

UK Supply Chain Regulations & Risk (CBPMs)

– Emerging market risks in UK Medical Cannabis

V1.4

Client Confidential

© Glass Pharms Ltd 2026



Intentionally Blank

Table of Contents

Introduction	4
Regulatory Oversight	4
Regulatory Basis & Normative References	5
Medical Standards.....	5
Cultivation.....	5
Manufacturing of medicines	5
Financial Crime	5
Controlled Drugs	5
Microbiological Standards	6
UK Microbial Standards.....	6
International Microbial Standards	7
Irradiation Decision Tree	8
Mycotoxin Limits.....	8
UK Market Experience on Microbiological Standards	9
Heavy Metals	9
Additional Controls.....	9
Unlicensed Medicine Best Practice	10
Approved Formats for CBPMs	11
Principal Prescribed Formats.....	11
Formats Without an Authorised Medical Administration Device	12
Criminal Activity	13
PoCA Risk and Compliance	13
UK Market Experience on PoCA.....	13
European Supply Chain.....	13
European Medical Supply Chain Criminal Events.....	13
May 2025 – 7.3 tonnes seized in Portugal.....	13
February 2026 – 40 tonnes seized in North Macedonia & 5 tonnes in Serbia.....	13
Appendix 1 – MHRA Guidance on CBPMs.....	14
Appendix 2 – MHRA Guidance on CBPMs.....	15

Introduction

Glass Pharms® is on a mission to underpin the UK cannabinoid medicines market with affordable high-quality products. We are also passionate about doing so in a way that makes a positive contribution towards reducing climate change.

This whitepaper describes the regulatory environment and supply chain risks that exist in the UK. Regulatory compliance, including financial crime legislation, is of paramount importance to us, particularly as our main investor is listed on the London Stock Exchange main market.

Regulatory Oversight

There are multiple regulators who have oversight of cannabis based medicines in the UK. There are also a number of overseas agencies with influence through international law and standards.

