Feedback on Draft Australia National Tobacco Strategy 2022-2030

Submission by the Africa Harm Reduction Alliance (AHRA), 22nd March 2022

1. About the authors.
   We are South African physicians who have sub-specialised in harm reduction science and policy matters, relevant to alcohol, tobacco, food, drugs, HIV and Covid-19.
   We are co-founders of the Africa Harm Reduction Alliance (AHRA). This non-profit organisation promotes harm reduction as a public health tool to prevent and control disease and premature death, linked to lifestyle habits and abuse of various activities, including alcohol, sugar, tobacco and drugs. AHRA fully supports tobacco control, as outlined in the Framework Convention on Tobacco Control (FCTC), and specifically, tobacco harm reduction (THR) as a public health strategy (Article 1d of the FCTC).

2. Plea to consider tobacco harm reduction (THR) as part of tobacco control. This document is a plea for the consideration and inclusion of tobacco harm reduction science, preferred regulatory frameworks and regulated products in tobacco control. These elements should enable consumers to move from the most harmful to least harmful products containing tobacco and / or nicotine.

3. Overhaul of regulation needed to save lives. We write to recommend a complete overhaul of the approach to tobacco harm reduction in Australia. In general, it seems as if the government, regulators and public health establishment are overly focused on trivial or implausible risks, while downplaying or ignoring the very considerable public health opportunities and manageable risks. Vaping (e-cigarettes), oral nicotine pouches and heated tobacco products, as well as other tobacco harm reduction options are beneficially disruptive to the tobacco and nicotine market. Moreover, they are also disruptive, but complementary to Australia's model of tobacco control. If these THR products can be regulated within sound, evidence-based product standards, as intended for adult smokers (not youth), with cognisance of environmental protection and be traceable to combat illicit trade, it promises to provide a net benefit to public health in Australia.

4. Innovation. Policymakers in Australia should challenge opponents of innovation. Throughout history, valuable innovations have met resistance from entrenched interests threatened by new approaches to addressing longstanding problems. Currently, the Australian model of tobacco control strongly favours punitive, restrictive and coercive measures imposed by the state.

The idea of innovative producers interacting with empowered and well-informed consumers in a regulated market – in which smokers control their own risks, on their own initiative, and at their own expense – is counter-cultural and simply not a level playing field. While probably not its intention, the effects of the Australian National Tobacco Strategy regulatory hostility to safer alternatives to smoking are to protect the cigarette trade, obstruct Australian cigarette smokers from quitting smoking, and add to the burden of smoking-related disease.

5. Evidence. (As reference, please use the free, downloadable E-book on tobacco harm reduction, available at tobaccoharmreduction.net). The evidence is strong and accumulating. The arguments for a different approach to tobacco harm reduction and nicotine policy are not new and their credibility has only strengthened with time and as more evidence and data become available.

6. Institutional bias and inertia. Despite a robust evidence base in favour of THR, the Australian government, regulators and public health establishment have unfortunately become more hostile and *less* open-minded to tobacco harm reduction. The heart of the problem is the institutional biases of those making and influencing the policy and regulatory decisions. Rather than to regard THR as a complementary measure to save lives, the tobacco control community has not fully embraced the potential benefits of tobacco harm reduction, most importantly, to prevent disease and premature death in cigarette smokers.

7. THR products – an evolving solution for adult smokers. For those adult smokers who cannot or will not quit tobacco (primarily cigarettes), a range of much safer products has emerged over the last 10 years, acting as a "fire escape". These products also make tobacco harm reduction a realistic and practical public health strategy for most smokers. There are broadly four categories of products that support tobacco harm reduction. Their common defining feature is that they allow for nicotine use, but with no combustion of tobacco and inhalation of smoke. These are:

    a. Vaping products (e-cigarettes)
    b. Oral nicotine pouches
    c. Heated tobacco products
    d. Oral tobacco pouches (such as "Swedish snus")

