Registered pharmacy inspection report

Pharmacy Name: Chemist4U, 34a-37 Greenhey Place, Skelmersdale,

Lancashire, WN8 9SA

Pharmacy reference: 9011784

Type of pharmacy: Internet / distance selling

Date of inspection: 30/08/2022

Pharmacy context

This is a registered pharmacy which is based in a warehouse unit in Skelmersdale, West Lancashire. The pharmacy dispenses NHS prescriptions and has private dispensing contracts for various NHS funded services. It also dispenses private prescriptions and sells a range of medicines, including pharmacy-only medicines. It operates an online prescribing service through its own website and also through other third-party websites. People are sent their medicines by post, courier, or by delivery drivers. Enforcement action has been taken against this pharmacy, which remains in force at the time of this inspection, and there are restrictions on the provision of some services. The enforcement action taken allows the pharmacy to continue providing other services, which are not affected by the restrictions imposed.

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	1.4	Good practice	The pharmacy proactively reviews any negative feedback received via online review websites. They investigate the negative feedback to see whether an improvement to their service could be made.
		1.7	Good practice	The pharmacy uses third-party contractors to assess their data protection procedures and security methods.
2. Staff	Standards met	2.2	Good practice	Members of the pharmacy team routinely complete learning modules. This helps them to continually develop their skills.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards met

Summary findings

The pharmacy identifies the risks associated with its services and takes action to manage them. Members of the pharmacy team follow written policies and procedures to help them work effectively. And they review things that go wrong, so that they can learn from them and avoid similar mistakes being repeated. The pharmacy has robust processes in place to protect people's information. And it carries out regular audits so that it can identify weaknesses in its systems and improve them.

Inspector's evidence

There was a set of standard operating procedures (SOPs) which were regularly updated. Members of the pharmacy team had signed to say they had read and accepted the SOPs. The pharmacy had an up-to-date business continuity plan. An accuracy checking pharmacy technician (ACPT) explained that the pharmacy team had been split into two during the height of the Covid pandemic to help ensure that adequate staffing continuity plans were in place if team members experienced Covid. This meant the pharmacy had been able to operate without any unplanned closures.

The pharmacy carried out a comprehensive "global services audit" every 3-months, and it was last completed in June. The audit covered all aspects of the business, and different sections were completed by senior management across the pharmacy. At the end of the audit, the superintendent (SI) reviewed the audit to create a "corrective and preventative actions" plan to address any shortcomings it identified. The pharmacy operations manager explained how the audit had been applied to NHS dispensing of prescriptions and how it had helped to manage and mitigate associated risks. For example, full review had been carried out to ensure that adequate staffing levels were maintained in each part of the dispensing process. A staffing profile spreadsheet was then used to maintain the correct staffing hours required in each area.

The pharmacy had completed risk assessments of its activities at various levels throughout the business. The risk assessment for each service followed a methodical and detailed template. The highest-level risk assessments covered a particular service the pharmacy operated, such as NHS dispensing services, or selling over-the-counter medicines. More specific risk assessments would then be completed for specific areas within that service. For example, quantities or combinations of sales for individual over-the-counter medicines prescribed by the pharmacy's in-house prescribing service. They then used a scoring system to identify whether the risks associated within that service were being adequately managed. Any areas which scored too highly would need action to be taken to help reduce the risk.

There was a comprehensive risk-assessment for the online prescribing service. This considered the risks around providing the service with reference to accessing people's records and the information provided on the consultation form. Risks of providing treatment at a distance were identified, along with the action to be taken to mitigate the risks. For example, the risk of prescribing remotely for skin-conditions could be reduced by requesting submission of photographic evidence to aid diagnosis. The risk-assessments included information to be used when prescribing and stipulated information that should be given to the patient. They also included any clinical guidelines indicating when treatment would not appropriate. There was also consideration for the maximum quantities of medicines and durations of treatment.

There were also risk assessments for each individual medicine prescribed. These followed a template produced by the NHS Specialist Pharmacy Service. The risk assessment identified any potential safety issues around the presentation of the medicine or other characteristics of use. The pharmacy included details about the nature of the risks and what controls were put in place to manage these risks. The risk assessments were reviewed annually by the superintendent and pharmacist prescriber. A change in service, such as the introduction of a new medicine would prompt an earlier review. The audits carried out by the pharmacy were used to help inform risk assessments.

