EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Cross-border healthcare and tobacco control

EXPERT GROUP ON TOBACCO CONTROL
MEETING OF THE SUBGROUP ON TRACEABILITY AND SECURITY FEATURES

- SUMMARY RECORD –

Date: 7 November 2019
Location: CCAB, European Commission

1. Welcome and introduction

The Chair welcomed the participants to the last meeting of 2019, and introduced new members of the Track & Trace team. SANTE informed those gathered about planned Subgroup meetings for 2020. The Subgroup approved the agenda.

2. Communication from the Commission

2.1. *ID issuer coding structure*

SANTE thanked Member States that have supplied the relevant information and highlighted areas where either gaps remain or there are issues with the information provided. SANTE recalled that this issue was discussed at the last Subgroup meeting and asked Member States to update the list of links to the coding structure of each competent ID issuer.

The Chair emphasised the matter's importance in terms of impact on data quality and the development of a mobile app.

2.2. *Compilation of Subgroup discussions*

SANTE informed the participants that a document compiling all the discussions of the Subgroup on Traceability and Security Features is now available on the European Commission's dedicated Track and Trace webpage and gave a brief explanation of its structure.

The Chair advised that the document is searchable but also includes an index for ease of reference.

2.3. Flat files

SANTE informed the meeting that the library of flat files is almost complete, with files from just one Member State outstanding. No validation has been performed as yet to check that the flat files received conform to the Regulation.

SANTE invited participants to ensure that any outstanding flat files are sent to the library as soon as possible. In response to the inquiry of a participant, SANTE clarified that there is no EU-wide flat file but that Dentsu facilitates a batch download of all flat files transferred by ID issuers to the secondary repository.

2.4. National Administrators

SANTE updated the participants about the state of play with the official designation of National Administrators.

SANTE recapped on the role of the National Administrator (NA), underscoring that by default a national administrator is responsible for all users in a Member State to whom he or she grants data access rights even if those users are from a different authority within the Member State. This default rule can be adjusted if requested by a Member State.

SANTE presented statistics on advanced user usage of QuickSight. The Chair recommended Member States contact Dentsu if they have any issues, reminding that bi-monthly webinars are organised to explain new features. The Chair stressed that Member States are encouraged to participate in the webinars.

2.5. Data storage contracts

SANTE gave a brief update on progress with data storage contracts since the last meeting. Two contracts have been approved and one is pending.

2.6. Facilitating reporting of stolen goods

SANTE advised that the issue of reporting stolen tobacco products was raised at the Dentsu workshop the day before. The Implementing Regulation requires economic operators to report stolen products at unit level UI level. In earlier discussions, the Subgroup had acknowledged that economic operators may not always be in a situation to meet this reporting obligation without additional information provided to them. The Subgroup therefore discussed the possibility of providing a reporting interface to economic operators and competent authorities at the level of the secondary repository in order to facilitate the reporting of stolen goods. SANTE asked Member State representatives to indicate whether or not they would be interested in this option, and to provide input on the operational scope of such a technical solution.

2.7. WHO FCTC WG on Track & Trace

SANTE and OLAF, on behalf of the Commission, will participate in the FCTC Working Group on Track & Trace, which takes place at the end of November in Panama City. The EU will act as one of the key facilitators (together with Brazil, Senegal and Sri Lanka). The WG will discuss a number of issues related to the requirement of the Parties to establish a track and trace system. An important point of discussion is going to be the design and set-up of the 'global information-sharing focal point'. Some Member States advised that they plan to attend.

2.8. Russian request for meeting with ID issuers

SANTE recalled a meeting that took place between the German Printing House, the issuer of the Russian traceability system and SANTE. The Russian ID issuer recently had informed SANTE about its intention to conduct additional meetings with other ID issuers. SANTE referred back to earlier discussions on the regulatory requirements under the EU tobacco traceability legislation. SANTE advised that ID issuers should be cautious about accenting to any technical proposal that would render the UI structure non-compliant and/or hinder an EU ID issuer from controlling the uniqueness and content of the UI. SANTE offered to the ID issuers concerned that it would be available to join at least parts of the meeting with the Russian ID issuer by video link.

3. Presentation by Sopra Steria

A representative from the contractor Sopra Steria presented on the ongoing work on the expert study on the development and configuration of automatic alerts to be generated by the EU traceability system.