8. Reduced risk. Switching from smoking to smoke-free products greatly reduces risk. Nicotine is the most important reason why people smoke, but nicotine itself is not the cause of the disease burden. All the low-risk products share a common characteristic – they do not involve combustion (burning) and there is no smoke to inhale. They however, do provide nicotine and can satisfy smokers who would not otherwise wish to quit or would find it hard to quit. They are much less harmful – with likely risk reductions of one to two orders of

magnitude – though not harmless. When a smoker completely switches from smoking to a low-risk product, he/she avoids nearly all the incremental health risks of continued smoking. This allows for "harm reduction", a well-established concept in public health policy, for example with drugs, alcohol and HIV. Dr Letlape was intimately involved in campaigning for access to anti-retroviral therapy for HIV patients in South Africa, which is a recognised form of harm reduction. Likewise, Dr Human has been involved in harm reduction in drugs, alcohol, food and tobacco for the last 25 years.

9. The evidence for the reduced relative risk of smoke free products is strong. We invite you to read the Science section of the THR book in tobaccoharmreduction.net. This outlines the evidence for radically reduced risk from the basic physical and chemical processes involved and the toxicology of emissions.

10. Absolute risks are also very low. When a nicotine user switches from smoking to using smoke free products, the incremental risk falls deeply and rapidly. When there are new users of smoke free products, the risk to their health is low and may prove to be negligible over the long term. The evidence for this comes, for example, from comparisons with permitted occupational health exposure thresholds, which can be taken as a proxy for safely managing long-term health risks.

11. Sufficient science to provide reassurance about long-term risk. The argument that the long-term risks are not yet known is a dubious statement for a product that has been in the market for about 12 years. Claims are often made that it took decades for the harms of smoking to emerge and that regulators should therefore, adopt a "precautionary" approach. However, this argument is not as watertight as many seem to assume it is. Bioscience and toxicology have advanced immeasurably since the 1950s. Therefore, there is generally no need to wait decades to determine risks associated with toxic exposures. For example, if cigarettes were introduced today; we would know immediately that they are highly dangerous. It would thus not be necessary to wait for many years for smoking-related cancers and heart disease to develop.

12. The precautionary approach also applies to policies that deny access to safer alternatives to cigarettes. Many tobacco control activists claim that because of uncertainty about the future, regulators should take a "precautionary approach" and prohibit or apply excessive regulation to smoke-free nicotine products. In fact, in a situation where it is uncontroversial that the current dominant product in the marketplace –cigarettes – is very harmful, the main risk is *not* the introduction of much safer products (albeit with some residual uncertainty about risk). The main risk comes from excessive policies that limit access to much safer products, thereby causing harm by protecting the cigarette trade and denying smokers safer options to quit. The precautionary principle demands assessment of both the

risks of no intervention and the perverse consequences of intervention and weighing the consequences of uncertainty.

13. Reduced population harm. Evidence from various scientific sources, shows reduced risk products are a substitute for smoking and reduce population-level harms. Initially, we should expect these smoke free products to displace smoking. That is because they provide much of what smokers are looking for (nicotine, sensory effects and flavour, hand-to-mouth movement, ritual aspects etc.) but without many of the costs (harm to health, financial burdens, stigma and marginalisation). The evidence of beneficial population effects is sourced from:

    - Randomised controlled trials – comparing vaping with Nicotine Replacement Therapy (NRT) in a clinical setting;
    - Observational studies – studying how behaviours change over time;
    - Population trends – low and rapidly falling smoking prevalence where there is uptake of alternative nicotine; and
    - User testimony – many users eloquently testify that vaping was the reason they quit smoking.

14. Opposition. Tobacco control activists have gone to extraordinary lengths to try to show that introducing much safer products will somehow cause more harm than not introducing such products. This argument is so strange that its proponents should provide a high level for proof. Whereas the Bloomberg philanthropic network has contributed significantly to global public health, it remains to be seen if its active opposition to THR is actually preventing tobacco-related disease and premature death. Or as Marc Gunther of the "The Chronicle of Philanthropy" puts it, whether it is doing more harm than good.

15. Alternatives needed to save lives. Australia's tobacco control policies demand all possible alternatives to help smokers quit. A deliberate government policy of raising taxes in this situation creates an ethical imperative to maximise the options to quit smoking, especially for those who are more dependent. The smoke free products greatly expand the range of options to quit smoking without reducing or compromising any of the more traditional options. In England, the government promotes vaping as part of its quit smoking strategy, as the case study will show.