The pharmacy undertook a quarterly audit of prescriptions written by its prescribing service. This involved selecting a random sample of consultations and reviewing the consultation outcomes. The outcomes of this audit would then be discussed individually with each prescriber to help improve practice. An example audit was seen for one prescriber where it identified several good interventions. But it also identified an opportunity to provide people with further counselling about obtaining blood tests. The pharmacy audited 15 consultations for each prescriber regardless of their prescribing volume. This meant it was not proportionate to the PIP's prescribing activity. They also undertook an audit of the POM register and identified people who had received three or more supplies of any medicines within a three-month period. This then prompted a review of the consultation records to ensure only appropriate supplies were made.

The pharmacy had a CCTV camera in operation above each of the picking, labelling, accuracy checking and packing stations. A photograph was taken every time a prescription went through the station and was stored on a cloud-based system. The pharmacy operations manager explained that this system helped to review what had happened when things went wrong as the image could be retrieved if there was a near miss incident or a dispensing error to help the pharmacy team to reflect and learn. It was also useful to help prove whether medicines had been supplied in the event of a complaint from a patient. Near miss incidents were electronically recorded and discussed with the pharmacy team member at the time they occurred. The near miss records were reviewed each month by the pharmacy manager, and the outcome of the review was fed back to the pharmacy team. Any dispensing errors which occurred were reported online, and learning points were identified as part of the report.

The pharmacy team obtained feedback from people from a variety of sources including TrustPilot, patient satisfaction surveys, email, and phone. The complaints procedure was described on the pharmacy's website. The customer service team replied to negative feedback and investigated events leading to a negative review. The pharmacy team were able to provide examples of contact from healthcare professionals. For example, they had been contacted by a GP who was concerned that his patient had been prescribed a weight loss injection. The GP claimed the persons BMI was 25 and so the medication was not appropriate. The SI had called the GP to inform that the prescribing team had used SCR to check the person's weight upon initiation. At this point their BMI was 30 and so treatment was deemed appropriate.

A current certificate of professional indemnity insurance was seen. The correct responsible pharmacist (RP) notice was displayed conspicuously in the pharmacy. It was also available for people to view on the pharmacy's website. The CD register was in order, with CD running balances kept and audited weekly. Patient returned CDs were recorded appropriately.

An information governance (IG) policy was available. The pharmacy team had completed IG training, and each member had signed a confidentiality agreement. Confidential waste was segregated and removed by a waste carrier. The website had safeguards in place to help reduce the risk of unauthorised access to people's data. Penetration tests were conducted by an external company to test

the effectiveness of their web-based security and identify any weaknesses that needed addressing. The global service audit reviewed current IG actions each quarter to ensure any outstanding actions were followed up.

Safeguarding procedures were included in the SOPs. Professional members of the team had completed level 2 safeguarding training. A national directory containing the details for local safeguarding boards was available using an app on team member's phones. The pharmacist was able to give an example where a person had requested two hormone-containing medicines at the same time which may have suggested a safeguarding issue. As the person had declined SCR access, the pharmacy team did not make a supply and it was escalated to the SI. The person's GP was informed. The pharmacist gave further examples of signposting to local services such as sexual health clinics.

Principle 2 - Staffing ✓ Standards met

Summary findings

There are enough staff to manage the pharmacy's workload and they are appropriately trained for the jobs they do. Members of the pharmacy team complete regular training to help them keep their knowledge up to date. And they use their knowledge to help make sure people are using their medicines safely.

Inspector's evidence

The responsible pharmacist, a pharmacy operations manager who was also a pharmacist, six accuracy checking pharmacy technicians (ACPT), fourteen dispensers, three of whom were training to become pharmacy technicians, and two packers were on duty in the NHS prescription area. The pharmacy team worked well together in a busy environment and managed the workload adequately.

The pharmacy training lead, who was one of the ACPTs, kept training records for each team member. Ongoing training was provided through online courses and in-house training. Team members were required to complete monthly training modules. And details of the training to be completed were attached to the staff communications board.

The pharmacist recorded clinical interventions online and records of recent interventions were provided. A recent example involved a patient who had been prescribed clopidogrel and omeprazole. The prescription was stopped from proceeding through the dispensing process, until the GP had been contacted. As a result of the intervention, the GP changed the prescription from omeprazole to an alternative medicine that did not interact with clopidogrel.

