General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Aktive Pharmacy, Unit 37A, Bates Industrial Estate, Church Road, Harold Wood, Romford, RM3 0HU

Pharmacy reference: 9010197

Type of pharmacy: Internet / distance selling

Date of inspection: 31/10/2019

Pharmacy context

This is a distance selling pharmacy located in an industrial estate. The pharmacy dispenses medicines predominantly to people residing in care homes. The vast majority of people using the pharmacy are based in the UK. The pharmacy is closed to the public and situated in an industrial park and medicines are delivered to people by a delivery driver or via Royal Mail. The pharmacy also sells over-the-counter medicines via their website and dispenses some private prescriptions generated by two online EU based prescribers in Romania and Hungary. The pharmacy also provides flu vaccinations.

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	N/A	N/A	N/A
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 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

Overall, the pharmacy's working practices are safe and effective. The pharmacy asks its customers and people who use its services for their views. It largely keeps the records it needs to so that medicines are supplied safely and legally. Team members know how to safeguard vulnerable people.

Inspector's evidence

Standard operating procedures (SOPs) were up to date. Team members had read SOPs relevant to their roles and signed individual training records. Team roles were defined within the SOPs. SOPs had been tailored to the services offered by the pharmacy and covered areas such as: contacting patients by phone or email and ID checking.

Near misses were brought to the attention of the dispenser as they were identified and these were then rectified. The dispenser then made an entry onto the near miss record sheet and a discussion was held as to how this could be avoided in the future. Near misses were shared with the team. When putting away the stock when it came in, if team members noticed items had similar packaging they would notify their colleagues. Examples given of recent similar packs included different strengths of furosemide and lansoprazole oro-dispersible tablets. Different strengths of medicines were also separated on the shelves. Team members had also been instructed to type out people's full name when labelling prescriptions as there had been mistakes in the past where people had the same surname. There was little evidence of a formalised review of the near misses record.

Dispensing incidents were investigated by the pharmacists. An incident had occurred where zopiclone had been included in a pack, as the change had not been communicated to the pharmacy team by the care home. Following this, the pharmacist had requested all care homes to ensure a medicine change form was faxed to the pharmacy anytime there was a change in someone's medication.
The pharmacist had a good working relationship with the care home teams and the GPs. Each care home had a dedicated GP who the pharmacist regularly communicated with. The pharmacist had supplied all care homes with packs containing forms which needed to be sent to the pharmacy when communication needed to be passed on. All care homes were required to send the forms back with a record of the name of the person who was sending the form back.

The pharmacy had current professional indemnity insurance. The pharmacy had a complaints procedure in place with a notice displayed on the notice board and there was an explanation on the website telling people how they could make a complaint. Annual patient satisfaction surveys were also carried out. Complaints were usually sent in writing to the pharmacy. Following feedback from care homes that some people were running out of their medicines mid-cycle, the RP had found that it was generally those where a change had been made mid-cycle and this was not in sync with the medicines in the multi-compartment compliance packs. Care homes had been requested to complete a form with any details of medicines that people were due to run out of and the RP carried out checks. Care homes were then requested to order a prescription to cover the person until the new cycle started.

The correct responsible pharmacist (RP) notice was displayed. Team members were aware of the tasks that could and could not be carried out in the absence of the RP.

Records for private prescriptions and responsible pharmacist (RP) registers were well maintained. CD

registers were generally well maintained but there were some missed headers. The pharmacist said that emergency supplies were not given as prescriptions could be obtained before medicines were supplied. Unlicensed medicines were also not dispensed.

Most team members who accessed NHS systems had individual smartcards with the exception of the newly qualified dispenser and the new dispenser who had started. The superintendent pharmacist's (SI) smartcard had been plugged into the system but was not logged in. The team were reminded about keeping these cards and passwords secure. As the pharmacy was closed to the public, private information could not be seen. The SI had access to Summary Care Records; consent was gained prior to access. Consent was either gained from the individual or from a family member who had power of attorney.

The pharmacist carried out regular audits at care homes which included medicines management and administration. He described that as part of the checks he would see how medicines which needed refrigeration were stored, and how frequently the fridge temperatures were checked and recorded. He also carried out risk assessments and training sessions for staff working at the care homes. The pharmacist intended to send the inspector copies of previous risk assessments and audits carried out following the inspection.

