General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Chemist Corner, 3 Brook Lane, OLDHAM, OL8 2BD

Pharmacy reference: 1110431

Type of pharmacy: Closed

Date of inspection: 24/07/2019

Pharmacy context

This is a pharmacy which provides its services from a closed unit on the corner of a busy road in a residential area. People cannot visit the pharmacy in person. The pharmacy dispenses and delivers NHS prescriptions to patients homes and sells over-the-counter medicines via eBay. The pharmacy has its own website (www.chemistcorner.co.uk) which provides information about the pharmacy.

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	1.1	Standard not met	The pharmacy has not assessed key risks in relation to the sales of medicines via eBay and there is no standard operating procedure for the service.
2. Staff	Standards not all met	2.2	Standard not met	Some members of the pharmacy team are not qualified or appropriately trained for the activities they carry out.
		2.3	Standard not met	The pharmacy sells excessive quantities of medicines without challenge and without obtaining sufficient information to be able to assess whether they are safe and appropriate.
3. Premises	Standards not all met	3.1	Standard not met	There is misleading and incomplete information on the pharmacy's website and the eBay site.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy has supplied a prescription only medicine to people via eBay without a prescription which is unlawful. The pharmacy cannot demonstrate that they are obtaining information from people to ensure medicines sold on eBay are appropriate.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy adequately manages risks in relation to prescription services and completes all the records that it needs to by law. It has written procedures on keeping people's private information safe. But it does not identify and manage all of the risks involved with the sales of medicines via eBay. It does not have clear procedures in place for this service, so members of the team might not understand their roles and responsibilities and who is accountable for what.

Inspector's evidence

There were up-to-date standard operating procedures (SOPs) for most of the services provided, with signatures showing that members of the pharmacy team had read and accepted them. Roles and responsibilities were set out in SOPs. The pharmacy team members were performing duties which were in line with their role and a dispenser was clear what activities could be carried out in the presence and absence of a pharmacist.

There was a SOP for the sales of general sales list (GSL) and pharmacy (P) medicines but it did not cover the selling of medicines via eBay. The pharmacist superintendent (SI) confirmed there was not a separate SOP for this procedure. She had not carried out a risk assessment before commencing the service. She was not able to demonstrate that information was received from the customer prior to the supply of P medicines, to ensure the sales were clinically appropriate and a prescription only medicine (POM) Anusol HC ointment 30g had been offered for sale and sold on several occasions. There were no steps in place to identify that the customer was who they claimed to be, and there was no method of monitoring orders to identify inappropriate sales or quantities. The SI had not read the GPhC Guidance for registered pharmacies providing pharmacy services at a distance, despite receiving a copy by email in April 2019, and she had not reviewed any of the SOPs in light of this new guidance. The name of the responsible pharmacist (RP) was on display, but it had been covered by another notice showing a different RP, so the details were not visible. This was not in line RP regulations and could be confusing for the pharmacy team.

There was a SOP for dispensing errors and near misses. The SI said there had not been any dispensing errors which had reached the patient since she had started in role in 2017 but she would record the error on the patient's medication record (PMR) and follow the SOP, if an error did occur. A few near misses had been recorded each month and the SI explained she discussed each one with the pharmacy team at the time. Near misses had been reviewed quarterly during 2018 and an annual patient safety report had been completed. A near miss audit had been carried out in 2018 and an action introduced to minimise errors was completing duties in line with a rota, so there was 'no need to rush'. Following incidents 'check strength' alert labels were on the dispensary shelves in front of several medicines including isosorbide mononitrate and diazepam.

There was a SOP for dealing with customer complaints. How to raise concerns about the pharmacy was on the pharmacy's website. The complaints procedure and the details of who to complain to and the local Patient Advice and Liaison Service (PALS) was in the practice leaflet, which was also available via the website. A dispenser described how he would deal with a customer complaint which was to refer it to the SI, who said she would attempt to resolve the situation. She said the usual feedback was that people had not received their preferred brand of medication, when a generic had been prescribed, so

she would make a note of this on their patient medication record. A customer satisfaction (CPPQ) survey was carried out annually. The results were available on the pharmacy's website, although they were not easy to locate. Areas of strength (99-100%) was 'satisfied with pharmacy staff and services' and staff are 'polite and listen'. Areas with the lowest score (45-47%) was providing advice on stopping smoking, healthy eating and physical exercise. The pharmacy's response to the results were not published. There was a 99.8% positive feedback on eBay from 14,714 sales.

