Gloria Maria de Oliveira Latuf

De: Coordenacao de Cooperacao Internacional - COCIN
Enviado em: quinta-feira, 8 de abril de 2021 11:56
Para: Stefania Schimaneski Piras; Gloria Maria de Oliveira Latuf
Cc: Felipe Oliveira Dias
Assunto: ENC: Information request on electronic smoking devices' regulation.
Anexos: Questions from ANVISA dr1.docx

Prezadas,

Encaminho resposta do Canadá em anexo.

Vocês poderiam me ajudar a esclarecer a dúvida levantada no corpo do e-mail?

Atenciosamente,
Felipe

De: Breton, Chantal C (HC/SC) [redacted]
Enviado: quinta-feira, 8 de abril de 2021 11:47
Para: Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>
Assunto: FW: Information request on electronic smoking devices' regulation.

Good morning,

I hope this message finds you well.

We are wondering if it would be possible to provide further clarity on question #5 below. Specifically, what is meant by health legislation/standard for the Tobacco Industry? Are there specific sections of the Tobacco and Vaping Products Act or specific regulatory requirements that Brazil is interested in with respect to electronic smoking devices?

Thank you in advance for your guidance.

Kind regards,

Chantal

Chantal Breton *(she/her, elle/la)*
Policy Analyst | Analyste des politiques
Tobacco Control Directorate | Direction de la lutte au tabagisme
Health Canada | Santé Canada
[redacted]

From: Coordenacao de Cooperacao Internacional - COCIN [mailto:cooperacao@anvisa.gov.br]
Sent: 2021-03-26 1:24 PM
To: Info@hc-sc.gc.ca
Cc: Johnson, Sonia (HC/SC); Beaton, Dana (HC/SC); Choiniere, Denis (HC/SC); Gingras, Sunita (HC/SC); Anderson-

Golhor, Kemba (HC/SC)
Subject: Information request on electronic smoking devices' regulation.

Dear colleagues,

We hope this message finds you well and safe.

On behalf of ANVISA's Tobacco Regulation Office, we kindly reiterate the consultation below.

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

De: Coordenacao de Cooperacao Internacional - COCIN
Enviado: quarta-feira, 2 de dezembro de 2020 17:13
Para: Info@hc-sc.gc.ca <Info@hc-sc.gc.ca>
[redacted]
Assunto: Information request on electronic smoking devices' regulation.

Dear colleagues,

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.

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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 harm reduction 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.

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

Questions from ANVISA

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

A: Vaping products are subject to the *Tobacco and Vaping Products Act* (TVPA) and either the *Food and Drugs Act* or the *Canada Consumer Product Safety Act* (CCPSA), depending on whether or not the product is marketed for therapeutic use. The provisions of the TVPA apply to all vaping products, including those regulated under the *Food and Drugs Act*, except where they are expressly excluded from the application of the TVPA and some of its provisions (e.g. through the *Regulations Excluding Certain Vaping Products Regulated Under the Food and Drugs Act from the Application of the Tobacco and Vaping Products Act*).

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?

A: The TVPA limits certain types of promotions of vaping products. Subject to certain exceptions, section 30.43 prohibits 1) the promotion of "health benefits" of vaping and 2) the promotion by comparisons between vaping and smoking with respect to their respective health effects. The objectives of section 30.43 are (1) to prevent the public from being deceived or misled with respect to the health hazards of using vaping products and (2) to protect young persons and non-users of tobacco products from inducements to use vaping products.

Despite these limits, vaping manufacturers and retailers are allowed to communicate information about vaping to the public, including information of a scientific nature, as long as it is not communicated in a promotional manner.

The TVPA includes regulation-making powers to set out exceptions to s. 30.43, for instance through authorized health risk statements, taking into account the evolution of scientific knowledge on the health effects of vaping. No such regulations have been adopted at this time.

Manufacturers of vaping products who wish to market their products for therapeutic or health purposes, may be permitted to do so if they obtain the proper authorization under the *Food and Drugs Act*.

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)?

A: See previous answer

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?

A: See Answer to Q2

5- Are there any records of non-compliance with the health legislation/standard by the Tobacco Industry? If so, in which aspects?

A: You will find information on vaping compliance and enforcement at: https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/compliance-enforcement.html