

Registered pharmacy inspection report

Pharmacy Name: J P Pharmacy, Attenborough Court Owen Square,
Aldenham Road, Opposite Bushey Station, WATFORD, WD19 4FN

Pharmacy reference: 1116527

Type of pharmacy: Community

Date of inspection: 29/07/2020

Pharmacy context

The pharmacy is in a mainly residential area opposite Bushey Station. It dispenses NHS and private prescriptions, sells over-the-counter medicines and provides health advice. The pharmacy dispenses medicines in multi-compartment compliance aids for people who have difficulty managing their medicines. Services include prescription collection. The pharmacy is working towards healthy living status. This was a targeted inspection following receipt of information that the pharmacy has been buying unusually large quantities of codeine linctus. All aspects of the pharmacy were not inspected on this occasion. The inspection took place during the Covid-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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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 identify and manage the risks involved in buying and selling excessive amounts of codeine linctus. So it is putting patient safety at risk.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy buys and sells excessive amounts of codeine linctus without safeguards against misuse.
5. Equipment and facilities	Not assessed	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy doesn't adequately manage all of the risks associated with providing its services. It is buying and selling excessive amounts of codeine linctus, putting patient safety at risk. The pharmacy does not record all its mistakes so may miss opportunities to learn and prevent the same errors happening again. The pharmacy has written procedures for its services which show staff how to complete their tasks safely. They are due to be reviewed and updated. The pharmacy generally keeps the records it needs to so that most medicines are supplied safely and legally. The pharmacist keeps private information secure.

Inspector's evidence

The responsible pharmacist (RP) said there was a low rate of near misses and that the near miss log sheet required reprinting. A completed near miss log was produced and an annual patient safety review (PSR) was compiled in line with Pharmacy Quality Scheme (PQS) requirements. 'Lookalike, soundalike' (LASA) medicines had been separated and the RP had completed Centre for Pharmacy Postgraduate Education (CPPE) LASA training. LASA medicines which had been separated included sumatriptan and sertraline, propranolol and prednisolone and amlodipine and amitriptyline tablets to reduce the risk of picking errors. The PSR referred to actions involving other members of the pharmacy team although at the time of the visit the RP said he worked alone.

The RP attributed the low rate of near misses to working alone. Baskets were available, if needed, to separate prescriptions and medicines during the dispensing and checking procedures. The RP explained that he downloaded electronic prescription service (EPS) tokens and printed the dispensing labels on a Monday. On Tuesday he dispensed the prescriptions and left the labelled medicines on the dispensing bench and checked them on a Wednesday. The dispensing audit trail on the dispensing labels was completed and the medicines were bagged. The name of the patient was attached to the bag before storing in the retrieval system. The prescription was not stored with the bagged items and warning stickers were not attached to the prescription bag. When asked how the RP was alerted to high risk items and counselling needs or making sure a controlled drug was not going to be supplied after 28 days, the RP explained that he knew all his patients and rechecked the prescriptions when they were collected. The RP was observed rechecking prescriptions when members of the public collected their prescriptions. Medicines that were owed to people had usually been received into stock by the time the prescription was due to be collected. People sometimes called the RP if they were prescribed a new medicine giving him a chance to order it in advance. There was an 'owings' book if needed.

There was a set of standard operating procedures (SOPs) which included RP procedures, a locum pack and business continuity plan. There was a practice leaflet and the complaints procedure was displayed for people to see. The SOPs were due for review and the RP said he was planning to update these procedures either through the National Pharmacy Association (NPA) or another pharmacy buying group he was thinking of joining. There were some training records for previous staff members who were no longer employed by the pharmacy. A pharmacy protocol for selling medicines and giving advice detailed appropriate questions to ask when people were purchasing medicines over the counter. Advice to the pharmacy team member included referring to the pharmacist if the same person regularly bought the same medicine or if there was an increased demand for a particular product.

Although not on display, 18 x 200ml Care codeine linctus SF and 6 x 200ml Pinewood codeine linctus SF tartrazine free were stored under the counter. When asked the RP said sales of codeine linctus were due to people asking for it and he would only sell one bottle of codeine linctus per person and refused to sell two bottles of codeine linctus per person. The RP said he did ask what the codeine linctus was for and recommended other medicines which were on display. The RP said he did not sell codeine linctus without suitable questions and he did not sell it to everybody. The RP said he would not sell codeine linctus to the same person during the same week and he would refer a repeat purchaser of codeine linctus to the doctor. Ensuring there were robust measures in place to restrict sales of codeine linctus and safeguard vulnerable people was discussed.

