General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Saffron Apothecaries Ltd, 1 Wood Street, MANSFIELD, Nottinghamshire, NG18 1QB

Pharmacy reference: 1035568

Type of pharmacy: Community

Date of inspection: 30/09/2019

Pharmacy context

This is a community pharmacy on the outskirts of the town centre. The pharmacy sells over-the-counter medicines and it dispenses NHS and private prescriptions. The pharmacy provides substance misuse services to local people. It also provides advice on the management of minor illnesses and long-term conditions. It supplies medicines in multi-compartmental compliance packs, designed to help people remember to take their medicines. And it delivers medicines to people's homes and two local care homes.

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	1.3	Standard not met	Pharmacy team members have not signed all procedures relating to their roles. And there is evidence that they do not complete all tasks in accordance with these procedures. There are occasions where pharmacy team members work outside of their defined roles by undertaking some tasks without the direct supervision of a pharmacist. This obscures the lines of accountability and may increase risk.
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 not all met	4.2	Standard not met	Pharmacy team members do not always identify the risks in the way they deliver services such as the supply of medicines in multi-compartmental compliance packs. And they don't demonstrate how they work in accordance with procedures for this service.
		4.3	Standard not met	The pharmacy does not consider the stability requirements of some of the medicines it supplies in multi-compartmental compliance packs. And it does not always have appropriate arrangements in place for restricting access to medicines requiring safe custody.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy has processes to help identify and manage risks associated with most of its services. But pharmacy team members have not signed all procedures relating to their roles. And there is evidence that they do not complete all tasks in accordance with these procedures. There are occasions where pharmacy team members work outside of their defined roles by undertaking some tasks without the direct supervision of a pharmacist. This obscures the lines of accountability and may increase risk. The pharmacy keeps people's private information secure. And it generally keeps all records it must by law. The pharmacy responds appropriately to feedback it receives about its services. Pharmacy team members act openly and honestly by sharing information when mistakes happen. And they have the skills and knowledge required to protect the safety and wellbeing of vulnerable people.

Inspector's evidence

The pharmacy had a set of up-to-date standard operating procedures (SOPs). These included responsible pharmacist (RP) requirements, controlled drug (CD) management, dispensary processes and services. The SOPs also contained details of compliance with the Falsified Medicines Directive (FMD). The latest version of SOPs had been implemented in January 2019. But there were some gaps in training records associated with the procedures as not all team members had signed them. Pharmacy team members could discuss their roles confidently. For example, a dispenser discussed and demonstrated how the repeat prescription collection service operated. A medicine counter assistant explained how she was unable to sell a Pharmacy (P) medicine if the responsible pharmacist took absence from the pharmacy. And she was aware that assembled bags of medicines could not be handed out during this time. But on the date of inspection some pharmacy team members had set up a Methasoft machine by priming it with methadone ahead of the pharmacist arriving at the pharmacy. They explained the machine had been set-up due to a high-demand for the service just after opening. Both the RP and pharmacy team members confirmed no dispensing activity had begun prior to the RP arriving. A discussion took place about the requirement for all activity involving CDs to be conducted under the direct supervision of a pharmacist.

The pharmacy split its work between two dispensaries. The main dispensary on the ground floor was used to manage acute workload, repeat prescriptions and the delivery service. The upstairs dispensary was used to manage the supply of medicines to care homes and the multi-compartmental compliance pack service. Workflow in both dispensaries was organised. There was designated space for labelling, assembly and accuracy checking medicines. A bench at the front of the downstairs dispensary was dedicated to acute prescription workload. And these prescriptions were prioritised by the team. The pharmacy employed two accuracy checking technicians (ACTs). The ACT on duty discussed her role and felt confident to refer to the pharmacist if required. The pharmacy team followed a written audit trail which identified pharmacists had clinically checked prescriptions prior to an ACT completing the final accuracy check of a medicine.

