Inside the U.S. Regulatory Maze: Insights from the EVO NXT GINN Panel

At EVO NXT 2025 in Milan, a standout session hosted by GINN brought together leading experts to decode one of the most complex challenges in the nicotine pouch industry: navigating the U.S. regulatory landscape. The panel, moderated by Dr. Sydney Hiller of Sanova, featured Rachel Schmidt (ALINC Consulting), Dr. Jessica Zdinak (AraC Science), and Chris Allen (Broughton), each providing unique insights into the Premarket Tobacco Product Application (PMTA) process and broader U.S. policy shifts.

Setting the Stage: The U.S. Market and Its Challenges

Dr. Sydney Hiller opened the discussion with an overview of Sanova's work supporting international regulatory science, including full PMTA submission development. She outlined the lifecycle of a regulated nicotine product—from design and study execution to post-market surveillance. With regulatory changes accelerating in the U.S., understanding this lifecycle is more critical than ever.

Inside the Tobacco Control Act: Rachel Schmidt's Regulatory Deep Dive

Rachel Schmidt, a former Assistant Director at the FDA's Center for Tobacco Products, provided a grounded perspective on U.S. law. Emphasizing the difference between

regulation and law, she clarified that the Tobacco Control Act (TCA), enacted in 2009, remains the governing statute and cannot be revoked without congressional action.

Schmidt warned that recent changes within the FDA—such as leadership restructuring and the dismantling of entire offices—have created uncertainty. She highlighted key legal facts: applications must be reviewed within 180 days, only four reasons for denial exist, and manufacturing or labeling issues are as disqualifying as health concerns. Most importantly, she urged applicants not to resubmit denied applications without professional guidance. “Get help,” she advised. “Don’t hit repeat.”

Science-Driven PMTAs: Chris Allen on Strategy, Data, and Quality

Chris Allen, CEO of Broughton, emphasized that the PMTA process is not a checklist but a narrative. “You’re telling the story of your product’s public health benefit,” he explained. Allen highlighted the interdependence of PMTA modules—particularly Modules 3 (product composition) and 4 (manufacturing)—and how consistency, shelf stability, and toxicological impact all play into the FDA’s determination.

He also debunked common myths, such as the belief that selling can begin after submission. “There are only three legal pathways to market,” Allen said. He pointed out that thoughtful data-driven strategies—such as using scientific rationale to reduce batch sizes in studies—can save millions and accelerate timelines. His key message: a well-funded, well-structured PMTA rooted in science and storytelling is essential.

Consumer-Centric Science: Dr. Jessica Zdinak on Behavior and Perception

Dr. Jessica Zdinak shifted focus to human factors, emphasizing that the success of a nicotine pouch is not just about reduced risk—it’s about adoption. Through randomized controlled trials, perception studies, and real-world use monitoring, Zdinak’s team at AraC ensures that products are not only safe but appealing and usable for U.S. consumers.

Her takeaway: “You must demonstrate your product can actually transition smokers off combustibles—and that it won’t attract unintended users.” She underscored the importance of using U.S.-based data for Module 6 studies and highlighted randomized controlled trials as the gold standard for behavioral science validation.

From Risk to Responsibility: Final Lessons for Market Entry

All three panelists agreed on one core principle: success in the U.S. market requires more than regulatory compliance—it demands strategic foresight, consumer understanding, and scientific integrity.

Schmidt reiterated the importance of reading FDA decisions and aligning applications with legal criteria. Allen emphasized preemptive planning and high-quality data as the best ways to avoid costly delays. Zdinak reminded attendees that labeling, packaging, and user perception can make or break a product's trajectory in a heavily scrutinized environment.

As U.S. policies continue to evolve, this session served as a vital roadmap for manufacturers, brands, and regulatory professionals aiming to bring novel nicotine products to market.

🧠 **Watch the full panel interview here:** https://youtu.be/52y7_o-Pz_Q

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