

Health Canada and Swedish Match meeting: Tobacco/nicotine – August 27, 2019

Subject:

Meeting to discuss its experience with the US FDA regulatory pathways and scientific data on snus [tobacco/nicotine]

Date:

August 27, 2019

Participants:

Health Canada (HC)

- James Van Loon
 - Director General, Tobacco Control Directorate (TCD) (Chair)
- Ed Morgan
 - Director General, Policy, Planning and International Affairs Directorate
- Mathew Cook
 - Acting Director, Tobacco Products Regulatory Office, TCD
- Dana Beaton
 - Director, Office of Policy and Strategic Planning, TCD
- Manager, Science Division, Office of Research and Surveillance, TCD

- Senior Policy Analyst, Office of Policy and Strategic Planning, TCD

Swedish Match (SM)

- Jim Solyst
 - Vice President, Federal Regulatory Affairs
- Tryggve Ljung
 - Vice President, Scientific Affairs

Introduction:

A meeting was held at the request of SM to provide a briefing on its experience with the US Food and Drug Administration (FDA) regulatory pathway process as well as scientific data on snus.

The Chair opened the meeting by doing round table introductions.

The Chair reminded participants that this meeting is subject to disclosure as per HC's [Openness and Transparency policies](#). In the interest of transparency, the department stated that it would be making a record of the meeting publicly available. A copy of the [handling of information and privacy notice](#) was mentioned and acknowledged.

HC also referred to Article 5.3 of the [World Health Organization Framework Convention on Tobacco Control](#), its international obligation to protect tobacco control policies from the vested interests of the tobacco industry.

Subjects:

Introduction to Swedish Match and snus

SM introduced its company by explaining its vision of a world without cigarettes. SM offers nicotine-containing products and indicates that they are “safer alternatives to cigarettes that can contribute significantly to improved public health”.

SM provided an overview of products available in Sweden, including snus and their new Zyn product. They discussed the “Swedish Experience” which involved a transition from male smokers switching to using snus as a ‘cessation device.’ This shift resulted in a lower prevalence of smoking in the country. SM indicated that Norway has observed a similar trend. They noted that this was one of the most important pieces of evidence to support their products.

SM described its internal quality standard called “GOTHIATEK”. This standard sets a maximum allowable limit of tobacco-specific nitrosamines (i.e. carcinogens found in tobacco products). SM noted that this standard has improved the quality of products which has resulted in a reduced risk to consumers.

Swedish Match experience with the US FDA regulatory pathways

SM provided an overview of the US FDA regulatory pathways for tobacco products, from an industry perspective. They noted that applicants must demonstrate that products are appropriate for public health and that a Modified Risk Tobacco Product (MRTP) designation is very difficult to achieve.

SM described their experience during the process, lessons learned and requirements for achieving an MRTP designation, such as

evidence requirements, post-market plans and a consumer perception study.

Path forward for Swedish Match: product science

SM provided an overview of their new Zyn product, which they describe as a nicotine-containing non-tobacco product. They presented constituent levels in Zyn as compared to snus and moist snuff as well as results from their pattern of use study. SM indicated that they will be required to do a “likelihood of use” study to better understand the potential impact of modified risk claims on non-tobacco users and youth.

Conclusion:

HC asked SM what their plans are for introducing their products in Canada, to which SM indicated that it is not a market they are looking to expand to at this time as they are currently unable to meet the demand in the US.

The meeting was then concluded.

Documents:

- Swedish Match’s presentation “A World Without Cigarettes”
- Background Document regarding the Swedish Match experience with the US FDA Regulatory Pathways