Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00541**

15 June 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 17 May 2026. You wrote:

> *This FOI was originally submitted on Thu, 9 Apr 2026 at 16:09*
>
> *Dear Freedom of Information Officer,*
>
> *I am writing to make a request for information under the Freedom of Information Act 2000. My request concerns the regulatory framework governing the importation of unlicensed cannabis-based products for medicinal use (CBPMs) under Regulation 167 of the Human Medicines Regulations 2012, and specifically the Clinical Letter of Need (or clinical needs justification) that importers are required to hold as a condition of import notification.*
>
> *I set out my requests below, grouped by theme. Where any part of a request cannot be answered in full, I ask that the remainder be answered and that the exemption relied upon for any withheld information be clearly identified.*
>
> *Request 1: Internal Assessment Criteria for Clinical Needs Letters*
> *1a. Please provide any internal guidance, policy documents, standard operating procedures, or criteria used by the MHRA to assess whether a clinical needs justification submitted with a Regulation 167 CBPM import notification is adequate.*
>
> *1b. Please confirm whether the MHRA applies a minimum evidential standard — for example, whether prescribers are required to cite peer-reviewed clinical evidence, randomised controlled trial data, or any other specific category of evidence — and if so, provide any documentation setting out that standard.*
>
> *1c. If no formal assessment criteria exist, please confirm this in writing.*
>
> *Request 2: Rejection of CBPM Import Notifications on Clinical Needs Grounds*
> *2a. Since 1 November 2018 (the date on which specialist doctors were permitted to prescribe CBPMs), how many Regulation 167 import notifications for CBPM products has the MHRA received in total, broken down by calendar year?*
>
> *2b. Of those notifications, how many has the MHRA objected to or rejected on the*

grounds that the clinical needs justification was inadequate or absent?

2c. If the answer to 2b is zero, or near zero, please provide any documentation explaining the MHRA's rationale for not objecting to notifications on clinical needs grounds.

Request 3: Audit and Review of Clinical Needs Justifications
3a. Has the MHRA conducted any internal audit, review, or quality assessment of clinical needs letters or justifications submitted with CBPM import notifications since November 2018? If so, please provide any reports, summaries, or findings arising from that work.

3b. Has the MHRA commissioned or received any external review of the adequacy of the clinical needs letter framework as applied to CBPM imports? If so, please provide those documents.

3c. Has any internal concern been raised — including in board papers, meeting minutes, correspondence with ministers, or submissions to the ACMD — about whether the clinical needs letter requirement is functioning as an effective patient safety mechanism? If so, please provide relevant documentation.

Request 4: The 2020 Bulk Importation Policy Change
4a. Please provide any legal advice, legal analysis, or internal documentation assessing whether the March 2020 policy change permitting licensed wholesalers to hold advance bulk stock of imported CBPMs is compatible with the named-patient basis of the Regulation 167 exemption, as set out in the Human Medicines Regulations 2012.

4b. Please confirm whether, following the 2020 policy change, the MHRA updated its guidance on what clinical needs documentation importers must hold, and if so, provide that updated guidance.

4c. Please provide any correspondence between the MHRA and the DHSC or Home Office in relation to the legal basis for the March 2020 bulk importation change.

Request 5: UK Manufacture from Imported Raw Cannabis Material
The MHRA's guidance distinguishes between the importation of finished unlicensed medicinal products and the UK manufacture of unlicensed products from imported raw materials. In the CBPM sector, a number of operators import raw cannabis material under Home Office Schedule 1 licences and subsequently package or process that material into finished products in the UK.

5a. Does the MHRA consider such activity — importing raw cannabis and packaging or processing it into a finished CBPM in the UK — to constitute "manufacture" within the meaning of the Human Medicines Regulations 2012, requiring a Manufacturer's Specials (MS) licence?

5b. Where a CBPM is produced in this way, does the MHRA consider the Regulation 167 clinical needs letter requirement to apply to: (i) the raw material import only; (ii) the finished product supplied to patients; or (iii) both stages? Please provide any guidance or policy documentation addressing this question.

