ROYAL NORWEGIAN MINISTRY
OF HEALTH AND CARE SERVICES

EFTA Surveillance Authority
Rue Belliard 35
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BELGIUM

Your ref	Our ref	Date
81910-908231	18/1517-4	18 June 2018

Request for information - Complaint against Norway concerning the classification of Cannabidiol-oil ("CBD-oil") supplements made from industrial hemp

The Norwegian Ministry of Health and Care Services refers to your letter of 28 March 2018 regarding a request for information after a complaint against Norway concerning the classification of Cannabidiol-oil ("CBD-oil") supplements made from industrial hemp.

The EFTA Surveillance Authority has asked the Norwegian Ministry of Health and Care Services to answer the following:

1. Please provide information on the classification of CBD-oil products, in particular with THC levels below 0,2% and without THC, and the reasoning for such classification.

Answer:

In Norway, the Norwegian Medicines Agency (NoMA) is responsible for the classification of substances, herbs and products as medicinal or non-medicinal products according to the Norwegian Act on Medicinal Products. Many products on the market are borderline between medicinal products and other product categories. Directive 2001/83 article 1(2) contains a definition of medicinal products. The definition is implemented into the Norwegian Act paragraph 2 on Medicinal Products and is the starting point for any classification. Nevertheless, even in the EU/EEA, where there is a common definition of a medicinal product, the countries can interprete the definition differently.

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Additionally, NoMA is responsible for administering the legislation on narcotic and psychotropic substances, including evaluating whether or not a product falls under the Norwegian Regulation on Narcotics.

NoMA performs evaluations of the classification of specific products as medicinal or non-medicinal. This is done on a case-by-case basis, according to case-law from the EUCJ, taking into account all aspects of the product. The evaluation results in a classification as a medicinal or a non-medicinal product. If a product is classified as a nonmedicinal product, NoMA does not evaluate what other legislation the product will be regulated by. However, NoMA does evaluate whether or not a product falls under the Norwegian Regulation on narcotics, i.e. if a product contains a narcotic substance as defined in the Regulation. If a product contains a substance covered by the definition of «narcotic substance», the product will be regarded as a narcotic, and regulated as such.

The EFTA Surveillance Authority refers in its letter of 28 March 2018 to CJEU Case C-319/05, European Commission v Germany, concerning Germany classifying a garlic preparation in capsule form as a medicinal product, is mentioned in your letter. NoMA recognizes that this is one of the CJEU-cases describing the conditions that must be fulfilled in order to classify a product as a medicinal product by presentation and by function. It does, however, not specifically concern products consisting of CBD and/or THC. The case is the opposite of the question relating to CBD-products as a garlic product in capsule form, whose effect on physiological functions is no more than the effects which a foodstuff consumed in a reasonable quantity may have on those functions, can not have a significant effect on the metabolism. The CJEU therefore concluded that it could not be classified as a product capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83. Cannabidiol-oil is, however, one of the active ingredients in the cannabis plant. Whether or not a product is regulated as a narcotic is a separate issue that is not directly related to the classification of products as medicinal/non-medicinal.

In order for NoMA to perform a classification of a product as medicinal/non-medicinal, an application has to be submitted along with e.g. relevant scientific documentation about the product, its contents, labelling and information on the presentation of the product. NoMA has just recently received three classification applications regarding CBD-products, and has therefore not yet made a formal classification of a product containing CBD. However, NoMA has previously received several questions regarding the classification of CBD-products that are not classification applications, and NoMA has therefore performed a preliminary assessment of CBD-products in general, in order to provide advisory information on the regulation of these products. The preliminary assessment has taken both the definition of «medicinal product» and the definition of «narcotic substance» into consideration.

The advisory information that NoMA has given in response to questions regarding the legal status of CBD-products is the following: Products containing cannabidiol (CBD) could generally be considered medicinal products or narcotics. If a product contains

tetrahydrocannabinol (THC) (any amount exceeding zero), it is regarded as a narcotic in Norway.

The reasoning for the advisory information regarding the classification of CBD as medicinal/non-medicinal is the available scientific documentation and information of CBD-products used in clinical trials. Examples are given here:

- WHO Technical Report Series No. 1009, 2018 describes the therapeutic usefulness of CBD (http://apps.who.int/iris/bitstream/handle/10665/260546/9789241210188-eng.pdf?ua=1).
- EMA has granted orphan designations for the use of cannabidiol in several diseases/conditions; prevention of graft-versus-host disease, treatment of Dravet syndrome, treatment of Lennox-Gastaut syndrome, treatment of West syndrome, treatment of graftversus-host disease, treatment of perinatal asphyxia and treatment of tuberous sclerosis.
- A marketing authorization application for a product containing cannabidiol has been submitted to EMA.[1]
- There are several studies on the medicinal use of cannabidiol in the literature. The most recent is a randomized, double-blind placebo-controlled phase 3 trial using 20 mg/kg oral cannabidiol as an add-on novel antiepileptic drug in patients with Lennox-Gastaut syndrome, indicating that cannabidiol is effective.[2]

The available scientific documentation on cannabidiol, implies that products containing cannabidiol are medicinal products by function if cannabidiol is present in therapeutic doses. NoMA has not established a cut-off dose below which there is no current scientific justification for significant therapeutic effects. As mentioned, NoMA has received three classification applications regarding CBD-products, and these will be evaluated in due time. NoMA suspects that the advisory information has been perceived as more than just advisory information.

