From: New Nicotine Alliance (UK) in collaboration with
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To: Senior Advisor Tobacco Policy, Public Health Services
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Thank you for the opportunity to comment and participate in Tasmania's public discussion on e-cigarettes. Australia and its states and territories have often set trends in tobacco policy and what happens in Australia often has global significance. In the case of e-cigarettes and the wider concept of tobacco harm reduction (the availability of low risk alternatives to smoking for those who cannot or do not wish to quit using nicotine), Australia is setting a terrible and misguided example. It has adopted illiberal prohibitionist policies that protect the cigarette trade, deny smokers better and safer products, and will ultimately cause more misery, disease and death. E-cigarettes present an opportunity far greater than any conceivable threat. It is hoped that a thorough and open discussion of the potential for e-cigarettes would help to change this and position Tasmania as a leader in overhauling the approach taken throughout Australia as a whole. This perspective is elaborated in this submission in four parts:

- Part 1: Comments in response to the main questions posed in the response template
- Part 2: Comments on the positioning of tobacco harm reduction in tobacco control
- Part 3: Comments on some of the controversial aspects of e-cigarettes,
- Part 4: Sources and links that will assist interested parties become familiar with the evidence and how to interpret it.

In addition we have attached a more detailed briefing for further information - *E-cigarettes, vaping and public health: a summary for policy-makers*[1]

We would be pleased to assist in any way.

Sarah Jakes on behalf of The New Nicotine Alliance (UK)
Declaration: the New Nicotine Alliance is a UK-based registered charity concerned with improving public health, through a greater understanding of risk-reduced nicotine products and their uses. It receives no funding from tobacco, e-cigarette or pharmaceutical companies or their affiliates.

Clive Bates
Director, Counterfactual Consulting and Advocacy
Declaration: I was Director of Action on Smoking and Health (UK) from 1997-2003 and a founder of the Framework Convention Alliance in 2000. My interest is in public health strategies to reduce cancer, heart and respiratory disease through tobacco harm reduction. I have no competing interests.

Part 1: Comments in response to questions posed in the response template

1. Options to prevent uptake

Option 1.1: Continue with the status quo

a) Do you support maintaining the current arrangements governing the promotion and sale of electronic cigarettes in Tasmania?

No. The direction should be to *liberalise* from the current arrangements to make access to e-cigarettes significantly easier than access to cigarettes – not to ban the former while the latter are freely available. The *de facto* prohibition on nicotine-containing e-cigarettes amounts to a regulatory protection for the cigarette trade and an unethical denial of options for smokers to radically reduce their risks. While Tasmania is constrained by poorly designed policy and regulation determined at federal level it should take great care not to add to the harms and unintended consequences imposed via federal regulation.

The framing of this section reflects a serious flaw in Tasmanian and Australian tobacco control policy: that is the mistaken objective to 'prevent uptake' of e-cigarettes. If smokers wish to choose to use an e-cigarette instead of smoking some or all of the time, that is a good thing and should be encouraged not obstructed. Even concern about youth uptake should recognise that youthful experimentation with e-cigarettes may be a beneficial diversion from smoking.

Option 1.2: Public education

a) Do you support public education activities to inform the community about the potential health and safety risks associated with using nicotine-free electronic cigarettes?

No. Normally it would be wise to provide the public with information on risks and benefits of public health choices. But this applies only if the public authorities present coherent and evidence-based information to the public that is both factually correct and not misleading (it is possible to make statements that are true but misleading or misunderstood when communicated). Messages should also be balanced and proportionate: recognising substantial benefits as well as communicating the likely magnitude of any risks. On the basis of the briefing document accompanying the consultation, the Tasmanian health authorities have not yet acquired a sufficient understanding of the science and ethics of e-cigarettes to underpin credible public communication. Until then, it would be improper to spend public money on communicating distorted information that would mislead and harm the public.

b) Do you think community education and awareness raising activities would be sufficient to prevent electronic cigarette uptake by non-smokers, ex-smokers and young people?

This question betrays a flawed and unethical approach to public communication and education as it takes no account of the benefit to smokers of switching, and makes no reckoning of the relative risk to non-smokers in comparison to the substantial benefit to smokers. It is not the appropriate role of public authorities to provide false and misleading information designed to secure a particular pre-determined behaviour change outcome. Non-smokers may enjoy vaping for little risk to themselves

or those around them, just as some people enjoy caffeine or modest alcohol consumption. Ex-smokers may find it reduces craving and loss, and protects against relapse to smoking in times of stress. Certain young people may benefit from vaping if it is likely that, in the absence of e-cigarettes, they would have otherwise smoked. It is not the appropriate role of the state to second guess these preferences and impose a preferred outcome through misleading public information.