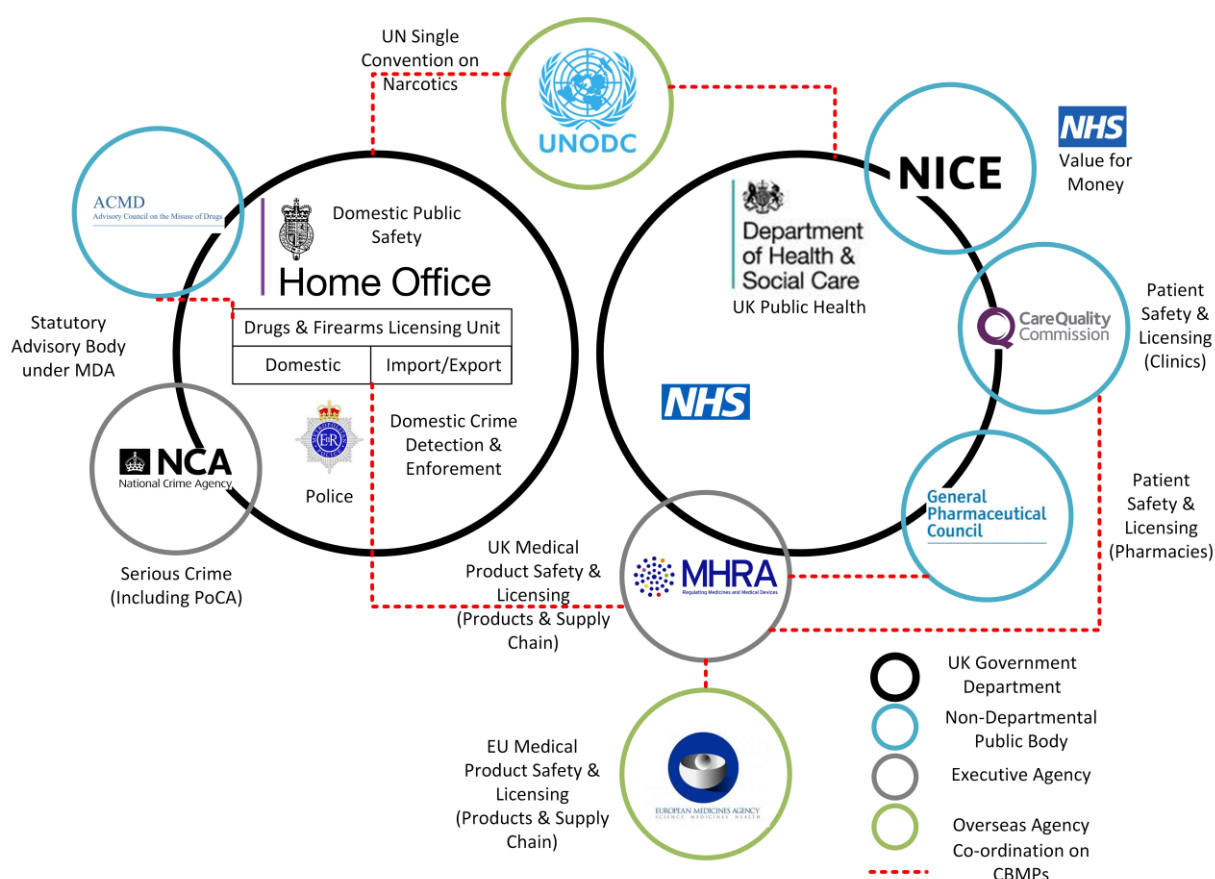


Figure 1 UK and Relevant Overseas Regulators

The Home Office is responsible for the legal supply chain, following the relevant controlled drugs legislation. The MHRA are the executive agency responsible for drug safety. The UN have influence through the Single Convention on Narcotics and the European Medicines Agency still have influence on medicine standards which remain aligned in the UK.

The UK is one of the most tightly regulated markets from a controlled drugs perspective but affords some flexibility on the type of medication delivered through the Specials Medicines framework. The prescribing of Specials is a the prerogative and risk of the prescribing physician. CBMPs must be prescribed by a physician on the Specialist Register.

Regulatory Basis & Normative References

Medical Standards

Cultivation is governed by GACP (EU, 2024 revision – HMPC)¹ not GMP.

Manufacturing of medicines is governed by: EudraLex Volume 4 (EU GMP)² ;

EU GMP Annex 7 (Herbal Medicinal Products)³

British Pharmacopoeia (BP) 2024 / Ph. Eur. 11.5⁴;

MHRA guidance (CBPMs – manufacturing/import/distribution)⁵

EMA Reflection Paper (Microbiological aspects of herbal products)⁶

Financial Crime

POCA (Proceeds of Crime Act) 2002⁷; criminal property (recreational cannabis) cannot be converted to medical cannabis lawfully.

FCA Statement (Cannabis-related businesses)⁸

Controlled Drugs

The primary controlled drugs legislation in the UK is the Misuse of Drugs Act 1971⁹ (MDA). The Misuse of Regulations 2001¹⁰ builds upon the MDA, specifically aimed at healthcare professionals and legislates the possession, production, supply and administration for authorised individuals. It was amended in November 2018¹¹ to legalise Cannabis Based Products for Medicinal use in humans (CBPMs).

Bulk cannabis flower is typically considered Schedule 1 by the Home Office, requiring a tightly controlled licence. Finished unlicensed cannabis medicines (CBPMs) are typically considered Schedule 2. Controlled drugs licences in the UK for cannabis are particularly difficult to obtain. They typically have very tight conditions where cannabis is included and are difficult to amend.

Each import or export of cannabis requires both a domestic controlled drugs licence to be in place and a shipment specific licence for importing or exporting each and every time.

