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Breakout session summary
Session 16 -Science for regulation

A sound regulatory policy requires a foundation of sound science. Its purpose is to enable open and effective communication among stakeholders. It also allows for dissemination of factual information regarding differences among products along the risk continuum. Regulation based on science enhances available information and encourages the development of products with risks lower than those of existing cigarettes.

For the time being, however, there are no uniform scientific standards to regulate tobacco products. Issues that still need to be solved include testing and reporting: What is to be measured? How and how often? Which reference products can be used? What should be done with the data? And how should new products, such as e-cigarettes, be treated?

Premarket stewardship is another challenge, with products requiring premarket clearance, as stipulated, for example, by the U.S. Food and Drug Administration's (FDA) substantial equivalence rule. Pre- and post-market evaluation of population risks, product standards, engagement, and cooperation among scientists and among regulators—but also between scientists and regulators—are further matters that need to be looked into. In this context, the continued pursuit of tobacco harm reduction (THR), in the shape of heat-not-burn products, smokeless tobacco, e-cigarettes and nicotine-replacement therapy (NRT), plays an important role.

Much of current tobacco regulatory policy, however, appears to rely more on theory than scientific evidence, the panel concurred. Government health agencies and many tobacco control organizations have not uniformly endorsed the science of THR as a viable addition to current policies, thus leaving the status quo in place. According to the panel, future efforts could include the establishment of robust scientific evidence before regulation, as well as a regulatory structure and guidance for modified-risk tobacco products (MRTPs). In addition, a comprehensive nicotine policy should be carved out, and e-cigarettes should be positioned as NRTs.

The continuum of risk has become an important factor in discussions about regulation. To develop a common standard, it is essential to scientifically assess the dependence potential of individual tobacco products. While tobacco is exempt from drug controls, the same methods can be used to guide development and performance standards. The methods assess, for example, the effects on brain receptors and transmitters involved in addiction and a product's physical dependence and withdrawal potential. Dependence potential is a continuum, influenced by product designs that determine mode and ease of use, dosing, and speed of delivery. For tobacco products, a panelist suggested, comparisons to evaluate their place on the continuum can be evaluated using the methods described in the FDA's 2015 guidance for determining the abuse-deterrent level of opioids. The continuum of addiction risk of tobacco products would range from NRTs (low risk), through Swedish snus and oral

smokeless to pipes and cigars to cigarettes (highest risk). In order to work and maintain beneficial use, replacement therapies must sustain physical dependence, address needs and provide pleasure, ideally at lower levels than the substance of concern. Hence with regard to vapor devices and modified-risk products, the question is how appealing and addictive they should be; the challenge for these products will be to balance nicotine delivery, product appeal and abuse potential.

A great part of research in the field of tobacco comes from Coresta, which for almost 60 years has been the industry's main institution to deal with tobacco science. The organization currently has 150 members in 40 countries. There are two study groups, Agro-Phyto and Smoke-Techno, which are each subdivided into two further groups. For the Agro-Phyto part, these are Agronomy & Leaf Integrity and Phytopathology & Genetics.

The achievements of these subgroups include, for instance, the industry-wide promotion, guidance and adoption of good agricultural practices and the reduction in use of crop protection agents. In the Smoke-Techno group, the two subgroups Smoke Science and Product Technology deal with technical specifications and analytical methods as well as in vitro toxicology, smoke analysis and consumer behavior; to date, they have developed 81 recommended methods, of which 37 have been adopted by ISO.

They have also released guides and reports on chemical and physical tobacco, product, and smoke analysis and carried out collaborative studies and proficiency tests for labs' accreditation. Furthermore, they have developed reference materials for smoking machine setup and smokeless tobacco product analysis.

Studies set up by other bodies outside the tobacco industry, panelists consented, are often biased, not realistic and lead to falsified results. Data are deliberately mixed so that only unfavorable results are obtained, often by questionable experiment settings. But the results of these debatable studies are most often quoted by the media—which reveals a fundamental problem: The tobacco industry, with its legacy issues, has difficulties communicating science. Moreover, it has only just realized how important scientific journals and the public opinion are. In its communication efforts, it lags behind health advocates, whose campaigns, by the way, always follow the same pattern, as one panelist pointed out: Create the problem; make it a "health" issue; provide "evidence"; focus on children; blame the industry; exclude the industry.

It's a pattern that seldom fails to impress the public because it doesn't consider tobacco companies as reputable organizations. Science, however, is made credible and also newsworthy when research is done by a respected organization and the results are published in a peer-reviewed journal. Studies need to be timely, relevant and meaningful.

For the time being, scientific studies connected to the tobacco industry, particularly with regard to their funding, are difficult to get published. To solve the tobacco industry's legacy issues in this respect, panelists called for a change of dynamics in the science for regulation. As a potential model they named the communication strategies of the pharmaceutical industry, which takes people with it during the whole development process of a new drug. With the advent of new products such as e-cigarettes

and modified-risk products, the tobacco industry now has a story to tell, as opposed to the past when it relied on only one product. Panelists concluded that, in the future, the tobacco industry needs to be more proactive with regard to the communication of their scientific achievements.