EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Substances of human origin and Tobacco control

Brussels, 20 January 2015

MEETING WITH E-CIGARETTE INDUSTRY STAKEHOLDERS ON DEVELOPMENT OF A COMMON E-CIGARETTE NOTIFICATION FORMAT

SUMMARY RECORD

Participants: Dominik Schnichels, Anna Eva Ampelas, Ingrida Pucinskaite-Kubik, Matus Ferech, Patricia Murray (DG SANTE unit D4);

Peter Beckett, Tom Pruen (ECITA); Ray Story, Renato Addis (TVECA); Arnaud Dumas De Rauly, Rémi Parola, Charly Pairaud (FIVAPE); Henrik Brostrom, Sandra Costigan (Nicoventures); Thilo Paschke, Julia Wolf (JTI); Charles Hamshaw-Thomas (Zandera); Steve Stotesbury, Kerstin Reichmann (Imperial Tobacco Group); Julian Shellard (Blu eCig); Barbara Frey (NJOY); Mark Dignum, Judith Rowland (Nerudia); Markos Markopoulos, Dimitris Petropoulos (Nobacco); Massimiliano Mancini (Flavourart); Marcello Balestra (Puffcigarette); Liam Humberstone, Richard Hyslop (Totally Wicked), Germana Barba, Maurice Smith (PMI/Nicocigs).

Observers: EUREST

Date: 20 January 2015

Place: CCAB-3B

Background

The meeting was organized on the initiative of DG SANTE unit D4 with the following objectives:

1) To inform industry stakeholders regarding upcoming implementation tasks under Directive 2014/40/EU with a focus on the development of a common notification format for e-cigarettes as set out in Article 20.13 of the Tobacco Products Directive 2014/40/EU.

2) To present a draft data dictionary for the common notification format for e-cigarettes being developed by the EUREST consortium under a request for service under Framework Contract EAHC/2013/Health/23 and gather feedback.

Introduction

DG SANTE provided an overview of the upcoming implementation tasks under Directive 2014/40/EU in the area of e-cigarettes, and clarified that the focus of the meeting would not be to discuss Directive 2014/40/EU as such, its implementation in general or related legal matters, but the development of the common EU notification format for e-cigarettes, to be laid down via an Implementing Act as set out in Article 20.13 of the Directive. More specifically the aim would be to provide industry stakeholders with an opportunity to present their views on the draft data dictionary being developed by the EUREST consortium for the purpose of the common notification format. The draft data dictionary had been submitted to the participants prior to the meeting.

Industry representatives thanked DG SANTE for the opportunity to provide feedback. They agreed with the rules of transparency proposed (publication of minutes on the DG SANTE website).

The ongoing work of EUREST and the draft data dictionary was presented to the participants. DG SANTE outlined the main sections of the draft data dictionary and explained what kind of information was likely to be requested under the notification format. Finally, it highlighted a number of points for discussion that could usefully be addressed during the meeting and stressed that the document is still in its early draft form.

General comments

Stakeholders highlighted the need for a workable notification format that takes into account the relative novelty of the market, the lack of agreed standards and the interest of industry to protect trade secrets. DG SANTE – whilst expressing some understanding – underlined the need to respect the relevant requirements of the legislation. Regarding the costs for manufactures/importers, DG SANTE said that the contractor is tasked to assess this issue in a next phase of the project. Some stakeholders expressed concern that high costs of implementation will be disproportionately burdensome for SMEs with large product ranges and urged DG SANTE to consider the impact of this.

Discussion Points

Reporting of product

DG SANTE underlined the need to establish a link between identical products placed on different Member State markets to facilitate a uniform application of the legislation, including for products marketed under different names. Participants asked that multiple reporting of the same product should be limited to the extent possible. It was also suggested that identification should be at the product level rather than SKU level.

DG SANTE indicated that one way of facilitating the reporting could be through the use of product identification codes.

