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June 20, 2020

Dear Sirs:

I am writing to you as founder of factasia, a not-for-profit regional consumer advocacy. We thank you for this opportunity to present our position on harm reduced alternatives to conventional cigarettes and to urge you to regulate this sector appropriately, proportionately and effectively.

About one out of every nine Australian citizens smokes cigarettes and it is estimated that smoking kills 18,000 citizens each year (<https://www.betterhealth.vic.gov.au/health/healthyliving/smoking-statistics>).

So the current initiative to regulate less harmful alternatives to smoking, such as e-cigarettes (vapes) and Heated Tobacco Products (HTP), also known as heat not burn products (HNB) is both timely and extremely important. But it is vital that Australia follows the evidence and recognises the importance of establishing a proportionate regulatory framework to ensure that adult Australian smokers can have legal access to these life-saving products and confidence that the products made available satisfy internationally recognized manufacturing standards.

This is all about “**harm reduction**”. How can we all reduce the harm done to smokers and many millions of non-smokers who are exposed to the smoke of conventional tobacco products? Specifically, we are talking about adult citizens who choose to use nicotine.

There cannot be a smoker left anywhere who does not know the risks inherent in smoking, but still half a billion Asians, including around three million adults in Australia, choose to do so. Many smokers find it difficult to quit, or enjoy their nicotine and don't want to give up.

We agree with the tobacco control experts who say providing less harmful alternatives to cigarettes should be part of government strategies. E-cigarettes are one such alternative.

Globally, experts in 'harm reduction' regard “e-cigarettes” containing nicotine as a valuable tool to reduce death and disease associated with smoking. The support for e-cigarettes from the anti-smoking experts has become dramatic: one leading medical expert in the UK calls them “at least 95 percent safer than smoking”, an opinion that has been rigorously scientifically proven, peer-reviewed, accepted, shared and endorsed by leading scientists, health professionals, researchers and regulators worldwide.

In short:

- independent tobacco control experts want harm reduced nicotine legalised, and these are now legal and proportionately regulated in Europe and the US as a result of their data.
- harm reduced products such as vape and HNB give smokers a path **away** from smoking.
- harm reduced products have been proven by independent medical researchers **not** to be a gateway for non-smokers to start taking nicotine.

To be clear: there has NEVER been a recorded death from vaping regulated nicotine products since the introduction of the e-cigarette in 2001. But over the same period of time, more than 130 MILLION smokers worldwide have died from tobacco-related illnesses and disease. This includes many hundreds of thousands of our Australian brothers and sisters.

Smoking is not a disease, it is a habit. A habit that has long term health consequences. Nicotine dependency is NOT an illness. Nicotine itself is not a particularly harmful compound, as even the WHO has admitted when it suggested smokers having a hard time quitting smoking using pharmaceutical companies NRTs can continue using nicotine

patches, sprays and gums *ad infinitum*. WHO has stated clearly that: “there are no known health consequences associated with long-term nicotine use”. This position is echoed by many other leading health bodies including the UK’s Public Health England (PHE). It is the smoke in cigarettes that kills smokers, NOT the nicotine.

Less harmful alternatives, such as vapes and HNB, have been adopted by many millions of former smokers who have discovered that it IS possible to quit smoking using these technologies, without medical intervention. In countries such as Japan, South Korea, the UK and throughout Europe, many millions of former smokers are now leading smoke-free lives and greatly improved health, and smoking rates continue to fall as more smokers switch to less harmful alternatives. Many governments, including the UK and Canada, are now actively encouraging adult smokers to try vaping as part of their tobacco control efforts, and it is working. Smoking rates continue to fall in these countries and former smokers are leading longer, more productive and healthier lives.

Sadly, the opposite is true in Australia where smoking rates have stalled as a consequence of its flawed approach to alternative nicotine products.

It is unconscionable that Australia continues to ignore the evidence and is now seeking to further restrict access by adult smokers to these life-saving technologies by considering legislation to require a doctor’s prescription to purchase nicotine-containing vape products.

Most smokers started smoking at an early age, well before they reach adulthood and gained the capacity to make informed decisions, and by the time they realized that it is harming them, it is extremely difficult for most to simply quit. Vaping and HNB have helped many millions of former smokers to transition away from cigarettes permanently by exercising their choice to adopt these far less harmful products and completely stop using deadly tobacco products.

This is an example of Harm Reduction at its finest.

We treat addictions such as alcoholism and drug dependency using a variety of interventions, many of which employ the proven and effective strategy of Harm Reduction. Seat belts, crash helmets, condoms, water filters - these are all examples of harm reduction.

