



PHILIP MORRIS ApS

Copenhagen, October 12, 2018

Till Socialdepartementet
Diarienummer S2018/04914/FS

We thank you for the opportunity to comment on the proposed amendments to “Lagen om tobak och liknande produkter”.

Three proposals are made:

1. Allow the possibility to delegate the role of ID Issuer to another entity than the State or a municipality;
2. The government, or the authority designated by it, should be granted the right to issue a regulation on fees to generate and issue unique identifiers.
3. The Public Health Agency should be given the authority to decide to delegate the role of being an ID Issuer to a third party.

These changes should enter into force on May 1, 2019.

While we have no objection to these three proposals, we firmly believe that the proposed date of entry into force endangers a timely and smooth transposition of the TPD’s articles 15 and 16 in Sweden.

Indeed, please allow us to highlight the urgency of selecting and appointing the ID Issuer for the Swedish market.

As you know, your ID issuer will have two main tasks:

- **The registration of the whole production and distribution network through the issuance of Identifier Codes** for all economic operators, production facilities, warehouses and production machines within the territory of Sweden.
- **The generation and issuing of Unique Identifiers (UIs)** for the unit packets of cigarettes and roll-your-own. Without these UIs, it is not possible to activate the track and trace system as this means that there will not be UIs to be placed on the packs.

These two tasks make it critical that Member States have appointed fully operational ID issuers already by March 20 2019, when the whole system needs to be tested, including registration of all economic operators, facilities and machines, and the interfacing with the entire repositories system.

Failure to register the economic operators or no operating ID Issuer in any EU Member States will result in the traceability systems in those countries not being operational by May 20, 2019. In turn, this will automatically impact the operational readiness of the entire EU-wide traceability system.

As long as they are not able to appoint an ID issuer themselves, or it would not be operational in time, Member States should consider to temporarily entrust these obligations to an ID issuer from another Member State, as foreseen in Article 4.5 of the Implementing Regulation.

We remain at your disposal should you need further clarification on the above.

Respectfully,

Klaus Berg

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Danmark