The aim should be to provide realistic information about risk, benefits and options that are open to the public. As argued previously, for many smokers e-cigarettes may provide an extremely effective alternative to smoking. A modest effort to look for testimonies of e-cigarette users' experience would confirm this[2]. Here is one of many, in their own words:

> *Vaping has probably saved my wife's and my own life's, I was a smoker for 50 years, nothing I have ever tried has had the impact of vaping, this alone was the only thing that saved me, how can governments legislate against something that is saving so many peoples life's.*

It is not appropriate for Tasmania Public Health Services to have an objective of preventing such positive experiences arising in Tasmania on the basis of unlikely uptake by non-smokers, ex-smokers or young people (who would not otherwise have smoked), and relatively minor risks to those that do.

Option 1.3: Restrictions on sale and advertising

a) Do you support the introduction of restrictions on the sale and promotion of electronic cigarettes in Tasmania?

No. This is an irresponsible regulatory protection for the incumbent cigarette trade against a disruptive entrant that likely offers a reduction of risk of at least 95 per cent. Again, no attempt has been made to recognise or assess the unintended consequences of denying e-cigarette vendors the means to compete with cigarettes. It also prevents e-cigarette manufacturers communicating innovations and building trusted to brands to take on the cigarette trade. The approach to e-cigarette advertising taken in Britain through the Codes of the Committee on Adverting Practice strikes a proportionate balance – preventing glamorisation and marketing explicitly to youth, but balanced with granting the commercial freedoms necessary to compete with the cigarette trade[3].

For a public body it is better to conceptualise e-cigarette advertising as market-based, public health and anti-smoking advertising, which also places no call on taxpayers' funds.

Option 1.4: Prohibit sale to people under 18 years of age

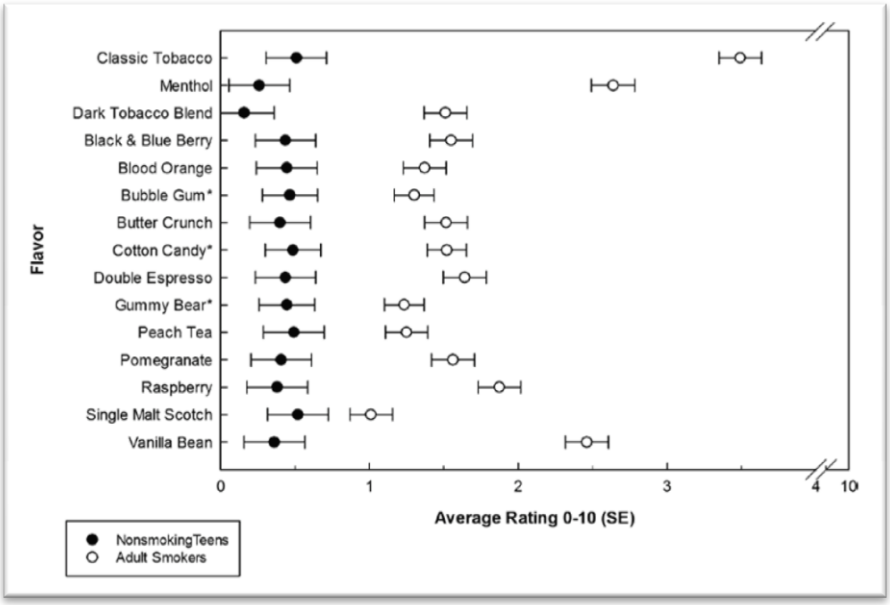
a) Do you support extending existing restrictions on the sale of tobacco to children to include electronic cigarettes?

Yes. In most jurisdictions this is a politically important measure to provide reassurance that e-cigarettes are not targeted at the young. In reality it is unclear whether it is actually an optimum approach from a public health perspective: if it has the effect of denying under-18s access to e-cigarettes as an alternative to smoking it may be causing harm. Fortunately, it is likely the ingenuity of young people would in any event mitigate the harms arising from poorly conceived prohibitions.

