## General Pharmaceutical Council

# Registered pharmacy inspection report

Pharmacy Name: New Hall Lane Pharmacy, 270 New Hall Lane,

PRESTON, PR1 4ST

Pharmacy reference: 1116346

Type of pharmacy: Community

Date of inspection: 23/01/2020

## **Pharmacy context**

This is a community pharmacy located in a residential area of Preston. It is situated on a major route between the city centre and the M6 motorway. The pharmacy dispenses NHS prescriptions, and provides a range of services including seasonal flu and travel vaccinations, a minor ailment service and emergency hormonal contraception. The pharmacy also offers a private prescribing service operated by a pharmacist independent prescriber. Prescriptions are issued after face-to-face consultations or online consultations via the pharmacy website (www.nhlpharmacy.co.uk). An aesthetic service is also offered with various cosmetic treatments being prescribed and administered. A range of pharmacy medicines are sold over the counter and online. The pharmacy also employs an optician on Sundays to offer eye tests in the consultation room, and staff make appointments for this service during the week.

## **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 have clear procedures to support its prescribing service or online supplies. And it does not carry out any audit of these services. So it cannot demonstrate that risks associated with these services are being identified or managed.
		1.2	Standard not met	The pharmacy does not carry out a full assessment of the risks associated with the medicines it offers on its website. And it cannot show that prescribing is in line with good practice or UK national guidance.
		1.6	Standard not met	The pharmacy does not keep clear records showing why requests for medicines are approved or refused. So it cannot demonstrate how these judgements are made.
		1.8	Standard not met	The pharmacy does not have adequate safeguards in place to prevent vulnerable people from obtaining medicines that could cause them harm.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacist prescriber cannot provide evidence to show he has the knowledge and experience he needs to safely prescribe all of the medicines that are available on the pharmacy's website or to effectively administer aesthetic treatments.
		2.6	Standard not met	The pharmacy website offers medicines that are liable to abuse. And their high profit margins mean there is a financial incentive to supply that could compromise professional judgement.
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website allows prescription only medicines to be selected for purchase before starting a consultation with a prescriber.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not have adequate controls in place to make sure the medicines it supplies will be used safely. It does carry out robust identity checks to make sure people who order medicines from its

Principle	Principle finding	Exception standard reference	Notable practice	Why
				website are who they say they are. It does not get enough information to make sure people only receive medicines that are appropriate for them. And it does not have a clear policy about supplying medicines to people who make repeated requests. The prescribing service does not share information about the medicines it supplies with the person's GP.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

## Principle 1 - Governance Standards not all met

#### **Summary findings**

Members of the pharmacy team follow written procedures to provide NHS services, to help them work safely and effectively. But there are no written procedures for the prescribing service or the online services. And the pharmacist does not record the reasons why medicines are supplied or refused. So the pharmacy cannot show how it manages the risks associated with all its services. And it does not have adequate safeguards in place to prevent vulnerable people from getting medicines that could cause them harm.

## Inspector's evidence

There was a set of standard operating procedures (SOPs) for the pharmacy's NHS services, and these had been signed by members of the pharmacy team to confirm they had been read. But there were no SOPs for the prescribing service or the online sales service. Various checklists were on the wall of the dispensary to monitor compliance with a number of professional requirements. These included fridge temperature records, expiry date checks, and the completion of near miss records. The checklist was ticked once the tasks had been completed. Dispensing errors were recorded on a standardised form and reviewed by the SI. The pharmacy technician said the SI would investigate the error and share his findings with the pharmacy team. Near miss incidents were recorded on a paper log. The pharmacy technician explained that records of near miss incidents were reviewed to help identify any common trends, and this was discussed with the pharmacy team. The pharmacist would also highlight mistakes to staff at the point of accuracy check and ask them to rectify their own errors. Several near miss incidents had involved atenolol and allopurinol being mixed up, so the stock had been separated and highlighted on the dispensary shelf.

