General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Ritecare Pharmacy, Unit 106 Compass Network Centre, Compass Industrial Park, Speke, Liverpool, Merseyside, L24 1YA

Pharmacy reference: 9010595

Type of pharmacy: Internet / distance selling

Date of inspection: 05/11/2019

Pharmacy context

This pharmacy offers services to people through its website www.ritecarepharmacy.co.uk. The pharmacy dispenses NHS prescriptions, many of which are supplied in multi-compartment compliance aid packs to help people take their medicines at the right time. The website also allows people to buy pharmacy only (P) medicines through a third-party supplier - (Weldricks pharmacy). The pharmacy is also associated with a website owned by a seperate company (www.prescriptiontoday.co.uk). This website offers an online prescribing service, using a prescriber based in Romania. The website mainly offers opioid medicines for the treatment of pain and medicines for the treatment of insomnia. The pharmacy's NHS business and its dispensing for the online prescribing service are managed as completely seperate operations, but both are provided from the same registered premises.Subsequent to the inspection the pharmacy decided to suspend all supplies of medicines prescribed by the online service.

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 risks involved with the online prescribing service are not adequately managed. The pharmacy cannot provide assurance that prescribing is always undertaken in line with good practice guidance and UK national guidelines (including GMC guidance).
		1.2	Standard not met	The pharmacy cannot provide assurance that it effectively monitors and reviews the online prescribing of high-risk medicines to prevent misuse or abuse.
		1.5	Standard not met	The pharmacy cannot demonstrate that its indemnity arrangements provide cover for dispensing prescriptions issued by the online prescribing service. And it cannot demonstrate that the online prescriber it is associated with has adequate professional indemnity arrangements in place.
		1.6	Standard not met	There are no clear records available relating to clinical interventions, monitoring of high-risk medicines or to justify prescribing decisions when people have not provided consent for their GP to be contacted.
		1.8	Standard not met	The pharmacy is failing to safeguard vulnerable people because it does not have adequate controls in place to ensure supplies of opiates and sleeping tablets are appropriate or that the medicines are not being abused.
2. Staff	Standards not all met	2.6	Standard not met	The superintendent takes sole responsibility for dispensing prescriptions from the online prescribing service. And the high profit margins of this service disincentivise any refusal to supply, which may prejudice professional judgement.
				The pharmacy's systems do not ensure that

Summary of notable practice for each principle

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3. Premises	Standards not all met	3.1	Standard not met	people using the online prescribing service always receive the most appropriate medicine for effective treatment. Because the website is arranged so that a person can choose a medicine and its quantity before there has been an appropriate consultation with a prescriber.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy supplies large quantities of opioids and other medicines liable to abuse. But it is not able to demonstrate that effective safeguards are in place to make sure they are clinically appropriate. The pharmacy cannot provide assurance that the online-prescriber proactively shares all relevant information about prescriptions with other health professionals involved in the care of the person (for example, their GP). Or; that the prescriber contacts the person's GP in advance of issuing a prescription to seek confirmation that the prescription is appropriate for the patient and that appropriate monitoring is in place. Or; that the prescriber makes a clear record setting out their justification for prescribing in circumstances where they have decided to issue a prescription when the person does not have a GP or does not consent to share information.
		4.3	Standard not met	The pharmacy does not have a robust date checking procedure and medicines which have passed their expiry date are not always separated from current stock.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy does not have appropriate governance arrangements in place. It does not identify or manage all of the risks involved with the online prescribing service it is associated with. And it does not review or monitor the safety and quality of the service it provides associated to online prescribing. The pharmacy does not keep records to demonstrate whether there is adequate professional control when high-risk medicines are supplied. This means the pharmacy cannot show that the online prescribing service is safe. And vulnerable people might be able to obtain medicines that could cause them harm. And the pharmacy cannot demonstrate that appropriate indemnity arrangements are in place to protect people who use the online prescribing service.

Inspector's evidence

The pharmacy had a large NHS business of around 10,000 prescription items each month that was provided via its own website. It also dispensed around 2,000 private prescriptions each month issued by an online prescriber via a third-party website (www.prescriptiontoday.co.uk). The pharmacy had been associated this website since March / April 2019 and the superintendent pharmacist (SI) explained that the number of online prescriptions had increased significantly in the last few weeks. The online prescribing service used a doctor who was apparently registered with the Irish Medical Council (IMC), but was based in Romania. The prescribing service was therefore not subject to inspection or oversight by any UK regulators. The SI could not provide any evidence of checks being carried out to confirm that the online prescriber was appropriately registered and able to lawfully prescribe for UK patients. Nor could he provide assurance that the prescriber has appropriate indemnity arrangements in place. The SI said that he had been informed by his lawyer that the prescriber was able to issue prescriptions to people in the UK because of his registration with the Irish Medical Council, but he did not provide any evidence to support this claim.