¹ https://www.ema.europa.eu/system/files/documents/scientific-guideline/hmmp-guideline-gacp_en.pdf

² https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

³ https://www.gmp-compliance.org/files/guidemgr/vol4_an7_2008_09.pdf

⁴ <https://www.pharmacopoeia.com/content/html/479>

⁵ <https://mhrainspectorate.blog.gov.uk/2022/11/16/mhra-process-for-approving-manufacturing-authorisations-or-api-registrations-in-relation-to-unlicensed-cannabis-based-products-for-medicinal-use/>

⁶ https://www.gmp-compliance.org/files/guidemgr/reflection-paper-microbiological-aspects-herbal-medicinal-products-and-traditional-herbal-medicinal-products_en.pdf

⁷ <https://www.legislation.gov.uk/ukpga/2002/29/part/7>

⁸ <https://www.fca.org.uk/news/statements/listings-cannabis-related-businesses>

⁹ <https://www.legislation.gov.uk/ukpga/1971/38/contents>

¹⁰ <https://www.legislation.gov.uk/uksi/2001/3998/contents>

¹¹ <https://www.legislation.gov.uk/uksi/2018/1055/contents/made>

Microbiological Standards

In the UK, only Ph. Eur. 5.1.4 and 5.1.8B standards are used for microbiological quality of medicinal cannabis. 5.1.8C is not applicable in the UK. Non-compliant product must not be irradiated simply to meet limits; microbial quality must be achieved via preventive controls and validated, routine processes.

“According to GMP criteria, good quality cannot be controlled at the end of the process but should be built in and should include the quality of the starting material. Minimisation of microbial content of herbal materials during cultivation, harvesting, storage and processing is essential because the possibility of reducing the microbial bioburden in herbal materials by means of postprocessing treatments is very limited.”⁶

UK Microbial Standards

Test	Inhalation (5.1.4)	Oral (5.1.8B)
TAMC	≤ 100 CFU/g	≤ 50,000 CFU/g
TYMC	≤ 10 CFU/g	≤ 500 CFU/g
E. coli	Absent in 1 g	Absent in 1 g
Salmonella spp.	Absent in 10 g	Absent in 10 g
Staphylococcus aureus	Absent in 1 g	Absent in 1 g
Pseudomonas aeruginosa	Absent in 1 g	Absent in 1 g

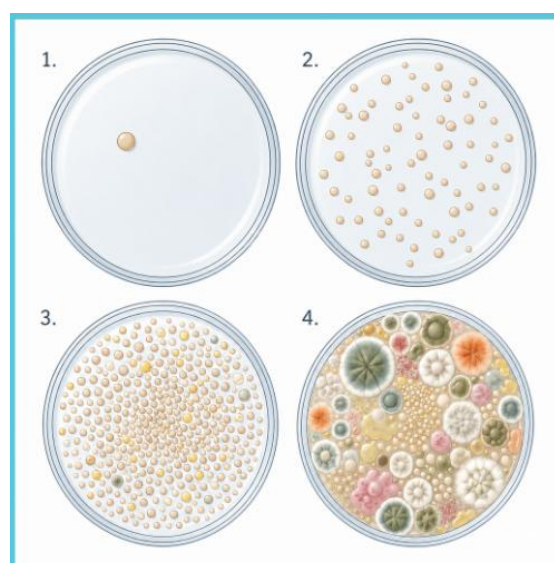
International Microbial Standards

Microbial Limits Comparison (BP & Canada, TAMC & TYMC only)

Standard	TAMC (CFU/g)	TYMC (CFU/g)
BP 5.1.4	≤ 100	≤ 10
BP 5.1.8B	$\leq 50,000$	≤ 500
BP 5.1.8C (Min German Import)	$\leq 100,000$	$\leq 10,000$
Canada (Cannabis)	$\leq 100,000$	$\leq 50,000$

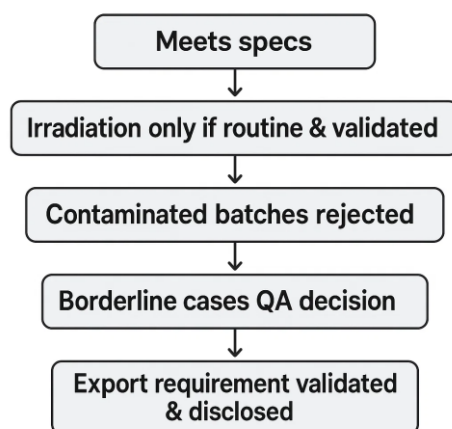
The difference between these standards is not academic. It determines the amount of yeast and mould contamination that may remain in the finished flower. Figure 4 converts the TYMC limits in Table 2 into a direct visual comparison. Dish 1 represents BP 5.1.4, Dish 2 BP 5.1.8B, Dish 3 BP 5.1.8C and Dish 4 Canada (Cannabis). The progression makes the point clearly: as the standard becomes less stringent, the permitted fungal burden increases markedly. For the patient, particularly the immunocompromised patient, these are not equivalent microbiological specifications.