5c. Please provide a list of all current holders of Manufacturer's Specials licences whose licensed activities include the manufacture or assembly of CBPM products.

5d. Has the MHRA conducted any review of whether operators in the CBPM sector who import raw cannabis and package it in the UK are doing so under appropriate

authorisations? If so, please provide any findings.

Request 6: Yellow Card Adverse Event Reports — Unlicensed Imported CBPMs
6a. Since November 2018, how many Yellow Card adverse event reports has the MHRA received in relation to unlicensed imported CBPM products, broken down by year?

6b. Of those reports, how many involved psychiatric adverse events (including psychosis, suicidal ideation, self-harm, or death), broken down by year?

6c. Has the MHRA published any signal assessment or pharmacovigilance review in relation to psychiatric adverse events associated with unlicensed imported CBPMs? If not, please confirm whether any such review is planned or in progress.

Notes on Scope and Format
This request does not seek any personally identifiable information relating to individual patients. All requests are for aggregate data, policy documents, or internal correspondence of a regulatory nature.

Where information is held in electronic form, I would prefer it to be provided electronically.

I am happy to clarify any aspect of this request if it would assist the MHRA in processing it efficiently.

I note the 20 working day statutory deadline under the Freedom of Information Act 2000 and request that the MHRA acknowledge receipt of this request.

MHRA Response
Request 1: Internal Assessment Criteria for Clinical Needs Letters
No formal assessment criteria exist for the clinical needs justification submitted with Regulation 167 cannabis-based products for medicinal use in humans (CBPM) import notification. However, the procurement of unlicensed CBPMs in the UK is limited to the following:

- doctors on the GMC Specialist Register
- specialist Importers with a Home Office import and Domestic licence and MHRA licence
- registered pharmacies or retail pharmacy businesses (with Home Office Domestic licences, where appropriate)
- licensed wholesale dealers for supply to the order of any of the above

Further information on the supply of unlicensed CBPMs is available from our website, via the link below:
https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials

Ultimately, it is the decision of the prescribing physician to whether a patient should be prescribed any unlicensed medicine in the UK.

Request 2: Rejection of CBPM Import Notifications on Clinical Needs Grounds
Please see below the numbers of Notifications of Intent (NOIs) for CBPM products by year from 01 January 2019 to 31 December 2025.
2019 - 302
2020 - 2211
2021 - 6763
2022 - 16072

2023 - 11506
2024 - 31031
2025 - 6355

Regarding the number of notifications MHRA has objected to or rejected, we hold no information relevant to this. Refused/rejected NOIs for intent to import unlicensed CBPMs are not introduced into the MHRA Import Notification System.

Request 3: Audit and Review of Clinical Needs Justifications
According to MRHA Guidance Note 14, Section 2.2 and 2.3 , page 6, *"responsibility for deciding whether an individual patient has "special needs" which a licensed product cannot meet should be a matter for the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber responsible for the patient's care. The requirement for a "special need" relates to the special clinical needs of the individual patient. It does not include reasons of cost, convenience or operational needs (see Section 10 of this guide). Anyone supplying an unlicensed medicinal product, where an equivalent licensed medicinal product is available must be satisfied as to the existence of a special need for the unlicensed medicinal product. MHRA expects that documentary evidence of this special need should be obtained by manufacturers, importers or distributors and that this evidence should be made available on request of the Licensing Authority. This may take the form of a prescriber's letter, however an alternative fully documented audit trail through the supply chain confirming special need may be acceptable."*

The MHRA does not perform a clinical evaluation of the declared special clinical need, this is the responsibility of the prescriber responsible for the care from the individual patient.

No internal audit, review or quality assessment of the clinical needs letters or justifications submitted with CBPM import notifications since November 2018 has been done. Neither have we commissioned or received any external review of the adequacy of the clinical needs letter framework as applied to CBPM imports. MHRA is not aware of any internal concern about whether the clinical needs letter requirement is functioning as an effective patient safety mechanism.

