Medicines & Healthcare products Regulatory Agency

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Thank you for your letter of 11 October regarding cannabidiol (CBD).

I can confirm that Agency officials are meeting with Peter Reynolds and a meeting is scheduled to take place in early November.

At present, the MHRA has offered an opinion that products containing CBD should be regulated as medicinal products. If companies do not accept this then we can use the statutory determination process to formally classify their product(s). The classification of borderline medicinal products is a complex area which is set out in Part 9 of the 2012 Human Medicines Regulations[1]. The MHRA's Guidance Note 8 – 'A guide to what is a medicinal product' provides useful guidance in this regard[2]. 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"*

When MHRA first became aware of the sale of products containing CBD many of the companies were marketing products with overt medicinal claims, meaning they satisfied the first part of the definition of a medicinal product. MHRA advised the companies to cease making claims and also advised that it was reviewing the mode of action of CBD. MHRA is now of the view that CBD exerts a mode of action which satisfies the second limb of the definition and, in line with this, is of the opinion that CBD products are medicines and should obtain a marketing authorisation before they can be sold. I note that the case for CBD products being regulated as medicines is not disputed by Clear.

MHRA's clinical assessors have reviewed relevant scientific and clinical evidence to support the mode of action of CBD in the treatment of a range of medical conditions. It should also be noted that the European Medicines Agency has given CBD products an orphan designation[3] on four occasions, for

[1] http://www.legislation.gov.uk/uksi/2012/1916/contents/made

[2] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/506397/a_guide_to_what_is_a_medicinal_product.pdf

[3] Medicines for rare diseases are termed orphan medicines. The EMA offers range of incentives available to encourage development of these medicines. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000029.jsp

three different clinical conditions. Information regarding this designation is attached and I understand that a new drug application to the US Food & Drug Administration (FDA) is scheduled for the first half of 2017 for a CBD product used in the treatment of a severe form of childhood epilepsy.

A medicine is generally required to have a marketing authorisation (product licence) before being placed on the market. However, unlicensed medicinal products containing CBD could be made available to individuals on prescription. Regulation 167 of the Human Medicines Regulations 2012 provides an exemption from the need for a marketing authorisation for a medicine which is supplied:

- in response to a bona fide unsolicited order;
- formulated in accordance with the specification of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber;
- for use by an individual patient on the prescriber's direct responsibility to fulfil a "special need";
- manufacture and import is by the holder of an appropriate authorisation (of which there are a number);
- import from outside the UK is notified in advance to the licensing authority.

An unlicensed medicine may not be advertised, but a manufacturer, importer or wholesaler may advertise the service they provide. An unlicensed medicine can only be supplied in order to meet the special needs of an individual patient. Responsibility for deciding whether an individual patient has "special needs" which a licensed product cannot meet should be a matter for the prescriber responsible for the patient's care. See MHRA Guidance Note 14 for further information regarding the supply of unlicensed medicinal products.

The scheduling of cannabis is a matter for the Home Office however, I note that the status of cannabis as a Schedule 1 substance does not preclude manufacturers from researching and developing cannabis-based medicines. Sativex has been developed by GW Pharmaceuticals for the treatment of Multiple Sclerosis and is available in the UK. Sativex contains two active cannabinoids, Tetrahydrocannabinol (THC) and CBD, extracted from herbal cannabis.

I trust that this addresses the points that you make in your letter.

Yours sincerely

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