General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Medix Pharmacy, 84 High Street, STEVENAGE, Hertfordshire, SG1 3DW

Pharmacy reference: 1032309

Type of pharmacy: Community

Date of inspection: 15/05/2019

Pharmacy context

The pharmacy is situated in the High Street of the Old Town. There are two parts to the pharmacy's activities. During the day, it dispenses NHS and private prescriptions to people in the local community and it has a travel clinic. Several people have prescriptions dispensed which are issued by the drug and alcohol team. The pharmacy offers a prescription delivery service to the surrounding villages, as well as the town. It also supplies medicines in multi-compartment compliance packs to people who need this support, though this had been suspended during the refit. At the time of the inspection, there were plans to provide cosmetic services as well. During the night, the pharmacy operates as an online pharmacy, led by the superintendent pharmacist, providing a dispensing service for people living outside the UK.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; Statutory Enforcement

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	1.1	Standard not met	The pharmacy does not adequately identify and manage the risks associated with the provision of medicines to people overseas. It has not fully assessed the risks associated with this service. It cannot show that it undertakes adequate checks to make sure that processes delegated to other parties protect the health and wellbeing of patients. And some of the supplies it makes do not comply with current UK law. • The pharmacy supplies veterinary prescription only (POM-V) medicines against prescriptions written by a non-RCVS qualified practitioner (to overseas patients). This is unlawful. • The pharmacy supplies human licensed prescription only medicines (POMs) for animals against prescriptions by a non-RCVS qualified practitioner (to overseas patients). This is unlawful. • The pharmacy cannot demonstrate how the identities of patients are checked. • The pharmacy cannot demonstrate that there are adequate processes to ensure higher-risk medicines, including methotrexate and misoprostol, are supplied safely.
		1.2	Standard not met	The pharmacy cannot show how it monitors the safety of the prescriptions it dispenses to ensure the medicines provided are safe for the patient they are sent to. It relies on another organisation to do these checks. And the pharmacy cannot show how it has satisfied itself that these checks are always made. It does not make records of the checks made.
		1.3	Standard not met	Pharmacy professionals involved in the supply of medicines overseas do not fully understand their responsibilities or accountabilities. The superintendent pharmacist is relying on other organisations to carry out professional checks to make sure that the medicines the pharmacy supplies are safe and appropriate. But the pharmacy cannot show that these checks are undertaken appropriately.
		1.6	Standard not met	The pharmacy does not make accurate or complete records about the supplies it makes

Principle	Principle finding	Exception standard reference	Notable practice	Why
				of prescription-only medicines to patients overseas. Its records do not comply with UK law. The pharmacy cannot always show what it has dispensed for people overseas. And it does not keep delivery records to show what it has sent to people overseas.
		1.8	Standard not met	The pharmacy does not have adequate systems to safeguard the welfare of vulnerable people overseas who receive its services.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	Some of the information provided to the public about the pharmacy and its services on the website www.medixpharmacy.co.uk is misleading. For example, but not exclusively, the MHRA link implies that the website is owned by the pharmacy.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not label medicines for people overseas with all the information required. The pharmacy doesn't always undertake appropriate professional checks to ensure supplies of medicines are lawful and safe to make. And the pharmacy does not keep adequate records, so it cannot show what it has supplied or what has been delivered.
		4.3	Standard not met	The pharmacy cannot show that it has stored medicines which require cold storage correctly.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The day-time pharmacy service is generally safe and team members understand their roles and responsibilities. But the risks associated with the pharmacy's night-time online service are not fully managed. And pharmacy professionals involved in this part of the service do not fully understand their responsibilities or accountabilities. It does not assess risks in the online business, relying on others to do so. The record keeping for the online business does not comply with legal requirements in the UK. The pharmacy does not make accurate records of the supplies it makes to overseas patients. It cannot show what has been dispensed or sent to whom. And it does not have any systems for safeguarding the welfare of vulnerable overseas people who receive its services.

Inspector's evidence

The pharmacy was visited on several occasions to identify the processes involved in this business. This inspection covers all the business carried out at the pharmacy premises.