The pharmacy operated an online prescribing service. It employed one directly employed pharmacist independent prescriber (PIP), and three PIPs employed through contractual arrangements. The SI was also trained as a PIP. These PIPs were responsible for all of the prescribing for the online service, with 40-50% prescribed by the directly employed PIP. Members of the pharmacy team felt able to challenge prescribing decisions of in-house pharmacist prescribers. An example was given where an ACPT spotted an issue with a prescription for an erectile dysfunction medicine. She reported this to the responsible pharmacist who in turn queried the prescription with the pharmacist prescriber. The prescriber had made a clerical error which had resulted in two similar medicines being prescribed together, and so the prescription was corrected before being given back to the pharmacy team. The pharmacist prescriber gave an example of good communication with the dispensing team, when a medicine had needed to be supplied urgently. Despite the prescription being issued after the usual cut off time, the team had arranged for the medication to be sent urgently.

The pharmacy team attended monthly meetings to discuss how the pharmacy was performing, dispensing incidents, training and any other business. A copy of the minutes for the meeting dated 6th July 2022 was provided. The pharmacy also held a 'staff council' bi-monthly meeting with one representative from each area present, to provide feedback and suggestions to the management about employment matters. The pharmacy team were aware of the whistle blowing policy and knew how to report concerns if needed. The policy was available for the team to refer to. The pharmacy team members said that the regular pharmacists were approachable, supportive and that they were happy to

ask them questions when needed.

The pharmacist prescribers had their own documented 'formulary'. This stated which conditions they were experienced and competent to prescribe for and the medicines associated with this. The pharmacy also recorded what training and development has been completed for each condition. The pharmacist prescribers kept a development portfolio to document their ongoing learning. There was no incentive scheme for prescribing.

Principle 3 - Premises Standards met

Summary findings

The pharmacy premises are suitable for the services it provides. But some of the websites it is associated with are misleading or lack information. So people may not always understand which healthcare professionals are providing the prescribing service.

Inspector's evidence

The premises were suitable for the services provided. The pharmacy was clean and tidy. The temperature in the pharmacy was controlled by air conditioning units. Lighting was adequate. The pharmacy employed a cleaner who cleaned all areas regularly. The pharmacy team members were responsible for keeping each of the dispensing stations clean and tidy. The premises were maintained in an adequate state of repair. The pharmacy team had use of a staff area and several WCs with hand wash basins and antibacterial hand wash. A room was available for the pharmacist to have private conversations on the telephone with patients.

The pharmacy website contained details about who owned the pharmacy, its location, and contact details. The webpage showing who the current RP was also provided further information about who regulated the pharmacy.

Part of the pharmacy's website was an 'Online Clinic'. This included details about the prescribers. People could commence a consultation from a conditions page, and it was clear that the final treatment choice would be decided by the prescriber. The pharmacy also worked with the websites 'sons.co.uk' and 'my-bmi.co.uk' by providing prescribing and dispensing services for consultations started through these websites. The website displayed the name of the pharmacy and registration number on this site. But it was sometimes not clear that it would be a pharmacist who was prescribing the medication as the site uses the word 'physician' and pictures of the medical director on the website. This could be misleading to people using the site. Following the inspection, changes were seen to have been made to the associated websites, so that people could start consultations from individual prescription-onlymedicines. However, when this was brought to the attention of the SI, the changes were reversed. This meant consultations could only be started from a conditions page. The SI gave an assurance that, to avoid similar incidents in future, he had implemented a new process so that he would have to sign off any changes to the before they went live.

Principle 4 - Services Standards met

Summary findings

The pharmacy provides a wide range of services, many of which are easy to access using its websites and a mobile app. The ordering systems have safeguards built in to help make sure people are using their medicines appropriately. And members of the pharmacy team routinely speak to patients who are taking certain high-risk medicines to ensure they are up to date with their blood tests. But when people answer online questionnaires to request medicines, the system makes clear when an answer would prevent the supply. This could make it easier for people to circumvent the controls by deliberately providing false answers.

Inspector's evidence

The pharmacy's services could be accessed via its website www.chemist-4-u.com, as well as associated websites. People could also contact the pharmacy via email, Whatsapp, Twitter, and live chat. It also had its own branded mobile phone app which included a messaging function. The pharmacy website included an 'ask the pharmacist' function, which sent messages directly to one of the pharmacy's pharmacists, so that they could respond.

The pharmacy's website hosted a variety of medical guides written by content writers. The content of these guides had apparently been checked and approved by a pharmacist before being made available on the website. Product pages for medicines also contained information about using the specific medicine listed, and they also provided signposting information to other websites. For example, the NHS, and MHRA's yellow card reporting scheme.

The pharmacy provided a dispensing contract for a number of NHS funded services. These services were CQC registered and were provided by UK regulated health care professionals. Some of the services involved people being prescribed medicines remotely by telephone or video call. If the prescriber felt it was necessary to provide medicines to a patient, they would issue a private prescription which was electronically sent to the pharmacy. The prescription was assembled and checked, and medicines were sent in a plain brown box small enough to fit through a letterbox. It also contained information leaflets to help counsel the patient, and contact details for the service provide if the patient had any questions.