The superintendent pharmacist (SI) worked regularly at the pharmacy. He was qualified as an independent prescriber and was the only prescriber involved with the pharmacy's prescribing service. He explained that he provided face to face consultations to people who visited the pharmacy and said these were typically for acute illnesses and aesthetic treatments. He had also been providing an online prescribing service for a few months via the pharmacy website. This offered a limited range of medicines to treat conditions including narcolepsy, asthma, and erectile dysfunction. The SI said he had selected the range of medicines after viewing what other online prescribers were offering, and to treat conditions that he felt competent to prescribe for. He had created a number of documents which listed the medicines he had selected under various indications. The documents were used as a formulary and contained details about standard dosages, contraindications, cautions in use, and side-effects which he had obtained from the BNF. But there was no evidence of any risk assessments having been done to help identify and manage the risks associated with the prescribing service or the individual medicines. The prescribing service was currently issuing about 10 prescriptions a month, approximately half of which were online. The SI explained that people using the prescribing service were asked questions relevant to their treatment and these were usually based on information from the BNF and the medicine's license. He said he would use NICE guidance to ensure his prescribing fell in line with good practice. But there were no audits carried out to confirm whether this was the case. The pharmacy also offered a range of pharmacy medicines for sale on line but there was no evidence of any risk assessments being carried out to determine the risks associated with supplying the individual medicines at a distance. And there were no written policies available to explain about how decisions should be made when supplying medicines on line.

A responsible pharmacist (RP) notice was prominently displayed in the retail area. Roles and responsibilities of the pharmacy team were described in individual SOPs. The pharmacy technician was able to explain what her responsibilities were and was clear about the tasks which could or could not be conducted during the absence of a pharmacist. The pharmacy had a complaints procedure and a notice in the retail area advised people they could discuss any concerns or feedback with the pharmacy team. A current certificate of professional indemnity insurance was available and the SI had personal professional indemnity insurance for his prescribing activities, which specified that it included prescribing medicines online, aesthetics and Botox.

Records for the RP, private prescriptions, emergency supplies and unlicensed specials appeared to be in order. Controlled drugs (CDs) registers were maintained with running balances recorded and checked at least once a month. Two random balances were checked. One was found to be accurate but the second balance was found to have a deficit of 28 tablets. The pharmacist promptly identified this as a missed entry and amended the records. Patient returned CDs were recorded in a separate register. There were some records available for the prescribing service. Questionnaires completed by people using the online service were retained, and records of face-to-face consultations were kept showing the information provided by the patient. But some of the information was generic, for example, a medical history for one patient listed 'inhalers' as some of the medicines they had taken. And the prescriber did not keep records of counselling or advice he gave to the patient, so it was not clear whether he routinely highlighted any possible 'red flag' symptoms. There were some examples of requests for medicines that had been refused, but the reasons for refusal were not clearly recorded. An admin assistant at the pharmacy would notify the patient of the refusal, either by e-mail or by phone call, but they did not keep records of the phone conversations.

An information governance (IG) policy was in place. The pharmacy team had received in-house IG training and each member of the team had signed a confidentiality agreement. When questioned, the pharmacy technician was able to describe how confidential waste was segregated to be removed by a waste carrier. A privacy notice was on display in the retail area and described how people's data was handled and stored by the pharmacy. The website had SSL encryption and its server used 'ModSecurity' and anti-virus software.

Safeguarding procedures were included in the SOPs. Members of the pharmacy team had in-house safeguarding training and the pharmacist said he had completed level 2 safeguarding training. Contact details for the local safeguarding board were available. The pharmacy technician said she would initially report any concerns to the pharmacist on duty. But the SI admitted that there were no procedures in place to refer people if there was a concern about misuse or overuse of medicines ordered through the pharmacy's online service.

## Principle 2 - Staffing Standards not all met

#### **Summary findings**

There are enough staff to manage the pharmacy's workload. Members of the pharmacy team are appropriately trained for the jobs they do. And they complete some additional training to help them keep their knowledge up to date. The pharmacist is an accredited prescriber. But he cannot show whether he has enough knowledge and experience to safely prescribe all of the medicines that are offered on the pharmacy's website. And his professional judgement may be influenced by the high profit margins of some of the medicines.

