Public submission from World Vapers' Alliance to the Brazilian Health Regulatory Agency

About the World Vapers' Alliance

The World Vapers' Alliance (WVA) amplifies the voices of vapers worldwide and empowers them to make a difference in their communities. Our members are vapers associations and individual vapers from all over the world. More information can be found on www.worldvapersalliance.com

About this consultation and why the World Vapers' Alliance is responding to it

The Brazilian Health Regulation Agency's (ANVISA) draft proposal of a resolution on electronic smoking devices aims to tighten the trade ban that has been in place in the country since 2009 and prohibit the use and possession of vaping products. These measures would turn millions of users into criminals.

The ban on the commercialisation of electronic cigarettes in Brazil was introduced a decade and a half ago under the belief that vaping is as bad or worse than smoking. This assumption has been largely disproved and vaping has not only been shown to be far less harmful than smoking but has also been proven to be one of the most effective tools for smoking cessation. The ban is anachronistic and unscientific and therefore should be repealed.

Moreover, the ban has not worked. Millions of Brazilians access products through the informal market, where products offer fewer guarantees of quality and safety and do not pay taxes, and where minors have easy access to products they should not have access to. In addition, the growth of a black market for vaping products controlled by mafias poses a security problem.

On the one hand, it makes millions of smokers believe that vaping is worse than smoking and prevents them from switching to a safer alternative. On the other hand, those who choose to switch are forced to buy products that are less safe than they would be under intelligent regulations. In short, the ban has been a failure.

The measures added to the ban in this proposal continue to move in the wrong direction. The World Vapers' Alliance is participating in this consultation to provide scientific evidence on vaping and the public health effects of the ban and comments on the proposed measures.

How to read this document:

ANVISA's public consultation asks whether we agree with the proposal and allows us to comment on it. We make a general comment on the proposal and explain why we disagree with it. The public consultation also allows us to respond and propose changes to each of the articles, which is why we are proposing an amendment to the proposal in its entirety. We also attach, at ANVISA's request, the bibliographical references on which we base our response.

Finally, we respond to ANVISA's question about the effects we believe the proposed regulation may have.

ANVISA: Do you support this proposed regulation?

☐ Yes

☒ I have another opinion

If you wish, please detail your opinion:

WVA:

The ban is founded on erroneous beliefs and has a very adverse impact on public health.

Vaping is much less harmful than smoking, 95% less harmful according to the UK public health agency Public Health England. Well over a hundred organisations and government institutions agree, as shown in this list compiled by The Safer Nicotine Wiki. Its lesser harm is explained by the difference in constituents compared to cigarettes and the absence of combustion, as explained by King's College London's literature review on the subject: *"the use of vaping products rather than smoking leads to a substantial reduction in exposure to toxicants that promote cancer, lung disease and cardiovascular disease."* Thus, the cancer risk of e-cigarettes compared to traditional cigarettes is less than half a percent.

In addition, vaping is one of the most efficient tools for quitting smoking. The highly regarded health NGO Cochrane run a meta-review of 88 studies and found that *"there is high certainty evidence that e-cigarettes with nicotine increase quit rates compared to nicotine replacement therapy."* A Queen Mary University clinical trial which involved 900 smokers found vaping to be twice as effective for quitting smoking as nicotine replacement therapies. There is also evidence that those who switch from smoking to vaping improve their health enormously. It has been found that smokers who switch demonstrate significant improvement in vascular health and nicotine dependence.

In short, the Royal College of Physicians summarised the role of vaping and stated that *"e-cigarettes meet many of the criteria for an ideal tobacco harm-reduction product. (...), they can in principle deliver a high dose of nicotine, in the absence of the vast majority of the harmful constituents of tobacco smoke (...)."*, while tobacco treatment Colin Mendelsohn concluded that *"the overall benefits of vaping are considerably greater than the harms and are likely to improve public health."*

In summary, vaping can help millions of Brazilians quit smoking and improve their health. In turn, it would reduce the costs of treating smoking-related diseases borne by the national public health system. However, the ban promotes the belief that vaping is as bad or worse than smoking, discouraging millions of smokers from switching to this less harmful alternative.

