

How Might Lessons Learned from the U.S. Inform Regulatory Development in Other Countries?

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India status – Socio-political landscape

- Virtually unknown to the Indian subcontinent until the 1500s, India is today the second largest producer of tobacco with an estimated annual production of 800 million kilograms. About **50 million households** depend on tobacco industry for livelihood.
- According Global Adult Tobacco Survey, a staggering **267 million** Indians continue to smoke cigarettes and use smokeless variants such as gutka. Some **900,000 people die** every year due to this addiction, ranking India among the top four countries in the world for smoking-related deaths. The World Health Organization had last year estimated the economic burden of tobacco-related diseases in India at **USD 16 Billion** (Rs 1,04,500 crore) annually.



Global regulatory impact

The new FDA policy of **shifting the focus from nicotine to the delivery systems**, which goes to the heart of the problem, can have far-reaching impact on public health in a country like India which has a huge tobacco burden and where access to public healthcare is minimal at best, making the role of preventive measures even more critical.

The effectively bans having an adverse effect on countries like India, where minimal or **no studies** have been conducted, short term or long term.

India will do well to learn from this approach since its stakes are much higher, and not insist on banning ENDS altogether, thereby denying its **120 million smokers** access to technology that can be the difference between life and death for them.



India - Strategies

Policy needs scientific evidence	<ul style="list-style-type: none">• Share more studies with Indian regulators• Independent studies in India with focus on ENDS• Evidence based switch to less risky alternatives
Products need regulation and manufacturing practices	<ul style="list-style-type: none">• Drives manufacturers to invest and innovate• Safety and standards to drive mature players v/s home grown industry.• Vapable nicotine is not covered under any existing law
Information, Education and Knowledge	<ul style="list-style-type: none">• Communication process by both manufacturers and government or private bodies• Consumer forums and communities for education on safety and standards