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By email:

Secretary Ramon Lopez
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FDA draft General Guidelines for the Regulation of Vapor Products and Heated Tobacco Products

Dear Dr. Domingo

We are writing as long-standing specialists in public health and tobacco control (see About the authors). We would like to make some general points then specific observations regarding the draft guidelines for the regulation of vaping and heated tobacco products[1]. These products are alternatives to cigarettes with much lower risk to the user and could play a significant harm reduction role in addressing the disease burden of smoking. As the FDA makes its policy in this area it is essential to assess the available science and regulatory options within a logical framework that considers, in particular, the plausible and likely unintended consequences of regulation. ***We believe that many of the regulatory measures proposed will have serious and harmful unintended consequences. These will protect the cigarette trade from competition and innovation, implicitly promote smoking and have harmful consequences for public health in the Philippines.***

1 General principles

1. **Non-combustible products are much safer.** Nicotine and tobacco products that do not involve combustion are, beyond any reasonable doubt, far less harmful than smoking products and may pose minimal risk overall. This is because almost all the tobacco-related harm is caused by *smoke* – the inhaled toxic products of combustion of cured tobacco leaves. While it is difficult to make a precise estimate of the reduction in risk arising from avoiding combustion, it is likely to be one to two orders of magnitude – crudely, a 90-99% lower risk.

2. **Non-combustible products are displacing smoking**. There is compelling evidence that e-cigarettes are substitutes for smoking – mostly by helping smokers to quit or by diverting users from becoming smokers. The evidence from randomized controlled trials, observational studies, and population data converges on reduced risk products displacing smoking and having a beneficial impact on health. This is also consistent with countless testimonials from users who have struggled to quit smoking by alternative means. There is no evidence to support 'gateway effects' from low-risk to high-risk products. The net flow is strongly in the other direction.

3. **Regulators need to focus on unintended consequences of regulation**. From the two observations above, it follows that the most significant challenge for a regulator is avoiding inadvertently causing harmful unintended consequences. That means the harmful effects of mandating restrictions, burdens, costs, or communications that have the effect of making

[1] Food and Drug Administration (Philippines), *General Guidelines for the Regulation of Vapor Products and Heated Tobacco Products, Draft for consultation*. Accessed 4 June 2020 [link]

smoking relatively more attractive and making switching to low risk products more difficult, less appealing or more expensive. The Royal College of Physicians (London) in its 2016 report highlighted this danger:

> However, if [a risk averse and precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (*Nicotine without Smoke: tobacco harm reduction*, Section 12.10 page 187 – link)

4. **Harms from regulation are plausible and significant**. The key insight is that, despite good intentions, regulation in this field can have exactly the opposite of the effect intended – it can protect the cigarette trade, support the tobacco industry and promote smoking. There are very few examples of governments recognising the risk of poorly designed regulation and no sign it is understood by officials at the World Health Organisation. In section 2 of this submission, we examine where many of the provisions in the guidelines for regulation have plausible unintended consequences leading to more smoking and ill-health, not less.

5. **Risk-proportionate regulation resolves the regulator's dilemma**. The question for regulators is how to achieve the 'balance' mentioned by the Royal College of Physicians, given this is a treacherous landscape in which a regulation can work in the opposite way to that intended. The answer is to use 'risk-proportionate regulation'. That means the strength of regulation should be proportionate to the risk the product poses to users, with the aim of encouraging migration from high-risk to low-risk products. The table provides examples of how this should work:

Measure	**Cigarettes, hand-rolling tobacco and other combustibles**	**Vaping, heated tobacco smokeless and oral nicotine**
Taxation	High taxes	Low or zero tax (sales tax only)
Illicit trade	Track and trace (FCTC protocol)	Complaint-driven
Advertising	Prohibit other than within trade	Control themes and placement
Warnings	Graphic warnings depicting disease	Messages encouraging switching
Plain packaging	Yes	No
Ingredients	Control reward-enhancing additives	Blacklist material health hazards
Flavours	Prohibit	Allow, subject to health hazards
Flavour descriptors	Not applicable if flavours banned	Control appeal to youth/trademarks
Age restrictions	No sales to under-21s	No sales to under-18s
Internet sales	Banned	Permitted with age controls
Product standards	Control risks and reduce appeal	Control risks

