General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Boots, 164 High Street, Musselburgh, MUSSELBURGH, Midlothian, EH21 7DZ

Pharmacy reference: 1042766

Type of pharmacy: Community

Date of inspection: 15/04/2021

Pharmacy context

This is a community pharmacy on the main street of a small town close to a city. It dispenses NHS prescriptions including supplying medicines in multi-compartment compliance packs. And it supplies medicines to people living in care homes. The pharmacy offers a repeat prescription collection service and a medicines' delivery service. It also provides substance misuse services and dispenses private prescriptions. The pharmacy team advises on minor ailments and medicines' use. And supplies a range of over-the-counter medicines. This pharmacy was inspected during the COVID-19 pandemic.

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 adequately manage all risks. This includes untidy medicines storage, and using emergency procedures that are out of date.
2. Staff	Standards not all met	2.1	Standard not met	The pharmacy deploys team members in such a way that for periods of time there are not enough suitably qualified and skilled team members to provide its services safely and effectively.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.3	Standard not met	The pharmacy does not always manage its medicines appropriately, including ordering, storage and disposal arrangements.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy does not identify and manage all its risks. It stores its medicines on untidy shelves and stores similar looking and sounding medicines together. And team members are using out-of-date emergency procedure information. Pharmacy team members mostly follow written processes to help provide services safely. And they review the accuracy of their dispensing. But the changes they make do not always last. The pharmacy keeps most of the records it needs to by law. But some records of when the pharmacist is working are incomplete. Team members keep people's private information safe and know who to contact if they have concerns about vulnerable people.

Inspector's evidence

The pharmacy had put strategies in place to keep people safe from infection during the COVID-19 pandemic. It had screens up at the medicines' counter and dispensary and hand sanitiser at the premises entrance. Team members offered masks to people if they had forgotten to wear one. But most people coming to the pharmacy wore face coverings and team members all wore fluid resistant masks. The pharmacy had tape marking the floor to encourage people to socially distance. The premises were quite large, so the pharmacy was not limiting access. But sometimes there was a long queue up the middle aisle of the premises. This was observed with eight people queueing. Team members washed and sanitised their hands regularly and frequently. And they cleaned surfaces and touch points several times during the day. A team member cleaned the consultation room immediately after use.

The pharmacy had standard operating procedures (SOPs) which were mostly followed. A few examples of not following them were noted, including not always auditing the running balances of controlled drugs when storing and recording new stock, not always auditing the running balances weekly, and observation of a team member sharing their till password. Pharmacy team members had read SOPs, and the pharmacy kept records of this. The pharmacy superintendent reviewed them at least every two years and signed them off. They were also signed by a pharmacist in the pharmacy. Staff roles and responsibilities were recorded on individual SOPs. Team members could describe their roles and accurately explain which activities could not be undertaken in the absence of the pharmacist. But team members dispensed care home prescriptions from 7am each morning, and there was not always a pharmacist signed in as responsible pharmacist. The pharmacy managed dispensing, a high-risk activity, with baskets used to differentiate between different prescription types and separate people's medication. But as described below some medicines were stored untidily creating risk of error. Medicines were mixed on the shelves, including two medicines that had been involved in an error previously. The medicines were not put back on the shelves in a timely manner after dispensing. The untidiness and clutter increased the risk of error during dispensing. The pharmacist signed prescriptions to confirm that a clinical check had been carried out to enable accuracy checking pharmacy technicians to carry out final accuracy checks of dispensed medicines. The pharmacy had a business continuity plan and emergency cascade information, but the one's available were both out of date (Sept 2019 and July 2017 respectively).

Team members used 'near miss logs' to record dispensing errors that were identified in the pharmacy, known as near miss errors. And they recorded errors that had been identified after people received their medicines. They reviewed all near misses and errors each month to learn from them and they

sometimes introduced strategies to minimise the chances of the same error happening again. The pharmacy had made several changes to processes in the care home dispensary after reviewing an incident. This included re-visiting the SOP regarding high-risk medicines and using laminated cards to highlight these throughout the prescription's journey. This enabled all team members involved with that prescription to adhere to the process for high-risk medicines. But changes made following review of another incident had not been sustained. Two products were stored adjacent to each other despite an incident report stating that one had been moved. The pharmacy had a complaints procedure.

