

Registered pharmacy inspection report

Pharmacy Name: Modi Pharmacy, 118 Colley Gate, HALESOWEN,
West Midlands, B63 2BU

Pharmacy reference: 1038351

Type of pharmacy: Community

Date of inspection: 06/08/2019

Pharmacy context

This community pharmacy is located on a main road leading directly to Halesowen town centre. The surrounding area is a mix of residential properties and other retail units including a local convenience store. The pharmacy dispenses prescriptions and it provides medicines in multi-compartment compliance aids to help make sure people take their medicines at the right time. Several other NHS services are also available including Medicines Use Reviews (MURs), the New Medicine Service (NMS), and a substance misuse treatment service. The pharmacy had recently changed ownership prior to the inspection.

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	1.7	Standard not met	The storage location of some prescriptions may mean that some personal data is visible to members of the public, which could increase the likelihood of confidentiality breaches.
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	The pharmacy's current processes for the assembly of multi-compartment compliance aid packs introduces some unnecessary risks, including contamination. And the pharmacy cannot always demonstrate that it conducts appropriate risk assessments to make sure that deliveries of medicines are safe and secure.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy asks for feedback so that it can review suggestions and make improvements to its services. It keeps the records it needs to by law and it has some written procedures to help make sure the team completes tasks safely. But these are not always updated to reflect current practice, so the team might not always work effectively. The pharmacy has some systems in place to help keep people's private information safe. But it is not always clear how it meets some data protection requirements to show how it uses and processes people's personal data. And some patient identifiable data may be visible to the public, which could breach confidentiality.

Inspector's evidence

A set of written standard operating procedures (SOPs) were available on the premises. The procedures had a review date of August 2019 and had been produced by the previous owner. Consequently, some of the information contained within the procedures was no longer reflective of current practice as certain systems were no longer available for use and contact details were inaccurate. This may mean that team members are not always able to complete tasks effectively. The pharmacist, who was also the superintendent pharmacist (SI) said that he would make it a priority to review the procedures and update them accordingly. The team were aware of their roles and were observed to work within their competence. They demonstrated an understanding of the tasks and activities which were permissible in the absence of the responsible pharmacist (RP). The pharmacist provided confirmation in writing that insurance covering pharmacy services was provided through the National Pharmacy Association (NPA).

Near misses were recorded electronically. Only the pharmacist currently had access to the system which may restrict the ability for team members to record and learn from their own mistakes. The pharmacist confirmed that there had been 'one or two' near misses since he had taken over, but these had not been recorded and the team were unaware of any previous changes that had been made in response to near misses. The pharmacist confirmed that the details of any dispensing incidents would be recorded using the electronic system, no such incidents had occurred since the change of ownership.

The pharmacist confirmed that he would be responsible for investigating any concerns which were raised. The details of the complaint procedure had not been updated to reflect the change in ownership and there was no advertisement in patient facing areas, so people might not always be aware of how they can raise a concern. The pharmacy had previously participated in a Community Pharmacy Patient Questionnaire (CPPQ) and previous results appeared positive.

The correct RP notice was conspicuously displayed near to the medicine counter. The RP log was compliant, as were records for private prescriptions, emergency supplies and specials procurement records, which provided an audit trail from source to supply. Controlled drugs (CD) registers kept a running balance and a balance check had been carried out at the change of ownership. A patient-returns CD register was in use and previous destructions were signed and witnessed.

Several information governance procedures were available and pharmacy team members were completing a workbook covering the General Data Protection Regulation (GDPR). A privacy notice

displayed the details of the previous owner. The pharmacist reported that he had registered with the Information Commissioner's Office, but confirmation of this and an updated privacy notice could not be provided on the day. The team demonstrated a general understanding of confidentiality. They segregated confidential waste into designated bags for removal by a waste contractor and were in possession of their own NHS Smartcards. One newly employed team member was in the process of completing the necessary paperwork to obtain a smartcard. Completed prescriptions were stored out of public view. However, prescriptions with medications which were owing were placed on shelves in the dispensary. Whilst this was out of view of the medicines counter, the shelves were in direct view of any person entering the dispensary to access the consultation room, which was located at the rear of the premises. When walking through the details of patient's names and prescribed medications were clearly visible which could breach patient confidentiality.