Figure 2. Conceptual illustration of increasing TYMC levels corresponding to Table 2: 1 = BP 5.1.4 (≤ 10 CFU/g); 2 = BP 5.1.8B (≤ 500 CFU/g); 3 = BP 5.1.8C ($\leq 10,000$ CFU/g); 4 = Canada (Cannabis) ($\leq 50,000$ CFU/g). The illustration visualises the relative permitted yeast and mould burden and is not intended to depict exact colony counts.



Irradiation Decision Tree

Irradiation should be considered a warning sign that cannabis has been repurposed from recreational origins where microbial standards are lower. Irradiation should only be used where part of the original preparation of the product, as part of a fully validated process.⁶



Irradiation does not remove mould if it is present in the material. Any mould present may become less pathogenic but may still be allergenic. Mycotoxins will survive Irradiation¹².

Mycotoxin Limits

Mycotoxin limits vary significantly between Canada and the EU/UK. Analytical equipment in Canada may not be setup to have sufficient sensitivity to meet the appropriate standards:

Analyte	UK / EU limit (Ph. Eur. / BP)	Canada limit (NHPs)	Practical implication
Aflatoxin B1	≤ 2 µg/kg	< 5 µg/kg	Canada permits ~2.5× higher B1 than Ph. Eur.; material passing Canada can fail UK release.
Total aflatoxins (B1+B2+G1+G2)	≤ 4 µg/kg (applied where total limit is specified)	< 20 µg/kg	Canada tolerance is 5× higher than Ph. Eur. expectations for herbal drugs.

¹² [Detection of Mycotoxigenic Fungi and Residual Mycotoxins in Cannabis Buds Following Gamma Irradiation | MDPI](#)

UK Market Experience on Microbiological Standards

Financial gain has driven unscrupulous parties to repurpose cannabis grown for recreational purposes into a “medical” grade through irradiation to achieve microbial standards. This approach does not remove mould or mycotoxins¹³. Where mould is present, it is not removed by irradiation, simply made non-viable. The mould may become less pathogenic but remains allergenic, mycotoxins persist with the prospect of patient risk and reputational damage.

There have been multiple instances of full product recall in the UK due to mould contamination¹⁴¹⁵.

Heavy Metals

Heavy Metal limits also vary by territory. Cannabis is an excellent absorber of heavy metals and highly susceptible to unsafe accumulation of heavy metals, where contamination of soil or water exists.

Element	UK / EU limit (ICH Q3D)	Canada limit (NHPs)	Which is stricter at 1 g/day
Arsenic (total)	15 µg/g	9.8 µg/g	Canada
Cadmium	5 µg/g	6.3 µg/g	UK / EU
Lead	5 µg/g	9.8 µg/g	UK / EU
Mercury (total)	30 µg/g	20.3 µg/g	Canada

Additional Controls

- Microbial testing must be performed by an independent lab prior to shipment to an EU GMP manufacturing site, unless GLP standards or EU GMP processing is co-located or equivalent where a mutual recognition agreement is in place with the MHRA.
- Physical GMP audit of cultivation site every 2 years should be performed in person (not remotely).
- Contamination risk assessment by GACP grower. GACP grower should provide a detailed risk assessment for contamination risk.

¹³ [Irradiated cannabis might still harbour toxic fungi and residues, McGill study finds | Newsroom - McGill University](#)

¹⁴ [Patients Are Finding Big Problems with Their Medical Weed,](#)

¹⁵ [UK prescription cannabis recalled that 'may be contaminated with mould'](#)

Unlicensed Medicine Best Practice

The MHRA and ABPI have established a clear hierarchy of risk based on product origin¹⁶.