Identification of ingredients

Participants underlined that the submission of several chemical names for each ingredient should not be required (e.g. if an ingredient has a CAS number, then it is not required to provide other identifiers such as a FEMA number). Questions were asked regarding the level of detail required for ingredients reporting, taking into account a.o. that some

companies buy (flavour) mixtures from third parties. DG SANTE – referring to the Directive – indicated that all individual substances that are put into the e-liquid should be reported. Some companies suggested that weighing of nicotine added to the liquid in 'grams' would be a preferable method of reporting, whilst others maintained that the reporting in concentration levels (mg/ml) is doable and applied in practice. The need for manufacturing tolerance on ingredient quantities was raised and DG SANTE offered the opportunity to submit written proposals.

Emissions reporting

DG SANTE explained that there is currently no agreed method for measuring e-cigarette emissions, but that standardisation bodies are expected to start working on this issue. One possibility for the interim period would thus be to ask manufacturers/importers to select a method of their choice, as long as the choice is reasonable, complies with certain limited specifications (e.g. regarding the device or e-liquid chosen for testing in combination with own products), is well described and justified in the notification and that the results are reproducible. The participants said that they would welcome such an approach. The participants also asked that the emissions for which extensive information is to be provided be limited to a clear number.

On the question of reporting on emissions for devices, which can be used with a variety of liquids, some participants felt a generic liquid should be defined, but there was no agreement which liquid should be selected. Others suggested that companies should be allowed to choose from their own range of liquids. Yet again others mentioned that the most commonly used liquid for the device in question should be selected, but it might be difficult to identify this liquid for the manufacturer of the device (in such a case the manufacturer should use best estimates). It was also suggested by a participant that there is a difference between products that use high propylene glycol and those that use high glycerine levels in their liquids and that this should be considered.

As regards the power level, some participants suggested setting a defined level at which testing should be carried out, but the participants could not agree on a common value. The participants also indicated that the choice of atomiser should be left to the manufacturer.

Nicotine uptake

Participants asked for guidance on how nicotine uptake and consistent dosing should be measured, and on the concept of high purity. Regarding the purity of ingredients, DG SANTE explored with participants whether pharmaceutical grade ingredients should be used, where possible. Most participants agreed that pharmaceutical grade (EP or USP) should be used for the excipients and for nicotine. One association pointed out that some pharmaceutical grade ingredients (e.g. flavours) are not available and suggested that, where this is the case, food grade would be the next best alternative.

On nicotine uptake, DG SANTE indicated that the approach discussed for emissions methods could also be used for nicotine uptake. Most companies were in favour of an approach centred on reporting the weight of nicotine in e-cigarette vapour. One company said that pharmacokinetics (blood plasma measurements) should be used, others disagreed, with one association stressing that this approach would render SMEs unviable, as would any testing on live subjects. Participants agreed to reflect and come back with a proposal. On the concept of consistent dosing, DG SANTE clarified that this does not mean that, irrespective of the strength and duration of the puff, the doses must always be

the same. Rather it means that – all relevant circumstances being equal – the nicotine content in the puffs should be equal. One company suggested there needs to be a tolerance level around this and that consistent dosing depends on the way in which the individual uses the product as well as factors such as battery degradation and levels of liquid remaining in the cartridge. DG SANTE welcomed suggestions, but stressed the importance of consistency across batches.

Trade secrets

Stakeholders inquired how trade secrets and proprietary information would be protected. DG SANTE asked which parts of the information provided by industry might be commercially sensitive or constitute proprietary information or trade secrets. Referring to Article 20.8 of the TPD, it should be possible for manufacturers/importers to indicate, within reason, which information should remain confidential. DG SANTE invited stakeholders to submit comments in writing, in particular as regards trade secrets in the data dictionary.

In this respect the question of an appropriate cut-off limit below which ingredients – whilst being reported to the authorities – do not need to be made available to the general public. DG SANTE requested suggestions be sent in writing.

It was also pointed out by one participant that the obligation to provide a declaration of non-risk cannot be complied with for heated PG and glycerol. DG SANTE asked for further details to be sent in writing.

Conclusions

DG SANTE thanked the e-cigarette industry representatives for their attendance and input. It indicated there would now be a 2 week period during which they could submit comments in writing. DG SANTE also explained that at a later stage the contractor would contact stakeholders with a questionnaire regarding costs associated with the notification format.

DG SANTE explained the time line of the legislation by referring in particular to the implementation plan which is published on the DG SANTE website, and updated regularly.