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Health systems, medical products and innovation
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INDEPENDENCE AND PERCEIVED COMPLEXITY OF THE EU SYSTEM OF TOBACCO TRACEABILITY

Q: Isn't it a weakness of the EU system that it is overly complex?

A: Precision should not be mistaken for complexity. The EU system is based on a precise set of rules defining responsibilities and requirements both for the independent providers and the tobacco industry. Among others there are exact rules on how and when the traceability information needs to be collected and stored.

Instead of a single provider of a turnkey system, the EU system allows for the co-existence of multiple providers of various technical blocks. This sort of complexity is not a weakness of the EU system, it is rather its strength. The system can easier adapt to technological development.

Entrusting the system with a monopoly provider always bears serious risks of which the Parties to the WHO FCTC Protocol on Illicit Trade (ITP) should be aware. In particular, it is likely to lead to a lock-in situation in which a monopoly provider focuses on maximising its long-term economic gains. A monopoly provider that is free of effective competition and exposed to a wrong set of incentives, e.g. remuneration per traceable item, will be subject to the same economic incentives as the tobacco industry, i.e. both sides will be interested in maximising the long-term volume of the tobacco market. This invites tacit, if not even explicit, collusion between the two sides.

Whenever possible, the EU system therefore introduces competition which reinforces compliance, since rivalling providers are often ready to denounce wrongdoings of their competitors.

Q: Has the EU, in establishing its system, delegated any of its ITP obligations to the tobacco industry?

The ITP requires its Parties not to delegate their obligations to the tobacco industry. Article 8 thereof lists these obligations, each Party shall: establish and control a tracking and tracing system, require unique, secure and non-removable identification markings, require the prescribed information to be available, recorded at the specific time, properly formatted and accessible via the global-information-sharing focal point on request, and finally require the further development and expansion of its system's scope.

In the EU system, none of these obligations is performed by the tobacco industry.

Q: Isn't it a weakness of the EU system that it allows the tobacco industry to choose providers that will store the traceability data?

A: The EU legislators decided to require the tobacco manufactures to contract out the storage of tractability data to independent third party providers. This is how the costs associated with data storage are passed over to the tobacco industry and should be clearly distinguished from the situation in which the tobacco industry itself would store the data.

The EU legislators also introduced a series of measures that together guarantee a high level of data integrity and no interference from the tobacco industry:

- The Tobacco Products Directive (TPD) 2014/40/EU excludes the tobacco industry from accessing the traceability data, unless, in duly justified cases, the European Commission or the EU Member States decide to grant limited access;
- The TPD requires the European Commission to verify each provider of the primary repository (that stores the traceability data relating to the products of an individual tobacco company), in particular with regard to its independence from the tobacco industry;
- Independence criteria are clearly defined in Commission Implementing Regulation (EU) 2018/574 (CIR) and include:
 - independence from the tobacco industry in terms of legal form, organisation and decision making;
 - independence from the tobacco industry in financial terms, which requires that a newly proposed provider cannot generate more than 10% of its annual worldwide turnover from goods and services supplied to the tobacco sector;
 - absence of conflicts of interests with the tobacco industry of the persons responsible for the management of a proposed provider;
- The CIR introduces a secondary repository which provides for a copy of all traceability data from all the primary repositories in one single place. The European Commission selects the secondary repository's provider, which carries out its tasks under a direct concession contract with the European Commission;
- The TPD requires that all the data storage facilities are subject to annual audits. The CIR requires that the system maintains the full audit trail of all operations concerning the stored data, including the history of user access;
- The CIR provides the public authorities with the live visibility over the traceability data and a technical possibility to carry out bulk downloads at any time.

Together the above measures fully ensure that the traceability data is protected from any potential interference by the tobacco industry.

Q: How is the EU traceability marking secured against cloning?

A: The EU system introduces several measures that together make the EU traceability codes highly secure. These are:

- Randomised serialisation – codes include a serial number that has a negligible probability to be guessed;

- Codes are fully contextualised with information about the product, its place of manufacturing (including machine), intended market and intended shipment route ahead of being delivered to the production line;
- Application of codes is followed by the verification process, whose parameters are stored (logged) in an anti-tampering device that must be installed on every production line;
- Codes are completed with time stamps, which enable further methods of monitoring;
- Codes are reported multiple times along the supply chain, their location cannot change without prior notification; in line with the validation rules, the system rejects any duplicates.

Q: Are the EU independence criteria sufficient if several historic vendors to the tobacco industry are active as the providers of data storage and as the ID issuers for the purpose of the EU system of tobacco traceability?

A: Full exclusion of all providers with any minor past commercial contacts with the tobacco industry is unrealistic. What matters is that the providers do not depend on the tobacco industry, neither legally, nor financially, nor as relates to the management.

Independence should not be only a backward-looking exercise. Main focus is on present and future compliance. For these reasons, the “entry criteria” are only a part of the EU system’s design. The EU system includes regular checks. Every year the authorities can require from each independent provider a full list of services provided to the tobacco industry during the last calendar year. This allows for adaptation if circumstances change. The EU system also introduces economic incentives for providers to comply, notably competitive pressure on individual providers.

Q: What is the EU security feature?

While the ITP requires that a traceability code or stamp are secure, the EU legislators decided to introduce an additional measure. The TPD includes the requirement of marking the tobacco products with a security feature. Most of the EU Member States have decided to apply fiscal markings for this purpose.

The EU encourages other ITP Parties to take similar additional measures in their fight against illicit trade.

Q: What is an added value of including a time stamp in the EU traceability marking?

A: At the outset, it is recalled that Article 8 of the ITP requires that a date stamp (e.g. YYMMDD) must form part of the unique identification markings. Therefore, a time stamp can be introduced at a negligible cost of two extra characters in the code (assuming the time stamp’s precision to a single hour, i.e. YYMMDDhh). The introduction of date and time stamps presents the same technical challenge and in both cases necessitates an inline process on the production line.

As to its added value, a time stamp increases the security of traceability codes because it helps in more precise monitoring of the application process on the production line. It also facilitates investigation in potential wrongdoings of the individuals present during a given work shift.

Q: Is the EU system a good fit for all the ITP Parties?

A: It is ultimately for each ITP Party to decide which system it wants to use. The EU system presents one possible design. The EU system fully complies with the ITP.

For more information on the EU system of tobacco traceability, please see:

https://ec.europa.eu/health/tobacco/tracking_tracing_system_en