



# Joint submission from the Thoracic Society of Australia and New Zealand and Lung Foundation Australia

Inquiry into the Use of Electronic Cigarettes and Personal Vaporisers in Australia

## About the Thoracic Society of Australia and New Zealand (TSANZ)

The TSANZ mission is to lead, support and enable all health workers and researchers who aim to prevent, cure and relieve disability caused by lung disease. TSANZ is the only Peak Body in Australia that represents all health professionals working in all fields of respiratory health.

TSANZ has a membership base of approximately 1500 individual members from a wide range of health and research disciplines. TSANZ is a leading provider of evidence based guidelines for the treatment of respiratory disease in Australia and New Zealand, undertakes a large amount of professional education and training, is responsible for significant research administration and coordinates an accredited respiratory laboratory program.

## About Lung Foundation Australia (LFA)

Lung Foundation Australia (LFA) is a national organisation that works to reduce the impact of lung disease in Australia. LFA promotes lung health, supports patients, funds research, develops education, trains health professionals, and undertakes community awareness activities and advocacy around Australia. All activities take an evidence-based approach.

#### Terms of Reference

The Standing Committee on Health, Aged Care and Sport will inquire into and report on the use and marketing of electronic cigarettes (E-cigarettes) and personal vaporisers in Australia, in particular:

- 1. The use and marketing of E-cigarettes and personal vaporisers to assist people to quit smoking;
- 2. The health impacts of the use of E-cigarettes and personal vaporisers;
- 3. International approaches to legislating and regulating the use of E-cigarettes and personal vaporisers;
- 4. The appropriate regulatory framework for E-cigarettes and personal vaporisers in Australia; and
- 5. Any other related matter.

## Summary

There is no good public health claim for an unregulated approach to e-cigarettes and personal vaporisers. There is a strong case for a total ban on these products as they are currently available.

Currently, e-cigarettes and personal vaporisers are being marketed as a harmless life choice, without any cautionary labels or health warnings. **The use of these devices causes injury to the lung.** There is no reason to support an approach to regulating a product which causes ill health, contains known carcinogens and other toxic compounds.

The most compelling argument for these devices, and it is an argument based on anecdotal and personal experiences rather than an evidence base, is for use in smoking cessation. It is likely that these devices are less harmful than smoking cigarettes, however they are not harmless. If they are to be used as cessation aids, then this is a therapeutic device and must be regulated as such by the Therapeutic Good Administration (TGA).

#### Recommendations

Our recommendations are based soundly on the precautionary principle. The precautionary principle states that if there is a suspected risk of harm and the scientific information is lacking, such that there is an absence of scientific consensus, then the burden of proof that it is not harmful falls on those wanting to progress the issue.

With respect to e-cigarettes and personal vaporisers the recommendations are:

- 1. E-cigarettes and personal vapours should not be readily available given the clear evidence that these devices cause harm to the lungs.
- 2. For use in any setting other than cessation these devices should be banned.
- 3. If the Committee accepts they have a place in smoking cessation, these products must be classed as therapeutic devices and regulated through the TGA.
- 4. If they are not banned then they should:
  - a. Be restricted in their sales to over 18 years
  - b. Be sold out of sight/behind the counter to prevent tobacco company marketing
  - c. Carry clear pictorial health warnings
  - d. Have clear labelling of all ingredients at the level of compound and concentration as appropriate for a therapeutic inhaler.
  - e. Have appropriate toxicology data for all compounds in the device, measuring both systemic and local effects
  - f. Be sold in tamper-evident and childproof packaging
  - g. Be nicotine free. Any product containing nicotine should require regulation through the TGA (see recommendation 1)
  - h. If these products are to be available they must be subject to strategies to prevent normalisation of their use amongst young people e.g. banning their use in cars carrying under 18s; banning use in indoor spaces and places where children predominate such as playgrounds; and marketing restrictions.
- 5. Further independent, academic research is required to develop our knowledge base about these products.

# TOR 1: The use and marketing of E-cigarettes and personal vaporisers to assist people to quit smoking

The claim that e-cigarettes and personal vaporisers may assist people to quit smoking is a therapeutic claim. If the Committee accepts this claim then these devices must be regulated as therapeutic devices through the TGA, with an appropriate scientific background of randomised controlled trials.

#### A harmful alternative

The current situation in Australia sees the use of e-cigarettes and personal vaporisers being promoted as a healthier alternative to smoking, with claims for cessation being implied, yet the absolute safety of inhaled super-heated aerosols from the these devices remains unknown [1]. TSANZ and LFA accept that the inhaled products produced by these devices may be less harmful than smoking cigarettes, although the evidence is not unequivocal [2-5]. Both are harmful.

E-cigarettes and personal vaporisers deliver organic compounds, heavy metals and toxic substances to the bronchi and distal lungs in an aerosol form for absorption into the lung circulation. This area should be protected from the deposition of any substance that is known to produce or potentiate a range of respiratory diseases. Normally, the lungs have a surface fluid lining that is extremely thin so that the volume of this fluid is less than 5mls. At the conclusion of a vaping session, it has been estimated that half of the lining fluid composition is derived from the vaping inhaler [6]. This is critically different from an asthma spray in which 99% of the propellant is exhaled unaltered in a gaseous form, with the active drug in powder form being left behind. Further, for e-cigarette users who are also current smokers, the lung lining integrity which is altered through cigarette smoke exposure may result in increased exposure to toxins within the aerosol [7].

