General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: The Hormonist, Unit 16, Freetrade House, Lowther Road, Stanmore, HA7 1EP

Pharmacy reference: 9011688

Type of pharmacy: Internet / distance selling

Date of inspection: 23/05/2022

Pharmacy context

This is a private pharmacy, in Harrow, Greater London and is closed to the public. The pharmacy does not have an NHS contract. And it does not sell over-the-counter medicines. It only dispenses private prescriptions for hormone replacement from prescribers who are associated with an online company (https://balancemyhormones.co.uk/) regulated by the Care Quality Commission (CQC). And it delivers them direct to people's homes.

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

The pharmacy has adequate processes in place to identify and manage risks. It protects people's private information appropriately. Members of the pharmacy team deal with their mistakes responsibly. But they are not always recording all the necessary details. This could mean that they may be missing opportunities to learn, spot patterns and prevent similar mistakes happening in future. The pharmacy has some operating instructions in place to guide its team members. But it has not always maintained all its records, in accordance with the law or best practice.

Inspector's evidence

The pharmacy was newly registered with the GPhC. The inspector was told that the pharmacy's volume of dispensing was low and the pharmacy didn't appear to be busy at the time of the inspection. The pharmacy held a range of documented standard operating procedures (SOPs) to support its services. This included one for COVID-19. The SOPs were due for review in November 2023 and provided some guidance for the team on how to carry out tasks correctly. The staff had read as well as signed them. However, the pharmacy's incident management process was missing. The pharmacy's team members understood their roles and responsibilities. The correct notice to identify the pharmacist responsible for the pharmacy's activities was on display. The superintendent pharmacist (SI) had completed a risk assessment for health and safety matters but a tailored, comprehensive risk assessment about the specific service that the pharmacy provided was not seen.

The pharmacy had some systems in place to identify and manage the risks associated with its services. The pharmacy had a suitable amount of workspace available to dispense prescriptions with designated stations for individuals to work on and to complete different tasks from. The pharmacy was kept clear of clutter. The SI clinically screened prescriptions before the dispensing assistant labelled and dispensed the medicine(s). There were also some auditable processes in place (see below and Principle 4). The pharmacy had recently obtained people's feedback about the service they had received from the pharmacy. This was through a survey that the superintendent had created. Some comments were seen during the inspection, but the results were still being analysed. Some of the pharmacy's systems had also been modified in response to people's needs. Previously, people were supplied needles and syringes mixed in together with their medicine(s). The pharmacy team had subsequently created a pack which contained these separately, along with a QR code on the front for people to order more if required. People using the pharmacy could raise concerns through the online website (see Principle 3). The pharmacy also had a designated book in place to record any near miss mistakes and incidents, but only a few details were seen recorded and some records in these books had been used to record interventions. The SI said that she discussed errors with the staff informally after they had happened but there were no details about their review recorded.

The owner explained that when people signed up to the service at 'Balance My Hormones', they were contractually obliged and consented to have their prescriptions dispensed from this pharmacy. The superintendent confirmed that the pharmacy and prescribers at 'Balance My Hormones' used encrypted applications to electronically receive and send private prescriptions to the pharmacy. This complied with the legislation. The prescriptions could not be forwarded to anyone else. Each prescription had a unique electronic signature/code attached which ensured it remained under the sole control of the prescriber and was tamper evident (see Principle 4).

The pharmacy had some policies to protect people's confidential information and for safeguarding vulnerable people. Staff had been trained on both. They generally knew who to refer to in the event of a concern and explained that the medicines were only available to people over the age of 18. When people signed up to the service from 'Balance My Hormones', they were assigned case managers, who obtained relevant photographic ID before issuing prescriptions. The pharmacist was trained to level 2 through the Centre for Pharmacy Postgraduate Education (CPPE) and the owner was trained to level 3. However, the pharmacy did not hold any relevant information about any safeguarding agencies. As the pharmacy supplied medicines to people nationwide, this could lead to a delay in reporting concerns and holding the relevant information was advised at the time. The team segregated confidential waste and used an authorised carrier who disposed of this for them. The pharmacy's systems were secure with individual passwords and encrypted programmes.