2 Specific issues with draft Philippines FDA guidelines for regulation

6. **The guidelines understate both the public health support for tobacco harm reduction and the strength of the evidence to support it.** The introductory analysis (Part I Background/Rationale) understates the degree of support for vaping and heated tobacco products as a public health harm reduction strategy among public health experts and academics. For example, seventy-two international experts wrote to the Director General of the World Health Organisation calling on him to reassess the agency's hostility to these products: *Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction*, October 2018 [link]. The evidence supporting this strategy is strong: the products show much lower risks and it is clear that they have the effect of reducing smoking uptake and accelerating declines in smoking prevalence and cigarette consumption. While there will always be some uncertainty about the long-term risks (in both directions) and population effects, *the extensive data we do have* are compelling and show these products are highly beneficial to public health and that should be the operational assumption of regulators in this field unless and until there is conflicting data.

2.1 Marketing Authorisations

7. **Pre-market authorisation for certain vaping and heated tobacco products (1.5 & 1.6 and Section 6) favours the cigarette trade.** The requirements for pre-market authorisation represent significant costs and delays for manufactures and may prove to be an excessively high barrier to entry. This may mean the PMAs are never made and the process functions as a *de facto* prohibition for the products that require PMA or applications are only made by cash-rich tobacco companies that can afford to cross-subsidise the regulatory burdens imposed on reduced-risk products from their cigarette revenues. The high costs and technical demands are compounded by a lack of transparency about what the data will be used for, how the applications will be evaluated and what the pass/fail criteria will be. In this sense, the draft guidance is copying the worst features of the highly burdensome and bureaucratic system that is being slowly introduced in the United States (we have yet to see what effect that system has on the marketplace, so the US does not form a reliable precedent). The process as set out is a significant barrier to market entry and innovation that will favour large companies in the vaping and heated tobacco market and the cigarette trade, which is not subject to pre-market application even though combustible tobacco products are far more harmful and more addictive than vaping or heated tobacco products. The likely effect will also be to stimulate cross-border legal and illicit trade for the product categories subject to pre-market application. The PMA should be reserved only for novel products and potentially novel risks and the *notification* approach used in the European Union adopted instead for vaping and heated tobacco products.

8. **Heated tobacco products should not face excessive barriers to entry or unnecessary restrictions (1.6) – the proposal favours the cigarette trade**. These products have been instrumental in cutting cigarette volumes by around one-third in Japan – a major public health victory. These products have succeeded in Japan through ease of access to the market, relatively light regulation of marketing and low taxation – risk-proportionate regulation. The FDA's restrictive proposals for HTPs will protect the Philippines cigarette trade from the type of competition cigarettes have experienced in Japan, at a cost to public health. There is no reason to require pre-market authorisation for products that are widely used in in many countries

without any problems. The US FDA's PMTA process for the iQOS has not achieved anything of value, but delayed introduction of the product and has so far excluded equivalent competitors, It meant that Americans could only have access to the first generation iQOS product while Europeans and Japanese consumers could access the third generation and product innovations for safety and usability as they become available.

9. **Limit of 20mg/ml for e-liquids without pre-market authorisation (1.6) favours the cigarette trade**. This is an unnecessary barrier to products, such as Juul, that have been highly successful in helping smokers to switch to vaping. These products use stronger liquids because of their small size and small batteries can only vaporise lower volumes of liquids. For smokers seeking a given nicotine dose, a lower volume of liquid will need a higher concentration of nicotine. The smaller size, simplicity and convenience of products like Juul is critical in helping smokers take the first step to switching. More generally, stronger liquids are important to reach the heavier, more dependent smokers, to help novice vaping users as they become accustomed to using new products and to encourage those who have tried to use vaping products in the past and found them too weak. Smoking products provide a nicotine dose and pharmacokinetic profile that is rarely matched by safer alternatives, but cigarettes do not have to be evaluated for 'abuse liability' or addictiveness. The proposal will help to protect the cigarette trade by making it harder to provide products that assist in the transition from smoking to vaping – a market barrier to entry that favours the tobacco industry and presents a barrier to switching that harms the consumer.