Request 4: The 2020 Bulk Importation Policy Change
MHRA holds no legal advice, legal analysis, or internal documentation assessing whether the March 2020 policy change permitting licensed wholesalers to hold advance bulk stock of imported CBPMs is compatible with the named-patient basis of the Regulation 167 exemption, as set out in the Human Medicines Regulations 2012. This change was led by the Home Office and any further information in relation to this change should be referred to them.

The updated guidance on the supply of unlicensed CBPMs is linked below:
Supply unlicensed medicinal products (specials) - GOV.UK

With regards to correspondence between MHRA, Department of Health and Social Care (DHSC) and the Home Office concerning the legal basis for the March 2020 bulk importation change, we have searched our records and we hold no correspondence relevant to this enquiry.

Request 5: UK Manufacture from Imported Raw Cannabis Material
In response to your question asking if MHRA considers importing raw cannabis and packaging or processing into a finished CBPM product in the UK to constitute manufacture within the meaning of the Human Medicines Regulations 2012 (thus requiring a Manufacturer's Specials [MS] licence), yes, we do consider this to constitute manufacture.

In response to your question concerning the Regulation 167 clinical needs letter, this letter applies to the finished product supplied to patient, however the quantities of raw material imported must be justified based on the likely demand of those finished products, please see link below for more information.
https://assets.publishing.service.gov.uk/media/5e58eefb86650c53a363f77c/Cannabis_Guidance__unlicensed_CBPMs__updated_2020.pdf

With regards to your request for a list of all current holders of MS licences who manufacture or assemble CBPM products, a list of sites of MS licence holders is periodically published on the MHRA website, please see link below.
https://assets.publishing.service.gov.uk/media/6a22f0172cdcfdb7436ac015/MS_Register_-_June_2026.csv

MHRA does not hold a specific list of MS licence holders for CBPM products, as cannabis-based products is not a specific category we capture as part of the MS licence.

With regards to your question concerning whether any review has been done of operators in the CBPM sector, MHRA work closely with the Drugs and Firearms Licensing Unit (DFLU) of the Home Office to ensure all sites involved in the importation or manufacture of CBPM are appropriately licensed and inspected. An MS licence cannot be granted without an inspection by the MHRA. As inspection findings are specific against individual licence holders/applicants, it is not possible to provide generic inspection findings in response to your request.

Request 6: Yellow Card Adverse Event Reports — Unlicensed Imported CBPMs
We can confirm that, from 1 November 2018 up to 31 May 2026, there have been 286 UK suspected adverse drug reaction (ADR) reports associated with unlicenced cannabis-based products for medicinal use (CBPM). None of these reports have a fatal outcome.

Each Yellow Card submitted to the MHRA that relates to a product with an unknown regulatory status (including CBD products) is reviewed on a case-by-case basis. Where appropriate, the MHRA updates its product dictionary to ensure accurate capture of the reported information. This process supports standardised reporting and consistent data analysis across pharmacovigilance systems. It should be noted that the MHRA does not routinely record whether a product has been imported as part of its pharmacovigilance activities.

Please find attached Annex 1 containing tables with the requested yearly breakdowns. Please note that a single Yellow Card report may contain multiple suspect reactions, therefore the total number of reactions will not equal the total number of unique reports.

I can confirm that the MHRA performs signal detection activities for “special” unlicensed medicines, including cannabis-based products for medicinal use. As part of these processes, all adverse reaction reports submitted via the Yellow Card scheme are assessed, and cumulative data are reviewed at regular intervals. Where a potential safety concern is identified, this is recorded within a Safety Topic and evaluated to determine whether regulatory action is required. At present, the MHRA has not recorded any Safety Topics relating to cannabis-based products for medicinal use.

The observed increase in Yellow Card reports for 2023 is primarily attributable to a higher volume of submissions originating from an individual clinic. It is important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different products. This context is

important when interpreting year-on-year trends, as fluctuations may be influenced multiple factors including reporting behaviours and organisational service changes.

When considering the spontaneous data provided, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the CPBM product, only that the reporter had a suspicion it may have. The fact that symptoms occur after the use of a product, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.
- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different products. Incident reporting rates are influenced by the seriousness of adverse reactions, their ease of recognition, the extent of use of a particular product, and may be stimulated by promotion and publicity.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/