Stefania Schimaneski Piras

De: Coordenacao de Cooperacao Internacional - COCIN
Enviado em: quinta-feira, 3 de setembro de 2020 08:09
Para: Stefania Schimaneski Piras
Cc: Felipe Oliveira Dias
Assunto: ENC: Consultation on electronic smoking devices' regulation.

Prezada Stefania,

Encaminho resposta recebida da Itália.

Atenciosamente,
Felipe Dias
COCIN/AINTE

De: [redacted]
Enviado: quinta-feira, 3 de setembro de 2020 05:02
Para: Coordenacao de Cooperacao Internacional - COCIN <cooperacao@anvisa.gov.br>
Cc: [redacted]
Assunto: Fwd: Consultation on electronic smoking devices' regulation.

Dear Madam/Sir,

Please find attached the required information.

Kind regards

Ministero della salute
Direzione generale della comunicazione e dei rapporti europei e internazionali

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

Yes ENDS, ENNDS and HTP are authorized for sale in Italy.
Legislation which regulate the sale of these products is Law n.6/2016 which transposes the European Directive 2014/40/UE (TPD).
In particular articles 20 and 21 of the law 6/2016 (articles 19 and 20 of the Directive 2014/40/UE)

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 they can't. It is forbidden by article 14 of the law 6/2016 (article 13 of the TPD)

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)?
The products cannot be marketed with the claim that they pose reduced risk to users' health.

4- If the products can be marketed with the claim that they reduce risks, does this information appear on the product label? If so, are there regulations to define how this information should be displayed on the label?

The products cannot be marketed with the claim that they pose reduced risk to users' health.

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

There are few products found not compliant with the law (for example because of the refill containers contain more liquid than admitted, contain a concentration of nicotine higher than admitted, information contained in the leaflet are not sufficient, the device and refill containers are not child proof, ecc).
There are some lawsuits still pendent on advertising of electronic cigarettes on billboards.
There are many violations of the ban for online sales of ENDS, the Italian Customs and Monopolies Agency constantly monitors the physical presence on the territory or on the Internet of unauthorized shops and in case of online sales closed the websites.

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.

There are some other aspects that are not regulated by our legislation which you could take in account for a future regulation of those products, in particular:
- the device (both for ENDS, ENNDS ang HTP) should be included in the definition of the products (it could prevent the advertising of the device which is totally related to the tobacco products);
- the powerfulness of the battery, which is determinant for nicotine uptake during inhalation.
- the presence of new products which use nicotine not in tobacco leaves or in liquids but in salts. These nicotine salts are included in cartridge for e-cigarettes (like Juul) or in pouches for chewing or sucking (like Epok or Lyft).

Da: "Coordenacao de Cooperacao Internacional - COCIN" <cooperacao@anvisa.gov.br>
A: "[redacted]
Inviato: Martedì, 25 agosto 2020 19:49:04
Oggetto: Consultation on electronic smoking devices' regulation.

Dear Sir/Madam

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 your support 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 claim that they reduce risks, 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

--
Stefania Valdarnini

Da: [redacted]
A: [redacted]

Cc: [redacted]
Inviato: Mercoledì, 2 settembre 2020 13:30:50
Oggetto: Fwd: Consultation on electronic smoking devices' regulation.

Therefore, we would like to rely on your support 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 ENDS, ENNDS and HTP are authorized for sale in Italy.
Legislation which regulate the sale of these products is Law n.6/2016 which transposes the European Directive 2014/40/UE (TPD).
In particular articles 20 and 21 of the law 6/2016 (articles 19 and 20 of the Directive 2014/40/UE)

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 they can't. It is forbidden by article 14 of the law 6/2016 (article 13 of the TPD)

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)?
The products cannot be marketed with the claim that they pose reduced risk to users' health.

4- If the products can be marketed with the claim that they reduce risks, does this information appear on the product label? If so, are there regulations to define how this information should be displayed on the label?
The products cannot be marketed with the claim that they pose reduced risk to users' health.

5- Are there any records of non-compliance with the health legislation/standard by the Tobacco Industry? If so, in which aspects?
There are few products found not compliant with the law (for example because of the refill containers contain more liquid than admitted, contain a concentration of nicotine higher than admitted, information contained in the leaflet are not sufficient, the device and refill containers are not child proof, ecc).
There are some lawsuits still pendent on advertising of electronic cigarettes on billboards.
There are many violations of the ban for online sales of ENDS, the Italian Customs and Monopolies Agency constantly monitors the physical presence on the territory or on the Internet of unauthorized shops and in case of online sales closed the websites.

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.

There are some other aspects that are not regulated by our legislation which you could take in account for a future regulation of those products, in particular:
- the device (both for ENDS, ENNDS ang HTP) should be included in the definition of the products (it could prevent the advertising of the device which is totally related to the tobacco products);
- the powerfulness of the battery, which is determinant for nicotine uptake during inhalation.

- the presence of new products which use nicotine not in tobacco leaves or in liquids but in salts. These nicotine salts are included in cartridge for e-cigarettes (like Juul) or in pouches for chewing or sucking (like Epok or Lyft).

Da: [redacted]
A: [redacted]
Cc: [redacted]
Inviato: Martedì, 1 settembre 2020 9:32:32
Oggetto: Fwd: Consultation on electronic smoking devices' regulation.

Gentilissimi,
come concordato, si inoltra la sottostante mail pervenuta dalla Brazilian Health Regulatory Agency - ANVISA per un cortese contributo di competenza al fine di dare riscontro quanto prima al richiedente.
Cordiali saluti.
Lucio Lemme

Da: [redacted]
A: [redacted]
Inviato: Lunedì, 31 agosto 2020 10:48:13
Oggetto: Fwd: Consultation on electronic smoking devices' regulation.

Da: "Coordenacao de Cooperacao Internacional - COCIN" <cooperacao@anvisa.gov.br>
A: [redacted]
Inviato: Martedì, 25 agosto 2020 19:49:04
Oggetto: Consultation on electronic smoking devices' regulation.

Dear Sir/Madam

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 your support 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 claim that they reduce risks, 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

--
Stefania Valdarnini

--
Stefania Valdarnini