

# Registered pharmacy inspection report

**Pharmacy Name:** Western Elms Pharmacy, 351-353 Oxford Road,  
READING, Berkshire, RG30 1AY

**Pharmacy reference:** 1028990

**Type of pharmacy:** Community

**Date of inspection:** 03/08/2021

## Pharmacy context

This is a community pharmacy on a busy main road in a multicultural area of Reading, Berkshire. The pharmacy dispenses NHS and private prescriptions, sells a range of over-the-counter medicines, and provides health advice. It also offers the New Medicine Service (NMS), local deliveries and a pharmacy-led COVID-19 vaccination service. The inspection took place during the COVID-19 pandemic. It was carried out jointly with NHS England in response to some concerns about the vaccination service.

## 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
<b>1. Governance</b>	Standards not all met	1.1	Standard not met	The pharmacy is not identifying and managing several risks associated with its services as indicated under the relevant failed standards and Principles below. There is no evidence that the team has read and understand the pharmacy's standard operating procedures. The pharmacy has not been managing its COVID-19 vaccination service safely or in line with the appropriate operating procedures and legal mechanisms. And it has inadequate systems in place to help prevent the spread of infection from COVID-19.
		1.2	Standard not met	The safety and quality of the pharmacy's services are not regularly reviewed and monitored. The pharmacy is unable to fully demonstrate that it records all its mistakes, monitors and informs others or learns from them.
		1.6	Standard not met	All necessary records to verify that pharmacy services are provided safely should be readily available for inspection. The pharmacy has been unable to demonstrate that it has been keeping all the records it requires to prove this. At the point of inspection, the pharmacy was unable to locate any records to verify that it had been recording supplies of unlicensed medicines as required by law. And, there were no records available about the COVID-19 vaccination service.
		1.7	Standard not met	The pharmacy is not protecting the privacy, dignity and confidentiality of patients and the public who receive its services. The pharmacy has been inappropriately storing and leaving confidential information in the retail space for people using the pharmacy's COVID-19 vaccination service. Team members frequently share each other's passwords and there were no information governance processes seen.
<b>2. Staff</b>	Standards not all	2.4	Standard not met	The pharmacy does not have a culture of openness, honesty and learning. The

Principle	Principle finding	Exception standard reference	Notable practice	Why
	met			pharmacy has no independent whistleblowing process in place where the team can feel comfortable to raise concerns. And there are no resources provided to the staff to help keep their skills and knowledge current.
		2.5	Standard not met	Members of the pharmacy team are not empowered to provide feedback and raise concerns about meeting the GPhC's standards and other aspects of the pharmacy services. Staff are reluctant and fearful to raise issues in front of management or to discuss concerns for fear of losing their jobs. A culture of fear exists.
<b>3. Premises</b>	Standards not all met	3.1	Standard not met	The pharmacy's services are not provided from an environment that is appropriate for the provision of healthcare services. The pharmacy is unclean and it is cluttered. This includes the storage areas and part of the retail space. There is evidence that the pharmacy is risking unauthorised access to medicines and needlestick injury from how it is currently storing used sharps and medicines returned by the public for destruction.
		3.3	Standard not met	The pharmacy's premises are not maintained to a level of hygiene appropriate to the services it provides. The pharmacy is dirty. It is not being cleaned regularly. This includes the toilets and the handwashing facilities. And the pharmacy's processes to keep people safe from infection during and after having their COVID-19 vaccination are inadequate.
<b>4. Services, including medicines management</b>	Standards not all met	4.4	Standard not met	The pharmacy cannot fully verify that it has the appropriate procedures in place to raise concerns when medicines or medical devices are not fit for purpose. The pharmacy is not always opening emails about the drug alerts issued by the Medicines and Healthcare products Regulatory Agency. And it cannot demonstrate that it has actioned the drug alerts appropriately.

Principle	Principle finding	Exception standard reference	Notable practice	Why
<b>5. Equipment and facilities</b>	Standards met	N/A	N/A	N/A

## Principle 1 - Governance Standards not all met

### Summary findings

The pharmacy doesn't effectively manage all the risks associated with its services. This includes the risks from COVID-19. The pharmacy has instructions to help with this. But it cannot show that its staff have read them. This could mean that they are unclear on the pharmacy's current processes. The pharmacy does not adequately protect people's private information. And, it has not been able to show that it is maintaining all of its records, in accordance with the law or best practice. Members of the pharmacy team generally deal with their mistakes responsibly. But they are not always recording all the necessary details. This could mean that they may be missing opportunities to spot patterns and prevent similar mistakes happening in future.