The pharmacy dispensed between 100 and 120 private prescriptions each day. The medicines supplied were almost all opioid painkillers or z-drugs (zopiclone and zolpidem) for the treatment of insomnia. The SI was not able to provide any evidence of any risk assessments being carried out in relation to the remote supply of opioids and z-drugs. He was aware that these two drug groups were liable to abuse, overuse and misuse, but said he believed that the prescribing service took sole responsibility for identifying these risks.

A person wishing to obtain medicines via the online prescribing service would be required to complete a consultation questionnaire which comprised of both closed yes/no type answers and some free-type text boxes. If they selected an answer that would prevent supply, this would be immediately indicated with a message advising them to refer to their GP. It was then possible to change the answer to circumvent the system and potentially obtain an inappropriate supply. The prescriber and the pharmacy were not made aware of any altered answers on the consultation questionnaire. Part of the questionnaire asked the person if they would consent to the pharmacy contacting their GP to inform them about the supply. The

SI said that he had not received any prescriptions where consent to contact the person's GP had been granted. This lack of consent did not prevent a prescription being issued and the pharmacy did not have any records to explain why the prescriber believed it was still appropriate to issue a prescription.

Identity (ID) checks were completed on every account using a LexusNexus soft credit check. This was completed by the Prescriptiontoday team. This checked the person's ID by first name, surname, address and date of birth. Additional photo ID was only requested when the credit check was uncertain about the identity of a person. The SI said photo IDs were required for about 10% of people using the website. However, there was no face to face correspondence, so this did not prevent the possibility of a person using somebody else's identity, with or without their consent. This was a possible safeguarding concern as a child or a vulnerable person could potentially use someone else's credit card to obtain medicines from a third party.

The prescriptiontoday.co.uk website operated a usage block – to prevent people from placing an order above the maximum permitted total quantity within a 28 day time period, and a block on multiple accounts using the same address. Prescriptions were electronically sent to the pharmacy and automatically printed.

The pharmacy did not carry out any audits to evaluate the service linked to their online activity. The pharmacy worked with an online prescribing service that was not regulated by any UK authority but did not carry out any clinical audits to assess the appropriateness of the prescribing. There was no monitoring of the suitability of the communication systems between the pharmacy, the prescriber and the company that operated the website.

The SI explained that a patient's husband had emailed the pharmacy requesting that they do not supply his wife with dihydrocodeine because she had a problem with these. He said the patient had therefore been blocked from obtaining medicines from the prescriptiontoday website. But there was no record of the refusal to supply documented on the patient's medication record.

There were up to date Standard Operating Procedures (SOPs) for the services provided, with signature sheets showing that the pharmacy team had read and accepted the SOPs that were relevant to their role. Roles and responsibilities of staff were set out in the SOPs. The incorrect responsible pharmacist (RP) notice was conspicuously displayed and this was corrected when pointed out.

Dispensing errors were recorded and reported to the National Reporting and Learning System (NRLS) and the SI provided an example of this. Near miss errors were reported on a near miss log and the second pharmacist said that because of some near miss errors with amlodipine and amitriptyline, the stock had been separated. The pharmacist said near miss records were reviewed for trends and patterns, but these reviews were not documented.

The SI said that any complaints raised would be escalated to him if necessary. He said he would always try to resolve complaints in accordance with the complaints SOP. The pharmacy website included a section on complaints and comments.

An in-date certificate of professional indemnity insurance was on display. The SI was unable to provide assurance that the policy covered the dispensing activity for prescriptions received and supplied from the prescriptiontoday.co.uk website.

Subsequent to the inspection a copy of the online doctor's indemnity insurance policy was provided but it was written in Romanian and therefore it was unclear whether it provided appropriate cover.

The CD register, responsible pharmacist (RP) record, unlicensed specials record, and private prescription record were in order. Running balances in the CD register were kept and audited regularly.

