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: 29 February 2016, 14.00 – 16:00

(1) Welcome and Introduction

DG SANTE welcomed the participants. The Chair briefly summarised the work to date and recalled that as deadlines are tight the aim is to ensure that basic requirements can be met in May, with refinements foreseen after this date. It was highlighted that every effort is being made to make the tool as user friendly as possible. The Chair said that new documents have recently been uploaded on CircaBC, which all participants should by now be able to access, and more will follow in coming days.

(2) Update on the progress and discussion

An update on the general architecture of the system was presented by the DG SANTE IT representative. Also briefly presented was a mock-up of the reporting tool that Member States' authorities will use to view submitted data.

It was explained that a separate XML has been foreseen to facilitate the introduction of changes to submitter information (submitter name, address etc.). It was added that a sequence diagram has been developed to illustrate this more clearly and would be shared with participants via CircaBC.

It was further explained that a new method for submitting attachments is currently foreseen, according to which they will be uploaded in advance to the EU-CEG. Submitters will create a reference number for these attachments that they will subsequently include in their submission XML. This will reduce the size of submissions as well as the burden for submitters, who will be able to refer to previously uploaded files. The reference numbers will be created based on a commonly used standard to create IDs. The roadmap for testing was then presented. It was explained that the registration for e-Delivery connectivity testing (required for system to system uploads) will open at the beginning of March and take place throughout the month, via a simple exchange of messages between the company and the Commission access point (managed by DG DIGIT). Information on this process will be shared on CircaBC. Further information on the next phase of piloting (in which standalone users will also be involved) will be provided towards the end of the month. During this second testing phase, test data will be sent. Participants were asked if they would agree to Member

States being provided access to this test data. As there was no disagreement SANTE said that it would operate under the assumption that this approach is acceptable, but participants could reply in writing if they so wish.

For the assignment of submitter IDs, SANTE explained it is preparing technical solutions which it hopes to present in coming weeks. A slide containing some pre-registration data that may be required was shown and companies were asked for their views.

The current reference table for product type was also presented.

Finally, SANTE announced that a dedicated webpage has been launched to which information related to the EU-CEG will be added over coming weeks.

The main discussion points can be summarised as follows:

- One company asked whether the submitter ID needs to be changed if the legal entity is changed. SANTE said it would come back to this. It was clarified that companies based outside the EU are also eligible to apply for submitter IDs if they are importing/placing products on the EU market.
- One company asked if it will be possible to import XML files to the stand-alone application. SANTE explained this is not currently foreseen and the information needs to be typed manually, after which the tool will create the XML files.
- Companies asked if it will be possible for one company to use both submission options (system to system and standalone) for different product types, as they are keen to be able to do so. SANTE replied that it will look into the question. It clarified however that if companies begin by using the standalone option (e.g. as a transitional solution), they can at a later date switch to the system to system option on a permanent basis.
- Companies asked if real or mock data can be used when the second phase of piloting begins. It was clarified that mock data is acceptable but that it would be useful if this could be as realistic as possible, including presentation for multiple MSs. It was added that the current versions of the XSDs and reference tables will be provided in coming days to facilitate this.
- Regarding the pre-registration data for assignment of submitter IDs, companies asked what would be an appropriate verification file to upload. SANTE said it does not intend to fix a specific type but leave this to companies, as official documents may vary from country to country. It should simply prove relevant activity within an EU Member State. It would recommend uploading a verification file, however, as this will facilitate the identification process.
- Regarding the reference table for product type, one company asked whether the correct field filters will operate depending on product chosen. SANTE clarified this is the intention. It was explained that the data dictionary documents to be shared will provide some business rules in this respect. It was explained that the aim of the reference table is to capture as many product types as possible. Regarding the ‘other’ product type option, it was explained that this was added as it cannot be excluded that some products have not been explicitly covered. It was clarified that the other reference tables will be shared, and that though these are not finalised they are unlikely to be substantially modified from these versions.

- Regarding emissions to be notified for e-cigarette products, it was clarified that a reference table will be provided, but that this is not intended as exhaustive. If needed additional emissions should be provided under 'other'.
- One company recalled that MS are individually obliged to publish public data and asked how they will do this. SANTE explained that from a technical point of view the reporting tool will provide MS with the option of downloading public versions of the submitted data (based on what the companies have indicated in their submissions). Beyond this, acceptance of these confidentiality claims is the discretion of MS. The implementing acts have set out what the Commission will consider to be public data.

(3) Conclusions

SANTE thanked participants and said that a further set of documents would be uploaded to CircaBC in coming days. It reminded that companies intending to use the system to system option should register for connectivity testing (for stand-alone users there are no pilot activities as yet). Regarding submitter ID assignment, companies were asked to send any comments on pre-registration data that should be required. The PPTs shown will be circulated in coming days as well as draft minutes for comments. SANTE said it had taken note of specific questions (including possibility of parallel use of the two submission options and use of one access point for multiple users). The next webinar is foreseen in coming weeks and a face-to-face meeting is considered for April.

List of Participants

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