Medicines & Healthcare products Regulatory Agency

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

ADVISORY NOTICE

Dear Sir/Madam,

ADVERTISING OF UNLICENSED CANNABIS-BASED PRODUCTS FOR MEDICINAL USE (CBPMs)

MHRA is responsible for the administration and enforcement of medicines legislation in the UK. A complaint has been received concerning the advertising of cannabis-based products for medicinal use (CBMPs) on your website at [redacted]

Medicinal products which are placed on the market are required to be authorised in accordance with The Human Medicines Regulations 2012 (S.I.2012/1916) (HMR). Among other things these provide that, unless exempt, no medicinal product shall be placed on the market unless an appropriate authorisation has been granted by the licensing authority.

It is an offence to sell or supply or to advertise a medicinal product which does not have authorisation.

A "medicinal product" is defined in Regulation 2 of the Human Medicines Regulations and consists of two 'Limbs':

1. *Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.*

2. *Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.*

If a product satisfies either of the above criteria it may be classed as a medicinal product. In broad terms, when classifying a product, the Agency looks at the way it is presented and its actual or perceived function, that is, its effects (when administered) on human physiology.

Advertising

Regulation 279 of the Human Medicines Regulations 2012 states:

A person may not publish an advertisement for a medicinal product unless one of the following is in force for the product-

a) a marketing authorisation
b) a certificate of registration
c) a traditional herbal registration or
d) an Article 126a authorisation

“Advertisement” is defined in Regulation 7 and includes any activity designed to promote the prescription, sale, supply or use of a medicinal product. Unfortunately, what constitutes a "medicinal claim" is not closely defined in the legislation but as a rough guide unacceptable medicinal claims include the following:

- references to medical conditions such as colds, headaches, cuts and bruises, skin disorders, headlice, hangovers, smoking addiction, obesity, arthritis, depression, stress and all childhood disorders and serious diseases etc.

- references to treatment or alleviation of adverse conditions such as decongests, relieves pain, reduces inflammation, calms, stops itching, cures insomnia etc.

- references to interference with the normal operation of a physiological function such as burns fat, increases metabolism, reduces blood pressure, lowers cholesterol levels, prevents jet lag etc.

Marketing

The following forms of marketing are unacceptable in products that are unlicensed:

- References to medical conditions.
- Comparison with licensed medicines.
- References to interference with the normal operation of a physiological function.
- Product names which refer to adverse medical conditions.
- References to medical and/or clinical research and testing.
- References to the health risks of not taking a particular product.
- Editorial medicinal claims.
- Testimonials that include/imply medicinal claims.
- Graphics that imply medicinal uses.
- References to, or reproduction of "generic" information.
- Juxtaposing with any examples of the above.

Unlicensed medicines (‘Specials’)

While medicines should have appropriate authorisation before being placed on the market, certain products may be supplied as unlicensed medicines by an appropriate prescriber in exemption to this requirement.

An unlicensed medicinal product (a ‘Special’) may only be supplied in order to meet the special (clinical) needs of an individual patient and must be manufactured on the order of a prescriber. This is set out in Regulation 167 of the HMR. Responsibility for deciding whether an individual patient has special clinical needs which a licensed product cannot meet is a matter for the prescriber responsible

for the individual patient's care. An unlicensed medicine may be supplied following a bona fide unsolicited order and must be formulated in accordance with the specifications of an authorised healthcare professional for use by an individual patient under their direct personal responsibility**.**

The advertising of unlicensed medicinal products to members of the public is prohibited. This includes cannabis-based products for medicinal use (CBPMs).

Your product

As stated above, medicinal cannabis is an unlicensed special medicinal product which can only be prescribed on the responsibility of an individual prescriber to meet the needs of an individual patient. While the advertising of certain prescription services may be permissible, under Condition B of Regulation 167(3) of the HMR, no advertisement relating to a specific unlicensed 'special' may be published by any person.

1. Notwithstanding the use of the term [redacted] as a synonym for medicinal cannabis throughout, the intended purpose of your website is to enable the purchase by patients of unlicensed CBPMs for the treatment of a range of serious adverse medical conditions and disorders following an online consultation.

2. The statement on your website that [redacted] is incorrect; on 1 November 2018 CBPMs were added to Schedule 2 of the Misuse of Drugs Regulations 2001 (MDR). [redacted] is a broad category of traditional and modern medicines derived from plants.

3. It is stated on your website that [redacted] prescribe [redacted] by which you mean medicinal cannabis, [redacted]

4. The medical conditions for which [redacted] provide prescriptions for unlicensed CBPMs are advertised on your website to include [redacted]

5. MHRA also has evidence of videos of promotional activities posted on your Facebook page regarding the supply of unlicensed CBPMs for the treatment of adverse medical conditions. The prohibition on the advertising of unlicensed medicines includes the proactive display of information about products at conferences and exhibitions.

6. While providers of prescription services for CBPMs must register with the Care Quality Commission (CQC), it is not the case that CQC regulate medicinal cannabis.

What you should do now

The information in this letter sets out the MHRA's view regarding the unlawful advertising of medicinal cannabis products (CBPMs) for the treatment and prevention of a range of serious adverse medical conditions and disorders on your website and in social media.

In advance of further regulatory action MHRA are minded to offer you the opportunity to remove all references to the use of CBPMs for the treatment of adverse medical conditions and disorders from your website and social media with immediate effect. This means the removal of any reference to any adverse medical condition in any context.

You should notify MHRA, in writing, that this action has been taken **within 28 days of the date of this letter.**

Further guidance

MHRA *Guidance Note 8: A guide to what is a medicinal product* is available on the MHRA website and provides guidance on the classification process for medicinal products:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/759581/012__GN8_-_final_2018_combined_doc_Oct.pdf

The Agency reserves the right to change its view in the event of any information or evidence which has a bearing on the status of the products, including the way in which they are presented and promoted. This also includes any information which we have not assessed.

Thank you for your assistance.

Yours faithfully,

[redacted]
Borderline Lead
Healthcare, Quality and Access
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU