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Submission to the Government of Taiwan Tobacco Hazards Prevention and Control Act Amendment Bill International Network of Nicotine Consumer Organisations¹

The International Network of Nicotine Consumer Organisations (INNCO) is the collective voice for the most influential nicotine consumer organisations in twenty countries around the world. To address the burden of disease created by smoking tobacco, we promote the use of alternatives low-risk products such as e-cigarettes, smokeless tobacco and heated tobacco products that provide users with nicotine, but put them at much lower risk. We believe this approach can achieve rapid results in Taiwan and with the support of the people who are most at risk.

The government of Taiwan is seeking comments on its proposals to amend the Tobacco Hazards Prevention and Control Act (TWCA) of 1997. We wish to comment on the proposal to prohibit the manufacture, import, sale or display of e-cigarettes as part of Article 14 of the Amendment Bill. We strongly urge the government of Taiwan not to implement this measure.

- The prevalence of smoking in Taiwan is reported at 17.1 percent (29.9 percent among men and 4.2 percent among women). This translates into a smoking population of 3.27 million in 2015, an increase of 170,000 from the previous year. That is 3.27 million people who could potentially benefit if the switch from smoking to e-cigarette.
- E-cigarettes are <u>certain</u> to be much less hazardous than smoking because there is no combustion involved. It is the toxicants generated during combustion of tobacco leaf that cause nearly all the harm arising from tobacco use – these are no present in e-cigarette vapour or only at much lower levels.

Disclosure: The submission has been prepared with the assistance of Clive Bates, an adviser to INNCO. INNCO and Clive Bates campaign for public health and the rights of consumers. They have no competing interests with respect to tobacco, nicotine or pharmaceutical industries.

- E-cigarettes are an acceptable alternative to smoking for many smokers who can dramatically reduce health risks and improve welfare when they switch.
- There is no credible evidence that these products cause young people to smoke or increase the overall harm to society
- We can see no justification ethical, scientific or legal for banning much less risky alternatives to smoking while allowing cigarettes to be available everywhere.
- We do not believe it is the role of the Ministry of health to protect the cigarette trade from competition and to grant tobacco companies privileged access to the consumer nicotine market. We ask: why is the Ministry of Health helping the tobacco industry in this way?
- We believe WHO has provided poor scientific advice to FCTC delegates about ENDS and tobacco harm reduction. This has drawn intense criticism experts² (Chinese mandarin translation available)

Royal College of Physicians assessment of e-cigarettes

We invite the Minister to consider the 2016 report of the London-based Royal College of Physician's, *Nicotine without smoke: tobacco harm reduction*³. The Royal College is one of the oldest medical institutions in the world and was the first to highlight the dangers of smoking in its landmark 1962 report, *Smoking and Health*⁴.

Five quotes from the Royal College of Physicians' report provide a basis for outlining the main issues relating to e-cigarettes, smoking cessation and tobacco harm reduction:

- 1. The relative risk of e-cigarettes compared to cigarettes
- 2. Gateway effects and renormalisation of smoking
- 3. The impact of vaping on smoking cessation
- 4. The danger that Taiwan's proposed ban on vaping products will increase smoking
- 5. Taiwan should adopt a tobacco harm reduction strategy

1. The relative risk of e-cigarettes compared to cigarettes

"Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure." (Section 5.5 page 87)

This carefully worded statement takes the practical approach of focussing on what scientists do know, rather than unknown or unknowable information that will only become available over many

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UK Centre for Alcohol and Tobacco Studies, Commentary on WHO report on ENDS and ENNDS, October 2016 [link]

[PDF] Translation [Chinese Mandarin PDF]

Royal College of Physicians, *Nicotine without smoke: tobacco harm reduction,* Tobacco Advisory Group. 28 April 2016, London [link]

⁴ Royal College of Physicians, Smoking and Health, 1962, London [link]

decades and only if the right studies are put in place. The judgement of relative risk is based on the completely different physics and chemistry of tobacco smoke and e-cigarette aerosol – some we do not have to wait 50 years for. The former is the product of complex chemical reactions in high-temperature combustion of dried tobacco leaf. The latter is the electrical heating at much lower temperature of an inert liquid bearing nicotine and flavourings – there is no combustion. Most of the important harmful toxins in tobacco smoke are products of combustion. For this reason, they are either not detectable in e-cigarette aerosol or present at very low levels.

The result is that the overall toxicity of the e-cigarette aerosol is very much lower than cigarette smoke. As one would expect from such an organisation, the Royal College of Physicians has expressed its statement with careful reflection of uncertainties in both directions, but with a steer to make it clear that 5% of the risk of smoking is a conservative estimate. At present, there is no credible evidence to suggest these products will cause any serious disease or premature death. However, the claim is not that they are safe, just very much *safer*.