The pharmacist had completed level two safeguarding training through the Centre for Pharmacy Postgraduate Education (CPPE) and a dispenser provided an appropriate response to a safeguarding scenario which was posed. Concerns regarding vulnerable people were referred to the pharmacist and the contact details of local agencies were displayed in the dispensary, these were undated, but the team believed that they had recently been reviewed to confirm accuracy. The details of a chaperone policy were displayed at the entrance to the consultation room.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to manage the current dispensing workload and team members work in an open culture. They receive training for their roles, but structured ongoing learning and development is lacking. So, the team may not always be able to show how they keep their knowledge and skills up-to-date.

Inspector's evidence

On the day of the inspection, the regular pharmacist was working, alongside two dispensers, one of whom was a trainee who had been employed for approximately four-weeks. Both dispensers worked part-time, and one was providing cover for the regular full-time dispenser, who was on annual leave. The pharmacy also employed two additional part-time dispensers and two delivery drivers. As most team members worked part-time, they were able to provide additional cover when required and the pharmacist reported that he would be reviewing the staffing levels to ensure that they were sufficient. The team expressed that the current workload was manageable but previous months had been more difficult. Following the departure of the previous pharmacy manager, the pharmacy had been reliant on locum cover in the interim period prior to the change of ownership. On the day, there were a few prescriptions from the previous day which were waiting to be dispensed. These were repeat prescriptions, for which stock had been ordered.

A dispenser discussed the types of questions that she would ask to help make sure a sale was appropriate. This included identifying symptoms, any medications which had already be tried and whether the patient was taking any regular medications. Concerns were referred to the pharmacist. The dispenser was unaware of some high-risk medications which may be susceptible to abuse, but said that as she was still training, she was referring sales to the pharmacist and team members were seen to approach the pharmacist when they were unsure.

There was limited ongoing training provided by the pharmacy. A dispenser reported that she would read in her own time about any new products or upcoming changes, but no protected learning time was available. Team members had previously had development reviews and the pharmacist discussed plans to meet with staff to review their development and address any potential training needs.

The team were seen to work openly during the inspection, they appeared comfortable in discussing issues as well as highlighting any areas for improvement and were happy to approach the new regular pharmacist. The pharmacist confirmed that he had not set any targets for professional services.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is clean and well maintained. It has a consultation room to enable it to provide members of the public with an area for private discussions. But this is not clearly advertised, so people may not always be aware of its availability.

Inspector's evidence

The pharmacy's premises including the external facia were well maintained and in a good state of repair. The pharmacist was responsible for arranging any necessary maintenance work and the pharmacy team members completed daily cleaning duties. The premises were generally clean and tidy on the day and there was adequate lighting throughout. An air conditioning unit maintained a temperature appropriate for the storage of medicines.

The retail area had chairs available for use by people less able to stand and the floor space was clear from any obstructions. There were health promotion displays located in various areas and pharmacy restricted medicines were secured from self-selection. The pharmacy had a consultation room located at the rear of the premises. There was no noticeable signage to promote the availability of the room, which may mean that people are not always aware that the pharmacy can provide an area for confidential discussions. The room was spacious and appropriately maintained.

The dispensary was of an adequate size for the current workload. There was a good use of shelving for medicine storage and sufficient work bench space to allow for the segregation of dispensing and checking. A separate sink was available for medicines preparation and was equipped with appropriate hand sanitisers. And additional storage areas and WC facilities were also appropriately kept.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy gets its medicines from reputable sources. It stores them appropriately and carries out some checks to make sure that they remain fit for supply. The pharmacy advertises some of its services, but restrictions to the entrance of the premises means that services may not always be accessible to everybody. It manages some services suitably but current processes for the assembly of multi-compartment compliance aid packs introduces some unnecessary risks, including contamination. And the pharmacy cannot always demonstrate that it conducts appropriate risk assessments to make sure that deliveries of medicines are safe and secure.

Inspector's evidence

The pharmacy had a single step to the front. No ramp facility was available and team members reported that one wheelchair bound patient could not access the premises and instead knocked the entrance door to gain assistance from staff. There was limited advertisement of the pharmacy's services in the entrance window and an up to date practice leaflet was not yet available. The pharmacy team had access to some information to support signposting, including some health promotion literature which was displayed and printed local area contacts.