Insurance arrangements were in place. A current certificate of professional indemnity insurance was on display in the pharmacy. The SI said she believed the cover included selling medicines on eBay, but she would confirm this with the insurer provider. The RP record and the controlled drug (CD) register were appropriately maintained. Two CD balances were checked and found to be correct. Adjustments to methadone balances were attributed to manufacturer's overage following an assessment to see if the adjustment was within a reasonable range. Patient returned CDs were recorded and disposed of appropriately.

Most members of the pharmacy team had read and signed a confidentiality agreement and there were confidentiality and data protection SOPs. The SI's brother who was involved in selling medicines via eBay had not signed a confidentiality agreement or confirmed he had read any SOPs, so there may be a risk to patient confidentiality. Confidential waste was collected in a designated place and shredded. A dispenser correctly described the difference between confidential and general waste. The delivery driver obtained the recipients signature on an individual address label, to avoid them seeing other patients' details.

The SI had completed centre for pharmacy postgraduate education (CPPE) level 2 training on safeguarding. The delivery driver said he would voice any concerns regarding vulnerable adults to the pharmacist working at the time. There was a children and vulnerable adult protection policy.

Principle 2 - Staffing Standards not all met

Summary findings

The pharmacy has enough staff to manage its workload but the team members are not all qualified for the jobs they do, which increases the chances of mistakes happening. Team members get some ongoing training. But this does not happen regularly, so their knowledge may not be always fully up to date. The pharmacist superintendent can not demonstrate that she is exercising professional judgement when the pharmacy sells medicines on eBay. So some people may receive medicines which are not appropriate for them.

Inspector's evidence

There was a responsible pharmacist (SI), two NVQ2 qualified dispensers (or equivalent), and a delivery driver on duty at the time of the inspection. The staff level was adequate for the volume of work during the inspection and the team were observed working collaboratively with each other. Planned absences were organised so that not more than one person was away at a time. The dispensers worked extra hours when required to cover absences. The SI's husband assisted in the pharmacy when required. The SI explained that he had been on an accredited dispensing training course for a long time and was making slow progress. She said she did not know when he commenced the training but would check this and ensure it was completed within the specified time as stated in the GPhC's minimum training requirements. The SI worked most days in the pharmacy.

The brother of the SI was unqualified and was responsible for selling medicines via eBay. He was not on any accredited training course. The SI said the P medicines were dispatched from the pharmacy and her brother dealt only with administration and customer service issues and would refer any professional issues to her. She said she met with him most days, sometimes in the pharmacy or at an address in Manchester, where the GSL medicines were stored.

There were training records showing that the dispensers had completed some training since completing their qualifications. For example, controlled drugs in the electronic prescription service and public health campaign, but there was no structured ongoing training and team members did not have regular protected training time to ensure their training was up to date. Team members were given formal appraisals where performance and development were discussed and were given positive and negative feedback informally by the SI. Day to day issues were discussed as they arose. A dispenser said he felt there was an open and honest culture in the pharmacy and he would feel comfortable talking to the SI about any concerns he might have. He said the team were like a family and they were free to make suggestions or criticisms informally and were comfortable admitting errors. There was a whistleblowing policy.

The SI said she was empowered to exercise her professional judgement and could comply with her own professional and legal obligations. She said she authorised all sales of P medicines on eBay and would refuse to authorise a sale, if she felt it was inappropriate. But she was unable to demonstrate any input into the process. She said targets were not set for activities in the pharmacy and she didn't feel under any pressure to authorise the sales on eBay.

Principle 3 - Premises Standards not all met

Summary findings

The pharmacy premises are clean and provide a safe, secure and professional environment for people to receive healthcare from. Some parts of the pharmacy website and information on eBay are misleading, which means people may not have enough information to make an informed decision about their care.

Inspector's evidence

The pharmacy was closed to the public and the front door locked automatically when closed. The pharmacy premises were clean and in a reasonable state of repair. The lighting was adequate, but the room temperature was 27 degrees Celsius throughout the inspection, which was too high for the safe storage of medicines. It was exceptionally hot weather at the time and only expected to last a day another day. There was a fan in operation and the SI confirmed she would obtain an additional fan for the following day. The SI explained major maintenance problems would be reported to the landlord, but smaller problems which required a quick response would be dealt with locally. The premises were very small consisting of one triangular shaped room which was accessed directly from the front door. There was no back door. GSL medicines, which were supplied via eBay, were stored in a separate unit which had a different address to the pharmacy. This was because there was not enough space on the pharmacy premises. It was not inspected as part of this inspection.