Risk assessments and audits were also carried out for pharmacy-only (P) medicines sold over the internet. The pharmacist explained that he had noticed an increase in the number of people purchasing an antihistamine medicine. An investigation had found that the price of the medication was incorrect on the website and lower compared to other pharmacies. This was then amended.

Team members including the pharmacist had completed safeguarding training. Details of the safeguarding boards was displayed in the dispensary. Team members were able to describe the steps that they would take in the event that they had any concerns. The pharmacist described an incident where he had spoken to a manager at a new care home that the pharmacy had started supplying medicines. And he had picked up that they were not regularly carrying out reviews when people were being given their medicines covertly. The pharmacist explained that these reviews needed to be completed monthly unless the patient had a long-term condition which required the person's medicine to be administered in this way.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members for its services, and they work effectively together and are supportive of one another. They have the appropriate skills, qualifications and training to deliver services safely and effectively. They do ongoing training to help keep their knowledge and skills up to date. And they feel comfortable about raising any concerns.

Inspector's evidence

At the time of the inspection the pharmacy team comprised of the RP (a locum pharmacist), the regular pharmacist, three trained dispensers (one was on the technician training course) and a registered pharmacy technician. The technician left at the start of the inspection and said that she dealt with the wholesale side only.

The pharmacist felt that there was an adequate number of team members. The pharmacy had a policy in place that there could only be one team member off at any given time. The pharmacy employed regular locum pharmacists who were familiar with the pharmacy's processes. The pharmacist said that there were usually two pharmacists when packs had to be checked. The pharmacist had been due to provide training at a care home on the day of the inspection and had arranged a locum pharmacist to cover. Other arrangements had been made for the training.

Team member performance was managed formally by the SI with reviews held every three months. During the review working practices such as dispensing, performance and ways in which team members could improve was discussed. Key performance indicators (KPIs) were set for team members. There was an ability for team members to advance in their roles. And the trainee technician hoped to become an accredited checking technician.

The regular pharmacist was the trainee technician's tutor. And the trainee was given study time. The trainee would speak to her tutor if she was unsure of any areas or needed additional help, she said that she was well supported by her tutor.

All three dispensers used the Pharmaceutical Services Negotiating Committee (PSNC) website to read up on changes in pharmacy and for information. In addition to this the trainee technician also independently completed the Centre for Pharmacy Postgraduate Education (CPPE) training packs. She said that if she had read something which she was uncertain of she would speak to the regular pharmacist. The newly qualified dispenser referred to his training manuals from time to time to refresh what he had learnt.

Team meetings were held every Monday. During the meetings the team discussed the tasks that needed to be completed, any changes to workflow or any concerns. The team all felt that they were able to share concerns and feedback ideas to the pharmacists and SI. The technician trainee produced minutes for meetings, she said that she usually typed these up but had not had a chance to type up the minutes for the most recent meetings. The minutes displayed on the notice board were from 5 September 2019. Minutes were passed onto any team member who was absent during the meeting. A notice board was used to display any relevant information.

Targets were not set for the trainee technician and other team members, apart from a training target

and making sure tasks were completed in a timely manner. This included getting prescriptions from the surgery back on time, making sure acute items were delivered promptly, and any changes were made quickly.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are clean, safe, and well-maintained. And they provide a suitable environment for the services it provides. The premises are secured from unauthorised access. The pharmacy's website displays the required MHRA logo to help people identify that the website can legally sell medicines.

Inspector's evidence

The pharmacy was located in a gated business unit which was closed to the public. The unit was spacious and clean. There was ample storage and work space available which was allocated for certain tasks. Two tables were dedicated to preparing and checking the multi-compartment compliance packs. The pharmacist said that packs for two homes were usually checked per week. Medicines were arranged on shelves in an organised manner. There was a clean sink in the dispensary but this was not used; instead a sink labelled 'for dispensary use' which was situated in the staff area was used. Cleaning was done by the team with a rota and matrix in place. A separate room was dedicated to the pharmacy's wholesale side.

The premises were kept secure from unauthorised access. The room temperature and lighting were adequate for the provision of pharmacy services.

The pharmacy's website had the required EU distance selling logo displayed to help people identify that the website could legally sell medicines. And it stated the address and contact details of the pharmacy. Details of the superintendent pharmacist could be found under the complaints section on the website. Details of the pharmacy's GPhC registration could be found on the website.

