A White Paper the Way Forward for Tobacco Harm Reduction (THR) in Malaysia

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Executive summary

In Malaysia, The General End Game (GEG) proposes to prohibit tobacco smoking and vaping for individuals born from the year January 1st, 2007.

It is proposed that this should not be incorporated into the Control of Tobacco Product and Smoking Bill 2022 until it has been reviewed and revised in line with scientifically backed tobacco harm reduction principles, such as allowing the use of regulated e-cigarettes or vape as an alternative to tobacco cigarettes.

Tobacco harm reduction is an internationally accepted public health strategy to lower the health risks to individuals and wider society associated with the use of tobacco products. This approach is widely practised in areas where an “abstinence-only”. approach is ineffective, such as syringe exchange programmes that offer less harmful options for drug users.

Harm reduction (HR) takes into consideration scientific evidence to determine the best way forward in tobacco control. Existing gaps in scientific research and cultural differences should be identified and addressed by locally commissioned research studies to further strengthen the effectiveness of the approach.

The purpose of this white paper is to discuss some of the recent government policies from countries which have led the way and have been instrumental in implementing tobacco control.

This white paper sets out **four** (**4) main key** areas for consideration in tobacco control in Malaysia, they are:

1. **Prevention & tobacco control policies**
2. **Cessation, and accessibility of nicotine replacement therapy (NRT) and smoking cessation products**
3. **Tobacco harm reduction (THR) recommendations and principles; and**
4. **Management of environmental & side effects.**

RECOMMENDATION 1
Prevention

It is recommended that Malaysia could adopt some of the strategies from New Zealand and the UK to help implement its own regulatory policies on conventional (combustible) tobacco products. Specific control measures can include:

1. Reducing affordability by increasing taxation **and** reducing the size of the cheap and illicit market
2. The imposition of standardised packaging and labelling requirements
3. Prohibiting all advertising promotion and sponsorship
4. Restrictions on where, how and to whom tobacco products can be sold.
5. Smoke free policies determining where tobacco can be used.

It is recommended that an interagency or inter-ministerial regulation is in place for stronger enforcements to curb the sale of illegal cigarettes and their alternatives:

1. Industry/organizations can play a strong role e.g., self-regulatory policies.
2. Investment and training for authorities to eradicate black market sales of all forms of tobacco products.
3. Enforcement policies should focus on supply chain and NOT victimise consumers.

RECOMMENDATION 2
Cessation

The burden of disease caused by smoking can be prevented by helping smokers to quit. This means that smoking cessation advice should therefore be a ***key*** important and ***routine c***omponent of medical care and should be easily accessible.

Quitting smoking demonstrates substantial improvements in preventing the progression of smoking related diseases. Hence, clinical management should include referrals for smoking cessation and support. Studies show that there is an important role for helping patients to quit smoking.

A report from the Surgeon General states that smoking cessation interventions have increased substantially since the 1990s with more innovation together with polices that help to motivate smokers to quit.

Therefore, we recommend that health professionals be effectively trained to help the process of cessation among smokers:

1. Training is an important part of tobacco control policies and training content will differ according to the role of the healthcare professional as well as their level of patient contact.
2. It is important to note that all healthcare workers who have face to face-to-face contact with patients will need training. They should be able to ascertain smoking cessation status, advise patients about quitting and to *be* able to deliver individual tailored smoking cessation support which must be dependent upon the smoker's needs and context.
3. Healthcare professionals should be reminded not to impose moral judgment on smokers, not to discriminate or penalise smokers. This will help to reduce stigma against smokers and treat each smoker with dignity and respect in their own rights as individuals.
4. It is also important that health professionals are trained to not only understand the phases of smoking cessation but to also be able to recognise when a smoker may benefit from switching to other methods such as THR.
   (See recommendation 3).

RECOMMENDATION 3
The Principles of Tobacco Harm Reduction (THR)

THR PRINCIPLE 1:

Tobacco harm reduction is a viable and complementary component to strengthen national tobacco control strategies.

THR PRINCIPLE 2:

Policies must be in place to ensure the safety and quality of reduced harm products (RHPs).

THR PRINCIPLE 3:

A risk-proportionate regulatory regime should be applied to RHPs to enable complementarity with existing interventions designed to reduce the prevalence of combustible tobacco use.

THR PRINCIPLE 4:

Policies must be in place to ensure equitable & affordable access to adult smokers, whilst limiting access to youth.

Three (3) points are recommended that should be emphasized to prevent the unintended consequences of using RHP in THR and these are:

1. Safety and efficacy of RHP: This includes the device, its component, nicotine and other components of the liquid, and the functional aspect of the products.
2. Prevention of never smokers and Youth from Uptake: advertising, retail outlet, age restriction, awareness campaign.
3. Promotion and incentivize adult smokers: As a cessation tool, alternative to cigarettes. Risk proportionate regulation and taxation.

RECOMMENDATION 4
Management of environmental and side effects

There is no strong evidence regarding the harmful effects of e-cigarettes as discussed.

We recommend that THR could be a good alternative to help those smokers who are having difficulties in quitting.
We also recommend that THR could be used to help smokers who are having problems quitting.
We recommend that vape products should use more organic and biodegradable ingredients, with technological advancement.

CONTENTS

1. Background and key facts about tobacco smoking

According to the World Health Organisation (WHO) combustible tobacco smoking kills approximately 8 million people each year. There are approximately 1.3 billion smokers worldwide and 80% of the smokers live in Low- and Medium-Income Countries (LMIC) *(1)*. It is well documented that smoking is more prevalent in lower income groups; the more disadvantaged a person is the more likely they are to smoke and to develop smoking related diseases leading to premature death (*2)*.

In the year 2020, 22.3% of the global population used tobacco (37% of all men and 7.8% of the worlds women) *(1)*. The economic costs of tobacco use places a high burden on countries that includes significant health care costs for treating tobacco related diseases as well as the loss of human capital from tobacco attributable diseases *(1)*.

2. Statement from the Malaysian Tobacco Harm Reduction Focus Group

The tobacco epidemic is one of the biggest public health threats the world has ever faced, killing more than 8 million people a year, including around 1.2 million deaths from exposure to second-hand smoke *(1).*
All forms of tobacco are harmful, and there is no safe level of exposure to tobacco. Cigarette smoking is the most common type of tobacco used worldwide. Other tobacco products include waterpipe tobacco, various smokeless tobacco products, cigars, cigarillos, roll-your-own tobacco, pipe tobacco, bidis and kreteks *(1)*.

The prevalence of tobacco use disorder is high with over 1 billion individuals' worldwide using tobacco. Although tobacco use is often viewed as trivial and minor the effects of nicotine on an individual's health and behaviour can lead to profound morbidity over a period of time *(3).*

Smoking within disadvantaged socioeconomic groups remains high, despite active tobacco control measures. A systematic review carried out in 2017 showed that cigarette smoking worldwide is significantly associated with lower income groups *(4).*

Furthermore cigarette smoking has also been found to be linked to an increased risk of relapse in substance use disorder *(5)*. It is comorbid with mental health problems and recent studies have reported this to be the case in patients with bipolar mood disorder and illicit drug use*(6)*. A systematic review and meta-analysis which analysed studies between 1997-2017 found that schizophrenia in substance use disorder is highly prevalent in patients with schizophrenia and that the prevalence rate has not changed over time *(7).*

Smoking addiction is known to be at least partly, a psychological condition, where behavioural change is more likely if people can replace their bad habits with ones that are similar in routine whilst at the same time being less harmful. Products mimicking the smoking experience have been found to be helpful in aiding smokers to switch away from cigarettes *(8).* A complete ban on alternative products would deprive smokers the choice to switch to something less harmful to reduce the impact of negative health outcomes for the smokers and the communities around them.
With regards to quitting the most important environmental trigger identified from smokers is advice from a health professional *(9).*

In Malaysia, The General End Game (GEG) proposes to prohibit tobacco smoking and vaping for individuals born from the year January 1st, 2007*(10)*.
It is proposed that this should not be incorporated into the Control of Tobacco Product and Smoking Bill 2022 until it has been reviewed and revised in line with scientifically backed tobacco harm reduction principles, such as allowing the use of regulated e-cigarettes or vape as an alternative to tobacco cigarettes.

Tobacco harm reduction is an internationally accepted public health strategy to lower the health risks to individuals and wider society associated with the use of tobacco products. This approach is widely practised in areas where an “abstinence-only” approach is ineffective, such as syringe exchange programmes that offer less harmful options for drug users *(11)*.THR takes into consideration scientific evidence to determine the best way forward in tobacco control. Existing gaps in scientific research and cultural differences should be identified and addressed by locally commissioned research studies to further strengthen the effectiveness of the approach.

Harm reduction refers to a range of pragmatic policies, regulations and actions which are designed to either reduce health risks by providing safer forms of products or substances or that which encourages less risky behaviours.

It is important to note that harm reduction does not focus only on the eradication of products or smoking behaviour instead the humane response behind harm reduction is to ***reduce*** the risks therefore enabling individuals to survive and live better lives through access to safer nicotine products (SNPs) *(12)*. The focus is on *encouraging* people to switch to safer alternatives especially where quitting smoking altogether is not possible or in the case of recalcitrant smokers.

In 2019, the U.S. Food and Drugs Administration (U.S. FDA) acknowledged the continuum of risk among tobacco products by authorizing marketing of products through the modified risk tobacco product (MRTP) pathway*(13)*. Nicotine replacement therapy (NRT) products such as nicotine patch and gum that are allowed to be sold over the counter (OTC), alternatives such as heat-not-burn (HNB) and e-cigarettes must be permitted as options for smokers attempting to quit. These products must be regulated in Malaysia to work as a harm reduction tool.

3. The Purpose of this White Paper

The purpose of this white paper is to discuss some of the recent government policies from countries which have led the way and have been instrumental in implementing tobacco control.

This white paper sets out four (**4)** main key areas for consideration in tobacco control in Malaysia, they are:

Prevention & tobacco control policies, cessation, and accessibility of NRT and smoking cessation products, tobacco harm reduction (THR) recommendations and principles, and management of environmental & side effects.

Each of these recommendations (supported by literature and policies from other countries) will be discussed in the following pages of this paper.

4. RECOMMENDATION 1: Prevention

Prevention is a key aspect of tobacco control. Published in 2017 by the WHO on the global monitoring of tobacco use and prevention policies, MPOWER is an acronym to describe the key factors in understanding this process. They are:
Monitoring of tobacco use and prevention policies, **p**rotecting people from tobacco smoke, **o**ffering help to quit tobacco use, **w**arn about the dangers of tobacco, **e**nforce bans on tobacco advertising promotion and sponsorship, **r**aising taxes on tobacco *(14)*.

4.1 Addressing the root cause of tobacco abuse

An important consideration regarding tobacco use is the need to address and understand the root causes of its use. Factors such as poverty, education, health, and the need to understand how to break the behavioural cycle associated with tobacco use are of key importance. Smokers are more likely to come from household's that include a smoker or from those who have experienced exposure to smoking behaviours. In one UK study a systematic review and meta-analysis which explored young people and smoking discovered that living with family members who smoke presented with a high risk for initiation for smoking *(15).*

There is also a strong link between poverty with socioeconomic status being a major determinant of tobacco use and the role of tobacco use in disadvantaged groups is always a major concern. The Pennsylvania Adult Smoking Study – it was found that SES (socioeconomic status) measures for smoking as an outcome measure indicated important SES measures included household income, number in the household, type of property and occupation. It was found that generally those in the lower income group smoke more frequently and have higher levels of dependence and tobacco smoke exposure *(16)*.

