General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Cornwell's Chemists Ltd, 11 High Street, NEWCASTLE, Staffordshire, ST5 1RB

Pharmacy reference: 1036938

Type of pharmacy: Community

Date of inspection: 29/05/2019

Pharmacy context

This is a community pharmacy located in the town centre. Most people who use the pharmacy are from the local area. The pharmacy dispenses mainly NHS prescriptions and sells a range of over-the-counter medicines. It supplies a large number of medicines in multi-compartment devices to help people take their medicines at the right time. An automated dispensing robot is used in this process. The pharmacy also assembles multi-compartment devices for six other pharmacies in the company.

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 generally manages risks to make sure its services are safe. It takes some action to improve patient safety and members of the team record their mistakes so that they can learn from them . It asks its customers for their views and generally completes the records that it needs to by law. The team members have completed training to keep people's private information safe. And know how they can help to protect children and vulnerable adults.

Inspector's evidence

There were Standard Operating Procedures (SOPs) for the services provided but most of these had been prepared in 2015 and there was no record that they had been recently reviewed, so might not be up to date. There were SOPs available for the automated dispensing robot which had been recently introduced to assemble multi-compartment devices to six other pharmacies in the company (spokes).

The main operator of the robot had been given an individual copy of the SOP for the 'hub' pharmacy and she confirmed she had read it. Most SOPs had signatures showing that members of the pharmacy team had read and accepted them. The pharmacy team members were performing duties which were in line with their role. They were wearing uniforms but nothing to indicate their role, so this might be unclear to people visiting the pharmacy. The name of the responsible pharmacist (RP) was displayed as per the RP regulations.

Dispensing errors and near misses were discussed with the members of the pharmacy team who were involved, and reported on Pharmapod, which the pharmacist superintendent (SI) accessed. Members of the pharmacy team said they did not know if these were routinely reviewed for trends and patterns, so some learning opportunities may be missed. But incidents were reviewed on an individual basis, depending on the incident.

Clear plastic bags were used for assembled CDs and insulin to allow an additional check at hand out. Following an incident when a patient received the wrong patient's multi-compartment device, the process was reviewed, and an additional check was introduced for scanning the tray containing the assembled multi-compartment device against the labelling sheet to ensure the two were correctly matched.

A separate near miss log was used to record errors with the robot. These were quite rare and were usually due to a missing, extra or broken tablet or capsule in a compartment. An accuracy checking technician (ACT) explained that these were technical errors with the robot, and were individually corrected, to avoid a re-occurrence, e.g. changing the pipette size or changing the setting to 'fragile' for tablets which were prone to break during the process.

There was nothing on display highlighting how people could make a complaint but there was a feedback machine on the medicine counter where people could record their rating of their experience in the pharmacy. The trainee medicine counter assistant (MCA) said the machine produced a print out and the SI received this information at head office. It was discussed within the pharmacy team. A customer satisfaction survey was carried out annually. The results of the most recent survey were on display in the window of the pharmacy and on the NHS choices website.

Insurance arrangements were in place. Private prescriptions were recorded in a designated book but there were some private instalment prescriptions (FP10PCD forms) from March and April 2019, which had not been submitted to the appropriate authority at the end of the month, which was not in line with regulations. The RP record was electronic. It was not accurate, as the time recorded as the start time was often after the pharmacy had opened and RP duties had commenced. And the time the RP ceased their activities was not routinely recorded. The controlled drug (CD) register was appropriately maintained. Records of CD running balances were kept and these were regularly audited. A CD balance was checked and found to be correct.

All members of the pharmacy team read and signed a confidentiality agreement, and these were with the new starter information. Confidential waste was collected in designated bags which were collected by the waste company 'Green plan-it'. A trainee dispenser correctly described the difference between confidential and general waste. The delivery driver knew what it meant to maintain patient confidentiality.