SANTE thanked the presenter, advised that the slides would be circulated and stressed that high security measures are being followed whenever the real-life data is being analysed (including offline analysis in secured data rooms at the Commission premises). The Chair invited volunteers from among the Member States to share their experiences to feed into the project.

4. Discussion

4.1. Data quality

SANTE advised of the publication of the document 'Common Reporting Mistakes' on the Commission website. Translations of the document should be available in all EU languages by the second half of November. MSs are encouraged to publish and distribute the document among stakeholders in the sector. SANTE has developed an additional information sheet outlining the reporting rules for the main logistic events. A number of MSs requested it be translated into all EU languages. SANTE agreed that this will be done.

SANTE stressed the importance of ensuring that economic operators understand their reporting mistakes, which is an essential step in order to improve data quality.

4.2. Release of technical specification version 1.4

SANTE noted that the technical specifications were published in mid-October by Dentsu. The main technical changes are aimed at improving the validation rules to ensure that the traceability system operates in line with the regulatory requirements. One Member State raised practical and legal questions concerning the requirement in the new specification that tobacco products be scanned at the same level of aggregation when they are sent and when they are received. In SANTE's view, the update of the technical specifications does not introduce any additional or unexpected regulatory changes to the traceability system. A number of preventive measures are being taken to limit the market impact as much as possible, including: a soft launch (warning messages in the first month before error messages kick in from 1 February); a generous rollout timeframe (3 ½ months, 1 ½ months longer than legally required); guidance documents and educational efforts by MSs and SANTE. A small correction of the initial release (v. 1.4.1) was necessary to ensure that the receipt of goods that arrive at a facility other than the one initially intended is not blocked by the system.

4.3. Reporting of dispatches to embassies/international organisations

SANTE invited Member States that host international organisations to take the floor to offer new information on this topic. A participant advised that, having consulted with customs colleagues, dispatches to international organisations, and also embassies, have a customs and excise aspect while extraterritoriality is limited to immunity status considerations. Therefore, the territory on which an international organisation or embassy is located should not be considered a territory in its own right but belonging to the hosting MS. As such, dispatches of tobacco products should always be considered as normal dispatches (unless they form part of a diplomatic consignment, which is normally not the case), regardless of the associated country. Several MSs confirmed this position.

SANTE concluded that, with this in mind, the nature of the transaction should always determine the type of reporting that must take place. For example, international organisations that receive tobacco products and make them available to their staff members act as first retail outlet and as such require the necessary identifier codes. On the other hand, in the case of an embassy employee to whom products are delivered directly on the embassy premises by a distributor, the embassy has no formal role under the traceability regime. The distributor acts in this case as the first retail outlet (in certain situations this may constitute cross-border distance sales, applicable rules on prohibitions should be kept in mind).

4.4. Transloading to vending vans

SANTE referenced discussions on this topic in the 16 October Subgroup meeting, where it was concluded that "*economic operators should be advised to register a facility indicating the (geographic) location at which products are shifted/moved from a van/truck to a vending van. An arrival message referencing the F-ID of that location will be required. It must be followed by a dispatch message for each vending van.*" One economic operator had proposed to insert the word 'many' or 'multiple' in the destination field of transloading messages. Participants agreed that this goes against the idea of reporting on transloading activities and also does not comply with the rules set out in Annex II to the Implementing Regulation.

4.5. Letter from 'Independent Retail Europe'

SANTE advised that a letter had been received from the European retail association Independent Retail Europe, which asked that the letter be shared with Member States. The Subgroup discussed the different points highlighted in the letter.

On reimbursement

SANTE noted that the Subgroup concluded in previous meetings that a one-off reimbursement does not appear to be in line with Article 15(7) of the TPD. Scanning obligations exist both for logistic and transactional information and the latter requires the use of technical equipment beyond scanning devices, which manufacturers therefore must reimburse. The TPD does not provide any guidance on an appeal process. SANTE noted that, in the absence of any specific rules provided by a MS, economic operators may therefore be advised to resort to national judicial procedures if they believed a manufacturer is not complying with its reimbursement obligations. One MS advised that their market surveillance authority is looking into this question and it will update the Subgroup of any developments, including on any ensuing court proceedings.

