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: 18/06/2021

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 to request the pharmacy to order and supply their NHS repeat prescriptions. The pharmacy also specialises in prescribing and supplying oral contraceptives (OC) and non-prescription emergency hormonal contraception (EHC) to people living in the UK via its other website www.helloeve.co.uk. This inspection was completed during the COVID-19 pandemic.

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	1.2	Good practice	The pharmacy audits and reviews its contraceptive services to make sure they are safe.
		1.8	Good practice	The pharmacy has specific safeguarding policies in relation to its contraceptive services.
2. Staff	Standards met	2.2	Good practice	New team members receive the appropriate training for their roles and the pharmacy effectively supports them to complete this. The pharmacy regularly reviews the performance and development of its prescribers to make sure they have the right skills and knowledge.
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

The pharmacy suitably manages the risks associated with its services. It audits and reviews its contraceptive services to make sure they are safe. The pharmacy has written instructions to help make sure the team works safely. And it has specific safeguarding policies in relation to its contraceptive services. 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

To protect against spreading the COVID-19 virus, staff wore masks and regularly used hand sanitiser throughout the working day. Dispensed medicines were packed for delivery in the warehouse section to minimise the number of staff in the dispensary. Most staff members had received one vaccination, and some had received two doses. All of them had completed a health risk assessment. Most team members regularly self-tested using lateral flow tests, and the pharmacy had procedures which required them to self-isolate if they displayed any of the recognised symptoms.

The pharmacy had written procedures that it kept under review. These covered the safe dispensing of medicines, responsible pharmacist (RP) regulations, controlled drugs (CDs) and providing the OC and EHC services. And the team members understood the procedures that were relevant to their role and responsibilities.

The pharmacy's written procedures for the EHC and OC services clarified that they had been drafted using the guidelines from the Faculty of Sexual and Reproductive Health (FSRH) of the Royal College of the Obstetricians and Gynaecologists. An external medical panel reviewed these procedures, and the pharmacy amended them following any recommendations from the panel. The pharmacy's medical director, a general practitioner (GP) who had a diploma in family planning and reproductive health and was a health system strategist, checked the FSRH's guidelines every quarter. The medical director communicated any changes to these guidelines to the prescribing team, during monthly meetings, so the procedures were updated regularly. The prescribing team consisted of three pharmacist independent prescribers (PIPs or 'prescribers') who worked remotely. Truepill Ltd was also registered with the Care Quality Commission (CQC) but the services had not been inspected.

The superintendent explained that the pharmacy completed quarterly audits of the prescribing practises for the EHC and OC services that identified the reasons why medication requests were cancelled or rejected. The OC prescribing service was additionally audited for requests from people aged over forty years or who experienced migraines and may be more at risk. These audits were intended to identify any patterns and highlight any prescribing that may not be safe, so that changes could be made to the pharmacy's clinical guidance in keeping with best practice. These findings were presented at the prescribing team meetings.

Recent data that the pharmacy had gathered from the prescribing audits showed that the prescribing team did not prescribe an EHC or an OC when it was not safe to do so. For example, when people did not respond to their queries or they had an ongoing medical condition or were taking another medication that made it unsuitable to prescribe. They also did not prescribe an OC when people had requested a further supply too soon, they had a raised body mass index (BMI) or were at higher risk of a

blood clot. And the data showed that the prescribing team did not prescribe EHC when people had requested it twice in the same month or indicated that their menstrual bleed was late.

The prescribing and pharmacy teams had written procedures for reporting and analysing prescribing and dispensing mistakes. It stated that the medical director and lead pharmacist, who was the superintendent, would review these reports each month. They used systems for measuring the level of harm and the chance of the mistake happening again to calculate the overall risk to people. As a result, they clinically reviewed any incidents that they classified as significant events and discussed them at the prescriber and pharmacy team meetings.

The dispenser and checker initialled dispensing labels, which helped to clarify who was responsible for each prescription medication they had supplied and this 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 included providing a written report to the person raising the complaint explaining the learning and remedial action the pharmacy had taken. This helped staff to effectively respond to any concerns. The complaints procedure was explained on the Truepill and helloeve websites, but it was located low down on the terms and conditions page, so it may not be easy for some people to find. The helloeve service received positive feedback across several key areas in its last patient satisfaction survey conducted in February 2021. The pharmacy planned to use the annual Community Pharmacy Patient Questionnaire (CPPQ) to obtain feedback about Truepill's NHS services. But it had not been able to complete this survey since it opened in 2019 because of COVID-19.

