General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Wainfleet Chemist, 3 High Street, Wainfleet, SKEGNESS, Lincolnshire, PE24 4BS

Pharmacy reference: 1034325

Type of pharmacy: Community

Date of inspection: 04/09/2019

Pharmacy context

This is a community pharmacy in a small rural market town close to the Lincolnshire coast. The pharmacy sells over-the-counter medicines and dispenses NHS and private prescriptions. It offers 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.

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	2.5	Good practice	Pharmacy team members are empowered to make suggestions about how the pharmacy provides its services. And the pharmacy listens to and uses this feedback to inform the safety and efficiency of its services.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	4.2	Good practice	The pharmacy undertakes clinical audits for high-risk medicines. It uses the information gathered in audits to evaluate the outcomes for people taking these medicines.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy identifies and manages the risks associated with its services. It keeps people's private information secure. And it responds appropriately to feedback it receives. Pharmacy team members work with surgery teams to support people's access to medicines. They act openly and honestly by sharing information when mistakes happen. And they demonstrate a sound understanding of how to recognise and report concerns relating to vulnerable people. The pharmacy generally keeps all records it must by law. But some gaps in the responsible pharmacist record has resulted in incomplete audit trails.

Inspector's evidence

The pharmacy had a set of up-to-date standard operating procedures (SOPs). The superintendent pharmacist reviewed SOPs every two years. And had very recently implemented a new set of superseding SOPs in the style of flowcharts with supporting information contained within each individual SOP. They were clear and easy to read. And they included the roles and responsibilities of pharmacy team members. Pharmacy team members were currently working through the SOPs and signing to accept they had read and understood them. The previous version of SOPs which contained some completed training records was also available for inspection.

Pharmacy team members had clearly defined roles and worked within their scope of competencies. The medicine counter assistant explained what tasks could not be carried out should the responsible pharmacist (RP) take absence from the premises. And the dispenser discussed aspects of her job role and was observed working in accordance with dispensing SOPs. Workflow in the dispensary was efficient with separate space used for labelling, assembly and accuracy checking. The pharmacy had a separate designated space to the side of the dispensary for completing workflow associated with the supply of medicines in multi-compartmental compliance packs. This helped limit the risk of distraction when managing tasks associated with this high-risk service.

Pharmacy team members took ownership of the mistakes they made during the dispensing process by engaging in feedback with the pharmacist at the time they were identified. Following this feedback an entry in the near-miss error reporting record was made. And this entry was signed by both the team member and pharmacist. Entries did not include details of contributory factors to help identify trends. And the pharmacy didn't undertake documented near-miss reviews. But the RP, who was the superintendent pharmacist, explained how he reviewed the record regularly to help identify patterns in mistakes. And both the dispenser and RP demonstrated actions taken to reduce risk following mistakes. For example, separating 'look alike and sound alike' (LASA) medicines on the dispensary shelves. The RP explained how he was considering acting by further separating prednisolone and prochlorperazine following a recent near-miss.

The pharmacy had an incident reporting procedure in place. And the RP explained how he would manage and record an incident. The pharmacy had not had a need to report any recent incidents. But the RP explained how a very close near-miss had prompted reflection, shared learning and risk-reduction actions to separate different strengths of tramadol on the dispensary shelves. The RP explained how he followed a process of checking the medicine before applying a mental break. He went

back to check it a second time as he bagged the medicine and found this was an effective risk management strategy.

The pharmacy had a complaints procedure in place. And it provided details of how people could leave feedback or raise a concern about the pharmacy through its practice leaflet. Pharmacy team members were attentive to the needs of people visiting the pharmacy. For example, they were observed liaising with surgery teams on behalf of people whose prescriptions had not been received through the Electronic Prescription Service (EPS). The team explained the pharmacy had not received any formal concerns for some time. Most feedback related to medicine availability. And the RP discussed how he managed this by speaking with the GP surgery and notifying them of stock issues and suggesting suitable alternatives. The pharmacy also engaged people in feedback through an annual 'Community Pharmacy Patient Questionnaire'.

