EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Health in all Policies, Global Health, Tobacco Control

Stakeholder Technical Working Group on Reporting and Notification Formats under Articles 5 and 20 of Directive 2014/40/EU
Final Summary record

Webinar date: 31 March 2016, 14.00 – 16:00

(1) Welcome and Introduction

DG SANTE welcomed the participants. The Chair briefly summarised the work to date and said that the documents uploaded on CircaBC at the beginning of the month remain valid for now, and that any further changes/new documents will be added as soon as possible once ready. The Chair also reported from the connectivity pilot testing (for system-to-system/e-Delivery submissions) and explained that to date 9 companies had registered with successful connectivity already established in some cases. Registration will remain open for some more weeks to allow others to text their connectivity. Regarding end-to-end pilot testing (i.e. with payload), the Chair explained that registration for both user types (system-to-system and stand-alone client) will open next Monday 4 April, with actual end-to-end piloting due to start in mid-April.

(2) Update on the progress and discussion

An update on the general architecture of the system was presented by the DG SANTE IT representative. Following this a short presentation on the process for submitter ID registration was given, including a preview of the registration form and the information that will be required.

The main discussion points can be summarised as follows:

- Participants asked whether system to system submissions can be made for multiple submitter IDs from one access point (i.e. using one certificate), as some companies would be interested in acting on behalf of another in this way (especially companies with affiliates). SANTE said it would come back to companies on this but that it is technically difficult, each submitter ID will be linked to one certificate only, and under the current version of the European Commission reference implementation of the AS4 access point, Domibus, only one access point per certificate is possible.
- Following from a question raised at the previous webinar, SANTE explained that a solution had now been found to allow companies (who choose do so) to make use of

both the stand-alone client and system-to-system tools simultaneously. Companies will be given the opportunity to indicate in the submitter ID registration form which option(s) they will chose.

- It was clarified that it will be possible to have multiple users using the same submitter ID. Companies can authorize users in the web page which is used for uploading submissions. The main user which is indicated in the registration for a Submitter ID can grant access to others. In the Standalone client there is no authentication.
- The issue of potential discrepancies between the data dictionary documents and XSD documents uploaded on CircaBC was raised by participants. SANTE replied it will make sure the latest versions of each document are uploaded as soon as the check is complete.
- Participants asked how much the XSDs are likely to change between now and end April, and stressed that any changes following this date will be problematic. SANTE said it is aware of companies' need to receive updates in a timely manner and will upload any changes/new documents as early as feasible. It will also highlight any changes made to previous documents so that these are easy to identify.
- Participants also requested that the XML for the error messages would be published as soon as possible, to which SANTE agreed and said it was working on.
- One participant asked whether it would be possible to generate XML files without the stand-alone application and submit them using the same web application which is currently used for Standalone users. SANTE replied that while this is technically possible at the moment, it is nevertheless foreseen to release a new version of the stand-alone client tool. This version will likely upload XML directly to EU-CEG and the web application will be disabled. After that direct uploads will no longer be available and AS4 access point will be needed to send XML if Standalone application is not used.
- A participant asked what is meant by submission 'version'. Another asked what year should be used to form the product ID in the case of modifications/substantial modifications (type 2 submissions). SANTE said it believes the new product ID should be formed using the year in which the modification/substantial modification is reported/notified.
- It was explained that registration for submitter IDs will likely open from mid-April. Companies will fill in a registration form to be placed on the EU-CEG webpage, and submit it to the email address indicated. Some time will be needed on the side of the Commission to process applications but it will endeavour to do this as efficiently as possible. Should further information be required from applicants it may revert to them to request this.

(3) Conclusions

SANTE thanked participants. It said that, as requested, it hopes to organise a face-to-face meeting towards the end of April, and that participants will receive further details on this shortly. It said that it had noted the main points raised during the meeting, including potential discrepancies between XSD and data dictionary documents and the need to publish the error

codes as soon as possible. It reminded registration for the next pilot phase will open on Monday.

List of Participants

FlavourArt
Nicopure Labs
Nerudia
Karelia
PMI
Scandinavian Tobacco Group
German Smoking Tobacco Association
JTI
Landewyck
BAT
Cuts Ice
Ritchy EU
House of Oliver Twist
ECMA
Swedish Match
Totally Wicked
Danneman
Oettinger Davidoff
Karelia
Agio
Pöschl Tabak
ESTA
Imperial Tobacco Ltd.

Commission services

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