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Warsaw, May 15, 2026

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To the authors of the report entitled Health outcomes associated with the use of e-cigarettes, heated tobacco products, and nicotine pouches. Joint Research Centre for the European Commission, i.e.:
Perez-Cornago, A., Sarasa-Renedo, A., Jarach, C., Wollgast, J., Maragkoudakis, P.
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Dear Sirs,

I have carefully read your report to the European Commission entitled Health *outcomes associated with the use of e-cigarettes, heated tobacco products, and nicotine pouches*. This has forced me to share my comments with you.

The aim of the study is noble, but unfortunately the conclusions drawn and the methodology leave us unsatisfied, in my opinion, and I believe that it would be appropriate to make significant changes to your analysis and report.

Here are the most important observations and comments on your report:

1. The title page states the date 2026, but it is worth noting that the search for materials was completed in November 2024 ("end of report extraction 11/2024").
2. A serious weakness of your analysis is the lack of a time limit on the searched reports. Your analysis takes into account reports even from 2014, i.e. those that had to be based on primary research from even earlier years, when not only research, but also some products were not yet on the market. It seems that the time horizon of the analysis should be limited to the last 3-5 years, otherwise it is difficult to consider the presented conclusions as objective and based on up to date scientific research.
3. For all users of your report, the methodology is extremely important. It is worth noting that the report is based on secondary evidence, i.e. studies of secondary sources and the conclusions were not drawn on the basis of primary research (in accordance with the principles of EBM, evidence-based medicine). In Table 1, out of 32 items of the included reports from 2014-2024, only eight (8) are clearly marked as having been prepared on the basis of systematic reviews. What is more, as many as ten (10) reports included in the analysis are from before 2020. This seems to be a serious limitation on your work. Rejecting reports that were not based on systematic reviews and old ones (made before 2023 or at least before 2021) would lead to completely different conclusions than those presented. This is essential for the ongoing debates that are taking place and will continue to take place in connection with the update of the EU Tobacco Directive. There are many overarching pieces of legislation in the European Union that mandate the creation of EU legislation based on up-to-date and best scientific evidence – not on outdated reports that have been based on even older primary studies and that have not been compiled through a systematic review. Based on the information in Table 1, it is worth noting that, apart from one WHO report from 2015, no other WHO report included in the analysis was based on a systematic review.

4. You write several times that there are no sufficient evidence with a long follow-up period for novel products of recreational nicotine use. Note, however, that some conclusions do not require long-term studies to draw conclusions. For example, it is difficult to suspect nicotine pouches of carcinogenic effects, since the pouches do not contain tobacco toxins, but only cellulose, flavors and pharmacopoeally pure nicotine. Nicotine is not a carcinogen. Smoking regular cigarettes, on the other hand, is a serious risk factor, including cancers of the mouth, throat and larynx. Unfortunately, your report does not contain any conclusions regarding the potential harmfulness of nicotine pouches compared to regular cigarettes based on quantitative systematic analysis. Therefore, you may be interested in the analyses and conclusions from the chemical pathway of evaluation in the systematic review of primary studies indicated below.
5. From the point of view of evidence-based policy making, the most important are comparative studies with ordinary cigarettes. Quantitative analysis is of great importance here and is feasible (as the systematic review to which I refer below) has shown. Your report lacks a reference to regular cigarettes, which pose the greatest threat to public health. In my opinion, the assessment of the toxicity of regular cigarettes should not be overlooked, and the purpose of the analysis should be extended.
6. The WHO does not conduct open debates based on scientific evidence.

I am the lead author of a systematic review of primary studies in three separate evaluation tracks. I will be happy to engage in a polemic with you if there is a place and time for discussions based on the "best available evidence". You can find the analyses at the following links:

The executive summary: https://krislanda.eu/media/thr-tobacco-harm-reduction-systematic-review-przeglad-systematyczny/

Full text of 3x systematic reviews may be found at the bottom of the website: https://www.rynekzdrowia.pl/Polityka-zdrowotna/Profil-bezpieczenstwa-wzglednego-wybranych-metod-rekreacyjnego-stosowania-nikotyny-RAPORT,257571,14.html
https://www.rynekzdrowia.pl/Plik/207959.html
https://www.rynekzdrowia.pl/Plik/207960.html

https://www.rynekzdrowia.pl/Plik/207961.html

THE OVERVIEW OF INSTRUMENTS OF ANTINICOTINE POLICIES USED IN THE WORLD: https://www.korektorzdrowia.pl/kasp/instrumenty-polityki-antynikotynowej/

If some of my comments need to be corrected, something has been misunderstood by me or I have made a mistake, I kindly ask you to point it out or comment on it in any response from you.

Sincerely,

Krzysztof Łanda