Administrative decisions by NoMA may be appealed, if the applicant disagrees with the decision. The appellate instance is the Ministry of Health and Care Services.

With regards to the Norwegian Regulation on narcotics, a product containing a narcotic substance is regulated as a narcotic. NoMA is aware of the discussions taking place in Europe and the United Nations regarding cannabis-related products, and will be heedful of any development and decisions made.

Norway is aware of the fact that extracts and tinctures of cannabis are listed under schedule I of the UN Single Convention on Narcotic Drugs, as well as included in the Norwegian legislation, and as such, CBD-products that are extracts could be considered narcotics independent of the content of THC. Norway would like to point out that the WHO Expert

[1] GW Pharmaceuticals – press release, http://ir.gwpharm.com/news-releases/news-release-details/gwpharmaceuticals-and-us-subsidiary-greenwich-biosciences-1. [2] Thiele, E.A. et al., *Lancet* 2018, Vol. 391 (10125): 1085.

Committee on Drug Dependence (ECDD) has commented on the regulation of CBD in their technical report from the meeting in November 2017: *«CBD is not specifically listed in the schedules of the 1961, 1971 or 1988 United Nations International Drug Control Conventions. There is no evidence that CBD as a substance is liable to similar abuse and produces similar ill effects to substances in the 1961 or 1971 Conventions (including cannabis and dronabinol (THC), respectively). The purpose of the pre-review was to determine whether current information justifies a critical review by the Expert Committee of information that may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions. As CBD is not currently a scheduled substance in its own right (only as a component of cannabis extracts), current information does not justify a change in this scheduling status nor does it justify scheduling of the substance. However, where CBD is produced for pharmaceutical purposes as an extract of cannabis, cannabis extracts and tinctures are included in the 1961 UN Single Convention on Narcotic Drugs. The pre-review of cannabis extracts and tinctures will take place at the fortieth ECDD meeting in May 2018. Therefore it is also recommended that extracts or preparations containing almost exclusively CBD (cannabidiol; (1'R,2'R)-5'-Methyl-4-pentyl2'-(prop-1-en-2-yl)-1',2',3',4'- tetrahydro-[1,1'-biphenyl]-2,6-diol) be subject to critical review at that meeting.»* The next meeting of ECDD is taking place in June this year (not in May).

Norway is further aware of the fact that several European countries allow cultivation of industrial hemp (specified varieties of the plant) containing not more than 0.2% THC, grown for fibre. It appears that the countries have varying legislation concerning the use of industrial hemp. Following an evaluation of the legislation in Norway in 2009/2010, it was decided that the cultivation of industrial hemp is not allowed.

If an oral CBD-containing product were to be regarded as a non-medicinal (and non-narcotic) product following a case-by-case evaluation, it is assumed that the product most likely would be regulated by the legislation on novel foods, cf. the novel food catalogue.

The inclusion in the novel food catalogue on cannabidiol is the following :
«Extracts of Canabis sativa L in which cannabidiol (CBD) levels are higher than the CBD levels in the source Canabis sativa L are novel in food. Cannabidiol (CBD) is one of the cannabinoids in Cannabis sativa plant. In the European Union, the cultivation of Cannabis sativa L. varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % of the plant.»

The following information is given regarding the novel food catalogue :
«The Novel Food Catalogue lists products of animal and plant origin and other substances subject to the Novel Food Regulation, based on information provided by the EU Member States.
It is a non-exhaustive list and serves as orientation on whether a product will need an authorisation under the Novel Food Regulation. EU countries may restrict the marketing of a product through specific legislation. For information, businesses should address their national authorities.

In some cases, it shows information on the history of use of food supplements and ingredients used exclusively in food supplements in the EU countries. If foods and/or food ingredients were used exclusively in food supplements, new uses in other foods require authorisation under the Novel Food Regulation.»

The following is given in the preamble of Regulation 2015/2283 on novel foods regarding the borderline between novel foods and medicinal products:
«Directive 2001/83/EC of the European Parliament and of the Council (1) applies in cases where a product, taking into account all its characteristics, may fall both within the definition of 'medicinal product' as laid down in that Directive and within the definition of a product covered by this Regulation. In that respect, where a Member State establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, it may restrict the placing on the market of that product in accordance with Union law. Moreover, medicinal products are excluded from the definition of food as laid down in Regulation (EC) No 178/2002 and should therefore not fall within the scope of this Regulation.»

A product that is considered to fall within the definition of a medicinal product in Norway, following a formal classification, will therefore not be regulated by the legislation on novel food, but instead be regulated by the legislation on medicinal products (i.e. Norwegian Medicines Act).

2. Where certain CBD-oil supplements have been classified as medical products in Norway, please provide reasoning for such classifications, in particular in light of Article 1(2) of Directive 2001/83/EC (as amended by Directive 2004/27/EC), as interpreted by the CJEU.

Answer:
As NoMA has not yet made a formal classification evaluation of a specific CBD-product it is not possible to provide ESA with the reasoning. However, NoMA has given the reasoning for the advisory information given regarding the legal status of CBD (cf. question 1). As mentioned, the classification applications that NoMA has received will be evaluated in due time.

Yours sincerely

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This document is signed electronically and has therefore no handwritten signature