ACHI
INSPIRING HEALTHY ACTS

MODIFIED-RISK TOBACCO PRODUCTS

MARCH 2019

Arkansas House Bill 1565, which would provide funding for a National Cancer Institute-designated cancer center in Arkansas, contains provisions regarding modified-risk tobacco products. If enacted, the bill would trigger an automatic 25 to 50 percent excise tax reduction for a product that is designated as a modified-risk tobacco product by the U.S. Department of Health and Human Services. The current excise tax on cigarettes in Arkansas is $1.15 per pack, which generated revenue of nearly $165 million in state fiscal year 2018.

Background

In 2009, Congress granted authority to the federal Food and Drug Administration (FDA) to designate certain products as modified-risk tobacco products (MRTPs). This legislation coincided with the introduction of new e-cigarettes and vaping products. However, it was not until 2016 that the FDA exercised its authority to regulate these new products. Under the federal Tobacco Control Act, a product seeking to make modified-risk claims to the public can only be introduced into the market after application for and receipt of a risk modification order by the FDA.

What is a modified-risk tobacco product?

According to the FDA, “modified risk tobacco products (MRTPs) are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.”[1]

1401 W. Capitol Avenue
Suite 300, Victory Building
Little Rock. Arkansas

501-526-2244
achi@achi.net
achi.net

A tobacco product may receive a *risk* modification order for claims of reduced *risk* if the FDA determines that the product will:

- Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
- Benefit the health of the population, including users and non-users of tobacco products.[2]

Alternatively, a tobacco product may receive an *exposure* modification order for claims of reduced exposure (e.g., claims that a product has "no tar") if the FDA determines that:

- An order would be appropriate to promote the public health;
- Scientific evidence is not available and cannot be made available without conducting long-term studies required to receive a risk modification order; and
- Existing evidence that is available in the absence of long-term studies shows that a measurable and substantial reduction in morbidity and mortality among tobacco users is reasonably likely in future studies.[3]

The FDA has not yet granted modified-risk status to any tobacco products via the application process. There are currently four MRTP applications under scientific review.

Conclusion

States relying on the federal process for determining modified risk should carefully examine the scientific review conducted on each product to assess for any localized impacts. Additionally, states seeking to reduce taxes on MRTPs should compare the level of the tax benefit to the level of potential risk reduction for a tobacco user and the expected use of the MRTP in the population. Tax reductions that are automatically triggered without an assessment of the evidence could result in the inability of the state to offset the level of risk that nonetheless exists with all tobacco products.

[1] https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm410712.htm
[2] 21 U.S.C. § 387k(g)(1)
[3] 21 U.S.C. § 387k(g)(2)