The RP and ACTs had completed centre for pharmacy postgraduate education (CPPE) level 2 training on safeguarding. One of the ACTs said she would voice any concerns regarding children and vulnerable adults to the pharmacist working at the time and knew the concern should be reported to the local safeguarding lead. The RP said he would look up the details of the local safeguarding lead in the area if any concerns were reported to him. The delivery driver said he would report any concerns he came across when delivering medication to people's homes to the pharmacist. He described an incident when he called an ambulance when he found a patient collapsed when he arrived at their home.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy team members complete training for the jobs they do and do some ongoing learning. But this does not happen regularly, and is not always recorded, so their knowledge may not be always fully up to date. The team members work well together. And they are comfortable providing feedback to their manager.

Inspector's evidence

There was a locum pharmacist (RP), two ACTs, an NVQ2 qualified dispenser (or equivalent), two trainee dispensers, a trainee MCA and a delivery driver on duty at the time of the inspection. The staff level was adequate for the volume of work seen during the inspection and the team were observed working collaboratively with each other and the patients. The pharmacy team had been stretched recently as members of the team had left and there had been two vacancies. One of these vacancies had been filled but there was still an outstanding vacancy. One of the dispensers was working extra hours to cover this. Planned absences were recorded in a diary so that not more than one person was away at a time.

The SI was present for part of the inspection. He explained that he was based at a head office which was located close by. One of the trainee dispensers was the designated robot operator and explained that she had been trained by a trainer from the robot's company 'Synmed', as part of the service provided by them. Members of the pharmacy team had completed accredited training courses. The pharmacy team did not have regular protected training time and ad hoc training such as when the new product Viagra Connect was introduced, was not usually recorded. A new member of staff explained that she had completed data protection training online and was shadowing other members of the pharmacy team for the first few weeks. She said she had read some of the SOPs but was still working her way through them.

Informal discussions were held most mornings when any issues were discussed, and concerns could be raised. A member of the pharmacy team 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 the staff could make suggestions or criticisms informally.

The RP said he felt empowered to exercise his professional judgement and could comply with his own professional and legal obligations, e.g. refusing to sell a pharmacy medicine because he felt it was inappropriate. He said targets were set for medicine use review (MUR) and new medicines service (NMS), but he didn't feel under pressure to achieve them.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are reasonably clean and provide a safe and secure environment for people to receive healthcare.

Inspector's evidence

The pharmacy premises including the shop front and facia were spacious and in a reasonable state of repair. The retail area was free from obstructions, professional in appearance and had a waiting area with some comfortable seating. The temperature and lighting were adequately controlled. The ground floor of the pharmacy had been re-fitted to a good standard when the robot was introduced. The first floor, where the staff facilities were located, was less well maintained. Maintenance problems were reported to head office. The response time was sometimes slow but generally appropriate to the nature of the issue.

There were two separate stockrooms on the ground floor where excess stock and assembled multi-compartment devices were stored. Staff facilities included a small kitchen area and two WCs with wash hand basins and antibacterial hand wash. There was a separate dispensary sink for medicines preparation with hot and cold running water. Hand sanitizer gel and disposable gloves were available.

Space was adequate in the dispensary and there had been a refit to extend the dispensary and make a dedicated area for the robot. The work flow was organised into separate areas with designated checking areas for both the pharmacist and ACTs.

There was a consultation room equipped with a sink. The desk in the room looked dirty and the chairs were stained which compromised the professional image of the pharmacy . The availability of the room was not highlighted so people might not realise it was available. The room was used when carrying out services, e.g. supervised administration of methadone solution and when customers needed a private area to talk.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy offers a range of healthcare services which are generally well managed to help make sure people receive their medicines safely. It sources medicines safely and carries out some checks to ensure medicines are in good condition and suitable to supply. But it does not usually provide people receiving multi-compartment devices with packaging leaflets, so they may not always get all the information about their medicine that they might need.

Inspector's evidence

The pharmacy, consultation room and pharmacy counter were accessible to all, including patients with mobility difficulties and wheelchair users. There was an automatic door.