Prescribers should follow the following guidance when selecting pharmacological intervention options:

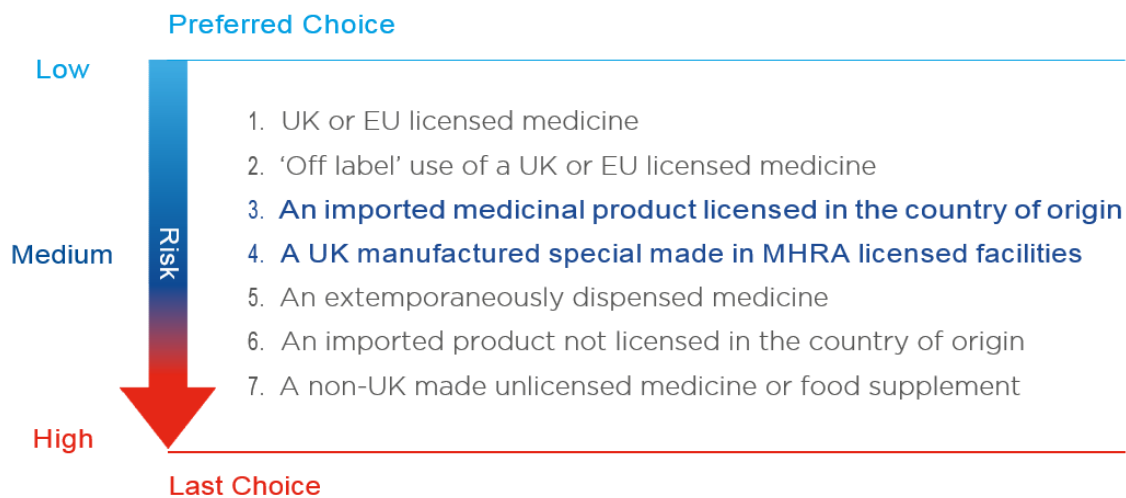


Figure 3 ABPI Hierarchy of risk based on product origin adapted from MHRA guidance

Licensed medicines should be used in preference to unlicensed medicines.
If a UK product can meet the clinical requirement, it should not be imported.

UK manufactured unlicensed medicines should be used in preference to imported products.
“Specials” must not be advertised as provided by condition B of regulation 167 of the Human Medicines Regulations 2012

The sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products;

The advertising of unlicensed medicinal products, including CBPMs, to members of the public is prohibited.

¹⁶ <https://www.abpi.org.uk/media/f01jspbi/policy-position-the-use-of-unlicensed-specials-to-treat-nhs-patients-v2.pdf>

Approved Formats for CBPMs

The General Pharmaceutical Council (GPhC) states in its 2025 review of registered pharmacies providing cannabis-based products for medicinal use that dried flower may be used with a dry-heat or vaporiser device and that “MHRA approved vaporisers should be used”. The wording should be understood in the context of UK medical-device regulation: devices are placed on the market through the applicable conformity-assessment and certification framework rather than receiving a medicines-style marketing authorisation. The practical principle is that, where a CBPM requires a separate administration device, the device should be medically certified and intended for that use rather than simply being consumer vaporisation hardware.¹⁷

Principal Prescribed Formats

Dried flower. Dried cannabis flower is the predominant CBPM format prescribed in the UK. NHSBSA-derived private-prescription data for England show flower accounting for approximately 83% of dispensed CBPM items in H1 2025. Administration is by controlled heating rather than combustion. Two established medically certified Class IIa vaporisation systems are available for cannabinoid administration: the Storz & Bickel® VOLCANO MEDIC 2 and MIGHTY+ MEDIC. These are distinct from the manufacturer’s consumer vaporisers, with a medical intended purpose and supporting medical-device certification.¹⁸ These devices have been certified for use with dried flower or liquid dronabinol only.

Sublingual oils. Sublingual and oral oils form the second-largest prescribed dosage-form category. They do not ordinarily require an electrically powered administration device. The prescribed dose is defined volumetrically and translated into a stated quantity of THC, CBD or other cannabinoid, providing a direct pharmaceutical dosing pathway.

