

# Is Swedish market for CBD oils closed?

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## Introduction

In August 2019 the Administrative Court prohibited several companies from selling products containing CBD. The decisions were essentially based on the finding that the use of 'CBD' in the products' names amounted to a statement which presented them as having properties which treated medical conditions. Following these decisions, the Swedish Medical Products Agency (MPA) seems to have widened the definition of 'medicinal products' when it prohibited two companies from selling oils which contained CBD. This was seemingly based on the reasoning that the mere fact that the oils contained CBD constituted such a presentation that they were within scope of the definition of a medicinal product.

## Facts

In one of these cases, a company which was subject to the prohibition ordered by the Administrative Court in 2019 changed the name of some of its products which contained CBD so that the word 'hemp' was used instead of 'CBD'. However, other aspects of the products remained the same, such as:

- the size of the bottles;
- the concentration and contents;
- the description of use; and
- the dosage.

In the other case, the company sold a product named 'Original Oil'. On the company's website, it was described as an "[o]rganic and THC free CBD oil" containing "10% organic hemp essence (CBD)". Its website had previously included statements regarding certain effects that the oil had on medical conditions, as well as references to a World Health Organisation (WHO) report discussing medicinal findings relating to CBD. This information was later removed. The website also provided that CBD oils are not medicinal products and cannot treat medical conditions.

In both cases, the MPA assessed whether the products were to be defined as medicinal products and thus required a marketing authorisation.

## Decisions

With regard to the first company's products, the MPA put significance on the fact that the offered products were of the same size, concentration and description as the previously prohibited products, albeit now not using 'CBD' in their name. It was thus concluded that the company was selling the same products which the Administrative Court had prohibited. The MPA then noted that the products' information provided that they contained CBD and that a header on the website mentioned "CBD oils". This, according to the MPA, made it clear for consumers that the products contained CBD.

The MPA further held that a WHO report, among other things, provided that CBD had shown some effect in treating epilepsy and, potentially, other medical conditions. It was also noted that two medicinal products which contained CBD existed in Sweden and that information from the European Commission showed that CBD is not used as food. This, according to the MPA, entailed that it was logical for the actual and intended consumer to assume that products which contain CBD are for medicinal use.

The MPA further held that:

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- the products' appearance was reminiscent of medicinal products;
- there was no known use for products containing CBD other than for medicinal use; and
- product reviews online indicated that consumers buy the relevant products for medicinal use.

With regard to the other company's products (ie, Original Oil), the MPA similarly found that it was evident that the products contained CBD. The MPA further noted that the website's previous references to the WHO report regarding CBD and the information regarding CBD's alleged effects on medical conditions had been removed. Despite this, the MPA held that it was probable that said information had contributed to a perception among consumers' that CBD had medicinal effects. According to the MPA, the fact that the company's website now informed consumers that the products did not treat medical conditions did not significantly affect their perception of CBD.

Thus, in both cases, the MPA found that the relevant products were to be defined as medicinal products as they were presented as having properties for treating or preventing medical conditions. Since the products had not obtained marketing authorisations, they were prohibited under penalty of a fine.

## **Comment**

While the MPA identified numerous circumstances in both cases which altogether indicated that the products had been presented as having properties for treating medical conditions, significant weight was given to the fact that it was apparent to consumers that the products contained CBD. The Administrative Court had previously based its decisions to prohibit CBD oils on the finding that the use of 'CBD' in the product name amounted to a statement which presented the product as having properties which treated medical conditions. However, the MPA now seems to believe that if consumers are aware that a product contains CBD, it is a medicinal product. In neither of the decisions was it sufficient to remove CBD from the name. Rather, it seems that solely by containing CBD, the MPA defines a product as a medicinal product (since it is hard to imagine where a product for oral consumption which does not specify its contents would be allowed).

The MPA's reasoning thus seems to lie in a blurry area where a medicinal product is defined as such due either to the effect of its substances or to its presentation. The MPA seems to hold that solely by containing a certain substance, a product can be regarded as presenting itself as having properties for the treatment of medical conditions, despite not *de facto* containing a substance which has a proven medical effect. Rather, it is enough that consumers expect it to have such an effect.

The decisions have been appealed to the Administrative Court. If the MPA's decisions are upheld, based on the same reasoning, it could be argued that the market for oils which contain CBD but do not have a marketing authorisation is effectively closed in Sweden. If that is the case, the question remains: exactly on what grounds has the market been closed?

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