

ENC: Information request on electronic smoking devices' regulation _ Nova Zelândia

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

Seg, 21/12/2020 11:30

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

Bom dia.

Resposta da Nova Zelândia.

Att.,
Stefania

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

Enviada em: segunda-feira, 21 de dezembro de 2020 11:25

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 Nova Zelândia.

Cordialmente,
Felipe Dias

De: [REDACTED]

Enviado: domingo, 20 de dezembro de 2020 23:30

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

Cc: [REDACTED]

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

Hello

As requested here are the answers to your questions relating to the control of ENDS etc.

Kind regards

Brendon Baker (on behalf of Sally Stewart)

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

Sent: Saturday, 5 December 2020 8:21 am

To: [REDACTED]

Subject: Information request on electronic smoking devices' regulation.

Dear Ms Sally Stewart,

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?*

Yes – through the Smokefree Environments and Regulated Products Act 1990 - <https://legislation.govt.nz/act/public/1990/0108/latest/DLM223191.html?src=qs>

- 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 these products cannot currently marketed with these claims. Future Regulations, which are in the process of development, will consider the use reduced risk claims.

- 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?*

No, the Smokefree Environments and Regulated Products Act 1990 only came into force on 11 November 2020

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

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