Review of: "Evidence-based policies benefit the men and women who smoke"

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The paper focuses an important issue in public health: the production of evidences to inform decision making processes in public health policies towards smoking individuals. However, considering the authors' arguments on the need of scientific evidence for design and implementation of tobacco regulations in view of innovative smoke-free products, it is important to highlight that the paper presents numerous problems from the beginning. The title of the paper is misleading, since the text neither presents an in-depth discussion on the scientific evidences on the so-called innovative smoke-free products nor analyzes evidence-based policies that showed benefits for men and women who smoke. In addition, the authors of the paper declare that there are “no potential competing interests", although all three authors indicate that they "are employees of Philip Morris International" under “Funding”. Throughout the text, the authors indicate that their intention is to review the “recent WHO study group on tobacco product regulation (TobReg) report”, and to highlight the need for proper use of scientific evidence to support reports of international organizations that are intended to support public policy decision making at national level among countries worldwide. However, the authors fail to indicate the scientific evidence that supports their arguments, according to the elements presented below:

- Page 2, first paragraph: The authors claim that "Philip Morris International has dedicated over two decades to developing and assessing smoke-free products with the potential to reduce the harms and risks of smoking. These smoke-free products do not burn tobacco, and as a result emit significantly lower levels of harmful and potentially harmful chemicals (HPHCs) than cigarettes"; yet, there are no references to studies on the evidence that there are “significantly lower levels of harmful and potentially harmful chemicals". In the following paragraph, the authors state that “These new products are not risk-free, and they deliver nicotine, which is addictive";
- Page 2, second paragraph: The authors state that "Today however, the WHO has yet to leverage the language in the FCTC to encourage the development of products that have the potential to reduce the harms caused by smoking. Nor have they established policies that enable and encourage adult smokers who do not quit to instead switch to smoke-free alternatives"; however, it seems to me that the tasks proposed should not comprise responsibility of an international organization directed towards health promotion and disease prevention. Encouragement to develop new products and enabling adult individuals to switch products should be tasks of enterprises with their R&D and marketing teams;
- Page 2, third paragraph: The authors accuse that "Key pieces of scientific evidence have been omitted, resulting in conclusions that are misleading, and some of the scientific evidence has been exaggerated in a way that misrepresents the original content and context of the findings", and that "undue emphasis is placed on minor findings in order to

discredit and undermine some of the key conclusions". Although it is a very serious accusation, there are no examples on these alleged malpractices, and there are no references of studies published in the literature that could indicate the "proper" scientific evidence;

- Page 3: The authors argue that "there is a clear and worrying disconnect between scientific evidence and conclusions and recommended policy", and accuse the report to contain "science-focused chapters" that "have been framed in order to support a predefined set of conclusions and policy recommendations" in detriment of the population health, yet, there are no specifics on the framing indicated on these serious accusations;
- Page 3, first paragraph: The authors indicate that "this response is not a comprehensive point-by-point analysis of the report"; however, it is my understanding that the paper should be a better piece on evidence-based policies if the authors dedicated time to perform an in-depth analysis of the report and, besides presenting their concerns, pointed out directly the issues on the report and showed directly the scientific evidence that supports their point of view. It is not possible to establish a scientific dialogue if one part does not show the evidence of interest. In addition, the authors proceed indicating that "we are sharing our perspective, based on our scientific research and understanding, as well as our knowledge of adult smokers"; however, none of the references in the paper refers to "their research", unless the authors are mentioning "understanding", "knowledge" and "scientific research" that were performedd only for market research purposes and, therefore, are confidential and not supposed to be shared with the scientific community;
- Page 3, third paragraph: The authors indicate that “adult smokers” should be able to have "access to products that are a better choice than continuing to smoke cigarettes" ; however, the whole paper bases its arguments on substitution instead of quitting smoking. Yet, there are no mentions to differences in prices or to differences in types of smoke-free products (that may be manipulated to use other substances than the originally intended), which could be important barriers to current smokers (in the case of prices) or could lead to other important public health issues (in the case of misuse of the smoke-free devices currently available, like the open-tank systems mentioned further in the fourth paragraph);
- Page 3, fourth paragraph: The authors indicate that "e-cigarette users in Great Britain are using open tank systems" that "pose a challenge for regulators"; yet they fail to acknowledge the worst implications of the product: smokers substituting cigarrettes for e-cigarrettes may use substances that produce more harm in comparison to traditional cigarrettes, therefore, how could a "real world" study designed to provide scientific evidence to support public policy ignore that the device may be worst than other options?
- Page 4, first paragraph: The authors state that there is information "substantiated by peer-reviewed scientific data from the manufacturer", although they did not include any references on the subject;
- Page 4, second paragraph: The authors claim that "Policy decisions should be informed by the entirety of the available scientific evidence base", whilst they do not present any available scientific evidence base in their paper;
- Page 4, second paragraph: The authors criticize the absence of engagement of the tobacco industry in the discussion presented in TobReg report, although other regulated sectors ("pharmaceutical products and medical devices") are usually involved in the discussion pertaining their products. However, it is important to point that: (1) the pharmaceutical products and medical devices are dedicated to treat and recover individuals' health, whilst tobacco products are not; and (2) these sectors usually invest resources on R&D based on clinical research and real world