### Inspector's evidence

At the time of the inspection, the pharmacy had a range of documented standard operating procedures (SOPs) but they were from the previous ownership, dated from 2016 and had been signed by the team in 2018. The inspector saw updated electronic versions issued by the present owner, but they had not been signed and there were no roles defined for the staff. This meant that it was not possible to verify whether all the members of the pharmacy team had read and, understood them, or knew which ones were specific to their tasks. In addition, there were no SOPs on site about the COVID-19 vaccination service. The company's operation manager arrived shortly after the inspection started and opened up the electronic versions on screen. However, they had also not been signed by the team. An incorrect notice to identify the pharmacist responsible for the pharmacy's activities was on display. This is a legal requirement and should have been changed at the start of the responsible pharmacist's shift. The inspection took place in the early afternoon and the notice was also not visible to anyone standing in the retail area.

The inspector saw limited systems in place to identify and manage the risks associated with COVID-19. Hand sanitisers were present for staff to use. The premises had been modified (see Principle 3), there were various posters on the door including one asking people to wear masks. There were also markings on the floor to indicate where people could stand to observe social distancing. However, there were too many markers in the central aisle that were within 10cm of each other on the floor. It was unclear which side of the pharmacy was for the usual services and which was for the COVID-19 vaccination service. The inspector with the colleague from NHS England & Improvement (NHSE&I) upon entering the pharmacy were not spoken to, directed or marshalled by the only volunteer in the retail space. As a result, the inspector and NHSE&I colleague walked down the wrong aisle and were in the way of people exiting from the consultation room after they had received their COVID-19 vaccination. This led to people hesitating and appearing to be concerned about crossing paths with each other.

Not all the team members were wearing masks, some staff had their mask on incorrectly which gave no protection to the wearer or to other people using the pharmacy. The pharmacy was dirty (see Principle 3) and there were limited infection control processes seen in place. The inspector saw that the chairs in the retail space were not being wiped down in between people using them for the COVID-19 vaccination service. And the consultation room was not cleaned in between use. The inspector noted that as the pharmacist was letting each person out of the consultation room, the next person was immediately called in. Staff confirmed that the pharmacy was not cleaned regularly, they said that they wiped down the pharmacy's surfaces when they could, but a deep clean had not been undertaken.

Members of the pharmacy team also confirmed that they had not had any risk assessments completed for COVID-19. This included occupational ones despite some members of the team being from the Black, Asian and ethnic minority (BAME) group so possibly at greater risk.

The pharmacy was cluttered and there was a risk of unauthorised access to medicines (see Principles 3 and 4). There was outdated and incorrect information on display about the pharmacy's complaints process. This meant that people may not have been able to raise any complaints easily. The dispensary had an adequate amount of workspace, but the rear bench was full of baskets waiting to be assembled. Staff said that they separated medicines which were similar and used dividers, but the team had been only sporadically recording their near miss mistakes. There was information missing or incomplete details recorded. Although the near miss mistakes had been reviewed every month, there was little documented evidence of any learning happening. In addition, some incidents had not been reported to the appropriate authorities.

Staff had been trained on safeguarding vulnerable people. They knew who to refer to in the event of a concern. The responsible pharmacist (RP) had been trained to level 2 through the Centre for Pharmacy Postgraduate Education (CPPE). The pharmacy had details on display about data protection, but the information related to the previous ownership. Confidential waste was separated and removed by an authorised contractor. However, at the inspection, the pharmacy had left confidential information visible in the retail space. This was people's sensitive personal data for the COVID-19 vaccination service. The volunteer had a list of people's names and details at the check-in desk by the front door and the pharmacist who was vaccinating was leaving people's assessments and vaccination record sheets on a table by the medicines counter. The inspector noted that none of this information was covered or protected, it was freely accessible to anyone entering the pharmacy and frequently left unattended by both the volunteer and pharmacist. This meant that unauthorised access to confidential information was possible. In addition, staff confirmed that they used each other's NHS smart cards to access electronic prescriptions. They knew each other's passwords and one smart card had been left in the computer terminal by a member of staff who was not present. This terminal was being used at the inspection. No processes to verify the pharmacy's information governance systems were seen.

