General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Truepill Ltd, Unit 1, Fifth Street, Trafford Park, Manchester, Greater Manchester, M17 1JX

Pharmacy reference: 9011171

Type of pharmacy: Internet / distance selling

Date of inspection: 30/12/2019

Pharmacy context

This pharmacy is situated in a business park. It is a distance-selling pharmacy, so people do not visit it in person. It mainly supplies NHS prescription medicines which it delivers to people in the region. The pharmacy has its own website, www.truepill.co.uk where people can register and request the pharmacy to order and supply their NHS repeat prescriptions. The pharmacy also specialises in supplying oral contraceptives (OC) and emergency hormonal contraception (EHC) to people living in the UK via its other website www.helloeve.co, which offers a prescribing service.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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's clinical governance procedures are lacking. It cannot show that it has adequate systems and procedures or risk assessments to demonstrate its contraceptive services are safe.
		1.8	Standard not met	The pharmacy lacks any clear safeguarding policies or procedures. So, team members might be less confident identifying and supporting potentially vulnerable people, especially in relation to its contraceptive services.
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 for offering contraceptive services contains inaccurate and misleading information, and important details are missing. The helloeve website does not contain the pharmacy owner's details or identify the superintendent pharmacist. It does not make clear which healthcare professionals provide the services or indicate their location. The details of the prescribing service and the prescribers' registration details, country of registration, profession, are not stated on the website. The terms and conditions section of this website suggests that doctors provide the emergency hormonal contraception (EHC) service, when they do not, and the website incorrectly states the services are CQC registered. Neither of the pharmacy's websites contain any information explaining how people could check the pharmacy's registration status with the GPhC.
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 not all met**

Summary findings

The pharmacy does not manage all of the risks associated with its services. It has written instructions to help make sure the team works safely. But these do not cover all of the services, and it is sometimes unclear how the pharmacy manages and operates its online contraceptive services. And it does not have a clear safeguarding policy in relation to supplies of contraceptives. The pharmacy team records and reviews its mistakes so that it can learn from them, and it keeps people's information secure.

Inspector's evidence

The pharmacy had written procedures that it kept under review. These covered the safe dispensing of medicines, responsible pharmacist (RP) regulations and controlled drugs (CDs). So, the team members understood the procedures that were relevant to their role and responsibilities. However, the pharmacy did not have written procedures explaining how the OC and EHC services were provided, so it was not entirely clear how these were managed or operated.

The dispenser and checker initialled dispensing labels, which helped to clarify who was responsible for each prescription medication they had supplied and assisted with investigating and managing mistakes. The pharmacy team discussed and recorded mistakes it identified when dispensing medicines and it addressed each of these mistakes separately. The team reviewed each month's records for any trends. However, staff usually did not record the reason why they thought they had made each mistake. So, they could miss additional opportunities to learn and mitigate risks in the dispensing process.

The pharmacy had a complaint handling procedure, which helped staff to effectively respond to any concerns. It was trialling a patient survey, so it was working towards gathering people's views of its NHS and private services.

The pharmacy had professional indemnity insurance cover for the services it provided. The RP, who was the resident pharmacist, displayed their RP notice. The pharmacy maintained the records required by law for the RP, CD and private prescription transactions. It also kept the OC prescriptions in an organised manner. The pharmacy maintained the records for the non-prescription EHC service. It had not received any prescriptions for medicines to be manufactured under a specials licence, so it did not have any corresponding records for these.

The team checked CD running balances between every five to six weeks, so there could be a delay in detecting and resolving discrepancies. Two randomly selected balances were accurate, and the pharmacy held a minimal amount of CD stock.

The pharmacy displayed its privacy policies on its websites, and it had written information governance procedures for staff to follow. Staff had completed General Data Protection Regulation training and they stored and destroyed people's confidential papers securely. They used passwords to protect access to people's electronic data they but did not always use their own security cards to access people's electronic NHS information, which could compromise the accuracy of the associated audit trail. The team obtained people's written consent to provide the electronic prescription service.

The RP had level two safeguarding accreditation, and the trainee dispensers completed safeguarding

training as part of their accreditation course. But the pharmacy did not have a system for verifying people's identities. And it did not have a written procedure for identifying and handling safeguarding concerns, in particular when it received EHC requests. So, the team may not know how to handle some safeguarding issues.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to provide safe services. The team members work well together. New team members receive the right training for their roles and the pharmacy supports them to complete this.