The pharmacy had professional indemnity insurance cover for the services it provided. The RP, who was a locum pharmacist, displayed their RP notice. A random recent sample of electronic OC prescriptions indicated that the pharmacy's prescribers were issuing legally valid prescriptions. The pharmacy maintained the records required by law for the RP, CDs and private prescription transactions. It also kept the OC prescriptions in an organised manner. The team checked CD running balances each week to promptly detect and resolve any discrepancies. The pharmacy maintained appropriate records for the non-prescription EHC service. It had not received any prescriptions for unlicensed medicines, so it did not have any corresponding records for these.

The pharmacy displayed its privacy policies on its websites. The helloeve privacy policy explained that the pharmacy owner may have to check a person's Summary Care Record (SCR). The superintendent explained that the prescribing or pharmacy teams sometimes asked for people's consent to access the SCR, but this was not automatically requested as part of the online EHC or OC questionnaires.

The pharmacy had written information governance procedures for staff members to follow. Team members had completed General Data Protection Regulation training and they stored and destroyed confidential papers securely. They used passwords to protect access to people's electronic data and they used their own security cards to access people's electronic NHS information to maintain the accuracy of the associated audit trail. The team obtained people's written consent to provide the NHS electronic prescription service.

The pharmacy's identification and verification policy for the EHC and OC services adopted the FSRH's guidance on standards for online service providers that stated the FSRH did not support the creation of obstacles which may prevent users from accessing these services in keeping with other sexual health

service providers. The helloeve website automatically checked if a person's name, date of birth, email address and telephone number were valid. The website declined anyone who was under eighteen years old, and these people were signposted to an alternative service. The system created an account from a person's email address, which acted as their unique identifier. This meant that any EHC or OC requests placed using the same email address were linked to one account. The prescriber was presented with the person's account order history as the default screen before they proceeded with any other action. So, they could clearly see any multiple requests for supplies for an EHC or OC when a person used the same email address. However, there was no system for detecting multiple EHC or OC requests from the same delivery address. The superintendent confirmed that the prescribers manually verified a person's home address by using external online identity service, or by accessing their SCR to check their identity. The prescribers could also request additional identification documents to confirm a person's identity if needed and the consultation would not proceed unless a person submitted these. The pharmacy had an automated system that detected any payment details that did not match the account details and multiple use of the EHC or OC services within a short time. It sometimes received requests for the EHC or OC services from male service users. It referred these requests back to the prescriber and requests were refused. These measures helped to confirm the person's age or gender and identify multiple medication orders from the same address or with a short time period.

The pharmacy's safeguarding policies referred the EHC and OC prescribers to FSRH's guidance on online services (2019), which included the ethical and legal issues to consider when arranging contraception for someone with a learning disability and supporting them to make their own decisions about contraception. It also covered assessing their competence to consent to treatment by their ability to understand the information provided, weigh up the risks and benefits, and express their own wishes. The RP had level two safeguarding accreditation, and the dispensers had completed safeguarding training as part of their accreditation course. The superintendent added that all prescribers, pharmacists and dispensers who processed EHC and OC orders have completed safeguarding children and vulnerable adults training to help identify vulnerable individuals.

The superintendent explained that the prescribers counselled people who repeatedly requested an EHC on the benefits of using an alternative regular contraceptive such as an OC or IUD mainly via Email and occasionally by telephone. They explored if people were having any difficulties accessing the appropriate service for these contraceptives and signposted them to their GP or local sexual health centre if they refused an EHC request.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to provide its services safely. The team members work well together. New team members receive the appropriate training for their roles and the pharmacy effectively supports them to complete this. The pharmacy regularly reviews the performance and development of its prescribers to make sure they have the right skills and knowledge.

Inspector's evidence

The dispensary staff present included the RP, an Accredited Checking Technician (ACT), a dispenser and a trainee dispenser. A locum dispenser was also providing cover while the pharmacy recruited a permanent full-time dispenser. The other staff, who were not present, included the superintendent, who was the regular pharmacist.

The medical director oversaw the EHC and OC services. The superintendent, who had completed the CPPE's EHC training, and the three pharmacist prescribers provided the online EHC prescribing service. The prescribers also provided the online OC prescribing service. The medical director appraised each prescriber's performance and development needs annually using CQC guidance for reference. As part of the recruitment process, the medical director assessed each prescriber's competency via a series of test medication requests. And each prescriber had to provide at least one continuing professional development example on reproductive prescribing each year. They had completed the FRSH's training on post-COVID-19 prescribing.