The RP said different people came to buy codeine linctus and it was sometimes difficult to tell people apart when they were wearing masks. The RP explained that he had been threatened and racially abused by people trying to buy codeine linctus. The RP said if he was threatened, he tried to stand his ground and he said he tried to refuse to sell codeine linctus even if threatened. The RP said he thought people buying codeine linctus may be connected with each other, but he had no evidence for this. He also said if he called the police for help they would not come.

Multi-compartment compliance aids were prepared according to a matrix for around 23 people which included people in 'assisted living' accommodation nearby. Compliance aids were generally prepared on a Saturday in a separate area of the dispensary. EPS prescriptions were received from the surgery and any changes in medication were highlighted. Compliance aids were re-dispensed to deal with mid-cycle changes. New patients who would benefit from having medicines supplied in a compliance aid were risk-assessed by the prescriber and the surgery then liaised with the RP. Labelling for compliance aids supplied to people in the assisted living accommodation included a description identifying individual medicines and patient information leaflets (PILs) were supplied. For other people still living in their own homes, the lack of PILs and description meaning people may not be able to identify individual tablets and capsules was discussed. The RP gave an assurance that moving forward, PILs would be supplied with each set of compliance aids. High risk medicines were mostly not supplied in a compliance aid except for alendronate which was de-blistered and placed in a weekly compartment to be taken on a Sunday.

To protect patients receiving services, there was professional indemnity insurance in place provided by NPA expiring 3 April 2021. The RP record was generally complete and only showed the RP's details and no other locum pharmacist details for the record seen. The private prescription records were complete and mostly for supply of antibiotics. The RP explained that there was a dentist nearby who issued these prescriptions. There was one private prescription for a controlled drug which required submission to the NHS in accordance with regulations and a copy to be retained at the pharmacy. Invoices dated 22 July 2020 and 24 July 2020 were seen for purchases of codeine linctus on each invoice.

There was an information governance (IG) folder which contained templates for confidentiality agreements. Confidential waste paper was collected for shredding. The computer was password protected and backed up regularly. The RP used his own NHS card. The RP said the NHS Data Security and Protection toolkit had been submitted and the privacy notice was displayed for people to see.

The pharmacist had completed the risk assessment for vulnerable staff including BAME employees. He worked alone and when asked what additional measures had been put in place to manage the risk of Covid-19 infection he explained that he allowed one person into the pharmacy at a time. He did not wear a mask because he found that people had difficulty understanding him during telephone calls.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacist manages the current workload and services. And he has completed training modules to keep his knowledge up to date.

Inspector's evidence

The RP said he regularly attended evening training events and had most recently attended an event provided by the Local Pharmaceutical Committee (LPC) on the PQS and supervised consumption. There was evidence of completed training for a previous PQS in a folder and included dementia friends, safeguarding, risk management, sepsis and LASA medicines. The RP said he was in the process of undertaking healthy living training. The pharmacist had completed the risk assessment for vulnerable staff including BAME employees. The RP was aware of changes to the re-validation process. The RP said his father, who was in the pharmacy at the beginning of th

e visit, came to keep him company and help with tasks such as removing rubbish. The RP said his father did not assist with dispensing or sale of medicines.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy's premises are generally safe, clean and suitable for the provision of services. People can have a private word with the pharmacist in the consultation room.

Inspector's evidence

The premises were generally clean although the dispensary bench was a little cluttered. The lavatory facility was clean and handwashing equipment was provided. The consultation room was reasonably tidy and there was handwashing equipment. The consultation room was signposted and protected patient privacy. It was not locked but the RP showed that it could be secured if necessary. There was sufficient lighting including natural light and ventilation units which could be hot or cold.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy provides some services in a way that puts patient safety at risk. It is buying and selling excessive amounts of codeine linctus without doing enough to make sure it is not being misused.

And the pharmacist does not always keep a record when checking that medicines are safe for people to take. People with different needs can easily use the pharmacy's services. The pharmacy gets its medicines from reputable suppliers.