Inspector's evidence

The staff present included the RP and two trainee dispensers who started working at the pharmacy around two months ago. The only other staff member, who was not present, was another trainee dispenser. The pharmacy had enough staff to comfortably manage its workload. Repeat medicines were ready for dispatch by 4pm against prescriptions received that morning. EHC requests and OC prescription orders were typically completed the same day that the pharmacy received them. The RP said that the staffing resource would be reviewed if the number of prescriptions dispensed increased. The pharmacy did not have any targets for the volume of services it provided.

Despite many of the staff being relatively new, they worked well both independently and collectively. They used their initiative to get on with their assigned roles and did not need constant management or supervision. The trainee dispensers were receiving the guidance they needed to keep progressing towards accreditation. However, they did not have any protected study-time, so they invariably had to study outside of their working hours.

The RP said that they did not know if the GP who provided the OC prescribing service had any specialism in prescribing contraceptives. They also said that they thought the PIP, who worked in the GP’s surgery, had completed a training module in reproductive prescribing.

The pharmacy had an effective strategy for covering planned and unplanned leave. It only allowed one of its staff to be on planned leave at any time. And the other team members increased their working hours to cover their colleague’s absence if necessary.

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

Summary findings

The premises are clean, secure and spacious enough for the pharmacy's services, and it provides a professional environment for healthcare services. The pharmacy's websites provide limited information about its services. Its helloeve.co website has details missing and it contains information that could be misleading.

Inspector's evidence

The pharmacy was situated inside a warehouse unit. Its dispensary and office were suitably maintained, and it was professional in appearance. The open-plan dispensary area provided enough space for the volume and nature of the pharmacy's services. A consultation room was unnecessary because people did not visit the premises. The level of cleanliness was appropriate for the services provided. And staff could secure the premises to prevent unauthorised access.

The pharmacy was registered with the Medicines and Healthcare products Regulatory Agency (MHRA) to supply prescription and non-prescription medicines via both of its websites. Its parent company's identity, the pharmacy's address, registration number, contact telephone number and email address were displayed on the contact page of its main website, www.truepil.co.uk, which could be easily found at the top of the home page. The superintendent's details were also available on the pharmacy's main website. However, these details were in an obscure location at the bottom of a job vacancy page, so people may have difficulty finding this information. Several randomly selected pages from the pharmacy's main website each displayed the MHRA distance-selling logo. Information on who regulated the pharmacy was included in the terms and conditions section on the website, which could be accessed from the bottom of each webpage. However, there was no information explaining how people could check the pharmacy's registration status with the GPhC.

The EHC and OC services were offered via the www.helloeve.co website, which also stated that the Care Quality Commission (CQC) regulated these services. However, the RP confirmed that the pharmacy owner was in the process of applying for this registration, so this was misleading as the service was not registered with the CQC.

The RP and another pharmacist provided the online non-prescription EHC service, and their name and registration number were displayed on the www.helloeve.co website. However, the website did not make clear that they were pharmacists or explain how people could check their registration status. Furthermore, the terms and conditions section of the website suggested that doctors provided the EHC service, when they did not.

The pharmacists provided the EHC service from the pharmacy. However, the service's location was not stated on the helloeve website. The website had a contact telephone number that directed callers to the pharmacy, and it had an email address that the RP said the pharmacy could access, but this was unclear from the website. The website did not include the pharmacy owner's details or identify the superintendent pharmacist.

The RP said that another pharmacist, who was an independent prescriber (PIP), and a local GP provided the online OC prescribing service remotely from the GP's surgery. They later said that the GP did not provide this service. The website did not include the address from where the PIP provided the

prescribing service, or their identity, registration details and country of registration, profession, or how to check their registration status. It also did not state the pharmacy's location or that it would dispense any OC prescriptions that the PIP had issued.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's working practices are reasonably safe. But it could do more to demonstrate that it manages the prescribing service safely. The pharmacy gets its medicines from licensed suppliers and manages them effectively to make sure they are in good condition and suitable to supply.

Inspector's evidence

The pharmacy operated Monday to Friday 9am to 5pm. Most people's prescriptions were received via the NHS Electronic Prescription Service, and the pharmacy had the corresponding medication ready for dispatch on the day it received them.

The pharmacy's EHC and OC services were only offered to anyone over the age of eighteen years. People registered online for the OC and EHC services via www.helloeve.co. The pharmacy team did not verify the identity of these people or know how this was done. And they did not have access to the clinical information that the PIP offering the OC service gathered about people, such as annual checks of the patient's body mass index (BMI) and blood pressure, any medication interactions, and their ability to adhere to the dosage regimen, as described in BNF guidelines. The pharmacy operated a supply only function and simply dispensed the electronic OC prescriptions that it received from the prescribers. So it did not monitor OC supplies or audit the prescribing.