4.2 Tobacco products and regulation

It is important that tobacco products (conventional cigarettes and all other derivatives) are regulated to address the issues of illegal demands such as underage smokers and online buyers to name some examples. Malaysia could explore some of the policies

which have been implemented in other countries. What follows is a discussion regarding policies that have been implemented in New Zealand and the UK.

New Zealand was the first country to implement the Generational End Game (GEG) in 2022 with a plan to make the country smoke free by 2025 *(17).* This could set the precedent for other countries to follow suit. In their legislation bill there are three **(3)** key strategies:

1. To drastically reduce nicotine content in tobacco so it is no longer addictive (known as “denicotinisation” or “very low nicotine cigarettes” (VLNC))
2. To implement a 90% to 95% reduction in the number of shops that can sell tobacco
3. To make it illegal to sell tobacco to people born in 2009 or later (thereby creating a “smoke free generation”).

With reference to the UK, a comprehensive tobacco control strategy has been in place since 1998. Some of the approaches used in the regulation are:

1. Reducing affordability by increasing taxation and reducing the size of cheap and illicit market.
2. Imposing packaging and labelling requirements
3. Prohibiting all advertising, promotion and sponsorship, restriction on where and to whom tobacco products can be sold *(18).*

In 2015, The UK parliament passed new packaging regulations for cigarettes which included plain tobacco packaging. The main objective for this legislation was twofold. Firstly, to reduce the appeal and uptake of smoking among young people and secondly to encourage smoking cessation and reduction of relapse after quitting. Hence from May 2017 all tobacco products were packaged in a dull colour and with no imagery *(19).*

An example from Canada shows that from the year 2000 tobacco companies began to include messages encouraging smoking cessation and information about the harm of smoking via inserts inside interiors of cigarette packs to match the warnings on the packages *(20).* In 2012 the messages were updated with 8 new messages which were focused on promoting self-efficacy or response efficacy with the inserts featuring

coloured graphics. A longitudinal study of the inserts indicated that they were read by over one in four smokers, specifically those intending to quit or smokers who had recently quit. Smokers who read the inserts frequently were more likely to make a quit attempt *(21)*.

4.3 (Recommendations for consideration)

Therefore, we recommend that Malaysia could adopt some of the strategies from New Zealand and the UK to help implement its own regulatory policies on conventional (combustible) tobacco products. Specific control measures can include:

1. Reducing affordability by increasing taxation and reducing the size of the cheap and illicit market
2. The imposition of standardised packaging and labelling requirements
3. Prohibiting all advertising promotion and sponsorship
4. Restrictions on where, how and to whom tobacco products can be sold
5. Smoke free policies determining where tobacco can be used.

It is suggested that Malaysia could adapt such a policy; however, it is acknowledged that government agencies may not have the manpower and jurisdiction to address these issues.

4.4 (Recommendations for consideration)

Therefore, we recommend that that an interagency or inter-ministerial regulation is in place for stronger enforcements to curb the sale of illegal cigarettes and their alternatives:

1. Industry/organizations can play a strong role e.g., self-regulatory policies
2. Investment and training for authorities to eradicate black market sales of all forms of tobacco products
3. Enforcement policies should focus on supply chain and NOT victimise consumers.

5. RECOMMENDATION 2: Cessation

The burden of disease caused by smoking can be prevented by helping smokers to quit. This means that smoking cessation advice should therefore be a ***key*** important and ***routine c***omponent of medical care and should be easily accessible *(19*).

Quitting smoking demonstrates substantial improvements in preventing the progression of smoking related diseases. Hence, clinical management should include referrals for smoking cessation and support. Studies show that there is an important role for helping patients to quit smoking *(19)*.

A report from the Surgeon General states that smoking cessation interventions have increased substantially since the 1990s with more innovation together with polices that help to motivate smokers to quit *(22)*.

It has been shown that systematic treatment of smokers is highly cost effective in almost all settings (*23)*.

A systematic review carried out by Wilson et al (2017) found that Multi-component interventions and those examining behavioural interventions which incorporated mindfulness training, financial incentives, motivational interviewing and extended telephone-delivered counselling may be effective in the short-term, particularly for smokers on low incomes and people with a mental illness *(24).*

Recommendations from the report 2021 *(19),* suggested that health care professionals such as doctors, pharmacists and other professionals have a ***key and unique role*** to play in helping to prevent smoking and to provide support to those who wish to quit. This is especially important since smokers are more likely to use heath care services than non-smokers. Since every health care professional will encounter smokers at some point this therefore presents with an important opportunity to identify smokers and hence refer them for quit smoking support; by doing so this will lessen the burden on the health care system *(19).*

5.1 (Recommendations for consideration)

Therefore, we recommend that health professionals be effectively trained to help the process of cessation among smokers:

1. Training is an important part of tobacco control policies and training content will differ according to the role of the healthcare professional as well as their level of patient contact.

2. It is important to note that all healthcare workers who have face to face-to-face contact with patients will need training. They should be able to ascertain smoking cessation status, advise patients about quitting and to *be* able to deliver individual tailored smoking cessation support which must be dependent upon the smoker's needs and context.

3. Healthcare professionals should be reminded not to impose moral judgment on smokers, not to discriminate or penalise smokers. This will help to reduce stigma against smokers and treat each smoker with dignity and respect in their own rights as individuals.

4. It is also important that health professionals are trained to not only understand the phases of smoking cessation but to also be able to recognise when a smoker may benefit from switching to other methods such as THR

(SEE RECOMMENDATION 3).

5.2 The importance of the phases of cessation and the why THR should be an option

NRT may not be fast enough to cure the addiction against smoking. The level of nicotine that is needed to gradually quit must be studied and known by experts to help those wanting to quit. THR as an alternative and supported by a health professional would be prudent *(25).*

One such example of understanding the phases of cessation can be known by understanding. Prochaska & DiClemente's stages of change purports that smokers go thorough different stages during the cessation process "stages of change" is a central concept in the transtheoretical model. Smokers can be classified into one of three

stages. *Pre-contemplation* describes smokers who are not thinking of quitting. *Contemplation* describes smokers who will consider quitting in the next 6 months. *Preparation* describes smokers who intend to quit in the next 30 days and have made a 24-hr quit attempt in the past year. According to the definition, smokers who intend to quit in the next 30 days but have no quit attempt in the past year are not classified as preparation but contemplation stage (25).

A large-scale Korean study with over 2000 participants showed the associations between the characteristics of the smokers and the stages of change were all statistically significant. The age-stratified analyses showed that all the socioeconomic and smoking characteristics were significantly associated with the stages in males, while education and residence had significant associations in females *(26).* This is only one of many studies that demonstrates the significance of understand the phases of cessation as well as readiness to quit.

5.3 Addressing the accessibility of NRT and other cessation products.

Whilst it is accepted that there will be physical and financial constraints, regarding access to NRT and other cessation products, at the same time it is important to address the issue of accessibility. Currently in Malaysia smoking cessation products are available through prescription. Only NRT gums and patches are allowed for sale as over the counter (OTC). The fact is, many countries already offer smoking cessation products as over the counter (OTC), e.g., the United States, Canada, the United Kingdom, Australia, New Zealand, Finland, China, Japan, and South Korea, as well as European countries like France, Germany, Italy, and Spain, among others (*27)*.

5.3.1 Understanding smoking cessation phasing and concerns on NRTs (recommendations for consideration):

1. Cessation phasing is crucial, and all experts must be trained to guide the nicotine levels towards gradual quitting. Those who are unsuccessful should be offered alternative approaches **(see RECOMMENDATION 3).** Training or advocacy in this area is ***crucial***. This is particularly important for those smokers who have used NRT, varenicline and have failed or suffered adverse effects; in this context it would be prudent for them to explore THR as an alternative,

accompanied by professional support to include counselling and behaviour change *(25).*

2. Policy makers should address the accessibility of cessation products including NRTs, including physical and financial constraints.
3. A program could be implemented whereby smokers can be rewarded for their incentives to quit. Some examples from Thailand the Philippines were reported in a systematic review where it was found that offering incentives helped quitting *(28*).

6. RECOMMENDATION 3: Tobacco Harm reduction (THR)

The controversy of tobacco harm reduction (THR)

Taken literally, Tobacco Harm Reduction (THR) —means reducing the harm created by tobacco. It is a major aim of health professionals working in tobacco control who strive to achieve lower risks to patients. However, the term “tobacco harm reduction” (THR) has become the source of one of the most divisive, often acrimonious debates in tobacco control history. Intense emotions, on both sides, have obstructed objective consideration of complicated THR issues.

This section of the paper seeks to examine the data underlying those issues with the goal being to raise awareness of THR as well as to invite rational discussion among interested parties as well as the wider population. For reference: Harm Reduction International (HRI) defines harm reduction for illicit drugs as follows:

6.1 Definition of Harm reduction

Harm reduction refers to policies, programmes, and practices that aim to reduce the harm associated with the use of psychoactive drugs in people unable or unwilling to stop. The defining feature [is] the focus on the prevention of harm, rather than on the prevention of the drug use itself…Harm reduction complements approaches that seek to prevent or reduce the overall level of drug consumption (12).

6.2 Defining tobacco harm reduction (THR)

THR refers to the substitution of a lower risk option which includes lower risk nicotine and tobacco products, e-cigarettes, nicotine replacement therapy, low nitrosamine products. These options are primarily focused on those individuals who cannot quit or who refuse to quit smoking.

6.3 Principles of THR

1. The objective is to reduce harm to the health of smokers who are unable or unwilling to stop.
2. The focus is on ***reducing harm*** and ***not on preventing*** the use of nicotine itself.
3. It is important to emphasise that THR ***complements—it does not replace***—evidence-based approaches to prevent smoking initiation, assist smokers to quit, and protect non-smokers from second-hand smoke.

Recently, some scholars have adopted the term harm *minimization* instead of reduction. They believe “minimization” more effectively connotes the objective’s importance, emphasizing the goal of getting harm down to zero. In contrast, “reduction” covers minor to major improvements.

6.4 Principal findings from empirical studies on THR

(1) Whilst longitudinal studies suggest that vaping increases never-smoking young people’s odds of trying smoking, national survey data indicates that adolescents’ 30- day smoking prevalence decreased at an unprecedented rate precisely whereas vaping increased. Use of all other tobacco products also declined.

(2) Recent population-level studies add evidence that vaping is increasing adult smoking cessation.

(3) Vaping is likely to make a positive contribution to public health *(29).*

6.5 Harm Reduction History in Public Health & Tobacco Control

Harm reduction has a long and successful history in public health.
Examples include:

- Needle exchange to minimize the spread of HIV/AIDS.
- Sex education for adolescents, and condom distribution in schools, to reduce teen pregnancies and sexually transmitted infections.
- Methadone as a substitute for heroin.
- Motorcycle helmet laws to reduce the severity of head injuries. • Designated driver programs to reduce drunk driving.

Such policies confront fervent public opposition, with a strong underlying tone of moralism. Nevertheless, the field of public health has often embraced harm reduction policies, always with a pragmatic focus on what works.

In tobacco control, experiences with the principal early examples of alleged “harm reduction”—filtered and low-tar-and-nicotine cigarettes—provides ample reason for scepticism about THR. Both were tobacco industry public relations ploys, that is they were moves to reassure smokers that, instead of quitting, they could switch to ostensibly “safer” cigarettes.

