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Session 4: FDA and TPD—Challenges for manufacturing

The current main challenges for tobacco product manufacturers are the new requirements set by the U.S. Tobacco Control Act and the European Union's revised Tobacco Products Directive (TPD2). Meeting these requirements will be tough particularly for smaller manufacturers, who lack the resources of their larger counterparts.

In the case of FDA regulation, tobacco companies face many new tasks: To comply with the legislation, they need to convert their equipment and utensils to stainless steel, for example. Furthermore, they have to put into place document and purchasing control systems. The latter stipulation is especially challenging because manufacturers have no direct control over vendors. Makers of tobacco products must also implement manufacturing and process control systems; they have to evaluate and accept incoming raw materials and goods. For nonconforming manufactured goods, they have to install a process to control the labeling and packaging activities. Handling product complaints is also part of their tasks.

One of the biggest challenges of FDA regulation, however, is the requirement to identify and trace products down to the individual batches and lots of finished products, as well as keeping records of all such activities.

Tracking-and-tracing rules are even stricter in the EU. Tobacco products, regardless of where they are made, must be compliant with TPD2 by May 2016 if they are to be sold in the EU. TPD2's articles 15 and 16, which regulate traceability and security features, respectively, require tobacco products to be traceable down to each individual unit and, within the supply chain, up to the last operator before retail.

Tobacco companies are also struggling with uncertainty. In most EU countries, TPD2 legislation has yet to be transposed into national law, and time is running out for manufacturers to bring their processes into line with requirements still unknown.

The requirement to print a "unique identifier" presents a challenge, as well. The unique identifier, which needs to be on every single unit of tobacco products—including RYO, pipe tobacco and cigars, as well as on every type of packaging—must contain a lot of information within a limited space. For this reason, two-dimensional codes are being employed.

Because the codes are printed at high speeds, their readability will be influenced by a number of factors, such as the product substrate material, the printing technology and the artwork.

Dot codes have proven to be more suitable than a data matrix code because they provide a high density of information in a small space and can be easily read by cameras from different angles and from relatively long distances. Dot codes have also been used by the pharmaceutical, confectionery and beverages industries.

Panelists agreed that there is no one-stop shop in the fight against counterfeiters. One of the problems in the manufacturing process of tobacco products is that no two production lines are the same, and there is no ready-made track-and-trace system for the tobacco industry on the market. As a result, a system needs to be developed from scratch, and manufacturers need tremendous cross-sectional support and leadership.

Because TPD2 still lacks a technical standard for effective tracking and tracing, tobacco manufacturers have suggested using a proprietary solution. Philip Morris International (PMI) had proactively developed and implemented its own track-and-trace system, Codentify, in order to comply with the World Health Organization's 2010 Protocol to Eliminate Illicit Trade in Tobacco Products.

The company licensed Codentify, free of charge, to its main competitors, British American Tobacco, Japan Tobacco International and Imperial Tobacco Group. Today, Codentify is used in 50 markets. However, because Codentify was developed by the tobacco industry rather than independent suppliers, regulators have refused to adopt it as a standard—even though tobacco manufacturers say they are prepared to have Codentify audited by an independent company to prove that it is suitable for TPD2.

Tobacco is one of the most smuggled and counterfeit goods in the world; illicit trade of tobacco products is currently estimated to account for 10 to 12 percent of the total global tobacco market. While legal cigarette sales volumes decreased in 2013, illicit volumes continue to grow, costing governments worldwide between $40 billion and $50 billion a year in tax revenues.

In June 2015, several stakeholders, including a tobacco industry supplier of track-and-trace solutions, founded the Coalition Against Illicit Trade (CAIT). The coalition will focus on encouraging cooperation among those affected by illicit trade, sharing best practices and working towards practical solutions that can be applied across industries.