## Inspector's evidence

The SI worked at the pharmacy as the regular pharmacist. The pharmacy also employed a pre-registration pharmacist (pre-reg), a pharmacy technician, a dispenser, three pharmacy students, a new starter, and a driver. Two admin assistants were employed to help provide the online services and the SI said their roles involved telephone calls, paperwork, and postage of general sales list medicines. All members of the team had completed the necessary training for their roles. The normal staffing level was a pharmacist, a pre-reg, and one to two dispensers. The volume of work appeared to be adequately managed.

Members of the pharmacy team completed some additional training, for example e-learning packages about common ailments. Training records were kept, and staff were allowed learning time to complete training. Various certificates were on display with details about the training which had been completed by the SI. This included the pharmacist's independent prescribing course and training courses related to Botox and dermal fillers provided by 'D1 Derma Medical'. But the D1 Derma Medical course had not been approved by the Joint Council for Cosmetic Practitioners (JCCP), and the course completed was not a Level 7 Higher Education England (HEE) course. So the pharmacist could not demonstrate whether he had appropriate skills and knowledge to be able to provide the aesthetics service safely. When the pharmacist was questioned about his scope of practice as a prescriber, he said he had completed some training for each of the treatments he prescribed. But he did not have any records of this training. He provided examples of some of the training resources that he had used, including his clinician peer, NICE guidance, and the BNF. The SI did not receive an appraisal or any review of his prescribing. So he may not be made aware of any areas of his practice which could be improved.

The pharmacy technician knew the questions she should ask when selling a pharmacy only medicine. She knew that some medicines were liable to abuse and said if she thought a sale may not be appropriate, she would refer to the pharmacist. The pharmacy team kept records to show prescribing interventions, advice they provided to people for self-care, and the number of people who were signposted to other services. The pharmacy technician said the SI was approachable, supportive and was happy to answer any questions she had. Staff had regular appraisals and a member of the team said she felt that the appraisal process was a good chance to receive feedback and identify areas for her to develop. Staff were aware of the whistleblowing policy and said that they would be comfortable reporting any concerns to the SI. There were no formal targets set for professional services. However; the SI was the main person who authorised any requests for medicines received through the pharmacy's website. He was also the sole director of the company. There was no independent review of his decision-making process, and some of the medicines had high profit margins and were liable to misuse or abuse. This meant there was a risk that the pharmacist's professional judgement could be

impaired by the financial benefits of approving a request.					

## Principle 3 - Premises Standards not all met

#### **Summary findings**

The pharmacy premises provide a suitable environment for the services provided and consultation rooms were available to allow private conversations. But the pharmacy website does not provide clear information about who provides its services. So people who use the website may not fully understand how services are provided. People can select medicines on the website before they start a consultation with a prescriber. So they may not always receive the most appropriate medicine for their treatment.

#### Inspector's evidence

The pharmacy was clean and tidy, and appeared adequately maintained. The size of the dispensary was sufficient for the workload and access to it was restricted by use of a gate. Customers were not able to view any patient sensitive information due to the position of the dispensary. The temperature was controlled by the use of air conditioning units. Lighting was sufficient. The staff had access to a kitchenette and WC facilities. A consultation room was available with access restricted by use of a lock. The space was clutter free with a computer, desk, seating, adequate lighting, and a wash basin. The patient entrance to the consultation room was clearly signposted. A separate consultation room was used for the substance misuse service.

The pharmacy website www.nhlpharmacy.co.uk could be used to purchase medicines and to access the prescribing service. The website described the service as an 'online doctor', which was misleading because prescriptions were issued by a pharmacist prescriber. It contained details about the company's name and the company's address and there were phone numbers and an email address. But it did not show the pharmacy's address, registration number, superintendent details, or how to check the details on the GPhC's register. The MHRA compulsory logo was displayed on each page. The website was presented in a way which allowed prescription-only-medicines and their quantity to be selected before the consultation had taken place.

