APPLICABILITY OF SWEDISH EPIDEMIOLOGICAL DATA TO THE UNITED STATES

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DISCLAIMER 1

The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy. The information is being provided to TPSAC to aid the committee in its evaluation of the issues and questions referred to the committee.
DISCLAIMER 2

This presentation contains statements of preliminary findings and interpretations of the data and information reviewed to date. It must be emphasized that this presentation does not represent final findings, recommendations, or conclusions, and that no final regulatory decision on the status of these applications has been made. Due to the large volume of information contained in the applications, it is not feasible to provide a comprehensive review for discussion at this meeting. Although the entire applications are referred to the Committee, this presentation may not include all issues relevant to the final regulatory recommendation and instead is intended to focus on issues identified by the Agency for discussion by the Committee.
OUTLINE

• General Overview of Swedish Match North America, Inc. (SMNA) Applications

• Considerations Related to the Applicability of Swedish Data to Tobacco Use Behaviors Among U.S. Consumers

• Summary
SMNA MRTP APPLICATIONS: TOBACCO USE BEHAVIOR IN SWEDEN AND OTHER SCANDINAVIAN COUNTRIES

National Surveys:
- Swedish Survey of Living Conditions (ULF)
- Swedish Annual Level-of-Living Survey
- Norwegian SIRUS-funded surveys

Cohort Studies:
- Vasterbotten Intervention Programme (VIP)
- Children’s Smoking and Environment in Stockholm County (BROMS) Cohort
- WHO Multinational Monitoring of Trends and Determinants of Cardiovascular Disease (MONICA) Project
- The Study of Twin Adults: Genes and Environment (STAGE)

Randomized Clinical Trials:
- Serbia 2008-2010 (Joksic et al. 2011)
- 5 U.S. trial sites 2009-2010 (Fagerstrom et al. 2012)
FDA REVIEW PROCESS

Section 6.2: “Effect on Tobacco Use Behavior among Current Users”
Section 6.3: “Effect on Tobacco Use Initiation among Non-Users”

Examine strength of the evidence base
• Study design
• Methodology
• Bias/threats to internal validity
• Generalizability of results
SALES OF SNUS AND CIGARETTES IN SWEDEN, 1916-2010

“The Swedish data establish that (i) there is conclusive evidence of switching from smoking to snus use at both the population and individual levels, (ii) switching from cigarettes to snus is more common than switching from snus to cigarettes, and (iii) snus has been used as a smoking reduction and cessation aid by individuals in Sweden.” (SMNA applications, Section 6.2.1 p. 588)
CONSIDERATIONS RELATED TO THE APPLICABILITY OF SWEDISH DATA TO TOBACCO USE IN THE U.S.
• Health risks associated with product use

• Behaviors resulting from the modified risk marketing, including, but not limited to, the extent to which:
  • Current tobacco users switch completely to the MRTP or become dual users,
  • Former tobacco users will take up the MRTP, and
  • Never tobacco users initiate with the MRTP.
“...the introduction of the Swedish snus, the proposed MRTP, can result in a net population-level benefit, particularly if it is adopted by a sufficient number of smokers. If introduction of an MRTP results in more tobacco users compared to the base case, however, a survival deficit may result. The size of the effect, positive or negative, depends on the particular exposure patterns evaluated” (SMNA applications, Section 6.5.3 p. 721)
FACTORS CONTRIBUTING TO TOBACCO USE*

- Biological/psychological factors
- Knowledge, attitudes and beliefs
- Consumer preference (i.e. taste, mouth feel)

- Sociocultural context
  - Traditional products
- Tobacco control policy
  - Health warning labels
  - Tobacco taxes
  - Marketing restrictions
  - Smoke-free rules
- Diversification of tobacco market

- Marketing campaigns
- Point-of-sale advertising

- Product design
- Product packaging

Modified risk messaging on tobacco product packaging is currently prohibited in Sweden and has not historically been displayed on snus packaging.