Pharmacy activities undertaken during the day had written standard operating procedures (SOPs) to tell the team how they should undertake the work in the pharmacy. The procedures were last reviewed in 2017 and had been signed by the staff. They were generally followed. Some of the SOPs which covered the Responsible Pharmacist (RP) legislation and which are required by law could not be found. However, the day-time staff knew what to do in the absence of a pharmacist and were clear about their roles and responsibilities. The regular day-time pharmacist had no knowledge of the night-time activity in the pharmacy.

There was a separate set of SOPs to cover the night-time online service supplying medicines to people overseas. These had been signed by the night-time staff. These SOPs did not include the records that needed to be made for the night-time business. When the night-time service was discussed with the superintendent pharmacist (SI), he said he had no knowledge of the changes in GPhC guidance for registered pharmacies about supplying pharmacy services at a distance. There were no plans in place to review this service in light of the guidance. The inspection of the two parts of the business required several visits and the SI said he had suspended the online business pending the results of the inspection.

Some prescriptions dispensed through the night-time service were for animals. The prescriptions were written by a pharmacist independent prescriber (PIP) who cannot legally prescribe POM-V or human medicines 'under the cascade' for animal use. When asked why he had dispensed these prescriptions, the SI said that he had not realised that the prescriptions had been for animals.

The written procedures said that the team should log any mistakes they made in the dispensing process in order to learn from them. The team members who worked during the day had logged three in 2019. There was no evidence recorded of near-misses being made by the staff involved in the night-time service. There was a re-fit going on at the time of the first visit and this was given as the reason for the low level of recording. The day-time team said that they discussed near misses and took steps to prevent recurrences, such as separating sertraline and sildenafil, which had been a common picking error. The limited near miss recording may hinder the ability of the pharmacy to identify risks in the dispensing process, establish any patterns or trends and coaching needs, and adopt appropriate remedial actions to minimise risks.

During the hours that the pharmacy was open to the public, the pharmacy conspicuously displayed the RP notice and the record required by law was up to date and filled in correctly. There were two records kept for RP, one for the night-time activities and one for the day-time service. The timings of these did not overlap.

The pharmacy had not posted its latest customer survey information on the NHS website, and the staff could not say what learning had been taken from it. There was a complaints procedure, with a notice telling people how to make a complaint.

The pharmacy had professional indemnity and liability insurance with the NPA. It was not clear if this covered sending medicines abroad. The SI initially told the inspector that the supply of medicines to people overseas was covered by the owners of the website (AMX Holdings) which generated the business, and that his insurers were not aware of this part of his business. Later the SI said that he had checked with the NPA and said he should be covered but that he had not told them that his online business was to send medicines abroad. However, he had taken separate insurance with another provider. The treatments to be provided in the beauty clinic were not yet set up and the insurance for these services was being investigated. The RP was seeking the best cover for her and her patients. The pharmacy used CityDoc for all its current vaccination and patient group direction supplies. These services were said to be covered by their insurance.

Record keeping for both parts of the business differed considerably. The day-time pharmacy team recorded private prescriptions and emergency supplies on the PMR computer although the details of the prescriber and the date of the prescription were not always accurate. The records of private prescriptions dispensed for overseas patients were said to be made by AMX Holdings and initially supplied on a monthly basis to the SI. The private prescriptions were removed to safe storage at the end of the month, so it was not possible to check the accuracy of the records made against the prescriptions on the first visit. Those records viewed did not have all the information required by law. There was no record in the pharmacy for May 2019 prescriptions but the prescription forms were present. There was the record for prescriptions from April 2019 but no prescription forms were present. On further investigation, having received both the prescription forms and the record for June and July, there was not a clear correlation between the prescriptions seen, what was actually supplied, and the records made. The SI could not identify which prescriptions had been dispensed and which had not been. He said that if he did not dispense a prescription, he left it in the pile with the other prescriptions, without marking it. He could not explain why the prescription 'record' provided did not correlate to the prescriptions he claimed had been dispensed.

