

06 Nov 2019 | News

UK Cracks Down On Unauthorized CBD

by David Ridley

In the last 12 months, 20 separate notices have been issued by the UK medicines agency to firms selling unauthorized CBD supplements in the country, according to data recently published by the regulator.

The UK's Medicines and Healthcare products Regulatory Agency has been cracking down over the last twelve months on unauthorized cannibidiol (CBD) supplements marketed in the country, according to data recently published by the agency.

Since last October, the MHRA has issued a total of 20 notices to CBD supplement manufacturers, including eight "urgent" Regulation 165 notices, which are issued by the regulator when products not authorized to be marketed in the UK "pose a risk to patient health."

Regulation 165 of the UK's Human Medicines Regulations (HMR, Part 9) empowers the MHRA to issue notices to companies to cease selling or advertising products that have transgressed the "borderline" between dietary supplements and medicinal products.

The MHRA can issue two types of emergency notices, "urgent" or "other" notices, depending on whether the unauthorized sale of the products pose an immediate risk to public health or the firm has made unauthorized medicinal claims respectively.

As well as the eight urgent notices issued to firms selling unauthorized CBD products in the UK – with all seven issued in one month, March 2018 – the MHRA also delivered eight "other" notices in the last 12 months. (See below)

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"Other" notices are issued when firms make "clear medical claims" for their products – which

have not been approved as medicines, and therefore are not allowed to make claims to “treat, prevent or cure disease” – MHRA told HBW Insight, and the companies responsible have “not voluntarily complied with a MHRA request to remove or reword the material within a set timescale.”

In all cases where an emergency notice is issued, the MHRA said it would have already “engaged with a company at the voluntary compliance stage not only to ensure that they are aware of the breaches of the HMR, but also to assist them to achieve compliance.” “A notice will be issued where it is apparent that a company is not intending to engage with this procedure,” it added.

Details of product names, retailers or manufacturers were not disclosed by the regulator. However, the MHRA said that any company not complying with either of these notices would be referred to the agency’s enforcement officers, who would “take appropriate enforcement action to achieve compliance,” ranging from “a further warning notice to a prosecution in the courts.”

Single CBD Firm Gets Five Warnings In One Month

Usually, the MHRA said it dealt with borderlines under Part 9 of the UK’s Human Medicines Regulations by issuing a “provisional determination” in writing to the relevant company.

According to the regulations, a provisional determination advises the firm that its product is not authorized to be sold in the UK in its current form, giving reasons for the determination as well as the chance to challenge this determination.

If no challenge is made, or if the challenge is deemed unsatisfactory, the MHRA will issue a “final determination,” which requires the offender to “cease to sell, supply or offer to sell or supply the product from the date specified in the notice until a marketing authorisation, traditional herbal registration, certificate of registration or Article 126a authorization is granted in respect of the product.”

CBD manufacturer CBDO – which sources its “organic” hemp from Slovenia and sells on the UK market through its website cbdo.co.uk – received a total of five final determination notices in one month, according to an MHRA report.

CBDO’s Organic CBD Oil (10ml), Organic Water Soluble CBD Drops (10ml), Premium Natural Organic Hemp Flower, Organic Hemp Tea Bags and Organic CBD E-Liquid For Vaping were each the subject of separate notices issued by the MHRA on 11 October 2018.

Each of the products was “presented for the treatment of a wide range or serious adverse medical conditions, all of which could only be achieved through a significant modification to human physiology,” MHRA explained.

Nevertheless, CBDO is still advertising its products on its UK website as having “anti-inflammatory properties” and the “ability to help several previously un-treatable diseases.”

“CBD oil has been known to help certain people fight cancer and relieve symptoms of irritable bowel diseases, improve schizophrenia symptoms, relieve anxiety and help you get more sleep,” the company claims.

While CBDO noted on the website that these health claims had not been evaluated by the US Federal Drugs Administration and were “not intended to diagnose, treat or cure any disease,” it seems likely that they would still fall foul of UK food and medicines regulations – they may even be the same claims made in 2018.

The MHRA told HBW Insight that it was “unable to comment on individual cases under investigation.” However, the agency said that, as with failure to comply with “other” or “urgent” notices, “in cases where there is a failure to comply with a final determination notice, which is an offence, the matter is referred to the agency’s enforcement team for further action.”