Medicines & Healthcare products
Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]

20 May 2024

MHRA reference: FOI2024/00067

Dear [redacted],

Thank you for your information request, which we received on 19 April. You asked for:

> *"I am currently writing a news piece on the legality of medicinal CBD-containing lozenges in several jurisdictions, including the United Kingdom. Therefore, I would like to kindly ask you the following questions:*
> *· What is the legal status (whether they allowed and, if so, whether they subject to special requirements/restrictions) of medicinal cannabis products containing/made of:*
> *o Phyto-derived cannabinoids*
> *o Synthetic cannabinoids, including chemically-modified cannabinoids (e.g. THCA converted to THC).*
> *o Fermentation-derived cannabinoids*
> *· What are the restrictions on the formats of medical cannabis products? Are there any lozenge-specific format restrictions?*
> *· Are pre-packaged medical cannabis products permitted? If so, are they subject to special requirements?*
> *· Is there any specific dosage recommendation on cannabinoids besides the FSA's recommendation?*
> *· Can medical cannabis products be promoted to physicians and/or patients?*
> *Additionally, I would really appreciate it if you could provide me with some market-related data, such as the number of medical cannabis patients, the number of prescriptions approved and the number of licensed medical professionals that can prescribe from March 2023 to March 2024."*

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We have dealt with your request under the Freedom of Information Act 2000 (FOIA).
We confirm that we hold the information which answers your questions.
We have separated your questions below and provided our answers beneath each.

"On the legality of medicinal CBD-containing lozenges in the United Kingdom

1. *What is the legal status (whether they allowed and, if so, whether they subject to special requirements/restrictions) of medicinal cannabis products containing/made of:*
   a. *Phyto-derived cannabinoids*
   b. *Synthetic cannabinoids, including chemically-modified cannabinoids (e.g. THCA converted to THC).*
   c. *Fermentation-derived cannabinoids"*

Our response:
Please also note, we have checked our records and there are currently no marketing authorisations for CBD lozenges. The available CBD lozenges are novel foods as categorised in 2019 and overseen by the Food Standards Agency.
Any CBD product marketed as containing 'medicinal CBD', or with any other medicinal claim, would fall under medicines regulations. According to our records there are three licensed cannabis products, Sativex, Epidyolex, and Nabilone. Further information about these products can be located by searching the following website, MHRA Products | Home.

MHRA regulates medicines for human use, medical devices and blood products for transfusion. The definition of a "medicinal product" is set out in the Human Medicines Regulations 2012 and if a product is caught by the definition, it must hold relevant authorisations and or / licences to allow its sale and supply within the UK. There is an exemption from holding a Marketing Authorisation if a medicine is supplied as 'special' by an appropriate prescriber. A 'special' can only be supplied in order to meet the special needs of an individual patient and may not be advertised.

To address parts d-f of your question:

   d. *"Phyto-derived cannabinoids*
   e. *Synthetic cannabinoids, including chemically-modified cannabinoids (e.g. THCA converted to THC).*
   f. *Fermentation-derived cannabinoids"*

We do not hold information on the above in terms of a specific formalised position on the legal status, restrictions or requirements for items in the above list. The suitability of medicinal cannabis product containing phyto-derived cannabinoids, synthetic cannabinoids, including chemically-modified cannabinoids or fermentation-derived cannabinoids as active substances would be considered at the time of review of the marketing authorisation application, or following a request from a potential applicant for MHRA Scientific Advice.

The legal status of the marketing authorisation or unlicensed medicine would be by prescription only. The Misuse of Drugs Regulations 2001, as amended by the Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018, provide that the prescriber must be a Specialist doctor registered on the General Medical Council (GMC) Specialist Register to be able to issue prescriptions for unlicensed CBPMs.

For products with a marketing authorisation, the product is available for patient use as other Schedule 2 drugs. See Regulation 16A of the 2001 Regulations.