## Principle 4 - Services Standards not all met

#### **Summary findings**

The pharmacy's services are easy to access. It gets its medicines from recognised sources, stores them appropriately and carries out regular checks to help make sure that they are in good condition. But the pharmacy supplies medicines without having enough controls in place to make sure they will be used safely. It does not check properly to make sure people who order medicines from its website are who they say they are. And it does not get enough information to make sure people are always getting medicines that are appropriate for them.

## Inspector's evidence

Access to the pharmacy was level via a single door and was suitable for wheelchair users. There was also wheelchair access to the consultation room. Various posters and electronic displays gave information about the services offered. Pharmacy staff were able to list and explain the services provided by the pharmacy. If the pharmacy did not provide a particular service staff were able to refer patients elsewhere using a signposting folder. The pharmacy opening hours were displayed at the entrance of the pharmacy, and a range of leaflets in the retail area provided information about various healthcare topics. Information was also available on the website which enabled people to telephone or email the pharmacy.

The NHS dispensing service operated separately from the online service and the prescribing service. Online requests were processed in an upstairs room away from the dispensary. Medicines for online supplies were picked and assembled in the downstairs pharmacy before being placed in a parcel and taken to the upstairs mailroom. There was normally only one pharmacist present. This meant that the prescribing pharmacist also performed the clinical check of dispensed medicines. So there was no independent oversight to assess the suitability of prescribed medicines.

Approximately 200-500 general sales list (GSL) medicines were supplied as online purchases via the pharmacy's own website, Amazon and eBay. The pharmacy also sold a range of pharmacy medicines via its website. When orders for P or POM medicines were received through the website, the pharmacist would be required to approve or refuse the request. When people selected a prescription-onlymedicine on the website, they were required to complete a questionnaire. The pharmacist reviewed this and if he approved the supply the order details and a paper token of the prescription were printed. The questionnaire asked different questions depending on the medicine selected, usually there were around 10 to 20 questions. Most of the questions only permitted a 'yes or no' response. If an inappropriate answer to the yes/no questions was selected, a prompt appeared which informed the person completing the form about this. It was then possible to change the answer and potentially obtain an inappropriate supply. The pharmacist would not be made aware about any altered answers on the questionnaire. Some questions did have free type text boxes, such as 'why are you choosing this pharmacy instead of seeing your GP', and there was an open question requesting further details about the person's medical history. The patient was not asked to provide contact details for their GP or for consent to share information with their GP. The pharmacist said he would consider all of the information provided in the questionnaire to decide whether to approve a request. He said he would contact the patient if he required further information or to provide counselling. A number of questionnaires were seen which had been used to approve requests for modafinil. But they did not include any information about whether the person had been diagnosed with narcolepsy by a specialist,

or if their condition was being monitored. So the prescriptions issued for modafinil may not be in-line with national guidance or the product's license, and the medicine may not be suitable for the patients.

People who purchased pharmacy medicines via the website were also asked to complete a questionnaire to explain why they wanted the treatment. Records showed that 1295 bottles of codeine linctus had been sold via the pharmacy's website in the previous 13-month period. A number of repeat orders were seen for codeine linctus which had been supplied to the same people over a period of time. Examples included a patient who had obtained 12 bottles in 8 months, and another patient who had obtained 18 bottles in 11 months. There was a further patient that had been supplied with six bottles in two months, and another patient that had been supplied with 10 bottles in 10 months. The SI estimated that up to 40 bottles per week were also sold to customers who visited the pharmacy. He confirmed that he did not have a specific policy about how often particular medicines could be supplied to a person. He said he used his professional judgement to decide on a case by case basis using the information provided and any information they held about the person making the request.

Requests for medicines via the website were initially processed by an admin assistant. She said it was a requirement for the person's shipping address and billing address to match, otherwise the request would be refused. The pharmacy did not request any other documentation to confirm a person's identity and there were no advanced identity checks built into the system. So there was a risk that fraudulent requests for medicines would not be detected. The admin assistant said she would complete some manual checks against the person's records using their name, email address and postcode, to see if they matched anyone else's details. But this was not automated so it was possible that duplication could be overlooked. The admin assistant provided examples of some multiple accounts she had found that appeared to belong to the same person. She said she would block these accounts and contact the person to inform them about this. But a search of the records found five different accounts that appeared to belong to the same person. These accounts had not been identified or blocked and they had been used to obtain 18 bottles of codeine linctus in an 11-month period.