Principle 4 - Services ✔ Standards met

Summary findings

Overall, the pharmacy's services are managed appropriately, and it gets its medicines from reliable sources and stores them properly. It takes the right action in response to safety alerts to make sure that people get medicines and medical devices that are safe to use. The pharmacy's team members identify higher-risk medicines and largely provide appropriate advice to help people use their medicines safely.

Inspector's evidence

Services were accessed over the internet or telephone. The pharmacist said that new patients usually joined the pharmacy due to word of mouth. The pharmacy either collected prescriptions or they were sent electronically to it. The prescriptions were then dispensed and delivered. Most people using the pharmacy were based in Essex or Greater London and were within driving distance from the pharmacy. The pharmacy team usually communicated with people over the phone. The pharmacist said that due to the working environment there was a lot more time to speak to people, going over what needed to be discussed and making sure that people's understanding was checked. The pharmacist had not come across any instances where someone had not been able to speak English. The team were multilingual and said that if a situation arose where they did not speak the language spoken by the person they would ask if there was someone who could translate. The pharmacy team had a good working relationship with a community pharmacy nearby and referred people who lived locally to this pharmacy.

People usually contacted the pharmacy over the telephone if they required counselling or had any questions. Most queries were from care home staff about their residents. The pharmacist asked them to update the medication administration and record sheets (MARR) and fax a copy to the pharmacy. The pharmacist explained that each of the care homes had a GP who was assigned to them. The pharmacist said that he had a good working relationship with the GPs.

P-medicines were available to purchase via the pharmacy's website. Audit trails were maintained for cancelled orders. Some were seen for people trying to order products which were open to abuse (such as codeine linctus) within a short time interval, others were from people ordering from abroad. The pharmacy had a small range of P-medicines which were segregated on a shelf. These contained painkillers (paracetamol, NSAIDs and Solpadol), antihistamines, codeine linctus and Viagra. People were asked to complete a questionnaire when ordering P-medicines online; the pharmacists screened the questionnaire before supplies were made. The pharmacist called and spoke to everyone who ordered medicines via this route. Previously the pharmacy had also sold the morning after pill, and the pharmacist had checked time limits before supplying the medicines. The pharmacy had a policy in place for codeine-based products. P-medicines were only supplied to people in the UK and no medicines were sent abroad. Medicines were sent by Royal Mail tracked delivery and were taken to the Post Office by dispensers. There had not been any delivery issues.

The pharmacy's website had some prescription-only medicines (POMs) displayed amongst the P-medicines. The RP said that POMs were not supplied via this route. He said that he had highlighted to the SI that zolmitriptan was on the website.

The pharmacy had an established workflow in place. Prescriptions for care homes residents were either ordered by the care home or by the pharmacy. The pharmacy operated using a 28-day cycle and

prompted care homes to order prescriptions seven to ten days in advance. Where the pharmacy ordered the repeat prescriptions, team members contacted care home staff to confirm items required before repeat slips were sent to the GP. Care homes who ordered prescriptions directly from the GP sent the pharmacy a copy of the repeat slip for audit purposes. Most prescriptions were received via the electronic prescription service. Once prescriptions were received they were screened by the pharmacist and compared against previous dispensing. The system also highlighted any changes. Care homes also notified the pharmacy of any changes. If they had not been notified the pharmacy confirmed changes with either the care home or GP. All communication was requested in writing which was then filed in a communication folder. This was kept in the main dispensing area for a month before it was filed away under the care home's name. Filing individual's records together would make it easier to refer to in the event that there were any questions or queries in the future.

The pharmacy used multi-compartment compliance packs called 'Multimeds'. Each time slot was labelled with the person's details and medicines inside. People's photographs were also printed on each pack where these had been provided. Medication administration and record sheets were provided to carers; these included drug descriptions or photographs to help carers identify medicines. Patient information leaflets were provided with every cycle. Team members signed the 'dispensed by' and checked by' boxes on the blister packs. The 'dispensed by' and 'checked by' boxes on medication labels for bulky items were also signed. Baskets were also used as part of the dispensing process to separate people's medicines. Interim (acute) prescriptions were generally dispensed and supplied on the same day.

All CDs including Schedule 4 CDs were marked with purple CD stickers to notify the care workers at the care home that these were controlled drugs.

The pharmacist and team were aware of the change in guidance for dispensing sodium valproate. The pharmacy had two regular people who fell in the at-risk group; the RP had spoken to both of their GPs and reviewed this. The pharmacist had not been aware of the need to use the warning labels. The inspector reminded him of the requirements.