The pharmacy had an indemnity insurance certificate, expiring 30 June 2021. And the locum pharmacist stated that he had his own indemnity insurance. The pharmacy displayed the responsible pharmacist notice and had a responsible pharmacist (RP) log. The pharmacy had private prescription records including records of emergency supplies and veterinary prescriptions. It kept unlicensed specials records and controlled drugs (CD) registers with running balances maintained and regularly audited. It had a CD destruction register for patient returned medicines but some items had not been recorded. Team members signed any alterations to records, so they were attributable. The RP log was not always completed as required by legislation or standard practice. For example, care home dispensing was undertaken before the responsible pharmacist (RP) arrived using 'absence', as allowed by RP regulations. But pharmacists did not always record that they were the RP during that time. A discrepancy had been identified the previous day during a controlled drug register audit. The pharmacist had placed a marker in the CD register and had planned to investigate this on the day of inspection. The pharmacy backed up electronic patient medication records (PMR) each night to avoid data being lost.

Pharmacy team members were aware of the need for confidentiality. They had all read a SOP and usually undertook annual training. They segregated confidential waste for secure destruction. No person identifiable information was visible to the public. But a team member was observed sharing her till password with another team member who had not been trained to use the tills. Team members had also read information on safeguarding. They knew how to raise a concern locally and had access to contact details and processes. The pharmacist was registered with the Disclosure Scotland 'Protecting Vulnerable Groups' (PVG) scheme. Team members were aware of the 'Ask for ANI' (action needed immediately) and 'safe space' initiatives for victims of domestic abuse. The pharmacy displayed show material informing people of these initiatives and how to access support.

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

Summary findings

The pharmacy does not always have the right team members working in the right place to manage the work effectively. It does not set aside time for training and development to help team members improve their skills and knowledge. Team members can share information and make suggestions to improve ways of working and improve safety. They know how to raise concerns if they have any. The pharmacy team members learn from errors to avoid the same thing happening again.

Inspector's evidence

The pharmacy team consisted of a full-time pharmacist manager who had been in the pharmacy for four weeks and a full-time pharmacist who had been in the pharmacy eight weeks and was leaving soon. There was one full-time and two part-time accuracy checking pharmacy technicians (ACPTs), who worked in the care home dispensary on the first floor. And six full-time and four part-time dispensers. They worked a variety work patterns across six 11-hour days. Some worked in the care home dispensary and some worked in the main dispensary. Not all team members were trained in all processes yet. Six dispensers were undertaking accredited training. Deliveries were made by drivers from a central hub.

The manager explained that typically there were two or three ACPTs and four pharmacy advisors (dispensers) at any time in the care home dispensary. And there were two pharmacists, two to three pharmacy advisors in the dispensary and two to three pharmacy advisors on the shop floor/medicines' counter. When the inspector arrived, there were two pharmacists and two pharmacy advisors in the dispensary. Team members were unable to manage the workload. A team member (locum pharmacist) acknowledged the inspector after 15 minutes of waiting at the counter. A person had been waiting at the medicines counter throughout that time, and there was constantly a queue of seven or eight people. The pharmacy manager was also in the pharmacy, but not in the dispensary or retail area at that time. He explained that currently a pre-registration pharmacist and ACPT from another branch were helping in this branch, but neither were working at the time of inspection. The pre-registration pharmacist had moved with his tutor from his original branch on a temporary basis, to maintain his training. During the inspection other team members started their shifts. While the inspector was in the care home dispensary there were two ACPTs and three dispensers working there. They were managing the workload but were behind with where they would usually expect to be. But they explained that medicines would be supplied to care homes on time. Team members were behind putting medicines back on the shelves and the medicines on the shelves had not been tidied.

The pharmacy did not provide learning time during the working day for team members to undertake regular training and development. A trainee pharmacy advisor described doing coursework at home. And another, who had worked in the pharmacy for over two years, had not been trained for the role. She had been registered on the course but not had 'off-the-job' training time or practical experience. She worked as a medicines counter assistant and was observed to be competent, although she had not completed training for this role either.

Over the past few weeks, additional team members had been in the pharmacy supporting the implementation of a new computer system, 'Columbus'. And they had helped to train team members.Team members described lacking confidence and competence using 'Columbus'. This was

observed, with some team members trying to help others which interrupted workflow and slowed processes in the dispensary. This was adding to why the pharmacy was struggling with the workload.