One of the earliest filtered cigarettes, Kent, explicitly advertised itself as “*the one cigarette that can show you proof of greater health protection*.” *(30).*

Ironically, its “exclusive Micronite filter” contained asbestos. Two decades later, a prominent low-tar-and-nicotine brand, named True, ran a series of advertisements showing intelligent-looking models with the tagline,

“*Considering all I’d heard, I decided I’d either quit or smoke True. I smoke True.”*

Advertisements such as these conveyed the message that the novel cigarettes were safe enough, compared to conventional “full-strength” cigarettes, to permit smokers to smoke them instead of quitting.

The campaigns worked. Millions of Americans switched to filters and then to low-tar-and-nicotine cigarettes. Both categories dominated the market within a decade of their introduction. Both were eventually demonstrated to be no less hazardous than their predecessors, and both were eventually responsible for millions of premature deaths *(30).* Hence there is a lot of hostility and negativity towards harm reduction *(31).*

This attitude constitutes a barrier to the acceptance of harm reduction because THR involves companies' manufacturing and profiting from the sale of nicotine and tobacco products, some marketed by the mainstream tobacco companies.

If the experiences with filtered and low-tar-and-nicotine cigarettes warrant scepticism about a new generation of purported harm reduction products, another experience offers reason to believe that THR might genuinely reduce harm.

6.6 Harm reduction in Sweden

For decades, large proportions of Swedish males have substituted snus, a low-nitrosamine smokeless tobacco, for smoking. Swedish males have the lowest male smoking rate in Europe: 8% in 2016. However, including snus, males' total tobacco use prevalence, 25%, is not especially low. Yet Swedish males have by far the lowest tobacco-related mortality risks of men in all European Union countries. In all 4 disease categories in Swedish males' death rate is lower than that of the lowest of all other EU countries *(32).*

In contrast, Swedish women, few of whom use snus, have average smoking rates among European women and average to high rates of tobacco-related death rates. Extensive research has found few health risks associated with snus. Swedish males' use of snus thus serves as an impressive natural experiment in successful tobacco harm *reduction (32).*

6.7 Harm reduction & tobacco control policy implementation in the UK

The UK White paper *Smoking Kills* published in 1998 *(33)* introduced an extensive and comprehensive range of tobacco control measures and has been at the forefront of the global smoking epidemic of the 20th century and is now a world leader in smoking prevention. The UK has adopted a complementary harm reduction policy strand that is embedded in national policy. Guidance of which comes from the National Institute of Clinical excellence (NICE).

Furthermore, tobacco harm reduction is strongly advocated for and supported by Action on Smoking and Health (ASH), a public health charity set up by the Royal College of Physicians in the UK with their principal being to end the harm caused by tobacco *(34).*

6.8 Reduced Harm Products (RHP)

The opponent of THR cited unknown long-term effect, protecting the youth and non-smoker from nicotine addiction, cardiovascular and respiratory hazard such as EVALI and popcorn lungs, re-normalisation of smoking, among others, as reasons to deny the implementation of THR strategy *(35).*

The proponents of THR on the other hand based their argument on the growing scientific evidence of the benefit of using **Reduced Harm Products (RHP)** as an alternative to tobacco smoking. It is also proven scientifically to be more effective in smoking cessation compared to the traditional smoking cessation methods. Notable bodies such as NHS UK, (Royal College of Physician) *(18*) UK, and FDA (*13*) agreed that nicotine vaping product (NVP) particularly and other RHP generally, pose a very much less harm if smokers switch completely to RHP.

Despite attempts by anti-THR activists to undermine its position on SNP, Public Health England reaffirmed that vaping plays an important role in helping smokers to quit and consequently, health professionals need training in the use of vaping devices.

Vaping was specifically mentioned as part of the UK Department of Health target to go smoke free by 2030. Australian government officials remain in lockstep over continued de facto prohibition *(36)* . However, in January 2020, after a careful review of the evidence, the Royal Australian College of General Practitioners published new Australian Smoking Cessation Guidelines in January 2020 *(37).* The Guidelines cautiously endorse vaping nicotine as a quitting aid for smokers who have been unable to quit with the available therapies, if they request help from their doctors to start vaping. This aligns with the 2018 decision by the Royal Australian and New Zealand College of Psychiatrists to acknowledge vaping as less risky than smoking, while the Royal Australasian College of Physicians now accepts the value of vaping as part of a cessation strategy *(37)*

6.8.1 Facts about RHPs

As a class, RHPs are significantly less harmful than combustible tobacco products, and replacing use of combustible tobacco products with RHPs can significantly improve health outcomes.

Unlike the combustion of cigarettes that produces approximately 7,000 Harmful and Potentially Harmful Constituents (HPHCs), and of which at least 70 are proven or suspected carcinogens (38). THR products do not combust tobacco or other substrate and hence, the absence of smoke production leads to a 90-95% reduction in emission of HPHCs on average (39), (40). As such, THR product users' consequent exposure to carcinogens and toxicants is substantially reduced (as is bystanders' exposure). Clinical studies have indicated that this reduction in exposure can lead to improvements in clinical risk markers such as oxidative stress, endothelial dysfunction, lipid metabolism, inflammation and lung function *(41)(42)*.

While THR products are not risk-free, as is also the case with NRTs and smoking cessation drugs, the substitution of combustible tobacco products with scientifically substantiated THR products reduce exposure to harmful toxicants *(42).* This can reduce the risk of premature morbidity and mortality caused by smoking (43), which

can translate to a beneficial impact on population health *(12), (13)* and ultimately, cost savings for the healthcare delivery system.

6.9 THR and the right to health

The notion of non-smokers' right to health – especially bystanders and children – underpinned tobacco control developments through the 1980s and 1990s. Those involved in the campaigns, especially in the US, saw themselves as warriors (in relation to the passive smoking hazard) battling the economic and political interests of tobacco companies. Backed by the evidence of the palpable damage caused by smoking and the increasing efforts to ban public smoking, campaigners seized the moral high ground as smokers became the new social pariahs. The tables have turned; those whose rights now need protecting are those who want to avoid smoking and instead use safer products. Harm reduction as a social movement arose from the work of drugs and HIV activists who focused on the right to health, with nobody left behind. However, smokers are left behind, primarily those on low incomes living in poverty and deprivation around the world, with no attractive and effective exit routes out of smoking, who smoke the most and consequently suffer most from smoking-related disease and death. The whole panoply of marginalisation, discrimination and isolation *(44).*

Therefore, here are our recommendations pertaining to incorporating tobacco harm reduction (THR) in policy making, based on four (4) THR principles:

6.9.1 THR PRINCIPLE 1:

Tobacco harm reduction is a viable and complementary component to strengthen national tobacco control strategies.

Tobacco control efforts have primarily focused on (i) prevention of initiation (*ii*) cessation for smokers, and (iii) protection from environmental tobacco smoke *(45).*

Policies supporting abstinence to tobacco and nicotine products should be the preferred approach to create health and economic benefits. However, policies facilitating the switch to THR products that can reduce a smoker's exposure to toxicants can reduce the negative impact that combustible tobacco products has on

the health of smokers and those around them *(46).* As such, tobacco harm reduction is a viable strategy to support individual autonomy in controlling one's health outcome. Countries have a responsibility under the right to health to not deny access to THR products to smokers who want to quit using combustible tobacco products given the potential to improve their health outcomes *(47).*

6.9.2 THR PRINCIPLE 2:

Policies must be in place to ensure the safety and quality of RHPs.

Appropriate product safety standards should be put in place to protect RHP users. This may require the submission of product safety assessments, limitations on the amount of additives that may be carcinogenic, mutagenic, and/or are toxic additives, and the inclusion of a reporting structure for adverse events and product performance *(48).*

The requirement of establishing a body to regulate the THR products, including the following:

1. restrict e-cigarette tanks to a capacity of no more than 2ml.
2. restrict the maximum volume of nicotine-containing e-liquid for sale in one refill container to 10ml.
3. Restrict e-liquids to a nicotine strength of no more than 20mg/ml.
4. Requirement for nicotine-containing products or their packaging to be child-resistant and tamper evident.
5. Ban certain ingredients including colourings, caffeine and taurine include new labelling requirements and warnings.
6. Require all e-cigarettes and e-liquids are notified and published by the regulation body before they can be sold.

6.9.3 THR PRINCIPLE 3:

A risk-proportionate regulatory regime should be applied to RHPs to enable complementarity with existing interventions designed to reduce the prevalence of combustible tobacco use.

THR products should not be over-regulated such as by requiring them to establish

“safety” or “efficacy” as with pharmaceutical products. The restriction of access to THR products could have the unintended effect of entrenching the use of cigarettes and other harmful combusted forms of tobacco use and perpetuating the health burdens such products cause.

In addition, THR products can play an effective role in tobacco harm reduction if governments avoid over-medicalizing THR products, such as by classifying these products as prescription-only medicine, to avoid stigmatizing smokers who would like to consider switching to THR products.

A risk-proportionate taxation regime should be applied to THR products to encourage smokers who otherwise continue to smoke to switch from combustible tobacco products to scientifically substantiated THR products *(49), (50)* and attract investments that promote research and innovation into RHPs. In doing so, potential population health, economic and social gains and benefits such as a reduction in national health expenditure and overall improvement in national productivity (*51)* can be achieved.

Policies supporting abstinence to tobacco and nicotine products should be the preferred approach to create health and economic benefits. However, policies facilitating the switch to THR products that can reduce a smoker’s exposure to toxicants can reduce the negative impact that combustible tobacco products has on the health of smokers and those around them *(46)*. As such, tobacco harm reduction is a viable strategy to support individual autonomy in controlling one’s health outcome.

6.9.4 THR PRINCIPLE 4:

Policies must be in place to ensure equitable & affordable access to adult smokers, whilst limiting access to youth.

THR products should be made at least as accessible and affordable as combustible tobacco products to adult smokers to facilitate the replacement of combustible tobacco products with THR products.

THR products should be prohibited from sale to minors who are not of legal age to smoke. Additional controls to further curb initiation by and minimize appeal to vulnerable youths should be imposed on THR products*(52), (53) (54)*. This includes

implementing labelling and warning requirements, restrictions on ingredients, flavours, and product descriptors, as well as appropriate advertising, marketing and sale restrictions. For example, the current regulatory and health measures applied to alcohol and tobacco can similarly be applied to THR products in a risk-proportionate manner *(42), (55)*.

There must be a fine balance struck between implementing restrictions and regulatory controls to minimize access by youth whilst enabling access to smokers who want to move away from combustible tobacco products to RHPs.

6.10 Raising awareness about THR

Below is a discussion regarding THR which can be useful in raising awareness as well as to propose how THR can be used as a complement to smoking cessation.

Smokers should be encouraged to quit smoking. They should be informed about the harms of continuing to smoke, and the benefit of quitting. They should be informed about the different methods of quitting and the facilities available to assist them quitting.

Educating smokers regarding their options with respect to THR is very important. Safety should be a key factor as well; below are some recommendations supported by research as to how perception can be created. The inclusion of inserts inside cigarette packets containing information about THR and its benefits could be fruitful. Earlier in paper it was mentioned that inserts in a Canadian study helped to change attitude – so this implies that this could be the same in this case *(20).*

Education on how to quit using THR is also recommended, which could take place in the medical community and the education of health professionals regarding the complementary benefits of THR.

