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: 13/06/2022

Pharmacy context

This is a distance selling pharmacy (www.aktivepharmacy.co.uk). The pharmacy premises are located on an industrial estate and are closed to the public. Medicines supplied by the pharmacy are delivered to people via courier. The pharmacy does not hold an NHS contract. It works with an online prescribing service operated by a company called Pilldoctor, which can be accessed via the pharmacy's website. Prescriptions are issued by a Pharmacist Independent Prescriber (PIP) and most are for treatment of 'lifestyle' conditions such as erectile dysfunction and weight management. The pharmacy also dispenses prescriptions issued by a 'transcribing service' for people who live overseas. Enforcement action has been taken against this pharmacy, which remains in force at the time of this inspection, and there are restrictions on the provision of some services. The enforcement action taken allows the pharmacy to continue providing other services, which are not affected by the restrictions imposed.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; 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's risk assessments do not adequately cover all of its services. It often supplies high-risk medicines to people without informing their GP. And it is not able to demonstrate the justification for prescribing for people who do not give consent to share information with their GP.
		1.2	Standard not met	The pharmacy does not always make enough checks to be satisfied the medicines it supplies are suitable. And it does not always follow up with the patients to check how their treatment is working. So it cannot provide assurance that the medicines are always being used safely.
		1.6	Standard not met	The pharmacy cannot provide assurance that the online prescribing service is making appropriate records about its clinical decisions.
		1.8	Standard not met	The pharmacy's safeguarding policy is a generic one for community pharmacies and does not take into account the pharmacy's model or range of medicines supplied. So it cannot provide assurance that vulnerable people are being safeguarded.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website contains inaccurate information. And it allows people to select a prescription-only medicine (POM) before starting a consultation, which is inappropriate.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not always make sure enough information is obtained from people to make sure the medicines it supplies are being used safely.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy works with an online prescribing service that is not registered with a UK regulator. But it cannot provide assurance that it is effectively managing the risks associated with supplying medicines prescribed by this service. It has completed some risk assessments, but these do not cover all of its services. The pharmacy often supplies high-risk medicines to people without informing their GP. And it doesn't always make enough checks to be satisfied the medicines are suitable or follow up with the patients to check how the treatment is working. So, it cannot provide assurance that the medicines are always being used safely.

Inspector's evidence

The pharmacy's business involved the supply of prescription-only medicines (POMs) and pharmacy medicines (P) to people based in the UK and overseas. The pharmacy did not have an NHS contract but worked with two separate prescribing services. One was an online prescribing service that could be accessed via the pharmacy's website. This service offered treatments for a wide range of conditions, including: asthma, erectile dysfunction, hair-loss and weight-loss. The other prescribing service (the transcribing service) provided prescriptions for people who lived overseas, mostly in the USA and Canada. This service issued prescriptions, signed by a GMC registered doctor, that had been transcribed from original prescriptions which had been issued in the patients' home countries.

The pharmacy had a range of up-to-date standard operating procedures, training records were not seen for all team members. The team member who had just joined the pharmacy was seen to be reading the SOPs during the inspection. Documented risk assessments were available for some of the medicines prescribed by the online service, including: emergency hormonal contraception (EHC), Orlistat, MySIMBA, Ozempic, Rybelsus, Saxenda and Caverject. But there were no risk assessments available for any of the erectile dysfunction treatments. A risk assessment had been completed for dispensing international prescriptions. However, this did not cover the risks involved with the transcribing service and focussed mainly on the delivery aspect and the legality of the prescriptions.

The risk assessments included actions to mitigate the risks that had been identified. However, it was seen that some risk assessments such as that for Saxenda heavily focussed on the delivery aspect of the service. As part of the risk assessment the pharmacy had not considered counselling people on how to use the medicines or the associated side-effects. For other medicines where the pharmacy had identified the need for counselling, they had produced bespoke information leaflets for specific treatments, and these were provided when the medicines were supplied, to help people take their medicines correctly. But it was noted that a leaflet for Rybelsus included incorrect advice to take it with food, when this medicine should be taken on an empty stomach.

