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In the UK, pharmacists play a pivotal role in ensuring medicines are safely dispensed to patients. Among the diverse loads they handle daily, “unlicensed specials” — bespoke medicinal products without full marketing authorization — often present unique challenges. One frequently asked question is: **can a pharmacist refuse to dispense an unlicensed special?**

This post dives into the regulatory framework, professional obligations, sourcing requirements, and patient safety considerations driving pharmacists’ decisions, especially in sensitive areas like prescribed cannabis medicine — which in the UK is *vaporised* rather than smoked. We’ll also look into the significance of devices in these treatments to clarify when a refusal to dispense aligns with good practice rather than gatekeeping.

## What is an Unlicensed Special?

“Unlicensed specials” are medicines specially prepared for patients when licensed medicines are unsuitable or unavailable. Because they lack a marketing authorization, there’s no formal approval from the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) for safety, efficacy, or quality in the usual way.

Examples might include tailored-strength hormone creams, paediatric suspensions, or niche cannabis-based products.

## Professional Obligations of Pharmacists Regarding Unlicensed Specials

Pharmacists in the UK must [thelondoneconomic.com](https://www.thelondoneconomic.com) follow the General Pharmaceutical Council (GPhC) Standards. Among these, key points relevant to unlicensed medicines are:

- **Patient safety first:** Ensure the product is appropriate, safe, and that the benefits outweigh risks.
- **Professional judgement:** Assess prescription validity and quality of the product and supplier.
- **Communication:** Clarify details with prescribers if concerns arise.
- **Ethical dispensing:** Do not dispense if the product poses identifiable risks, lacks adequate evidence, or the source is dubious.

Crucially, pharmacists have no absolute legally mandated duty to dispense every prescribed medicine. They can refuse if the product or prescription raises safety or regulatory red flags — but such refusals must be justified professionally, communicated clearly, and aligned with patient care.



## Sourcing Requirements and Quality Checks

Unlicensed specials rely heavily on sourcing from reputable, MHRA-licensed manufacturers and wholesalers. Pharmacists must perform diligent checks including:

- Verification that the manufacturer operates under Good Manufacturing Practice (GMP).
- Confirming batch quality, stability data, and product documentation.
- Ensuring labelling is clear and accurate for safe use.

If a pharmacist suspects the special is from an unreputable source or that adequate quality/compliance is lacking, they are professionally obligated to halt the supply to protect the patient.

## Patient Safety Checks Specific to Unlicensed Cannabis-Based Medicines (CBPMs)

One topical example is prescribed cannabis-based medicinal products (CBPMs) in the UK. It's crucial to understand some points often misunderstood in public discourse:

### UK Prescribed Cannabis is Vaporised, Not Smoked

The term "*smokable cannabis*" is often wrongly linked to NHS or private prescriptions — this is inaccurate and misleading in the UK context.

- All legally prescribed cannabis medicines are designed for vaporisation (vaping), not combustion (smoking).
- Combustion releases harmful by-products such as tar, carbon monoxide, and carcinogenic compounds.
- Vaporisation heats the medicine to release cannabinoids without burning plant matter, reducing harmful toxicants.

This difference is clinically and professionally important. Pharmacists must advise patients accurately about device use and administration methods.

### The Device is Part of the Treatment

Unlike many tablets or creams, the vaporiser device used for CBPMs is integral to treatment effectiveness and safety.

- An inconsistent device can result in under- or overdosing.
- Devices must be prescribed by a clinician or sourced as per MHRA requirements.
- Pharmacists must ensure device compatibility, quality, and dosing consistency alongside the medicine itself.

If the device or its supply chain is questionable, refusing to dispense might be justified to safeguard patient safety.

## When Can a Pharmacist Refuse to Dispense an Unlicensed Special?

Summarizing professional grounds for refusal:

1. **Unclear or unsafe prescription:** If the prescription lacks clear instructions, dosing information, or raises safety concerns.
2. **Poor quality or unlicensed source:** If the medicine or device is from a supplier without proper MHRA licensing or GMP certification.
3. **Potential harm outweighs benefit:** The pharmacist judges the risk to the patient outweighs benefit.
4. **Availability of licensed alternatives:** When an appropriate licensed medicine exists but the prescriber opts for an unlicensed alternative without justification.
5. **Patient informed consent:** If the patient isn't fully informed about the unlicensed status or risks.

In these situations, pharmacists must communicate openly with both prescribers and patients to clarify options and ensure safe care continuity.

## Regulatory Framework for Unlicensed Specials Dispensing

Aspect Regulatory Body Relevant Regulations/Standards Pharmacist Conduct & Ethics General Pharmaceutical Council (GPhC) Standards of Conduct, Ethics, and Performance Medicines Authorization & Manufacturing Medicines and Healthcare products Regulatory Agency (MHRA) Medicines Regulations 2012, GMP Good Dispensing Practice GPhC / MHRA Guidance Guidance on Specials, Patient Safety Checks Cannabis-Based Medicines Home Office / MHRA Controlled Drugs Regulations, MHRA Cannabis Guidelines

## Key Takeaways for Patients and Pharmacists

- **Pharmacists have a professional right — and duty — to refuse dispensing unlicensed specials if safety or quality cannot be guaranteed.**
- **Communication is essential:** Both patients and prescribers should be kept informed about any concerns or alternative options.
- **Prescribed cannabis in the UK is vaporised, never smoked; device quality and compatibility are as crucial as the medicine itself.**
- **Pharmacists' assessments rely on regulatory frameworks, sourcing checks, and risk-benefit analyses, always prioritising patient health.**

## Final Thought

Unlicensed specials fill a vital gap when licensed medicines fall short, but they've never been exempt from careful scrutiny. Pharmacists act as guardians of quality and safety — their discretion to refuse dispensing is not arbitrary

but rooted in steadfast professional obligations and patient advocacy. Especially with emerging areas like prescribed cannabis, recognizing nuances such as vaporisation versus smoking and the critical role of devices ensures care remains evidence-based, safe, and trustworthy.



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