2. Gateway effects and renormalisation of smoking

"There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking. To date, there is no evidence that any of these processes is occurring to any significant degree in the UK. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely." (Recommendations)

This summary address a number of claims made by tobacco control activists to the effect that the availability of a low-risk alternative to smoking would somehow increase smoking. It is worth recognising just how counter-intuitive these claims are, and as such should require a very credible evidence base before they are accepted as remotely plausible. The RCP draws the opposite, more intuitive, conclusion from the evidence, namely that: (1) people use safer products to reduce their risks; (2) that the promotion of vaping promotes vaping, not smoking; (3) any 'gateways' seem more likely to be 'exits' from the more harmful to less harmful products.

3. The impact of vaping on smoking cessation

"E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes. E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking." (Recommendations)

The RCP makes the important observation that e-cigarettes are *consumer* products, and that their success in part derives from their appeal to those who would never even try to quit smoking via conventional methods or are unwilling or unable to quit. E-cigarettes are not medical aids to reduce craving and withdrawal during a quit attempt, but an alternative way of taking the recreational drug nicotine. It important, therefore, not to treat e-cigarettes as medicines, to misapply concepts like 'efficacy' or to rely on randomised controlled trials that are suited to singular interventions, such as administering a drug.

The 'efficacy' of e-cigarettes is not a property of the device and liquid, but the outcome of a complex ecology of behavioural influences, including properties of the product, but also peer support, marketing, beliefs about risk and scare stories in newspapers, local availability, the attitude to smoking/vaping in the social and work environment, and the policy framework – packaging,

warnings, restrictions, diversity, marketing, taxation etc. Users tend to progress over time, acquire vaping skills and switch products to more complex configurations, lower nicotine liquids and more diverse flavours as they migrate away from tobacco. A period of dual use may be part of a transition that lasts longer than any RCT ever would, but ends in permanent smoking cessation. Because of their poor efficacy, conventional smoking cessation techniques also involve prolonged "dual use", but this occurs serially with successive quit attempts and relapses back to smoking then the next quit attempt and so on until success or through an indefinite cycle of cessation and relapse.

4. The danger that Taiwan's proposed ban on vaping products will increase smoking

"A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult." (Section 12.10 page 187)

The RCP draws out the most challenging question for regulators. By regulating or communicating with excessive caution, well-intentioned authorities can make the situation worse, cause avoidable harm to consumers and protect the cigarette trade. In forming the EU Tobacco Products Directive provisions on e-cigarettes (and the ban on snus), far too little attention was paid the risk that the measures proposed would have harmful unintended consequences. These could arise by reducing appeal, making the products harder to use, by hampering innovation, by raising prices, by denying the means to communicate and, above all, by creating regulatory barriers to entry that have the effect of protecting the incumbent cigarette trade against disruptive innovation. Taiwan's health leadership should take great care to avoid compounding these errors.

5. Taiwan should adopt a tobacco harm reduction strategy

"However, in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK." (Recommendations, original emphasis).

Taking all the available evidence into account, the organisation that first reported on <u>Smoking and Health</u> in 1962, endorses a tobacco harm reduction approach including the promotion of ecigarettes. We urge the Government of Taiwan to follow this advice.

We believe it the advice of Royal College of Physician is a more reliable guide to the science and policy issues than the information provided to WHO FCTC COP-7 delegates by the convention secretariat⁵, which we have previous noted has been subject to severe expert criticism⁶.

WHO FCTC Convention Secretariat, Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS). Paper for COP-7, FCTC/COP/7/11, September 2016 [link]

UK Centre for Alcohol and Tobacco Studies, Commentary on WHO report on ENDS and ENNDS, October 2016 [link]

[PDF] Translation [Chinese Mandarin PDF]

Proportionate and Effective Regulation of Electronic Cigarettes

INNCO supports the **proportional regulation** of e-cigarettes and e-liquid. As consumers we have a vested interest in safeguarding our own health, safety and enjoyment!

We acknowledge the need to ensure children and young people's access to products intended for adults. This extends to alcohol, tobacco and e-cigarettes. Good regulations are essential to ensure that cheap poorly made e-cigarettes, fake batteries and e-liquid is of a consistently high quality.

However, we believe that it is essential for governments to approach the regulation of e-cigarettes in such a way that whilst consumers are protected by consistent standards, their access to a wide range of flavours and the latest technology is not restricted.