Inspector's evidence

There was level access to the pharmacy through double doors. People could complete a consultation in the consultation room via the Medicspot laptop, using available equipment to monitor their blood pressure, oxygen levels and temperature. There had been low uptake of this service due to restrictions as a result of Covid-19. The RP said Covid-19 tests had been available at the pharmacy but he had withdrawn the service and asked Pharmadoc to remove the pharmacy's details from their website. When asked the RP said sales of codeine linctus were due to people asking for it and he would only sell one bottle of codeine linctus per person and refused to sell two bottles of codeine linctus per person.

The RP said he did ask what the codeine linctus was for and recommended other medicines which were on display. The RP said he would not sell codeine linctus to the same person during the same week and he would refer a repeat purchaser of codeine linctus to the doctor. The RP explained that he did make OTC interventions and described advising a customer not to buy ibuprofen because she already took aspirin. A record of interventions regarding over-the-counter (OTC) medicines including codeine linctus was not maintained. So the pharmacy could not show how vulnerable people were safeguarded from misusing this medicine.

The RP said the pharmacy had no patients in the at-risk group, but he was aware of the procedure for supply of sodium valproate to people in that group and information on the pregnancy prevention programme (PPP) to be explained. There was printed information to give to people in the at-risk group. The pharmacist explained the procedure for supply of isotretinoin to people in the at-risk group.

The RP said the prescriber would be contacted regarding prescriptions for more than 30 days' supply of a controlled drug (CD). He demonstrated the patient medication record (PMR) of someone prescribed more than 30 days' supply of schedule 3 CDs and how he had contacted the surgery so the prescription could be amended. The RP said he sometimes recorded interventions in the 'notes' section of the PMR.

The RP said most people had been switched from warfarin but if he was supplying warfarin, people were asked for their record of INR along with blood test due dates. The INR was not always recorded on the PMR. Advice was given about side effects of bruising and bleeding. Advice was given about a diet containing vitamin k in green vegetables and cranberries which could affect INR. People taking methotrexate were asked about their blood test dates which were sent to the surgery and the

prescription was released for dispensing. Lately, people attended the hospital for blood tests because of Covid-19.

There was a discussion about ensuring interventions were recorded to show appropriate clinical checks were carried out such as for high-risk medicines. For instance, sodium valproate, warfarin and CDs.

The pharmacy had conducted audits in line with the PQS scheme. Audits included identifying people who were not prescribed a proton pump inhibitor (ppi) while taking non-steroidal anti-inflammatory drugs, people with diabetes who were due for foot and retinopathy screening, people taking lithium and sodium valproate following national guidelines. Storage of venlafaxine and venlafaxine modified release preparations had been risk-assessed to minimise risk of picking errors as part of the risk management training.

The RP said that although delivery was not offered as a service, he would deliver medicines to people's homes on the way home. During the recent lockdown, a volunteer who had been vetted did deliver medicines but not CDs. The people were contacted first to say the volunteer was going to deliver their medicines. The volunteer set the package down at the door and stepped back to wait for the package to be taken in by the person.

Medicines and medical devices were obtained from Alliance, AAH, Phoenix, Colorama and Doncaster. The RP said codeine linctus was usually obtained from AAH and Doncaster. There were additional storage cupboards above the dispensary shelves used to store items such as empty compliance aids and dispensing cartons. Floor areas were not all clear as items were stored in tote boxes. Stock was stored neatly on the dispensary shelves and was date-checked regularly. No date-expired medicines were found in a random check. There were no open liquid medicines, but the RP said he marked them with a date when opened. Medicines were generally stored in original manufacturer's packaging. Cold chain items were stored appropriately in the medical fridge. Falsified medicines directive (FMD) software and a scanner had been installed but the RP said not all packs had a barcode, so he could not scan all packs of medicines. Waste medicines were stored in appropriate containers separate from other stock.

Compliance aid labelling did not always include a description to identify individual medicines in the compliance aid. Patient information leaflets (PILs) were not routinely supplied with each set of compliance aids so patients would have the most up-to-date manufacturer's information on their medication. The RP did give an assurance that moving forward PILs would be supplied with each set of compliance aids.

Most prescriptions were cleared from the retrieval system within three months and the RP said he would check when working on a Saturday. Warning stickers were not attached to the prescription bag. When asked how the RP was alerted to high risk items, counselling needs or checking a controlled drug was not going to be supplied after 28 days, the RP explained that he knew all his patients and rechecked the prescriptions when they were collected. The RP was observed rechecking prescriptions when members of the public collected their prescriptions.

Principle 5 - Equipment and facilities ✓ Not assessed

Summary findings

Inspector's evidence

This principle was not inspected.

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.