The pharmacy had a near-miss error reporting process in place. It used a red card system to notify its team members of near-miss errors. This involved the RP or ACT placing a red card in the top of the basket and handing the basket of assembled medicines back to the person who had made the mistake. The person then re-checked their work to identify the error. Pharmacy team members expressed that

this system worked well as it meant they learnt better from finding their own mistakes. The accuracy checker provided feedback to the person involved in the mistake and completed the near-miss error record following the mistake being corrected. Near-miss errors in the upstairs dispensary were generally discussed and recorded between the dispenser and ACT. The pharmacy were in the process of moving to an electronic recording system to help it identify trends in near-miss errors. And it had completed a formal review of patient safety events for August 2019 using this system. This review helped identify learning points and actions required to reduce risk. Pharmacy team members explained they had been briefed about these key learning points. For example, to slow down during the dispensing process and thoroughly check their work. But the report was kept on the computer. This meant it was not readily available for pharmacy team members, to assist them in implementing the learning points discussed.

The pharmacy had an incident reporting procedure. The RP explained how he would manage a dispensing incident and go on to report the incident on the computer system. The pharmacy's area manager reviewed reports. And some follow up actions designed to help reduce risk and improve safety in the pharmacy were documented. Pharmacy team members explained they were briefed about any incidents. And they could demonstrate how the pharmacy had responded to risks identified by these types of mistakes. For example, 'look-alike and sound-alike' (LASA) medicines were separated in the dispensary drawers. And the pharmacy had reviewed its storage arrangements for ramipril capsules and tablets to help prompt additional checks of the formulation selected during the dispensing process.

The pharmacy advertised its concerns procedure. And pharmacy team members on duty could explain how they would manage and escalate a concern about the pharmacy. A pharmacy team member demonstrated how the pharmacy held brand specific medicines to fill some prescriptions. And the pharmacy team followed up with surgeries when these brands were not available. It had implemented notes on people's medication records to remind them of the requirement to dispense a specific brand when required. The pharmacy also promoted feedback through their annual 'Community Pharmacy Patient Questionnaire'. And it published the results of this questionnaire for people using the pharmacy to see.

The pharmacy had up-to-date indemnity insurance arrangements in place. The RP notice was updated to reflect the details of the RP on duty as the inspection process began. Entries in the responsible pharmacist record complied with legal requirements. The pharmacy maintained its CD register electronically. The samples of the CD register examined were compliant with legal requirements. The pharmacy maintained running balances in the register. And it checked these balances against physical stock weekly. A physical balance check of morphine sulfate 30mg/ml injections complied with the balance in the register. The pharmacy maintained its CD destruction register for patient returned medicines electronically. And pharmacy team members generally entered returns in the register on the date of receipt. The pharmacy kept records for private prescriptions and emergency supplies within an electronic Prescription Only Medicine (POM) register. Emergency supply records met legal requirements. But private prescription records did not always contain an accurate date of prescribing. The pharmacy retained completed full audit trails on certificates of conformity for unlicensed medicines in accordance with the requirements of the Medicines & Healthcare products Regulatory Agency.

The pharmacy displayed a privacy notice. Information governance processes were covered within SOPs. Pharmacy team members demonstrated how they stored personal identifiable information in staff only areas of the pharmacy. And these areas were protected from unauthorised access. The pharmacy had submitted its annual NHS data security and protection (DSP) toolkit as required. It disposed of confidential waste by using a heavy-duty shredder.

The pharmacy had procedures and information relating to safeguarding vulnerable people in place. Contact information for local safeguarding agencies was readily available. Pharmacy team members had completed some learning on the subject through reading procedures and discussing requirements. Pharmacy professionals had completed level two training on the subject. A pharmacy team member explained how safeguarding requirements were also covered in mandatory coursework relating to her role in the pharmacy. And she had been asked by her tutor on several occasions how she would recognise and report a concern. Pharmacy team members could explain how they would report a safeguarding concern to the RP in the first instance. And the RP was aware of reporting requirements.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough skilled and knowledgeable people working to provide its services. It supports its team members by promoting learning relating to their roles. And pharmacy team members have the opportunity to discuss their learning and development with their manager. Pharmacy team members take part in regular conversations relating to risk management and safety. And they are aware of how they would provide feedback about the pharmacy should they need to.