The RP had completed the CPPE's EHC training, and the service was usually available across the pharmacy's operating hours. People who requested the non-prescription EHC service first completed an online questionnaire on www.helloeve.co. The completed questionnaires were forwarded to the pharmacy, which the pharmacist reviewed. They recorded the reasons for approving and declining the sale. They also recorded when they consulted the prescribers to decide on an appropriate course of action, or if they referred the EHC request to them. The pharmacy also kept a record of the EHC product it supplied. The EHC product was a Pharmacy only medication. It did not supply EHC against a prescription or under a patient group direction.

In relation to the NHS dispensing service, the pharmacy had written procedures for dispensing higher-risk medicines that covered anti-coagulants and methotrexate. Staff had not read these procedures and they did not have a written process to follow for dispensing lithium, so they might not know what they should do when they supplied these medicines. The RP had completed a valproate audit, which confirmed that the pharmacy did not have anyone in the at-risk group. However, the team did not have the MHRA approved valproate advice booklets or cards to give people when needed. The RP contacted people who were taking an anti-coagulant or methotrexate to confirm that they understood their dose, checked if they were experiencing any side-effects or interactions with the first supply or during a Medicines Use Review (MUR). The team did not always confirm their blood test results.

The pharmacy team used baskets during the dispensing process to organise its workload. But it only left a protruding flap on part-used medication stock cartons, which could be overlooked and lead to quantity errors.

The pharmacy obtained its medicines from a range of MHRA licensed pharmaceutical wholesalers and stored them in an organised manner. It had the software and hardware to comply with the Falsified Medicines Directive, but staff had not completed the training on using it, and the RP was unsure

regarding when they would implement it.

The pharmacy suitably secured its CDs; it did not have any date-expired and patient-returned CDs, but it had kits to denature them. The team suitably monitored the medication refrigerator storage temperatures, and records indicated that it monitored medicine stock expiry dates in recent times. The superintendent said that the minimal amount of stock held had been regularly date checked prior to keeping these records. The team took appropriate action when it received alerts for medicines suspected of not being fit for purpose, but it did not keep any records confirming this. It disposed of obsolete medicines in waste bins kept away from medicines stock, which reduced the risk of these becoming mixed with stock or supplying medicines that might be unsuitable.

Staff usually prepared CDs for dispatch on the same day that they received the prescription, so they made sure they only supplied CDs against a valid prescription. The team used packaging that maintained the cold chain for medicines that needed to be kept refrigerated during transit. The pharmacy used two external couriers to deliver medication, and it had the option of next day or one to three-day delivery. Both the team and people expecting to receive orders could track next day deliveries online while it was in transit, and records confirming medication had been delivered could also be accessed online. The pharmacy risk-assessed people's requests to deliver their medication if the courier could not personally hand it to a recipient at the destination address. This included confirming that there were no children or animals, but it did not take into consideration how secure the storage location was. One of the couriers took images of where it left these parcels, which provided some evidence of the medication reaching its intended destination. CD and medicines requiring cold storage were only shipped on the next-day delivery service and had to be given to a named recipient either at the destination or a neighbouring address. The RP said that the couriers rarely reported losing any dispatched medicines. However, one of the couriers did not officially declare any packages as lost until eighteen days after it took receipt of them from the pharmacy. And the pharmacy had not considered what action to take if people reported not receiving their medication shortly after the anticipated delivery date.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment that it needs to provide its services effectively, which it properly maintains. And it has the facilities to secure people's information.

Inspector's evidence

The team kept the dispensary sink clean, it had hot and cold running water and an antibacterial hand sanitiser, and a range of clean measures. So, it had the facilities to make sure it did not contaminate the medicines it handled and could accurately measure and give people their prescribed volume of medicine. Staff had access to the BNF and cBNF online, which meant they could refer to the latest pharmaceutical information if needed.

The pharmacy team had facilities that protected people's confidentiality. It viewed their electronic information on screens not visible from public areas and regularly backed up people’s data on its patient medication record (PMR) system. So, it secured people’s electronic information and could retrieve their data if the PMR system failed. The staff spoke to people directly via the telephone. And members of the public did not visit the pharmacy, so it was unlikely that unauthorised persons could see patient data at the pharmacy.

The pharmacy stated on its websites that it stored people’s electronic information on its own secure servers that it did not share with any other organisation, and behind firewalls. Any payment transactions were encrypted using Secure Sockets Layer (SSL) system to provide online communication security. This supported information security principles such as encrypting the data transmitted between the patient and pharmacy. And it ensured that the data submitted was that received. The RP said that the OC prescriptions and completed EHC questionnaires were transmitted to the pharmacy encrypted. The systems were password protected so the OC prescriptions and the prescriber’s signature could not be easily changed.

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.