Japan Society for Tobacco Control

日本禁煙学会

http://www.jstc.or.jp/ E-mail desk@nosmoke55.jp
〒162-0063 東京都新宿区市谷薬王寺町 30-5-201
Tel 03-5360-8233 FAX 03-5360-6736

Statement from the Japan Society for Tobacco Control

US FDA does not recognize IQOS as a risk reducing tobacco product due to the lack of long term scientific data

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Manabu Sakuta, Chairperson, Japan Society for Tobacco Control, General incorporated

In April 2019, the FDA (US Food and Drug Administration) authorized IQOS (I Quit Ordinary Smoking) for commercial sale in the United States.

Philip Morris (PM) has requested that IQOS be recognized as a modified risk tobacco product (MRTP) for several years. As part of its review, the FDA has now classified it as a modified exposure tobacco product (METP), and it was approved for sale on 7 July 2020 as a tobacco product to potentially reduce exposure to toxins. The FDA determined that the evidence from IQOS did not support issuing a risk modification classification due to many types of long-term risks, but that it did support issuing an exposure modification classification due to the fact that IQOS aerosols were shown to contain significantly lower levels of toxins and potential carcinogens relative to combusted tobacco cigarette smoke.

Nevertheless, the FDA did not recognize IQOS as a "risk reducing tobacco product" because scientific data has not verified that long-term risks were reduced, including the risk of addiction, despite any claims from PM publicity and advertisements.

Whether or not health and other risks are generally reduced over the long term is awaiting further investigation. In addition, the FDA and others will continue to examine the number of people who use both combustible tobacco and IQOS, as well as examine the use of IQOS by minors.

Many experts, including those at the World Health Organization (WHO), have questioned whether the reduction of exposure to toxins generally occurs. Certainly, some toxins decrease, and the toxicological report found a reduction of 15 toxins or

potential toxins, but exposure to other toxins may increase. Because of the continued ambiguity about many kinds of potential harms, the FDA adopted the label 'exposure modification', but it did not use the term 'exposure reduction' for the heated tobacco device.

According to a WHO statement1) regarding the US FDA statement, "just because the FDA consented to the sale of the product does not mean that the product is safe or 'was granted an FDA seal of approval'. And just because an FDA order recognizes that amount of harmful substances is relatively lower, it is incorrect to assume that the product from the company is safe for consumers. Likewise, it is not permissible to state that the FDA has recognized that the use of this product has no health hazards."

1) WHO statement regarding heated tobacco and the FDA's decision on IQOS
http://www.jstc.or.jp/uploads/uploads/files/information/WHO20_7_22.pdf