Inspector's evidence

On duty during the inspection was the RP (a locum pharmacist who had worked with the company for several years), an ACT, five qualified dispensers, a medicine counter assistant and two delivery drivers. The pharmacy also employed a full-time regular pharmacist, a full-time pharmacy manager (ACT), another qualified dispenser and two more part-time delivery drivers. Most staff worked full-time hours. But there was some flexibility within the team to change hours and days off to help cover leave.

Pharmacy team members confirmed they felt supported in their roles. They received regular information which assisted them in learning about new requirements. For example, a dispenser explained changes to the scheduling of gabapentin and pregabalin. And pharmacy team members demonstrated how the pharmacy team marked all its CD prescriptions to help prompt additional checks during the dispensing process. The pharmacy kept training records for its team members. And these included records of regular appraisals. One dispenser was enrolled on a level three course in pharmacy services. She received training time during working hours and lunch breaks. And explained how the manager would often sit with her during breaks to help answer any questions she had relating to her training role. Another member of the pharmacy team had recently qualified as a dispenser. And this staff member confirmed she had received the time and support required to complete her training at work.

The pharmacy dispensed a high number of prescriptions. The atmosphere in the pharmacy was calm and pharmacy team members were observed concentrating on the tasks at hand. Pharmacists managed the supply of substance misuse medicines and the needle exchange programme. The RP explained how workload in the dispensary was adapted from traditional pharmacy models to help support this role. For example, the RP accuracy checked the managed workload. A qualified member of the team then undertook an additional check of these medicines and bagged the medication. Pharmacy team members were observed applying care when carrying out these tasks. The RP explained how the pharmacy's area manager monitored the delivery of the pharmacy's services. He explained how pharmdata.co.uk was used to monitor year-on year performance. The RP discussed how he applied his professional judgement when undertaking services such as Medicines Use Reviews (MURs) and the New Medicine Service (NMS). Pharmacy team members helped to identify people eligible for these services during the dispensing process.

The pharmacy team communicated mainly through small team briefings and one-to-one meetings with the manager. But the pharmacy did not frequently hold a structured team meeting. This meant that pharmacy team members could potentially miss out on some shared learning opportunities. Pharmacy team members spoke positively about their working environment. And they felt able to provide

feedback to their manager and regular pharmacist. The pharmacy had a whistleblowing policy and its team members were aware of how they could raise and escalate a concern.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is secure and suitably maintained. People using the pharmacy can speak with a member of the pharmacy team in confidence in a private consultation room.

Inspector's evidence

The pharmacy appeared modern. It was clean and well maintained. Pharmacy team members reported maintenance concerns to their area manager. And tradespeople known to the company attended to fix any issues. There were no outstanding maintenance issues found during the inspection. The pharmacy had heating and air conditioning. A portable air-conditioning unit and fans were used in the upstairs dispensary during summer months. Lighting throughout the premises was sufficient. Antibacterial soap and paper towels were available at designated hand washing sinks.

The public area was small and open plan. It led directly to the medicine counter. To one side of the counter was a sign-posted treatment room. The room led to a large window at the side of the dispensary. And the pharmacist provided substance misuse services to people at this window. A second-room to the side of the medicine counter was sign-posted as the consultation room. This was a good size and professional in appearance. The RP explained how people attending for any service could use this room.

The downstairs dispensary was accessed up a step from the medicine counter. It was well-organised and a good size for the services provided. The pharmacy team used space at the back of the dispensary to complete administration tasks associated with the prescription ordering and delivery service. To the side of the dispensary was an office and staff facilities. Upstairs there was further staff facilities, a large store room, an office and a second good size dispensary. The store room was used to hold dispensary sundries and overflow stock.

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

Summary findings

The pharmacy's services are not always managed in line with its procedures and this increases the risks of mistakes. The pharmacy assembles multi-compartmental compliance packs far in advance of people requiring these packs. And without evidence of always having a valid prescription. The team members cannot demonstrate how they apply the necessary safety checks when dispensing medicines in these packs. They remove some of the medicines that they supply in these packs from the original packaging too early. This risks the medicines not working as effectively when a person comes to take them. The pharmacy obtains its medicines from reputable sources. But it does not restrict access to all of its medicines as required by law. The pharmacy does ensure its services are accessible to people.