Unfortunately, there are some influential international entities with vested interests and personal agendas, both moral and commercial, that continue to seek to undermine the mountain of independent, peer-reviewed evidence that has been researched over the last decades and which clearly shows harm reduced nicotine products to be much safer, far more acceptable to smokers and unequivocally more effective at getting smokers to quit than conventional pharmaceutical companies’ nicotine cessation therapies such as patches, sprays and gums. These powerful lobbies, which include the [REDACTED] and the Pharmaceutical industry, continue to throw hundreds of millions of dollars into efforts to destroy the public’s confidence in these life-saving technologies. These groups, and the money they wield, have corrupted global medical associations including WHO and FCTC, national cancer and other medical associations, the media and even some government health departments, by ‘donating’ vast funds to support these institutions provided they follow the anti-harm reduction agenda that is tied to the funding.

Pharmaceutical companies are seeking to defend their multi-billion dollar smoking cessation/nicotine replacement therapies that vapes and HNB threaten, while philanthropic associations seek to impose their ‘we know best’ moralistic ideologies – not to mention that [REDACTED] have invested millions into a start up company [REDACTED] that aims to develop and market a flavour-free ‘pharmaceutical’ nicotine delivery system [REDACTED] for smokers – a clear conflict of interest that explains in part why [REDACTED] are as anxious as Big Pharma to destroy the vape and HNB industry by any means possible.

Accordingly, the media and regulators are constantly barraged with misleading statements, flawed science, disinformation and unfounded scare tactics to persuade them to adopt a negative stance to harm reduced products. While this may be in line with the aims of the vested interests who seek to destroy the less harmful nicotine segment to protect their own commercial interests, it is in no way helpful to the millions of Australians who smoke and who wish to quit but find it hard to do so using ‘approved’ quit or die methods. It also denies the facts and evidence that clearly show such products to be far less harmful than smoking and far more effective than conventional NRTs at

getting smokers to quit, not to mention denying adult consumers of the right to access such products, at great cost to their health and to society in general.

Harm reduction, together with the right to health, is enshrined in both the WHO and FCTC mission statements on tobacco control. The fact that many FCTC delegates choose to ignore this fact and continue to deny the science and the core obligations of their mission statement does not mean that clear-thinking, open-minded regulators who are willing to study the independent, unbiased evidence need to follow this egregious denial of basic rights and common sense and deny their citizens the right to choose less harmful alternatives to smoking.

Despite some of the harshest and irrational regulations already in place, currently there are a host of harm reduced nicotine products available to Australian adult smokers. It is therefore possible to monitor and tax these products. If the government were to impose its unreasonable restrictions on the manufacture, importation and sale of these products, current vapers would either revert back to smoking deadly cigarettes or turn to the grey market to source supplies. While it may be the case that vapes and HNB products available in the grey market are of an acceptable standard, citizens would have no real assurances that the products they are buying conform to international manufacturing standards. Sensible and proportionate regulation of the import, manufacturing, marketing and sales of these products will ensure the safety and confidence of smokers who wish to quit smoking, or who have already switched to less harmful alternatives, but would be unable to continue doing so legally using harm-reduced nicotine products without a doctor's prescription.

This proposed regulation is even more absurd when one considers that: "the rescheduling process, if agreed to, would clarify that nicotine products for human use require a valid prescription (except for **tobacco cigarettes** or registered smoking cessation products such as gums, sprays and patches).

This proposal cements deadly cigarettes, a huge revenue earner for the Australian government, as the only viable choice for current and future smokers and ignores the clear, unequivocal, independent evidence that pharmaceutical smoking cessation products are significantly less effective than less harmful nicotine consumer products such as vapes and heat no burn at getting smokers to quit PERMANENTLY.

We would also like to comment on some of the issues that revolve around the harm reduced nicotine product debate that you appear to be getting confused about:

flavour bans: banning flavours other than tobacco (note: there is NO tobacco used in the production of tobacco flavours used in vapes) and menthol simply serves to make vaping less appealing to adult smokers and will not serve to re-educate their palates away from the very flavours associated with smoking that they are trying to avoid.

Youth vaping: firstly, any legislation should explicitly ban the sale, marketing or use of these adult products to underage youth. Secondly, we need to understand that vaping and other harm-reduction technologies are an effective method for ADULTS to quit smoking. Thirdly, there is NO evidence showing that underage vapers take up smoking – the so-called 'Gateway Effect'. In fact, in EVERY piece of research undertaken anywhere in the world, around 99% of kids that vape were smoking cigarettes before they started vaping and wherever an increase in youth vaping is observed, it is ALWAYS accompanied by a similar decline in youth smoking rates. In other words, even kids are using vapes to quit smoking, not the other way round. This is as true for Australia as it is for everywhere else, despite the cherry-picked statistics that regulators are being presented with.