In addition, the ban on the commercialisation of vaping devices has been a failure. Devices continue to be accessible on the black market, with an estimated 4 million users in Brazil. Of course, on the black market, the devices offer fewer guarantees than they would on the legal market. The ban has also failed to protect minors, 25% of whom are estimated to have had access to e-cigarettes on the informal market.

The ban has only succeeded in preventing many smokers from switching to a safer alternative, in making access to products more difficult for adult vapers and exposing them to greater risks, and in allowing minors to vape. Therefore, insisting on a ban and also banning the use and

possession of vapes is a very serious mistake that will criminalise more than 4 million Brazilians. Brazil needs to reject the prohibition and follow the example of countries that have adopted smart regulation and promote vaping among smokers, such as the UK and Sweden.

ANVISA: Draft: Prohibits the manufacture, import, commercialisation, distribution, storage, transport and advertising of electronic smoking devices.

WVA: Draft – WVA's Proposed amendment: Legalises and regulates the manufacture, import, commercialisation, distribution, storage, transport and advertising of electronic smoking devices.

WVA: Draft – WVA's Justifications/comments: As explained in our comments to the proposal and cited in the bibliographical references, vaping is less harmful than smoking and the most effective smoking cessation tool. It should be treated and regulated as such.

The lower harm profile of vaping and its widespread use as a smoking cessation aid should rule out the prohibition which, in addition, has been a complete failure. The prohibition has only damaged public health in Brazil, allowing minors to access the products, posing risks to adult vapers and preventing smokers from switching.

Vaping should be legalized and regulated in Brazil accordingly. A smart regulation should be implemented to allow smokers to switch. The regulation should therefore make vaping products available and accessible to adult smokers while preventing minors from vaping.

ANVISA: Bibliographical references: If you wish, please provide bibliographical references below to support your argument.

WVA:

1. Public Health England. (2015). *E-cigarettes: an evidence update.* Public Health England, London.
2. Institute of Psychiatry, Psychology and Neuroscience (2022). *Nicotine vaping in England: 2022 evidence update.* Report commissioned by the Office for Health Improvement and Disparities in the Department of Health and Social Care, carried out by King's College London academic.
3. Stephens, W. E. (2018). Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke. *BMJ Publishing Group Ltd, 27*(1), 10-17.
4. George, J. et al. (2019). Cardiovascular Effects of Switching From Tobacco Cigarettes to Electronic Cigarettes. Journal of the American College of Cardiology, 74(25), 3112-3120.
5. Klonizakis, M. et al. (2021). Short-Term Cardiovascular Effects of E-Cigarettes in Adults Making a Stop-Smoking Attempt: A Randomized Controlled Trial. Multidisciplinary Digital Publishing Institute, Biology 2021(10), 1208.
6. Carusso, M., Emma, R., & Distefano, A. (2021). Electronic nicotine delivery systems exhibit reduced bronchial epithelial cells toxicity compared to cigarettes: the Replica Project. Scientific Reports, 11(24182).
7. Tobacco Advisory Group of the Royal College of Physicians. (2016). Nicotine without smoke: Tobacco harm reduction. Royal College of Physicians, London.