Liquid vaporisers. Liquid cannabinoid vaporiser formulations form the third principal prescribed format and a newer inhaled category. The Jupiter platform underpins certified systems including the Curaleaf Que Medical Inhalation Device, which is CE-certified as a Class IIa medical device and uses a timed inhalation cycle with dedicated cartridges. A second Class IIa platform, the Airo Medical Inhalation System, was developed with Jupiter Research and is paired with SOMAí Pharmaceuticals’ EU-GMP inhalation extracts and cartridges.¹⁹

¹⁷General Pharmaceutical Council, [Registered pharmacies providing cannabis-based products for medicinal use \(CBPM\), October 2025](https://assets.pharmacyregulation.org/files/2025-10/Registered-pharmacies-providing-cannabis-based-products-for-medicinal-use-October-2025.pdf): <https://assets.pharmacyregulation.org/files/2025-10/Registered-pharmacies-providing-cannabis-based-products-for-medicinal-use-October-2025.pdf>

¹⁸Cannamonitor, [UK Medical Cannabis Market Doubles Again — and Flower Loses Share](https://cannamonitor.com/uk-medical-cannabis-market-doubles-again-and-flower-loses-share/), 14 May 2026. Analysis of NHSBSA private-prescription dispensing data for England: <https://cannamonitor.com/uk-medical-cannabis-market-doubles-again-and-flower-loses-share/>; Storz & Bickel, [Our Medical Devices: VOLCANO MEDIC 2 and MIGHTY+ MEDIC](https://support.storz-bickel.com/hc/en-us/articles/35845749331601-Our-Medical-Devices): <https://support.storz-bickel.com/hc/en-us/articles/35845749331601-Our-Medical-Devices>

¹⁹Curaleaf International, [Curaleaf Laboratories Launches UK’s First CE-certified Liquid Medical Cannabis Inhaler](https://curaleafinternational.com/curaleaf-laboratories-launches-uks-first-ce-certified-liquid-medical-cannabis-inhaler/), 1 September 2025: <https://curaleafinternational.com/curaleaf-laboratories-launches-uks-first-ce-certified-liquid-medical-cannabis-inhaler/>; SOMAí Pharmaceuticals, [Airo Brands Announces CE-Certified Medical Inhalation Device in Partnership with SOMAí](https://somaipharma.es/news/airo-brands-announces-ce-certified-medical-inhalation-device-in-partnership-with-soma/), 28 October 2025: <https://somaipharma.es/news/airo-brands-announces-ce-certified-medical-inhalation-device-in-partnership-with-soma/>; Jupiter Research, [Curaleaf International in Partnership with Jupiter Research Secures EU Medical Device Certification](https://www.jupiterresearch.com/curaleaf-international-in-partnership-with-jupiter-research-secures-eu-medical-device-certification-for-europes-first-handheld-liquid-inhalation-device/), 12 May 2025: <https://www.jupiterresearch.com/curaleaf-international-in-partnership-with-jupiter-research-secures-eu-medical-device-certification-for-europes-first-handheld-liquid-inhalation-device/>

Other oral formats. Other prescribed CBPM formats include pastilles and related oral preparations. These do not require a vaporisation device and can be presented as defined unit doses.

CBPM format	Administration	Device position	Principal control
Dried flower	Dry-heat inhalation	Class IIa medical vaporisers available	Controlled temperature and defined medical-device intended purpose
Sublingual / oral oils	Measured oral or sublingual dose	No powered device normally required	Concentration plus measured volume defines dose
Liquid vaporisers	Closed cartridge inhalation system	Class IIa platforms available	Timed inhalation and dedicated cartridge system
Pastilles	Oral unit dose	No separate device required	Defined pharmaceutical unit dose
Hashish, crumble and other concentrates	Heated material inhalation	No medically certified device identified specifically for these formats	High potency; patient-selected quantity; no inherent metering

Table 4. Principal CBPM formats and administration-device position

Formats Without an Authorised Medical Administration Device

Highly concentrated cannabis preparations - including hashish, crumble, wax and similar concentrates - present a materially different administration risk. These materials can contain substantially higher cannabinoid concentrations than dried flower. A small error in the mass selected by the patient therefore translates into a proportionately larger error in the quantity of THC administered. Unlike a metered cartridge, measured oil or unit-dose pastille, concentrates do not inherently provide an accurate patient dose.