The pharmacist had generated a chart with details of everyone who was on a high-risk medicine. He regularly reviewed the chart. For people who were supplied warfarin, he checked the INR with the care home. INR details had previously been recorded on the old electronic patient record system but this had been updated in the last few months and at the time of the inspection INR results were not being recorded. The pharmacist had formulated counselling sheets for some medicines such as lithium which was supplied to the care homes.

Some medicines were not placed in the compliance packs, such as high-risk medicines like warfarin and methotrexate, CDs, or medicines which needed to be taken at different times to the rest of the medicines such as alendronic acid.

The pharmacist visited care homes at least monthly. During these visits he also had discussions with GPs about giving covert medicines to people, if people in respite were being discharged with appropriate medicines, and if there was a change required in someone's medicines as well as advising on alternative medicines. Audits were also carried out during the visits. These covered staff training, storage and disposal of medicines, record keeping, administration of medications and CDs. Action plans were generated if necessary to help the care home meet requirements.

The pharmacy automatically ordered prescriptions for approximately ten other people who resided in their own homes. People who were supplied inhalers or feeds were required to contact the team after which the prescription was ordered. Prescriptions were dispensed by the dispensers, checked by the

pharmacist and then delivered by the driver.

The pharmacy had a designated delivery driver. Signatures were obtained when medicines were delivered. This helped the pharmacy show that the medicines had been delivered safely.

The pharmacy dispensed private prescriptions for Saxenda (a medicine used to help with weight loss). Prescriptions for these were issued by an EU prescriber via the PillDoctor website. The pharmacist said that 'fraud' checks were done offsite and he was sent a copy of the prescription via a messaging service with the original form also sent. The pharmacy did not have access to the questionnaire that the person had filled out only the prescription form. The pharmacist said that roughly three prescriptions for Saxenda were dispensed each week. Prescriptions were labelled using the electronic patient medication record system and an entry was made in the private prescription record. The RP usually called people up before making the supply and asked questions using a checklist. This included checking on weight loss. Every six months people needed to go and see a doctor (the pharmacy had not had anyone continue treatment for longer than that period). The pharmacist said people's GPs were notified when they first started treatment and this was done via fax, although records of this were not seem. The dispensed medicine was packaged in a box licensed for cold chain distribution (medicines could be stored for five days in this), these were taken to the Post Office and sent by tracked next day delivery. If delivery failed the package was sent back to the pharmacy and medicines were discarded.

The pharmacist carried out regular risk assessments for the supply of Saxenda. Results from this were discussed with the team. As part of the risk assessment the pharmacist identified what the hazard was, who might be harmed, what had been done, how the risk could be controlled and what action had been taken and by whom. This was updated once the task had been completed.

A signed an in-date patient group direction was in place for the flu vaccination services. Flu vaccinations were provided off-site by the SI. The second pharmacist was currently undergoing accreditation.

Following the inspection, the SI provided evidence that the pharmacy had several patient group directions (PGDs) for supplying antimalarials as part of a travel clinic. These PGDs were not seen during the inspection.

Medicines were obtained from licensed wholesalers. Fridge temperatures were monitored daily and recorded; these were observed to be within the required range for the storage of medicines. The dispenser was able to describe the action she would take if the temperatures fell outside of the required range; which included re-checking the temperature in an hours' time. This temperature was not recorded. CDs were held securely.

Expiry date checks were carried out every three months by the team. Short dated stock was highlighted. There were no date-expired medicines found on the shelves checked. A date-checking matrix was in place. Waste medicines were segregated from stock and collected by a specialised contractor.

The pharmacy was compliant with the Falsified Medicines Directive (FMD); medicines were decommissioned once the packs had been checked before they were sealed. The pharmacy team checked online daily for drug recalls. These were printed, actioned and filed to keep an audit. The action taken was recorded on the sheet along with the name of the team member who had actioned the recall. The recent alerts for different formulations of ranitidine and some supplements was seen.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely. And it generally maintains it well.

Inspector's evidence

The pharmacy had calibrated glass measures, and tablet counting equipment. Equipment was clean and ready for use. A separate tablet counting triangle was used for cytotoxic medicines to avoid cross-contamination. A fridge of adequate size was available.

Reference sources were available including access to the internet. Some of the copies of the British National Formulary were outdated, but the pharmacist said he used the online version. The pharmacy was closed to people and the public. The computers in the dispensary were password protected. Confidential waste was segregated and collected by a waste company for destruction.

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.