Any awareness campaign must be based on the correct and accurate understanding and perception of smoking harm and tobacco harm reduction.

These include lobbying by NGO's, workshops, meetings, and conferences (57). Furthermore, campaigns should be targeted and selective. The collaboration between various agencies and organizations are necessary. The general population should also be encouraged to be involved.

Young people and non-smokers should be educated about the harm of tobacco and any kind of addiction. They must always be reminded that smoking of any kind including RHP is not healthy and should not be taken for recreational purposes.

Efforts must be made to inform the public of the damage done by smoking to health, smokers and non-smokers alike, to the economy, and to the environment.
The medical community, policy makers and legislators particularly must be made aware about RHP. They must be informed about the potential benefit of RHP and the importance of regulating the products.

6.10.1 (Recommendations for consideration):

1. The danger of tobacco combustion and the benefit of switching to RHP
2. The different types of RHP and their advantages
3. The purpose of RHP which is to aid SMOKERS to quit smoking and reduce the harm created by continuous smoking and not for non-smokers and youth for recreational purposes.
4. The possible harm of RHP but must be explained about the relative harm compared to combustible tobacco smoking. It must not be exaggerated to the extent of creating fear that will inhibit smokers to switch.
5. The importance of using the regulated RHP which complies to the standard.
6. The goal which is to quit nicotine addiction altogether.

6.10.2 Promotion of other products

Promotion of RHP should aim at encouraging SMOKERS to switch and avoid attracting non-smokers and youth to take up RHP. This is particularly important to reduce the problem of nicotine addiction and to avoid the creation of new nicotine addicts.

Promotion should be targeted and selective. The content of the promotion must be, whenever possible, intended to reach exclusively and efficiently the targeted and selected groups. Efforts must be taken to ***identify*** SMOKERS and non-smokers. This can be carried done for example during clinic visit, point of sales or even working places and public places. As mentioned earlier in this report this could be carried out during smoking cessation sessions.

The possible means of promotion varies from physical to virtual promotion. Promotional inserts in the packages of cigarettes and any tobacco products seems viable. It can be done either by physical, printed insert or virtual through QR scan. This method will ensure that the promotion will only be seen by smokers.
Technological means such as apps and QR scan can also be used to register smokers for further promotion, monitoring and control.

It can be incorporated in existing apps such as MySejahtera. The issue of personal data protection should not be an issue since it has been practiced during Covid-19 pandemic. Promotions that have the potential to attract youth and non-smokers to RHP uptake must be prevented. This includes the lifestyle and child themed promotions.
Examples are sporting, relaxing holidays, social event, cartoons, colourful appearance, and naming of products that reflect the themes.

Manufacturers and retailers must be warned and punished for the breach of the regulation of promotion. Online promotions must be carefully monitored especially through social media which is widely used the younger generation. The US Food and Drug Administration (FDA) have enforcement in place to regulate these products*(56).*

6.11 Harm reduction & population health

The emergence and consumer success of e-cigarettes as a partial or complete substitute for smoking presents with a significant potential opportunity to help reduce the harm caused by smoking. It is an encouragement for smokers to use other products rather than tobacco cigarettes *(57).*

The concerns that e-cigarettes are not hazard free are of course justified but this hazard could be minimised by a combination of technological development and appropriate regulation *(57).*

6.11.1 Special Groups

Special consideration should be accorded to vulnerable groups such as those with mental health problems and substance use disorder as discussed earlier in this paper the prevalence of smoking is high in these groups. Switching to another alternative such as e-cigarettes is favourable. On the road workers such as lorry drivers, and E-hailing drivers to name examples should also be considered as special groups; workers in the vice industry should also be included in the consideration.

6.11.2 Youths

It is proposed that there should still be the age limit of 18 years as is the case for the UK although a recent report suggests that it could be raised to the age of 21 years *(58).* In addition, we recommend the Malaysian Government to explore youth protection by considering the following strategies:

1. Prevention of never smokers and Youth from Uptake: restricting advertising, limiting retail outlet location, age restriction, awareness campaign **(See Section 6.12.2)**
2. Education via mass media & social media that the purpose of RHP is to aid smokers to quit smoking and reduce the harm created by continuous smoking and not for non-smokers and youth for recreational purposes **(See Section 6.10)**

The Government should be cautious with prohibition measures, in this case the GEG would apply increasingly to adults as the 2005 age cohort grows older. A prohibition does not make banned products disappear, same as age restriction does not make these products unavailable to people beneath the age threshold *(59)*. We foresee those above the age threshold will initially supply those younger, but over time market would be supplied by cross-border trade, internet sales, and underground networks which eventually promotes bribery and corruption. Furthermore, it is unclear how adult

tourists from a different jurisdiction and visitor economy would respond. There exists a need for thorough assessment and the risks properly balanced against any possible benefits.

6.11.3 Pregnant women

It is well documented that smoking in pregnancy is associated with increased risks of miscarriage, stillbirth, prematurity, low birth weight (LBW) perinatal, neonatal, sudden infant death and poorer infant cognition and behavioural outcomes *(19)*
Health systems should capitalise on pregnant women's motivation to quit, hence offering smoking cessation is crucial. NICE guidelines from 2010 recommend the following principles for women who smoke *(60)* :

1. ***Engagement – of all pregnant women to identify those who smoke***
2. ***Referral – as a default for all women identified as smoking***
3. ***Support – for those referred who accept this***

6.12 Managing RHP

Because RHP is a relatively new range of products of nicotine delivery much is not yet known about its safety and efficacy. However, most of the current evidence points towards the benefit of switching to RHP from combustible tobacco as discussed previously in this paper.

The UK also has regulation in place for e-cigarettes and other unlicensed nicotine which are regulated by the EU General Product Safety Directive *(18)*.

In the UK e-cigarette marking must comply with compulsory advertising codes which are administered by the Advertising Standards Authority (ASA).

In 2014 the ASA introduced a sector-specific set of rules and requirements in which the advertising of e-cigarettes they are:

1. Advertising must be socially responsible.

2. Not to promote any design, imagery or logo that might be associated with a tobacco brand or that which shoes the use of a tobacco product in a positive light.
3. To make it clear that the product being advertised is an e-cigarette and not a tobacco product.
4. Advertising must not undermine quit smoking messages.
5. Must not contain health or medicinal claims unless the product has a medicines licence.

6.12.1 Manufacturing Standards

A set of standards must be formulated and enforced. RHP products must be assured of safety, efficacy, acceptability, affordability, and selectivity. The standards in countries like the UK, New Zealand and USA and regions such as Europe can be emulated (*56).*

These standards include the device, its components and tobacco/nicotine content. Attention should be given to the user and their surrounding be it the bystander or environment.

The device and its components must be safe for the users and their surroundings. The incidence of device explosion albeit rare can be avoided by proper device design and good quality battery. The heating mechanism and parts must ensure minimizing the production of by products such as heavy metals, aldehyde and other HCPC's.

Formulation of tobacco or e-liquid and its packaging must be balanced between efficacy for quitting aid and toxicity or potential unintended intoxication. Adulteration must be avoided and prevented to avoid incidence like EVALI. The effective concentration of nicotine remains a debate among health professionals, but the experience of other countries can be referred.

Non-smokers and children must be deterred access to RHP. This can be done by appropriate design of the device and formulation of e-juice. The design, formulation and naming of the device and e-juice must not be attractive to this population.

Flavours and nicotine content are important ingredients in RHP to ensure acceptability and efficacy of quitting smoking and preventing relapse. Unfortunately, they are appealing to non-smokers and children and cause addiction. A balanced standard for flavours and nicotine content must be formulated. It is important to state at this juncture that according to the report by the Royal College of Physicians; all the UK evidence and almost all the international evidence regarding the use of e cigarettes being used by children and young people indicates that concerns are *(18).*

6.12.2 Recommendations for prevention of unintended consequences of RHP in THR (recommendations for consideration):

1. Safety and efficacy of RHP: This includes the device, its component, nicotine and other components of the liquid, and the functional aspect of the products.
2. Prevention of never smokers and Youth from Uptake: advertising, retail outlet, age restriction, awareness campaign.
3. Promotion and incentivize adult smokers: As cessation tool, alternative to cigarette. Risk proportionate regulation and taxation.

6.13 Regulations

A comprehensive, balanced and risk proportionate regulations and taxing systems must be formulated to ensure the safety, efficacy, and affordability of RHP as part of tobacco harm reduction strategy in tobacco control.

Regulations must involve all interested parties and stakeholders. It must consider the supply and demand chain of RHP. The aim is to ensure the protection of health without depriving justice and human right.

Manufacturers (including importers) and retailers on the supply side must comply to the quality and safety standards. They must ensure that the good quality and safe RHP is accessible only to the intended group which is the smokers.

Manufacturers must design RHP that is safe and efficient for the purpose of smoking cessation. It must not be appealing to children and non-smokers such as fancy

designs, design with fancy flashy lights, fancy packaging, multi-purpose device, easy to conceal device, exotic flavours, exotic names of flavours and device.

Manufacturers must document the device, its components and e-juice. It must be properly and correctly labelled. The package must or preferably come with inserts describing the product along with warning and advice. They must in any way ensure that the product does not contain known harmful components such as low-quality battery, THC, VEA, diacetyl etc.

Retailers must be licensed and monitored. They are preferably equipped with correct knowledge on RHP. They must ensure that RHP only be sold to SMOKERS. Age verification is required to avoid sale to the underage users.

RHP sales should be restricted to the licensed tobacconist or retailer that segregates a specific counter for RHP. Retailers must not put any appealing display that can possibly attract non-smoker and children such as photos of celebrity or influencer or health promotion. A set of standards in the UK have been set up to monitor the restrictions (*61)*. Online sales should also be subjected to the regulations imposed on retailers.

RHP user or potential user must prove their age upon buying and using the product. This can be done either by producing their identification card or by scanning the QR code incorporated in apps such as MySejahtera.

6.14 Monitoring and Enforcement

Monitoring is essential to evaluate the safety and efficacy of RHP. RHP is relatively new products with unknown long-term effect. As discussed earlier in this paper evidence shows that RHP is very much less harmful relative to combustible cigarette smoking and proven with high certainty that it is more effective for tobacco cessation than the conventional cessation method.

Enforcement is a critical part to avoid misconduct that will eventually lead to harmful consequences. The best enforcement is self-enforcement and it rely solely on awareness. More effort to increase awareness is needed.

Adulteration of e-juice, substandard device manufacturing, irresponsible sales, profit oriented marketing and promotion are among misconduct that must be condoned.

6.15 Taxation

Taxation needs to be risk proportionate – cigarettes with a higher tax, less harmful will have a lower tax.

This will encourage price-conscious users to switch less harmful alternatives. Taxation from the alternative products could be used to fund enforcement and regulatory costs.

6.16 Public awareness about THR

The use of social media could be a useful platform as well as dissemination through accurate news mediums the purpose of which to combat fear mongering about THR. It should be noted that these strategies will only be possible with proper regulation of vape products (*19).*

6.16.1 THR and public opinion in Malaysia

Research carried out in 2022 by the Data metrics research and information centre (DARE*) (62)* found that there is a potential reduction in Malaysia's smoking rate arising from non-combustible products. For example, an estimate regarding the potential absolute number of smokers quitting smoking by switching to vaping is 140,000-220,000 smokers (representing 2.9 percent – 4.5 percent on a yearly basis).

