POSTMARKET SURVEILLANCE AND STUDIES

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OUTLINE

• Introduction
• Overview of Swedish Match North America, Inc. (SMNA) plan for postmarket surveillance and studies
• Considerations for postmarket surveillance and studies
INTRODUCTION
“The Secretary shall require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the applicant conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product.”

- Section 911(i)(1), **Bolded and italicized for emphasis**
POSTMARKET SURVEILLANCE AND STUDIES UNDER SECTION 911 OF THE FD&C ACT

• “Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance.” – Section 911(i)(2)

• “The results of postmarket surveillance and studies shall be submitted to the Secretary on an annual basis.” – Section 911(i)(1)

• FDA has recommended that applicants submit plans for postmarket surveillance and studies with their application.
OVERVIEW OF SMNA PLAN PROVIDED IN THE APPLICATIONS
SMNA DRAFT PLAN FOR POSTMARKET SURVEILLANCE AND STUDIES

• SMNA sets out their postmarket surveillance and studies plan in Chapter 9 of their Applications titled “Development of Swedish Match Postmarket Program”

• Applicant’s description of objectives:
  • “to evaluate the benefit to the population as a whole of the labeling changes proposed in this MRTP Application”
  • “to monitor and collect information regarding unanticipated and undesired events related to the Snus Products…” and “....to contribute to the establishment of an adverse event reporting mechanism.” (SMNA applications, p. 751)
• Data sources Applicant proposes to use:
  • Postmarket surveys to collect information on consumer perceptions and behavior
  • Reporting of unanticipated adverse events

• The Applicant notes that the postmarket surveys will build on information gained from their premarket consumer perception survey and will be used to generate data to inform their Dynamic Population Model.
Chapter 9 of the SMNA Modified Risk Tobacco Product Applications:
- “Development of Swedish Match Postmarket Program”
- “Draft-Preliminary Outline of Postmarket Survey Protocol”

Formal study protocols are not required until 30 days after receiving notice from FDA, thus the scope of the review to date has focused on general considerations in the development of postmarket surveillance and studies.
CONSIDERATIONS IN THE DEVELOPMENT OF POSTMARKET SURVEILLANCE AND STUDIES
SOME FACTORS TO CONSIDER FOR ASSESSING IMPACT

• 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.

• Consumer perceptions about the MRTP, which may ultimately influence subsequent behavior
FACTORS INFLUENCING 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
  - Marketing campaigns
  - Point-of-sale advertising

- Diversification of Tobacco Market

- Product design
- Product packaging

SURVEILLANCE AT THE BRAND AND PRODUCT LINE LEVEL

• Most national tobacco surveys monitor product categories, rather than specific product brands or product lines.
  • An MRTP order is issued for a specific product or products.

• The Applicant proposes to use postmarket surveys to collect information on consumer perceptions and behavior.
  • Surveys that are national in scope may result in limited numbers of users of products that are the subject of these applications.
  • Even smaller samples of users would be available to examine potentially susceptible populations.
CHALLENGES IN ASSESSING SNUS USE BY BRAND AND PRODUCT LINE IN NATIONAL SURVEYS

• National Adult Tobacco Survey, 2012-13
  • Overall sample size = 60,192
  • 327 adults report current snus use (51 daily users)
  • Corresponds to a weighted prevalence of 0.9%

• National Youth Tobacco Survey, 2013
  • Overall sample size = 18,406
  • 206 middle and high school students report past 30 day use of snus
  • Corresponds to a weighted prevalence of 1.3%

• In 2014, General Snus represented 6% of U.S. convenience store snus sales (Nielsen)
USE OF REAL-WORLD BEHAVIOR DATA TO INFORM POPULATION MODELING

• The Applicant intends to use postmarket surveys to inform their Dynamic Population Model.

• The Applicant’s model relies on estimates of product use transitions, such as rates of initiation, cessation, and switching.

• Cross-sectional surveys may be limited in the ability to measure these types of transitions.

• More information is needed on how survey measures would be used to generate age-specific initiation, cessation, and switching rates, and how they would be derived and implemented in the model.
SUMMARY

• Upon issuance of a risk modification order, an Applicant would be required to conduct postmarket surveillance and studies to assess its impact on consumer perception, behavior and health.

• Unique challenges to the conduct of postmarket surveillance and studies include the need to collect information at the product brand and product line level.

• Given these challenges, a postmarket surveillance and studies program would be strengthened by incorporating multiple lines of evidence to ensure that the order continues to benefit the population as a whole.
THANK YOU

QUESTIONS?