Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00667**

20 July 2026

Dea[redacted]

Thank you for your Freedom of Information (FOI) request received on 21 June 2026. You wrote:

> *Dear MHRA Freedom of Information Team,*
> *This request is made under the Freedom of Information Act 2000.*
> *It is submitted as part of an ongoing, transparent research programme examining the regulatory, criminal-law, equality, and real-world impacts of the framework governing cannabis-based products for medicinal use (CBPMs). The programme builds on material previously submitted to the Advisory Council on the Misuse of Drugs (ACMD) Call for Evidence on CBPMs, which closed on 17 October 2025, and on subsequent analytical updates and correspondence provided to the ACMD as the evidence base has continued to develop.*
> *Background*
> *Attached are Department of Health and Social Care responses FOI-1683941 and FOI-1688183.*
> *In those responses DHSC states, amongst other things, that:*
> *• responsibility for informing patients how to take prescribed medicines rests with prescribers and dispensing pharmacies;*
> *• product labels and clinics would be expected to communicate information concerning the correct route of administration;*
> *• healthcare regulators are responsible for ensuring healthcare professionals meet professional standards; and*
> *• DHSC would expect communication to specify in clear terms that smoking prescribed cannabis-based products for medicinal use is illegal and therefore a criminal offence.*
> *Also attached is a Patient Communication Evidence Pack containing representative examples of patient-facing packaging and dispensing labels supplied with prescribed cannabis-based products for medicinal use.*
> *The examples demonstrate communication of matters including:*
> *• route of administration;*
> *• vaporisation instructions;*
> *• smoking warnings;*
> *• storage requirements;*
> *• controlled-drug status; and*
> *• driving-related warnings.*
> *FOI_1D1b - MHRA*

19/06/2026
This request concerns recorded information relating to communication to patients of the legal consequences arising from Regulation 16A(3) of the Misuse of Drugs Regulations 2001.
For clarity:
• this request concerns formally recorded information only;
• it does not seek draft material;
• it does not seek informal communications;
• it does not seek legal advice;
• it does not seek opinions regarding the merits of the policy.
Requested Information
1. Has MHRA considered whether patient-facing information relating to prescribed cannabis-based products for medicinal use should communicate the legal consequences arising from Regulation 16A(3) of the Misuse of Drugs Regulations 2001?
2. If the answer to Question 1 is yes, please provide the records documenting that consideration.
3. If the answer to Question 1 is no, please identify any organisation, authority or office-holder regarded as responsible for considering that issue.
4. If MHRA has not considered the issue itself, does MHRA hold any recorded information identifying any requirement, expectation or mechanism through which communication of those legal consequences should occur?

MHRA Response
To date, only one cannabis-based product has been granted a marketing authorisation in the UK, Sativex Oromucosal Spray (PL 61050/0001) that is currently granted to SVX Therapeutics Limited. Information for healthcare professionals and patients is available through the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL), which are published on our website and available via the link below:
https://products.mhra.gov.uk/search/?search=PL+61050%2F0001&page=1

Further information from the Home Office on the scheduling of Sativex and changes to the Misuse of Drugs Regulations 2001 is provided below:
https://www.gov.uk/government/publications/scheduling-of-the-cannabis-based-medicine-sativex

The elements on the label of unlicensed medicines are defined and should comply with the British Pharmacopeia monograph requirements, and MHRA guidance:
Cannabis_Guidance__unlicensed_CBPMs__updated_2020.pdf

The inclusion of "*legal consequences arising from Regulation 16A(3) of the Misuse of Drugs Regulations 2001"* would not be appropriate to feature in the labelling of a medicinal product.

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
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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/