DARE also projected a drop to 4 million of Malaysian smokers by 2025 when compared to 4.88 million in 2019. These figures are promising as they represent a potential RM1.33 billion (18 percent in 2025) with regards to savings on healthcare.

Furthermore, an opinion poll has produced favourable results in terms of the Malaysian public's opinions and understanding related to THR; results are set out below:

6.16.2 Public perception about THR in Malaysia

According to the DARE report 2022 *(61)* Malaysians would like to have THR.
The responses are as follows:

80% of respondents believe that the adoption of THR in Malaysia would help smokers quit traditional tobacco cigarettes.

58% of the respondents know that studies have demonstrated that THR products are less harmful compared to traditional cigarettes.

95% of respondents mentioned that it is a must for the government to become involved in implementing THR strategies.

50% of the respondents do not think that there is an active THR strategy development by the government.

98% of the respondents would support the implementation of THR strategies if proven to be effective in reducing smoking levels.

The difficulties many smokers face in quitting and the presence of a cohort of smokers unable or unwilling to try, as well as the significant health risks associated with smoking, are drawing increased attention towards Tobacco Harm Reduction (THR) interventions. THR products provide nicotine in a less harmful way than conventional cigarettes for smokers who are otherwise unable to quit.

These include products known as Electronic Nicotine Delivery Systems (ENDS), such as e-cigarettes and heated tobacco products, as well as other THR products such as Swedish Snus. ENDS products provide an experience (often known as vaping) much closer to that of smoking a conventional cigarette and may be effective when other approaches such as NRT have failed. In jurisdictions such as the UK, usage of these products is being supported as a central tenet in tobacco control and tobacco harm reduction policies *(63).*

Based on commentary paper by Fagerstrom *(64);* the following is recommended for smokers who are having difficulties in quitting:

- Recalcitrant smokers should be advised to consider using non-combustible tobacco products instead. In countries like Japan and New Zealand, HNB is marketed as consumer products rather than pharmaceutical (medicinal) items.
- Similarly, snus and nicotine pouches are made available as consumer products in available markets.
- Healthcare professionals should be equipped with information on each category of non-combustible product so that accurate information is passed on to their smoking patients.

6.17 Freedom of choice & protection of human rights

Health professionals and those helping smokers to quit or for those switching to other products should not impose their own opinions. Freedom of choice is crucial. Allowances should be made to embrace the concept of THR before implementing radical changes via the GEG. Smokers should be treated with dignity and respect free from discrimination. They should be able to decide for themselves and this is especially salient for those who are struggling to quit.

The implementation of GEG should be carried out in a phased approach with an integrated strategy by recognising alternative HRPs to complement smoking cessation as well as reducing the supply and demand. A zero tolerance or prohibitive approach will only serve to increase an illicit tobacco trade.

It is important that the human rights of smokers are protected, and it is recommended that THR is a more favourable option than GEG.
A recent article suggested a set of principles which could be applied to freedom of choice *(65).*

The following principles should be adopted with regards to freedom of choice:

Smokers should be rewarded to incentivise behavioural change.

There should be a focus on decreasing traditional products while restrictions and taxes related to healthier alternatives should be minimised.

There should be a focus on creating an environment that incentivises innovation.

It is important that all smokers have the autonomy to choose and that they should be free from stigma and opinions from healthcare professionals.

Making allowances for THR will protect smokers' rights.

7 RECOMMENDATION 4: Management of environmental and side effects

The UK Government has reiterated the benefit of e-cigarette vaping over cigarette smoking, endorsing that e-cig is likely to be 95% less harmful than cigarettes. With the support of medical societies like the Royal College of Physicians (RCP), its National Centre for Smoking Cessation and Training (NCSCT) and the National Health Service (NHS) has aborted the traditional "quit or die" approach and now actively supports e-cigarette-based interventions alongside smoking cessation programs at local stop-smoking services *(66)*.

It has also been reported that countries with a relatively high adoption of alternative nicotine products like HNB and snus (the UK, Sweden, Norway, New Zealand, and Japan) have been able to achieve lower smoking rates.

7.1 E-cigarettes as an alternative

Whilst it is acknowledged that e-cigarettes are not harmless both the US National Academies of Sciences, Engineering, and Medicine together with an independent review commissioned by the Department of Health and Social Care in England have concluded that e-cigarette use is likely to be much less harmful than smoking. Cigarette smoke contains more than 7000 chemicals; 80 of which are known to be carcinogenic and hence harmful to humans *(36).*

From an environmental perspective, the number of chemicals in an e-cigarette aerosol is orders of magnitude lower and toxicants common to both products are present in much lower concentrations than in smoke from combustible cigarette. Human biomarker studies confirm that exposure to tobacco smoke toxicants is much lower with e-cigarette use than with cigarette smoking. Although it is acknowledged that nicotine is the addictive agent common to both products, chemicals other than nicotine cause nearly all the cigarette smoker's health risks *(67).*

Public Health England (PHE), the British government's equivalent to the Center for Disease Control and Prevention in the U.S., also reconfirmed the finding that vaping is at least 95 percent safer than smoking. One key finding: vaping products that contain nicotine were the most popular aid products used by smokers trying to quit in England in 2020. The report also found more than 50,000 smokers stopped smoking in 2017 through the aid of a vaping product. This is despite the fact 38 percent of smokers still erroneously believe vaping is as harmful as traditional smoking.

The general message is that "the best thing that a smoker can do is to stop smoking completely" and evidence shows that vaping is one of the most effective quit aids available. The Director of Health Improvement at Public Health England (PHE) stated that these products help around 50,000 smokers to quit per year. "The evidence has been clear for some time that, while not risk-free vaping is far less harmful than smoking."

7.2 Biomarkers of toxicant exposure

- Significantly lower exposure to harmful substances from vaping compared with smoking, as shown by biomarkers associated with the risk of cancer, respiratory and cardiovascular conditions.
- Similar or higher exposure to harmful substances from vaping compared with not using nicotine products.
- No significant increase of toxicant biomarkers after short-term second-hand exposure to vaping among people who do not smoke or vape.

7.3 Biomarkers of potential harm

These are measurements of biological changes in the body due to exposure to smoking or vaping. A review found no major causes of concern associated with vaping. Furthermore a Cochrane Review published in 2022 which included 78 studies and 22,000 participants made the following conclusion **"***levels of carbon monoxide are significantly lower among people who stop smoking and using e-cigarettes than among those who continually combustible cigarettes or people who use e-cigarettes while continuing to smoke"(68).*

7.4 The environmental impact of tobacco

The environmental and health impacts of tobacco are diverse and are particularly harmful to low- and middle-income countries *(69).*

For example, growing tobacco harms soil; tobacco curing results in deforestation; tobacco manufacturing produces environmental harm; transportation of tobacco increases air pollution; tobacco smoke has a health impact on the health of the population and in a single year cigarette smoke contributes to thousands of cancer-causing chemicals and other dangerous toxins and finally cigarette butts cause harm to the environment and their filters do not biodegrade. Tobacco packaging contributes to 2 million tons of waste per year *(69)*.

7.5 Recommendations Management of environmental and side effects

There is no strong evidence regarding the harmful effects of e-cigarettes as indicated in this paper.

Therefore, we recommend that THR could be a good alternative to help those smokers who are having difficulties in quitting.
We also recommend that THR could be used to help smokers who are having problems quitting.

We recommend that vape products should use more organic and biodegradable ingredients, with technological advancement.

8 Conclusion

Smokers are very heterogeneous, and treatment should therefore be tailored and based upon systematic assessments of individual patient characteristics.

THR offers smokers a more comprehensive multimodal broad-spectrum approach to total abstinence.

Each smoker is unique and must be observed as an individual and within his/her context.

The cornerstone of good treatment is a thorough behavioural assessment before tailoring them to THR, NRT or both.

- There is now a need for health professionals to focus on objective assessments of THR.
- Tobacco harm reduction (THR) is a viable and complementary component to strengthen tobacco control strategies as well as to discuss the potential costs and benefits of THR.
- Healthcare professionals should be kept informed on each product category characteristics (e.g., HNB offers tobacco taste, snus/nicotine pouch is speedily absorbed for fast “kick”), quality specifications and regulatory control on non-combustible products so that they can educate patients towards choosing & using only well-regulated products.

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10 APPENDICES (Discussion notes)

SYNTHESIS OF DISCUSSION POINTS

29th January 2023, 9am to 5pm,

Sofitel Hotel, Frangipani Meeting Room,

Kuala Lumpur Damansara, Bukit Damansara, Kuala Lumpur

Integration and Synthesis of Recommendations White Paper: Way forward for Tobacco Harm Reduction in Malaysia

Outline of recommendations

A. Prevention

B. Cessation

C. Harm Reduction

D. Management of Environmental & Side Effects

A. Prevention

1. Address the root cause of tobacco abuse in households - poverty, education, health, behavioural vicious cycle.

2. Tobacco products (conventional cigarettes and all other derivatives) need to be regulated to address illegal demands (underage smokers, online buyers, etc)
    a. The UK has a regulatory guideline that we can follow
    b. Limit the number of retailers to reduce accessibility to products, following the NZ GEG model (denicotinization)

3. Interagency or inter-ministerial regulation is needed for stronger enforcements to curb sales of illegal cigarette and alternatives.
    a. Government agencies may not have enough manpower and jurisdiction to tackle this issue.
    b. Industry/Organizations can play a strong role eg. self-regulatory policies
    c. Need collaboration with other relevant ministries and agencies
    d. Investment and training for authorities to eradicate cigarette/smokeless tobacco black markets.
    e. Don’t victimise consumers, but the focus should be on the supply chain.

B. Cessation

1. Doctors, pharmacists, and health professionals who assist smokers wishing to cease or switch to less harmful alternatives are encouraged to receive proper training or advocacy.
    a. They should not impose their moral judgement on smokers.
    b. Don't discriminate or penalize smokers to reduce stigma against smokers.
    c. Treat with dignity and respect their rights as individuals.

2. Address the accessibility of NRT and cessation products.
    a. There are physical and financial constraints.
    b. Adopt according to best practice globally.
    (Incorporate Case Study on accessibility, for informed decision making)

3. Create a programme with incentives for smokers to quit while tracking their quitting progress.

4. Cessation phasing is crucial.
    a. The NRT may not be fast enough to cure addiction.
    b. The level of nicotine that is needed to gradually quit must be studied and known by experts to help quitters.
    c. Those who have problems quitting/specific populations/ marginalized groups should be given the alternative approach.