Some of the pharmacy's records were compliant with statutory and best practice requirements. This included a sample of registers seen for controlled drugs (CDs). On randomly selecting CDs held in the cabinet, their quantities matched the stock balances recorded in the corresponding registers. Records of CDs that had been returned by people and destroyed at the pharmacy were complete and the pharmacy had suitable professional indemnity insurance arrangements in place. Records verifying that fridge temperatures had remained within the required range had been appropriately completed. However, the RP record had missing details, records about emergency supplies made at the request of people did not have the nature of the emergency recorded. A few incorrect details about prescribers had been documented within the electronic private prescription register or details were missing. And staff could not locate any records to verify that supplies of unlicensed medicines had been made appropriately. In addition, there were no records present at the pharmacy about the COVID-19 vaccination service (see Principle 4). This included information about who had been the vaccinating or supervising pharmacist on any given day or records about the stock of COVID-19 vaccines.

## Principle 2 - Staffing Standards not all met

### Summary findings

The pharmacy does not have a culture of openness, honesty, or learning. There appears to be a culture of fear where members of the pharmacy team are unable to openly discuss or raise concerns about the company or the pharmacy's internal workings. This could mean that issues are not being dealt with appropriately. And, the pharmacy team is not provided with any resources to keep their skills and knowledge up to date. But the pharmacy has enough staff to manage its usual workload safely. And the team is appropriately trained.

### Inspector's evidence

At the inspection, the pharmacy team included the RP who was a locum pharmacist and two, appropriately trained, dispensing assistants. The pharmacy manager had recently left the company's employment and there was a part-time medicines counter assistant who also worked at another of the company's pharmacies in the area. Staff for the COVID-19 vaccination service included a volunteer from the Royal Volunteer Service and a pharmacist who was vaccinating people. The latter said that she usually worked at another branch. The pharmacy's team members said that they were up to date with the workload and that they normally covered each other as contingency.

However, the inspector was told that the COVID-19 vaccination service did not always have enough independent staff to manage this service. The pharmacy team was not informed beforehand about who the vaccinator would be and only found out on the day. They did not verify the identity of the vaccinator. The superintendent (SI) had confirmed in earlier assurance visits with the NHS that two volunteers would be present at each of their sites, one would marshal and direct people, whilst the other would enter data. Staff said that the volunteers did not always turn up, so they had to take on their role in addition to their usual tasks. This had happened the day before the inspection as no volunteers had arrived and the COVID-19 vaccination service had been fully booked. The pharmacy staff were also responsible for entering data about people using the COVID-19 vaccination service. The latter did not always happen on the day and staff said that they had only just caught up with this task.

The company's operation manager arrived shortly after the inspection started. He said that his coming to the pharmacy was usual, but the staff said that they hardly saw him. They also became very fearful to talk to the inspector and NHSE&I when he arrived and were reluctant to speak frankly in front of him. After taking them to one side, the team members said that they couldn't raise concerns easily, there were no whistleblowing processes in place where complaints could be raised and dealt with confidentially or independently of the owner or superintendent. The staff also told the inspector and NHSE&I that they feared for their jobs if they raised a concern relating to the internal workings of the pharmacy. They felt that they were constantly being watched and listened to because of the CCTV cameras which were also in staff areas.

Staff knew which activities were permissible in the absence of the RP and when to refer appropriately. They used an appropriate sales of medicines protocol before selling over-the-counter medicines. Team members said that they had regular performance reviews. However, they had no access to resources for ongoing training and no material provided by the company to keep their knowledge up to date.

## Principle 3 - Premises Standards not all met

### Summary findings

The pharmacy's premises are inadequate for delivering the level of healthcare services it provides. The pharmacy has introduced some measures to help reduce the spread of COVID-19 inside its premises. But the pharmacy does not have a satisfactory cleaning rota. This has left the pharmacy cluttered and dirty. And it is not good enough for people using its services. The pharmacy is also leaving unlocked boxes containing used sharps in the retail space, putting people at risk of a needle stick injury.

