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ecigintelligence.com/iqos-reaction-it-works-for-pmi-but-what-about-the-little-guy

Daniel Mollenkamp

There have been mixed reactions from within the industry to the announcement by the US Food and Drug Administration (FDA) that it would allow Philip Morris International (PMI)'s heated-tobacco device IQOS and its associated consumables onto the US market.

Members of the US vapour industry have long complained that the premarket approval process was excessively burdensome, pointing out that only one product, Swedish snus, had successfully navigated it. Now, the FDA has a more recent example of a product that has made it through the premarket tobacco product application (PMTA) process. From the FDA's perspective, this is an example of the process actually working.

However, Gregory Conley, president of the American Vaping Association (AVA), said approval of IQOS was not a sign that the tobacco regulatory system in the US works.

"Unless the FDA's regulatory system is reformed, no one but the largest of tobacco companies will ever get a vaping product through the FDA's premarket approval process," he said.

Azim Chowdhury, a lawyer for Washington law firm Keller and Heckman, told ECigIntelligence that the PMTA approval of IQOS could mean the industry looks very different once the submission dates for e-cigarette PMTA applications kick in, when very few products will have made it through the process.

One generation at a time

Indeed, one of the key takeaways from this announcement, Chowdhury said, is that companies really need to move on the premarket processes.

Moreover, he pointed out, only one generation of IQOS has been approved by the FDA. For future changes and generations, since substantial equivalence (SE) – another means to market – only applies to grandfathered products and not ones approved by the PMTA process, PMI will

need to file another PMTA.

They will not have to reinvent the wheel entirely, but in international markets the company has already released newer generations, like IQOS 3.

Wells Fargo securities analyst Bonnie Herzog said the FDA's decision was a "positive catalyst" for PMI and Altria Group, and that she expects "both stocks to trade up nicely on this news". Altria maintains an agreement for "commercialisation rights" to IQOS in the US.

Herzog said the PMTA provides an "immense competitive advantage" for IQOS and that it may also make physicians more comfortable in recommending the product to patients as a smoking cessation tool.

Historic milestone

At PMI's annual stakeholders meeting for 2019, held yesterday in New York, executives said the FDA decision was a "historic milestone and an important step forward".

They said they were looking forward to working with the agency to implement the order and reaching "the right audience" – current adult smokers.

PMI closed 2018 with "robust" performance thanks to IQOS, which has accelerated business growth and reached 9.6m users by the year's end.

The Swiss-based company said it expected an "even better" performance for 2019 and that the number of IQOS users surpassed 10m during the first quarter of the year.

IQOS is now available in 49 markets worldwide. Its best performing market is Japan, where it had 16.9% market share for the first quarter of 2019, followed by Lithuania (11.9%), Greece (8.7%) and South Korea (7.3%). Market share in the EU was 2.1%, up 1.3 percentage points over the same period of 2018.

In the question and comment section of the event a few tobacco control groups accused PMI of "violating the laws" of various countries and at international level. Mostly, questioners wanted to know how PMI could claim this was the year of "unsmoke" even while it profits from the combustibles trade.

"Very simply, you're distorting the facts," one executive replied to a tobacco control group activist. PMI denied all accusations of violating the law.

What This Means: So far, the heated tobacco category has done quite well internationally for PMI, which has turned to smoke-free products to secure its future, as shown by last year's financial results. It remains an open question how IQOS will fare in the US market once it begins

to be rolled out there. While it has had a great start in Asia – especially in Japan and South Korea – and to some degree in Europe, that may not be much guide to its coming reception in the US.

Importantly, the FDA has yet to rule on the modified risk tobacco product (MRTP) applications for IQOS and its associated consumables, which would allow them to be marketed as "reduced risk" or "reduced exposure" to American consumers.

Altria and PMI may be able to profit from the first mover advantage in the US market, but the PMTA process may not hold such promise for medium or small players in the vape industry. As Azim Chowdhury says, the industry may look "completely different" in a couple of years.

– Daniel Mollenkamp *ECigIntelligence staff*