

From: [REDACTED] (SANTE)
Sent: mercredi 26 juin 2019 09:27
To: [REDACTED]
Cc: [REDACTED] (SANTE); SANTE B2 TOBACCO CONTROL
Subject: RE: Urgent - Secondary Repository processing issue causing loss of sales

Dear [REDACTED]

I am writing to follow on our earlier exchange on 4 and 5 June 2019, which related to [REDACTED]'s unexpected problems in validating the messages containing correct unique identifiers. I would like to confirm that as agreed, our unit informed the Member States about the incident in the late afternoon of 5 June 2019. According to [REDACTED], the problem in question was fully resolved in the early morning of 7 June 2019. On the same day, our unit forwarded the information concerning the incident's closure to the Member States. According to [REDACTED] that incident was of the one-off nature and should not reproduce itself.

In general, I can assure you that we follow very closely the system's functioning. In over a month from the launch date, the overall operational statistics indicate that there are no major blocking issues. All the main data flows function and where needed adequate actions are being taken to eradicate initial bottlenecks at the level of the primary and the secondary repositories.

This brings me to the earlier correspondence received from your company during the period before the system's launch, in which you expressed your concerns about the timely launch of the system (i.e. your letters of 11 and 23 April 2019). I have been asked to respond to them.

As you are surely aware, the Commission took all possible actions to allow for the timely launch of the EU system of tobacco traceability, including the adoption of Commission Decision (EU) 2019/691, which authorises the economic operators to use the services of another appointed ID issuer in the temporary absence of the competent entity. The modalities of this Decision were presented during the technical briefing of 6 May 2019.

In this context, please note that it remains for each competent national authority to determine the absence of a relevant ID issuer. For the time being, the Commission has been notified of the absence of the ID issuer in only one Member State, i.e. Romania. At the same time, as you may be aware, several Member States started to take actions concerning the requests for unique identifiers that the economic operators submitted to non-competent ID issuers.

During the technical briefing of 6 May 2019, we also reminded the economic operators as to the exhaustion of stock provision contained in Article 37(1) of Implementing Regulation 2018/574. We underlined that the primary objective of that provision was to avoid the need for recalling products that entered the supply chain prior to the launch date. We added that it was understandable that some economic operators might decide to overstock certain quantities of products to mitigate their company-level risks. However, we also insisted that that was not a call for piling up the products for another year. We hope that our presentation clarified that the Commission's services took the balanced and realistic approach to this matter.

To conclude, in our overall appreciation, the EU tobacco traceability system was successfully launched and all the necessary steps were taken to address the existing risks in the pre-launch phase. There are no barriers to place the compliant products on the market. The further smooth functioning of the traceability system should be in the best interest of all the involved parties, including the authorities and the legal private operators. It is also important to recall the particular responsibility of individual manufactures and importers who have a direct contractual relationship with the primary repositories. High availability of the latter is one of the critical factors for uninterrupted reporting of the trade in the products of any given manufacturer or importer.

Kind regards,



SANTE/B2



European Commission

Directorate-General for Health and Food Safety

Unit B2 – Cross-border healthcare and tobacco control

B232

B-1049 Brussels/Belgium



From: [REDACTED] (SANTE)

Sent: Wednesday, June 5, 2019 11:42 AM

To: [REDACTED]

Cc: [REDACTED]

Subject: RE: Urgent - Secondary Repository processing issue causing loss of sales

Dear [REDACTED]

[REDACTED] has asked me to respond, on her behalf, to your email of 4 June 2019.

[REDACTED] has also informed us about unexpected problems in validating the messages containing correct unique identifiers. We understand that the system collects the messages but sends back a warning that wrongly indicates the use of incorrect (legacy) unique identifiers. In this sense, the system still allows for reporting of all the product movements and the related transactions. From [REDACTED] we understand that in view of the aforementioned warnings, the competent national authorities asked your business partners to refrain from handling the affected goods. We are also informed that [REDACTED] has acknowledged the technical issue and is working on resolving it as soon as possible.

As far as [REDACTED] acknowledges the technical issue, we are ready to confirm it with the relevant national authorities. However, we have certain doubts as regards the fact that your company should have also been aware of the issue at an earlier stage, i.e. the same error must have occurred in relation to the messages generated at your facilities before the products arrived at your trade partners. We would respectfully but urgently request for a revision of your internal procedures in this regard.

In order to inform the relevant national authorities, we would like you to let us know about the full list of Member States in which your business partners encounter the same situation as in Poland, Germany, Croatia and the Czech Republic.

Please note that an ultimate decision of how to address this temporary and short-lived problem will remain with the competent national authorities. Pursuant to Article 23 of Tobacco Products Directive 2014/40/EU Member States are exclusively responsible for the enforcement of the Directive, including the implementing and delegated acts provided for therein.

Kind regards,

[REDACTED]
[REDACTED]

SANTE/B2



European Commission

Directorate-General for Health and Food Safety

Unit B2 – Cross border healthcare and tobacco control

B232 [REDACTED]

B-1049 Brussels/Belgium

[REDACTED]
[REDACTED]

From: [REDACTED]

Date: 4 June 2019 at 20:07:56 GMT+2

To: [REDACTED]
[REDACTED]

Subject: Urgent - Secondary Repository processing issue causing loss of sales

Dear [REDACTED]

I hope this email finds you well.

Please see attached a letter that you will also receive via ordinary mail, which highlight a relevant issue which requires a urgent solution.

Best regards,

[REDACTED]

British American Tobacco

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Belgium

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Mob. [REDACTED]

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[REDACTED]

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