Canice Ward
Medicines Regulatory Group

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Registered Pharmacies

From: Canice Ward
Room D 4.6, Castle Buildings
Upper Newtownards Road
Belfast, BT4 3SQ
Tel: (028) 9052 3703
E-Mail: canice.ward@*health-ni.gov.uk*

15 August 2019

Dear Colleague,

CBD/CANNABIS/CANNABIDIOL/HEMP OILS

The Medicines Regulatory Group (MRG) is aware that some pharmacists may be offering CBD oils and/or other such related oils and products for sale from registered pharmacies.

There are a number of matters pharmacists must consider before offering to sell or supply such products.

Human Medicines Regulations 2012

CBD oils cannot be marketed as medicinal products unless they have a Marketing Authorisation issued by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA) under the Centralised Marketing Authorisation process.

Advertising the medicinal benefits of such products through any platforms including pharmacy posters and literature or social media and internet sites which give rise to medicinal claims could be unlawful and would likely render the product an unauthorised medicinal product. It is an offence, unless otherwise exempted, to sell or supply, or offer to sell or supply, an unauthorised medicinal product.

More information is available from the MHRA at:

https://www.gov.uk/government/news/mhra-statement-on-products-containing-cannabidiol-cbd , https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials and https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines

Misuse of Drugs Act 1971 / Misuse of Drugs Regulations (Northern Ireland) 2002

Cannabidiol (CBD) as an isolated substance, in its pure form, is not controlled under the Misuse of Drugs Act 1971 or the Misuse of Drugs Regulations (Northern Ireland) 2002. It is our understanding that it is very difficult to isolate pure CBD. If a CBD product contained any controlled cannabinoids, unintentionally or otherwise, such as Tetrahydrocannabinol (THC), the product could be controlled under Misuse of Drugs legislation.

Having recently tested numerous products our experience is that some products in fact do not fully disclose their contents or provide a full spectrum analysis at an appropriate level of sensitivity to accurately and consistently determine their true content or control status. In this context the presumption has to be one of caution - that is, that a CBD containing product would be controlled under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations (Northern Ireland) 2002 as a result of its other cannabinoid content.

Any person supplying, or offering to supply, a Class B controlled drug in this manner would likely be committing an offence under the Misuse of Drugs Act 1971.

Further information is available from the Home Office at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/778357/Factsheet_Cannabis_CBD_and_Cannabinoids_2019.pdf

Novel Foods

If pharmacists are offering CBD oils for sale as food products then they must make sure the product is authorised to be sold as such. Some CBD products may require a Novel Food Authorisation before being placed on the market. Local authorities, including Trading Standards and Environmental Health Officers, are responsible for the enforcement of novel foods legislation.

More information is available from the Food Standards Agency: https://www.food.gov.uk/business-guidance/novel-foods

Professional Matters

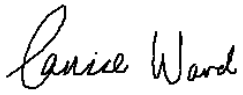
Pharmacists will be aware of their professional obligations detailed in the Pharmaceutical Society of Northern Ireland's Code of Ethics and Professional Guidance and Standards documents. Pharmacists must use their professional judgement when choosing to supply or to offer to supply CBD products.

The Pharmaceutical Society should be contacted in relation to professional matters.

This letter is intended as general guidance only and does not constitute legal advice. Pharmacists should seek their own independent legal advice to ensure they are compliant with any relevant legislation.

MRG Inspectors continue to monitor the sales of such products in pharmacies and in the general retail sector. If any breaches of the various pieces of legislation mentioned above are identified by MRG, or other responsible statutory agencies, pharmacists leave themselves vulnerable to potential legal and/or professional proceedings.

Yours Sincerely



Canice Ward
Medicines Regulatory Group
Department of Health