2. *"What are the restrictions on the formats of medical cannabis products? Are there any lozenge-specific format restrictions?"*

***Our response*:**
In terms of medical cannabis products in relation to lozenge-specific format restrictions, we do not hold information on the above. To explain further, we do not have specific guidance for marketing authorisation applications for cannabis products rather the guidance and legislation that applies to medicines, such as the Human Medicines 2012 is applied / utilised. The suitability of a particular dosage form would be considered at the time of review of the marketing authorisation application, or following a request from a potential applicant for MHRA Scientific Advice.

3. *"Are pre-packaged medical cannabis products permitted? If so, are they subject to special requirements?"*

Our response:
It is not clear what is meant by 'pre-packaged' but if a product does *not* hold a marketing authorisation, it may be supplied as an unlicensed medicine, provided it is compliant with the requirements. Refer to the MHRA guidance 'The supply, manufacture, importation and distribution of unlicensed cannabis-based products for medicinal use in humans 'specials':

https://assets.publishing.service.gov.uk/media/5e58eefb86650c53a363f77c/Cannabis_Guidance__unlicensed_CBPMs__updated_2020.pdf

and MHRA Guidance Note 14 'The supply of unlicensed medicinal products ("specials")':
https://assets.publishing.service.gov.uk/media/645e19f5ad8a03000c38b3bc/The_supply_of_unlicensed_medicinal_products__special_GN14.pdf

4. *"Is there any specific dosage recommendation on cannabinoids besides the FSA's recommendation?"*

***Our response*:**
Under Section 1(1) (a) of the FOIA, this information is not held. Dosage recommendations are not within the MHRA remit, unless they pertain to a product with a marketing authorisation, in which case the product SmPC should be consulted. The FSA's recommendation of a limit of 10mg per day applies to the CBD products generally available as foods, not medical cannabis.

5. *Can medical cannabis products be promoted to physicians and/or patients?*

Our response:
Medicinal products that do not have a UK Marketing Authorisation or equivalent are prohibited from advertisement, please refer to the MHRA Blue Guide on the Advertising and Promotion of Medicines in the UK. Advertising to the public is permitted for medicines legally classified pharmacy sale (P) or General Sale List (GSL), subject to compliance with the Regulations. The Regulations prohibit the issue of any advertisement wholly or mainly directed to the general public which is likely to lead to the use of a prescription only medicine (POM).

In terms of authorised medicines, the below resource may be of interest to you. In terms of a formal reply under FOI, Section 21 (information reasonably accessible by other means) applies. Journalists and patient organisations should see appendix 5. Guidance on advertising to physicians is also available on the link immediately below.

Advertise your medicines - GOV.UK (www.gov.uk)
Appendix_5.pdf (publishing.service.gov.uk)

Please also refer to the section on advertising in the MHRA guidance 'The supply, manufacture, importation and distribution of unlicensed cannabis-based products for medicinal use in humans 'specials'

https://assets.publishing.service.gov.uk/media/5e58eefb86650c53a363f77c/Cannabis_Guidance__unlicensed_CBPMs__updated_2020.pdf

6. *"Additionally, I would really appreciate it if you could provide me with some market-related data, such as the number of medical cannabis patients, the number of prescriptions approved and the number of licensed medical professionals that can prescribe from March 2023 to March 2024."*

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Our response:
Under Section 1(1) (a) of the FOIA, we confirm that this information is not held. The Department for Health and Social Care can be contacted at the below webpage; the contact details are toward the bottom of this webpage.

Department of Health and Social Care - GOV.UK (www.gov.uk)

We have noted that this set of questions has also been submitted to our organisation via the News centre. The above response will serve to address both (identical) requests.

For future requests, we kindly ask that you submit these to one contact point only, duplicated requests cause a burden on resources and in some circumstances can result in a refusal of your request under Section 14 (vexatiousness) of the FOIA.

We hope this information is useful for you.

This concludes our response to your request.

If you have a query about this response, please contact us at

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group
Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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Re-use of our information