**Current EU requirements:** Use of any packaging language that promotes or encourages consumption of the product is prohibited, including language suggesting that the product is less harmful than other tobacco products, or has healing, natural, organic or other implicit benefits.¹

**History of Warning Labels in the EU¹⁻³:**

- 1992 amendment: oral tobacco product warning “causes cancer” in addition to “tobacco seriously damages health”
- 2001 legislation: “this tobacco product can damage your health and is addictive”
- 2014 legislation: “this tobacco product damages your health and is addictive”

1. EU Tobacco Products Directive Article 13, 2014
“Swedish Match believes that the most fundamental difference between the US and Scandinavian experiences stems from snus’s status as a traditional Swedish and Norwegian product. This product history greatly contributed to the grassroots movement.” (SMNA applications, Section 2.5.2.3.3.5, p.109)
“The movement began as, and remains to this day, a grassroots phenomenon. In other words, the shift from cigarettes to snus throughout Scandinavia was not the product of a nationally coordinated initiative originating from the centers of political activity, but rather was a trend which started with common citizens at a local level. Indeed, both the Swedish and Norwegian experiences occurred in the complete absence of a national coordinated advertising campaign, and with very little support from the countries’ public health and medical communities.”

(SMNA applications, Section 2.5.2.3.3, p.106)
“If FDA were to issue MRTP orders for the Snus Products, public awareness and knowledge of this particular type of cigarette alternative is likely to increase substantially, possibly leading to the type of grassroots movement that has occurred in Sweden and Norway.” (SMNA applications, Section 2.5.2.3.3.5, p.110)

“Word-of-mouth sales have already contributed to the steady increase in snus sales in the United States, which are expected to continue to rise among current smokers if the Snus Products are permitted to be marketed as MRTPs.” (SMNA applications, 2.5.2.3.3.5, p.111)
CURRENT SNUS USE IN THE U.S.
Convenience Store Sales (Nielsen)

- From 2010-2014, sales of units of snus represented 3-5% of U.S. smokeless sales\(^1,2\)
- From 2010-2014, sales of units of General Snus grew from 0% to 6% of the U.S. snus sales\(^2\)

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<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
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<td>CAMEL SNUS</td>
<td>71.8%</td>
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<td>81.2%</td>
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<td>1.3%</td>
<td>4.5%</td>
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2. Internal FDA/CTP analyses, utilizing Nielsen *Convenience Track* sales data collected from a nationally representative sample of US convenience stores.
LOW OVERALL PREVALENCE OF SNUS USE; HIGH LEVELS OF DUAL USE IN THE U.S.

Snus Use: U.S. Adults in 2012-2013 (National Adult Tobacco Survey (NATS))\(^1\)
- 5.5% reported ever use; 0.9% reported current use (0.2% women; 1.5% men)
- 68.9% of current snus users also reported current cigarette smoking
- Males and young adults- highest prevalence of ever and current snus use

Snus Use: U.S. Youth in 2013 (National Youth Tobacco Survey (NYTS))\(^2\)
- 4.1% reported ever use; 1.3% reported past-month use (0.7% females; 1.8% males)
- 69.3% of current snus users also reported past-month cigarette smoking

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SUMMARY
SUMMARY: CONSIDERATIONS REGARDING THE APPLICABILITY OF DATA ACROSS COUNTRIES

- Differences in the sociocultural environment and consumer preferences, among other factors, may lead to differences in product uptake between countries.

- The net population health impact of the modified risk marketing order depends on the likelihood that U.S. tobacco users and non-users will initiate use of the MRTPs.

- Current U.S. warning labels, which SMNA proposes to change, are similar to those displayed in Sweden.
SUMMARY: CONSIDERATIONS REGARDING THE APPLICABILITY OF DATA ACROSS COUNTRIES

- Modified risk messaging has not appeared on snus packaging in Sweden.
- Swedish epidemiological data may be limited in informing the potential impact of risk modification marketing on U.S. tobacco users and non-users.
THANK YOU

QUESTIONS?