HEALTHCARE & LIFE SCIENCES - SWEDEN

E-cigarettes no longer considered medicinal products in Sweden

May 25 2016 | Contributed by Advokatfirman Lindahl

AUTHORS

Jonas Löfgren

Annie Kabala

The Supreme Administrative Court has ruled that e-cigarettes not marketed for smoking cessation purposes should not be classified as medicinal products. This is contrary to the Medical Product Agency's long-standing position and rulings of the first and second-instance courts. As a result, the EU Tobacco Product Directive (2014/40/EU) rules for e-cigarettes will apply to e-cigarettes in Sweden from May 20 2016, when the directive must be implemented in national legislation.

Facts

The Medical Product Agency had ordered a company to stop selling e-cigarettes with nicotine-containing liquids. The agency argued that the products had a high nicotine content, which is a pharmacologically active substance with an established medical use, primarily for smoking cessation.

The distributor argued that the e-cigarettes in question did not have a sufficiently strong pharmacological effect on the body's functions to be classified as a medicinal product. Even if the e-cigarettes did have such an effect, they had no health benefits. The distributor claimed that it sold the e-cigarettes purely as a recreational product, with no claims that they were beneficial to health.

Both the first and second-instance courts dismissed the distributor's arguments and held that e-cigarettes and nicotine-containing liquids should be classified as medicinal products. The appeal court stated that the manufacturers' and distributors' perceptions of the products' use could not be considered decisive. The products were held to have scientifically documented pharmacological characteristics insofar as the active substance nicotine can be used to treat tobacco addiction, which results in nicotine cravings and withdrawal symptoms. This qualified as a beneficial health effect. The fact that the e-cigarettes were not used exclusively as medicinal products did not change this assessment and they were thus classified as medicinal products. The appeal court held that the Tobacco Product Directive does not prevent a member state from classifying e-cigarettes as medicinal products.

Decision

The Supreme Administrative Court held that all characteristics of a product must be considered when deciding on that product's classification, including:

- the way it is used;
- how it is distributed;
- how well known it is among consumers; and
- the risks which may be involved with use.

It is not sufficient that a product has a pharmacological effect on the body's functions. Referring to EU case law, the court stated that in order to be classified as a medicinal product, the product, if used

as intended, must be capable of appreciably restoring, correcting or modifying physiological functions in human beings. The mere fact that the active substance affects the body's functions is insufficient for it to be defined as a medicinal product.

The court did not consider that the Medical Product Agency's scientific reports conclusively highlighted the effects that e-cigarettes had on smoking cessation and therefore did not demonstrate any e-cigarette health benefits (one of the prerequisites for medicinal product classification). Further, in its assessment of how e-cigarettes are distributed and used, the court referred to a report from the European Commission which showed that only 2% of Swedish respondents used e-cigarettes to stop smoking and that they did not consider the product to have any long-term effects on their smoking.

The court also noted that the e-cigarette distributor in this case had stated that the e-cigarettes were developed as a healthier, recreational alternative to normal tobacco cigarettes. They were designed to mimic traditional cigarettes and simulated cigarette smoke through their vapour. The addition of various aromas made product use pleasant. The products were not sold with any particular instructions on how the user should cut down on smoking or nicotine addiction.

The court therefore found that e-cigarettes were not medicinal products.

Comment

The Swedish market for e-cigarettes has until now been almost non-existent. However, this is likely to change following this decision. The judgment focused on the actual use of the products on the market and how they are marketed. Considering that no e-cigarettes are currently registered as medicinal products in Sweden, and that sales of non-registered e-cigarettes were virtually non-existent pending this decision, the Swedish respondents' answers in the commission's report to which the court referred should be reasonably affected. The court considered that because the way that these products are used and distributed will likely change following this decision, that classification of the product could also change.

The Supreme Administrative Court decision is something of a surprise in light of the lower-court decisions and agency case law. While the legislature in the ongoing implementation of the Tobacco Product Directive had mentioned that it would await the outcome of the judgment, it is likely that this particular outcome was not anticipated. This means that the directive's rules for e-cigarettes will have to be put quickly into place in Swedish national law.

The judgment may also open up the possibility of introducing other smokeless nicotine products that would have been previously classified as medicinal products. It is uncertain whether the fact that e-cigarettes imitate tobacco cigarettes in terms of shape and vapour was decisive for the decision, and whether such anti-smoking products as lozenges or sprays could be considered general products. These questions remain unanswered.

For further information on this topic please contact Jonas Löfgren or Annie Kabala at Advokatfirman Lindahl KB by telephone (+46 8 527 70 800) or email (jonas.lofgren@lindahl.se or annie.kabala@lindahl.se). The Advokatfirman Lindahl KB website can be accessed at www.lindahl.se.

The materials contained on this website are for general information purposes only and are subject to the disclaimer.