General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Paydens Ltd, Gateway House, Wallis Avenue, Maidstone, Kent, ME15 9NE

Pharmacy reference: 9011382

Type of pharmacy: Closed

Date of inspection: 17/06/2021

Pharmacy context

The pharmacy offers a 'hub and spoke' service and supplies medicines in multi-compartment compliance packs to a large number of other pharmacies in the group. These pharmacies then supply these packs to people who live in their own homes to help them manage their medicines. The pharmacy also supplies pharmacy-only medicines and General Sales List medicines online (www.expresschemist.co.uk). And it offers other services, including chlamydia treatment and seasonal influenza vaccinations. It also provides medicines as part of the Community Pharmacist Consultation Service. And it holds a wholesale dealer licence and a Home Office license which allows it to supply some medicines to a local hospice. The inspection was carried out during the Covid-19 pandemic.

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	1.2	Good practice	The pharmacy records and regularly reviews any mistakes that happen during the dispensing process. It uses this information to help make its services safer and reduce any future risk. It carries out regular audits of its online services to ensure that these continue to be provided safely.
2. Staff	Standards met	2.2	Good practice	Team members undertake structured ongoing training to help keep their knowledge and skills up to date. And they get time set aside to complete it.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	4.2	Good practice	The pharmacy manages its services well and there is a clear focus on patient safety. And it makes changes to its services so that its medicines can be supplied at a distance safely. The pharmacy uses its dispensing robot's systems in a way which helps make its service safer for people.
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. And it is good at monitoring and reviewing the safety of its services on an ongoing basis. It provides its services safely. And it protects people's personal information well. People are able to provide feedback about the pharmacy. The pharmacy keeps the records it needs to keep by law, to show that its medicines are supplied safely and legally. And team members understand their role in protecting vulnerable people.

Inspector's evidence

The pharmacy adopted measures for identifying and managing risks associated with its activities. It had carried out risk assessments for supplying its services at a distance and also carried out workplace risk assessments in relation to Covid-19. And it had documented, up-to-date standard operating procedures (SOPs). Team members had signed to show that they had read and understood the SOPs.

The pharmacy routinely recorded near misses, where a dispensing mistake was identified before the medicine had reached a person. Team members were asked to identify their own mistakes before recording them on the company's electronic reporting system. The near misses were reviewed regularly for any patterns and learnings were shared throughout the company. Items in similar packaging or with similar names were separated where possible to help minimise the chance of the wrong medicine being selected. And shelf edges were highlighted to show where these medicines were kept. This helped to minimise the chance of the wrong medicine being selected. The pharmacy had recently received a report which showed the number of near misses the pharmacy made, compared to other pharmacies in the company. The responsible pharmacist (RP) explained that the number of near misses had reduced since the pharmacy had used dispensing robots.

Dispensing errors, where a dispensing mistake had reached a person, were recorded on the company's electronic reporting system. A root cause analysis was undertaken and any incidents were reported to the pharmacy's head office. A recent incident had occurred where a tablet had moved to the next slot in one of the multi-compartment compliance packs while being handled. The error was noticed by a team member at the 'spoke' pharmacy and was not supplied to the person. The spoke pharmacy rectified the error before the pack was supplied to the person. The pharmacist explained that the robot took pictures of all completed packs and the picture for this pack showed that it was correctly dispensed by the robot. Team members were reminded to handle the packs with care while removing them from the robot.

Following the last GPhC inspection, the pharmacy had carried out a clinical review in February 2020. Risk assessments had been carried out, including data security, medicine delivery and record keeping. Any action required was recorded by the clinical governance officer. A second audit was carried out in March 2021, and any improvements or changes were highlighted. The pharmacist had implemented near miss record and review processes for the online services. This was specific to the online systems and was different to the near miss processes for the main dispensary. The online service did not dispense medicines so the record and reviews were tailored to suit the online nature of the business.

There was ample workspace in the dispensary and it was free from clutter. There was an organised workflow which helped staff to prioritise tasks and manage the workload. There were separate

workstations for different tasks. Baskets were used to minimise the risk of medicines being transferred to a different prescription. The team members signed the dispensing label when they dispensed and checked each item to show who had completed these tasks. The accuracy checking technician (ACT) explained that black ink was used to initial the dispensing label in the 'dispensed by' box and coloured pen when it had been checked. And she knew which prescriptions she could check and knew that she should not check items if she had been involved with the dispensing process.

Team members' roles and responsibilities were specified in the SOPs. The RP explained that all team members could access the building and most could only access the area of the pharmacy they worked in. But the pharmacists and ACT could access all areas. The RP said that there were several pharmacists that worked in the pharmacy's head office in the building near to the pharmacy and they could provide cover where needed. And the pharmacist that worked in the online department could also provide cover if needed. The ACT said that she would not carry out any dispensing or checking tasks until there was a RP signed in.

The pharmacy had current professional indemnity and public liability insurance to cover all of its services. The RP log was completed correctly and the correct RP notice was clearly displayed. Controlled drug (CD) registers examined were filled in correctly, and the CD running balances were checked at regular intervals. The recorded quantity of one CD item checked at random was the same as the physical amount of stock available. There were signed in-date Patient Group Directions for the testing and treatment of chlamydia and for the influenza vaccination service. The nature of the emergency was routinely recorded when a supply of a prescription-only medicine was supplied in an emergency without a prescription. This made it easier for the pharmacy to show why the medicine was supplied if there was a query. The ACT explained that the pharmacy only made supplies against private prescriptions when the pharmacy had received the original prescription. The private prescription record was largely completed correctly, but the correct prescriber details were not always recorded. This could make it harder for the pharmacy to find these details if there was a future query. The RP said that he would ensure that this would be completed correctly in the future.

Patient confidentiality was protected using a range of measures. Confidential waste was shredded, computers were password protected and the people using the pharmacy could not see information on the computer screens. Smartcards used to access the NHS spine were stored securely and team members used their own smartcards during the inspection. Team members had completed training about the protecting people's personal information. The pharmacy sent people a letter to request consent for their medicines to be dispensed at the hub pharmacy. A record of consent was noted on their medication record at the spoke pharmacies. The hub pharmacy only received eMARs (Electronic Medication Administration Records) from people who had provided consent. The pharmacy's privacy policy was displayed on its website which explained how the pharmacy kept people's personal information secured.

The pharmacy's complaints procedure was available for team members to follow if needed and details about it were available on the pharmacy website. People could use the online complaint form or contact the pharmacy by phone or email if they wished to provide feedback about its services. The pharmacy also used an external site to gather feedback about its services. The ACT said that the hub pharmacy had not received any recent complaints.

The pharmacists and the ACT had completed the Centre for Pharmacy Postgraduate Education (level 2) training about protecting vulnerable people. Other team members had completed level one safeguarding training. The pharmacist providing the online service explained how the pharmacy routinely safeguarded people who were buying medicines online. And she said that there had not been any recent safeguarding concerns at the pharmacy. The pharmacy had contact details available for

agencies who dealt with safeguarding vulnerable people.

Principle 2 - Staffing ✔ Standards met

Summary findings

Team members are provided with structured ongoing training to support their learning needs and maintain their knowledge and skills. And they get time set aside in work to complete it. The pharmacy has enough trained team members to provide its services safely. And it increases the number of staff to ensure that its workload is well managed. They feel able to raise any concerns or make suggestions and this means that they can help improve the systems in the pharmacy. Team members can take professional decisions to ensure people taking medicines are safe.

Inspector's evidence

There was one pharmacist who was the RP, one ACT and seven dispensers working in the hub on the day of the inspection. And there was one pharmacist, six 'packers' and four office team members working in the online pharmacy area. Most team members had completed an accredited course for their role and the rest were undertaking training. There had been an increase in the workload during the pandemic, so additional people had been employed to ensure that this was managed safely. And team members could work additional hours where needed. The teams worked well together and communicated effectively to ensure that tasks were prioritised and the workload was well managed. The RP explained that the delivery driver and another non-dispenser had been enrolled on an approved dispenser course so that they could provide cover where needed.

