tablets complied with the balances in the register. The pharmacy maintained a CD destruction register for patient returned medicines. The team entered returns in the register on the date of receipt. The pharmacy held the Prescription Only Medicine (POM) register electronically. Records generally complied with legal requirements. But the date of prescribing and prescribers details were not always updated by team members during the dispensing process. This occasionally led to inaccurate information being recorded. For example, the system defaulted the date of prescribing to the dispensing date if this was not manually updated during the dispensing process. The pharmacy completed audit trails on certificates of conformity for unlicensed medicines as per the requirements of the Medicines & Healthcare products Regulatory Agency (MHRA).

The pharmacy held records containing personal identifiable information in staff only areas of the pharmacy. It displayed a privacy notice. And its team members were observed to work vigilantly in the front area of the dispensary. For example, they removed all personal identifiable information from the workbench when leaving the area. The team completed annual information governance training. And this learning included the requirements of the General Data Protection Regulation (GDPR). The pharmacy had submitted its annual NHS data security and protection (DSP) toolkit as required. Pharmacy team members put confidential waste in designated blue bags in the dispensaries. These were sealed and sent for secure destruction periodically.

All pharmacy team members completed mandatory safeguarding training. And pharmacy professionals had completed level two learning through the Centre for Pharmacy Postgraduate Education (CPPE). Some members of the team identified that there had been an increase in the number of people requiring support for mental health concerns. And team members explained they had not had specific training to support them in managing these concerns. A request for more training associated with how teams could support people with their mental health had been escalated. Despite not undertaking formal learning associated with mental health and wellbeing, team members demonstrated how they recognised both physical and mental health concerns. And they took time to speak with people and discuss their worries when a concern was identified. Team members provided examples of how concerns had been shared with GPs on occasion. And appropriate notes had been made on patient medication records. The pharmacy had contact details for local safeguarding agencies available should a need to escalate a concern arise.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy's services are provided by a team of committed and suitably skilled people. And it engages its team members in review processes relating to patient safety and risk management. Pharmacy team members complete regular learning relevant to their role. And they receive support and time at work to complete this learning. They feel confident raising any professional concerns they may have. And they feel able to implement their ideas to help improve working practices.

Inspector's evidence

In total the pharmacy employed two regular pharmacists, a full-time ACT, three pharmacy technicians and 17 qualified dispensers (pharmacy advisors). The store manager and two assistant managers were also qualified dispensers and another assistant manager was enrolled on an accredited dispensing training course. The pharmacy was also being supported by a part-time ACT. And company employed delivery drivers provided the prescription collection and medication delivery services. It was reported that two dispensers were on long-term leave on the date of inspection. The management team explained that the staff profile and skill mix was regularly reviewed. And team members worked flexibly to cover absence when required. The pharmacy had access to staff from the company's relief team if required. Both pharmacists on duty were members of the wider relief team. The RP provided regular support to the pharmacy to cover days off and annual leave. Team members explained the pharmacy had two pharmacists on duty six days each week.

Pharmacy team members in the main dispensary were observed prioritising acute workload during the inspection. And they confirmed the managed workload was up to date. Team members in the care home and Medisure dispensaries were managing their workload effectively. And they confirmed they were up to date with their working schedules. The pharmacy had some targets related to the services it provided. And managers regularly briefed pharmacy team members about these targets. A pharmacist explained how there was a current focus on completing Medicines Use Reviews (MURs) to support the pharmacy in meeting the number of MURs it was able to complete for the current year. Pharmacists were positive when speaking about the services they provided. And team members supported pharmacist by identifying eligible people for services during the dispensing process.

Pharmacy team members reported that they received time in work to complete ongoing learning relevant to their roles. This included reading SOPs and newsletters. And completing SOP quizzes to test the team members knowledge and understanding of SOPs. Team members also regularly engaged in e-learning regularly. This included mandatory training such as health and safety. And learning associated with minor ailments and healthy living campaigns. The pharmacy had a structured appraisal process. But multiple team members reported they had not received an appraisal within the last year. Managers on duty acknowledged this was an area which required attention.