The pharmacy had up-to-date indemnity insurance arrangements in place through the National Pharmacy Association (NPA). The RP notice contained the correct details of the RP on duty. Entries in the responsible pharmacist record were not completed in accordance with requirements. This was due to one pharmacist signing-in but not signing-out of the register when his role as RP ceased at the end of the day. A discussion took place about the requirement to manually sign-out of the electronic RP record maintained by the pharmacy. Samples of specials records and private prescription records complied with legal and regulatory requirements. The sample of the controlled drug (CD) register examined was compliant with legal requirements. The pharmacy maintained running balances of CDs and these were checked monthly against physical stock. Methadone balances were checked every couple of weeks. A physical balance check of MST Continus 60mg tablets complied with the balance in the register.

The pharmacy displayed a leaflet explaining how it managed people's personal information. Pharmacy team members discussed and demonstrated working processes designed to protect people's confidentiality. The pharmacy had submitted its annual NHS Data Security and Protection (DSP) Toolkit annually as required. It kept all personal identifiable information in staff only areas of the pharmacy. A cabinet in the consultation room was locked at the end of the working day and the room was protected from unauthorised access due to the layout of the premises. The pharmacy shredded confidential waste onsite.

The pharmacy had procedures and information relating to safeguarding vulnerable adults and children. The RP on duty had completed level three safeguarding training and the regular locum pharmacist had completed level two training. All staff had completed some learning on the subject including reading procedures and discussing reporting needs. And they had all completed training to become a dementia friend through the Alzheimer's Society initiative. Pharmacy team members were knowledgeable about how to recognise and report safeguarding concerns. The pharmacy had some systems in place to support vulnerable people. For example, checks to ensure multi-compartmental compliance packs had been collected. If these were not collected the pharmacy team made checks with surgeries about the person's health and wellbeing. The pharmacy also facilitated some weekly dispensing regimens.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough skilled and knowledgeable people working to provide its services effectively. It supports the learning needs of its team members and promotes access to continual learning. Pharmacy team members engage in regular conversations relating to risk management and safety. They are empowered to make suggestions about how the pharmacy provides its services. And the pharmacy listens to and uses this feedback to inform the safety and efficiency of its services.

Inspector's evidence

On duty at the time of the inspection was the RP, a dispenser, the medicine counter assistant and the delivery driver. The pharmacy also employed another two qualified dispensers and a trainee dispenser. A non-pharmacist director provided administration and business support to the pharmacy. And the pharmacy used a regular locum pharmacist to cover the superintendent's days off each Friday and Saturday and to cover holiday periods. All pharmacy team members worked part-time which provided some flexibility for covering leave.

The trainee dispenser was enrolled on an accredited training course. Pharmacy team members were committed to ongoing learning. And they demonstrated how they completed regular learning booklets associated with common ailments and healthy living promotions. The medicine counter assistant had recently completed her qualification. She explained she had received time at work to complete her course and had received full support when completing this training. For example, the pharmacist would sit down and go through her training needs regularly with her. The pharmacy did not have a formalised appraisal system in place. But pharmacy team members on duty confirmed they received regular feedback and support through informal discussions.

Pharmacy team members were observed listening to people's needs and they referred people to the pharmacist when required. The RP explained that he did not set any targets for the services provided. Pharmacy team members supported pharmacists by identifying people who may benefit from a service or conversation with the pharmacist and brought these to the attention of the RP during the dispensing process.

The pharmacy team communicated largely through small informal briefings throughout the working day. And pharmacy team members confirmed they could fully contribute to these discussions. But the pharmacy did not record the outcomes of these discussions. This meant that staff not on duty at the time could potentially miss out on these shared learning opportunities. The pharmacy had a whistleblowing policy in place. Pharmacy team members explained they were confident in sharing feedback or raising concerns if required and explained how they would do this. And they stated they felt fully supported and engaged in providing services. The RP worked closely with the locum pharmacist and had acted upon a number of suggestions to help inform the way in which the pharmacy delivered its services. For example, improvements to the system in place for managing owings.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is clean, secure and maintained to the standards required. 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 was on the high street, and within a local conservation area. The pharmacy was professional in appearance and it was secure. The public area was accessible to people using wheelchairs and pushchairs. There was a clearly sign-posted consultation room. The room was a good size and professional in appearance. And pharmacy team members used the room with people requiring a private conversation throughout the inspection.