Prescriptions were separated into baskets to help prevent medicines from being mixed up. Pharmacy team members signed 'dispensed' and 'checked' boxes as an audit trail for dispensing. The pharmacist discussed checks that he would make for people prescribed high-risk medications, to make sure that appropriate monitoring and counselling was provided. But records of monitoring parameters such as INR readings were not maintained as an audit trail to demonstrate this. Team members had a general awareness of the risks of the use of valproate-based medicines in people who may become pregnant. But they were not familiar with certain requirements of recent guidance produced by the Medicines and Healthcare products Regulatory Agency (MHRA) and copies of safety materials were not available on the day. The inspector provided advice on how to obtain the materials and the requirements of their provision.

Pharmacy team members were observed to take repeat prescription requests directly from patients and via the telephone. They kept a record using the patient medication record (PMR) system of which medications had been requested. And a paper audit trail was also used to identify unreturned requests. Where medications were owing, the pharmacy did not always produce owing notes for patients. These were only usually provided to people who were waiting in the pharmacy for their prescription and might mean that owing's are not always managed as effectively as they could be.

Medications for people using multi-compartment compliance aid packs were ordered by a dispenser. The team on the day were unfamiliar as to the exact process used. Each patient had a master record of medication, which was updated with the detail of any changes. There were several unsealed compliance aid packs being stored on the main work bench. The packs were partially completed but were missing some medications which had been ordered from the wholesaler and needed to be added. This could increase the risk that packs become mixed up and could increase the chances of contamination. Completed packs contained patient identifying details, the backing sheets provided descriptions of individual medicines, but no audit trail was recorded for dispensing, so those involved in

the process may not be identifiable. The team reported that patient leaflets were supplied.

Where possible, signatures were obtained to confirm the delivery of medicines. The delivery driver signed on behalf of people who were unable to do so themselves. There were instances where medication was posted through letterboxes or left in porches, sometimes following a verbal request. The team said that they would ask questions to ensure no children or pets were on the premises but did not keep a record of this. And no audit trails were kept demonstrating that adequate risk assessments had been conducted. The driver also stated that on occasion medications were left with neighbours, it could not be established whether patients had always consented to this. The driver said that this was sometimes done in response to neighbours offering to accept the delivery as they knew the patient was out.

Stock medicines were sourced through reputable wholesalers and specials from a licensed manufacturer. Stock was arranged in an organised manner. Medications were usually stored within their original packaging. But two examples were seen of medication being packed down into a brown medicine bottle. These were labelled with the name and strength of medicine but contained no details of batch number and expiry. The medications were removed from the shelves on the day. The team discussed the date checking systems, describing a traffic light system where short-dated medications were highlighted. But records to confirm this could not be located. No out-of-date medicines were identified from random samples on the day. Expired and returned medicines were placed into medicines waste bins. A cytotoxic waste bin for hazardous materials was not available and a small number of hydroxycarbamide capsules were located in a standard medicine waste bin. These were segregated, and the pharmacist agreed to remedy this. The pharmacy was not currently compliant with requirements as part of the European Falsified Medicines Directive (FMD). Equipment had been acquired as part of the change of ownership and the pharmacist was unaware if appropriate scanners were available or whether the necessary software was in place. The pharmacist was strongly advised to review this and check the actions that were required in order to become compliant. Alerts for the recall of faulty medicines and medical devices were received via an electronic reporting system. Examples were seen confirming that the most recent MHRA alerts had been acknowledged and addressed.

The pharmacy fridge was fitted with a maximum and minimum thermometer, the temperature was checked and recorded daily and was within the recommended temperature range. CDs were stored appropriately with expired CDs segregated from stock. Random balance checks were found to be correct and CD denaturing kits were available.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services and equipment is suitably maintained. But the computer screens may sometimes be visible to people accessing the consultation room, which could impact on confidentiality.

Inspector's evidence

The pharmacy had appropriate equipment, including glass crown-stamped and ISO approved measures. The measures were generally clean and were clearly marked to indicate their use. Counting triangles were available for loose tablets and a separate triangle was used for cytotoxic medicines. The pharmacy had access to some pharmaceutical reference texts and had internet access to facilitate further research.

Electrical equipment was in working order and had been subject to PAT testing in 2018. Computer systems and additional alert systems were all password protected. Screens were located out of view of the medicine counter but were visible to people who may be passing through the dispensary to access the consultation room. The team reported that the screen would be minimised at these times to reduce the risk of confidential information being seen. A cordless phone enabled conversations to take place in private, if required.

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.