assessment of products, and they publish their results in scientific journals, whilst the tobacco industry not always disseminate the results obtained in their research. In the same paragraph, the authors accuse that 'TobReg report minimizes the contribution of industry science and expertise, and their data are either outright ignored or misrepresented"; however, they do not indicate any part of the data, studies, references and other potential evidence from the industry throughout the paper;

- Page 5, first paragraph: The authors argue that there is a "disconnect between their recommendation that the burden of proof for product claims lies with the manufacturer" , although there is no mention in the references cited that may comprise a piece of evidence from the industry throughout the paper produced by members of the industry…It is important to question how many studies were necessary to bring to light the evidence on the harms of smoking traditional cigarrettes decades ago? How the burden of proof on product claims of the tobacco industry worked then? Why is it different now? On the same paragraph, the authors question that "Products simply cannot be scientifically substantiated prior to commercialization without the companies commissioning and funding studies. It would be extraordinary to expect that burden of substantiation to be placed on noncommercial entities"; however, they acknowledge that this works for pharmaceutical and medical devices companies;
- Page 5, second paragraph: The authors claim that "there is a growing body of independent evidence on the risks and potential benefits of novel and emerging tobacco and nicotine products", although they do not cite any piece of such evidence. In addition, they do not cite any references on the arguments on the "encouraging declining trend in the hospital admission rate for both ischemic heart disease and chronic obstructive pulmonary disease (COPD) exacerbations that temporally coincide with the introduction of heated tobacco products like IQOS";
- Page 6, third paragraph: The sentence shows a potential reference or footnote that is not shown anywhere in the text: "the understandability of the risk messages[xvii]";
- Page 7, first paragraph: The authors declare that "When communicating to non-smokers, describing the absolute risks is important, whereas when communicating with adult smokers, a comparison with both the risk of on-going smoking and smoking cessation becomes important. For this audience, it is also important that they understand that there is an absolute risk of using these products"; it would be important to indicate which communication strategies could deal with these different approaches for diverse individuals spread throughout the population, since one-by-one communication would be very expensive;
- Page 7, second paragraph: The authors indicate that studies mentioned in TobReg "compare the results of smoke-free products exposure to fresh air instead of cigarette smoke exposure"; yet, if there is sufficient evidence on the superiority of substitutes (as claimed by the authors), why is it necessary to perform other studies comparing smoke-free products to cigarette smoke exposure?
- The section "New products require new and standardized analysis methods" presents one of the few contributions of the paper to the field of knowledge (although maybe not the most original one) by indicating the "need for standardization in the survey questions, product use definitions or categories, sampling population and methods and follow-up intervals"; although it makes clear that the authors are not familiar with scientific research when describing studies as "snapshot in time vs. follow-up over time" (page 8, first paragraph);
- Page 8, first paragraph: The authors claim that there is need to "understanding about what is happening in the real

world"; however, most of their claims in relation to scientific research refers to performing clinical trials (which do not deal with real world conditions);

- The remaining of the text simply synthesizes the arguments in the text, claiming individuals from differerent organizations to gather and discuss about the subject, bringing no new information to the reader;
- Finally, 8 out of 15 citations in the text are really old (more than 10 years of publication).