

New legislation on tobacco-free nicotine pouches expected

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Introduction

In recent years, tobacco-free nicotine pouches, which are intended to be placed under the lip, have existed in a grey area with no clear rules or regulations to govern, for example, the warning labels which they must carry or their marketing. The government has therefore assigned to the Ministry of Health and Social Affairs the task of assessing and analysing how such products should be regulated. On 31 March 2021 the results of the analysis will be presented. This article discusses how the issue arose and possible resolutions.

Background

Sweden has a long tradition of using 'snus', a tobacco product that contains nicotine and is placed under the upper lip. It is used either in its loose form (like chewing tobacco) or in pouches, which has become the more popular method. While snus does not fall within the definition of 'food stuffs', it is equated with food stuffs according to national legislation. Therefore, it is within the Swedish Food Agency's remit. Snus is illegal in the European Union but is legal in Sweden by an exemption.

In 2016 a product similar to snus (ie, pouches which contained nicotine but no tobacco) was launched on the Swedish market. Its launch followed a judgment by the Supreme Administrative Court earlier that year which had ruled that e-cigarettes should not be classified as medicinal products, contrary to the Swedish Medical Products Agency's opinion and general belief at the time (prior to the EU Tobacco Products Directive 2014/40/EU).

Initially, the nicotine pouches were deemed to fall within the Swedish Food Agency's remit, like snus. However, in February 2019 the Swedish Food Agency declared that nicotine pouches were neither a food stuff nor encompassed by the definition of snus. Therefore, they could not be equated with food stuffs. Thus, the Swedish Food Agency stated that it did not consider nicotine pouches to fall under its supervision.

The nicotine pouches, which became increasingly popular among Swedish consumers, ended up in a grey area. The Swedish Food Agency did not intend to supervise them but they also did not fall within the Public Health Agency's remit. While the Public Health Agency supervises tobacco products (eg, cigarettes, e-cigarettes and certain aspects of snus), the relevant legislation on tobacco products and e-cigarettes does not encompass nicotine pouches.

Another possibility is that the nicotine pouches could fall within the Swedish Medical Products Agency's remit. There are nearly identical products which are marketed in Sweden as medicinal products for smoking cessation (ie, which intend to help smokers quit smoking). However, as a consequence of the aforementioned Supreme Administrative Court judgment, these are defined as medicinal products not due to their properties but rather due to the properties that they are claimed to have. The nicotine pouches are instead sold as stimulants and are not claimed to have properties that intend to treat any conditions. Thus, they are not defined as medicinal products.

Another remote possibility is that the products fall under the Swedish Chemical Agency's supervision. However, it is unlikely that this body would consider itself suitable to supervise these products considering their use, at least in comparison with the other authorities mentioned above.

The vacuum in which nicotine pouches have ended up means that they are not encompassed by any legislation which would regulate their marketing or advertisement. Similar legislation regarding cigarettes, e-cigarettes

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and snus is rigorous and there are strict rules on, for example, to whom and how these products may be advertised and the warning labels that they must carry. However, the four largest snus manufacturers have self-regulated certain aspects of the marketing and labelling of nicotine pouches.

It is against this background that the government has ordered the Ministry of Health and Social Affairs to present, among other things, its analysis on how nicotine pouches should be regulated and proposals on any necessary amendments to the legislation. For completeness, the scope of the Ministry of Health and Social Affairs' assignment is to assess the need for regulation on tobacco-containing and tobacco-free nicotine pouches.

Likely conclusion

It is remarkable that nicotine pouches have not yet been subject to any regulations. The rules and regulations on snus and cigarettes are detailed and strict with respect to their marketing and warning labels. The government describes the fact that similar legislation is not yet in place for nicotine pouches as "deeply unsatisfactory". Thus, nicotine pouches are likely to be regulated, but it remains to be seen how.

A reasonable expectation is that they will be included in the legislation on tobacco. This legislation already encompasses e-cigarettes and vapes in certain aspects. It should be possible to include nicotine pouches therein as well without encountering significant systematic issues. This is perhaps also the most efficient way to align the rules regarding warning labels and marketing to those of snus and e-cigarettes.

Regarding the possibility that nicotine pouches will fall within the legislation on medicinal products, while certain pouches which contain nicotine are sold as medicinal products, it is unlikely that the nicotine pouches in question will be considered as such based on their contents (however, this may be compared with the Medicinal Products Agency's decisions on CBD-containing products (for further details please see "[Is Swedish market for CBD oils closed?](#)"). It is widely accepted that snus products are used as stimulants and not intended to treat any conditions. Therefore, unless nicotine pouches are presented as intending to help smokers quit smoking or snus users (also known as 'snusers') quit using snus, such products are unlikely to fall within this scope.

Whatever the result of the Ministry of Health and Social Affairs' assessment, the days of self-regulation are likely to end. While it may be unknown exactly how or when nicotine pouches will be regulated for some time, the 31 March 2021 analysis will at least provide an indication.

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