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Another nail in the CBD coffin in Sweden

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Introduction

The Administrative Court of Uppsala has upheld the Swedish Medicinal Products Agency's (MPA's) decision to prohibit a Dutch company from selling cannabidiol (CBD) products for oral consumption on the Swedish market. In reaching this decision, the Court found that:

- the MPA had been competent to render the decision;
- the decision was not contrary to articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU); and
- the MPA had been correct in defining the CBD products as medicinal products.

The prohibition was thus upheld as the CBD product had not obtained a marketing authorisation.

Facts

In 2020, the MPA prohibited a company from selling CBD products (called "the Original Oil") for oral consumption. The sales had taken place online and the MPA found that the CBD product had been presented as having properties for treating or preventing medical conditions and thus had to be defined as a medicinal product. The product was not allowed to be sold as it had not obtained marketing authorisation (for further details, see "Is Swedish market for CBD oils closed?").

The company, registered in the Netherlands, appealed the decision to the Administrative Court of Uppsala, where three questions arose:

- Had the MPA been competent to render a decision prohibiting the Dutch company from selling CBD products in Sweden?
- Had the MPA been correct to define the CBD products as medicinal products that required a marketing authorisation?
- Were articles 34 and 36 of the TFEU applicable, such that it had to be assessed whether the prohibition was a justified quantitative restriction thereunder?

Decision

Competence of MPA

The Court answered the first question affirmatively – the MPA had been competent to prohibit the CBD product. In reaching this conclusion, the Court held that:

- the MPA is competent to carry out supervision in relation to the medicinal products legislation;
- the EU Medicinal Product Directive[(1)] presupposes that EU member states maintain the requirement of national marketing authorisations in the member state of destination in a cross-border situation;
- pursuant to EU case law, a product may be defined as a medicinal product in one member state and not in another member state; and
- the E-commerce Act (based on the EU Electronic Commerce Directive)[(2)] did not prevent prohibition due to national rules as it related to products and not services (the relevant legislation provides that national rules shall not prevent service providers from other member states from providing electronic services to Swedish recipients).

In light of this, the Court concluded that if the CBD product was defined as a medicinal product, the MPA had been competent to prohibit the sales.

Medicinal product definition

The Court then answered the second question affirmatively – the CBD product had been presented in such a way that it had to be defined as a medicinal product, which requires a marketing authorisation.

The Court noted that the product had been marketed in such a way that the so-called "well-informed consumer" would perceive it to have properties to treat or prevent disease. On its website, the company had marketed the product together with information on CBD's allegedly positive effects against certain conditions, referring to a report by the World Health Organization. The company had also made statements relating to the potential medicinal use of CBD in a podcast.

The fact that the company had removed such marketing, statements and the podcast more than two years ago was irrelevant. The Court thus concluded that consumers who had purchased the CBD product in question would still have believed that it had the properties with which it had previously been advertised. Therefore, the product had been presented in such a way that it had to be defined as a medicinal product.

Articles 34 and 36 of TFEU

Moving on to the third question, the Court referred to national case law and held that articles 34 and 36 of the TFEU were not applicable. A correct decision by the MPA to classify a product as a medicinal product did not constitute a restriction that had to be motivated in

accordance with article 36 of the TFEU.

The MPA had thus been correct to prohibit the sales of the CBD products for oral consumption and its decision was accordingly upheld by the Administrative Court of Uppsala.

Comment

This decision maintains the strict view in Sweden on CBD products for oral consumption – it may have been the final nail in the coffin for such products on the Swedish market.

However, there are still some questions to be answered as the Court did not go into detail regarding the assessment of what constitutes a presentation that renders a product a medicinal product. It would, for example, have been fascinating to know the Court's view if the company had made no statements relating to treatment of diseases but had only used the words "CBD oil" for its products. While this situation has not arisen, previous rulings from the administrative courts, as well statements from the MPA, strongly indicate that the sole mention of CBD on a product intended for oral consumption constitutes a presentation that renders it a medicinal product.

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Endnotes

(1) 2001/83/EC.

(2) 2000/31/EC.