Current e-cigarettes and personal vaporisers on the market can deliver an unregulated cocktail of chemicals which contain variable concentrations of nicotine, so it is not a surprise that we see insult and injury to the lungs. Pure nicotine has its own toxicity [8], and to add to it unrestricted components such as flavours that may be separately toxic and not approved for inhalation, either in solution form or in a chemically altered form that might emerge after superheating, is dangerous and irresponsible. **Adverse physiologic effects of e-cigarettes in the lung are immediate**. A laboratory study of 30 healthy individuals (smokers) who used an e-cigarette for just five minutes showed worsening in measures of airway and respiratory resistance, impedance, and exhaled nitric oxide. This response was deemed to be similar to that observed following tobacco cigarette exposure [9]. A recent systematic review of e-cigarette users also demonstrated **the incidence of self-reported adverse effects such as mouth and throat irritation, nausea, headache and dry cough were common**, however longer-term effects associated with more prolonged exposure are largely unknown [10].

## Claims for smoking cessation

It is even questionable as to whether e-cigarettes and personal vaporisers have any place in smoking cessation. Clearly these methods should only be considered after all other avenues have been exhausted and within a regulatory framework, with supply on prescription by a registered medical practitioner. There are many nicotine delivery systems already available for those who wish to quit smoking and there is a lack of evidence that e-cigarettes are superior to current best practice. The evidence of the efficacy of these devices in smoking cessation is weak. Furthermore, a Cochrane Collaboration review found there was no evidence that e-cigarettes were superior to nicotine replacement therapy [11].

TSANZ and LFA are supportive of the need to assist smokers to quit, however this also needs to be balanced against:

- 1) The effectiveness of the public policy approach which protects young people from becoming smokers in the first place
- 2) Minimisation of harm to smokers seeking to quit
- 3) Minimisation of the potential for an increase in poor respiratory health amongst the Australian population.

## Marketing

In assessing the claims for cessation, it is necessary to review the marketing tactics of the companies involved in the production and distribution of these devices. Advertising of e-cigarettes has increased markedly over recent years with a study from the Netherlands reporting a significant increase in people noticing e-cigarette advertisements between 2013 (13.3%) and 2014 (36.0%), across all media [12].

A social media analysis published in March this year has shown that e-cigarette and personal vaporiser users originally believed they utilised these devices to help quit smoking. This is spurred on by websites¹ which are pro e-cigarettes and vaping providing smokers with advice on how to quit using these devices, and recommendations and reviews of products. The language is borrowed from reputable 'cut down to quit' programs in an effort to market the product. However, there has been a rapid shift in the reasoning behind using e-cigarettes and personal vaporisers, with their popularity now associated with the social image attached to their use (i.e. access to smoke indoors, a fashion accessory, and less odour) [13]. Of significant concern is that this marketing is now directed at young people with the use of flavourings such as strawberry custard, chocolate and cereal, amongst others (Figure 1). There is increasing concern that the wide and poorly regulated marking of e-cigarettes will make smoking socially acceptable again and will undermine the smoke free legislation.





Figure 1 - E-liquid advertisement. Source: https://twitter.com/vapouround?lanq=en

<sup>1</sup> http://ecig-reviews.net/using-e-cigarettes-quit-smoking/ and http://www.ecigexpert.com/advice/quit-smoking/

The same marketing tactics used by *Big Tobacco* in the past are being used again in the promotion of these devices. All the major tobacco companies now have commercial interest in the e-cigarette/personal vaporiser market. E-cigarettes are showing up in mainstream media and being promoted by celebrities as fashionable – not unlike the former days of tobacco endorsements which are now outlawed. Even the advertisements for these products are similar to the old-style cigarette advertisements which existed prior to pre-plain packaging laws being introduced in Australia (Figure 2).

Australia has experienced remarkable success through its plain packaging approach: an approach being emulated as best practice internationally. The packaging on the IQOS e-cigarette is directly reminiscent of the cigarette packets of old and could be freely available in the market place to promote the tobacco company (Figure 3).



Figure 2 – History of cigarette packet control in Australia

Source: http://en.azvision.az/news/3546/the-battle-for-control-of-the-cigarette-packet.html







Figure 3 - Tobacco industry branding – packaging of the traditional cigarette now used for the ecigarette (IQOS).

In June this year, the Australian Competition and Consumer Commission commenced proceedings against two online e-cigarette retailers for making statements on their websites that their e-cigarette products did not contain toxic chemicals, when in fact they did (9). A lack of control over the online marketing space makes it almost impossible to manage the critical message to consumers that these products are not safe. This facilitates a cultural mythology of safety of these products.