Nicotine limits: limiting the amount of nicotine is another contentious issue. There are no such limits imposed on combustible products: to impose such limits on nicotine in vapes is unhelpful... it has been demonstrated for years that the lower the nicotine content of a cigarette, the more cigarettes a smoker requires to meet their body's cravings. The same is also true for vaping and HNB. If you restrict the amount of nicotine users can access in their devices, they will inevitably consume more to achieve the satisfaction they crave.

The government has a unique opportunity to act for the good of its citizens by recognizing that harm reduced nicotine products save lives and benefit all Australian citizens by reducing the death and disease caused by smoking. Smokers need to be able to access the life-saving technology of harm reduced nicotine products. This should be a key part of

Australia's Tobacco Control policy. Banning or restricting access to these products will inevitably cause more preventable death and disease.

We respectfully urge you to examine the peer-reviewed, independent science and research and follow science, reason, evidence and facts as you develop the right way forward to ensure your compatriots are given the best possible regulatory framework within which to choose to use less harmful alternatives to deadly smoking.

factasia recommends that Australia's government consider these five steps in its efforts to reduce the death and disease caused by smoking:

1. Accept the body of evidence from the anti-smoking and harm reduction experts. Restricting adult access to safer products is unethical and counter-productive in the battle to eliminate the death and disease associated with smoking.
2. Legalise e-cigarette use in Australia among adults, as has been legislated in countries such as the UK and in the EU where these and other non-combustible alternatives are understood by Public Health authorities to be much less harmful alternatives for smokers and eliminate passive smoking concerns to non-smokers.
3. Regulate for product quality and manufacturing standards like any other consumer product, and tax rationally – no one is suggesting e-cigarettes should be tax-exempt.
4. Underage use of vaping devices can and should be prohibited, it has always been within the power of the government to enact specific legislation in this regard. However, adult smokers should not be disadvantaged by regulations aimed at preventing youth uptake and a full range of products should be made available to adult smokers seeking to transition to less harmful alternatives to smoking.
5. In line with international best-practices policy development, the Australian Government should ensure that appropriate public consultation and a regulatory impact assessment be undertaken before any legislation is amended.

The Government has a chance to become a clear leader in progressive public health policy and in harm reduction in this vital sector. It's what citizens want, and it's good for them too.

About factasia

factasia.org is an independent, not-for-profit, consumer-oriented advocate for rational debate about – and sensible regulation of – the rights of adult citizens throughout the Asia-Pacific region to choose to use tobacco or other nicotine related products.

factasia does not promote smoking or the use of nicotine, opposes all under-age use of cigarettes or any other product containing nicotine, and does not engage in any manufacturing, marketing, distribution or retailing activities.

factasia's role is to act as a messenger, facilitating constructive dialogue between scientists and medical experts, legislators, regulators and the general public.

Cf:

APPENDIX 1

The enclosed online bibliography is a selection of THR evidence/science published in peer reviewed journals from 2019/2018 from across the globe.

[Moderators of real-world effectiveness of smoking cessation aids: a population study](#)

[Smokeless tobacco mortality risks: an analysis of two contemporary nationally representative longitudinal mortality studies](#)

[E-cigarettes and smoking cessation in the United States according to frequency of e-cigarette use and quitting duration: analysis of the 2016 and 2017 National Health Interview Surveys](#)

[Vaping in England: an evidence update February 2019](#)

[A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy](#)

[Patterns of e-cigarette use, biochemically verified smoking status and self-reported changes in health status of a random sample of vape shops customers in Greece](#)

[Comparing the cancer potencies of emissions from vaporized nicotine products including e-cigarettes with those of tobacco smoke](#)

[Comparison of nicotine and toxicant exposure in users of electronic cigarettes and combustible cigarettes](#)

[The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention](#)

[How do we determine the impact of e-cigarettes on cigarette smoking cessation or reduction? Review and recommendations for answering the research question with scientific rigor](#)

[Prevalence of population smoking cessation by electronic cigarette use status in a national sample of recent smokers](#)

[E-cigarettes: Balancing risks and opportunities](#)

[E-cigarette usage is associated with increased past-12-month quit attempts and successful smoking cessation in two US population-based surveys](#)

[E-cigarettes: Comparing the possible risks of increasing smoking initiation with the potential benefits of increasing smoking cessation](#)

[Managing nicotine without smoke to save lives now: Evidence for harm minimization](#)