We urge the Taiwanese government and Health Ministry to honestly evaluate **all the evidence on alternative nicotine products**. To take into account not just the media 'scare stories',
but to seriously evaluate all the research and qualitative evidence produced by many of the world's
leading academics and tobacco harm reduction experts, the majority of whom believe e-cigarettes
offer a huge opportunity to reduce the harm of tobacco smoke

"The risk-averse regulation of new nicotine products causes thousands of deaths annually, because it artificially strengthens the position of tobacco, blocks innovation and obstructs the marketing of safer products to smokers. It builds high barriers of entry in the alternative nicotine market, and otherwise distorts the market economy".

Profess Jean-François Etter, Head of the Tobacco Group Institute of Social and Preventative Medicine, University of Geneva⁷

Legislation which seeks to severely restrict e-cigarettes, compounds the monopoly of conventional cigarettes, destroys the opportunity for limiting risk and gives a rubber stamp of approval to those who believe smokers should either quit or die.

We believe that any new framework on the regulation of Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS) should not seek to duplicate those pertaining to traditional cigarettes and respectfully urge you to recognise them as a huge opportunity to reduce risk rather than as a potential threat.

Imposing excise tax on risk reduced products is a retrograde step in reducing tobacco related harm

Several studies have concluded that e-cigarettes are at least as effective as nicotine replacement therapies (NRTs) at encouraging adult smokers to give up cigarettes.⁸

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https://www.unige.ch/medecine/isg/en/staff/jean-francois-etter/

⁸ Brown, J., Beard, E., Kotz, D., Michie, S. and West, R. (2014), Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. Addiction, 109: 1531–1540. doi:10.1111/add.12623

The UK National Health Stop Smoking Service has recently produced detailed guidance⁹ to its staff supporting the use of e-cigarettes as tool to assist in quitting or reducing smoking. Electronic cigarettes are now the most popular form of smoking cessation support in the UK, and experts have concluded that on average e-cigarettes are approximately 50% more effective than using no aid or over the counter NRTs.¹⁰

With the additional burden of administration and costs for establishing any new taxation category on e-cigarettes, the net potential revenues are likely to achieve a mere fraction of those currently generated by tobacco. If, as evidenced by the introduction of e-cigarette tax in Italy, the imposition of tax results in a significant downturn in consumption (with subsequent retail closures and job losses) it may well result in a negative financial outcome.

Italy introduced a tax on all e-cigarette-related products in January 2014, their primary "justification" being to offset falling tobacco tax revenues. They levied a tax based on an average of 50% less than that applied to combustible tobacco, which resulted in the price of a 10ml bottle of E-liquid (with or without nicotine) being increased by 60% of its original retail price.

By May of 2015, the consumption of e-cigarettes had fallen by approximately 70%; consumers were incentivised to purchase online from overseas countries, domestic e-cigarette shops and businesses fell from 4,000 to 1,000 and in the first 11 months of 2016, the Italian Exchequer collected an estimated 3million Euros in tax revenue. This represented c. 0.3% of the tax revenues generated by combustible tobacco.

This is hardly a success story – it represents an unmitigated disaster at every level: employment, public health, local and domestic economy and the time and costs of government administration. Most of all it decreased the probability of saving lives by restricting smokers affordable access to harm reduction products – and that is a tragedy.

About INNCO

Formed in September 2016, INNCO is the collective voice for the most influential nicotine consumer organisations in twenty countries around the world: organisations who each recognise that there are safer ways to enjoy nicotine consumption than tobacco smoking.

There are currently estimated to be over 20.5 million consumers who have made an individual choice to switch to what they recognize is a significantly safer choice to combustible tobacco, including e-cigarettes, snus and other novel products.

INNCO aims to represent the views of consumers in promoting safer use of nicotine and to advocate for effective and proportionate regulation of safer nicotine products and their use. Representation

⁹ http://www.ncsct.co.uk/publication electronic cigarette briefing.php

¹⁰ West, R., et al., Estimating the population impact of e-cigarettes on smoking cessation in England, Addiction, 2016.

includes engagement with international health, regulatory and public health organisations concerned with nicotine consumption, to assure that consumers are effectively and equally represented as stakeholders.

INNCO seeks to achieve this through promoting credible science and research into safer nicotine use and increasing awareness and understanding within public health of the risk reducing and life-saving potential of new technologies.

We seek to ensure, regionally and internationally:

- 1. The recognition of the relative safety of smoke free nicotine products.
- 2. The need to avoid disproportionate regulation on the manufacture, distribution and the (overly) restrictive consumer access to these products
- 3. The taxation of products as consumer goods, with no tobacco duties or excises applied
- 4. That any restrictions on use in public areas and work spaces are justified on the basis of verifiable evidence
- 5. Any decisions made to restrict or limit the use of alternative nicotine products in private premises should be left to individual owners/managers.
- 6. That there should be no bans on the sale, supply, possession and use of safer forms of smokeless tobacco (e.g. snus), vaping products and E-Liquid containing nicotine, and where currently illegal they should be made legal.

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