Fwd: Europe Direct - 101000666757

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

Seg, 20/07/2020 13:27

Para: Stefania Schimaneski Piras <Stefania.Piras@anvisa.gov.br>
Cc: Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>; Terceira Diretoria <diretoria3@anvisa.gov.br>

Prezada Stefania,

Encaminho resposta da Comissão Europeia acerca dos questionamentos enviados.

Atenciosamente,
Felipe Dias

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De: EDCC <noreply@edcc.ec.europa.eu>
Enviado: segunda-feira, 20 de julho de 2020 09:54
Para: Felipe Oliveira Dias
Assunto: Europe Direct - 101000666757

Dear Felipe Dias,

Thank you for contacting the Europe Direct Contact Centre.

Further to your enquiry, we can inform you that if you are interested in national legislation regarding Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS) and Heated Tobacco Products (HTP), advertising practices and non-compliance investigations, we encourage you to contact the relevant national authorities or consult legislative databases of those countries for that information.

Regarding EU legislation, we can inform you that Article 20 of the Tobacco Products Directive (2014/40/EU) lays down rules for electronic cigarettes sold as consumer products in the EU. Please consult the full text of Article 20 here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AJOL_2014_127_R_0001

You may also find the national transposition of this Directive on the following page: https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=OJ:JOL_2014_127_R_0001

In order to facilitate the implementation of Article 20 of the Directive, the Commission adopted two implementing acts and a Commission report related to e-cigarettes:

Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers.

Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes.

Commission Report COM(2016) 269 final - Report from the Commission to the European Parliament and the Council on the potential risks to public health associated with the use of refillable electronic cigarettes.

Regarding tobacco labeling, we can inform you that the Tobacco Products Directive

(2014/40/EU) requires cigarettes, roll-your-own tobacco and waterpipe tobacco to carry combined health warnings consisting of a picture from the EU picture library, a text warning and information on stop smoking services. EU countries may also choose to apply the same requirements to other tobacco products such as cigars, cigarillos and pipe tobacco. The warnings should cover 65% of the front and back of packages. Tobacco products with combined health warnings must also carry a general warning and information message.

You may also be interested in Directive 2003/33/EC on advertising and sponsorship of tobacco products: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02003L0033-20030620

Regarding non-compliance, we can inform you that as stated in Treaties, public authorities and national courts have the main responsibility for the application of European Union law.

However, you may browse the infringement decisions (Member State breaches of EU law) relating to tobacco legislation on the following website: https://ec.europa.eu/atwork/applying-eu-law/infringements-proceedings/infringement_decisions/

Please find general information on tobacco legislation in the EU here: https://ec.europa.eu/health/tobacco/ecigarettes_en

We hope you find this information useful. Please contact us again if you have other questions about the European Union, its activities or institutions.

Dear colleagues,

The import, marketing and advertisement of electronic smoking devices (ESDs) 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 . 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 Electronic Nicotine Delivery Systems (ENDS) Electronic Non-Nicotine Delivery Systems (ENNDS) and Heated Tobacco Products (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 products or 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.

Best Regards,
Felipe Dias

- Check the EU response on https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response_en

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