



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
The Director

Brussels,
SANTE.DDG1.B/[REDACTED] (2019)6240287

Dear friends from the FCA,

As you know, the European Union (EU) has always been at the forefront of international efforts to advance the tobacco control agenda. Over the years, the FCA has gained our high respect for its professional and diligent work on the development, ratification and implementation of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC).

It is in this context that we have to express our puzzlement with the recent publication of the policy briefing titled "*What Lessons Can We Learn From The EU Tobacco Tracking and Tracing System?*" in the FCA blog.¹ The policy briefing includes a serious allegation that the EU system does not fulfil all the requirements of the FCTC Protocol on Illicit Trade (ITP). We have to strongly disagree with it. **The EU system fully complies with the ITP.** Moreover, its design can very well meet the needs of many other ITP Parties with basic ICT infrastructure in place.

The policy briefing leaves a strong impression of promoting a single provider of a turnkey system. However, favouring one single solution creates a monopoly and the creation of a monopoly always bears serious risks of which the ITP Parties should be aware. In particular, it stifles technical development and is likely to lead to a lock-in situation in which a single provider focuses on maximising its long-term economic gains. A single 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.

In several instances, the policy briefing factually confuses the advancements introduced by the Tobacco Products Directive (TPD) 2014/40/EU with the ITP. It is the TPD that introduces the requirement of marking the tobacco products with additional security features, the ITP only requires that a traceability code or stamp are secure. It is the TPD that introduces the concept of independence for testing the third party providers, the ITP requires its Parties not to delegate their obligations to the tobacco industry.

¹ See: <https://www.fctc.org/blog/what-lessons-can-we-learn-from-the-eu-tobacco-tracking-and-tracing-system/>

Article 8 of the ITP 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. None of these obligations is performed by the tobacco industry in the EU.

The concept of independence is one of many safeguards that the EU system includes in order to enable the public authorities to exercise the full control over the traceability system and the supply chain of tobacco products.

The policy briefing criticises the addition of a time stamp in the EU traceability markings. However, it is silent about the ITP requirement that a date stamp must form part of the unique identification markings. The technological challenge of including a time stamp as compared to a date stamp is virtually the same, both require an inline process on the production line.

We sincerely hope that you will consider removing several wrong allegations contained in the policy briefing or at least publish in your blog the enclosed explanatory document, in which we set out our response to the main strains of the criticism advanced in the policy briefing.

We are always open for constructive dialogue, free of interference from vested interests, with the FCA, health NGOs as well as any interested ITP Parties. Such a dialogue will help us in assessing the functioning of the EU system in the framework of the application of the TPD. The European Commission is legally obliged to carry out an assessment of the TPD by 20 May 2021 and this will also include looking at the functioning of the EU system of tobacco traceability.

Yours sincerely,

(Electronically signed)



Contact:



Enclosure:

Explanatory document on independence and perceived complexity of the EU system of tobacco traceability

c.c.:

WHO FCTC Secretariat, WHO Tobacco Free Initiative