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- Cross Border Healthcare and Tobacco Control Directorate-General for Health and Food Safety (DG SANTE) European Commission

Dear

The Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products placed an obligation on the Member States to appoint entities capable of generating and issuing unique identifiers by 6 May 2019.

We are concerned that some Member States may understand that a decision on which entity could potentially perform these duties is enough to comply with this requirement. You will be aware, however, that the correct reading of this obligation is that those entities must be fully operational by 6 May 2019, so that the traceability system envisaged by the Tobacco Products Directive is ready to go-live shortly thereafter on 20 May 2019.

As part of this, there must be sufficient time for the systems of the ID Issuers to interface with those of the tobacco manufacturers. It is our experience, after the work of integration carried out in Croatia, that a period of two months is required for that interface process. Both the ID Issuers and the manufacturers require this time to carry out detailed design, build and test activities if there is to be an appropriate, efficient interface.

While several Member States have designated ID Issuers, as evidenced in the Annex to the Summary Record of the Meeting of the Expert-Subgroup on Traceability and security Features of 17 January 2019, those have not yet shared their technical specifications, which are critical so that the interface process may be undertaken.

We are engaging with the Member States to expedite this. However, we would request that if the designated ID Issuers have not shared their technical specifications by 20 March 2019, or if some of the Member States still have not designated an ID Issuer, the Commission exercises its right under Article 4(5) of the Implementing Regulation and authorises economic operators to use the services of another ID Issuer for which the interface process has been completed.



In terms of a specific alternative ID Issuer, we would suggest AKD d.o.o. in Croatia, which is fully operational and has made its comprehensive technical specifications available.

We look forward to your assistance in ensuring we can work to support the EU goal of establishing a traceability system for tobacco products.

Yours faithfully,

