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Session 9: FDA Modified Risk Tobacco Product process

During the regulation stream panel session on the U.S. Food and Drug Administration (FDA) at the GTNF in Bologna in September, somebody said that the agency's requirements for submitting an application for a Modified Risk Tobacco Product (MRTP) order amounted to an absurd way of trying to communicate reduced-risk concepts to tobacco users. Later in the session, another person admitted that the procedure might be absurd but said that at least it was something that could be followed by manufacturers wishing to have products recognized as offering a reduced risk. Both of these statements seemed rather dispiriting for anyone keen on advancing the cause of tobacco harm reduction.

The session had been given an account of the procedure that Swedish Match (SM) had had to undertake to lodge an MRTP application with the FDA in respect of one brand of snus, and part of that procedure, the dialogue for which started in January 2011, had involved the company in submitting about 130,000 pages of supporting documents. If granted in full, the MRTP order would allow certain changes to be made in respect of that brand to the health warnings applied generally to oral tobacco products in the U.S. But it was still not known how the significance of those changes, should they be allowed, could be communicated to tobacco users.

One way in which the MRTP process was seen as being absurd was that it left to tobacco manufacturers the decision about whether information about reduced-risk products was communicated to consumers, whereas the duty for communicating meaningful information that came close to an accurate evaluation of the relative risks should lie with the regulators. Manufacturers, it was said, would undertake such a procedure only if they judged it to be in their commercial interests—if they believed that the benefits to them outweighed the cost of going through the MRTP process.

Another problem with the MRTP was that the evidence hurdle was too high. SM, which so far is the only company to have completed an MRTP application, was asking only that it should be allowed to say that whereas all tobacco products created a risk, consumption of its General snus brand created a lower risk than did smoking. The point was made that it should not require 130,000 pages of documents for that statement to be applied. It was incontrovertible that that statement was true in respect of all smokeless tobacco products on the U.S. market. The object of the exercise should be to give people reliable information on which to make informed choices, not to try to influence behavior in a way that the state found desirable.

In fact, the question was well-asked: What evidence was there to support the existing health warning on smokeless tobacco products that said consumption of this product was not a safer alternative to smoking? To pre-empt one possible reply: It was said that the precautionary principle was a tool of charlatans. And switching the focus away from the U.S. briefly, it was pointed out as an example that the people in the EU who had applied the precautionary principle in respect of snus had never accepted responsibility for having prevented something from going right.

There was, however, tacit support for the FDA, which, in four years, was said to have recruited more than 500 people to the Center for Tobacco Products, a monumental task for a new agency operating under new rules. The FDA was said to have the authority, capacity and capability to carry out its appointed tasks and had committed to making decisions on the basis of solid science.

One person made the point that harm reduction had two main elements, the first to do with the risk profile of the product and the second to do with the product's acceptability. There was no harm reduction if a product had zero risk but zero uptake by tobacco users.

But a third element is surely the uptake of any low-risk product by previous tobacco nonusers, and, in part, this is why an MRTP product has to be shown to be less risky to the individual consumer and to offer a health benefit for the overall population, though one view had it that demonstrating the latter was almost impossible.

One interesting question that hung in the air concerned what will be the repercussions beyond the U.S. of the decision made by the FDA on the SM application, especially in the lead-up to the seventh Conference of the Parties to the World Health Organization's Framework Convention on Tobacco Control.