

Feel free to contact us if you have any further questions or requests!

Best regards!



Sektor za splošne zadeve / *General Affairs Division*

JAVNA AGENCIJA REPUBLIKE SLOVENIJE ZA ZDRAVILA IN MEDICINSKE PRIPOMOČKE
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES OF THE REPUBLIC OF SLOVENIA

www.jazmp.si



From: SANTE-B2-TOBACCO-CONTROL@ec.europa.eu <SANTE-B2-TOBACCO-CONTROL@ec.europa.eu>

Sent: Thursday, August 5, 2021 4:08 PM

To: [redacted] @jazmp.si; [redacted] @jazmp.si; [redacted]

[redacted] @jazmp.si; [redacted] @jazmp.si

Cc: [redacted] ec.europa.eu; [redacted] ec.europa.eu;

[redacted] ec.europa.eu; [redacted] ec.europa.eu;

[redacted] @ec.europa.eu; [redacted] ec.europa.eu;

[redacted] @ec.europa.eu; [redacted] @ec.europa.eu;

sante-consult-b2@ec.europa.eu; SANTE-B2-TOBACCO-CONTROL@ec.europa.eu

Subject: RE: Nicotine pouches follow up

Dear EMACOLEX members,

We are reaching out to you regarding the emerging issue of regulation of borderline products containing nicotine. More specifically we refer to nicotine pouches. We address the EMACOLEX group, identified as the best forum for this consultation by unit SANTE B5 "*Medicines-policy, authorisation and monitoring*". Given the possible interplay between tobacco and the medicinal products legislations, unit SANTE B2 on "*Cross-border healthcare and tobacco control*" has been consulting the Expert Group on Tobacco Policy, on aspects concerning tobacco and related products legislation.

"Nicotine pouches" are (usually white) pouches/bags containing nicotine (either derived from plants or synthetic). They do not contain any constituents of the tobacco plant and are smokeless products for oral consumption, also often described as a tobacco-free version of oral tobacco (banned in the EU except for

Sweden). The pouches are intended to be placed between the upper lip and the gum, where nicotine is absorbed through the oral mucous membrane. The pouches themselves and the filler itself are not consumed but act as a container to deliver nicotine and flavour to the oral cavity.

In February 2020, a European market report on tobacco-free nicotine identified 17 brands marketed in the EU with 137 product presentations that varied in flavour, nicotine strength and portion weight. It needs to be noted that nicotine is an active ingredient of many medicinal products authorised for smoking cessation.

The European Commission has received requests from Member States regarding the most appropriate regulation of nicotine pouches since these fall out of the scope of the Tobacco Products Directive (2014/40/EU). The major challenge with these products is the absence of tobacco leaf, which is also the main difference between oral tobacco and nicotine pouches.

While these products remain unregulated in most Member States, they are accessible to anyone anywhere without fulfilling the requirements imposed to related products. More so, these products have nicotine in rather high concentrations and are attractive due to a wide variety of flavours. All of these factors together make these products a serious public health threat. We are aware that these products have been subjected to the medicinal products legislation in some Member States, while others considered their categorization as food or tobacco surrogate (specific national legislation).

In order to fully capture the current situation in Member States, we aim to consult the most relevant Member States' groups dealing with the above mentioned areas. For this reason, we would be grateful for your replies to our short electronic [survey](#) (please click on the link to access the survey). Your replies will provide an extremely valuable basis for further follow-up, both in your group as well as in the tobacco and possibly food sector (which you may wish to reach out at national level).

The full link to the survey is: <https://ec.europa.eu/eusurvey/runner/ede49243-22a9-450a-40b7-dfc44019c1a6>

We would be very thankful for your feedback **by 15 September 2021** at the latest.

Kind regards,



European Commission

Health and Food Safety Directorate General (SANTE)
SANTE B5 Medicines-policy, authorisation and monitoring



B-1049 Brussels, Belgium



European Commission

Health and Food Safety Directorate General (SANT
SANTE B2: Cross-border healthcare and tobacco c



B-1049 Brussels, Belgium

To elektronsko sporočilo in vse morebitne priponke lahko vsebujejo informacije zaupne narave, namenjene izključno naslovniku. Če ste elektronsko sporočilo prejeli pomotoma, prosimo, da obvestite pošiljatelja, sporočilo pa takoj izbrišete ali uničite. V takšnem primeru je prepovedano kakršno koli razkritje, kopiranje ali pošiljanje tega elektronskega sporočila in njegove morebitne priponke tretjim osebam.

This e-mail and its attachments are for the intended recipient only. It may contain confidential or privileged information, some or all of which may be legally privileged. If you received this e-mail by mistake you are kindly asked to notify the sender by replying to his email, and immediately delete or destroy this e-mail. You must not use, copy, print, disclose, distribute the content of this e-mail.