There was no information governance (IG) policy available. The SI said he had completed the NHS IG toolkit each year but had not implemented GDPR policies or provided training to the pharmacy team. An SOP was available which contained some information about how the pharmacy team should not share information with others. But members of the pharmacy team had not signed confidentiality agreements. A privacy notice was available on both websites. When questioned, the trainee dispenser was able to correctly describe how confidential waste was segregated to be removed by a waste carrier.

Both pharmacists said they had completed level 2 safeguarding training. A dispenser said she would initially report any concerns to the pharmacist. A safeguarding policy was in place and there were local contact details for seeking advice or raising a concern.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy has enough staff to manage its workload and the pharmacy team members are qualified or on accredited training programmes for the jobs they do. The team members work well together, and they are comfortable providing feedback to the pharmacist. The superintendent pharmacist is the only person involved with the supply of prescriptions from the online prescribing service, which may increase the risk of inappropriate supplies.

Inspector's evidence

The pharmacy team included two pharmacists – one of whom was the SI, four dispensers – one of whom was in training, and a delivery driver. The pharmacy team were appropriately trained or on accredited training programmes.

The normal staffing level was the SI, a second pharmacist, and three or four dispensers. The workload appeared to be managed. Staffing levels were maintained by part-time staff and a staggered holiday system.

A dispenser said she had not completed any additional training since finishing her dispensing course. And the pharmacy did not provide her with any further learning material. When questioned, she explained how she would speak to the pharmacist and contact the prescriber if she had a concern about a prescription, such as an unusual dose.

The trainee dispenser said she felt a good level of support from the pharmacist and the SI. She said she felt able to ask for help if she needed it. There was no appraisal programme but a dispenser said received informal feedback about her work from the pharmacist. The pharmacy team had a weekly meeting to discuss any ideas or concerns they had. Staff were aware of the steps they should take to report any concerns.

The SI said he managed, and took sole responsibility for, all aspects of the pharmacy services related to the prescriptiontoday.co.uk website.

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

Summary findings

The premises generally provides a professional environment for people to receive healthcare. But the pharmacy website contains some incorrect information, which may be misleading. The pharmacy is also associated with another website that allows people to select the prescription only medicines they want before they complete a consultation with a prescriber. This means people may be more likely to receive medicines that are not the most suitable for them.

Inspector's evidence

The pharmacy premises were not open to the public. People accessed its services via the pharmacy website www.ritecarepharmacy.co.uk. This contained details about the ownership, location, and contact details. Details of the superintendent were also displayed, but were incorrect. A current MHRA logo was displayed. People could purchase pharmacy medicines via a 3rd-party supplier, 'Weldricks' and a second MHRA logo was displayed for this service but there was no further information displayed about who supplied these products, which may cause confusion.

The pharmacy was also associated with a seperate website, prescriptiontoday.co.uk, that offered an online prescribing service. This website was operated by a different company. It had a current MHRA logo displayed and also details of the pharmacy and a link to the GPhC's register. People using the website could select a prescription only medicine they wanted and were then asked to complete a consultation questionnaire in order to obtain a prescription.

The pharmacy premises were clean and tidy, and appeared adequately maintained. The size of the dispensary was sufficient for the workload. A sink was available within the dispensary. The temperature was controlled by the use of electric heaters. Lighting was sufficient. The pharmacy team had access to a kitchenette area, including a separate staff fridge and WC facilities.

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

Summary findings

The pharmacy supplies medicines against prescriptions that are issued by an online prescribing service. But it does not carry out enough checks to make sure the medicines are safe and appropriate for the people they supply. The pharmacy gets its medicines from reputable sources but does not always store them appropriately. This means there is an increased risk of supplying a medicine that is not safe or fit for purpose.

Inspector's evidence

The pharmacy services could be accessed via the telephone, website and e-mail. The pharmacy team were clear about what services were offered and where to signpost to a service.

The pharmacy offered an NHS dispensing service and also a private dispensing service. The two services were managed separately so that they operated independently, and were accessed separately via different websites. The SI operated the private dispensing service. He said that a dispenser was sometimes involved in producing the dispensing labels for that service but he took sole responsibility for the supply of those medicines. A second pharmacist was employed who was only involved with the NHS service.

The NHS dispensing service included a care home delivery service. Deliveries were segregated after their accuracy check and a sheet was used to obtain signatures from the recipient to confirm delivery. But it did not identify deliveries for specific patients. So, the pharmacy may not be able to show if a delivery had been safely made.