No medically certified administration device has been identified whose stated intended purpose specifically covers the routine patient administration of hashish, crumble or comparable solid or semi-solid cannabis concentrates. The fact that a consumer vaporiser can physically heat such a material does not establish that the device has been assessed for that medicinal intended purpose. In the context of the GPhC expectation that medically appropriate vaporisers should be used, the combination of high potency, patient-dependent measurement and the absence of a specifically certified administration system creates a substantially less controlled pathway than established flower, oil, liquid-inhalation or unit-dose oral formats.

Criminal Activity

PoCA Risk and Compliance

Cannabis cultivated for recreational purposes or by a recreational grower constitutes criminal property under UK law. Any attempt to convert such material into a medical product, or to deal with its proceeds, risks offences under POCA (sections 327–329) because the property represents a benefit from criminal conduct. Only source plant material from licensed medicinal supply chains with documented chain of custody from licensed origin to release. Conduct enhanced due diligence on any third-party biomass/extract suppliers to confirm lawful origin.

UK Market Experience on PoCA

There have not been any prosecutions for PoCA offenses in the UK yet. This is despite the majority of medical cannabis currently being sourced from recreational growers before being irradiated and then processed for supply.

European Supply Chain

The European supply chain is complex to follow with free movement of goods between countries. Dedicated processing companies have been setup who have repurposed large quantities of recreational cannabis for the medical supply chain. This activity have been particularly prolific in Portugal and Spain. Continental growing has been centred in Portugal and Macedonia, where domestic markets are relatively small These markets have primarily targeted the much larger markets of Germany and the UK.

European Medical Supply Chain Criminal Events

There have been two major criminal events in the last twelve months.

May 2025 – 7.3 tonnes seized in Portugal

Judicial Police in Portugal co-ordinated and international raid on medical cannabis companies, seizing 7.3 tonnes of cannabis, 64 seizure warrants were issued in country with further arrests in Madeira, Spain, Bulgaria and Cyprus²⁰. The results was months of delay for product being routed through Portugal. This trade route remains severely affected.

February 2026 – 40 tonnes seized in North Macedonia & 5 tonnes in Serbia

Authorities in North Macedonia seized more than 40 tonnes of cannabis diverted from medical cannabis companies²¹. A further 5 tonnes that may have originated from the same source were seized in Serbia.

²⁰ <https://cannareporter.eu/en/2025/05/21/pj-seized-73-tons-of-cannabis-and-more-than-400-thousand-euros-see-the-images-here/>

²¹ [North Macedonia: Authorities seize more than 40 tons of cannabis diverted from medicinal cultivation companies – CannaReporter](#)