60-second validation time lag

Certain wholesalers and retailers have raised concerns about the validation lag time of 60 seconds which they fear will cause dispatch delays and impact on other operational procedures. Independent Retail Europe enquires as to whether there are plans to introduce a new target to reduce lag times. SANTE advised that this would require a revision of the legal act, which is currently not foreseen. The 60 seconds requirement reflects a conscious balance between technical feasibility (taking costs into account as well) on the one hand and the operational needs of the supply chain on the other. Participants also agreed that is not uncommon for a new regulatory framework to require industry actors to slightly adapt their operations in order to satisfy the new rules. Economic operators have been aware of the 60 seconds rule, as well as other requirements of the Implementing Regulation, since its adoption in December 2017.

On invoicing multiple times

SANTE advised in relation to the query concerning whether it is necessary to record invoice information multiple times (e.g. the wholesaler that handles the movement of tobacco and the wholesaler that handles the sale of tobacco both record the same invoice) that the obligation to report transactional information lies with the vendor. An invoice document should normally only be recorded once. However, several Member States raised doubts as to whether the same invoice document could be issued by different economic operators. Every invoice document should be recorded in the system by the issuing vendor, even if the multiple documents essentially relate to the same UIs.

On notification process for maintenance of the T&T system

SANTE noted that scheduled maintenance normally does not have any impact on the availability of the secondary repository and the router (e.g. maintenance work is currently carried out on a bi-weekly basis). Dentsu confirmed that sufficient back-up mechanisms are in place for possible outage scenarios. Dentsu's website contains a section with a live update on the operational status of the secondary repository and router (100% uptime since 20/05/2019). Scheduled interruptions (if ever to occur) would be communicated well in advance to all registered economic operators by e-mail.

5. Q&A

5.1. Timeframe for reporting on payments and invoices

On the timeframe for reporting payments that occurred several days after an invoice had been issued, SANTE noted that payments and invoices should be treated as separate events. The information should be transmitted within 24 hours of the occurrence of the transactional event. The event is deemed to have occurred as soon as it can be linked to the UIs concerned.

Reporting of transactional information in the case of chain transactions and triangular transactions

SANTE recalled previous discussions on this topic, resultant conclusions can be found in the respective summary records. Every transactional event and every logistic event must be recorded and transmitted to the secondary repository. In the case of chain transactions (or the special case of triangular transactions), the supplier must report the dispatch to the recipient and the latter, unless a first retail outlet, must report the arrival. The vendor(s) must report the related transactional information. If, for example, multiple purchasing activities are carried out by different economic operators in the chain, each economic operator is obliged to record and transmit the transactional information for which they are responsible (as a vendor).

5.2. Home-based sales agents

The Subgroup discussed cases in which sales are carried out by individuals who store products in their private homes and use private/company cars to deliver the products from their home to various retail outlets, and where no product orders are available in advance. The group concluded that these activities equate to that of vending van sales and should be recorded accordingly.

Therefore, such sales agents require an identifier code. Dispatches and arrivals must be recorded by the sales agent using the specific vending van message; transactional information must also be recorded. Their home address should receive a Facility ID and their private/corporate car be treated as a vending van.

5.3. Reporting on the return of products

SANTE advised that products can be returned to a facility other than the facility from where it was dispatched. There are no restrictions on the Facility ID in the product return arrival message.

5.4. Request to disclose EO-IDs and F-IDs to economic operators

One Member State queried the possibility to disclose EO-IDs and F-IDs generated by ID issuers to all economic operators. SANTE noted that this additional function is not necessary for economic operators to comply with their legal obligations. A one-time request to their business partners for the identifier codes would not appear to result in a disproportionate burden. At the same time, the unrestricted disclosure of identifier codes and related company information to any requesting person entails certain security concerns, in particular the potential abuse of EO-ID/F-ID to engage in false reporting activities. Disclosure of company registration information could enable third parties to link the identifier codes to an individual; this would raise data protection concerns.

A mere validity check (without the disclosure of identifier code information) appears to be compliant and is also offered in other areas, such as the VAT Information Exchange System. One MS noted that they already offer this service.

5.5. Functioning and enhancement of analytical tool(s) in secondary repository

SANTE advised that the standard interface and QuickSight environment are constantly being improved by Dentsu. Continuous improvements are heavily reliant on the feedback of MSs (who are the main users). Feedback should come from all users either during dedicated Dentsu workshops or by emailing comments directly. This is a common effort and all Member States are encouraged to participate in the Dentsu workshops and to send feedback to improve the system.

5.6. Reporting activities in Member States

SANTE noted that MSs can access information on movement activities in different Member States via QuickSight (the data set called product movements). To illustrate this, SANTE presented slides on recent reporting activities, advising that some variance among MSs can be expected due to market structures.

