General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Cohens Chemist, 1-3 Market Street, Little Lever, BOLTON, Lancashire, BL3 1HH

Pharmacy reference: 1033173

Type of pharmacy: Community

Date of inspection: 05/03/2020

Pharmacy context

This busy community pharmacy is located in the town centre. Most people who use the pharmacy are from the local area. The pharmacy dispenses NHS prescriptions and sells a range of over-the-counter medicines. It supplies a large number of medicines in multi-compartment compliance aid packs to help people take their medicines at the right time.

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 met	N/A	N/A	N/A
2. Staff	Standards not all met	2.2	Standard not met	Some people who work in the pharmacy are not qualified or appropriately trained for the activities they carry out.
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 adequately manages risks and it takes some steps to improve patient safety. The team has written procedures on keeping people's private information safe and protecting the welfare of vulnerable people. It generally keeps the records required by law, but some details are missing, which could make it harder to understand what has happened if queries arise.

Inspector's evidence

The pharmacy had up-to-date standard operating procedures (SOPs) for the services provided, with signatures showing that members of the pharmacy team had read and accepted them. Roles and responsibilities were set out in SOPs and in role and task matrices. Pharmacy team members were wearing uniforms, but nothing to indicate their role, so members of the public might not be clear about this. The name of the responsible pharmacist (RP) and his GPhC registration number was on display.

There was a 'Dispensing errors' SOP. Dispensing incidents were reported on a 'patient safety hub' on the intranet. An error had been reported in January 2020 when a brand of ranitidine oral suspension, which had been recalled by the manufacturer, had been supplied. One of the patient's parents realised this and informed the pharmacy. The actions taken to prevent a re-occurrence were recorded on the patient safety report and required the pharmacy manager and another member of the team to check the intranet every day for alerts. And a new file had been set up for alerts and recalls, which were printed off and the action taken recorded. The pharmacy manager explained that he had previously checked the intranet regularly, but he must have missed this particular recall. Near misses were reported on a log. There were no regular documented reviews apart from the annual patient safety review, but the pharmacy manager said he discussed near misses with the pharmacy team at huddles. He said the most common type of error was the wrong form of medication, such as ramipril tablets instead of capsules. The annual patient safety review indicated that the pharmacy manager had highlighted this to team members and instructed them to pay particular attention to the form of the medication. The report stated that the number of this type of near misses had reduced as a result. A priority highlighted on the patient safety report was 'the work environment to be as risk free as possible' and the team was supposed to be trying to keep the work areas clutter free. The team had been made aware of common look-alike and sound-alike drugs (LASAs), so extra care would be taken when selecting these, although the pharmacy manager did not think this was a particular issue in this pharmacy.

A notice was on display near the medicine counter with the complaint's procedure and head office's details. A customer satisfaction survey was carried out annually. The results of the 2017/2018 survey were available on www.NHS.uk website but nothing more recent was available.

Insurance arrangements were in place. A current certificate of professional indemnity insurance was on display in the pharmacy. Private prescriptions were recorded electronically and the records appeared to be accurate. The RP record did not include the time the RP finished their duties each day, so this provided an incomplete audit trail and was not in line with RP regulations. The records of medicines obtained from 'Specials' could not be located apart from the most recent certificates of conformity, which were in a basket in the consultation room. The patient details had not been recorded on these.

This was not in line with the Medicines and Healthcare products Regulatory Agency (MHRA) requirements and meant there was not a reliable audit trail of these supplies in the event of a problem or query. The pharmacy manager explained that this had been the duty of a member of the team who had recently retired, but he would get another member the team to take over this duty and add the relevant details. Controlled drug registers were untidy.

There was a staff confidentiality policy on the intranet and this included data protection. A notice was on display that a privacy statement was available, in line with the General Data Protection Regulation (GDPR), which could be viewed on the Cohens website. The pharmacy manager confirmed that he had discussed confidentiality with the team, and they understood the requirements, but said he did not think they had completed any formal training on confidentiality or GDPR. Confidential waste was collected in a designated place and either shredded on site, or sent to head office in sealed bags for destruction. A dispenser correctly described the difference between confidential and general waste. Assembled prescriptions awaiting collection were stored appropriately so that patient's details were not visible to other people in the pharmacy.