Pharmacy team members understood the importance of reporting mistakes and were comfortable owning up to their own mistakes. They had an open environment in the pharmacy where they could share and discuss these. Following a serious incident last year involving the care home service, the team had carried out a thorough review. All team members present in the care home dispensary during the inspection contributed to a discussion with the inspector and explanation of the review and improvements made. They had all been involved with the review and invited to make suggestions to make the process safer. The pharmacy superintendent shared information and incidents from elsewhere in the organisation for all team members to learn from incidents. Team members read this document 'Professional Standard' and signed to acknowledge this. The pharmacy team discussed incidents and how to reduce risks. Team members described the case studies included in the 'Professional Standard' as particularly useful and thought provoking. The team discussed these after all team members had read them. The company had a whistleblowing policy that team members were aware of. The company set targets for various parameters, and team members described how they used these to offer people services that they would benefit from. Team members were not incentivised.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are safe and clean, and suitable for the pharmacy services provided. The pharmacy has suitable facilities for people to have conversations with team members in private. The pharmacy team members respect and manage people's confidentiality. The pharmacy is secure when closed.

Inspector's evidence

These were large premises incorporating a retail area, dispensary at the rear of the premises and an upper floor with stockroom, care home services dispensary, staff areas and offices. The premises were clean, hygienic and well maintained. Team members cleaned surfaces and touch points more often than before the pandemic. There were sinks in the dispensary, staff room and toilets. These had hot and cold running water, soap, and clean hand towels. And there was hand sanitiser available in several places. Temperature and lighting were comfortable throughout the premises.

People were not able to see activities being undertaken in the dispensary. The pharmacy had a consultation room with a desk and chairs, and the door closed providing privacy. Team members seldom used this room currently due to social distancing constraints. But people who consumed their medication on the premises did so in this room which had a hatch through to the dispensary. A team member passed the medication through the hatch. And a team member cleaned the consultation room after use.

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

Summary findings

The pharmacy obtains medicines from reliable sources. But it stores many of its medicines untidily and these are not suitably separated. So, there is an increased risk of team members making mistakes when dispensing. The pharmacy usually helps people to access its services and it mostly supplies its medicines without delay. It provides safe services to care homes.

Inspector's evidence

The pharmacy was accessed by means of a level entrance and it had an automatic door, but it was not working. It was not known if team members had reported this maintenance issue. The pharmacy listed its services and team members signposted people to other services such as travel vaccination although there was currently little demand for this. It had a hearing loop in working order for people wearing hearing aids to use. And it could provide large print labels for people with impaired vision. All team members wore badges showing their name and role. The pharmacy provided a delivery service. Following the inspection, the inspector tried to call the pharmacy for some additional information, but the phone was not answered. It 'rang out' on several occasions. This meant that people who needed to speak to the pharmacist, including other healthcare professionals may not be able to.

Pharmacy team members followed a logical and methodical workflow for dispensing, with separate workstations for walk-in and collection service prescriptions. They used baskets to differentiate between different prescription types and separate people's medicines and prescriptions. As noted elsewhere, a new computer system, Columbus had recently been implemented and this was slowing down the dispensing process currently. Pharmacist information forms (PIFs) were automatically printed from the computer and the information to be printed could be amended at the time of labelling. There were examples of PIFs with small font due to unnecessary information being printed and there was a risk of important information being missed. An example of unnecessary information was when the system had detected a change in dose from 'take one daily', to 'one to be taken each day'. Team members initialled dispensing labels to provide an audit trail of who had dispensed and checked all medicines. They also initialled prescriptions to provide an audit trail of personnel involved at every stage of the dispensing process including labelling and handing out. The pharmacy usually assembled owings later the same day or the following day using a documented owings system.

Some people received medicines from 'Medicines Care Review' (MCR) serial prescriptions. The pharmacy usually dispensed these about a week before they were due to be supplied, but they were currently behind. If medicines were not ready as people expected, a team member dispensed them while the person waited. This service was not discussed any further as the pharmacy was too busy.

The pharmacy managed the dispensing and related record-keeping for multi-compartment compliance packs on a four-weekly cycle. Team members assembled four weeks' packs at a time, usually one week before the first pack was due to be supplied. The pharmacy supplied a variety of other medicines by instalment. Not many people received medicines in multicompartment compliance packs.

The pharmacy provided pharmaceutical services to many care homes. This service was managed in a purpose designed dispensary and storage area on the first floor. Team members were competent for

the different roles and followed SOPs. The dispensary was organised with logical streamlined processes in place. Team members rotated through the different tasks to ensure they were skilled at them all and did not become bored or complacent. Interim or emergency prescriptions for care homes were dispensed in this room and usually a pharmacist carried out the clinical and accuracy check on these. An ACPT usually carried out the accuracy check on routine dispensing for the care homes. The pharmacist initialled prescriptions when she carried out the clinical check before dispensing. Team members also initialled prescriptions to identify who had labelled, dispensed and carried out the final accuracy check. Team members had their own password for computers so there was an audit trail of who had processed prescriptions at each stage. The previous year there had been a serious incident involving this service although the initial cause was a prescribing error. The team had undertaken a review of all processes for supply of medicines to care homes and improved processes. All team members were engaged in a discussion around this. The review had reminded all team members to have closer contact with the care homes by phone, particularly when there were any changes to medication. They always used a 'missing items and queries form' to identify these issues. After a team member had addressed and resolved the issues with the care home, a record was made on this form and the pharmacist reviewed and signed it. Team members described this as useful and they felt it contributed to the pharmacy delivering a safe and efficient service.