Appendix 1 – MHRA Guidance on CBPMs²²

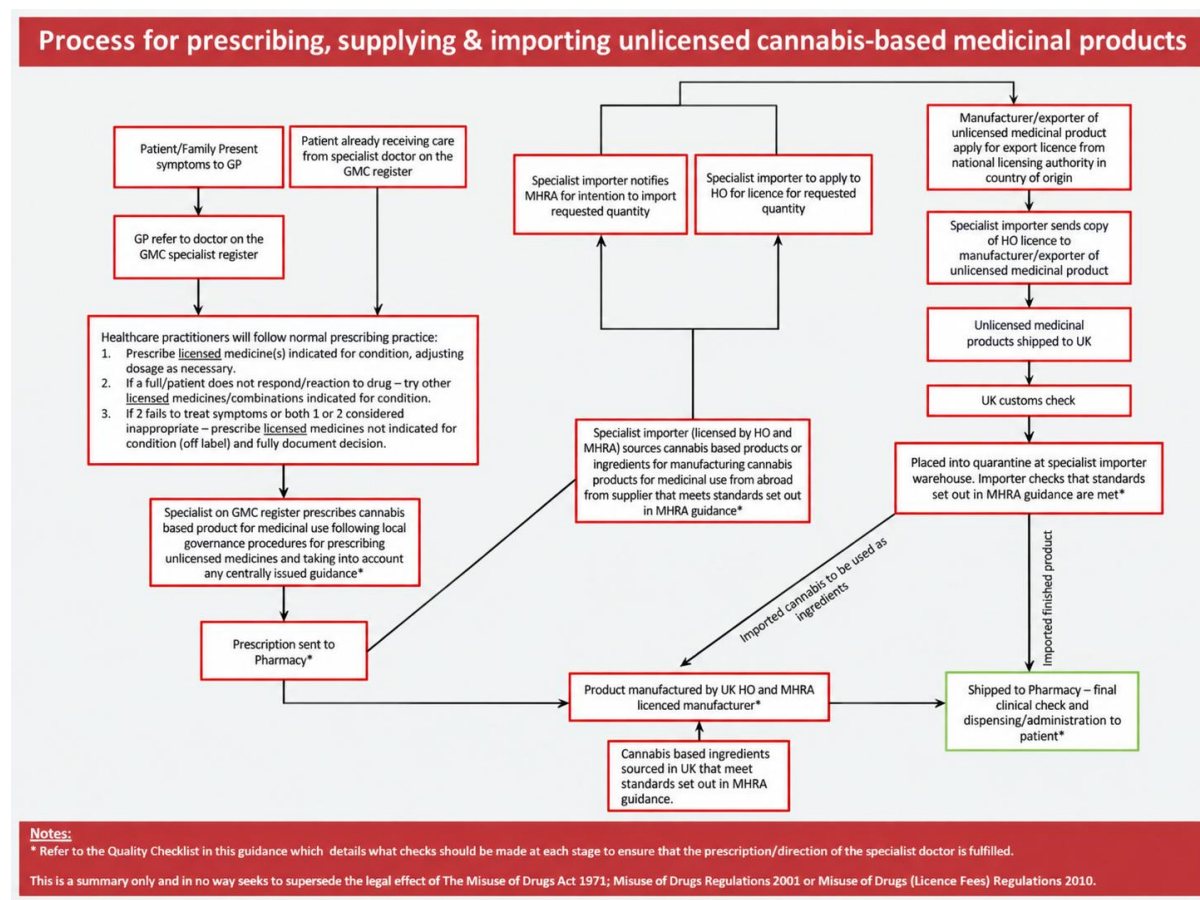


Figure 4 Appendix 1 from 2020 MHRA CBPM Guidance

²² [Cannabis Guidance unlicensed CBPMs updated 2020.pdf](#)

Appendix 2 – MHRA Guidance on CBPMs²³

APPENDIX 2 - Guidance on the hierarchy for the use of unlicensed medicines

This hierarchy is provided for guidance only and each case should be considered on its individual merit.

1. An unlicensed product should not be used where a product available and licensed within the UK could be used to meet the patient's special need.
2. Although MHRA does not recommend "off label" (outside of the licensed indications) use of products, if the UK licensed product can meet the special clinical need, even "off-label", it should be used instead of an unlicensed product. Licensed products available in the UK have been assessed for quality, safety and efficacy. If used "off-label" some of this assessment may not apply, but much will still be valid. This is better than the use of an un-assessed, unlicensed product. The fact that the intended use is outside of the licensed indications is therefore not a reason to use an unlicensed product. It should be understood that the prescriber's responsibility and potential liability are increased when prescribing off-label medicines.
3. If the UK product cannot meet the special need, then another (imported) medicinal product should be considered, which is licensed in the country of origin.
4. If none of these options meet the special clinical need, then a completely unlicensed product may have to be used, for example, UK manufactured "specials", which are made in GMP inspected facilities, but which are otherwise un-assessed (GMP inspection of "specials" manufacturers is not product specific). There may also be other products available which are unlicensed in the country of origin.
5. The least acceptable products are those that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin (but are in the UK). For example, the use of products from countries where they are classed as supplements, not pharmaceuticals, and may not be made to expected standards of pharmaceutical GMP. These should be avoided whenever possible.

Figure 2 Appendix 2 from the 2020 MHRA Guidance on CBPMs

²³ [Cannabis Guidance unlicensed CBPMs updated 2020.pdf](#)