Option 1.5: Prohibit sale of flavoured e-liquids

a) Do you support prohibiting the sale of flavoured e-liquids in Tasmania?

No. This is a very poor idea. Flavours are integral to the appeal of e-cigarettes and thus to their ability to attract smokers to switch and to prevent users relapsing to smoking. It is often asserted, as if it is obvious, that flavours with childish characteristics will appeal to adolescents. There is no evidence for this, just assertion. It is actually counter-intuitive: most adolescents are imitating *adult* behaviour, not reinforcing their status as children. The one study that has looked at the preferences of young people for e-cigarette flavours found extremely low interest. Teenagers were asked to rate their interest on a scale of 0-10 in using e-cigarettes and were offered a list of flavours. They reported minimal interest (average =0.41 out of 10), much less than adult smokers (1.73 out of 10) and interest did not vary much across flavours[4]. To the extent that any preferences were revealed among teens, 'Single Malt Scotch" and 'Classic Tobacco' were top.



Other studies confirm that adults are attracted to supposedly juvenile flavours like cherry crush, or fruit loop. For example a survey of users of the world's largest user forum found fruit to be the most popular flavour category[5] *for adults*. A similar survey of over 4,519 users found 44% used tobacco, 32% menthol/mint, 61% sweet, 15% nuts, 69% fruit, 37% drink, and 22% other[6]. Non-users should understand that flavours are an important aspect of vaping and integral to the experience. They are also part of a migration away from tobacco. Initial switchers tend to favour tobacco flavours but gradually move on to non-tobacco flavours often as part of a permanent switch from smoking.

Option 1.6 Regulate electronic cigarettes and tobacco in the same way

a) Do you support electronic cigarettes being fully regulated in the same way as tobacco?

No. This would amount to another improper regulatory protection for the cigarette trade. In most jurisdictions there are well-established principles governing regulation: for example, that regulation be proportionate and risk based and non-discriminatory (i.e. applied consistently). E-cigarettes are

very different in terms of physics, chemistry, health risk to the user, and any risk to bystanders. Furthermore, the far less harmful product, e-cigarettes, functions as a *harm reduction alternative* to cigarettes. Tough controls on harm make sense, but tough controls on 'harm reduction' can easily cause more harm. E-cigarettes can offer significant health benefits to smokers in alleviating symptoms caused by smoking[7]. There is no reason to regulate these products as something they are not – as tobacco products, poisons or medicines. They are consumer products and need light regulation to promote confidence in the quality of products and business practices of vendors. To regulate them as if they were cigarettes would be disproportionate to risk and highly discriminatory – in a way that will cause harm to health.

2. Options to prevent renormalisation of smoking and protection from second hand vapour

Option 2.1: Continue with the status quo

No. The question is based on a false premise. E-cigarettes have the aim and likely effect of *denormalising smoking* by providing a visible alternative on which business success depends. E-cigarettes normalise a pathway out of smoking – that is how the business functions. Where there is a growing market share for e-cigarettes, there is no sign of any 'renormalisation' effect. The UK's foremost experts in smoking cessation who also manage the surveillance of the market in nicotine products in England concluded[8]:

> *Evidence conflicts with the view that electronic cigarettes are undermining tobacco control or 'renormalizing' smoking, and they may be contributing to a reduction in smoking prevalence through increased success at quitting smoking*

The analysis in Tasmania appears to be based on a hypothetical risk for which no evidence or common sense intuition exists, but with no recognition of the far more plausible major benefit – that e-cigarettes will contribute to denormalising smoking by increasing awareness of an alternative.

Option 2.2: Prohibit use in existing smoke free public places

a) Do you support prohibiting electronic cigarette use in existing smoke free areas?

No. It is important to start by examining the appropriate role of the state in proscribing behaviours and the choices of citizens and property owners. The use of the law should be confined to those situations where it is imperative that the law overrides the preferences of the owners or managers of public spaces (which are often privately owned). That would be where there is clear evidence or reasonable expectation that one person's behaviour causes or can cause material harm to another – the so-called harm principle – and that these risks are not trivial or contrived. Otherwise, it should be a matter for the owner or manager to decide. There is no evidence that e-cigarette vapour poses any material risk to bystanders. It is completely different chemically and physically to second hand cigarette smoke.