There was a safeguarding SOP. The pharmacy manager and ACT had completed the Centre for Pharmacy Postgraduate Education (CPPE) level 2 training on safeguarding. Other staff had read the SOP but not received any formal training on safeguarding, so they might not be clear on what signs to be aware of. The pharmacy manager said the team knew to report any concerns to him, and the delivery driver confirmed that she would voice any concerns regarding vulnerable people to the pharmacist on duty. The pharmacy had a chaperone policy. There was a notice highlighting this to patients, but this was inside the consultation room so not visible to all. Some members of the pharmacy team had completed Dementia Friends training, so had a better understanding of patients living with this condition.

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

Summary findings

Pharmacy team members work well together in a busy environment and have the right qualifications for the jobs they do. But on some days work experience students work in the pharmacy and carry out tasks that they aren't trained or qualified to do, which increases the risk of errors. Pharmacy team members are comfortable providing feedback to their manager and receive informal feedback about their own performance. But they are not always effectively supported to complete training so there may be gaps in their knowledge.

Inspector's evidence

There was a RP (pharmacy manager), an ACT, three NVQ2 qualified dispensers (or equivalent) and a delivery driver on duty at the time of the inspection. The staffing level was adequate for the volume of work during the inspection and the team were observed working collaboratively with each other and the patients. Some members of the team described the pharmacy as 'short staffed' and explained that they did not have enough time to complete non-essential activities such as training, cleaning and date checking. They explained planned absences were organised so that not more than one person was away at a time, however there had been a long term absence due to sickness, which had been difficult to cover as the neighbouring branches were similarly short staffed. There was currently a vacancy for an additional member of the team, as there had been a recent retirement. The pharmacy manager felt there would be an adequate staff level once this vacancy was filled.

Members of the pharmacy team were qualified and their training certificates were on display in the consultation room. However, work experience students from a local college regularly worked in the pharmacy and carried out activities such as putting away dispensary stock and helping to assemble compliance aid packs. They were not qualified to carry out these duties and had not been enrolled onto an accredited dispensing assistant course, so this increased the risk of error. The accuracy checking technician (ACT) confirmed the students had read the SOPs, although this wasn't documented, and no one had tested their understanding of them. The ACT said the students were closely supervised in their duties, and their work was double checked.

There was little ongoing training and one member of the pharmacy team could not recall having completed any training during the previous year, apart from reading and keeping up to date with SOPs. So there was a risk that her knowledge might not be fully up-to-date, as she qualified around four years ago. The pharmacy team did not have regular protected training time and any training completed was usually done in their own time. Some team members started work early each day to get ahead, and this was unpaid.

The pharmacy team were not given formal appraisals, but a dispenser said she discussed her performance and development informally with the pharmacy manager. There were regular updates and communication from head office on the intranet which the pharmacy manager encouraged the team to read. He held team huddles where issues were discussed and concerns could be raised, although he did not record these, so some members of the team might miss out on the information, and issues raised might not be addressed. A dispenser said she felt there was an open and honest culture in the pharmacy and said she would feel comfortable talking to the pharmacy manager about any concerns she might have. She said there was an area manager who sometimes visited the pharmacy who she could talk to if she felt the pharmacy manager was not acting on her concerns, although this had not

been necessary. The dispenser said she felt comfortable admitting errors and tried to learn from them. She said she always double checked the form of medicines as this had been highlighted to her as a common mistake in the pharmacy.

The pharmacy manager said he felt empowered to exercise his professional judgement and could comply with his own professional and legal obligations. For example, refusing to sell a pharmacy medicine containing codeine, because he felt it was inappropriate. He said targets were set for prescription items, Medicines Use Review (MUR), New Medicine Service (NMS) and electronic prescription service (EPS) nominations. He said these were very important in the organisation and the team were under pressure to achieve them. The team bonus was dependent on meeting these targets, but he didn't feel targets ever compromised patient safety.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy generally provides a suitable environment for people to receive healthcare services. But some areas are untidy and less well maintained which detracts from the overall professional image. It has a private consultation room that enables it to provide members of the public with the opportunity to have confidential conversations.