C. Harm Reduction

1. THR is a viable and **<u>complementary</u>** component to strengthen tobacco control strategies (UK model)

2. THR - Differentiated approach for different vulnerable target groups:
    a. Youth:
        - We still have to limit the age, 18 years old and above.
    b. Women:
        - Medical personnel advise them especially pregnant women to stop smoking, and propose NRT if needed.
    c. People with Mental Health problems
    d. People with Substance-use disorder
        - Relapse risk is higher for those who stop smoking, instead of those who switch to e-cigarettes.
    e. 'On-the-road' drivers

    f. Sex workers
    g. Smokers who have used NRT, varenicline and failed/sustain adverse effects should be allowed to explore THR accompanied by professional counselling.
3. Raising Awareness on THR:

a. Smokers: Awareness of options available and safety for THR to create the right perception
    - Include inserts/infographic/warnings on THR & the benefit of switching on the packaging of cigarettes (instead of current graphic images) - Education on how to quit smoking through THR approach.
b. Medical Community: convince & educate the health professionals on THR.
c. Medical Societies & NGOs (eg. Cancer societies)
    - In France, National Cancer Society promotes THR awareness.
    - Occupational Health & Safety societies
d. Public awareness through social media
e. Disseminate accurate news/information based on science to combat fear mongering on THR.
   (All of these will only be possible with proper regulation of vape products)

4. Proposed Regulations: Different restrictions to different categories.

a. Business Approach
    - Monetizing for THR: Hologram, Vape Labs, Regulating & Licensing outlets, Training.
    - Special labs to certify/test all the products across the continuum of risk.
    - Adding monitoring & regulatory agencies, which will generate revenue taxes & employment opportunities.
    - Great Britain & Northern Ireland - Agency which look into standards of e-cigarettes.
    - Quote 40 sen tax, country will gain XXX in taxation.

b. Regulate manufacturers, retailers, sellers, instead of consumers.
    - NZ - regulations on who can sell - registered vendors
    - NZ - Labelling, flavouring, safety assessments, limitation of additives
    - Great Britain & Northern Ireland - Restrict nicotine strength, packages child proof, flavouring.
    - Philippines - Separate Vape law.

c. Taxation needs to be risk proportionate.
    - cigarettes- higher tax, less harmful - lower tax
    - Price-conscious users will tend to switch to less harmful alternatives.
    - Taxation from the alternative products can be used to fund enforcement and regulatory costs.

D. Management of Environmental & Side Effects

1. No strong evidence on harmful effects of E-Cigs (Refer to Pg. 186)
    - NHS: No evidence yet of second-hand effects of vaping
    - PHE: Benefits of non-combustible against combustible
    - 2022 Cochrane Review

- Indoor Air Quality Pollution: Benefits of non-combustible against combustible
- Fear-mongering needs to be tackled.

2. Vape products should use more organic and biodegradable ingredients, with technological advancement.

APPENDIX 2.

FOCUS GROUP NOTES.

Prof Sharifah

The prevalence of smoking within disadvantaged socioeconomic groups remains high despite active tobacco control measures. Research findings so far indicate that illicit substance use and cigarette smoking are highly comorbid. The generational end game (GEG) – which aims to prohibit tobacco and vape for anyone born from January 1, 2007 – should not be incorporated into the Control of Tobacco Product and Smoking Bill 2022 until it is reviewed and revised to scientifically-backed tobacco harm reduction principles, such as allowing the use of regulated e-cigarettes or vape as an alternative to tobacco cigarettes.

Tobacco harm reduction is an internationally accepted public health strategy to lower the health risks to individuals and wider society associated with the use of tobacco products. This approach is widely practised in areas where an “abstinence-only” approach is ineffective, similar to syringe exchange programmes that offer less harmful options for drug users. THR takes into consideration scientific evidences to determine the best way forward in tobacco control. Existing gaps in scientific research and cultural differences should be identified and addressed by locally commissioned research study to further strengthen the effectiveness of the approach.

The World Health Organisation Framework Convention Tobacco Control (WHO FCTC) acknowledges the role of harm reduction within the definition of tobacco control to improve public health outcomes. In 2019, the U.S. Food and Drugs Administration (U.S. FDA) acknowledged the continuum of risk among tobacco products by authorizing marketing of products through the modified risk tobacco product (MRTP) pathway. Besides nicotine replacement therapy (NRT) products such as nicotine patch and gum that are allowed to be sold over the counter (OTC), alternatives such as heat-not-burn (HNB) and e-cigarettes must be permitted as options for smokers trying to quit. These products must be regulated in Malaysia in order to work as a harm reduction tool.

Conventional cessation strategies fail with many patients and they struggle to find effective alternative measures. Smoking addiction is known to be at least partly, a psychological condition, where behavioral change is more likely if people can replace their bad habits with one that is similar in routine but is also less harmful. Products mimicking the smoking experience have been found to be helpful in aiding smokers to switch away from cigarettes. A complete ban on ANDS would deprive smokers the choice to switch to something less harmful to reduce the impact of negative health outcomes for the smokers and the communities around them.

ANDS such as e- cigarettes and heated tobacco products (HTPs) are not 100% safe, however there is a general international scientific consensus that they are less harmful than cigarettes. Among the independent findings that supports this include:

a) “The German Federal Institute for Risk Assessment confirmed in its previous study substantially reduced toxicant levels for selected HTPs and provided an initial assessment in 2017. The profound reduction (>99%) of key carcinogens according to Fowles and Dybing, such as benzene and 1,3-butandien, as well as substantial overall reductions of toxicants is expected to affect health risks, if people abstain completely

from other tobacco products. The calculated lifetime cancer risk of the HTP, using one data set by the manufacturer, was one to two orders of magnitude lower compared to combustible cigarettes but higher compared to e Cigarettes. In addition, there is a growing consensus that a complete switch to HTP can reduce toxicant exposure, as confirmed in recent investigations on biomarkers of exposure in smokers."
Mallock, N., Pieper, E., Hutzler, C., Henkler-Stephani, F., & Luch, A. (2019). Heated Tobacco Products: A Review of Current Knowledge and Initial Assessments. Frontiers in public health, 7, 287. b) An expert review of the latest evidence concludes that e-cigarettes are around 95% safer than smoked tobacco and they can help smokers to quit.
https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update
c) The China National Tobacco Quality Supervision and Test Centre has further confirmed that "Other than some carbonyls, ammonia, and N-nitrosoanabasine (NAB), the delivered releases from THS (tobacco heating system) 2.2 were at least 80% lower than those from 3R4F (reference cigarette manufactured by the University of Kentucky)." and "THS 2.2 delivered fewer harmful constituents than the conventional cigarette 3R4F".
Xiangyu Li, PhD, Yanbo Luo, PhD, Xingyi Jiang, BD, Hongfei Zhang, MD, Fengpeng Zhu, MD, Shaodong Hu, MD, Hongwei Hou, PhD, Qingyuan Hu, PhD, Yongqiang Pang, MD, Chemical Analysis and Simulated Pyrolysis of Tobacco Heating System 2.2 Compared to Conventional Cigarettes, Nicotine & Tobacco Research, Volume 21, Issue 1, January 2019, Pages 111–118. d) MSHR Local Research - Smoking Variations: Association With Lung Function 100% respondents who used HTP recorded healthy lung functioning.

Banning these lower-risk products would, quite inevitably, create an illicit market. By contrast, legalizing and regulating ANDS would allow marketing of products that adhere to set quality standards. Many countries have opted not to ban ANDS such as e-cigarette and chose to regulate them instead, e.g., the UK, the US and Australia. United Kingdom (UK) Government states "E-cigarettes around 95% less harmful than smoking while the New Zealand Ministry of Health which states quote 'Vaping has the potential to help people quit smoking and contribute to New Zealand's Smokefree 2025'. Countries supportive of THR strategies like the UK and New Zealand have shown continuous decrease in smoking rates in favor of using these less harmful products.

Reports of EVALI emerged after a string of reports on lung injuries among youths using vape in the US in 2019. The Centre for Disease Control and Prevention (CDC) identified that the real cause of the EVALI was the presence of vitamin E acetate which was added into illegal Tetrahydrocannabinol (THC) adulterated e-juices. As such, vaping was not real cause of the fatalities but the misuse and abuse of other products.

As such MSHR believes THR aspects has to be given important consideration for all future Malaysian tobacco related policies.

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Prof Siva Kumar

"Way forward for Tobacco Harm Reduction (THR) guided Tobacco Control in Malaysia"

1. **Guidelines on prescribing e-cig/NRT as OTC/varenicline for smoking cessation (abstinence model)**
2. **Guidelines on switching to alternatives (HNB, nicotine pouch, snus, etc.) (THR model)**

   FACT: As a class, RHPs are significantly less harmful than combustible tobacco

products, and replacing use of combustible tobacco products with RHPs can significantly improve health outcomes.

Unlike the combustion of cigarettes that produces approximately 7,000 Harmful and Potentially Harmful

Constituents (HPHCs), and of which at least 70 are proven or suspected carcinogens[5], THR products do not combust tobacco or other substrate and hence, the absence of smoke production leads to a 90-

95% reduction in emission of HPHCs on average[6],[7]. As such, THR product users' consequent exposure to carcinogens and toxicants is substantially reduced (as is bystanders' exposure). Clinical studies have indicated that this reduction in exposure can lead to improvements in clinical risk markers such as oxidative stress, endothelial dysfunction, lipid metabolism, inflammation and lung function[8],[9].

While THR products are not risk-free, as is also the case with NRTs and smoking cessation drugs, the substitution of combustible tobacco products with scientifically substantiated THR products reduce exposure to harmful toxicants[10]. This can reduce the risk of premature morbidity and mortality caused by smoking[11], which can translate to a beneficial impact on population health[12],[13] and ultimately, cost savings for the healthcare delivery system.

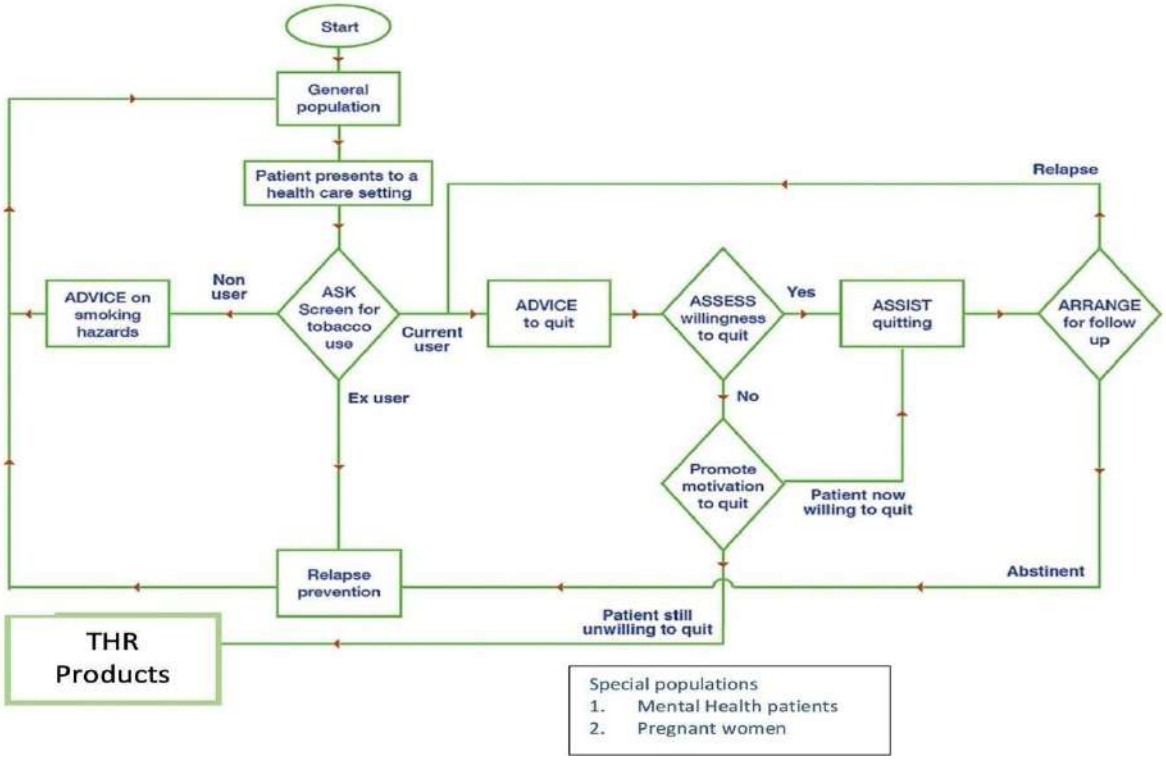
PRINCIPLE 1:

Tobacco harm reduction is a viable and complementary component to strengthen national tobacco control strategies.