Again, the Tasmanian analysis does not consider or even recognise the potentially harmful impact of bans on indoor vaping mandated by law. These include:

- Degrading the attractiveness of e-cigarettes as an alternative to smoking and so protecting the cigarette trade through reduced switching or increased relapse to smoking;

- The harmful effects of forcing vapers to join smokers to use e-cigarettes – discouraging switching and promoting relapse;
- The invasion of commercial freedoms and consumer choice together with loss of welfare to e-cigarette users and no concomitant gain for anyone else.

It is unlikely that owners and operators would take a *laissez faire* approach to allowing e-cigarette use and many places are likely not to allow it by their own choice. But if an office wants to have a vaping area, a bar wants a vape room or vaping night, a coffee shop chooses to cater for vapers, or an airport wishes to allow vaping in its terminals, then why should the state intervene with the force of law prevent them?

3. Do you have any other comments?

Yes. Some general remarks are set out below with a guide to better understanding the published literature, with links to informative sources.

Poor ethical framework. The overall approach to e-cigarettes as set out in the discussion paper is misguided: it exaggerates minor risks or risks that are purely hypothetical, but takes no account of the benefit to smokers. It also lacks an ethical framework to address these issues. At no point does the analysis reflexively pose obvious questions to test the ethical underpinning of the policy:

> *How can we justify preventing Tasmanian smokers having access to e-cigarettes as a much safer alternative to smoking, while we allow cigarettes to be widely available?*
>
> *How many extra people might we cause to continue smoke who might otherwise quit smoking through e-cigarettes, and what responsibility would we bear for any premature deaths that occurred as a result?*
>
> *We may not know everything about e-cigarettes, but given what we do know, what judgements should we make and how do we validate these or adjust our policy as knowledge evolves?*
>
> *Because we don't have complete knowledge of e-cigarettes, are we right to ensure that consumer choice is limited to only the products we are certain are highly dangerous?*
>
> *How likely is it that someone will take up vaping who would not otherwise have smoked, what harm would it cause and how would we weight this against the very significant health benefits to smokers who switch (or potential smokers who never start)?*

Unintended consequences. Finally, the analysis systematically ignores highly plausible unintended consequences that could arise from regulatory choice made in Tasmania and Australia generally. For the most part, these would have the effect of making e-cigarettes less effective and appealing as alternatives to smoking – and in doing so risk increasing smoking and protecting the cigarette trade.

Part 2: Comments on positioning tobacco harm reduction in tobacco control

E-cigarettes and fundamentals of tobacco control strategy

Tobacco control strategy should be focussed on reducing premature death and serious harms like cancer, cardiovascular and respiratory disease as rapidly as possible. To that end, the most effective tobacco control strategy has four main elements:

1. To provide strong incentives not to start smoking;
2. To motivate and help people to quit smoking tobacco;
3. To reduce harm to those who continue to use nicotine;
4. To reduce harm to non-smokers arising from exposure to toxins in second hand smoke

A *de facto* e-cigarette prohibition does not fit well into such a strategy. This is because it reduces the options to help people to stop smoking or to use nicotine in a way that is substantially less harmful. It makes it more likely that people will continue to smoke tobacco, and that non-smokers will be exposed to tobacco smoke rather than relatively benign vapour.

A precautionary approach?

We start from an assessment based on what is known of the chemistry of e-cigarette vapour that e-cigarettes are likely to present *at least 95% lower risk* to health than cigarettes (see below). Our overall concern, therefore, is that the *de facto* prohibition on e-cigarettes will prove harmful to health, unjustly protect the cigarette trade and deny many Tasmanian citizens options that could save their lives, presenting a significant ethical challenge to a prohibition. Although the proposal is framed as precautionary, given some remaining scientific uncertainties, this precaution is an illusion. We know *enough* to be confident that vapour products present very much lower risks than smoking. A prohibition is not precautionary because in practice the unintended consequences of a prohibition could be very harmful to health. It is *never* a responsible or cautious approach to ban new alternative products that are many times safer than the dominant market leader, cigarettes in this case – especially while cigarettes will continue to be freely available. There are no precedents for this kind of prohibition in any area outside tobacco control. In this market, banning low risk products is dangerous rather than precautionary.