Inspector's evidence

The retail area in the main part of the pharmacy was clean, spacious and in a good state of repair. It was free from obstructions and had a waiting area with three chairs. The temperature and lighting were adequately controlled, and the fixtures and fittings were in reasonable condition. Maintenance problems were reported to head office. The response time was appropriate to the nature of the issue and the job could be marked 'critical' if an urgent response was required. For example, when the security shutter was broken, the response had been within four hours and a recent problem with a leaking roof was promptly repaired.

The first floor and staff facilities were less well maintained. Some areas were not clean and were in a poor state of repair, with plaster coming off the walls. There were stockrooms, a staffroom with a kitchen area and two WCs on the first floor. There was an additional WC on the ground floor. Hand washing notices were displayed in the WCs, but the sinks were dirty and there was inadequate facilities to wash hands, compromising hygiene. The Staff were able to wash hands at the kitchen sink, where there was hot running water, hand wash and kitchen roll. Hand sanitizer gel was available for staff use. There was a separate dispensary sink for medicines preparation, which was clean.

There were two entrances into the pharmacy. The side entrance allowed access to a small waiting area and the consultation room. It was not possible to access the main part of the pharmacy from this entrance and it was mainly used for people receiving supervised medication and the needle exchange service. People wishing to use the consultation room from the main part of the pharmacy were required to walk around the outside of the building and in through the side entrance. There was a patch of mud outside this entrance and the floor in the waiting area was muddy. The consultation room was cluttered and untidy, and there was a ceiling tile missing, which detracted from its professional image. The availability of the room was highlighted by a sign on the door, but it was not visible from the main part of the pharmacy. The room was used when carrying out services such as needle exchange and MURs, and when customers needed a private area to talk. There was a notice near the medicine counter indicating the room was available, but it was not very prominent, so people might miss it and not realise the facility existed.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy offers a range of healthcare services which are generally well managed and easy for people to access. The pharmacy gets its medicines from licensed suppliers and it carries out some checks to ensure medicines are in good condition and suitable to supply. It stores medicines safely, but it does not always store stock medicines in an orderly manner, which might make the dispensing process less efficient and increase the risk of errors.

Inspector's evidence

The pharmacy, consultation room and pharmacy counter were accessible to all, including patients with mobility difficulties and wheelchair users. A list of the services provided by the pharmacy was displayed in the window along with the opening hours. There was some healthcare leaflets and a healthy living zone containing information on cancer awareness and men's health. A priority highlighted on the annual patient safety report was to be vigilant for symptoms of sepsis. Signposting and providing healthy living advice were not recorded. It was therefore difficult to monitor the effectiveness of the health promotional activities and improved patient outcomes. There had been information on the intranet about the Corona virus and stock issues with hand sanitizer gel and face masks. The relevant information had been relayed to the public through notices in the pharmacy's window.

Space was adequate in the dispensary, and the work flow was organised into separate areas with two designated checking areas, one for the pharmacist and one for the ACT. The dispensary shelves were not very neat and tidy and some of the benches were cluttered, reducing usable space. Dispensed by and checked by boxes were generally initialled on the medication labels to provide an audit trail. Different coloured baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. The baskets were stacked to make more bench space available. There was a home delivery service with associated audit trail. Each delivery was recorded, and a signature was obtained from the recipient. A note was left if nobody was available to receive the delivery and the medicine was returned to the pharmacy.

Stickers were put on assembled prescription bags to indicate when a fridge line or CD was prescribed. 'Pharmacist' stickers were used to highlight when counselling was required and high-risk medicines such as lithium, warfarin and valproate were targeted for extra checks and counselling. Patients receiving lithium were given advice about toxicity, and how to recognise the signs and symptoms. Their records cards were checked if they had them with them. INR levels were not routinely requested and recorded when dispensing warfarin prescriptions, but the pharmacy manager said he always checked this as part of MURs. The team were aware of the valproate pregnancy prevention programme. An audit had been carried out and one patient in the at-risk group had been identified. The pharmacy manager had a conversation with her about pregnancy prevention. One of the team confirmed that the valproate information pack and care cards were available so people in the at-risk group could be given the appropriate information and counselling, although they couldn't be immediately located. An audit of people prescribed non-steroidal anti-inflammatory drugs (NSAIDs) had been carried out and one or two people were referred for gastroprotection. Two or three people were referred for foot or retinopathy eye checks during a diabetes audit.

