EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Expert Subgroup Group on the Technical Implementation on the Common Reporting and Notification Formats under Articles 5 and 20 of Directive 2014/40/EU

DRAFT Summary record

Webinar date: 14 June 2016, 09.30 – 10:30

(1) Welcome and Introduction

DG SANTE welcomed the participants. The Chair briefly summarised the work to date and thanked participants for their efforts over past weeks regarding signatures of the Service Level Agreement for storage of data at Commission facilities. The group was informed that all 28 Member States had by now signed.

(2) Technical update from the Commission

DG SANTE explained that the layout of documents on CIRCABC has been reorganised, with the latest data dictionary versions uploaded on 07/06, including some key changes to resolve blocking issues. New documents are now the first ones visible with old versions contained in archived files.

It was explained that the XML generator is now available for industry to download and that all channels and tools should now be fully functioning for full product submission to be possible. Industry may still have remaining issues on its side, in particular with regard to system to system submissions. SANTE said it is helping companies on a daily basis with these issues and already many have been resolved. The focus of the next phase, from SANTE's point of view, will be to work to improve the overall usability of the system for users.

(3) Closure of the pre-stage procedure

DG SANTE outlined the temporary pre-stage procedure, which was opened in an initial phase in order to manage as efficiently as possible, minimise disruptions and ensure that secure data transfer would be possible. It was also intended to prevent any possible negative consequences in terms of timely placing on the market of new products. Products for which pre-stage information was submitted, and for which full submissions are subsequently made (via the EU-CEG) within the given deadline, will have their provisional submission date confirmed in the system.

SANTE explained that it strongly recommended companies submitting during the pre-stage procedure to focus on new products (i.e. those not already on the market on 20 May) and that participation/non-participation in the pre-stage procedure should have no consequences for products already on the market on 20 May 2016, for which the deadline for submission remains 20 November 2016.

SANTE said that it would circulate a breakdown of the submissions received per Member State following the webinar.

(4) Reporting tool and SAAS update

SANTE reminded participants that registration with both ECAS and SAAS is necessary to gain access to the Member State reporting tool. It was clarified that a mistake in the SAAS user guide previously circulated has now been rectified, and that users should select their organisations (instead of countries) in the system. Access for local administrators can then be granted by the national administrator (as per the user guide with screenshots provided to the group).

There were some requests from MS to have a further training session on access and reporting tool issues. SANTE said it would look into solutions to supplement the instructions already given. Member States continuing to experience SAAS access difficulties were advised email their concerns to the IT colleagues directly.

Regarding the development of the MS reporting tool, the Chair explained that final work is ongoing and it is hoped that it will soon be made available to all Member States. As no company has yet completed a full product submission via the EU-CEG, there is currently no viewable data in the tool.

(5) Conclusions

SANTE thanked participants and summarised the main points of the meeting. The Chair said that Member State cooperation in this task has been highly appreciated and that SANTE intends to continue this cooperation to further improve the system. It said it understands some Member States are continuing to have connection problems relating to the reporting tool and that it will look into this as well as into the possibility of proving further training. The next webinar will likely take place in September.