The dispensary was a sufficient size for the level of activity carried out. And pharmacy team members managed work space well. Work benches and floors were free from clutter. And the pharmacy was clean throughout. The RP confirmed a cleaner was employed to complete cleaning duties during opening hours. To the back of the dispensary was an overflow stock room, another large store room and staff facilities. On the first-floor level was an office.

Pharmacy team members reported maintenance issues to the superintendent pharmacist. And local tradespeople carried out repairs when necessary. There were no outstanding maintenance issues at the time of inspection. The pharmacy had a thermometer in the dispensary to monitor room temperature. And it had appropriate heating and ventilation arrangements. Lighting throughout the premises was sufficient. Antibacterial soap was readily available at designated hand washing sinks.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's services are easily accessible to people. The pharmacy has procedures to support its team members in delivering its services. And it has responded swiftly during unforeseen circumstances to ensure people receive continual access to their medication. The pharmacy undertakes clinical audits for high-risk medicines. It uses the information gathered in these audits to measure the outcomes for people taking these medicines. The pharmacy obtains its medicines from reputable sources. And it manages them appropriately to help make sure they are safe to use.

Inspector's evidence

The pharmacy was accessed through a simple push/pull door at street level. Details of its opening times and services were clearly advertised. The pharmacy had a hearing loop which was awaiting set up. The RP explained he had invested in this recently to increase accessibility. The pharmacy was working towards becoming healthy living accredited. It displayed details of national health campaigns which helped to engage people in conversation about their health and wellbeing. Pharmacy team members discussed the popularity of some of the health campaigns, such as children's oral health. The pharmacy team understood the requirements to signpost people to another pharmacy or healthcare provider if it was unable to provide a service.

The pharmacy team members demonstrated a good sense of community spirit and were friendly to people visiting the pharmacy. The pharmacy had reacted quickly during the town's recent troubles, caused by flooding. It had supported people by making emergency supplies of medicines to people who had to evacuate their homes urgently. And it had assisted other people whose medicines had been destroyed by the floods. The pharmacy team explained a local surgery in the town had closed in 2018. This had meant the pharmacy had become busier and people often attended for advice about their symptoms. Pharmacy team members promoted self-care where appropriate.

The pharmacy had good processes in place for identifying and counselling people on high-risk medicines. The pharmacy displayed the requirements of both the valproate and isotretinoin pregnancy prevention programmes (PPPs) in its dispensary. And valproate warning cards were readily available to issue to people in the high-risk group. The pharmacist annotated patient medication records (PMRs) with details of the counselling he had provided to people. The pharmacy also recorded its clinical interventions. And these records included recording INR monitoring details. The RP printed these records and reviewed them periodically. He explained this allowed him to follow up with surgeries or people taking the medicines if required. For example, checks were made to ensure suitable changes were applied to a prescription for a person identified to be taking multiple anti-platelet medicines. The RP also demonstrated how the pharmacy had risk-assessed the placement of high-risk medicines within the dispensary to reduce the risk of a mistake occurring during the dispensing process.

The surgery provided prescriptions to the pharmacy automatically for people enrolled on the multi-compartmental compliance pack service. 'When required' items, not dispensed into packs were not assembled until the point of collection. The RP explained how the pharmacy team checked if people required all their medicines when collecting. And the pharmacy marked prescriptions for items not dispensed. This helped to reduce the risk of people building up an excess supply of medicines. And it

had a positive cost impact to the NHS. Individual profile sheets were in place for each person on the service. And changes to medication regimens were recorded. The pharmacy completed one backing sheet for the first pack each month. It then photocopied this sheet and attached a copy to the remaining three packs. Packs were annotated individually with details of start dates. A sample of assembled packs contained full dispensing audit trails. The pharmacy provided descriptions of the medicines inside the pack to help people identify them. And it supplied patient information leaflets at the beginning of each four-week cycle of packs.

The pharmacy had recently started to dispense medicines to a care home. Prescriptions were managed in a very similar way to the community multi-compartmental compliance pack service. The home ordered their repeats through the pharmacy. This allowed the pharmacy to chase missing prescriptions and queries. The pharmacy produced the labels and ordered stock once it had received and checked the prescriptions. It then picked medicines for the packs against the stock ordered. The pharmacy dispensed one person's medication at a time to avoid any risk of cross-contamination of medicines between prescriptions during the dispensing process. It supplied medication administration records (MARs) to the home. And patient information leaflets were supplied at the beginning of each cycle. The RP explained how additional supporting information for high-risk medicines was supplied to the home, including paraffin safety leaflets for emollient preparations.