2.2 Products Standards

10. **Schedules of prohibited ingredients (Section 2 and Annex A & B) will make lower-risk products less competitive, inhibit switching and encourage prolonged smoking, and protect the cigarette trade.** The regulatory strategy for ingredients and contaminants should focus primarily on preventing the use of hazardous agents in quantities that pose a material risk to users, novel risks and psychoactive agents other than nicotine. The approach in Annex A & B goes far beyond this and *attempts to reduce the appeal of these products* by banning substances that are not hazardous, such as flavours or colours, at least in the quantities used in vaping or heated tobacco products. By using ingredients regulation to make the low-risk products *less attractive* (not merely less risky), the FDA is implicitly making cigarettes *relatively* more attractive, making switching less appealing and making prolonged smoking more likely.

11. **The ban on flavoured vaping liquids other than tobacco and menthol (Annex A part 2.9) is illogical and offers great protections to the tobacco industry**. The ban on flavours is especially ill-conceived as these products are inherently flavoured and there is no logic for only permitting the flavours that most closely resemble those available in cigarettes. Most smokers who take up vaping want to embark on a journey away from their life as smokers and seek out flavours like fruit or desserts to emphasise the difference. This is probably the single largest protection of the cigarette industry in the regulation and should be urgently reconsidered. There is no compelling evidence that particular flavours drive youth uptake of vaping, though if the whole product category is made unattractive to adults, it would likely be less attractive to adolescents as well. Youth vaping is driven primarily by curiosity, the social environment and emulating the actions of adults. To the extent that regulatory prohibition of vaping flavours supports cigarette use

among adults, it is also likely to have the same effect among adolescents. However, making products unattractive to adults is the wrong way to address youth uptake of adult products.

12. **Regulation of heated tobacco products as specified would make the category unviable (2.1 Annex B part 3).** Annex B (3) states "*Nicotine content per unit refill or cartridge of heated tobacco products (HTPs) shall not exceed 1 mg*". Cigarettes typically have nicotine *content* up to 15mg per stick. We would expect heated tobacco product refills typically to have 4-7mg of nicotine content, given they are made primarily from tobacco. The specification of 1mg may reflect a confusion between nicotine *content* (the mass of nicotine in the product) and nicotine *yield* (the mass of nicotine deposited on a filter when the product is mechanically smoked to an established protocol). These are quite different. A nicotine yield limit of 1mg nicotine applies in the European Union legislation. It is a limit for *yield*, not a limit for *content*.
13. **The ban on menthol in heated tobacco products (Annex B part 13) helps the cigarette trade.** If menthol is not banned in cigarettes, many smokers who want menthol will remain using menthol cigarettes. If menthol cigarettes are banned, it will likely be available on the black market. Even if menthol cigarettes are banned and unavailable, those preferring menthol will no longer have the pathway to a reduced-risk tobacco product (heated tobacco). Some may switch to menthol vaping, but others may stay with smoking and give up menthol. There is no logic or public health rationale to limit choice in a way that confers advantages to the cigarette trade.

2.3 Labelling and Packaging

14. **Use of graphic health warnings (Annex C part 4, Annex D part 3) miscommunicates relative risks and favours the cigarette trade**. There is no scientific basis for using warnings suggesting heated tobacco or vaping products have equivalent risk to cigarettes. The warning conveys risk in a variety of ways: its subject matter, graphic impact, size, colour, position etc. By using the same stylistic techniques as for warnings on cigarettes, the FDA is implying the risks are similar in nature (i.e. the same diseases and other risks) and similar in magnitude. This is not the case on either count. It means citizens are being implicitly misled about risks to health arising from use of these products, in a way that will discourage switching and prolong smoking.

2.4 Sale, Use, and Access Restrictions

15. **Banning online sales of vapour and heated products (4.1) will favour the cigarette trade and promote black and grey market activity**. Cigarettes are widely accessible throughout the Philippines and can be purchased in many shops and street corners. The oligopolistic structure and relatively homogenous nature of the product means a small number of producers can develop full distribution infrastructure with relatively few products – they have major advantages on account of their existing dominant position in the marketplace. The low-risk alternatives, by contrast, are market entrants, highly diverse, and have low volume per product line. They are evolving rapidly with innovation and new enterprise creating a product cycle of a few months. It is hard for such companies to develop a large-scale distribution infrastructure for the broad range of products and product variants available. This means online retailing is essential and the only practical way of holding the necessary inventory. The likely effect of the prohibition of internet sales will be two-fold: (1) to reduce consumer access and choice in a way

that benefits the cigarette trade; (2) to encourage internet sales across borders, for example from the major Chinese and Hong Kong based retailers. This will make the market harder to regulate and may present risks of unregulated products entering the market. A well-regulated internet-based trade for vapour and heated products is necessary and forward-looking.

