ENC: Consultation on electronic smoking devices' regulation.

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

Ter, 11/08/2020 16:26

Para: Stefania Schimaneski Piras <Stefania.Piras@anvisa.gov.br>
Cc: Felipe Oliveira Dias <felipe.dias@anvisa.gov.br>

Prezada Stefania,

Encaminho resposta da agência francesa sobre dispositivos eletrônicos para fumar.

Atenciosamente,
Felipe Dias
COCIN/AINTE

De: CARDENAS, Maria-Alejandra (DGS/SP/SP3) [redacted]
Enviado: terça-feira, 11 de agosto de 2020 16:26
Para: Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>
Assunto: RE: Consultation on electronic smoking devices' regulation.

Dear Colleagues,

Please, found bellow our answers to your questions about ENDS legislation:

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

Yes, both are authorized . French legislation are most of all in our Public Health code (articles L. 3513-1 until article L3513-19 : https://www.legifrance.gouv.fr/affichCode.do?idArticle=LEGIARTI000032549212&idSectionTA=LEGISCTA000032549210&cidTexte=LEGITEXT000006072665&dateTexte=20200811
and D3513-1 until D3513-10 https://www.legifrance.gouv.fr/affichCode.do?idArticle=LEGIARTI000041902446&idSectionTA=LEGISCTA000033045587&cidTexte=LEGITEXT000006072665&dateTexte=20200811). The basis of this regulation is the European Directive 2014/40/UE, who is a common base for all EU members states. (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014L0040&from=FR

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, promotion is forbidden as well reduce risks allegations.

3- If the products can be marketed with the claim that they reduce risks, how is this information disclosed by the health authority?

Not apply. Heated tobacco is a tobacco product, and they have to respect all Tobacco control obligations, as use health warnings for example.

Are risk-reduced products subject to the same regulation as conventional smoking products (fees, advertising and indoor use prohibition)?
-HTP are a tobacco products, so all tobacco control legislation are applicable.
- ENDS have advertising restrictions, health's warnings' obligations, and vaping use is ban on public transports, education facilities and work places.

4- If the products can be marketed with the reduced risks to users' health claim, does this information appear on the product label?

Reduce risks' mentions are not allowed

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?
Since 2016, ENDS and Tobacco products have to be notify to UE members' states by a Common portal. Manufacturers have the obligation to send all composition information, and market surveys, toxically analyses, etc. the analyses of this data shows important inconsistencies on product files, that will be analyzing by members states authorities.

I hope that this information will be useful.

Best regards,

Maria Alejandra Cardenas
Encadrement juridique de la lutte contre le tabac,
aspects nationaux et internationaux
Bureau de la prévention des addictions (SP3)

[redacted]

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De : Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>
Envoyé : mercredi 15 juillet 2020 20:23

[redacted]

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

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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