Ozempic and Rybelsus were being supplied for weight-loss but the medicines were not currently licensed for that use. The RP said that the prescribers informed people when they were being prescribed an off-licence medicine. The pharmacy also included a leaflet with the medicines they supplied to explain when they were being used off-licence.

The pharmacy kept records showing it had contacted people to follow up after they had been prescribed certain weight loss medicines for the first time. This involved correspondence 12 weeks after the initial supply to see how the person was getting on with their medication. It was unclear as to what

steps were taken if there was no response. The consultation focussed on how much weight had been lost. There was no consideration of the pharmacy checking whether any baseline monitoring had been carried out or seeking assurances that the medicine were safe to issue particularly with it being off-label and the potential risk associated with the medicine.

No audit records were available during the inspection but the SI subsequently provided some records of completed audits. These audits had looked at: conditions medicines had been prescribed for, broken down into weight loss and none weight loss, the number of prescriptions issued by online prescribers, any issues with delivery, patient consent for contacting their regular prescriber. And any IT issues, blocked accounts, off-licence prescribing, and where the prescriber had recommended an alternative medicine. Results from the three-monthly audits carried out on the supply and administration of both Ozempic and Rybelsus showed that out of the sample size of 15 people there were consistently two to three people who were either not being provided with lifestyle advice or not being followed up within a month of starting treatment.

The majority of the prescriptions dispensed were from the online prescribing service. The pharmacy team had access to the online prescribing platform and could see the records of conversations that had taken place between the prescriber and the patient. The pharmacy could also add notes to the consultation record. All pharmacy team members were given an individual log-in when they started working at the pharmacy. A separate software package was used by the pharmacy to receive prescriptions from the transcribing service.

The pharmacy asked people for consent to inform their regular doctor about any treatments they received via the prescribing service. But most people did not give consent, so the pharmacy did not normally share any information to make their GP aware of what medicines had been supplied. This was a particular concern when medicines which require ongoing monitoring were supplied, such as diabetic medicines which were being used off-licence as weight loss medicines. This meant the pharmacy did not have assurance that the treatment was being appropriately monitored or that it was compatible with any other treatments being administered.

The RP stated that if a person did give consent, the pharmacy would send information to the GP about the medicines it had supplied. A file was available in the pharmacy which had a record of people who had given consent for their information to be shared. The pharmacist described sending this information via email, fax, or telephone. But he was not able to provide any evidence of any such correspondence. There were no records kept of any emails being sent and no fax confirmation records Furthermore, there was no risk assessment for those people who had not consented for information to be shared especially with high-risk medicines being prescribed off label for weight loss. Where the person requesting treatment did not give consent for the pharmacy to share information with their GP, the online prescriber did not make any records to explain their justification for prescribing.

The pharmacy also sold some over-the-counter pharmacy (P) medicines via its website. If a person selected a P medicine to buy, they were redirected to the prescribing service website to complete a questionnaire. Completed questionnaires were then returned to the pharmacy for review before the medicines were supplied.

The pharmacy had systems in place to monitor and review mistakes made during the dispensing process. Dispensing mistakes which were identified before the medicine reached a person (near misses) were brought to the attention of the person who had made the mistake and recorded on a log. Near misses were discussed with team members. The RP said that there had been no dispensing errors.

The pharmacy had a current indemnity insurance certificate displayed and the RP explained that this

covered all activity undertaken by the pharmacy including supplies of medicines outside of the United Kingdom (UK). The pharmacy had indemnity cover for supplying medicines to the United States and Canada. The PIP had indemnity cover for prescribing and separate cover for prescribing weight-loss medicines.

The correct RP notice was displayed. RP records were generally well maintained. Private prescription records were made on the system. Not all prescribing decisions were recorded. When questioned a trainee dispenser was not aware which activities could or could not be carried out in the absence of the RP. The inspector informed him of the activities that could not be carried out.

The pharmacy's website contained details of its complaint procedure. People were also provided with a printed QR code with their medicines which took them to a feedback page when scanned. Previous feedback had mainly related to the prescribing service so had been passed on to them. As a result of feedback, the pharmacy had changed the way in which it carried out a follow up consultation after Saxenda was supplied, from a phone call to email.