Services were advertised in the window of the pharmacy with the opening hours. There was a small range of healthcare leaflets and a couple of posters advertising local services, e.g. a dementia support service and a social inclusion group. Books on common medical conditions were available for purchase. The pharmacy team were clear what services were offered and where to signpost to a service not offered, e.g. needle exchange. Signposting and providing healthy living advice were not recorded. It was therefore difficult to monitor the effectiveness of the health promotional activities.

The pharmacy offered a repeat prescription ordering service and patients indicated their requirements around a month in advance, when they collected their medication. Requirements were not checked again at hand-out, so un-required medicines might be supplied, and this could lead to stockpiling and medicine wastage.

There was a delivery service and a robust audit trail was in place using an application on the pharmacy's mobile phone. 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.

The dispensary shelves were reasonably well organised, neat and tidy. Dispensed by and checked by boxes were 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.

Stickers were put on assembled prescription bags to indicate when a fridge line or CD was prescribed. 'Speak to Pharmacist' stickers were available to highlight counselling was required and there was some targeting of high-risk medicines for extra checks and counselling. INR levels were requested and recorded when dispensing warfarin prescriptions. The RP was aware of the risks in pregnancy for female patients prescribed valproate and the need for an appropriate prevention programme, but he could not locate the valproate information pack and care cards. So, there was a risk that female patients would not be given the appropriate information and counselling. These were later located in a stock room.

Multi-compartment devices were assembled using a robot. There was a detailed checking process for the robot. A dispensing audit trail was recorded on the packaging and on a separate 'file patient list'.

The first check was carried out by the robot operator, following assembly by the robot. This was followed by a second accuracy check by an ACT as well as a check that the prescription matched the information input into the system. There was a separate designated checking area for the robot. A notice outlining the checking procedure was on display in the checking area to use as a reference by the ACTs. There was a partial audit trail for changes made to multi-compartment devices, but it was not always clear who had confirmed the changes and the date the changes had been made. Medicine descriptions were usually included on the labels to enable identification of the individual medicines. Packaging leaflets were not usually supplied, despite this being a mandatory requirement, so patients or their carers may not have all the information they require.

The trainee MCA knew what questions to ask 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 was clear what action to take if she suspected a customer might be abusing medicines such as a codeine containing product.

Date expired, and patient returned CDs were segregated and stored securely. Patient returned CDs were destroyed using denaturing kits. Pharmacy medicines were stored behind the medicine counter so that sales could be controlled. Recognised licensed wholesalers were used for the supply of medicines and appropriate records were maintained for medicines ordered from 'Specials'. No extemporaneous dispensing was carried out. The pharmacy was not compliant with the Falsified Medicines Directive (FMD). They were not scanning to verify products or decommission before handing out.

Medicines were generally stored in their original containers apart from medicines used in the robot. These medicines were removed from their original containers and stored for up to two weeks before they were placed in the automated dispensing robot cassettes. This was to avoid delays and increase efficiency when medicines were required by the robot. The original packaging was retained in the container showing the expiry date and batch number during storage. Date checking was carried out and documented. Short dated stock was highlighted. Dates had been added to opened liquids with limited stability. Expired medicines were segregated and placed in designated bins.

Alerts and recalls were received via e-mail messages from head office. Members of the pharmacy team said they were acted on but were unable to verify this as they could not locate any alerts or recalls from the current year in the designated file.

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 British National Formulary (BNF) and BNF for children were available and the pharmacist could access the internet for the most up-to-date information. There were four clean medical fridges. 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. There was a separate measuring pump for methadone solution. This was cleaned regularly. The pharmacy had a range of equipment for counting loose tablets and capsules, with a separately marked tablet triangle that was used for cytotoxic drugs. The triangles required cleaning to avoid the risk of contamination. Medicine containers were appropriately capped to prevent contamination.

The robot was serviced, and a maintenance contract was in place. The pharmacy team could contact a helpline if problems occurred. Engineers visited the pharmacy if necessary and could access the system remotely for some issues.

Computer screens were positioned so that they weren’t visible from the public areas of the pharmacy. Patient medication records (PMRs) were password protected. The main pharmacy phones were not cordless, and one was located quite close to the retail area, risking conversations being overheard.

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.