### Inspector's evidence

The pharmacy's premises consisted of a medium sized retail space and smaller dispensary. Staff and storage areas were to the rear and to one side of the medicines counter. The dispensary had an adequate amount of space to carry out dispensing tasks safely. However, at the point of inspection, most of the rear bench was cluttered, as was the storage area and corridor leading to the fire exit. This was full of clinical waste, medicines returned by the public for destruction and confidential waste requiring collection. Additional boxes of medicines returned by the public had also been stored in the retail space alongside unlocked sharps bins containing used boxes of needles. Although this area had a partial barrier around it that staff had created using hazard signs, it was inadequate to prevent people accessing them. This meant that there was a risk of unauthorised access to used medicines and a risk of needle-stick injury, particularly for children. This section of the pharmacy also had several boxes of the lateral flow tests for COVID-19 and an unlocked room with more supplies, including for the needle exchange service. The former looked unprofessional and the latter led to a further risk of unauthorised access.

The pharmacy had a sign-posted consultation room that was small but of an adequate size for its intended purpose. It contained lockable cabinets and appropriate equipment. The premises had been adapted to help prevent the spread of infection from COVID-19. There were several chairs in the retail space that during the inspection were predominantly being used for the COVID-19 vaccination service. They had clear, perspex barriers in between them. A screen had also been placed in front of the medicines counter to help shield the staff. However, at the point of inspection, the pharmacy was dirty. This included the floor, the toilets and all three sinks for hand washing purposes. Two of the sinks were filthy and black with grime. This included the one by the toilets. It was clear that they had not been cleaned for some time. As documented under Principle 1, infection control processes were also not being followed for the COVID-19 vaccination service.

## Principle 4 - Services Standards not all met

### Summary findings

The pharmacy does not always provide its services safely. It cannot fully demonstrate that it has been taking the appropriate action in response to safety alerts. This risks people receiving medicines and devices that are not safe to use. And the pharmacy's team members are not making any checks to help people with higher-risk medicines take their medicines safely. But the pharmacy obtains its medicines from reputable sources.

### Inspector's evidence

People could enter the pharmacy from the street through a wide, front door. There was enough space inside the retail space for people with wheelchairs or restricted mobility to use the pharmacy's services although space inside the consultation room was limited. There were several seats in the retail space for people to wait or to use for the COVID-19 vaccination service. There was no parking available outside the pharmacy as it was situated on a red route. Staff said that queues did build for the pharmacy's services, people had to wait outside and around the corner. There was no cover outside the pharmacy to provide shelter from any adverse weather. Team members stated that if people called or came inside to ask about how long the wait was, they asked them to wait in one of the nearby supermarket car parks, but they did not 'queue-bust' or tell people about this otherwise. The RP explained that the team wrote information down to help people who were partially deaf. They also used 'google translate' for people whose first language was not English and would seek advice from other pharmacy support organisations if needed. Staff had access to information where they could signpost people to other services if required. The pharmacy's retail space had plenty of information present but most of it was conflicting information with details of the previous ownership present. This could be misleading and make it difficult for people to know who to contact.

The pharmacy was providing a COVID-19 vaccination service. It had posters in the window to indicate this. There were many people inside the pharmacy waiting for this service and a volunteer was present, to check people's names off as they arrived. The clinic that was running was for the vaccine manufactured by AstraZeneca. As described under principle 1, the pharmacy had no signed SOPs on site. The pharmacy also had no paperwork or records on site to verify who had been vaccinating people or supervising the service. This included details of the legal mechanism under which the vaccinations were being administered. There were no records with the sign-off sheets for the patient group direction (PGD) or for the national protocol. The operations manager was asked to provide this following the inspection and the SI sent the details through after a second request. Pre-registration trainees were listed in this. For the latter, the inspector was told by the staff at the inspection that the RP drew up the doses into the syringes ready to be administered but then the pre-registration trainees delivered the rest of the service in full. Subsequent information sent by the SI to NHSE&I confirmed that this had been happening. However, this process was not fully in line with the national protocol.