The pharmacy did not have a WC or kitchen facilities. There was a dispensary sink for medicines preparation and it was also used for washing hands. There was a small boiler for hot water above the sink. The dispensers lived close by and went home at lunch time so used their own facilities. The SI used the facilities at one of the dispenser's homes if necessary.

The pharmacy website (www.chemistcorner.co.uk) had the pharmacy's GPhC registration number, name of owner, name of SI and address of the physical pharmacy. It carried the MHRA EU internet logo which authorised HI Weldricks Ltd to sell medicines on their behalf. The SI said no sales had been made through this website since she started in 2017. The website was misleading as it did not make it clear that sales of medicines would be processed by Weldricks, and the patient's details sent to the third party. The name and physical address of Weldricks who supplied these medicines was not prominently displayed on the pharmacy's website, and this was not in line with GPhC guidance.

Most sales of medicines from the pharmacy were via eBay. There was an MHRA EU internet logo on the eBay site but it authorised sales from the website www.chemistcorner.co.uk not the eBay website. The SI confirmed she would contact MHRA and make arrangement to ensure the pharmacy complied with their regulations. Passwords were required to access the pharmacy's eBay account, but the SI said she did not have these and only her brother, who was currently on holiday had the codes. Medicines were not being supplied during his holiday and it was stated on eBay that the seller was on holiday. Some of the information provided on the eBay site was misleading and could increase risk to patients. For example, there was a 'note to eBay - this is a general sales line' on pharmacy (P) medicines such as Day and night nurse, Stugeron and a prescription only medicine (POM) Anusol HC ointment 30g.

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

Summary findings

The pharmacy's prescription services are generally well managed, so people receive their prescribed medicines safely. The pharmacy gets its medicines from reputable sources. And it carries out some checks to ensure medicines are in good condition and suitable to supply. But the pharmacy does not make enough checks to ensure medicines which are sold via eBay are appropriate.

Inspector's evidence

People receiving the services of the registered pharmacy did so outside of the premises. Patients could communicate with the pharmacist and staff via the telephone or by e-mail messages. Services provided by the pharmacy were advertised in the window of the pharmacy, on the website and in the practice leaflet, available on the website. The pharmacy team were clear what services were offered and healthy living and signposting information was available on the website. The pharmacy supported healthy living campaigns such as bowel cancer and children's oral health and used a tally chart to record their activity. Leaflets were sent out to regular patients who they thought might find the information useful. Staff were multilingual, speaking different dialects of Urdu and Punjabi which helped some of the non-English speaking members of the community.

The pharmacy offered a managed prescription ordering service, but patients were not contacted before their prescriptions were due each month, to check their requirements, apart from patients from one surgery where this was mandatory. Ordering patients medication each month with minimal input from the patient means patients might mean they receive medicines they do not require, leading to medicine wastage and stockpiling.

All prescriptions were delivered but signatures were not always recorded from the recipient unless the medication was a CD, so there was not always a clear audit trail in the event of a query or problem. A note was left if nobody was available to receive the delivery and the medicine was returned to the pharmacy. Methadone solution was delivered to around 10 patients from instalments prescriptions (non-supervised). There was a SOP in place for this process and an audit trail was maintained for these supplies. The SI said this arrangement was on an individual basis with full agreement from the drugs and alcohol team. The delivery driver explained that he did not leave a CD with anyone other than the patient, unless he had received prior authority from the pharmacist, and said he would not deliver the medication if he had any concerns, such as the patient appearing to be under the influence of alcohol. Medicines sold on eBay were posted by Royal Mail service, which could be tracked.

Space was very limited in the dispensary, but the work flow was organised into separate areas with a designated checking area. The dispensary shelves were well organised, neat and tidy. Dispensed by and checked by boxes were initialled on the medication labels to provide an audit trail. Different coloured baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. The baskets were stacked to make more bench space available. Notes were put on assembled prescription bags to indicate when a fridge line or CD was prescribed. The SI said she would telephone patients if counselling was required, and by e-mail if required on medicines sold on eBay. The team were aware of the valproate pregnancy prevention programme. An audit had been carried out and there no regular patients in the at-risk group. A valproate information notice was on display in front of Epilim. Valproate care cards could not be located, but the SI said they were somewhere in the

pharmacy and she would find them if required for any new female patients, so they could be given the appropriate information and counselling.

