Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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Our Ref: RG/2015/000569

Date: 3 October 2016

Dear Mr [redacted],

[redacted]

Thank you for your email of 12th October 2015 to the Agency relating to the above named products. Please accept my apology for the delay in replying.

The MHRA is responsible for the safety, quality and efficacy of medicinal products. Under the 2012 Human Medicines Regulations, a product is regarded to be a medicinal product if it falls in either limb of the definition of a medicinal product.

- **Medicines legislation:**

In the UK, as in the rest of the EC, medicinal products which are placed on the market, are required to have marketing authorisations (formerly product licences) in accordance with part 5 of The Human Medicines Regulations 2012 (S.I. 2012/1916). Amongst other things these provide that, unless exempt, no medicinal product shall be placed on the market unless a marketing authorisation has been granted in accordance with Community provisions by the licensing authority or the European Commission. It is an offence to sell or supply or to advertise a medicinal product which does not have a marketing authorisation.

A "medicinal product" is defined in Article 1 of Council Directive 2001/83/EEC and included as Regulation 2 of the Human Medicines Regulations. The definition is as follows:

(1) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(2) Any substance or combination of substances which may be used by 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"

As advised previously in our letter of 31st August 2016 that we were reviewing the status of Cannabidiol (CBD Oil) in the UK.

The MHRA has now completed its review and has considered all information available to it relating to Cannabidiol (CBD Oil) and having taken into account all the scientific advice and evidence, it has come to an opinion that products containing Cannabidiol will satisfy the second limb of the definition of a 'medicinal product' (as above) because it may be used by 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.

A product will also satisfy the first limb of the above definition if medicinal claims are made for it in its presentation.

This means that the above named products will require a marketing authorisation to be granted for them before they can be legally sold, supplied or advertised anywhere in the UK. Therefore, you must cease to sell, supply, promote, advertise, or process orders for the above products until appropriate authorisation has been granted for them. You must confirm this in writing **within 28 days** from the date of this letter that you have taken the above steps.

Specified standards of safety, quality, and efficacy must be satisfied before a medicinal product can be granted a marketing authorisation. Proof of efficacy generally relies heavily on clinical trial evidence, and no products must be marketed pending any license application.

Please contact our Licensing Enquiries Section for a Licensing Pack on Tel: 020 3080 7400 or through https://www.gov.uk/medicines-medical-devices-blood/marketing-authorisations-variations-licensing; https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk

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.

I hope the above information is helpful and look forward to hearing from you shortly.

Yours sincerely,

Raj Gor
Medicines Borderline Section
Inspection, Enforcement & Standards Division