The pharmacists and ACT were aware of the continuing professional development requirement for the professional revalidation process. And they felt able to take professional decisions. Team members had access to online training and this was monitored by the RP. Each team member had their own training folder and kept a record of all training undertaken. The pharmacy's head office had newly appointed a training and development manager to ensure that all team members had completed the necessary training. Team members were allowed protected time to complete training during the day. If team members did not have time to complete training during work hours, they could request one hour paid study time so this could be completed at home. This had been recently implemented and the changes were supported by the pharmacy's head office.

The teams had informal morning 'huddles' to discuss any issues and allocate tasks. Information was usually passed on informally during the day. And there were formalised team meetings held around every three months, or sooner if needed. Team members had yearly appraisals and performance reviews, and these were documented. They felt comfortable about discussing any issues with the pharmacists or making any suggestions. The pharmacist providing the online services explained the improvements which had been made since the last inspection. And she felt fully supported with making these changes. The pharmacy regularly received updates and information from the pharmacy's head office. And the team had a good working relationship with the SI and could discuss any issues with him directly. The SI and the newly appointed compliance officer visited the pharmacy during the inspection. Targets were not set for team members. The pharmacy provided the services for the benefit of the people using the pharmacy.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises provide a safe, secure, and clean environment for the pharmacy's services. People are able to contact the pharmacy and speak with the pharmacist in private.

Inspector's evidence

The pharmacy was secured from unauthorised access. All areas in the pharmacy were bright, clean and tidy. The hub area was large enough for the workload and there was also room to expand. The area of the pharmacy where the online supplies were made was on a separate floor in the building. This area was also large and the office areas were separate from where the medicines were kept. Air-conditioning was available throughout the pharmacy and the room temperatures were suitable for storing medicines.

The consultation room used for private services such as vaccinations, was on the ground floor. The room was accessible to people using a wheelchair. It was suitably equipped and blinds were used to cover the external window. Conversations at a normal level of volume in the consultation room could not be heard from outside the room.

Toilet facilities were clean and not used for storing pharmacy items. There were separate hand washing facilities available. The staff area and kitchen were clean and also not used for storing pharmacy items.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy provides its services safely and manages them well. And it regularly reviews the types of medicines it provides online, to help make sure that it can provide them safely. The pharmacy gets its medicines from reputable suppliers and stores them properly. It responds appropriately to drug alerts and product recalls. This helps make sure that its medicines and devices are safe for people to use. People with a range of needs can access the pharmacy's services.

Inspector's evidence

The online pharmacy services and hub were not physically accessible to people using the pharmacy. People could access the pharmacy's consultation room for some services. Medicines ordered online were sent to people in discreet packaging by recorded delivery. The pharmacy website provided details about the delivery services, including contact phone numbers for people to use if they had any queries about their delivery. There were separate phone lines for the online pharmacy and the hub. And the pharmacist providing the online services had a separate phone line so that she could easily contact people if needed. The pharmacy's website had been updated recently to help make it clearer and better presented. It provided information about some health-related conditions and showed medicines which may be used to help relieve symptoms or treat the condition.

People had to complete a questionnaire if they wished to purchase a pharmacy-only medicine online and this was reviewed by a pharmacist before the medicine was supplied. Additional questionnaires were emailed to people for certain medicines to ensure that these were being supplied safely. The pharmacist said that she would contact a person if she had a query about a medicine which they had ordered online. This could be done via email or the text messaging service which had been recently implemented. The pharmacy had recently implemented identity checks which had to be submitted to the pharmacy before the supply was made of a pharmacy-only medicine. People were asked to submit a copy of their photographic ID with their order. If this was not done at the time of ordering, they were prompted to do this before the supply was made. The admin team checked that the address and post code on the person's ID matched the delivery address. A copy of the person's ID was uploaded onto the shared drive so that the admin team and pharmacist had access to it. A record of all communication to and from people who had ordered medicines was kept.