Inspector's evidence

The pharmacy was accessed from street level through a simple push/pull door. Signage above the door indicated that the pharmacy was known locally as Mansfield Delivery Chemist. And information published on nhs.uk confirmed this. Pharmacy team members explained the registered name of the pharmacy was changed when the current owners had taken over. This meant it could be potentially difficult for people to access information about the pharmacy. For example, published inspection reports. The pharmacy displayed details of its opening times and services. And notices in the public area promoted national health campaigns and local services. There was some seating provided to people who were waiting for a prescription or service. Pharmacy team members were aware of sign-posting arrangements in the event they could not provide a service or a medicine.

A good number of people accessed the pharmacy for supplies of medicines through a local minor ailments protocol (Pharmacy First). And the medicine counter assistant explained that GP surgeries promoted this service well. This meant people requiring minor interventions for common conditions were appropriately signposted to the pharmacy for advice and supply of a medicine through the scheme. The pharmacy's substance misuse services were also accessed throughout the day. And these services were led by the pharmacist.

The pharmacy had individual records for people receiving medicines in multi-compartmental compliance packs. And a dispenser demonstrated how these records would be checked against prescription forms to help identify changes. But packs were assembled far in advance of them being dispensed to people. For example, some backs for week commencing 25 November 2019 were observed waiting to be checked. Labels for the packs had been produced on 12 September 2019. Medicines to fill these packs had been picked against backing sheets and not original prescriptions as set out in the SOPs. And evidence of legally valid prescriptions being received for the packs was not found. This practice posed multiple risks. For example, it made it more difficult for the pharmacy to recognise and manage a change to a person's medication regimen. A sample of assembled packs included full dispensing audit trails and descriptions of the medicines inside to help people recognise them. But the backing sheets did not contain details of cautionary and advisory labels as required. The pharmacy only provided patient information leaflets for new medicines or to people who specifically asked for them. It had asked people to formally agree their preference for the receipt of this information. And these records were maintained within each person's profile form.

The pharmacy managed the supply of medicines to two care homes through a 28-day multi-compartmental compliance pack system. The supply of medicines in these packs included dispensing audit trails and the statutory cautionary and advisory labels were printed on the labels attached to packs. But a dispenser explained the pharmacy did not routinely provide patient information leaflets for these medicines. This meant that carers might find it difficult to read up-to-date information about a person's medication if they needed to. The pharmacy provided medicine administration record (MAR) sheets to both care homes. And short-term MARs were provided when the pharmacy dispensed acute medicines between cycles. For example, antibiotics. The care homes re-ordered medicines using a re-ordering MAR sent to the pharmacy. This meant the pharmacy team could check prescriptions against the MAR to identify changes and queries. It managed these queries through communicating them to the home. But it did not always record details of these discussions.

The pharmacy had limited processes for supporting its team members in identifying high-risk medicines. Pharmacy team members could discuss the requirements of the valproate pregnancy prevention programme (PPP). And there was a supply of warning cards to provide to people in the high-risk group. But it supplied some sodium valproate in multi-compartmental compliance packs. And this medicine was seen in pre-assembled packs due to start on 25 November 2019. The pharmacy team had not recognised that this medicine was not designed to be removed from its original packaging due to its limited stability once removed from this packaging. And pharmacy team members were not aware of the risks of handling some medicines, such as finasteride. The RP explained how he would counsel a person taking a high-risk medicine such as warfarin. But the pharmacy did not high-light this counselling in any way on prescription forms or on assembled bags of medicines. This meant there could be some missed opportunities to talk to people about their medicines.

