Re: Information request on electronic smoking devices' regulation.

Ana Trinidad Rivera F. [redacted]

Dom, 06/12/2020 20:23

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

Thank you for your email, Responses are incorporated below, to wit;

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

ENDS, ENNDS and HTPs are to be regulated based on the following Legislation/Orders

1. Republic Act 11467 entitled An Act Amending Sections 109, 141.....
which is a revenue measure to generate funds for the Universal health Care.
Under this measure (page 11) The FDA shall periodically determine and regulate, consistent
with evolving medical and scientific studies the manufacture, importation,sale, packaging, advertising and distribution of HTPs including banning the sale to non smokers or persons below twenty-one years old

Under the same legislation, (page 12 and 13)
The FDA shall periodically determine and regulate, consistent with evolving medical and scientific studies the manufacture, importation,sale, packaging, advertising and distribution of vapor products including banning the sale to non smokers or persons below twenty-one years
old and banning of flavorings

2. Executive Order No. 106 - issued by the Office of the President
Reiterates provisions provided for under RA 11467 and its related rules and regulations

3. Administrative Order NO 2020 -0055 - issued by the Department of Health,
implementing guidelines for RA 11467.

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?

If a company markets a product with <u>any claims</u>, it would be considered as a pharmaceutical product and would have to provide evidence as such.

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)?

If a company markets a product with any claims, it would be considered as a pharmaceutical product and would have to provide evidence as such. Hence, it should follow existing rules and regulations prescribed for a pharmaceutical product

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?

If a company markets a product with any claims, it would be considered as a pharmaceutical product and would have to provide evidence as such. Hence, it should follow existing rules and regulations prescribed for a pharmaceutical product

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

The regulations are still within the 18 month transitory period, hence reporting would commence upon the effectivity of this period.

We hope that the above information would be useful for the current discussions in your country.

Enclosed, please find copies of the aforementioned regulations cited above, for your ready reference

Please feel free to communicate with us should there be need to clarify any of your concerns

Kind regards
Ana

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On Sat, Dec 5, 2020 at 3:07 AM Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br> wrote:

> Dear colleagues,
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> We hope this message finds you well.
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> 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.

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[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