The controlled drugs (CD) registers were up to date and legally compliant. No CDs were supplied to people overseas. The fridge temperatures recorded were the current temperatures rather than maximum and minimum temperature ranges. The pharmacy was registered to do Yellow Fever vaccinations, and correct storage is imperative for these vaccinations.

The pharmacy team segregated confidential waste and it was shredded by a member of the team. Confidential material was kept in the dispensary or stock room, where it could not usually be accessed by people who should not see it. The team all had NHS smartcards but were seen to be using the card of the SI when he was not present. This meant that the team had knowledge of his PIN number which is against the terms of use of the cards. Prescriptions dispensed at night were reported to be stored off-site, but there was no evidence supplied about the security of this storage.

The RP had undertaken the required level of safeguarding training and the team were aware of what to do if they were worried about a local customer. In the past they had flagged their concerns to the police about a matter. The team had ready access to local contact telephone numbers if they needed to report

a concern about a vulnerable person. The safeguarding of people overseas was less clear and contacting patients would be difficult. The SI said that it would be the responsibility of AMX Holdings to do this. He said he only had a supply function.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough qualified staff to provide safe services for local people. The day-time staff have finished or are completing the right accredited training for their roles. The pharmacy does not have a formal approach to monitoring its team members development and it does not provide any training to staff beyond the required accredited training. So, it may not always be able to identify and resolve any knowledge gaps or other learning needs that its staff may have.

Inspector's evidence

The regular day-time pharmacist (the RP during the inspection) worked five and a half days each week, and she was planning to add another day to her working week in order to open the cosmetic clinic. The day-time pharmacist said she had no knowledge of supplies being made through an online service.

The SI worked part-time during the day, sometimes in the wholesaling business and sometimes in the pharmacy. He also worked at night, dispensing the prescriptions for people overseas. On occasions he had worked Friday 9am to 6 pm then 10pm to 1am overnight then again 9am to 6pm on Saturday. The SI stated that he did not require much sleep. Working for extended hours may increase the risk of mistakes due to tiredness or lack of concentration.

Other staff working during the day comprised a trainee technician, a dispenser, a counter assistant and two delivery drivers. The SI's mother did some administration jobs, and there was another administration assistant who had just started working in the pharmacy. She had been given training on the confidential nature of the role. The night-time service was undertaken by the SI, another pharmacist, and four packing staff, who were all untrained but had signed confidentiality agreements.

Those staff who were enrolled on the required accredited training courses were encouraged to complete their training, but were not provided with dedicated time to do so. They fitted it in when they could. There were no formal appraisals in place for staff and staff were not aware of what training would be available once their formal training was complete.

The RP said that she was able to give feedback to the superintendent pharmacist about the way the pharmacy was run and had made suggestions about changes which could be made. During the refit she had been left to arrange the medicines in the way she felt was best. The superintendent pharmacist did not set targets for the pharmacist.

Principle 3 - Premises **Standards not all met**

Summary findings

The premises are acceptably clean and generally provide a safe, secure and professional environment for people to receive healthcare. But some of the information provided to the public about the pharmacy and its services on the website www.medixpharmacy.co.uk is misleading. Fire-exits should always be kept clear.

Inspector's evidence

The pharmacy was being refitted during the first visit to the premises which meant that there were some areas were not as clean and tidy as the team would have liked. The day-time service being provided had been reduced to dispensing walk-in and repeat prescriptions. And no multi-compartment compliance packs were being dispensed due to the risk of contamination with dust. The fire door to the rear was locked and there was a vacuum cleaner obstructing the exit. The premises had air-conditioning.

Walk-in and repeat prescriptions were dispensed behind the counter, where staff could be seen by the public. There was a separate area where the multi-compartment compliance packs were usually dispensed. This area was quieter which helped staff to concentrate better when dispensing. A room further to the rear was used for storage and administration tasks and dispensing the overseas prescriptions. The wholesale dealing was done from a locked room at the rear of the building. This was also used to store envelopes and boxes for the online service.