16. **Age restrictions (4.3) should not create barriers to young adults switching to much safer products.** By the age of 18, there are already many young smokers in the Philippines regardless of the law and the good intentions of regulators. There is no reason to prevent them from switching to much safer products that substitute for the most harmful products. This regulation potentially allows another three years for a cigarette habit to become entrenched. The appropriate policy would be limit legal sales to 21 years for smoking products and 18 years for low-risk alternatives.

17. **Restrictions on vaping and HTP use product use indoors (4.6) will obstruct switching, promote relapse to smoking and protect the cigarette trade.** Smoking and vaping or HTP use should be treated differently, reflecting the very different risks posed to bystanders – these are negligible in the case of heated vapour products. However, there may be reasons for owners or managers to ban vaping in their private premises – for nuisance or aesthetic reasons, to reflect consumer preferences, for food hygiene, or because children may be present. The appropriate policy is to allow *the owner or manager* of premises to determine the vaping policy. If this can be done by designating vaping areas at will then this policy will work. However, overly restrictive policies on where low risk products can be used will degrade the incentive to switch. Forcing vapers into designated smoking areas will increase the likelihood of relapse. The results will be support for the cigarette trade and more smoking and more ill-health, not less.

2.5 Advertising, Promotion, and Sponsorship

18. **Bans on advertising and promotion of vapour and heated tobacco products (5.2, 5.5-5.8) will protect the cigarette trade from competition and obstruct innovation.** The draft regulation confines advertising to retail outlets selling vaping or heated tobacco products: "*Advertising activities shall be strictly prohibited except in FDA-licensed retail outlets for vapor products and HTPs*". This offers a great advantage to the incumbent tobacco trade, shielding cigarettes from competition by lowering consumer awareness and understanding of alternatives. Advertising is necessary to raise public awareness about new options to replace smoking and to encourage smokers to try to switch. Advertising is important in conveying advantages of new products and innovations. By confining advertising to retail outlets licensed to sell these products, the regulation would reduce advertising reach to those already interested and aware. In the case of retail outlets selling both established tobacco products and new low-risk products, the retailer has mixed incentives and may face pressure from wholesalers or tobacco manufacturers not to advertise competitor products. The appropriate way for a regulator to conceptualise advertising for low-risk alternatives to smoking is as 'anti-smoking advertising' with public health value provided at no cost to the public sector. The appropriate way to regulate advertising of these products is to control content and placement likely to attract younger people. For example, the restrictions specified in 5.3 and 5.4 could be developed and applied to advertising in a wider range of settings permitted for advertising.

3 Conclusion

As set out above, we are concerned that much of the proposed regulation of vaping and heated tobacco products will not serve its intended purpose but will have the unintentional effect of protecting the cigarette trade, prolonging smoking and damaging public health in the Philippines. It is not advisable to design the regulation of vaping and heated tobacco products without reference to the effect this could have on smoking behaviour, given smoking carries much higher risks. Regulators should also consider carefully their responsibilities to consumers, who are trying to protect their own health at their own expense and on their own initiative. There is no case to use regulation to obstruct responsible pro-health consumer behaviour. The danger is driving well-intentioned consumers towards black or grey market suppliers and less reliable products, making it more attractive to continue smoking or, worse, provoking relapse from vaping to smoking.

The proposed regulatory framework will support the short-term interests of the tobacco industry in three main ways. First, the regulations protect the cigarette trade from competition from new technology. Second, the regulations are less of a challenge to the vaping and heated tobacco businesses within tobacco companies. These are large scale undertakings have technical resources and the opportunity to cross-subsidise from cigarette sales whereas the regulation presents serious barriers to entry to their smaller, more specialised competitors. Third, the regulations will put a brake on the pace of innovation in the Philippines market, meaning the tobacco companies will be less exposed to disruptive entrants. The rest of the market would be supplied by unregulated black markets and cross-border internet sales rather than smaller scale legitimate domestic businesses.

4 Recommendation

We recommend a pause in the development of these regulations to assess the risk of plausible unintended consequences and to consider options for risk-proportionate regulation. This analysis should be developed as a part of an impact assessment for the regulatory proposals.

We hope these views are helpful. We are of course willing to follow up with more detail and address any questions, should that be of interest.

Yours sincerely

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