[Evidence review of e-cigarettes and heated tobacco products 2018](#)

[Potential deaths averted in USA by replacing cigarettes with e-cigarettes](#)

[E-cigarette initiation and associated changes in smoking cessation and reduction: The population assessment of tobacco and health study, 2013–2015](#)

[Examining the relationship of vaping to smoking initiation among US youth and young adults: A reality check](#)

[Acute impact of active and passive electronic cigarette smoking on serum cotinine and lung function](#)

APPENDIX 2

https://www.factasia.org/wp-content/uploads/pdf_files/survey-results-australia.pdf

Factasia/IPSOS Australian Adult Smoker Survey: Results

Australia Adult Smoker Survey: Results

KEY SPECIFICATIONS

AUDIENCE: SMOKERS AGED 18+ IN AUSTRALIA

SAMPLE SIZE: n=410

METHOD: ONLINE

FIELD DATES: 27 MAY – 10 JUNE 2015

RESEARCH SUPPLIER: [REDACTED]

COMMISSIONING ORGANIZATION: factasia.org

EXECUTIVE SUMMARY

The results contained in this report are derived from an online survey conducted from 27 May to 10 June 2015 among adult smokers aged 18+ in Australia. A total of 410 interviews were conducted by [REDACTED] on behalf of factasia.org. This study carries a margin of error of $\pm 4.9\%$ at the 95% confidence level.

The research found that even though large majorities of adult smokers are aware of e-cigarettes (61%), familiarity with the product is quite “soft” with only 17% saying they are “very familiar.”

Additionally, the study found adult smokers in Australia have strong opinions regarding the regulation of e-cigarettes. Specifically of note:

- More than eight out of ten adult smokers (84%) agree that “through tax and regulatory policies, the Government should encourage adult smokers to switch to less harmful alternatives to cigarettes and ensure they are not used by youth.”
- 82% agree with the statement “It would be wrong for the government to prevent or delay the introduction of less harmful alternatives to regular cigarettes for adult smokers.”
- Nine out of ten (93%) agree that “if a new product is scientifically proven to have the potential to reduce the risk of smoking as compared to conventional cigarettes, adult smokers should have the right to access this information.”

Additionally, support for these measures cut across the political spectrum, with wide ranging agreement among both Liberal and Labor supporters.

Finally, the research also found that three-quarters of adult smokers (75%) agree that “e-cigarettes represent a positive alternative to today’s cigarettes,” and two-thirds (65%) would “consider switching to e-cigarettes if they were legal, met quality and safety standards, and were conveniently available like regular tobacco products.”

ABOUT [REDACTED]

[REDACTED] ranks third in the global research industry. With a strong presence in 87 countries, Ipsos employs more than 16,000 people and has the ability to conduct research programs in more than 100 countries. Founded in France in 1975, [REDACTED] is controlled and managed by research professionals. They have built a solid Group around a multi-

specialist positioning – Media and advertising research; Marketing research; Client and employee relationship management; Opinion & social research; Mobile, Online, Offline data collection and delivery.

██████ is listed on Eurolist - NYSE-Euronext. The company is part of the SBF 120 and the Mid-60 index and is eligible for the Deferred Settlement Service (SRD).

S1. First, how old are you?

0%	Under 18	(TERMINATE)
15%	18-24	
13%	25-29	
12%	30-34	
11%	35-39	
6%	40-44	
11%	45-49	
8%	50-54	
10%	55-59	
6%	60-64	
8%	65 or older	

S2. Next, what is your gender?

51%	Male
49%	Female

Are you – or is any member of your immediate family – currently employed with/as:

(RANDOMIZE)		<u>% YES</u>	<u>% NO</u>
S3.	An advertising or public relations agency	0%	100%
S4.	A newspaper, radio, or television station	0%	100%
S5.	A market research or opinion research firm	0%	100%
S6.	An elected official	0%	100%
S7.	A senior or policy making role in government	0%	100%

[IF YES TO ANY S3-S7: TERMINATE]

S8. Do you ever use tobacco or nicotine containing products such as cigarettes, cigars, pipes, smokeless tobacco products, shisha, or e-cigarettes?

100%	Yes	
0%	No	(TERMINATE)
0%	Unsure	(TERMINATE)

And, for each of the following products, please indicate whether you are a regular user, an occasional user, a former user, or a complete non-user. (RANDOMIZE)

		% Regular User	% Occasional User	% Former User	% Complete Non-User
S9.	Cigarettes	75%	20%	3%	2%
S10.	Cigars	7%	22%	10%	61%
S11.	Pipes	6%	13%	12%	70%
S12.	Shisha	5%	17%	6%	72%
S13.	E-cigarettes	7%	23%	11%	59%

Thinking about e-cigarettes and other products...

