ENC: Information request on electronic smoking devices' regulation. _ Singapura

Stefania Schimaneski Piras <Stefania.Piras@anvisa.gov.br>

Sex, 18/12/2020 11:47

Para: Isabella Radd Pires da Silva <isabella.radd@anvisa.gov.br> Cc: Gloria Maria de Oliveira Latuf <Gloria.Latuf@anvisa.gov.br>

Isabella, bom dia.

Recebemos a reposta de Singapura.

Você pode gerar o PDF e salvar na pasta apropriada em fumígenos?

Obrigada!

Att.,

Stefania

De: Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>

Enviado: sexta-feira, 18 de dezembro de 2020 10:06

Para: Stefania Schimaneski Piras <Stefania.Piras@anvisa.gov.br>

Cc: Felipe Oliveira Dias <felipe.dias@anvisa.gov.br>

Assunto: ENC: Information request on electronic smoking devices' regulation.

Prezada Stefania,

Encaminhamos resposta recebida da Singapura.

Atenciosamente,

Coordenação de Cooperação Internacional

De:

Enviado: sexta-feira, 11 de dezembro de 2020 03:36

Para: Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>

Assunto: RE: Information request on electronic smoking devices' regulation.

Dear Colleague,

I am Dr Nisha Kesavan, Dr Derrick Heng's staff from the Ministry of Health, Singapore, and I am replying on his behalf.

Thank you for seeking Singapore's experience in tobacco control. Singapore takes a precautionary stance to prevent the introduction and entrenchment of these emerging and imitation tobacco products. Our policy goal is harm elimination rather than harm reduction, with the desired outcome as smoking cessation.

The importation, sale, distribution, purchase, use and possession of both ENDS and HTPs are currently prohibited in Singapore under Section 15 and 16 of the Tobacco (Control of Advertisements and Sale) Act (TCASA).

As Singapore does not authorise ENDS and HTPs, the rest of the questions posed are not applicable in the Singapore context.

Regards

Nisha Kesavan

Medical Officer (Non-Communicable Diseases) ■ Epidemiology and Disease Control Ministry of Health | Visit us at http://www.moh.gov.sg

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From: Coordenacao de Cooperacao Internacional - COCIN < cooperacao@anvisa.gov.br>

Sent: Saturday, 5 December 2020 3:15 AM

Subject: Information request on electronic smoking devices' regulation.

Dear Dr Derrick Heng,

We hope this message finds you well.

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?
- Can these products be marketed with the claim that they pose 2reduced 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.

 $[\%5b2\%5d][2] \ Regulatory \ Process: \\ \underline{http://portal.anvisa.gov.br/tabaco/cigarro-eletronico}$

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

^[1] Electronic Nicotine Delivery Systems (ENDS) Electronic Non-Nicotine Delivery Systems (ENNDS) and Heated Tobacco Products (HTP)