A range of over-the-counter medicines were available for purchase via the website. Anyone wishing to purchase pharmacy only medicines had to answer a series of product specific questions. The answers were reviewed by a pharmacy technician before the request could be approved. The technician could request further information if they felt it was necessary, refuse the supply if it was not appropriate, or escalate the request to a pharmacist to review. The person reviewing the requests could also send prewritten guides about the chosen medicine or provide bespoke counselling if they felt the person needed it. To help manage and review the process, the pharmacy completed monthly audits of opiate-based medicines and promethazine-based medicines sold. The audits scrutinised the records for any sales which may have been inappropriate, and an action plan was created to show any learning from the audits. Earlier in the year an audit had identified that people checking the requests had sometimes overlooked the flag which indicated there may be linked accounts. To help improve this, training was provided to all members of the team who approved medicine requests, and the electronic software used was updated to make the linked accounts flag more obvious.

The pharmacy's in-house prescribing service operated via the pharmacy's 'clinic' on its website and also via the websites www.my-bmi.co.uk, and www.sons.co.uk. For each of the websites people would select a condition before starting a questionnaire-styled consultation. The questions were designed to help the prescriber understand the person's medical history. But if a person selected an inappropriate answer to a closed question, a negative response would appear. And the answer could be changed without the prescriber's knowledge. This may help guide people through a questionnaire and make it easier to obtain inappropriate supplies.

The pharmacy asked for the person's consent to access the summary care record (SCR) for each consultation. The superintendent explained that this was a result of the risk assessment completed for the service. They had made this mandatory for certain higher risk treatments such as weight loss. The pharmacist prescriber gave an example of using the SCR to identify that a person was taking medication that was not disclosed on the consultation form. The pharmacist prescriber then contacted the person to discuss suitable options for them. The prescriber explained SCR access was not available for people accessing the service in Scotland or Northern Ireland. For these people, they were contacted to obtain more information, or to consent to further information being provided by their own GP. However, sometimes the prescriber based their decision making on verbal confirmations from the person they are speaking to. This meant for people receiving weight loss treatment in these regions, the pharmacy may not be able to always show a reliable method to prove people are always the weight or BMI they claim to be and demonstrate treatment was appropriate. The pharmacy's in-house prescribing service offered medication for pre-exposure prophylaxis of HIV (PreP). The prescriber used SCR as part of his checks, but the SCR records did not show previous HIV results. Current guidance requires people who take PreP should test for the presence of HIV every 3. To help manage this, the pharmacy offered a selftesting kit every three months to people accessing these medicines to ensure they remained appropriate.

The pharmacy requested consent to notify the persons GP for each prescription issued by a pharmacist prescriber. This was mandatory for medicines they had identified as higher-risk. The pharmacist gave an example where a GP had subsequently contacted the pharmacy and informed them of further clinical information that was not documented on the SCR or disclosed by the patient on the questionnaire. As a result, the pharmacist prescriber blocked any further supplies of this medicine to the patient.

The pharmacist showed examples where they had contacted the person by email in order to obtain more information. whereon one occasion a patient had not fully disclosed the medication they were taking, but this was identified from the SCR. The pharmacist had put the request on hold until further intervention could be made with the person. Another example involved a request for cream to treat facial acne, but the photo supplied showed that the treatment requested would not be appropriate.

Before any medicines ordered through the pharmacy's website were processed, the website completed a number of checks on the medication request to help identify any requests which may be potentially inappropriate. The identity of the person was checked using the Lexis Nexis identity software for any prescription only medicine requests. And the ingredients of the medicine were checked against previous orders to see whether medicines were being ordered too soon, or if there were any medicines which should not be taken together. There was a system check for other accounts on the website to see whether a person was trying to circumvent the restrictions in place.

The pharmacy operations manager demonstrated how the process for the Electronic Prescription Service (EPS) nominations worked for NHS prescriptions. He explained that the pharmacy was unable to dispense prescriptions for patients who had not signed up on the pharmacy website or mobile application to provide consent for the pharmacy to be nominated for EPS. The process appeared robust, and patients were required to provide a unique password as part of the sign-up process. The superintendent explained that previously there had been an option for patients to nominate the pharmacy for EPS during the "check out" stage on their website. He said this functionality had been removed to avoid any confusion for patients.

