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European Commission, DG SANTE, European Commission, DG SANTE,

Brussels, 17 December 2019

Concerns on the implementation of the EU's Track & Trace System and appointment Subject: procedure for the External Auditors

Dear

We have received a letter from the Commission inviting notification of the proposed external auditor under Article 15(8) of the Tobacco Products Directive (TPD) received during the week starting on 2nd December.

In your letter, the European Commission informed us of the criteria which it will use to approve or reject the proposed auditor. It also invites companies to notify the proposed firm for auditing their primary repository by 7th January 2020. Finally, your letter refers to "guidelines on the scope of the audit report" which the Commission seeks to publish in early 2020.

Considering the Christmas and New Year break, this deadline allows too little time for manufacturers to follow due process in selecting an appropriate auditor with expertise in Track and Trace. The deadline set by the European Commission without any form of consultation, is not required in any Regulation. Furthermore, it is not possible to select an appropriate audit firm without knowledge of the further guidelines which are supposed to be released only in early 2020.

We share the concerns raised in the letter that ESTA submitted to you last week and understand that you will review and communicate new timelines to the manufacturers shortly. This is much appreciated.

We are looking forward to your clarifications and remain,