Team members had completed safeguarding training. There was an SOP available for safeguarding which appeared to be a standard template. The SOP did not take into consideration the pharmacy's business model. The policy did not include any information on safeguarding vulnerable groups and the potential for abuse of some of the medicines the pharmacy supplied.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff for the services provided, and they receive training for their roles. Members of the team have regular meetings and they are asked for their views about how services can be improved.

Inspector's evidence

At the time of the inspection the pharmacy team comprised of the RP, a trainee dispenser and a new team member who had started on the day of the inspection., A customer services administrator who was employed by the prescribing service and a work experience student. were also present. The customer service assistant was managed by the SI but sometimes worked remotely and only came into the pharmacy a few days a week. The customer service assistant's role included checking through the online orders received, checking if payment had been made and that there were no issues with the ID checks.

The prescribing service was using one PIP who was actively working and issuing prescriptions via the online platform. The PIP was not present in the pharmacy during the inspection. The pharmacy had evidence of the training completed by the PIP, and additional evidence for training completed specifically related to weight loss medicines was sent following the inspection.

The trainee dispenser was enrolled on an appropriate training course. The new starter had not yet begun training. The SI planned to review her qualifications and gave an assurance that he would enrol her on the appropriate training programme if needed. The customer services assistant had completed an online training module on customer services.

The SI held reviews with team members and provided feedback on their performance. Team meetings were held weekly. Near misses, dispensing errors and complaints were discussed at these. The SI also arranged meetings in between if anything developed. However, as the team worked closely issues were normally discussed as they arose. The SI could communicate with prescribers using electronic messaging applications. Monthly meetings were held between the prescribing service and the SI During these meetings they discussed how they might improve services. For example, they had discussed using video calls or pictures in the consultation process to verify if the patient weight information was correct. But this had not yet been introduced. Following a meeting with the prescribing service, the SI explained how a decision had been made to stop supplying medicines for asthma as the SI felt these could not be supplied safely online. The SI explained that there was no financial incentive for the prescriber to provide a prescription.

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

Summary findings

The pharmacy's website allows people to select a prescription-only medicine prior to having a consultation, which is inappropriate. Some information on the pharmacy's website and on the website of the associated prescribing service is out of date and inaccurate. The premises are clean and appropriate for the pharmacy's services. And they are secured from unauthorised access

Inspector's evidence

The pharmacy's website included an NHS logo and had not been updated to show that the pharmacy no longer dispensed NHS prescriptions. It contained the address and contact details of the pharmacy, details of the superintendent pharmacist, and details of the pharmacy's GPhC registration. The pharmacy's website had a link to the PillDoctor website which people used to access the prescribing service. The prescribing service website had details of the prescribers who issued the prescriptions but this was out of date and the prescribers listed were no longer issuing prescriptions. The prescribing service website also listed Aktive Pharmacy as one of its dispensing pharmacies.

The pharmacy's website allowed people to choose a medicine prior to starting a consultation. Selecting the medicine took them to the page on the prescribing service website where they then had an opportunity to undertake a consultation.

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 workspace available which was allocated for certain tasks. Medicines were arranged on shelves in an organised manner. There was a sink in the dispensary. 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.

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

Summary findings

The pharmacy's services are not always managed effectively, to protect people's health and wellbeing. The pharmacy is associated with an online prescribing service which regularly prescribes medicines that require ongoing monitoring. But the pharmacy cannot provide assurance that the medicines are always prescribed appropriately, or that they are being used safely.

Inspector's evidence

The pharmacy's services could be accessed via the Aktive pharmacy or PillDoctor websites. There was a link to the prescribing service from the pharmacy homepage.

People were required to log into their account on the prescribing service website before completing an online consultation questionnaire. Responses that were needed ranged from free text boxes to selecting answers from a list. Completed questionnaires were reviewed by the prescriber and used to decide to either prescribe or to reach out to the person via the messaging tool if there were any concerns. Questionnaires had been generated by the SI and prescribers. Examples of supplies being refused were not seen during the inspection but the audits submitted following the inspection showed that the prescriber had refused a small number of prescriptions.

ID checks were carried out by the pharmacy using 'Lexis Nexus.' In the event that there was an issue with the ID checks people were sent a private message and asked to upload a photographic ID. No audits had been carried out to review failed ID checks.