16. Complementary to tobacco control. Tobacco harm reduction is supportive, not antagonistic to conventional tobacco control. The example of taxation above illustrates a general point: tobacco harm reduction works well with existing tobacco control measures that aim to increase the pressure to quit smoking or degrade the experience of smoking in various ways. This is because it increases the options to quit smoking. Because THR products more closely mimic the smoking experience, they will make it easier for many smokers. In doing so, THR

should improve the responsiveness to established tobacco control measures in a well-designed integrated system, such as the one currently used in England.

17. Smoke free products and smoking cessation products have a different public health model. Tobacco control activists often fail to appreciate the underlying mechanism by which smoke free products create a public health benefit. Smoke free consumer products work by replacing one pleasure with another, but at much lower health risk. This is the reason for their success: they do not involve a loss, and for many smokers, they offer a superior experience. In contrast, smoking cessation products aim to assist a smoker in moving from smoking to abstinence by managing withdrawal and craving. While both are legitimate approaches, they are very different and will suit different people in varying circumstances. Vaping has been working well in other countries and increasing numbers of South African vapers are citing compelling pro-health reasons for taking it up as an alternative to smoking.

18. Australia's regulatory approach demands a thorough regulatory impact analysis. May we request that current and future regulatory framework be subjected to adequate scrutiny. Too often, its proponents have not accounted for the negative effects that excessive regulation, or the *de facto* prohibition of smoke free alternatives to cigarettes has had and will continue to have by increasing smoking. The art of regulating these products rests on understanding and assessing likely perverse consequences of regulation with at least as much vigour as harmful effects of the products themselves. The Royal College of Physicians outlined this well in its 2016 report: "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; than it causes harm by perpetuating smoking. Getting this balance right is difficult." (Reference: Royal College of Physicians report, Nicotine without smoke: tobacco harm reduction, April 2016 (Section 12.10 page 187).

19. Getting the balance right. In the draft "National Tobacco Strategy 2022-2030", we would respectfully argue that the Government has not yet succeeded in getting "this balance right". We recommend that the government should seek further consultation and consider the possibility of an independent regulatory impact analysis.

20. Proportionate Regulation. Tobacco harm reduction should be integrated into public health strategy via "risk proportionate regulation". The approach adopted in Britain has been successful – position these products as adult alternatives to smoking, control marketing themes and placement, and avoid generating excessive public concern among adults, which in turns triggers youthful curiosity – one of main drivers of youth uptake. Overall, there are four main approaches to regulating these products:

    • Prohibition (as was instituted during the third wave of the Covid pandemic), leading to an unprecedented increase in illicit traded cigarettes. This approach denies users access to legal products and criminalises them or their suppliers. It protects the cigarette trade from competition, nurtures black markets and encourages risky workarounds.

    • Medical regulation applies an inappropriate therapeutic model to consumer products that do not function as medications but as a consumer alternative to smoking. This will default to prohibition of most smoke free products and only work for products resembling NRT.

    • Cigarette regulation takes an undifferentiated approach to all consumer tobacco and nicotine products. However, this is discriminatory as it favours the current cigarette trade by creating high barriers to entry to low-risk competitors. It is anti-proportionate in applying the same measures to much lower risk products.

    • Risk-proportionate regulation applies fiscal and regulatory measures in proportion to risk. It aims to encourage migration of smokers to low-risk products, by creating incentives for both consumers and producers to transition.

On reflection, the Australian government has failed to reach the target of 10% adult daily smoking set for 2018 in the National Tobacco Strategy 2012-2018. In our humble opinion, the Government of Australia, should decide strategically to exploit the opportunities of tobacco harm reduction and move to a system of risk-proportionate regulation covering all consumer nicotine products, including vaping, heated and smokeless tobacco products and novel oral nicotine. Legislators and policymakers should scrutinise both the claims of tobacco control activists, as well as those of us who support THR, to test the robustness of its net benefit to public health.

We stand ready to engage with the Australian government. In particular, we welcome the opportunity to present more scientific evidence of the benefits of tobacco harm reduction, as a complementary instrument to prevent tobacco-related disease and premature death in Australia.

Thank you.

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