LOXXESS
logistics & fulfillment

To whom it may concern

Re: Public Consultation on the Implementation of an EU System for traceability and security features pursuant to Articles 15/16 of the Tobacco Products Directive 2014/40/EU

Dear Sir or Madam,

Loxxess is a logistics company serving clients in a large variety of industries. This includes sectors whose products are subject to stringent regulatory oversight including pharmaceutical, chemical, and tobacco industries. Of particular importance for us is the implementation of the Falsified Medicines Directive (FMD - 2011/62/EU), as well as the Tobacco Products Directive.

We therefore welcome the opportunity to provide our views especially regarding traceability and the use of security features in the tobacco sector.

Since we process the aforementioned regulated product categories, it is of utmost importance to us and certainly also other logistics providers that any solutions prescribed for the tobacco sector meet the following key principles:

- the solutions and specifications need to allow for a **seamless integration into our existing IT and processing infrastructure**
- any specification should leave **us as a logistics service provider with the ability to choose equipment that can be used for both tobacco and also other verification or traceability requirements such as the chemicals, and or pharmaceutical industry**. A key example is the upcoming compliance with the FMD. The ability to use the same equipment and infrastructure in several industries would increase efficiency and avoid excessive cost and duplicate systems. Otherwise, we would face a monopoly situation that would be to the detriment of the European open market principles and ultimately us as a service provider.
- The above **two points require therefore the use of a set of internationally normed standards when it comes to data and coding generation (for the identification of products), data transmission, as well as data storage.** Proprietary solutions would not work and not allow for the most efficient and effective use of different systems in a supply chain environment.
- As a consequence and as it will be the case with the Falsified Medicines Directive, **we as a law abiding company should be allowed to choose our technology suppliers and operate the systems that affect both the pharmaceutical and the tobacco industries.** Any other approach regarding tobacco would impose unnecessary hardship on legitimate supply chain members. Of course, in the context of the FMD and also the Tobacco Products Directive, we are open for audit where applicable.

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As for the questionnaire, we would like to respectfully provide the following comments:

Question C1 - the options leave a lot of room for interpretation. We chose Option A1 because we believe that we and all other legitimate supply chain members should be enabled to operate the systems according to the specific environment that they operate in. Only then will it be possible to avoid unnecessary cost burden and ensure that all systems reliably provide the data and information that is required by the regulation. We do not believe in the effectiveness of government operated solutions; however, we are of course open for audit and inspections where needed. Please keep in mind that all Logistics companies operate systems with the help of IT and equipment suppliers. But it should be possible to select suppliers ourselves.

Question C13 and 15 - We believe that a limited set of internationally normed data carriers would be most effective in putting traceability for tobacco products in place. The data carriers should be readable by the same scanner equipment as we use them also for other product categories such as pharmaceuticals. Having analyzed at what is currently used, we would strongly recommend the following standards as they harmonize quite well with internal and external systems used for other product categories:

For data carriers:
* GS1 SGTIN (EPC-NVE-96),
* GS1 DataMatrix (ISO/IEC 16022 EC200);
* GS1 128 BarCode
* We have also seen in the tobacco industry new high-speed data carrier that is in the process of GS1 standardization - it is called GS1 DotCode. We would recommend to allow for such data carriers and also keep flexibility in the regulation to allow for further new technical developments

For data syntax and semantics, we recommend the widely used standards ISO/IEC 15418 (GS1 Application Identifiers and ASC MH10 Data identifiers and maintenance), as well as GS1 Tag Data Standard for the EPC/SGTIN

In order to allow for seamless integration, it will be also necessary to define a globally and widely used information exchange standard. We recommend the GS1 EPC Information Services Standard (EPCIS Version 1.1, 05.2014)

In case of further inquiries and questions, we would be happy to provide further information.

Sincerely,

Dr. Claus-Peter Amberger
CEO

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Wir arbeiten ausschließlich auf Grundlage der Allgemeinen Deutschen Spediteurbedingungen 2016 (ADSp 2016).
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