The pharmacy used coloured baskets throughout the dispensing process. This kept medicines with the correct prescription form and helped to inform workload priority. Pharmacy team members signed the 'dispensed by' and 'checked by' boxes on medicine labels to form a dispensing audit trail. And a stamp was used to confirm prescriptions had been clinically checked. 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. A dispenser demonstrated how the pharmacy managed its repeat prescription collection service. It maintained a full audit trail of what people had ordered. This allowed it to ensure the required medicines were correctly prescribed. And meant that it could chase queries about missing prescriptions or changes to medication with GP surgeries in a timely manner. The pharmacy kept delivery audit trails for the prescription delivery service and people signed to confirm receipt of their medicines.

The pharmacy sourced medicines from licensed wholesalers and specials manufacturers. Pharmacy team members discussed changes to medicine packaging following the introduction of FMD. And one computer had been fitted with a new scanner. But pharmacy team members confirmed they were not yet following any processes to decommission medicines. Team members on duty were not aware of when they would begin using equipment to support the pharmacy in meeting FMD requirements. The pharmacy received drug alerts electronically. And the RP demonstrated how all alerts on the system had been checked. Pharmacy team members were confident in explaining how they managed these alerts.

The pharmacy stored P medicines behind the medicine counter. This meant the RP had supervision of sales taking place and was able to intervene if necessary. The pharmacy stored medicines in the dispensaries and stock room in an organised manner and within their original packaging. The pharmacy team followed a date checking rota. This helped to manage stock and identify short-dated medicines. Short dated medicines were clearly marked. And the team annotated details of opening dates on

bottles of liquid medicines. Some open bottles of liquid medicines which had gone beyond their shortened expiry date were segregated and brought to the RP's attention. No other out-of-date medicines were found during random checks of stock across both dispensaries. The pharmacy had medical waste bins, sharps bins and CD denaturing kits available to support the team in managing pharmaceutical waste.

The pharmacy held CDs in secure cabinets. Medicine storage arrangements in the cabinets was orderly. Assembled CDs were held in bags with details of the prescription's expiry date annotated clearly. And there was separate storage room in the cabinets for holding patient returned and out-of-date medicines. Pharmacy team members pre-assembled buprenorphine doses in individual daily boxes. These boxes were labelled appropriately and stored neatly in a CD cabinet. Uncollected doses were transferred into a holding basket in another cabinet. And the pharmacy had appropriate risk-assessment processes in place to ascertain whether it could continue to use these medicines. The RP managed the supervised consumption service and was observed applying identification checks against the prescription and Methasoft record with the person attending. But despite the Methasoft system producing a dispensing label, this label was not attached to the cup containing the methadone which breached medicine labelling requirements. The RP confirmed it was possible to label cups during the dispensing process.

The pharmacy had two large medical refrigerators. These were clean and stock inside was stored in an organised manner. The team checked the temperature of the fridges daily. Temperature records confirmed that the fridges were operating between two and eight degrees Celsius as required.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has all the equipment and facilities it needs for providing its services. And it monitors its equipment to help provide assurance that it is in safe working order.

Inspector's evidence

The pharmacy had up-to-date written reference resources available. These included the British National Formulary (BNF) and BNF for Children. The internet provided the team with further information. Computers were password protected and the layout of the premises protected information on computer monitors from unauthorised view.

The pharmacy held bags of assembled medicines in two areas. Medicines for delivery were stored in the dispensary. Medicines waiting for collection were stored on shelves to the side of the medicine counter. Access beyond the medicine counter was protected by a heavy-duty gate and hatch. But it was possible to read some information on bag labels due to the way assembled bags were facing. This was bought to the attention of the counter assistant who acted to review the placement of the bags. The pharmacy team used a cordless telephone handset. This meant they could move out of ear-shot of the public area when having confidential conversations with people over the telephone.

The pharmacy used clean, crown stamped measuring cylinders for measuring liquid medicines. These included separate measures for use with methadone. Pharmacy team members calibrated the Methasoft machine daily as part of the set-up process. And in case of malfunction, the machine was covered through a support contract. Disposable cups and a good supply of equipment for the needle exchange service was stored safely in the pharmacy. The pharmacy had clean counting equipment for tablets and capsules. It monitored its equipment. For example, electrical equipment was subject to portable appliance testing.

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.