Tobacco control efforts have primarily focused on (i) prevention of initiation (*ii*) cessation for smokers, and (iii) protection from environmental tobacco smoke [14]

Policies supporting abstinence to tobacco and nicotine products should be the preferred approach to create health and economic benefits. However, policies facilitating the switch to THR products that can reduce a smoker's exposure to toxicants can reduce the negative impact that combustible tobacco products has on the health of smokers and those around them[15]. As such, tobacco harm reduction is a viable strategy to support individual autonomy in controlling one's health outcome. Countries have a responsibility under the right to health to not deny access to THR products to smokers who want to quit using combustible tobacco products given the potential to improve their health outcomes[16].

ALGORITHM FOR TREATMENT OF TOBACCO USE DISORDER



Principle 2: Policies must be in place to ensure the safety and quality of RHPs.

Appropriate product safety standards should be put in place to protect RHP users. This may require the submission of product safety assessments, limitations on the amount of additives that may be carcinogenic, mutagenic, and/or are toxic additives, and the inclusion of a reporting structure for adverse events and product performance [17].

The requirement of establishing a body to regulate the THR products:

7. restrict e-cigarette tanks to a capacity of no more than 2ml.
8. restrict the maximum volume of nicotine-containing e-liquid for sale in one refill container to 10ml.
9. restrict e-liquids to a nicotine strength of no more than 20mg/ml.
10. require nicotine-containing products or their packaging to be child- resistant and tamper evident.
11. ban certain ingredients including colourings, caffeine and taurine include new labelling requirements and warnings.
12. require all e-cigarettes and e-liquids be notified and published by the regulation body before they can be sold.

Principle 3: A risk-proportionate regulatory regime should be applied to RHPs to enable complementarity with existing interventions designed to reduce the prevalence of combustible tobacco use.

THR products should not be over-regulated such as by requiring them to establish “safety” or “efficacy” as with pharmaceutical products. The restriction of access to THR products could have the unintended effect of entrenching the use of cigarettes and other harmful combusted forms of tobacco use and perpetuating the health burdens such products cause.

In addition, THR products can play an effective role in tobacco harm reduction if governments avoid over-medicalizing THR products, such as by classifying these products as prescription-only medicine, so as to avoid stigmatizing smokers who would like to consider switching to THR products.

A risk-proportionate taxation regime should be applied to THR products to encourage smokers who otherwise continue to smoke to switch from combustible tobacco products to scientifically substantiated

THR products [18],[19],[20], and attract investments that promote research and innovation into RHPs. In doing so, potential population health, economic and social gains and benefits such as a reduction in national health expenditure and overall improvement in national productivity[21] can be achieved.

Policies supporting abstinence to tobacco and nicotine products should be the preferred approach to create health and economic benefits. However, policies facilitating the switch to THR products that can reduce a smoker’s exposure to toxicants can reduce the negative impact that combustible tobacco products has on the health of smokers and those around them[15]. As such, tobacco harm reduction is a viable strategy to support individual autonomy in controlling one’s health outcome.

Principle 4: Policies must be in place to ensure equitable & affordable access to adult smokers, whilst limiting access to youth.

THR products should be made at least as accessible and affordable as combustible tobacco products to adult smokers to facilitate the replacement of combustible tobacco products with THR products.

THR products should be prohibited from sale to minors who are not of legal age to smoke. Additional controls to further curb initiation by and minimize appeal to vulnerable youths[24][25][26] should be imposed on THR products. This includes implementing labelling and warning requirements, restrictions on ingredients, flavours and product descriptors, as well as appropriate advertising, marketing and sale restrictions. For example, the current regulatory and health measures applied to alcohol and tobacco can similarly be applied to THR products [27],[28] in a risk- proportionate manner.

There must be a fine balance struck between implementing restrictions and regulatory controls to minimize access by youth whilst enabling access to smokers who want to move away from combustible tobacco products to RHPs.

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White paper for Tobacco Harm Reduction (THR) January 2023

Paper prepared by Prof Hussain, Assoc Prof Tahereh Seghatoleslam and Mdm. Sharon How.

Taken literally, Tobacco Harm Reduction (THR) —means reducing the harm created by tobacco and is a major aim of health professionals working in tobacco control who strive to achieve. However the term“ tobacco harm reduction” (THR) has become the source of one of the most divisive, often acrimonious debates in tobacco control history. Intense emotions, on both sides, have obstructed objective consideration of complicated THR issues.

This paper seeks to examine the data underlying those issues with the goal being to raise awareness of THR as well as to invite rational discussion among interested parties as well as the wider population.

This paper provides a broad overview, with readers directed to more detailed reviews of specific issues. Though much of what follows is relevant for countries worldwide, the review focuses on issues and evidence pertaining to the United States. The UK perspective is also included in this report. Readers should note that different cultural and political contexts might influence interpretations of what constitutes the most important issues and evidence.

Defining Tobacco Harm Reduction

THR refers to the substitution of a lower risk option which includes lower risk nicotine and tobacco products, e-cigarettes, nicotine replacement therapy, low nitrosamine with these options being primarily focused on those individuals who cannot quit or who refuse to quit smoking. This is the general strategy and concept relating to tobacco harm reduction in the field of public health. Harm Reduction International defines harm reduction and illicit drugs as follows:

Harm reduction refers to policies, programmes, and practices that aim to reduce the harm associated with the use of psychoactive drugs in people unable or unwilling to stop. The defining feature [is] the focus on the prevention of harm, rather than on the prevention of the drug use itself…Harm reduction complements approaches that seek to prevent or reduce the overall level of drug consumption.[1]

Each of the three sentences applies to THR: the objective is to reduce harm to the health of smokers who are unable or unwilling to stop. The focus is on *preventing harm* and not on preventing the use of nicotine itself. It is important to emphasise that THR *complements*—it *does not replace*—evidence-based approaches to prevent smoking initiation, assist smokers to quit, and protect non-smokers from second-hand smoke.

Recently, some scholars have adopted the term harm *minimization* instead of reduction.2 They believe "minimization" more effectively connotes the objective's importance, emphasizing the goal of getting harm down to zero. In contrast, "reduction" covers minor to major improvements. Because harm reduction is the term used throughout the field of public health, it is the term used in the present paper.

Principal findings from empirical studies on THR: (1) while longitudinal studies suggest that vaping increases never-smoking young people's odds of trying smoking, national survey data indicates that adolescents' 30-day smoking prevalence decreased at an unprecedented rate precisely whereas vaping increased. Use of all other tobacco products also declined. (2) Recent population-level studies add evidence that vaping is increasing adult smoking cessation. (3) Vaping is likely to make a positive contribution to public health

Harm Reduction History in Public Health and Tobacco Control

Harm reduction has a long and successful history in public health. Examples include:

- Needle exchange to minimize the spread of HIV/AIDS.
- Sex education for adolescents, and condom distribution in schools, to reduce teen pregnancies and sexually transmitted infections.
- Methadone as a substitute for heroin.
- Motorcycle helmet laws to reduce the severity of head injuries. • Designated driver programs to reduce drunk driving.

Such policies confront fervent public opposition, with a strong underlying tone of moralism. Nevertheless, the field of public health has often embraced harm reduction policies, always with a pragmatic focus on what works.

In tobacco control, experiences with the principal early examples of alleged "harm reduction"—filtered and low-tar-and-nicotine cigarettes—provides ample reason for scepticism about THR. Both were

tobacco industry public relations ploys, moves to reassure smokers that, instead of quitting, they could switch to ostensibly “safer” cigarettes.

One of the earliest filtered cigarettes, Kent, explicitly advertised itself as “*the one cigarette that can show you proof of greater health protection.”*

Ironically, its “exclusive Micronite filter” contained asbestos. Two decades later, a prominent low-tar-and-nicotine brand, named True, ran a series of advertisements showing intelligent-looking models with the tagline,

“*Considering all I’d heard, I decided I’d either quit or smoke True. I smoke True.”*

Advertisements such as these conveyed the message that the novel cigarettes were safe enough, compared to conventional “full-strength” cigarettes, to permit smokers to smoke them instead of quitting.

The campaigns worked. Millions of Americans switched to filters and then to low-tar-and-nicotine cigarettes. Both categories dominated the market within a decade of their introduction. Both were eventually demonstrated to be no less hazardous than their predecessors, and both were eventually responsible for millions of premature deaths.

These experiences, and the industry’s behavior in general have created in the public health arena profound hostility toward the industry, which had manifested in many wanting to drive industries out of business which was a desire expressed by former WHO Director-General Margaret Chan

This attitude constitutes a barrier to the acceptance of harm reduction because THR involves companies’ manufacturing and profiting from sale of nicotine and tobacco products, some marketed by the mainstream tobacco companies.

If the experiences with filtered and low-tar-and-nicotine cigarettes warrant scepticism about a new generation of purported harm reduction products, another experience offers reason to believe that THR might genuinely reduce harm.

For decades, large proportions of Swedish males have substituted snus, a low-nitrosamine smokeless tobacco, for smoking. Swedish males have the lowest male smoking rate in Europe: 8% in 2016. However, including snus, males’ total tobacco use prevalence, 25%, is not especially low. Yet Swedish males have by far the lowest tobacco-related mortality risks of men in all European Union

countries. In all 4 disease categories in Swedish males' death rate is lower than that of the lowest of all other EU countries.

In contrast, Swedish women, few of whom use snus, have average smoking rates among European women and average to high rates of tobacco-related death rates. Extensive research has found few health risks associated with snus. Swedish males' use of snus thus serves as an impressive natural experiment in successful tobacco harm reduction.

Harm reduction & tobacco control policy implementation in the UK

The UK White paper *Smoking Kills* published in 1998 introduced an extensive and comprehensive range of tobacco control measures and has been at the forefront of the global smoking epidemic of the 20th century and is now a world leader in smoking prevention. The UK has adopted a complementary harm reduction policy strand that is embedded in national policy. Guidance of which comes from the National Institute of Clinical excellence. Furthermore, tobacco harm reduction is strongly advocated for and supported by Action on Smoking and Health (ASH) which is a public health charity set up by the Royal College of Physicians; their principal being to end the harm caused by tobacco.

Conclusion

Putting forward the evidence cited in this brief report THR can be a complement to and not a substitute for evidence-based tobacco control interventions.

There is now a need for health professionals to focus on objective assessments of THR as well as to discuss the potential costs and benefits of THR.

White Paper Draft: Way Forward for Tobacco Harm Reduction (THR) in Malaysia

29th January 2023, 9am to 5pm

Frangipani Meeting Room, Sofitel Kuala Lumpur Damansara, Bukit Damansara, Kuala Lumpur.
https://goo.gl/maps/648aVpEaCbJ6Y8Lp6

Name : Dr. Arifin Fii
Designation : President, Advanced Centre for Addiction Therapy Advocacy
Assigned topic : Management of Side Effect of Smoke Free Products (NRT, NVP, HNB, Nicotine Pouch) – EVALI, Addiction Potential

Presentation content:

Points	Recommendations	Reference document (insert link or citation in APA style)
1	Awareness Campaign	
2	Promotion	
3	Manufacturing Standards	
4	Regulations	
5	Monitoring and Enforcement	

BACKGROUND

Combustible tobacco smoking kills approximately 8 million people each year according to the latest WHO reports. There are approximately 1.3 billion smokers worldwide and 80% of the smokers live in Low and Medium Income Countries (LMIC). In the developed world majority of the smokers are in the underprivileged group of the population.