A dispenser provided a detailed explanation of how the care home service was carried out. Most of the medicines were supplied in multi-compartment compliance aids (MDS). Medicines administration record (MAR) charts were provided to help the care home manage administration. A photograph of each individual medicine was included on the MAR chart so that they could be easily identified. Initials were included on the MDS labels to provide an audit trail. The pharmacist said that patient information leaflets were not always provided but were sent every two to three months or when new medicines were prescribed. This meant patients may not always have the most up-to-date information about their medicines.

The second pharmacist said details about blood test results for patients who were taking high-risk medicines (such as warfarin, lithium and methotrexate) were sometimes provided by the care home. If they were missing, the pharmacy would contact the care home to confirm they had been completed, but details of the latest results were not recorded.

The staff were aware of the risks associated with the use of valproate during pregnancy. Educational material was available to hand out when the medicines were supplied. The pharmacist said she would

speak to any patients who were at risk and made them aware of the pregnancy prevention programme, which would be recorded on their PMR. The pharmacy team said they were not aware of any current patients who met the risk criteria.

People accessed the online prescribing service by using the prescriptiontoday.co.uk website. This allowed them to select a prescription only medicine from a limited range that was mainly opioids and z-drugs. They could choose the medicine they wanted, strength, and quantity before being asked to complete a consultation questionnaire. The questionnaire required answers to a series of questions. An alert was displayed if an answer meant the supply would not be allowed. This meant it was possible for the person to then change their response in order to obtain the medicine. Any such alterations were not visible to the pharmacy.

The consultation questionnaires were structured in a way that assessed the patient's compliance with the requested medicine and there was an assumption that this request was for repeat medication. In most cases there was only one free text question for symptoms and history of the condition being treated. The quality of the gathered information relied predominantly on the patient input.

A review of the patient medication record (PMR) for some patients using the prescribing service showed that they had been given repeat courses of opioids and Z drugs with no records kept to justify these supplies or to show any attempts to check the prescriber's decision. The SI said he was not responsible for the content displayed on the third party website or the information stored within. He said he was not able to check patients' records or their answers to the questionnaires. He said he was aware that the prescriber did not have access to patients' medical records and he was unable to provide any assurance that the prescriber was working within a shared care approach or sharing information with other healthcare professionals caring for the online patents. The SI said people using the website were asked to provide consent to share information with their GP. He said he did not know how may people had provided consent to share information but he did not think it was many. From the patient medication records reviewed there was no evidence that the pharmacy had checks in place to monitor the frequency of prescriptions, or the quantities of medication prescribed by the online prescribing service.

Dispensed medicines for the online prescribing service were sent via Royal Mail Track and Trace, or DPD courier. A signature was required upon delivery. Failed deliveries would be delivered to a collection point, which required ID to be supplied by the person collecting the medicine. The SI explained that any medicines returned because of a failed delivery would be disposed of appropriately and not returned to stock.

Medicines were obtained from licensed wholesalers and specials were ordered from specials manufacturers. Stock was stored tidily. Staff said date checking was carried out, but no record was kept. There were some out-of-date medicines present amongst the stock. The date of opening was written on stock bottles of medicines with limited shelf life once opened. There was a clean medicines fridge, equipped with a thermometer. The minimum and maximum temperature was being recorded daily and the record was complete. Patient returned medication was disposed of in designated bins. There was a CD cabinet in use that had been bolted to the wall. Patient returned CDs were destroyed using denaturing kits that were available. Patient returned CDs were recorded prior to being denatured and

were disposed of appropriately. A CD balance check for a random CD was carried out and was found to be correct.

The pharmacy was not yet meeting the safety features of the falsified medicine directive (FMD), which is now a legal requirement. The SI said the equipment had been ordered from their PMR supplier, and they were signed up to SecureMed. But the pharmacy team had yet to commence routine safety checks of medicines. Drug alerts were received by email from the MHRA. Alerts were printed, action taken was written on, initialled and signed before being filed in a folder.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

Members of the pharmacy team have the equipment and facilities they need for the services they provide.

Inspector's evidence

The staff had access to the internet for general information. This included access to the BNF, BNFc and drug tariff resources. All electrical equipment appeared to be in working order. There were no stickers attached to indicate they had been PAT tested.

There was a selection of liquid measures with British Standard and Crown marks. The pharmacy also had counting triangles for counting loose tablets including a designated tablet triangle for cytotoxic medication. Equipment was kept clean by the pharmacy team. Computers were password protected. A cordless phone was available which allowed the staff to move to a private area if the phone call warranted privacy.

What do the summary findings for each principle mean?

✔ 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.