

From: [REDACTED] (SANTE)
Sent: lundi 15 juillet 2019 16:17
To: [REDACTED]
Cc: [REDACTED] (SANTE); SANTE B2 TOBACCO CONTROL
Subject: RE: Urgent - Secondary Repository processing issue causing loss of sales

Dear [REDACTED]

Thank you for your email.

As you know, in line with Article 3(9) of Commission Implementing Regulation 2018/574, the ID issuer may establish and charge fees to economic operators solely for generating and issuing unique identifiers. These fees are to be non-discriminatory and proportionate to the number of unique identifiers generated and issued to economic operators taking into account the mode of delivery. The actual level of applicable fees is left to the discretion of each ID issuer and may depend on several factors that may differ across Member States and ID issuers, such as a level of general service (e.g. regular or extended working hours), technical aspects of delivery (incl. a level of IT integration with the systems of tobacco manufactures), modes of payment, overall volumes etc. It is also only natural to expect that the costs of establishing the service as well as of providing the identifier codes for economic operators, facilities and machines will be gradually recouped through these fees and that the pace of recoupment may differ across Member States and ID issuers.

For the avoidance of doubt, the Commission's estimate used in the impact assessment study provided for an average value of the basic service of generating unique identifiers across the entire EU. As such, this estimate can serve as a useful reference point, but in no respect should it be considered as binding on individual ID issuers. The impact assessment study also assumed a margin of error and we note that a large number of the ID issuers priced their services within the range assumed therein.

The basic mechanism of cost control embedded in the Implementing Regulation is a possibility of running a cross-border comparison, which of course should take due account of the existing differences among Member States and ID issuers. At the same time, some simplified comparisons, as for example to the legacy industry-run systems, may not be justifiable given that the Implementing Regulation imposes on the ID issuers certain additional tasks and responsibilities going beyond the generation of unique identifiers. Those additional tasks and responsibilities also naturally limited the extent to which direct price competition could be introduced in this particular part of the traceability system.

In response to similar requests from other market participants, we already facilitated a discussion of this topic in the Expert Subgroup on tobacco traceability and security features in order to draw Member States' attention to the levels of the fees adopted by the ID issuers.

I hope that the above explanations will help you to better contextualize your internal analysis of the fees, in particular by taking into account a broader range of potential cost factors that may differ across ID issuers. Should you still consider the level of the fees adopted by certain ID

issuers as overly high, I would recommend to first address your observations to the competent national authorities.

Kind regards,



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



From: [redacted]
Sent: Wednesday, July 10, 2019 9:30 AM
To: [redacted]
Cc: [redacted] SANTE B2 TOBACCO
CONTROL <SANTE-B2-TOBACCO-CONTROL@ec.europa.eu>
Subject: RE: Urgent - Secondary Repository processing issue causing loss of sales
Importance: High

Dear [redacted],

Many thanks for your answer and for your support to solve the problems in validating the messages containing correct unique identifiers. We hope the process will work smoothly way forward.

However, there is another issue we would like to raise which has to do with UID fees applied by the Service Providers across the EU Member States.

As you are aware, almost all Member States (except Italy, Lithuania and Estonia) have appointed a *single* national ID issuer. The foregoing means that each national ID issuer has been granted *exclusivity* such that they are not constrained by competition. Terms of appointment vary but we learned that in certain Member State issuers were granted 5 year contracts.

It is not clear to what extent Member States ran a tender process before appointing the ID supplier – and to the extent they did, whether they had due regard to proposed UID fees in selecting the issuer. In any event, the appointments were not made in accordance with the EC

public procurement regime. Prima facie the Concession Contracts Directive (as adopted into national legislation by April 2016) should have applied - subject only to the value of the concession exceeding the relevant limit. BAT considers the limit is likely to be exceeded in at least some Member States.

It is also not clear to what extent Member States (through the terms of appointment) sought to impose controls on the fees charged by ID issuers. Absent any such controls, each issuer is free to determine its own fees, subject only to Art 3(9) IR.