The pharmacy kept records of medicines it sold over the counter. There were no maximum quantities set for specific medicines. Team members were expected to raise a concern if they suspected someone was inappropriately requesting medicines, but the SI was unable to show how they would deal with this. People were able to communicate with the pharmacy about their medicines via the pharmacy website or the prescribing service website.

Weight loss medicines were not being appropriately monitored. Although checks were carried out on the person's weight, this relied only on information provided by the patient. Some consideration had been given to the fact that these medicines could affect blood sugar level. However, there was no evidence of people having undertaken any blood tests. Furthermore, there was no evidence of any requests for copies of people's medication summary or summary care record to identify any potential interactions or concerns. Although the questionnaire asked about medical and drug history there was no evidence of extra safeguards being in place to mitigate the risks of prescribing off-licence products. There was no evidence of the pharmacy referring to people's Summary Care Records or obtaining a confirmed clinical summary or medical history from the GP surgery, or any evidence of looking at a confirmed list of repeat medication the person may be taking.

The transcription service used a GMC registered doctor who issued prescriptions for people by transcribing from prescriptions that had originally been issued in the USA and Canada. The original international prescription was uploaded to the transcription service portal by an affiliate pharmacy in America. The SI described how checks were carried out before these prescriptions were uploaded. The pharmacy had sight of both the international and UK prescriptions and carried out checks to make sure

the prescription was legally valid. The pharmacy did not have any information to show whether the prescriptions were issued in line with UK guidelines. On the day of the inspection the trainee dispenser was seen to dispense a number of these prescriptions using a copy of the international prescription form. A few of the records were checked for these and UK issued prescriptions could not be found on the system. The SI explained that this was not normal practice and the UK prescription was normally used for dispensing and checking. He also gave an assurance that the medicines would not be supplied until the UK prescription was obtained. He explained that a copy of the international prescription was enclosed with the medicines when they were supplied.

Medicines were mainly posted to people residing in the UK, USA, and Ireland. The pharmacy team had carried out checks with the FDA to make sure that the medicines they dispensed could be sent to America. Delivery of medicines in the UK and to USA was via Royal Mail and deliveries were tracked and had to be signed for. Delivery of medicines to Ireland was via DHL special next day delivery. Medicines which required refrigeration were packed in Pharma Therma 10/15 cooling box after they had been placed in a cooling bag. Ice packs were also placed in the box to maintain the required temperature of between 2 and 8 degrees Celsius. People were provided with a leaflet containing storage information. The SI described that he had sent a test package to check if the cold chain was maintained and was satisfied that it was. But there was no documented evidence of this. Following the inspection an audit on the different packaging types was sent. The target time for delivery of fridge lines in the UK was between eight to twelve hours. This was to ensure that the cold chain was maintained. The SI explained that fridge lines were only sent to people living in the UK and confirmed that any medicines that came back to the pharmacy would be destroyed. Failed deliveries were recorded on a spreadsheet. However, there was no record made or link to the person's record on the system and information was not shared with the prescribers. The pharmacy did not deliver certain medicines at the weekend or before Bank Holidays.

Medicines were obtained from licensed wholesalers. Fridge temperatures were monitored daily and recorded. The records showed temperatures had been within the required range for the storage of medicines. However, the thermometer showed a maximum temperature of 8.8 degrees Celsius and a minimum temperature of -8.8 degrees Celsius. The current fridge temperature was 5.0 degrees Celsius. The SI gave an assurance that he would reset the thermometer and monitor the temperatures carefully. CDs were being stored securely.

Expiry date checks were carried out on an ongoing basis with different sections checked each week. Short-dated stock was highlighted. There were no date-expired medicines found on the shelves checked. Waste medicines were segregated from stock and collected by a specialised contractor. Drug recalls were received via email. The pharmacy dispensed a limited range of medicines. Alerts were printed, actioned, and filed to keep an audit.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for its services. It uses its equipment to help protect people's personal information.

Inspector's evidence

Reference sources were available including access to the internet. The electronic patient medication record system was password protected. Confidential waste was segregated and collected by a waste company for destruction. As the pharmacy was closed to the public this helped to protect people's confidentiality.

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.