8. Kosterman, R. et al. (2022). Is e-cigarette use associated with better health and functioning among smokers approaching midlife? Drug and Alcohol Dependence, 234, 109395.
9. Mendelsohn, C. et al. (2022). A critical analysis of 'Electronic cigarettes and health outcomes: Systematic review of global evidence. Drug Alcohol Review, 41(7), 1493-1498.
10. Holt, N.M., Shiffman, S., Black, R.A. et al. Comparison of biomarkers of exposure among US adult smokers, users of electronic nicotine delivery systems, dual users and nonusers, 2018–2019. Sci Rep 13, 7297 (2023)
11. Public Health England. (2015). E-cigarettes: an evidence update. Public Health England, London.
12. Institute of Psychiatry, Psychology and Neuroscience (2022). Nicotine vaping in England: 2022 evidence update. Report commissioned by the Office for Health Improvement and Disparities in the Department of Health and Social Care, carried out by King's College London academic.
13. Stephens, W. E. (2018). Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke. BMJ Publishing Group Ltd, 27(1), 10-17.
14. George, J. et al. (2019). Cardiovascular Effects of Switching From Tobacco Cigarettes to Electronic Cigarettes. Journal of the American College of Cardiology, 74(25), 3112-3120.
15. Klonizakis, M. et al. (2021). Short-Term Cardiovascular Effects of E-Cigarettes in Adults Making a Stop-Smoking Attempt: A Randomized Controlled Trial. Multidisciplinary Digital Publishing Institute, Biology 2021(10), 1208.
16. Carusso, M., Emma, R., & Distefano, A. (2021). Electronic nicotine delivery systems exhibit reduced bronchial epithelial cells toxicity compared to cigarettes: the Replica Project. Scientific Reports, 11(24182).
17. Tobacco Advisory Group of the Royal College of Physicians. (2016). Nicotine without smoke: Tobacco harm reduction. Royal College of Physicians, London.
18. Kosterman, R. et al. (2022). Is e-cigarette use associated with better health and functioning among smokers approaching midlife? Drug and Alcohol Dependence, 234, 109395.
19. Mendelsohn, C. et al. (2022). A critical analysis of 'Electronic cigarettes and health outcomes: Systematic review of global evidence. Drug Alcohol Review, 41(7), 1493-1498.
20. Holt, N.M., Shiffman, S., Black, R.A. et al. Comparison of biomarkers of exposure among US adult smokers, users of electronic nicotine delivery systems, dual users and nonusers, 2018–2019. Sci Rep 13, 7297 (2023)
21. George, J. et al. (2019). Cardiovascular Effects of Switching From Tobacco Cigarettes to Electronic Cigarettes. Journal of the American College of Cardiology, 74(25), 3112-3120.
22. Foulds, J. et al. (2021). Effect of Electronic Nicotine Delivery Systems on Cigarette Abstinence in Smokers With No Plans to Quit: Exploratory Analysis of a Randomized Placebo-Controlled Trial. Nicotine & Tobacco Research, 24(7), 955-961.
23. Niaura, R. (2016). Re-thinking nicotine and its effects. Truth Initiative, 3.

ANVISA: If you wish, you can insert a file.

WVA: https://worldvapersalliance.com/harm-reduction-vaping-fact-sheet/

ANVISA: You think the proposed regulation will have:

☐ A positive impact

☒ A negative impact

☐ A positive and negative impact

Describe the negative impacts here:

WVA:

The negative effect of the prohibition outlined above will be magnified. Millions of Brazilian smokers will continue to believe that vaping is as bad or worse than smoking, they will continue to smoke, and smoking-related diseases and deaths will not stop in Brazil. The Brazilian state will have to continue to allocate large amounts of resources to the treatment of these diseases. All this could have been prevented if vaping had been legalised and regulated and if its use had been promoted as a smoking cessation tool.

The black market will continue to grow and minors will have easier access to products of dubious quality on it. The criminal organisations that control it will become stronger and Brazil's security problem will worsen.

More than 4 million current users of vape products will be criminalised and treated as offenders. Many will be forced to quit vaping and return to smoking, risking their lives and the health of themselves and those around them.

WVA's conclusion remarks:

Vaping has been proven to be substantially less harmful than smoking and a great tool to quit smoking. Therefore, we urge the Brazilian authorities to consider all the evidence supporting vaping as a smoking cessation tool and take the necessary measures to make vaping products available for adult smokers while away from minors.

A comprehensive review of the literature can be found in our Vaping and Harm Reduction Fact-Sheet here: https://worldvapersalliance.com/harm-reduction-vaping-fact-sheet/

For any questions or comments, please contact the submitter of the response.