The pharmacy had enough staff to comfortably manage its workload. Repeat prescription medicines were ready for dispatch by 5pm against prescriptions received that morning. The pharmacist prescribers had maintained a prompt service despite an increase in EHC and OC service demand during the pandemic, as they usually issued EHC orders and prescriptions on the same day that they received a request for these services. And the superintendent checked for any outstanding requests throughout the working day. The pharmacy's customer services team were not aware of any people who reported a delay in receiving their medication. The pharmacy did not have any targets for the volume of services it provided.

The staff members worked well both independently and collectively. They used their initiative to get on with their assigned roles and they did not need constant management or supervision. One of the dispensers had started an NVQ level three dispenser course in April 2021. Both the NVQ three trainee and the trainee dispenser, who started working at the pharmacy in April 2021, said that their training was progressing well, and they were receiving the support necessary to keep developing their skills and knowledge. They received four hours protected study time each week, and the dispenser had a community pharmacy placement for one day each week as part of their training.

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. The other team members increased their working hours,

or a locum dispenser was temporarily recruited to cover their colleague's absence if necessary.

Principle 3 - Premises ✔ Standards 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 clear information about its services.

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. It had external metal shutters to protect all the windows and entry points.

The pharmacy's parent company's identity, the pharmacy's address and how to check its registration status, registration number, contact telephone number, email address and superintendent's details were displayed on the terms and conditions page of its main website, www.truepil.co.uk, which could be found at the bottom of the home page. The superintendent's details and how to check them were available on the 'about Truepill' page of the pharmacy's main website, so people should not have too much difficulty finding this information. Electronic links at the bottom of several randomly selected pages from the pharmacy's main website confirmed who regulated the pharmacy.

The EHC and OC services were offered online via the website www.helloeve.co, which also stated that the GPhC regulated these services. The website stated that both services operated from the pharmacy. The medical director's details were provided on the website.

The superintendent's and three prescribers' names, roles and registration numbers were displayed on the 'about us' page of the helloeve website. The website clarified that they were pharmacists and how people could check their registration status. The website listed the pharmacy's address, telephone number, email address, and the pharmacy owner's details.

People had to first complete an online questionnaire on the helloeve website for the EHC and OC services before they were presented with a page of potential medication options. The same page stated that the prescriber will review the responses provided and select the most appropriate medication. These measures helped to make sure people received medication that was safe and appropriate for them.

The Truepill website contained links to two other websites hellobetterman and helloahead. The pharmacy owner confirmed the hellobetterman website was not active and that the pharmacy was not involved in providing any part of the services promoted on the helloahead website.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's working practices are generally safe and effective. The team gets its medicines from licensed suppliers and manages them appropriately to make sure they are in good condition and suitable to supply. But the pharmacy could do more to make sure it can show that it provides the contraceptive services safely.

Inspector's evidence

The pharmacy operated Monday to Friday 9am to 6pm. Most NHS prescriptions were received via the Electronic Prescription Service, and the pharmacy had the corresponding medication ready for dispatch on the day it received them. The EHC and OC service were available across the pharmacy's operating hours.

People registered online for the OC and EHC services via the website www.helloeve.co.uk. The pharmacy team members demonstrated the external online identity service that the prescriber used to verify people's details, which included their age, but there were no records to confirm they had done this.

People had to complete an online questionnaire every time they wished to receive the EHC or OC services. These questionnaires were based on the FSRH's guidelines and they were reviewed annually or following a significant incident. These measures helped to make sure EHC or OC medication supplies were safe and appropriate.

The pharmacy team had access to the electronic dashboard for the EHC and OC services. The dashboard included details of a person's medication supply history, responses to the online questionnaire, the prescriber who had reviewed their request, and a section for team members to record any notes such as communications with other health care professionals. This helped the pharmacy to check that each EHC and OC request was appropriate before making a supply. The pharmacy also recorded the non-prescription EHC product it supplied on the dashboard.

People had to confirm on the EHC and OC online questionnaires whether they agreed to the pharmacy informing their GP about any relevant information, but most people did not consent to this. The pharmacy used a standard form to share information with GPs about EHC and OC medication it had supplied, but the prescribers did not always record why they had prescribed medication to people who had not provided consent. The superintendent explained that the prescribing team only accessed a person's SCR when it had their consent and felt it was necessary but this action was not always recorded. People had to provide their blood pressure, height and weight when responding to the EHC and OC online questions.

However, the prescribers did not always reference the BMI in the dashboard or provide additional notes to show or what additional checks had been completed. So, the reasons supporting their clinical judgements were sometimes unclear.