Pharmacy team members engaged in daily briefings to help organise workload. The pharmacy shared feedback from patient safety reviews through asking team members to read and familiarise themselves with the contents of the review. But the dispensary teams did not regularly hold structured meetings to help team members share learning as part of the review process. The pharmacy had a whistleblowing policy in place. This was advertised prominently. All pharmacy team members spoken to confirmed they

were confident in providing feedback. And they knew how to escalate a concern if they needed to. Team members shared some examples of how their feedback was taken onboard. For example, several members of the care home and Medisure dispensary team explained how they had streamlined processes associated with managing the download of Electronic Prescription Service (EPS) forms.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean and secure. It offers a professional environment for delivering healthcare services. Pharmacy team members actively promote the use of the pharmacy’s consultation rooms to people.

Inspector's evidence

The pharmacy was professional in appearance. It was secure and generally well maintained. Pharmacy team members reported maintenance issues to a designated help-desk. There were no outstanding maintenance issues found during the inspection. The pharmacy was clean and organised. Antibacterial liquid soap and paper towels were available close to designated hand washing sinks.

The public area was fitted with wide-spaced aisles which allowed easy access for people using wheelchairs and pushchairs. There were two sound proof consultation rooms available for people to speak in private to a member of the pharmacy team. There was also a parent and baby room to the side of the consultation rooms. And a semi-private hatch opened from the public area to the side of the dispensary. The rooms provided a suitable environment for providing the pharmacy’s services. And a pharmacist was observed using the room with people accessing services during the inspection.

The dispensaries were a suitable size for the level of activity carried out in each. Work benches in each dispensary were free from unnecessary clutter. And shelving above work benches were used to hold tubs and trays of assembled medicines waiting to be accuracy checked. Stock holding areas were neat and tidy. Floor spaces across the premises were free from trip hazards. Air conditioning was available in each dispensary. And lighting throughout the premises was bright.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's services are accessible to people. It has procedures to help identify and manage the risks associated with providing its services. The pharmacy has good processes to help recognise high risk medicines. And it provides people with relevant information about the medicines they are taking. It obtains its medicines from reputable sources. And it stores and manages it medicines safely and securely.

Inspector's evidence

The store was accessible through two open plan entrances leading from the shopping centre. The pharmacy was located on the back wall of the store. It displayed details of its opening times and services. And it had a designated space for displaying information related to national and local health campaigns. A range of information leaflets provided further details about the pharmacy's services. Pharmacy team members were aware of signposting requirements. And could explain how they would signpost people to other pharmacies or healthcare providers if they were unable to provide a service.

The pharmacy had up-to-date and legally valid patient group directions (PGDs) available to support the PGD services. The pharmacy's team members demonstrated how they identified eligibility for services through recording this on PIFs during the dispensing process. The pharmacy had completed a number of audits associated with the supply of higher-risk medicines and monitoring health and wellbeing for people with chronic diseases.

The pharmacy team members identified high-risk medicines and highlighted these prescriptions through the use of bright laminated cards. And prescriptions in the retrieval system found these cards to be in regular use. The cards included details of monitoring checks and counselling required when supplying these medicines. And examples of recording monitoring checks were provided. Team members in the care home dispensary explained how care homes were asked to supply monitoring records for people on warfarin. And a member of the Medisure team demonstrated notes which were attached to bags of assembled medicines to prompt people to call the pharmacy with their latest monitoring result. Pharmacy team members in each dispensary demonstrated the requirement to identify people taking valproate preparations. And the RP demonstrated a person's medication record which had been used to record details of a conversation a pharmacist had had with a care home about the requirements of the Valproate Pregnancy Prevention Programme (PPP). People in the high-risk group were suitably counselled and provided with valproate warning cards.