The pharmacy's professional indemnity insurance arrangements were through the National Pharmacy Association and due for renewal after 3 October 2022. The pharmacy's records, however, were not always fully compliant with statutory and best practice requirements. The pharmacy had not obtained or supplied any Schedule 2 or 3 controlled drugs (CDs). Hence, there were no records that needed to be kept. The superintendent pharmacist confirmed that the pharmacy had not made any emergency supplies. The record about the responsible pharmacist (RP) had odd gaps, and there were some gaps in the records verifying that fridge temperatures had remained within the required range when the pharmacy had first started trading in 2021. More recently, some of the records for the fridge temperatures were reading above eight degrees Celsius and there was no indication or details recorded to show that any action had been taken in response (see Principle 4). Electronic records of supplies made against private prescriptions had been maintained. They included the relevant, required information. At the point of inspection, however, no specific records about the supplies of unlicensed medicines had been kept either in records or registers that were maintained for this purpose only. The pharmacy could easily trace and locate the relevant details. This was discussed at the time. Following the inspection, the inspector confirmed that the pharmacy had implemented this in a written format but was looking to create or ensure electronic records which could be easily maintained.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload effectively. The pharmacy's team members work well together. But the pharmacy does not provide many resources to help keep the team's skills and knowledge relevant or up to date. This could affect how well they carry out tasks and adapt to change with new situations.

Inspector's evidence

The pharmacy's staffing profile included the regular pharmacist who was also the superintendent and a full-time, trained dispensing assistant. Both had only started working at the pharmacy this year. Their certificates to verify the qualifications they had obtained were seen. The dispensing assistant knew which activities were permissible in the absence of the RP, she knew when to refer appropriately and had regular discussions with the RP. But she confirmed that she did not know that much about the medicines that were supplied. The RP had been providing some in-house training for her, a staff reference booklet was available with some details and the RP had also created a comprehensive noticeboard with details about the different types of hormone treatment available. The RP said that she had researched this area herself to improve her own working knowledge by using reference sources and data from American sources. The pharmacy team was not provided with any other specific, or ongoing training to help improve their working knowledge. The owner was also present during the inspection. The inspector was told that he had been enrolled onto accredited training to work as a dispenser but because he had not started this course, he was not currently actively working in the pharmacy. Locum pharmacists covered the RP but also worked alongside her as needed. There were no targets set for the team.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy’s premises provide a suitable environment to deliver the service it provides. It has enough space to safely prepare and assemble prescriptions. And the pharmacy is kept appropriately clean.

Inspector's evidence

The pharmacy’s premises were inside an access-controlled building and the pharmacy itself consisted of a medium sized room. The pharmacy’s stock and equipment were all stored here along with a small kitchenette area to one side and clean WC facilities. The room was of an appropriate size for the pharmacy’s current volume of workload. It had different workbenches for the staff and pharmacists to use. The pharmacy was clean and tidy, appropriately ventilated, and well lit. There was also a separate room in one section where an operation linked to ‘Balance My Hormones’ took place, a member of staff was working here but said that this was separate to the pharmacy and she did not work in the pharmacy.

The pharmacy also had its own online website (https://www.thehormonist.com/). This website displayed the GPhC internet, voluntary logo, the superintendent pharmacist's (SI) details, information about the staff, the pharmacy’s opening times, how people could complain, and the pharmacy's contact details. The address provided was where the medicines were supplied from. The website had no reference to any medicines, including prescription-only medicines (POMs) but there was a link to 'Balance My Hormones' which did refer to some medicines. There was no option to choose a medicine, strength, or quantity. The website only gave details about the pharmacy and the people involved with this service.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy generally provides its services appropriately. The pharmacy sources its medicines from reputable suppliers. And it mostly has the right systems in place to receive and track prescriptions. But the pharmacy does not always record all the relevant information when interventions have been made, or when people have been advised about their medicines. This limits its ability to show that this has been happening regularly.