A pharmacist undertook clinical checks and provided appropriate advice and counselling to people receiving high-risk medicines including valproate, methotrexate, lithium, and warfarin. S/he or a team member supplied written information and record books if required. The pharmacy had put the guidance from the valproate pregnancy prevention programme in place. The pharmacy followed the service specifications for NHS services. It had patient group directions (PGDs) in place for unscheduled care, the Pharmacy First service, smoking cessation and emergency hormonal contraception (EHC). During the pandemic, the pharmacist had carried out some consultations by phone to reduce the time people spent in the pharmacy.

The pharmacy obtained medicines from licensed wholesalers such as Alliance and AAH. It obtained'special' medicines from appropriate sources. But later, on the day of inspection the inspector was notified of an incident whereby the pharmacy had not ordered a special medication. So, when the person came to collect it for their second month of treatment, the pharmacy had no medicine to supply. This could have had serious consequences if the treatment had been interrupted. But the pharmacy managed to obtain a supply from the specialist service at the hospital to provide the medicine that day.

The pharmacy stored most medicines in original packaging on shelves, in drawers and in cupboards. Some cupboards and shelves were over-filled, and different tablets were stored mixed together e.g. hydrocortisone/hydroxychloroquine tablets; indapamide/ibuprofen/imipramine/isosorbide mononitrate tablets; and chlorpromazine/chlorphenamine tablets. Chlorpromazine and chlorphenamine had been involved in a dispensing error a few months ago. There was a 'select with care' label on the shelf but it was not visible. At the time of the error a pharmacist had told the inspector that chlorphenamine had been re-located because it had been beside the chlorpromazine at the time of the error. The top and bottom shelves were particularly untidy, posing a selection risk. Team members explained that even if they made a selection error, Columbus would identify this enabling them to record it as a near miss and the wrong medicine would not be supplied. (Columbus included scanning bar codes, so identifying what had been selected.) Some medicines were not stored in original packs and were not properly labelled e.g. hydrocortisone tablets and co-codamol tablets. Team members working the previous day had not put away 'stock' medicines after dispensing and there were two trays of open packets to be returned to shelves. These were on a dispensing bench adding to the clutter and potentially causing a risk of error during dispensing. This could add to unnecessary owings

because medicines were not in the correct location, or other packets of the same medicines could be opened resulting in more than one open pack on the shelf, adding to the untidiness. The pharmacy stored items requiring cold storage in a fridge and team members monitored and recorded minimum and maximum temperatures daily. They took appropriate action if there was any deviation from accepted limits. Team members regularly checked expiry dates of medicines and those inspected were found to be in date. The pharmacy team did not always place obsolete medicines returned from people into the designated receptacle at the time of receipt. They left them untidily on bags on top of the receptacle. And bags of returned controlled drugs were stored untidily in the CD cabinet. The pharmacy protected pharmacy (P) medicines from self-selection. Team members followed the sale of medicines protocol when selling these.

The pharmacy actioned Medicines and Healthcare products Regulatory Agency (MHRA) recalls and safety alerts on receipt and kept records. Team members contacted people who had received medicines subject to patient level recalls. They returned items received damaged or faulty to suppliers as soon as possible.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs for the delivery of its services. The pharmacy looks after this equipment to ensure it works. The pharmacy team members raise concerns when equipment is not fit purpose.

Inspector's evidence

The pharmacy had texts available including current editions of the British National Formulary (BNF) and BNF for Children. It had Internet access allowing online resources to be used.

The pharmacy kept equipment required to deliver pharmacy services in the consultation room where it was used with people accessing its services. This included a carbon monoxide monitor maintained by the health board. The team was not using this equipment during the pandemic to reduce the chance of spreading infection. Team members kept crown-stamped measures by the sink in the dispensary, and separate marked ones were used for methadone. The pharmacy team kept clean tablet and capsule counters in the dispensary and kept a separate marked one for cytotoxic tablets.

The pharmacy stored paper records in the dispensary and care home dispensary, inaccessible to the public. It stored prescription medication waiting to be collected in a way that prevented patient information being seen by any other people in the retail area. Team members used passwords to access computers and did not leave them unattended unless they were locked.

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.