The Commission's 2017 Impact Assessment (IA) estimated a total EU annualized cost of €14m which BAT estimates to be equivalent to c. €0.40 per 1000 UIDs. In a number of reference Member States (Austria, Sweden, Finland, Latvia, UK) the appointed ID issuers are indeed charging at/around €0.40 per 1000 UIs.

However, more than half of the IDs issuers appointed by Member States are however charging more than €0.40 and a significant number are charging more than €1.00 per 1000 UIDs (*for example* Bulgaria, Croatia, Denmark, Germany, Romania, Slovakia, Slovenia, Spain).

The discrepancies are especially striking given that ID issuers frequently subcontract the work to the same companies. We believe that costs of providing the service are similar across Member States, and yet the fees charged by ID suppliers vary considerably.

BAT considers that a fee of c. €0.40 per 1000 UIDs would be reasonable and consistent with (i) the IA itself (i.e. upon which the IR is based), (ii) BAT's experience with operating its own track and trace regime for which it purchased codes from INEXTO at a cost substantially below €0.40 per 1000 codes (iii) the UID fees communicated by the appointed ID issuers in the above reference Member States and (iv) the general availability of the same subcontractors throughout the EU.

In BAT's view, any fees charged by any single ID issuer in excess of c. €0.40 per 1000 UIDs potentially amount to an abuse of dominance. Article 102 TFEU (and equivalent national provisions) prohibit any dominant supplier from abusing their position of dominance. Each national ID issuer is clearly dominant in its national market since it is a monopoly supplier. It is well established that excessive pricing amounts to an abuse of dominance in breach of Article 102.

A fee is excessive where it has no reasonable relationship to the economic value of the service supplied, having regard to the relevant cost and any benchmark comparators. We believe that any announced fees rising above c. €0.40 per 1000 UIDs are excessive, relative to (1) the value of service as anticipated by the IA, (2) the cost of providing the service, which should not vary significantly between Member States and subcontractors, (3) fees charged in benchmark Member States, and (4) our own experience with operating track and trace.

BAT further believes that consumers will ultimately bear the cost, since the cost of UID fees are likely to be passed on by way of higher prices. The effect is equivalent to specific excise tax, except that in this instance the benefit accrues to the ID issuer rather than to the relevant Member State. Based on the fees thus far communicated by the single ID issuers, BAT estimates

that the annualized cost to the industry is upwards of €28m: well in excess of the estimate of €14m in the Commission's 2017 Impact Assessment.

BAT finally points out that the burden on consumers is likely to increase substantially in future, as there is no mechanism in place for regulating future adjustments.

We would kindly request the Commission to urgently look into this matter, and consider any measures available to it to ensure that there is sufficient competition between national ID issuers.

We believe that this could be achieved in a number of ways; for example by allowing manufacturers to select ID issuers appointed by other Member States, or requiring Member States to appoint two or more ID issuers. Alternatively, the Commission could consider any options to achieve mandatory controls on fees, inclusive of a mechanism to regulate future increases, and/or mandatory annual public tendering.

As this matter is presently manifesting itself and resulting in unbudgeted cost, we would very much appreciate your early feedback. Please let us know in case you require further information.

Kind regards,

[Redacted]
[Redacted]

British American Tobacco

Aarlenstraat 80 Rue d'Arlon
B-1040 Brussels
Belgium
Tel +32 (0)2 627 88 83

[Redacted]
Email: [Redacted]
[Redacted]

From: [Redacted]
Sent: 26 June 2019 09:27
To: [Redacted]
Cc: [Redacted] SANTE-B2-TOBACCO-CONTROL@ec.europa.eu
Subject: RE: Urgent - Secondary Repository processing issue causing loss of sales

* This is an EXTERNAL email *

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,

[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] (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]

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]

[REDACTED]

British American Tobacco

Aarlenstraat 80 Rue d'Arlon

B-1040 Brussels

Belgium

Tel +32 (0)2 627 88 83

[REDACTED]

Email: [REDACTED]

[REDACTED]

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