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ecigintelligence.com/fda-gives-the-green-light-for-iqos-roll-out-onto-the-us-market

Daniel Mollenkamp

The US Food and Drug Administration (FDA) today announced it has given approval for Philip Morris International (PMI)'s IQOS in the US, along with its associated consumables.

In total, the agency has given the green light to IQOS, Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks, and Marlboro Fresh Menthol Heatsticks for entrance to the US market, meaning these products can now be sold in the US.

They are the first heated tobacco products to successfully navigate the premarket tobacco product application (PMTA) process, which members of the industry have often decried as overly burdensome. The application was submitted on 5th December 2016.

To meet PMTA standards, companies must undergo a relatively thorough investigation of their product's components, ingredients, manufacturing processes, packaging, labelling and health risks to prove to the FDA that allowing the product on the US market would be "appropriate for public health".

The reviews of IQOS and related consumables showed that "the products produce fewer or lower levels of some toxins than combustible cigarettes," the FDA said.

Specifically, the statement issued by the FDA said:

> [The FDA] found that the aerosol produced by the IQOS Tobacco Heating System contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke.
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> "For example, the carbon monoxide exposure from IQOS aerosol is comparable to environmental exposure, and levels of acrolein and formaldehyde are 89% to 95% and 66% to 91% lower than from combustible cigarettes, respectively."

The agency suggested that IQOS also makes dual use less likely as it delivers nicotine levels close to that of combustibles.

The agency has still not ruled on the modified risk tobacco product (MRTP) applications, which would allow the Richmond, Virginia-based Altria, the company which holds the US marketing agreement for IQOS, to market the products as “reduced risk” or “reduced exposure” and so give them a serious marketing edge.

Still, Altria and PMI have been preparing for some time to introduce IQOS, in particular, to the US market. The have commented publicly at least once that they were expecting approval some time this year.

Georgia on their minds

IQOS will make its first US appearance in Atlanta. Altria chairman and CEo Howard Willard said: “With FDA authorisation, PM USA will introduce IQOS in the US for adult smokers in Atlanta, Georgia to learn as much as possible, as quickly as possible, and intends to make the most of the company’s first-mover advantage in heated tobacco.”

Distribution will be from an IQOS store in Lenox Square in central Atlanata and also in mobile retail units. Altria announced it would sell its heated-tobacco consumables through about 500 retailers, including Circle K, Murphy USA, QuikTrip, RaceTrac and Speedway.

The company also said it would test a range of marketing, sales and consumer engagement approaches to the product.

As hammered home by last year’s financial results, and reported by ECigIntelligence, PMI has turned to smoke-free products to secure its future. So far, the heated tobacco category has done quite well for PMI, internationally.

When presenting the company’s 2018 results, CEO André Calantzopoulos said it had almost doubled heated tobacco in-market sales volumes, driven by growth in all the IQOS markets and the company’s ability to “successfully manage our transition to reduced-risk products”.

The rollout of IQOS onto the US market will have far-reaching implications for heated tobacco and the whole reduced-risk category and should prove good for the companies involved with its manufacture and marketing.

Marketing restrictions

However, in its announcement, the FDA emphasised that it had placed “stringent marketing restrictions” on the products to avoid youth exposure.

In addition to the standard tobacco product prohibitions on TV and radio advertising, the FDA has added restrictions to ensure advertising of IQOS is targeted towards adults, with special emphasis on social media and online marketing.

The packaging, labels, and advertising of these products will have to contain warnings about the addictiveness of nicotine. The FDA will also continue to collect information on the labelling, advertising, marketing plans (including information about specific adult target audiences), plans to restrict youth access and limit youth exposure to the products and their promotion and marketing.

Obviously, the restrictions are meant to curb the possibility of youth exposure. But while the current data on the youth question is limited, the available data does suggest, according to the FDA, that “few non-tobacco users would be likely to choose to start using IQOS, including youth”.

Mitch Zeller, director of the Center for Tobacco Products (CTP), commented that the agency will keep a leery eye on these products as they enter the market and that it will not be afraid to make sure their sale “remains appropriate” and that the marketing restrictions are complied with.

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