The consultation room had been finished. There were chairs set round a table for pharmacy consultations but the space available was somewhat impacted by a large clinic chair. There was no sink in the consultation room which could make it harder to maintain hygiene standards when taking blood samples and vaccinating people.

The pharmacy’s name appeared on a website, www.medixpharmacy.co.uk. The website gave information to people about the pharmacy, and the pharmacy’s regulator. Medicines could be chosen before the need to produce a prescription. The SI said he did not own or control this website. He said this website was operated by AMX Holdings. The website displayed links to the MHRA medicines seller register which showed that MDX healthcare, who own the Stevenage pharmacy, could sell medicines from the site. There were also logos for Royal Mail, Secure SSL encryption, ICO, NPA. The RPS logo had been removed following the first inspection.

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

Summary findings

The services that the pharmacy provides direct to local people during the day are generally safe and effective. But the pharmacy cannot show that it has stored medicines which require cold storage correctly. The supplies that it makes to people overseas are not labelled with all the information people may need to use their medicines correctly. It doesn't always make safety checks to ensure the medicines are suitable for the people who receive them. And the pharmacy does not keep all the records it should do so it cannot clearly show what it has supplied or what has been delivered.

Inspector's evidence

During the day-time service, the pharmacy used a dispensing audit trail to identify who had dispensed and checked each item. The use of baskets helped to ensure that prescription items were kept together and were easy to move from one area of the dispensary to another. Prescriptions where the person was waiting were put into red baskets to highlight this fact. (The night-time dispensing processes have not been observed, as they were suspended before they could be seen.)

Some people were being supplied their medicines in multi-compartment compliance packs. These packs were not labelled with all the information the person needed to take the medicines in the correct way as the cautionary and advisory labels were missing. The packs had tablet descriptions to identify the individual medicines, but these were not always accurate. There was a file containing the information for each person receiving a compliance pack which recorded any changes made to their medication. Prescriptions were not kept with the unchecked trays. This increased the risk of the packs being handed out without checking against a valid prescription.

Schedule 4 CD prescriptions were not highlighted to staff who were to hand them out. This could increase the chances that these are supplied to people after the expiry date of the prescription. People taking warfarin, lithium or methotrexate bringing their prescription into the pharmacy were not always asked about any recent blood tests or their current dose. So, the pharmacy could not show that it was monitoring these people in accordance with good practice. Overseas patients supplied medicines through the night-time service were not checked at all by the pharmacy. The SI reported that the owners of the website did this, so he did not have to. Women and children who were receiving prescriptions for valproate were not routinely counselled about pregnancy prevention.

The pharmacy used CityDoc for all its current vaccination and patient group direction supplies. This included rabies, hepatitis A and B, tetanus, chicken pox, typhoid and yellow fever. Compulsory, ongoing training was supplied by CityDoc and the RP had to complete the training successfully to offer these services. The pharmacy also supplied malaria prevention treatments using a CityDoc authority. The RP performed blood tests for CityDoc, sending the samples by post or courier, depending on what the test was for. She had undertaken the necessary training for this. There were plans to provide cosmetic fillers and Botox for people. This would be against prescriptions provided by a doctor in attendance on a Sunday morning. The pharmacist had completed a course in 'Botox and Fillers' from D1 Dermal.

The night-time business was generated from a website www.medixpharmacy.co.uk. This site had been owned by the Stevenage pharmacy, but they had sold it to AMX Holdings who now owned it. AMX Holdings used a firm 'Medimart Ltd', whose head office was in the Cook Islands, to co-ordinate all the prescriptions and labels required. The supplies were sent mainly to the US and were against prescriptions signed by a UK registered pharmacist independent prescriber (PIP) who was employed by Medimart, although he was paid by the SI 'due to currency exchange issues'. The UK prescriptions were generated from prescriptions written by prescribers in the country where the patient lived.