The pharmacy fridge in the dispensary was used to store the COVID-19 vaccine. This was lockable and large enough for this purpose. However, at the inspection, there were two types of the COVID-19 vaccine present, the one manufactured by Moderna and the other by AstraZeneca. The different brands of the COVID-19 vaccine had not been separated and were stored side by side and on the same shelf as the pharmacy stock. There were no records at the pharmacy about the vaccines that had been received. The pharmacy's staff confirmed that they had not been making any records or keeping any records

about the stock that they held. They only marked the date the vaccine had been received on the front of the packaging and at the end of each day reported the remaining quantity to the SI. This meant that the pharmacy had not kept separate logs about the batch numbers and expiry dates for each vaccine that had been received. The inspector and NHSE&I were also told that data entry was not live and that double bookings happened often.

The inspector and NHSE&I asked the vaccinating pharmacist about her process for the COVID-19 vaccination. On several points however, the inspector had to prompt her about what she should have been checking, asking, or counselling people about before and after administering the vaccine. This pharmacist said that she was based at another branch. She was operating under, and had signed the PGD, but she had no details with her at the time. This was advised during the inspection. The consultation room contained adrenaline vials for use in the event of an allergic reaction to the vaccine. However, no defibrillator was seen. The COVID-19 vaccination service is an NHS funded service and commissioned by NHSE&I. The evidence and concerns seen were shared with NHSE&I who are now managing this situation.

The pharmacy provided multi-compartment compliance packs to only a few people who needed controlled drugs or required any changes to their medicines. The remainder had been transferred to the company's hub in Reading. The team ordered prescriptions on behalf of people. They identified any changes that may have been made, said that they updated their records to reflect this and queried with the prescriber if required. The compliance packs were not left unsealed overnight after they had been prepared. Patient information leaflets (PILs) were routinely supplied but descriptions of the medicines inside the compliance packs did not always match the actual medicine.

The workflow involved prescriptions being prepared in one area and the same space was also used to assemble the few compliance packs that were prepared at the pharmacy. The RP checked medicines for accuracy from another section. The team used baskets to hold prescriptions and medicines during the dispensing process. This helped prevent any inadvertent transfer between them. After the staff had generated the dispensing labels, there was a facility on them which helped identify who had been involved in the dispensing process. Team members had largely been using these as an audit trail.

Once prescriptions had been assembled, checked for accuracy, and bagged, they were stored within a retrieval system. Stickers were used to identify fridge items and CDs. But the team had not been identifying people with higher-risk medicines. Staff had not been routinely asking for details about relevant parameters, such as blood test results for people prescribed these medicines or keeping any records about this. This included sodium valproate. Although the team was aware of the risks associated with valproates and there was literature available to provide to people at risk, this literature had been stored in the stock room and there was no evidence that it was actively being used.

The pharmacy's stock in the dispensary was generally stored appropriately. However, there were prescription-only medicines stored in the stock room which were in direct sunlight. The pharmacy's stock room also held a large amount of stock. The pharmacy used licensed wholesalers such as AAH, Alliance Healthcare, Phoenix, Sigma and Quantum Specials to obtain medicines and medical devices. The team date-checked medicines for expiry regularly and kept records of when this was done. Short-dated medicines were identified. There were no date-expired medicines or mixed batches seen. Medicines returned for disposal, were accepted by staff, and stored within designated containers. The containers had been stored as described under Principle 3. People requesting to return sharps or needles were appropriately referred elsewhere unless they were part of the needle exchange scheme. Staff said that they received drug alerts through the company's internal network and described actioning them appropriately. However, there were several emails on the pharmacy's email system that

had not been opened and the team could not locate any records to verify that the process had been followed.

## Principle 5 - Equipment and facilities ✔ Standards met

### Summary findings

The pharmacy has the appropriate equipment it needs to provide its services safely. And it only just keeps its equipment clean enough.

### Inspector's evidence

The pharmacy's equipment included current versions of reference sources, counting trays, legally compliant CD cabinets, an appropriately operating pharmacy fridge and conical measures. However, some of the latter could have been cleaner. The pharmacy had hot and cold running water available and internet access. Computer terminals were positioned in a manner that prevented unauthorised access.

### What do the summary findings for each principle mean?

Finding	Meaning
<span style="color: green;">✔</span> <b>Excellent practice</b>	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.
<span style="color: green;">✔</span> <b>Good practice</b>	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
<span style="color: green;">✔</span> <b>Standards met</b>	The pharmacy meets all the standards.
<b>Standards not all met</b>	The pharmacy has not met one or more standards.