International Law Office

April 5 2023

Sweden's new legislation on non-medicinal tobacco-free nicotine products

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Introduction

Sweden has been the only EU member state in which consumers can purchase snus (ie, snuff for oral use, in loose weight or in tobacco pouches) since it was banned in the European Union. The consumption of snus has increased during recent years in Sweden. One reason for this may be the introduction of non-medicinal tobacco-free nicotine products for oral use on the Swedish market.

In 2016, the Swedish Supreme Administrative Court ruled that e-cigarettes should not be classified as medicinal products, given their effects (for further details please see "E-cigarettes no longer considered medicinal products in Sweden"). Previously, all products containing nicotine had been classified as such. Following the ruling, e-cigarettes could only be classified as a medicinal product based on a specific claim (ie, to help users stop smoking).

The EU Tobacco Products Directive[(1)] covered only e-cigarettes and similar nicotine products. It did not consider pouches for oral use, since snus was banned in the European Union. The industry thus launched tobacco-free nicotine products for oral use in pouches on the Swedish market. The products were effectively not covered by any specific legislation. Therefore, manufacturers came to a unanimous agreement to apply similar rules as those that applied to snus (eg, a prohibition on sales for anyone under the age of 18).

Following a report by the Ministry of Health and Social Affairs presented in 2021 (for further details please see "New legislation on tobacco-free nicotine pouches expected"), the Swedish government has now presented a new act on tobacco-free nicotine products (the Nicotine Act). The Nicotine Act entered into force on 1 August 2022, changing the landscape for all stakeholders in the industry (for further details please see "New legislation for tobacco-free nicotine products expected in 2022"). This article discusses the content and ramifications of the new legislation.

Goal

The overarching goal cited during the preparation of the legislation was to create better communal conditions for better health. The Committee on the Rights of the Child and the government had expressed concerns regarding the marketing and use of unhealthy and dangerous products, including tobacco-free nicotine products. The government considered tobacco-free nicotine products to be a gateway for young people to nicotine addiction. This is something that the Swedish strategy for alcohol, narcotics, doping and tobacco politics for 2022-2025 strives to prevent.

Marketing and sponsorship

One of the primary targets of the legislation is the marketing of tobacco-free nicotine products. Since the marketing of such products is not covered by the Tobacco Act (covering the marketing of snus), the more general Marketing Act applies. The Marketing Act is much less rigorous than the laws governing other strictly regulated products, such as tobacco and alcohol. The opportunities to market tobacco-free nicotine products have been further assisted by the ability to flavour the products, as well as developments in technology.

The new legislation significantly restricts the possibilities for marketing, stating that any marketing must be carried out in "particular moderation" (the same requirement as for the marketing of tobacco and alcohol). The marketing of tobacco-free nicotine products is further prohibited from being advertised on television and radio, as is the case for alcohol and tobacco.

Guidance for the interpretation of the term "particular moderation" may be from taken primarily from the Alcohol Act, which is currently less strict than the Tobacco Act. The legislation remarks that the marketing shall be heavily restricted, and a great deal of restraint shall be exercised, in the selection of both marketing channels and methods. When interpretating whether marketing is "particularly moderate" considerable emphasis shall be put on whether it aims to maintain or increase consumption or contribute to a positive attitude towards the products.

The Nicotine Act further prohibits all sponsorship promoting tobacco-free nicotine products at events or activities to which the public has access. While the prohibition is not absolute, it prohibits all sponsorship that promotes the use of tobacco-free products, likely meaning that most if not all sponsorships are now prohibited. These restraints are also in line with existing tobacco and alcohol legislation.

Classification and supervision

The preparatory works of the Nicotine Act state that the reason behind the adoption of a specific law for tobacco-free nicotine products, instead of incorporating the products into the Tobacco Act, was that tobacco-free nicotine products are not governed by EU law. Further, the complexity of the current Tobacco Act makes it challenging to revise.

The new Nicotine Act has several similarities with the Tobacco Act and the Alcohol Act. As well as the "particular moderation" requirement, manufacturers of nicotine products must also notify the municipality before selling to consumers (this was previously the case for tobacco products; however, it now requires a licence). This has the effect that the municipalities are the supervisory authorities for compliance with the legislation, which is also the case for the supervision of retail sales of tobacco products. There is also a requirement for the retailer to self-monitor the sales, which is the same requirement as in the Tobacco Act and the Alcohol Act.

Tobacco-free nicotine products are further, as a clarification, classified as a food stuff. Therefore, they fall under the supervision of the Swedish Food Agency. As of 1 January 2023, tobacco-free nicotine products must be classified and labelled in accordance with the EU Classification, Labelling and Packaging Regulation[(2)] and the EU Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation.[(3)]

Several other authorities are responsible for the supervision of different elements of the distribution chain of these products. These include the Public Health Agency and the Swedish Consumer Agency.

The law prohibits sales of tobacco-free nicotine products to anyone under 18.

Comment

The Nicotine Act changes the legal landscape for manufacturers as well as retailers. From being a non-regulated product that manufacturers and retailers could distribute and market effectively freely, the products are now heavily regulated compared with snus products. This development has also been seen in other EU member states – in some, the products remain classified as a medicinal product, while in others they are completely prohibited. In other jurisdictions, nicotine products are banned if they contain no tobacco or are classified as a medicinal product.

Sweden has encountered further issues with the municipalities' supervision of compliance with the Nicotine Act. It is not intended that nicotine products shall be as strictly regulated as tobacco products, which are further regulated at an EU level – Sweden is thus obliged to impose a harmonised level of regulation of tobacco products. However, it appears that the municipalities are applying the Nicotine Act in a similar way to the Tobacco Act, thus effectively prohibiting essentially all marketing of nicotine products that are sold in retail stores. This will likely be subject to appeals with the administrative courts; precedents on the marketing of these products are highly desirable.

Sweden elected a new government at the end of 2022. At the end of February 2023, it sent out an amendment of the assignment to, among others, the Public Health Agency and the National Board of Health and Welfare to collect, compile and make accessible scientific knowledge of the health effects and damage caused by different tobacco and nicotine products. The amendment is thus that the health effects and damage caused by any product shall be described in relation to other products. This contradicts the actions of the previous government, which had opined that all tobacco and nicotine products should be considered equally damaging for consumers. By extension, this may in the future open up the possibility of performing a risk assessment based on the use of each product type, shifting the focus to lowering the detrimental effect on health by switching product type instead of cessation regardless of the product type.

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Endnotes

(1) 2014/40.

(2) 1272/2008.

(3) 1907/2006.