Each element of the NHS dispensing process was carried out in clearly designated areas of the pharmacy. An ACPT explained that this was to help minimise disruption and mitigate risk associated with each process. A pharmacist carried out an online clinical check of each prescription at the beginning of the process, which electronically recorded who completed the clinical check and when. Prescriptions that had been clinically checked were placed in an online 'queue' for a dispenser to create and print dispensing labels and a tracking label for delivery purposes. A dispenser from the 'picking' team then collected the stock medicines for each prescription, placed them into a plastic container and onto a rack next to the labelling stations. A dispenser from the 'labelling' team then added the dispensing labels to the respective medicines and checked this against the prescription before placing them back into the plastic container in readiness for a final accuracy check.

An ACPT demonstrated how the final accuracy check took place, which was in accordance with the SOP. She said due to the risks associated with the supply of some medicines, ACPTs were not able to carry out a final accuracy check on schedule 2 CDs, injectable fridge medicines, methotrexate and prescriptions for children under 12 years old. A pharmacist would complete the final accuracy check on these medicines. As part of the accuracy check, leaflets about high-risk medicines, such as opiate painkillers, were provided as a form of counselling. And a card contained the details of who had completed the accuracy check. But the pharmacy team did not carry out clinical check on receipt of a private prescription issued by the in-house prescribing service. This may increase the risk of inappropriate supply because best practice would suggest a second suitably competent person should be involved in carrying out the final check for clinical appropriateness. Once the accuracy check had taken place, the prescriptions were placed in the packing area for a member of the 'packing' team to package for delivery. The packers had received training for their role, including reading and signing the relevant SOPs, and were not pharmacy trained.

The pharmacy kept a record of all NHS prescriptions for warfarin, methotrexate and lithium. And they telephoned the patients every three months for monitoring purposes. INR results were routinely obtained from patients and were recorded on the patient medication record (PMR) computer system. The pharmacy had warfarin booklets and lithium booklets which were supplied to patients when needed. The pharmacy team were aware of the risks associated with the use of valproate during pregnancy. They had carried out a valproate audit and had not identified any patients who met the risk criteria. Patient information resources were available to supply with valproate. The pharmacy manager demonstrated how clinical checks were carried out and recorded online.

Medicines were dispensed into multi-compartment compliance aids for some people who needed additional help with taking their medicines. The compliance aids included individual medicine descriptions, patient information leaflets and a dispensing audit trail. Hospital discharge prescriptions were kept for the pharmacist to review and liaise with the GP if needed, regarding medication changes.

An ACPT explained how the prescription delivery service was provided for local residents. A secure mobile delivery app was used to provide an audit trail. If a patient was not at home when a delivery was attempted, the medicines were returned to the pharmacy. National deliveries were generally sent using various Royal Mail services. Bulky items were sent using a courier service. Refrigerated items were packed inside special packaging which helped to keep the medicines at the correct temperature for up

to 48 hours. The pharmacy had completed validation tests in Summer and Winter to ensure this method of postage remained suitable. The pharmacy also conducted regular sample audits for any CDs sent by post. These comprised of 20 deliveries per week which checked the medicine had been entered into the CD register, had been delivered to the patient, or returned back to the pharmacy if the delivery was unsuccessful. A recent audit had identified the most common issue was administrative due to mistyping the postage tracking numbers within the CD register. To avoid this the pharmacy had asked members of the team to check their work before saving the record.

Stock medications were sourced from licensed wholesalers and specials from a licensed manufacturer. Stock was stored tidily. Patient returned medicines were stored tidily in clinical DOOP bins. The pharmacy had a walk-in fridge for medicines that provided online monitoring of the temperature. The pharmacy had a service level agreement (SLA) in place with the fridge provider to ensure adequate callout and contingency measures were in place. The medication stock was date checked regularly and a record was kept. Short-dated medicines were highlighted. Alerts and recalls were received via email from the NHS and online. These were read, acted on by a member of the pharmacy team, and a record of these was kept.

Principle 5 - Equipment and facilities Standards met

Summary findings

Members of the pharmacy team have access to the equipment they need for the services they provide. And they maintain the equipment so that it is safe to use.

Inspector's evidence

The pharmacy team used the internet to access websites for up-to-date information. For example, Medicines Complete. Copies of the BNF and BNFc were present. Any problems with equipment were reported to the pharmacy manager. All electrical equipment appeared to be in working order. According to the PAT test stickers attached, the electrical equipment had been PAT tested in the last year.

There was a selection of liquid measures with British Standard and Crown marks. The pharmacy had equipment for counting loose tablets and capsules, including tablet triangles. Computers were password protected. A cordless telephone was present, and it was used to hold private conversations with people when needed.

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.	