SANTE noted that the Implementing Regulation provides for a few general exceptions (e.g. stock exhaustion, reporting timeframe, ATD); beyond these exceptions, it is not aware of any additional exceptions granted by a Member State. SANTE recalled the obligation of national authorities to enforce the provisions of the TPD, which includes the recording of movements/transactional information.

5.7. Mobile application

SANTE gave a short recap on a mobile inspection app. SANTE is currently looking into the aspect of providing an app at EU level, and advised that it expects to be in a position to provide a more detailed update at the next Subgroup meeting in January.

The Chair underlined that, regardless of whether this option materialises, Member States are not precluded from developing their own app (either in-house or via a procurement procedure).

5.8. Human-readable code

One MS noted that some manufacturers said they were not in a position to add the human readable code adjacent to the UI in the short roll-out phase of the system, especially in light of the recent changes to the technical specifications. SANTE clarified that each data carrier must include a human-readable code that enables electronic access to the information related to the unique identifiers stored in the repositories system. This requirement exists since the adoption of the Implementing Regulation and has not been affected or changed by any of the updates to the technical specifications.

6. Update from Member States

Member States were invited to provide feedback on developments in their market. Romania advised that its ID issuer had become operational on 31 October [2019]. The transfer of IDs went well and the ID issuer started to pre-issue codes as of 15 October. A number of other MSs provided updates concerning, among others: the new technical specification; access to data recorded by anti-tampering devices; a case before the courts involving tobacco traceability; a manufacturer been prohibited from supplying cigarettes or roll-your-own tobacco to consumers or retail outlets due to incorrect information related to the brand being provided; receipt of non-compliant product samples.

7. AOB

No discussion points.

8. Closing remarks

The Chair reminded the room that the compilation document, the common mistakes document and the information sheet would be circulated.

The Chair concluded that volunteers are sought to collaborate with Sopra Steria on their expert study.

The Chair urged MSs to make T&T an enforcement priority and encouraged them to intensify their actions, especially in terms of eliminating reporting mistakes, and to promote the use of the system across their national administrations.

The Chair thanked the Subgroup members for their work during what has been a very productive year before wishing them a Merry Christmas and a Happy New Year.

List of participants

Austria   (Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, Ministry of Finance - Tax and Customs Administration, State Monopoly Agency)

Belgium   (Customs and Excise Administration and FPS Health, Food Chain Safety and Environment)

Bulgaria   (National Customs Agency)

Croatia   (Agencija za komercijalnu djelatnost and Customs Administration)

Cyprus   (Department of Customs and Excise)

Czech Republic (Ministry of Agriculture, Czech Agriculture and Food Inspection Authority and State Printing Works of Securities)

Denmark   (Danish Safety Technology Authority)

Estonia   (Ministry of Social Affairs)

Finland   (Customs)

France   (Customs)

Germany   (Bundesministerium für Ernährung und Landwirtschaft and Bundesdruckerei GmbH)

Greece   (Independent Authority for Public Revenue and Ministry of Finance - General Secretariat for Information Systems)

Hungary   (Government office of the Prime Minister, Ministry without portfolio responsible for national property management, the National Tax and Customs Administration & ND Nemzeti Dohánykereskedelmi Nonprofit Zártkörűen Működő Részvénytársaság)

Ireland   (Department of Health and Office of the Revenue Commissioners)

Italy   (Customs Agency and Customs Monopolies Agency)

Latvia   (State Revenue Service)

Lithuania   (State Tax Inspectorate under the Ministry of Finance)

Luxembourg   (Direction de la santé and ID issuer Luxembourg)

Malta   (Customs)

Netherlands   (Ministerie van Volksgezondheid, Welzijn en Sport and Belastingdienst)

Norway   (Directorate of Health)

Poland   (Ministry of Finance and Revenue Administration Regional Office in Katowice)

Portugal   (Autoridade Tributária e Aduaneira and Tax and Customs Authority)

Romania   (General Directorate of Customs)

Slovakia   (Ministry of Finance - Financial Directorate and Datacentrum – and Slovak Permanent Representation)

Spain   (Comisionado para el Mercado de Tabacos. Ministerio de Hacienda y Administraciones Públicas, Fábrica Nacional de Moneda y Timbre and Ministry of Finance.)

Sweden   (Public Health Agency Sweden)

European Commission
DG SANTE   Filip Borkowski
                      Jan Hoffmann
                      Sascha Löwenstein
                      Melina Ballario
                      Veronica Miller