Apart from the loss of life, the financial burdens attributed to cigarette smoking is approximately 1.86 trillion dollars annually.
Despite billions of dollars spent annually for tobacco control, the prevalence of smoking is still high worldwide. 1 in 5 people smokes.

THR aims at reducing the harm of nicotine addiction resulted from combustible cigarette smoking with a much less harmful alternative of nicotine delivery – Smoke Free Products or Reduced Harm Products. These products are Nicotine Vaping Products (NVP), Heat Not Burn (HNB), Nicotine Replacement Therapy (NRT), Nicotine Pouch and Snus.

2	The New Zealand Government adopts a THR guided approach towards its Smokefree Aotearoa 2025 target. Both medical associations and non-profit organizations alike have increasingly endorsed e-cigarette as a smoking cessation tool. In December 2022, it released a tobacco control bill that significantly limits the number of retailers able to sell smoked tobacco products; aims to prevent young people from taking up smoking by prohibiting the sale of smoked tobacco products to anyone born on or after 1 January 2009; and aims to make smoked tobacco products less appealing and addictive. While it uses a Generational End Game (GEG) approach to smoked tobacco products, while regulating rather than ban vaping products.	1. https://www.parliament.nz/en/pb bills-and-laws/bills-proposed-laws/document/BILL_125245/smokefree-environments-and-regulated-products-smoked-tobacco 2. Action for Smokefree 2025 (ASH). (2017). Vaping and Harm Reduction. Retrieved May 18, 2021, from https://www.ash.org.nz/campaig_1 3. Mendelsohn, C. (2020, April 22) Australian and New Zealand medical specialists announce support for vaping. Australian Tobacco Harm Reduction Association (ATHRA). https://www.athra.org.au/blog/2020/04/23/australian-and-new-zealand-medical-specialists-announce-support-for-vaping/
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Guidelines on switching to alternatives (HNB, nicotine pouch, snus, etc) (THR model)

Points	Recommendations	Reference document (insert link or citation in APA style)
1	Based on commentary paper by Fagerstrom (2022): countries with relatively high adoption of alternative nicotine products like HNB and snus (the UK, Sweden, Norway, New Zealand, and Japan) have been able to achieve lower smoking rates.	Fagerström K. Can alternative nicotine products put the final nail in the smoking coffin? Harm Reduct J. 2022 Dec 1;19(1):131. doi: 10.1186/s12954-022-00722-5. PMID: 36456941; PMCID: PMC9714162.
2	Recalcitrant smokers should be advised to consider using non-combustible tobacco	https://www.skynews.com.au/world-news/new-zealands-

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Malaysia Society For Harm Reduction

Pioneer society championing the concept of Harm Reduction in Malaysia

White Paper Draft:

Way Forward for Tobacco Harm Reduction (THR) in Malaysia 29th January 2023, 9am to 5pm Frangipani Meeting Room, Sofitel Kuala Lumpur Damansara, Bukit Damansara, Kuala Lumpur. https://goo.gl/maps/648aVpEaCbJ6Y8Lp6

Name: DR. MOHAMMED KHAFIDZ BIN MOHAMAD ISHAK

Designation: PRESIDENT INSAF MURNI ASSOCIATION OF MALAYSIA (IMAM)

Assigned topic: CALL FOR ACTION (WHY IS THR CRUCIAL TO GEG SUCCESS)

Presentation content:

Points

Recommendations

Reference document (insert link or citation in APA 1

Protect the human rights of people who smoke and use tobacco. Allow room for THR before implementing GEG. Treat tobacco smokers with dignity and respect without discrimination. People should be able to decide for themselves.

https://www.euractiv.com/section/politics/short_news/eu-laws-block-danish-
https://www.candi.nhs.uk/wellbeing/smoking-and-nicotine-dependence/rights#:~:text=Tobacco%20smoke%20is%20a%20Class,any%20perceived%2

Educate the public not only on the harms of smoking but also educating smokers themselves to reduce or quit smoking. Malaysian prevalence of

https://www.nicorette.com.my/get-ready-to-quit/writing-down-goals-and-yourself?gclid=EAIaIQobChMIwcPkp-Dh_AIVQUorCh1NeQsEEAAYASAAEgJk0PD_BwE&gclsrc=aw.ds

https://www.uptodate.com/contents/quitting-smoking-beyond-the-basics#:~:text=Prepare%20for%20withdrawal%20symptoms.,tips%20on%withdrawal.

Malaysia Society for Harm Reduction

Pioneer society championing the concept of Harm Reduction in Malaysia. smoking

is 20% with stagnated decrease trend.

3

Policy makers, MOH, and media coverage should give priority in disseminating scientific evidence based information about THR . They should educate the public about the benefits of THR and correct the misleading information about THR.

https://pubmed.ncbi.nlm.nih.gov/25814920/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3691171/

https://www.nejm.org/doi/full/10.1056/nejmoa1808779

https://www.sciencedirect.com/science/article/abs/pii/S1551741120301030

4

Implementation of GEG should be done in a phased approach with integrated strategy by recognizing alternative HRPs to complement smoking cessation as well as reducing the

supply & demand. Zero tolerance or prohibitive approach will only increase illicit tobacco trade.

https://www.straitstimes.com/asia/australianz/new-zealand-aims-for-smoke-tobacco-law

https://www.thesundaily.my/opinion/vape-a-key-ally-to-achieve-tobacco-
https://www.youtube.com/watch?v=NStrcFbVf0M

https://www.todayonline.com/singapore/moh-study-new-zealands-cohort-be-applied-here-

1788131 5

Control illicit tobacco trade. Enforcement from authorities is a key

https://www.aljazeera.com/news/2020/8/29/bhutan-lifts-tobacco-ban-amid-
htpps://www.google.com/url?sa=t&rct=j&g=&esrc=s&source=web&cd

=&ved=2ahUKEwjJpPOA4

Malaysia Society for Harm Reduction

Pioneer society championing the concept of Harm Reduction in Malaysia.

factor to effective tobacco control.

White Paper Draft: Way Forward for Tobacco Harm Reduction (THR) in Malaysia

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https://goo.gl/maps/648aVpEaCbJ6Y8Lp6

Name : Adj Prof Dr Prem Kumar Shanmugam
Designation : CEO & Clinical Director Assigned topics:

1. Regulatory best practices
2. Guidelines on switching to alternatives (HNB, nicotine pouch, snus, etc)(THR model)

Presentation content:

Regulatory best practices for Malaysia consideration

Points	Recommendations	R ference document (insert link or citation in APA style)
1	The UK Government has reiterated the benefit of e-cigarette vaping over cigarette smoking, endorsing that e-cig is likely 95% less harmful than cigarette. With the support of medical societies like the Royal College of Physicians (RCP), its National Centre for Smoking Cessation and Training (NCSCT) and the National Health Service (NHS) has aborted the traditional "quit or die" approach and now actively supports e-cigarette-based interventions alongside smoking cessation programs at local stop-smoking services.	1. Public Health England (PHE). (2015). McNeill A, Brose LS, Calder R, Hitchman SC, Hajek P, McRobbie H. E-cigarettes: an evidence update. A report commissioned by Public Health England. London. https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update 2. Royal College of Physicians (RCP) (2021). Smoking and health 2021. A coming of age for tobacco control?: A report by the tobacco advisory group of the royal college of physicians. London: Royal College of Physicians. 3. https://www.ncsct.co.uk/usr/pub/Electronic_cigarettes._A_briefing_for_stop_smoking_services.pdf
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	prevent young people from taking up smoking by prohibiting the sale of smoked tobacco products to anyone born on or after 1 January 2009; and aims to make smoked tobacco products less appealing and addictive. While it uses a Generational End Game (GEG) approach to smoked tobacco products, while regulating rather than ban vaping products.	3. Mendelsohn, C. (2020, April 22). Australian and New Zealand medical specialists announce support for vaping. Australian Tobacco Harm Reduction Association (ATHRA). https://www.athra.org.au/blog/2020/04/23/australian-and-new-zealand-medical-specialists-announce-support-for-vaping/
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Points	Recommendations	Reference document (insert link or citation in APA style)
1	Based on commentary paper by Fagerstrom (2022): countries with relatively high adoption of alternative nicotine products like HNB and snus (the UK, Sweden, Norway, New Zealand, and Japan) have been able to achieve lower smoking rates.	Fagerström K. Can alternative nicotine products put the final nail in the smoking coffin? Harm Reduct J. 2022 Dec 1;19(1):131. doi: 10.1186/s12954-022-00722-5. PMID: 36456941; PMCID: PMC9714162.
2	Recalcitrant smokers should be advised to consider using non-combustible tobacco products instead. In countries like Japan and New Zealand, HNB is marketed as consumer products rather than pharmaceutical (medicinal) items. Similarly, snus and nicotine pouches are made available as consumer products in available markets. Healthcare professionals should be equipped with factual information on each category of non-combustible product so that accurate information is passed on to their smoking patients.	https://www.skynews.com.au/world-news/new-zealands-worldfirst-smoking-ban-made-viable-by-legal-vaping-harm-reduction-advocates-argue/news-story/ad52c508adcf3ac746dcccde74293af9
3	Healthcare professionals should keep informed on each product category characteristics (e.g., HNB offers tobacco taste, snus/nicotine pouch is speedily absorbed for fast “kick”), quality specifications and regulatory control on non-combustible products so that they can educate patients towards choosing & using only well-regulated products.	

4	A new paper provides an interesting perspective on how **risk-proportionate government regulation** can facilitate smokers to move away from cigarette and switching to less harmful alternatives, and incentivize cigarette companies to promote less harmful non-combustible products.	David T Levy, PhD, Frances Thirlway, PhD, David Sweanor, JD, Alex Liber, PhD, Luz Maria Sanchez-Romero, PhD, Rafael Meza, PhD, Clifford E Douglas, JD, K Michael Cummings, PhD,
		Do Tobacco Companies Have an Incentive to Promote "Harm Reduction" Products?: The Role of Competition, Nicotine & Tobacco Research, 2023;, ntad014, https://doi.org/10.1093/ntr/ntad014
5		

White Paper Draft: Way Forward for Tobacco Harm Reduction (THR) in Malaysia

29th January 2023, 9am to 5pm

Frangipani Meeting Room, Sofitel Kuala Lumpur Damansara, Bukit Damansara, Kuala Lumpur.

Name : Associate Professor Dr Rusdi Abdul Rashid

5 Recommendations:

1. Harm reduction approach is one of the pillars to address chronic smokers who are dependent on nicotine but not ready to quit for whatever reasons.
2. Suggest Gov put all nicotine delivery equipment under registration and monitoring by MOH and must have a prescription by a doctor for first-time use.
3. GEG, if implemented, must not have punitive elements but educational in nature with the option for treatment as well.
4. To make treatment available at an affordable cost lower than the cigar itself with some help and curb the sales of "rokok seludup secara habis habisan" before imposed GEG move.
5. To implement educational programs on a big scale at the national level on minimizing the harms of smoking at school at workplace.