Around 150 people received their medicines in multi-compartment compliance aid packs. There was a

partial audit trail for changes to medication in the packs, but it was not always clear who had confirmed these changes and the date they had been made, which could cause confusion in the event of a query. A record of who had accuracy checked the packs was not always made and the clinical check was not recorded on the patients record sheet 'MAP' as outlined in the SOP. This limited the information available in the event of a problem or error. Medicine descriptions were usually included on the packaging to enable identification of the individual medicines but these were hand written and some of the writing was very poor making it difficult to read. The pharmacy team confirmed packaging leaflets were included so patients and their carers could easily access all the required information about their medicines. One of the samples checked did not have any packaging leaflets but the dispenser said this patient had specifically requested not to receive any, although there was no documented record of this request. An assessment was not carried out by the pharmacist as to the appropriateness of a compliance aid pack, or if other adjustments might be more appropriate to the patient's needs, prior to commencing this service for a patient. So some patients might be receiving their medicines in a compliance aid pack who don't necessarily require one.

A dispenser explained what questions she asked when making a medicine sale and when to refer the patient to a pharmacist. She was clear which medicines could be sold in the presence and absence of a pharmacist and understood what action to take if she suspected a customer might be abusing medicines such as a codeine containing product.

CDs were stored in a large CD cabinet which was securely fixed to the floor. It was disorganised and untidy and some medicines were stored in more than one place in the cabinet, making finding stock and checking balances difficult. Date expired and patient returned CDs were not clearly segregated from each other. Pharmacy medicines were stored behind the medicine counter so that sales could be controlled.

The consultation room was accessible from the waiting area at the side entrance and contained an unsealed sharps bin full of sharps from the needle exchange service, which was a health and safety risk. It also contained some stock medicines such as Movicol, Fybogel and boxes of appliances. The pharmacy manager said the door to the side entrance and consultation room was usually locked when not in use, to prevent unauthorised access.

Recognised licensed wholesalers were used to obtain medicines. No extemporaneous dispensing was carried out. The pharmacy was not compliant with the Falsified Medicines Directive (FMD). It had the hardware needed to comply, but the team had not had any training and the pharmacy manager said he was waiting for further advice from head office before starting to scan medicines. Medicines were stored in their original containers at an appropriate temperature. There was a matrix for date checking, but it had not been completed and the team admitted they were behind with this, but said they always checked the expiry date as part of the dispensing process. Dates had been added to opened liquids with limited stability. Expired medicines were segregated and placed in designated bins.

There was a 'Recall and alert' SOP. Alerts and recalls were received on 'Cohens daily news' via the intranet. A copy was printed and retained in the pharmacy with a record of the action taken, so the team were able to respond to queries and provide assurance that the appropriate action had been taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely.

Inspector's evidence

Current versions of the British National Formulary (BNF) and BNF for children, and Martindale were available and the pharmacist could access the internet for the most up-to-date information.

There was a clean medical fridge. The minimum and maximum temperatures were being recorded regularly and had been within range throughout the month. All electrical equipment appeared to be in good working order. There was a selection of clean glass liquid measures with British standard and crown marks. Separate measures were banded and used for methadone solution. The pharmacy had equipment for counting loose tablets. It was not used very often, as most tablets were supplied in original packs, but it was not very clean and risked contamination. A dispenser said she would use tweezers to count out cytotoxic drugs and the pharmacy manager pointed out that methotrexate was obtained in foil strip to avoid the need to handle it. Medicine containers were appropriately capped to prevent contamination.

Computer screens were positioned so that they weren't visible from the public areas of the pharmacy. Patient medication records (PMRs) were password protected. Cordless phones were available in the pharmacy, so staff could move to a private area if the phone call warranted privacy.

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.