The superintendent explained that the prescribers mostly provided counselling via email and occasionally by telephone. This included giving people advice on adhering to contraceptive medication,

staying healthy and consulting their GP about using a long-term contraceptive. The EHC questionnaire did not specifically query if they were taking an OC or using other contraceptive methods, or if they had a contraceptive failure. But the pharmacy's written procedures stated to signpost people to a long-acting reversible contraceptive (LARC) service if they felt the a LARC may be more appropriate for the individual. The procedures included details of the LARC methods. The prescribing or pharmacy teams did not routinely signpost people for sexually transmitted infection (STI) screening when it may be relevant.

In relation to the NHS dispensing service, the pharmacy had written procedures for dispensing higher-risk medicines that covered anti-coagulants, methotrexate and lithium. Staff had read these procedures, so they knew what they should do when they supplied these medicines.

People new to the pharmacy received an advice pack with their first supply of anticoagulant, methotrexate and lithium. The pharmacy regularly provided these people advisory cards with future supplies. It notified people in writing when their medication review was due with their GP and followed this with an SMS text message or telephone call if necessary.

The pharmacy had recently completed a valproate audit, and it had counselled people identified in the at-risk group. The team had the MHRA approved valproate advice booklets or cards to give people when needed. The superintendent 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. But the team did not always confirm their blood test results.

The team used baskets during the dispensing process to separate people's medicines and organise its workload. It marked part-used medication stock cartons, so team members were more likely to notice this and supply the right amount of medication.

The pharmacy obtained its medicines from a range of MHRA licensed pharmaceutical wholesalers and stored them in an organised manner. It suitably secured its CDs, but it did not have the kits to denature them. The team monitored the medication refrigerator storage temperatures. Records indicated that the team regularly date checked the medicine stock. It 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 so it may not be able to effectively demonstrate this in the event of a query. The pharmacy 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 members 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. CDs and thermolabile medication were stored appropriately in the pharmacy until the external courier presented to collect them.

The pharmacy used three external couriers to deliver medication, which gave people the option of one to three-day delivery. Both the team and people expecting their medication could track their delivery online while it was in transit, and records confirming medication had been delivered could also be accessed online. To reduce the risk of supply delays, the pharmacy used one courier to deliver CDs, thermolabile and EHC medications because it provided a next-day delivery service between Tuesday and Saturday from 8am and 6pm.

The helloeve website clarified that online requests placed for EHC before 1pm would, if accepted, be delivered on the next appropriate delivery day. So, people could decide if the EHC medication would be

supplied within the necessary time frame. The staff explained that any requests for the EHC service that people initially made via the telephone before 3pm would also be delivered on the next relevant day, because the prescribers and pharmacy had enough time to process the request before the courier presented at 4pm. The pharmacy took the EHC service offline on bank and customary holidays because the team were on leave and supplies would therefore be delayed. The prescribers usually authorised the pharmacy to supply EllaOne in around seventy percent of the accepted EHC requests, because it could still be effective for up to 120 hours after intercourse. And they considered this option for any EHC requests that people made after Friday 3pm and Sunday to make sure the pharmacy could supply it in good time. The prescribers approved Ezinelle for most other accepted EHC requests.

The courier informed people via an SMS text message the hour in which it would deliver their EHC medication. A named recipient either at the destination or a neighbouring address had to sign the courier's documentation to confirm receipt of the medication. Another courier delivered the OC medication because of their reliability and UK coverage, which included the Scottish Highlands and Northern Ireland.

The prescribers usually prescribed three months OC to people. Around half of these prescriptions called for Microgynon, around a quarter called for either Cerelle or Yasmin, and the rest were for either Femodene, Cerazette or Cilique.

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.

The pharmacy had plans to help patients if they missed their delivery or their medication was not delivered. It monitored deliveries each day and any missed deliveries were transferred to the next working day. The pharmacy team contacted people following two consecutive failed delivery attempts to explore an alternative delivery option. The team disposed of any EHC or OC medication returned to the pharmacy.

The pharmacy documented any failed deliveries or returns from the courier on the patient's dashboard order notes. This meant that the pharmacy could create an automated report to review the delivery part of its service. The RP said that the couriers rarely reported losing any dispatched medicines.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

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

Inspector's evidence

A contract cleaner disinfected the IT and stationary equipment, telephones and door handles each morning. The team sanitised the work surfaces every working day. Each staff member had their own telephone headset and the two sets of dispensary doors were kept open during operating hours to reduce touching door handles and increase ventilation.

The team kept the dispensary sink clean, it had hot and cold running water, 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 members 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 maintained physical, electronic and procedural safeguards to comply with applicable standards to guard health information, including storing all information people provided to it on secure servers 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 superintendent explained that 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.