Several team members managed the supply of medicines in multi-compartment compliance packs to people living in the community. And other members of the wider pharmacy team could support this service if required. Each person receiving their medicines in multi-compartment compliance packs had their own individual profile sheet which provided details of their medication regimen. There was some crossing out on these sheets. And the pharmacy occasionally used white labels to cover information on sheets which was no longer relevant. Pharmacy team members used a bound communication book to record messages relating to the service. And this was checked regularly throughout each working day. They also documented messages and changes on pieces of paper which was stored in plastic wallets containing the profile sheets. But it was not always obvious which notes were current and which were

historic and no longer relevant. The service was managed over a four-week rolling cycle. And a Medisure progress record was in use to provide an audit trail throughout the four-week cycle. A sample of assembled packs included full dispensing audit trails and descriptions of the medicines inside to help people recognise them. The pharmacy provided patient information leaflets at the beginning of each four-week cycle of packs. And it recorded the start date on each pack to help people manage their medicines.

An area pharmacist provided regular site visits to care homes to support them in managing their medicines. And any relevant feedback from these visits was passed on to team members managing the care home services. The pharmacy supplied people in care homes with medication through original pack dispensing. And pharmacy team members discussed how they had implemented changes from dispensing in multi-compartment compliance packs to original packs in 2019. The pharmacy checked prescriptions received against re-ordering Medication Administration Record (MAR) sheets returned from most homes. A small proportion of homes did not provide copies of re-ordering MARs. And a team member explained in these instances prescription forms were checked against patient medication records. Any changes or missing items would then be communicated to homes in the usual manor, using a query record sheet. Queries were recorded and sent to the homes for missing prescriptions or changes to medication regimens. Pharmacy team members used carbon-copied communication sheets to record queries and conversations with care home teams. Prescriptions were clinically checked by a pharmacist following a member of the team 'priming' the prescription. The priming process included completing PIFs and producing MAR sheets. Medication ordering sheets were created during the priming process. These were sent to the care home dispensary medicine store. And a member of the team worked through the list and picked any items required from current stock held. These were put into designated totes ready for dispensing. And the remainder of items were ordered. Once received these were added to the totes. The totes were transferred to the care home dispensary. And team members picked medicines from the totes using the prescription forms. All prescriptions were dispensed at individual patient level. They were held in tubs or bags with the MAR, prescription and PIF until the accuracy check took place. Medication for each person was sent in bags or individual totes to each home. And a delivery audit trail was in place to support this service. The care home team managed interim prescriptions efficiently. One team member was assigned to interim dispensing each day. And this process was supported by a pharmacist. The pharmacy provided MAR sheets when dispensing interim medicines. It generally received interim prescriptions through EPS, faxes and scanned copies through secure emails. Processes were in place to retain and match copies of prescriptions against originals. And the pharmacy only dispensed CDs against original prescriptions.

In the main dispensary team members used tubs throughout the dispensing process. This kept medicines with the correct prescription form and helped to inform workload priority. Prescriptions for people waiting in the pharmacy were brought to the direct attention of a pharmacist. Pharmacy team members signed the 'dispensed by' and 'checked by' boxes on medicine labels to form a dispensing audit trail. They also signed a 'quad grid' on prescription forms to indicate who had assembled the medicines, clinically checked the prescription, accuracy checked the medicines and handed out the medicines. In the care home dispensary, the hand out section of the quad grid was used to indicate who had primed the prescription.

The pharmacy sent some prescriptions to its offsite dispensing hub. Team members explained they sent full prescriptions only to the hub. It dispensed any prescriptions with items which couldn't be dispensed by the hub locally. For example, split packs, CDs and cold chain medicines. And a team member demonstrated the process used for inputting data relating to prescriptions. All team members involved in this process had received training prior to undertaking tasks associated with the service. The pharmacy flagged prescriptions which required any manual input from a team member. For example, a

change in directions to ensure the instructions on the label were clear and easy to read. These prescriptions required a data accuracy check and clinical check by a pharmacist. Prescriptions with no changes required a clinical check only prior to being sent to the hub. Pharmacists were responsible for logging on to the system to complete these checks. And they recorded completion of this process through the quad grid on prescription forms.

The pharmacy kept original prescriptions for medicines owing to people. The team used the prescription throughout the dispensing process when the medicine was later supplied. It maintained delivery audit trails for the prescription delivery service and people signed an electronic point of delivery device (EPOD) to confirm they had received their medicine. The pharmacy used cool units to transport cold chain medicines through its delivery service.