Inspector's evidence

The pharmacy is registered as an internet pharmacy, but it does not receive any prescriptions through its website. Instead, the pharmacy receives and dispenses private prescriptions for hormone replacement therapy and some supportive medicines from prescriber's who are linked to an online website (https://balancemyhormones.co.uk/). This website and the pharmacy are co-owned by the same individual. People booked appointments face to face or remotely via this website, blood tests and consultations were required before prescriptions were issued. The 'Balance My Hormones' website lists details of the medical director and other members of the team but no specific details of the prescribers. However, the SI had compiled a list of the prescribers who issued the prescriptions. She said that she regularly checked the General Medical Council's (GMC) register but had not seen any other information which would help reassure and determine whether they were competent to prescribe in these areas. This was discussed at the time and the owner said that this information could be easily provided from the internal checks as well as training records that he maintained.

The pharmacy used different applications to access the prescriptions and the patient's medical history or notes in addition to the pharmacy's own internal dispensing system. Staff cross-referenced different details on each of the databases to ensure the information they were using were correct. The pharmacy received the private prescriptions from a specific work-based application. The prescribers had their own access to this and once the prescription had been created, it remained under the sole control of the prescriber. The pharmacy was alerted through its system workflow and after receiving it electronically, it was dispensed through the pharmacy's dispensing system. The superintendent and owner confirmed that the systems and applications being used were secure and encrypted.

The prescribers and case managers were currently responsible for counselling people about their medicines, the dose, side effects and injection technique. Although the prescribers and case workers generally handled the administration side, people could speak to the pharmacy direct if advice was required. The RP said that when unusual administration was seen, she asked for a copy of the counselling details that had been provided by the prescribers. The RP explained that she had given the owner or case manager advice to take back to patients on occasion but details about this had not always been recorded. In addition to querying unusual doses, the RP said that she checked the notes and blood test details sometimes, for new people, and had made interventions. Some of this information had been documented but this was not routinely being done.

Once the private prescriptions had been received and printed, they were labelled and dispensed by staff before being accuracy checked by the RP. Baskets were available to hold prescriptions and medicines during the dispensing process. This helped prevent any inadvertent transfer between them. Once staff generated the dispensing labels, as an audit trail, the pharmacy system helped identify who

had been involved in the dispensing process.

The pharmacy did not provide any additional services and it only dispensed medicines against private prescriptions as described above. The pharmacy did not stock, dispense or deliver Schedule 2 or 3 CDs. Once dispensed, the medicines were packed and sealed before being delivered. Staff confirmed that two to three different checks on different databases were made (and/or against the invoice) to ensure the person's address was correct and that it matched the relevant details. The pharmacy used a courier service (Royal Mail) that had tracking facilities and in-house records had also been maintained to verify this process. Specific, individually manufactured ice-cubes/packs were used to help keep medicines that required refrigeration cool during the delivery process, but no test deliveries had been completed. Neither were any data or data sheets present to determine that these medicines could be sent over a 24-hour period without adversely affecting their safety or quality. Staff confirmed that failed deliveries for fridge-lines were brought back to the pharmacy, they would be discarded, and replacements sent. However, the pharmacy had not been keeping any records about this situation. For other medicines and failed deliveries, the courier service held them overnight at a local depot, where the patient could collect them the following day.

The pharmacy was located on the first floor, accessed by steps. It was not readily open to members of the public. People were supplied with the pharmacy's contact details. If required, the team could generate labels with a larger sized font for people who were partially sighted.

The pharmacy's stock was stored in an organised way and clearly identifiable. Licensed wholesalers such as Alliance Healthcare, AAH, Sigma and Target were used to obtain medicines and medical devices. The team date-checked medicines for expiry regularly and kept records of when this had happened. Stock was rotated and short-dated medicines were moved to the front. Identifying them more easily was discussed at the time. The pharmacy supplied people with sharps bins so they could dispose of injections and had, on a few occasions disposed of items returned by people. The pharmacy had an arrangement with a waste disposal company for this and records were seen. Drug alerts were received by email, checked, and actioned appropriately. Records had been kept verifying this. However, there were some concerns noted with the pharmacy's ability to show that it had been storing and supplying temperature-sensitive medicines appropriately (as described above and under Principle 1).

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the appropriate equipment it needs to provide its services safely. And its equipment is kept suitably clean.

Inspector's evidence

The pharmacy’s equipment included some reference sources, clean, counting trays, several PC’s, and a pharmacy fridge. The pharmacy had hot and cold running water available as well as internet access. Computer terminals were positioned in a manner that prevented unauthorised access.

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.