Tobacco harm reduction is a critical strategy in tobacco control

At the heart of this strategy is the concept of 'tobacco harm reduction'. This concept recognises that smoking is primarily driven by seeking nicotine and that there are many people who cannot or will not stop using nicotine. It has been known for 40 years that people "*smoke for the nicotine and die from the tar*"[9]. This creates the prospect that providing nicotine without the tar and toxic gases in tobacco smoke could have significant health benefits. There is strong consensus among scientists that nicotine products that do not involve burning tobacco are far less risky than smoking. As the Royal College of Physicians explained in its landmark report, *Harm reduction in nicotine addiction*[10]:

> *This report makes the case for harm reduction strategies to protect smokers. It demonstrates that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.*

Thanks to rapid technological innovation, there is now a growing range of products that can meet this need: e-cigarettes and other electronic nicotine delivery systems (ENDS); nicotine inhalers; purified smokeless tobacco like snus; heated tobacco vaporisers; and an increasingly wide range of novel nicotine products such as strips, gums and lozenges. These products eliminate the tar because there is no smoke involved. It is this basic fact of physics and chemistry that provides the opportunity to reduce smoking-related disease. The harm reduction strategy works because it does not require a smoker to give up both smoking *and nicotine*, or the behavioural or social rituals that go with it - only the harmful smoke itself. Because it is easier for many smokers to switch to a low risk nicotine product than to quit smoking and nicotine completely, switching therefore increases that likelihood of success in reducing disease.

Arguments against prohibition of e-cigarettes

The World Health Organisation was careful in its 2014 briefing to avoid proposing prohibitions on ENDS, instead stressing regulation rather than prohibition, and judging that[11]:

> *ENDS, therefore, represent an evolving frontier, filled with promise and threat for tobacco control. Whether ENDS fulfil the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates (1)*

The citation (1) at the end of this specific statement by WHO refers to a commentary by Dr David Abrams, Executive Director of the Schroeder Institute for Tobacco Research and Policy Studies and Professor in the Department of Health, Behavior and Society at the Johns Hopkins Bloomberg School of Public Health writing in JAMA[12]. Abrams concludes:

> *The more appealing e-cigarette innovations become, the more likely they will be a disruptive technology. Although the science is insufficient to reach firm conclusions on some issues, e-cigarettes, with prudent tobacco control regulations, do have the potential to make the combusting of tobacco obsolete. Strong regulatory science research is needed to inform policy. If e-cigarettes represent the new frontier, tobacco control experts must be open to new strategies. Statements based on ideology and insufficient evidence could prevent the use of this opportunity before it becomes established as part of harm reduction strategy.*

It is clear that the leading edge in tobacco control is not in prohibition of these products, but in working out how best to exploit the huge opportunities while minimising any residual threats. In other words, tobacco control leadership means skilful design of regulation based on sound science, not ideology. Fifty-three experts in nicotine and tobacco science and policy wrote to Dr Margaret Chan, Director General of the WHO, to reinforce these points. They urged her organisation and the world community to take a positive approach to 'tobacco harm reduction' and to work towards exploiting the opportunities and to take a sceptical view of misleading scientific analysis[13 14].

> *The potential for tobacco harm reduction products to reduce the burden of smoking related disease is very large, and these products could be among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives. The urge to control and suppress them as tobacco products should be resisted and instead regulation that is fit for purpose and designed to realise the potential should be championed by WHO.*

Part 3: Comments on controversies about e-cigarettes

While we present the big picture above, there are many details to address that go beyond the scope of this submission. However, we believe it would be helpful to signal some of the available literature that may inform an evidence assessment. We provide a guide to some of the evidence on key points below:

1. **Toxicity.** The concentrations of toxins or carcinogens in e-cigarette vapour are generally tens to thousands of times lower than in cigarette smoke. Many toxins are simply not present at detectable levels or equivalent to the tolerances allowed in medical products[15]. This is the reason why experts believe e-cigarettes to be at least 95% lower risk than smoking[16 17] "

   > *From analysis of the constituents of e-cigarette vapour, e-cigarette use from popular brands can be expected to be at least 20 times safer (and probably considerably more so) than smoking tobacco cigarettes in terms of long-term health risk".*

2. **Second hand vapour exposure.** Exposure to second hand cigarette smoke is thought to create risks of disease in bystanders and is a legitimate cause for restrictions on use in the workplace. E-cigarettes do not emit smoke because there is no combustion. Any toxins and nicotine in exhaled vapour are at extremely low levels compared to the side-stream and mainstream emissions from cigarettes. In his detailed review of the toxicity evidence, Igor Burstyn concluded that risks to active users were well below thresholds used to set workplace exposure standards and concluded that[18]:

   > *Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern*.