The pharmacy sourced medicines from licensed wholesalers and specials manufacturers. Pharmacy team members spoken to about the Falsified Medicines Directive (FMD) were aware of some the requirements of the legislation. For example, tamper proof packaging. Some team members spoken to about FMD were aware the company were trialling computer systems to support compliance with FMD requirements in some pharmacies. But the team had not received a date of when any system would be implemented locally. The pharmacy was expecting to receive an upgrade to a new clinical computer software programme in Summer 2020.

The pharmacy stored Pharmacy (P) medicines behind the healthcare counter. This meant a pharmacist could supervise sales taking place and was able to intervene if necessary. The pharmacy stored medicines in the dispensaries and designated stock rooms in an organised manner and within their original packaging. The pharmacy team followed a date checking rotas. These covered all stock holding areas of the pharmacy including the care home stock and consultation rooms. The team annotated details of opening dates on bottles of liquid medicines. One out-of-date medicine was found during random checks of stock. The medicine was clearly labelled as short-dated which minimised the risk of it being supplied in error. It was removed from the shelf and brought to the direct attention of a team member for safe disposal.

The pharmacy held CDs in secure cabinets. Medicine storage arrangements in the cabinets was orderly. But there was some out-of-date CDs and patient returned medicines waiting to be securely destroyed. The team confirmed the pharmacy’s authorised witness was due to visit shortly to witness the destruction of the out-of-date CDs. The pharmacy held assembled CDs in clear bags with details of the prescription’s expiry date annotated clearly on the bag. The pharmacy also highlighted prescriptions for these medicines to prompt additional safety and security checks during the dispensing process. The pharmacy’s fridges were a suitable size for the amount of stock held. One fridge in the dispensary was not in current use. Fridges were clean and stock inside them was organised. The pharmacy stored some assembled cold chain medicines within clear bags inside the fridges. A pharmacist explained the team were waiting for a delivery of clear bags. Due to this the team was temporarily using paper bags to store some assembled cold chain medicines on the day of inspection. These were labelled well to prompt additional checks of the cold chain medicines inside. The team checked the temperature of the fridges in use daily. Temperature records confirmed that the fridges in current use were operating between two and eight degrees Celsius as required.

The pharmacy received drug alerts through the intranet. Details of alerts were checked across all three dispensaries and stock holding areas routinely. There was medical receptacles, sharps bins and CD denaturing kits available to support the team in managing pharmaceutical waste. But a designated waste room was not kept in an orderly manner. Totes of returns had been left in the room ready to be sorted into the designated waste receptacles. A caged area of the warehouse also had some returned

multi-compartment compliance pack racks which required dissembling and waste medicines removing and being segregated for disposal. There was no risk of waste medicines being mistaken for stock. But the team did acknowledge the risk of not keeping up-to-date with tasks such as managing pharmaceutical waste.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for providing its services. It monitors it equipment to ensure it remains in safe working order. And pharmacy team members act with care by using the pharmacy’s facilities and equipment in a way which protects people’s confidentiality.

Inspector's evidence

Pharmacy team members had access to up-to-date written reference resources. These included the British National Formulary (BNF) and BNF for Children. Internet access and intranet access provided further reference resources, including access to Medicines Complete. Computers were password protected and faced into the dispensary. This prevented unauthorised view of information on computer screens. Pharmacy team members had personal NHS smart cards. The pharmacy stored assembled bags of medicines waiting for collection and delivery in a retrieval system close to the entrance of the dispensary. Information on bag labels could not be read from the public area. It stored prescriptions relating to the assembled bags of medicines safely. The pharmacy had cordless telephone handsets. Pharmacy team members moved to the back of the dispensary when speaking with people on the phone. This meant that the privacy of the caller was protected.

The pharmacy had clean, crown stamped measuring cylinders for measuring liquid medicines. Counting equipment for tablets and capsules was available. This included separate equipment for counting cytotoxic medicines. A full range of equipment to support dispensing activity was available in the care home and Medisure dispensaries. This included disposable gloves and single use multi-compartment compliance packs. Equipment to support the vaccination services was readily available. The pharmacy’s electrical equipment was subject to portable appliance checks periodically. Stickers on equipment indicated checks were next due in December 2020.

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.