People were routinely asked to provide consent so that the pharmacist to check their Summary Care Record (SCR), and check that the medicine they had ordered online was suitable for them to take. If a person had requested to purchase more than one pack of a medicine, the pharmacist could check the person's SCR to see if the medicine had been recommended by their GP. The pharmacist assessed each request for a medicine on an individual basis. The pharmacy kept a record of access to the SCR, refusals, potential for misuse, referrals, self-care and complaints. The pharmacist sent people advisory notes which were tailored specifically to them and how they were to take their medicine. All invoices were signed by the pharmacist to show that they had authorised the supply, before the medicines were packaged and dispatched. The pharmacy monitored the online sales and subsequent re-ordering of medicines which could be misused or abused. The pharmacy could check the person's order history using their account details. And regular audits were carried out for medicines sent to a specific address or to a named person. The pharmacy routinely verified payment methods and checked for fraudulent activity. The pharmacy regularly reviewed which medicines were suitable to be offered for sale online.

One medicine had been removed from sale due to the potential for this to be misused. The internet services manager explained how the pharmacy's online system grouped certain medicines together if they contained the same, or similar medicines. This helped the pharmacy to minimise the chance of someone purchasing similar medicines. He regularly checked and updated the pharmacy's computer system to restrict medicines being sent to certain countries. And he mentioned that some countries customs would inform the pharmacy about certain prohibited items.

Orders for online sales of medicines were printed and team members selected stock against these. The pharmacy-only medicines were passed to the pharmacist for checking. Once these had been authorised, the items and paperwork were then packed, scanned and weighed. This helped to ensure that only the items on the order were in the packaging. If the parcel was not the expected weight, this would be highlighted and passed to the pharmacist to check. The pharmacy's admin team regularly checked which countries the pharmacy was allowed to send medicines to and kept the pharmacy team updated. Refusals for sales to these countries were made by the admin team and the pharmacist was informed.

The pharmacy provided seasonal flu vaccinations and these were provided against Patient Group Directions (PGD). The pharmacist said that these were largely provided to staff from the company, but occasionally these were also given to other people. There were signed in-date PGDs for the services. And the pharmacist had undertaken all necessary training, and completed the consultation skills and declarations of competence. The pharmacy also supplied treatment for chlamydia against a PGD. Referrals were received from sexual health clinics for these supplies.

The RP working in the hub said that any clinical checks for prescriptions were carried out at the spoke pharmacy. The hub did not dispense higher-risk medicines, such as warfarin or methotrexate, and these were dispensed at the spoke pharmacies. Medicines with limited stability were dispensed by the spoke pharmacies. The pharmacy only dispensed fridge items to the hospice and these were checked when handed over. Fridge items were kept in blue clear plastic bags to aid identification and CDs were kept in red clear plastic bags. This helped the drivers to identify these medicines and highlight these when handing them over. The RP said that the pharmacy did not currently make supplies of valproate medicines to people. He said that he would ensure that if there was someone in the at-risk group who needed to be on the Pregnancy Prevention Programme, he would speak with them about this and make notes on their medication record. The RP confirmed that the relevant patient information leaflets and warning cards would be provided every time a valproate medicine was supplied.

Stock was stored in an organised manner in the dispensary. Expiry dates were checked every three months and this activity was recorded. Stock due to expire within the next three months was marked. There were no date-expired items found in with dispensing stock and medicines were kept in their original packaging. The pharmacy kept lists for short-dated items and these were removed from dispensing stock around one month before they were due to expire. The pharmacy had teamed together with a recycling company and it recycled the foil packs the medicines were received in. The pharmacy donated the money from this to charity. The quarterly pharmacy newsletter had an article about how the pharmacy could reduce its environmental impact.