3. **Particulates**. Though particulates from diesel engines, power stations and cigarette smoke are harmful, it cannot be assumed that particles from ENDS vapour are harmful simply because they are the same size. The aerosol particles in e-cigarette vapour do not have the same aggressive surface chemistry and physics as smoke particles, which contains thousands of products of combustion. The size of the particles is of little importance if they are not actually toxic[19].

4. **Nicotine related risks.** For *any* nicotine user an e-cigarette product will be much less risky than continuing to smoke – that applies to pregnant smokers and adolescents. The safety profile of nicotine has been well established through years of trials of nicotine replacement therapy, and more recently through the assessment of health risks from Swedish snus, which provides nicotine but without smoke. Nicotine is not a carcinogen or a cause of cardiovascular disease. Though it is the addictive agent in cigarettes, there is no evidence of significant harm from nicotine use, *per se*[20].

5. **Smoking cessation.** There are now millions of ex-smokers who use e-cigarettes or smokeless tobacco. For example in Britain, there are 2.6 million e-cigarette users of which 1 million are ex-smokers[21]. They are not using e-cigarettes as a smoking cessation treatment, but as a relatively low risk alternative to harmful smoking as way of consuming nicotine. A Cochrane Review of e-cigarette *trials* suggests that, on the limited data available, vapour products are likely to be effective for smoking cessation[22]. Most studies have been observational, rather than trials and have generally shown success with e-cigarettes. For example, one of the best designed observational studies found[23]:

> *People attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies.*

6. **Gateway effect and renormalisation: unfounded**. There is no evidence anywhere in the world supporting a 'gateway effect' in which low risk products such as e-cigarettes cause people who would not have smoked to become cigarette smokers. Generally we have seen declines in teenage smoking accompany any rise in e-cigarette use and e-cigarette use highly concentrated among smokers. It is likely that e-cigarette use is an *alternative* to smoking in young people who would otherwise have started to smoke - and thus have a protective effect. Longer-term data are needed but there is no basis to draw any conclusion that use of e-cigarettes leads to an increase in smoking.[24]

7. **Proof of concept: the Swedish experience.** We have a strong proof of concept that alternative sources of nicotine can radically reduce smoking and related disease - and this is an opportunity that should not be wasted with badly designed legislation. In Europe, Sweden stands out as having by far the lowest smoking rate, 11% in Sweden compared to the EU average of 26%.[25] The reason for this is the high use of snus instead of smoking. This has led to very substantial reductions in disease in Sweden[26] that cannot be even partly replicated in the rest of the EU because snus has been banned in the EU other than Sweden.

8. **Professional practice**. There is now recognition among professional tobacco control and public practitioners that e-cigarettes (ENDS) can be used constructively to reduce harm. For example in Britain, cautious, evidence-based guidance for professionals has been developed by the National Centre for Smoking Cessation and Training and Public Health England, the government's public health agency. It provides a clear and measured assessment of science and best practice that could be valuable to any country wishing to exploit the opportunities and minimise the risks[27].

Conclusion – towards a credible endgame for tobacco related disease

The only thing really threatened by e-cigarettes is the manufacture, import, sale and consumption of *cigarettes*. To prohibit e-cigarettes when they compete with cigarettes but have far lower risk to the user would be an unscientific, unethical and a lethal error based on current evidence. Derek Yach, the former WHO Director for tobacco policy who led development of the global Framework Convention on Tobacco Control, summarises this perspective[28]

> *At the moment, it's estimated that there will be a billion tobacco-related deaths before 2100. That is a dreadful prospect. E-cigs and other nicotine-delivery devices such as vaping pipes offer us the chance to reduce that total. All of us involved in tobacco control need to keep that prize in mind as we redouble efforts to make up for 50 years of ignoring the simple reality that smoking kills and nicotine does not.*

We hope we have provided enough information and analysis to show that there is at least a deeper debate about the role of these products. Mandatory classification of these products as medicines is not a good policy: this applies large costs, burdens and restrictions that only major tobacco companies can meet and amounts to a regulatory protection of the cigarette trade, a barrier to innovation and denies smokers the wide variety of products and forms that are making this disruptive technology so successful[29]. Technological innovation provides a 21st century alternative that might one day make the cigarette obsolete.

Part 4: Sources and links

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