Q1. Have you recently seen, read, or heard anything about e-cigarettes?

61% Yes
 34% No
 5% Unsure

Q2. Regardless of whether you have recently seen, read, or heard, something about e-cigarettes, how familiar would you say you are with e-cigarettes?

17% Very familiar
 46% Somewhat familiar
 27% Not very familiar
 10% Not at all familiar
 0% Unsure

As you may know, e-cigarettes are battery powered devices that vaporize nicotine liquid to create an inhalable aerosol. E-cigarettes do not contain tobacco leaf and come in various shapes and sizes, and can be disposable, rechargeable, or refillable.

Q3. And, do you know whether or not e-cigarettes are legal in your country? If you don't know or are unsure, please indicate accordingly.

71% Legal
 5% Illegal
 24% Unsure

As you may know, in Europe and the USA, e-cigarettes are widely available and millions of people use them. Public health experts agree that they are probably much less harmful than cigarette smoking because they do not burn tobacco. Some public health experts believe they should be widely available for smokers to use instead of cigarettes. While others think they are not an effective method for smoking cessation and are concerned they could be a "gateway" to smoking among youth.

You will now be shown a number of statements made about e-cigarettes. For each of the following, please indicate whether you strongly agree, somewhat agree, somewhat disagree, or strongly disagree

		% Str. Agree	% Smwht. Agree	% Smwht. Disagree	% Str. Disagree	% Unsure	% Total Agree	% Total Disagree
Q4.	E-cigarettes represent a positive alternative to today's conventional cigarettes.	25%	50%	12%	5%	9%	75%	17%
Q5.	I would consider switching to e-cigarettes if they were legal, met quality and safety standards, and were conveniently available like regular tobacco products.	23%	42%	13%	11%	10%	65%	24%
Q6.	It would be wrong for the Government to prevent or delay the introduction of less harmful alternatives to cigarettes for adult smokers.	38%	43%	6%	4%	9%	82%	9%
Q7.	Through tax and regulatory policies, the Government should encourage adult smokers to switch to less harmful alternatives to cigarettes and ensure they are not used by youth.	40%	44%	6%	4%	6%	84%	10%
Q8.	If a new product is scientifically proven to have the potential to reduce the risk of smoking as compared to conventional cigarettes, adult smokers should have the right to access this information.	54%	38%	2%	0%	4%	93%	3%

Now, I have just a few more questions for statistical purposes...

ASKED AMONG REGULAR OR OCCASIONAL E-CIGARETTE USERS; n=121

D1. How long have you used e-cigarettes?

- 13% Less than 3 months
- 17% 3 to 6 months
- 27% 6 to 9 months
- 17% 9 to 12 months
- 10% 12 to 18 months
- 6% 18 to 24 months
- 8% Longer than 24 months
- 3% Unsure

ASKED AMONG REGULAR OR OCCASIONAL E-CIGARETTE USERS; n=121

D2. Why did you start using e-cigarettes? (CHECK ALL THAT APPLY)

- 65% As an alternative to regular cigarettes
 - 38% Convenience
 - 32% Price
 - 26% Flavors
 - 4% Friends
 - 3% Smoking cessation
 - 2% Try something new
 - 1% Others
 - 4% Unsure
-

ASKED AMONG REGULAR OR OCCASIONAL E-CIGARETTE USERS; n=121

D3. Where do you predominately buy your e-cigarettes?

- 27% Specialty e-cigarette store
 - 25% Grocery
 - 24% Convenience store
 - 9% Internet/Online store
 - 9% Kiosk
 - 2% Friends
 - 1% From other countries
 - 4% Unsure
-

ASKED AMONG OCCASIONAL E-CIGARETTE USERS; n=94

D4. What has kept you from using e-cigarettes more? (CHECK ALL THAT APPLY)

- 40% Price
 - 36% Accessibility to e-cigarettes
 - 29% Have not found them to be suitable alternative to regular cigarettes
 - 20% Flavor
 - 2% Don't have the need
 - 1% Short battery life
 - 15% Unsure
-

D5. Level of Education

- 4% Below year 10
 - 28% Year 10/11/12
 - 24% Certificate/TAFE
 - 14% Advanced diploma
 - 20% Bachelor degree
 - 2% Graduate diploma/certificate
 - 7% Postgraduate degree
 - 1% Refused
-

D6. Weekly Household Income

19%	AU\$99 – 599
36%	AU\$600 – 1399
33%	AU\$1400 - 4999
2%	AU\$5000 or more
12%	Refused
