



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

TECHNICAL BRIEFING
LAUNCH OF THE EU SYSTEMS OF TOBACCO TRACEABILITY AND SECURITY FEATURES

6 MAY 2019
10.30 – 12.00

MEETING VENUE:
Breydel Auditorium (Avenue d'Auderghem 45, Brussels)

– SUMMARY RECORD –

1. Welcome & introduction

DG SANTE opened the meeting and welcomed all participants, including those following the meeting via web-stream. After introducing the agenda, DG SANTE extended thanks to all of those who had followed the implementation and launching of the system since its early days.

During the opening presentation DG SANTE reminded the participants about the nature and scale of the problems caused by the illicit trade of tobacco products. Those problems were at the roots of the FCTC Protocol on Illicit Trade and the EU actions, in particular the inclusion of the provisions on traceability and security features in the Tobacco Products Directive (TPD) adopted in 2014.

Next DG SANTE gave a brief overview of the traceability system, its general architecture and main operators. The opening presentation was concluded with an outline of the key features of the system from the perspective of the public authorities, in particular the means by which the public control over the system will be exercised. The participants were also reminded about the simultaneous launch of the system of security features.

2. Update on implementation

2.1. General update

DG SANTE outlined its actions taken following the adoption of the secondary legislation in December 2017. Those were focused on offering the support to Member States and the stakeholders, and the timely delivery on each of the Commission's legal obligations (i.e. the review of the contracts for primary repositories and of the proposed providers, and the selection of an operator of the secondary repository and the system's router).

DG SANTE stressed the importance of the ongoing technical tests of the repositories system. It noted with satisfaction that the tests were successful and involved the broad range of the service providers and economic operators. In that context, DG SANTE expressed its regret that not all ID issuers could participate in the tests at that moment. It recalled that the Commission had repeatedly reminded the Member States as to their responsibilities in terms of the timely appointment of the national ID issuers.

2.2. Launch of secondary repository & router

It was recalled that the Commission had selected Dentsu Aegis Networks to become an operator of the secondary repository on 21 December 2018.

Dentsu gave a presentation on the state of play in relation to the preparations to the launch of the secondary repository and the router in the so-called production environment. It reminded the participants that the list of technical specifications and the data dictionary had been made available on 21 February 2019 and the technical tests had been initiated on 21 March 2019.

Thanks to very good cooperation with the other parties involved in the tests, Dentsu could announce that the production environment was ready to go live on 10 May 2019, at 10.00 CEST.

DG SANTE thanked Dentsu for its hard work and good cooperation with other IT providers, including the ID issuers and the providers of primary repositories.

2.3. Temporary provisions

DG SANTE informed the participants about two important temporary provisions that were aimed at assisting the economic operators in smooth transition into the new traceability system. Those provisions concerned the stock exhaustion and the use of another ID issuer in the absence of the competent ID issuer.

Regarding the first temporary provision, DG SANTE recalled that Article 37(1) of Implementing Regulation (EU) 2018/574 provided that: “cigarettes and roll-your-own tobacco that were manufactured in the Union or imported into the Union before 20 May 2019 and not marked by means of unit level UIs in accordance with Article 6 [of that Regulation] may remain in free circulation until 20 May 2020”. DG SANTE underlined that the primary objective of that provision was to avoid the need for recalling products that have entered the supply chain prior to the launch date. It added that it was understandable that some economic operators might decide to overstock certain quantities of products to mitigate their company-level risks. However, DG SANTE insisted that that was not a call for piling up the products for another year.

Regarding the second temporary provision, DG SANTE referred to Commission Decision (EU) 2019/691 of 2 May 2019 that was published in the Official Journal of the European Union on 3 May 2019. DG SANTE explained that the Decision was supposed to largely mitigate the negative effects of the temporary absence of one or more ID issuers in Member States by enabling the economic operators to rely on the services of another appointed ID issuer. DG SANTE underlined that the adoption of that Decision had no impact on Member States' obligation to appoint ID issuers.

DG SANTE outlined the following key aspects of the Decision: its conditional character (i.e. only in the temporary absence of the competent ID issuer), its time limitation (i.e. in any event no longer than until the end of the year), no coverage of the retail outlets, the

ID issuers' discretion to accept additional requests, the eventual transfer of identification codes to the competent ID issuer, and no change to the rules on charging the fees.

In case of any doubts as to the status of the ID issuers, the economic operators were referred to the competent authorities of Member States.

DG SANTE closed this part by expressing its regret that the Decision had to be adopted but still hoping that the Member States would take necessary actions to close the implementation gap in time.

3. Questions and answers

DG SANTE opened the session for questions from the participants. Given the availability of detailed guidelines on all main aspects of the system, the participants were asked to focus their questions on the Authorisation Decision as the only new element in the regulatory setting.

On the question on the retail outlets, which are not authorised to rely on the Decision, DG SANTE explained that the retail outlets and their operators will have to wait for the appointment of the competent ID issuer by the concerned Member State(s).

On the question whether the technical specifications were available to the public, Dentsu confirmed that it was the case and also encouraged to contact it directly for any further questions.

In response to the question how the economic operators should report the products shipped/sold to entities that were not in a position to register, DG SANTE informed that it will table an adequate solution to that problem during the Expert Subgroup on tobacco traceability and security features on 8 May 2019.

DG SANTE also promised to coordinate with Member States the publication of a list of the national ID issuers and of an overview of the Member States that decided to derogate from the first subparagraph of Article 4(1) of Implementing Regulation (EU) 2018/574.

DG SANTE refrained from speculating in which Member States the situation of the ID issuer's absence might actually occur. DG SANTE noted that all the Member States worked very hard on making the launch of the system possible.

On the final question on the implementation status of Article 16 of the TPD on security features, DG SANTE answered that it was not aware of any major concerns in that regard.

4. Closing remarks

DG SANTE recalled that the TPD deadline for the system's launch was in a fortnight. It stressed that the Commission will continue to monitor the situation closely via all the tools available to it, such as meetings of the Expert Subgroup, the live access to the traceability data and the conformity assessment of the applicable provisions.

DG SANTE thanked for the participation and closed the technical briefing.