Around 30 patients received their medication in multi-compartment devices. These were reasonably well managed but there was no audit trail for communications with GPs and changes to medication, so it was not always clear who had confirmed the changes and the date the changes had been made. A dispensing audit trail was completed, and medicine descriptions were usually included on the labels to enable identification of the individual medicines. Packaging leaflets were not always supplied, despite this being a mandatory requirement, so patients and their carers might not be able to easily access the information they need. Disposable equipment was used.

14,629 medicines had been sold via eBay since December 2017 when the pharmacy became a member. The SI explained that the medicines were ordered into the pharmacy and the GSL medicines taken to a property in Manchester as there was insufficient space to store and package them in the pharmacy. Her brother was in charge of this operation. The SI explained that the P medicines were retained in the pharmacy and her brother brought the labels for postage to the pharmacy, so they were supplied from the pharmacy. The contents were removed from their packaging and boxes flattened. This was to reduce the size of the package, so it was cheaper to post. This was stated on the eBay website, but might not be in line with MHRA requirements, as the product was not in its original state at the point of supply and was more likely to be damaged in transit. The SI confirmed she would contact the MHRA to verify if removing from original packaging in line with their requirements. The SI said when a request for a P medicine was received she would send the patient an e-mail asking questions to ensure the sale was appropriate such as the WWHAM questions. She said she would ask questions such as does the patient have diabetes and how long have they had the condition before supplying medication for vaginal thrush. She said when she had received a reply to the e-mail and could confirm that the sale was appropriate, she would authorise the supply and it would be posted out to the customer. If the supply was not appropriate she would e-mail the customer and provide a refund. She was unable to provide any copies of e-mails and said all the information from the eBay activities were on a lap top which her brother had in his possession. She said the account was protected with a password which she did not know, so could not access the information from a different computer. The SI explained there was no checks made that the patient was genuine and who they claimed to be, and there were no checks in place to identify inappropriate requests such as multiple orders to the same address or same payment details, large quantities or too frequent supplies. She said the range of medicines which were offered for sale were those which sold well, but they did not supply medicines at high risk of abuse such as codeine containing products. The SI admitted that the wording on the eBay site was misleading as it did not state that the pharmacist would need to request information and review it before making the supply and is stated 'we send all items on the same working day after clear payment before 2pm'. The prescription only medicine (POM) Anusol HC ointment 30g had been sold 117 times. The SI said she was responsible for all these sales, apart from one when she was on holiday. She said she did not realise that Anusol HC ointment 30g was a POM and she would contact eBay to have it taken off.

CDs were stored in a CD cabinet which was securely fixed to the wall/floor. The keys were under the control of the responsible pharmacist during the day and stored securely overnight. Date expired, and patient returned CDs were segregated and stored securely. Patient returned CDs were destroyed using denaturing kits.

Recognised licensed wholesalers were used for the supply of medicines and appropriate records were maintained for medicines ordered from 'Specials'. No extemporaneous dispensing was carried out. The pharmacy was not compliant with the Falsified Medicines Directive (FMD). They had the hardware and the software and were registered with Secure Med but were not scanning to verify or decommission medicines. The SI could not provide any explanation why they had not started this process.

Medicines were generally stored in their original containers. Date checking was carried out and documented. Short dated stock was highlighted. Dates had been added to opened liquids with limited stability. Alerts and recalls were received via e-mail messages from the NHS area team. The SI confirmed that were read and acted on if relevant to the pharmacy. The action taken was not always recorded so they might not easily be able to respond to queries and provide assurance that the appropriate action had been taken.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely.

Inspector's evidence

Current British National Formulary (BNF) and BNF for children. were available and the pharmacist could access the internet for the most up-to-date information. There was a clean medical fridge. The minimum and maximum temperatures were being recorded regularly and had been within range throughout the month, but the maximum was outside the required range (12 degrees Celsius) at the time of the inspection. The SI explained this was because the fridge had been opened that morning and may have been adversely affected by the higher than usual room temperature. The fridge's current reading was within range (5.5 degrees Celsius) and remained within range throughout the inspection. All electrical equipment appeared to be in good working order. Patient medication records (PMRs) were password protected.

There was a selection of clean glass liquid measures with British standard and crown marks. Separate measures were marked and used for methadone solution. The pharmacy had equipment for counting loose tablets and capsules, with a separately marked tablet triangle that was used for cytotoxic drugs. One the counting triangles was not very clean, risking contamination, but was cleaned when this was pointed out. Medicine containers were appropriately capped to prevent contamination.

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.