The pharmacy used coloured baskets throughout the dispensing process. This kept medicines with the correct prescription form and helped inform workload priority. Pharmacy team members signed the 'dispensed by' and 'checked by' boxes on medicine labels to form a dispensing audit trail. The pharmacy team kept original prescriptions for medicines owing to people. The team used the prescription throughout the dispensing process when the medicine was later supplied. It issued dockets for all owed medicines. And there was a robust audit trail in place for managing owings. People returning to the pharmacy without their issued docket were asked to sign for receipt of their owed medicine. The pharmacy's delivery driver demonstrated the audit trails for the prescription delivery service and most people signed to confirm they had received their medicine. The driver explained how he would sign on behalf of some people, if they could not sign. And the delivery driver explained how the pharmacy occasionally agreed to post medicines following a discussion with the person and information received to confirm it was safe to do so. For example, no children or animals could access the posted medicines. But the checks taken to assess the risk of this process were not documented within the delivery SOP.

The pharmacy sourced medicines from licensed wholesalers and specials manufacturers. Pharmacy team members demonstrated an awareness of the aims of the Falsified Medicines Directive (FMD). The RP demonstrated a scanner which had been ordered but had not yet been fitted. And the pharmacy had registered with SecurMed. The pharmacy stored Pharmacy (P) medicines behind the medicine counter. This meant the RP had supervision of sales taking place from his checking area. And he was able to intervene if necessary. The pharmacy stored medicines in the dispensary in an organised manner. Very occasionally medicines were stored outside of their original packaging and this practice was discouraged. The pharmacy kept a running list of short dated medicines it identified during monthly stock checks. And pharmacy team members annotated the opening date on to bottles of liquid medicines. This allowed them to apply checks during the dispensing process to ensure the medicine remained fit for purpose. No out-of-date medicines were found during a random check of dispensary stock.

The pharmacy held CDs in secure cabinets. Medicines were kept in a safe and orderly manner inside both cabinets. There was designated space for storing patient returns, and out-of-date CDs. The pharmacy marked all CD prescriptions which prompted additional checks of these high-risk medicines, including each prescriptions validity period. The pharmacy used two fridges to store medicines. Stock

inside the dispensary fridge was exceptionally organised and easy to find. A fridge in the consultation room was used to store bags of assembled medicines waiting for collection or delivery. Temperature records confirmed the fridges were operating between two and eight degrees Celsius as required.

The pharmacy had medical waste bins and CD denaturing kits available to support the team in managing pharmaceutical waste. The pharmacy received drug alerts through email. And it printed and retained details of actioned alerts along with 'Drug safety Updates' provided monthly by the Medicine & Healthcare products regulatory Agency (MHRA).

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for providing its services. It regularly monitors its equipment to help provide assurance that it is in safe working order. And pharmacy team members manage and use equipment in a way which protects people's confidentiality.

Inspector's evidence

The pharmacy had up-to-date written reference resources available. These included the British National Formulary (BNF) and BNF for Children alongside other clinical reference books. Pharmacy team members also had access to the internet which provided them with further resources. The pharmacy's computers were password protected and information on computer monitors was protected from unauthorised view due to the layout of the pharmacy. The pharmacy stored assembled bags of medicines in totes behind the medicine counter. This protected people's private information on prescriptions and bag labels from unauthorised view. Pharmacy team members used NHS smart cards to access people's medication records. And they used cordless telephone handsets. The RP was observed moving out of earshot of the public area when discussing confidential information over the telephone.

Clean, crown stamped measuring cylinders were in place for measuring liquid medicines. And these included a separate measure for use with methadone. The pharmacy had clean counting equipment for tablets and capsules, including a separate counting triangle for use when counting cytotoxic medicines. This triangle was stored in a separate basket along with methotrexate 2.5mg tablets. The pharmacy had a certificate on display in the dispensary. This provided evidence that portable appliance testing was up to date. The pharmacy had the necessary equipment readily available to support the supply of medicines in multi-compartmental compliance packs. This included a machine which de-foiled medicines from blister packs.

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.