The SI stated that he had been introduced to the UK PIP by Medimart. The PIP produced a prescription which was sent by post to the pharmacy from where the medicines were supplied. The pharmacy would enter a Medimart portal (which was IP specific) and download a scan of the original prescription, a patient information leaflet, a label, a customs declaration if needed and an invoice. The label would be pre-populated with information supplied from the original prescription by Medimart but with no cautionary or advisory labels as expected in the UK. It would have the name and address of the Stevenage pharmacy on. Patient information leaflets in the UK packet were supplied and a supplementary one was sent for the medicine and brand prescribed by the original prescriber. For example, the leaflet might be for Brilinta, the US brand of ticagrelor, but Brilique tablets supplied (the UK brand).

The SI assumed that the UK prescriber or Medimart did all the necessary clinical checks and did not think it necessary to do any himself. There was no evidence of any checks seen. No CDs were supplied, but prescriptions for Valoid, methotrexate, sodium valproate, antibiotics and other high-risk medicines were seen. The SI was vague about the clinical checks performed on these prescriptions. He said that he sometimes did a clinical check and on other occasions it was said that Medimart took care of this aspect of dispensing and that all he did was supply the medicines. One prescription seen was for a male patient with a date of birth in the future (December 2019) and was for 900 Cytotec tablets. The SI first said that he had dispensed 90 tablets, then he said that he had questioned the prescriber, then said that he could not contact him, so contacted the pharmacist at Medimart. On further questioning the SI said that he had questioned the date of birth and that it was incorrect. There was no record of any interventions made.

Once dispensed, the medicines would be packaged, ready for delivery, by staff who had not completed any accredited pharmacy training. The SI said the pharmacy in Stevenage had previously used a delivery service in Croydon where they had taken the parcels to on a daily basis. This had been done by the SI or his wife. They had since changed this and Medimart had arranged a courier to collect the parcels from the pharmacy. There were no records for any of the courier collections, who had been sent parcels, when they had been sent, or if they had been received safely by patients. There were also no records in the pharmacy of the medicines supplied to patients. Prior to the initial visit, Medimart had supplied the pharmacy with a list of what had been supplied on a monthly basis. In June and July this list had been supplied daily. But it was not clear from the signed prescriptions which had been dispensed and which had not been. (See also under Principle one.)

The day-time pharmacy got its medicines from licensed wholesalers, generally stored them in dispensary drawers and on shelves in a tidy way and did regular date checking. But not all prescription only medicines were fully protected from unauthorised access. There were 'use first' stickers on the shelves and boxes to indicate items which were short dated. Some medicines supplied to overseas

patients were obtained from the general pharmacy stock. The staff said they separated out any unusual items to put into the back stockroom for the SI. However, the SI said most of the medicines supplied to overseas patients were ordered from a separate wholesaler, Infohealth Ltd. The orders were created by Medimart and sent daily to Stevenage in cardboard boxes. The empty boxes were taken away at the end of each day.

Only the current temperatures of the medicines fridges were recorded, and not the maximum and minimum temperature ranges. This meant that the pharmacy couldn't show that medicines requiring cold storage had always been correctly stored. During the first visit, the minimum and maximum temperatures on the thermometer of one of the fridges were minus 3 degrees Celsius and 14 degrees Celsius but the recorded temperature was 3 degrees Celsius. The thermometer on another fridge was showing a range of minus 1 degree Celsius and 9 degrees Celsius but the temperature was recorded as 5 degrees Celsius. There were no temperature records for the third fridge which also contained medicines.

The pharmacy was about to change its patient medication record system to one which enabled it to comply with the Falsified Medicines Directive. Drug alerts were received, actioned and filed appropriately to ensure that recalled medicines did not find their way to people who used the pharmacy.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy generally has the right equipment for its services. It makes sure its equipment is safe to use.

Inspector's evidence

The pharmacy had a separate triangle marked for use with methotrexate tablets ensuring that dust from them did not cross contaminate other tablets.

There were various sizes of glass, stamped measures with separate ones labelled for methadone use, reducing the risk of cross contamination.

The pharmacy had access to up-to-date reference sources. This meant that people could receive information which reflected current practice.

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.