Medicines for national delivery were sent by Royal Mail services. GSL and pharmacy medicines were sent by a tracked service and prescription medicines were sent using a signed for service, which required a signature upon delivery. But there was no risk assessment completed by the pharmacy to make sure it was safe for medicines to be sent by post. So the pharmacy was not able to show whether this arrangement was always suitable. The pharmacy also had a local delivery service, mainly used for NHS services. A delivery sheet was used to obtain signatures from the recipient to confirm delivery. Unsuccessful deliveries would be returned to the pharmacy and a card posted through the letterbox indicating the pharmacy had attempted a delivery. CDs were recorded in a separate delivery book for individual patients and a signature was obtained to confirm receipt.

The pharmacy team initialled dispensed by and checked by boxes on dispensing labels to provide an audit trail. They used dispensing baskets to separate individual patients' prescriptions to avoid items being mixed up. The baskets were colour coded to help prioritise dispensing. Owing slips were used to provide an audit trail if the full quantity could not be immediately supplied. Dispensed medicines awaiting collection were kept on a collection shelf using an alphabetical retrieval system. But prescription forms were not always retained, so the pharmacy team may not have all of the information they need when medicines are handed out. Stickers were used to clearly identify when fridge or CD safe storage items needed to be added. Staff were seen to confirm the patient's name and address when medicines were handed out. The SI said schedule 3 and 4 CDs were highlighted so that staff could check prescription validity at the time of supply. But there were no examples available to confirm this. Highrisk medicines (such as warfarin, lithium and methotrexate) were not routinely highlighted. So the pharmacy team were not always aware when they were being handed out in order to check that the supply was suitable for the patient. 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 he would speak to any patients who were at risk to make sure they were aware of the pregnancy prevention programme. But this was not always recorded on the patient's PMR, so the pharmacy was not able to demonstrate whether patients had been counselled.

Some dispensed medicines were supplied in multi-compartment compliance aids. Before a person was started on a compliance aid the pharmacy would complete a DDA assessment or refer them to their GP to complete an assessment about their suitability. A record sheet was kept for each patient, containing details about their current medication. Any medication changes were confirmed with the GP surgery before the record sheet was amended. Hospital discharge sheets were sought, and previous records were retained for future reference. Disposable equipment was used to provide the service, and the compliance aids were labelled with medication descriptions and a dispensing check audit trail. Patient information leaflets (PILs) were routinely supplied. A 'methameasure' electronic measuring pump was used to dispense methadone mixture.

Stock medicines were obtained from licensed wholesalers, and any unlicensed medicines were sourced from a specials manufacturer. The pharmacy was not yet meeting the safety features of the falsified medicine directive (FMD), which is now a legal requirement. Equipment was installed but the pharmacy team had yet to commence routine checks of medicines. Stock was date checked on a 3-month rotating cycle. Records were kept showing what had been checked, and shelving was cleaned as part of the process. Short dated stock was highlighted using a sticker and liquid medication had the date of opening written on. Controlled drugs were stored appropriately in the CD cabinet, with clear segregation between current stock, patient returns and out of date stock. CD denaturing kits were available for use. The medicines fridges were clean and each was equipped with a thermometer. The minimum and maximum temperatures were being recorded daily and records showed they had been in the required range for the last 3 months. Patient returned medication was disposed of in designated bins located away from the dispensary. 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 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 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. Separate measures were designated and used for methadone. The pharmacy also had counting triangles for counting loose tablets including a designated tablet triangle for cytotoxic medication. There was an electronic methadone pump that was cleaned and calibrated each day.

Computers were password protected and screens were positioned so that they weren't visible from the public areas of the pharmacy. A cordless phone was available in the pharmacy which allowed the staff to move to a private area if the phone call warranted privacy. The consultation room was used appropriately; patients were offered its use when requesting advice or when counselling was required.

## 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.