Medicines in the dispensing robot were photographed, weighed and measured before being placed in the machine. A description of the medicine, including the colour was recorded on the robot's computer system. If the robot did not recognise a dispensed medicine, it would highlight this so it could be manually checked. The medicines were dispensed into a 'pod' which was labelled and then placed into the robot. The robot was able to detect any errors when the 'pod' was placed into the machine. The pharmacy provided feedback to the robot manufacturer and the pharmacist said that any issues were

attended to by the manufacturer usually the following day.

The RP explained that the spoke pharmacies were responsible for ensuring the necessary assessments were carried out to show that people needed their medicines in multi-compartment compliance packs. The pharmacy did not order prescriptions on behalf of people who received their medicines in multi-compartment compliance packs. This process was managed by the spoke pharmacies. The pharmacy received emails with lists of people who were due to have their packs dispensed. The pharmacies used eMAR sheets to show which medicines were needed and what time of day people needed to take their medicines. The clinical checks were carried out at the spoke pharmacy and the required information from the prescription was added to the pharmacy's computer system. The RP said that the information was received in advance so that any issues could be addressed before people needed their medicines. The pharmacy had access to the spoke pharmacy's patient medication records and could check information where needed. The RP said that the spoke pharmacies kept a record for each person which included any changes to their medication and kept any hospital discharge letters for future reference. The spoke pharmacies would inform the hub about any late changes to prescriptions prior to the packs being sent. These packs would usually be dispensed in the spoke pharmacy so that the person received their medicines on time. Packs were largely dispensed by the robot, but some were dispensed by hand if a medicine was not in the robot. The robot helped the dispenser identify which medicines were to be added to the pack. Team members scanned the medicine pack before dispensing it into the pack and the robot confirmed whether the correct medicine had been selected. The compartments where the medicines were to be placed were highlighted green and the rest were red. The robot informed team members about how many to put in each compartment. Packs were suitably labelled and there was an audit trail to show who had dispensed and checked each pack. Medication descriptions were put on the packs to help people and their carers identify the medicines and patient information leaflets were routinely supplied. The robot took a photo of the completed packs and this helped the pharmacy to investigate any mistakes. Team members wore gloves when handling medicines that were placed in these packs.

CDs were stored in accordance with legal requirements and they were kept secure. Denaturing kits were available for the safe destruction of CDs. CDs that people had returned were destroyed appropriately and recorded in a register with two signatures to show that the destruction was witnessed.

Deliveries from the hub were made by delivery drivers. The hub only delivered items to other pharmacies in the company or to the hospice. A nurse in charge of the ward would sign for deliveries made to the hospice. All deliveries were made during opening hours. The delivery driver was supplied with personal protective equipment including aprons, masks and gloves.

The pharmacy used licensed wholesalers to obtain medicines and medical devices. Drug alerts and recalls were received from the NHS and the MHRA. Any action taken was recorded and kept for future reference. This made it easier for the pharmacy to show what it had done in response.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely. And it uses its equipment to help protect people's personal information.

Inspector's evidence

Up-to-date reference sources were available in the pharmacy and online. Triangle tablet counters were available and clean, and a separate counter was marked for cytotoxic use only. This helped avoid any cross- contamination. Tweezers were available so that team members did not have to touch the medicines when handling loose tablets or capsules. And team members routinely wore disposable gloves while dispensing medicines.

Personal protective equipment was available throughout the pharmacy. Team members wore masks while in the pharmacy. But there was ample space between workstations which also helped minimise the spread of infection. There were hand sanitisers throughout the pharmacy and at the entrance. The shredder was in good working order. The dispensing robots were maintained by the manufacturer. The RP said that any maintenance issues were usually addressed within 24 hours.

Fridge temperatures were checked daily, and maximum and minimum temperatures were recorded. Records indicated that the temperatures were consistently within the recommended range. The fridge was suitable for storing medicines and was not overstocked.

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.