Fwd: Consultation on electronic smoking devices' regulation.

Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>
Seg, 17/08/2020 10:51
Para: Stefania Schimaneski Piras <Stefania.Piras@anvisa.gov.br>

Prezada Stefania,

Encaminho resposta recebida da Noruega.

Atenciosamente,
Felipe Dias

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De: [redacted]
Enviado: sábado, 15 de agosto de 2020 07:49
Para: Coordenacao de Cooperacao Internacional - COCIN
Assunto: Consultation on electronic smoking devices' regulation.

Dear colleagues,

Apologies for our late reply. Here are the answers to the first two questions from Norway:

1. **Are ENDS, ENNDS and HTP authorized in your country? If so, through which health legislation/standard are they authorized?**

Norway has since 1989 had a prohibition on the import and sale of novel tobacco products and nicotine products (i.e. products that were not on the market on 1989). ENDS and HTP fall under this prohibition. ENNDS are allowed, and are regulated the same way as tobacco products (age limit, display ban, advertising ban etc).

Norway is part of the European Economic Area Agreement, and follow EU-rules on many areas. EU Tobacco Products Directive 2014/40/EU (TPD) is expected to enter into force in Norway in 2021. The prohibition will then be lifted and replaced by a registration scheme for ENDS and an authorisation scheme for HTPs, in line with TPD Article 20 and Article 19(3). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AJOL_2014_127_R_0001. Norway will require registration also for ENNDS under the new system.

The Norwegian Public Health Institute in 2015 published a report on health risks associated with ENDS (https://www.fhi.no/en/publ/2015/e-cigarette-use-is-not-risk-free/), and are currently in the process of updating this report based on new knowledge.

2. **Can these products be marketed with the claim that they pose reduced risks to users' health? If so, which risks are reduced, and which scientific evidence supported this decision?**

No. ENDS must carry a health warning (TPD Article 20(4)(b)(iii) and reduced risk claims are prohibited by TPD Article 13. HTPs – if authorised by the health authorities – will be regulated in the same way as other tobacco products, including the prohibition in TPD Article 13.

Kind regards,
Helena Wilson

Norwegian Ministry of
Health and Care Services

Helena Wilson
Senior Tobacco Control Adviser
Department of Public Health
[redacted]

Fra: Coordenacao de Cooperacao Internacional – COCIN <cooperacao@anvisa.gov.br>
Sendt: 15. juli 2020 20:23
[redacted]
Emne: Consultation on electronic smoking devices' regulation.

Dear colleagues,

I hope this message finds you well despite the pandemic situation.

The import, marketing and advertisement of electronic smoking devices (ESDs) [1] are prohibited in Brazil by ANVISA's Resolution nº 46/2009. These prohibitions are based in the precautionary principle and in the absence of scientific evidence on safety and efficacy of these products. Almost ten years after the publication of the Resolution and aiming to discuss ESDs related issues based on current scientific knowledge, in 2019, ANVISA started a regulatory process to assess the current regulation[2]. In order to achieve this objective, the Agency is conducting a survey and an assessment of updated scientific evidences without conflict of interest on these devices.

Among the issues to be scientifically evaluated, the Tobacco Industry claims that these devices reduce the health risks to users when compared to cigarettes and other conventional tobacco products.

Therefore, we would like to rely on the support of Global Tobacco Regulator Forum (GTRF) members to clarify the following questions:

1. Are ENDS, ENNDS and HTP authorized in your country? If so, through which health legislation/standard are they authorized?
2. Can these products be marketed with the claim that they pose reduced risks to users' health? If so, which risks are reduced, and which scientific evidence supported this decision?
3. If the products can be marketed with the claim that they reduce risks, how is this information disclosed by the health authority? Are risk-reduced products subject to the same regulation as

conventional smoking products (fees, advertising and indoor use prohibition)?
4. If the products can be marketed with the reduced risks to users' health claim, does this information appear on the product label? If so, are there regulations to define how this information should be displayed on the label?
5. Are there any records of non-compliance with the health legislation/standard by the Tobacco Industry? If so, in which aspects?

We would appreciate if you could provide this and any other information that you consider relevant. We strongly believe that the reported experiences will be of great value to the current discussions in Brazil.

[1] Electronic Nicotine Delivery Systems (ENDS) Electronic Non-Nicotine Delivery Systems (ENNDS) and Heated Tobacco Products (HTP)
[2] Regulatory Process: http://portal.anvisa.gov.br/tabaco/cigarro-eletronico

Best Regards,
International Affairs Office
Brazilian Health Regulatory Agency - ANVISA