One of the key pillars of Australia's success in tobacco control policy has been the ability to make smoking socially unacceptable. E-cigarettes have not contributed, beyond any doubt, to an improvement in the smoking rates in Australia. It is our opinion that these products have the potential to sabotage the gains made in de-normalising tobacco use.

Any discussion about making these products available in Australia should focus solely on their use as a potential short-term cessation aid. As such they need to be regulated as a therapeutic device by the TGA and subject to the same marketing restrictions as other therapeutic products.

To safeguard the Australian population we must view these products like any other therapeutic product known to cause damage, and demand a high level regulatory oversight by TGA of the production, sale and use. We should not set a very dangerous precedent by permitting these products to penetrate Australian culture without appropriate regulation.

## TOR 2: The health impacts of the use of e-cigarettes and personal vaporisers

Harm reduction arguments acknowledge that the use of e-cigarettes and personal vaporisers MAY be less harmful than cigarettes, but they are NOT HARMLESS. The long-term health impact of e-cigarettes and personal vaporisers remains largely unknown.

Assessing the health impacts of the use of e-cigarettes and personal vaporisers requires assessment of several components:

- 1. Promotion of smoking uptake amongst young people who would not have otherwise started smoking
- 2. Product toxicity
- 3. Device injury

## Gateway to Smoking Claims

The protection of children and young adults is of upmost importance to us and our submission reflects this. Our concerns are twofold:

- 1. Evidence increasingly demonstrates the greater risk of transition to smoking traditional cigarettes, and
- 2. The use of these products damages the lung with or without nicotine.

Evidence from the USA demonstrates the **initial use of e-cigarettes is associated with a greater risk of subsequent cigarette smoking initiation**, and a greater chance of an individual who uses e-cigarettes as having also smoked a combustible cigarette in the past 30-days. This evidence was produced in a systematic review and meta-analysis of longitudinal studies of 17,389 adolescents and young adults [14].

Australia has consistently demonstrated its position as a world leading nation with an enviable track record on progressive tobacco control legislation. Through a range of multifaceted initiatives such as plain packaging, advertising bans, and public smoking restrictions, Australia now has one of the lowest rates of smoking in the developed world, especially amongst children and young adults [15]. We should be proud of this achievement in health status and not allow it to be jeopardised through high-risk industry dysregulation. Evidence shows, however, that youths are rapidly adopting e-cigarettes [16]. The US has seen the use of e-cigarettes in adolescents increase threefold in recent years [17, 18]. The transition of youth using e-cigarettes to using traditional cigarettes must be taken seriously. A longitudinal study of 2338 high school students published in 2016 found that adolescents who use e-cigarettes were more likely to start smoking traditional cigarettes [19]. Furthermore, statistics presented in the 2016 Report of the Surgeon General on e-cigarette use among youth and young adults, noted that in 2014, current use of e-cigarettes by youth was greater than the use of traditional cigarettes, and use by young adults (18-24 years of age) surpassed that of adults 25 years of age and older [20]. E-cigarette use among youths and young adults is a significant public health concern. The long-term effect from this increasing uptake and potential transition to traditional cigarettes needs to be explored.

Even if e-cigarette and smoking use in young people reflects an underlying risk mentality, the adverse health effects of the combination of tobacco and e-cigarettes should be avoided strenuously in young people by helpful legislation and social policy developments (20).

The position of TSANZ and LFA is to protect all Australians, including children and young adults from harm. There are currently no measures in consumer goods regulations which adequately do this. Youth transition from e-cigarettes and personal vaporisers to traditional cigarettes is highly likely and supported by the evidence in the literature. We do not support the availability of a product that causes

damage to the lung when used as it should be used and which is also very likely to encourage the uptake of cigarette smoking.

#### **Product Toxicity**

E-cigarettes and personal vaporisers are relatively new and research is emerging which suggests they are more harmful than hoped. A highly detailed summary of the lung toxicity of e-cigarettes has been published recently in the American Journal of Physiology [21]. This was funded by the US FDA and the National Cancer Institute. Whilst reading the review in its entirety would be informative for the Committee, we would like to emphasise several specific harms discussed therein:

## A. Harm in adolescent e-cigarette users

In a study of 45,000 adolescents in Hong Kong with e-cigarette use in the preceding 30 days there was double the risk of cough and sputum in both ever smokers and never smokers [22]. In a separate study of 40,000 adolescents in South Korea, e-cigarette use more than doubled the risk of asthma diagnosis and more than trebled the frequency of school absence related to asthma [23]. These adverse events are real, immediate and a cause for action to protect children and young adults from e-cigarettes whether containing nicotine or otherwise.

Data from international poison centres raise further cause for alarm with cases increasing related to the accidental exposure to nicotine and other chemicals from e-cigarettes (Figure 4), especially amongst minors [24]. Data from the USA demonstrates the high risk to minors, with 51% of all cases of e-cigarette exposures reported to the poison centre related to children. The most common exposure routes were ingestion (68.9%), inhalation (16.8%), eye exposure (8.5%) and skin exposure (5.9%). Worryingly, there was also one reported suicide due to intravenous injection of liquid nicotine [25].

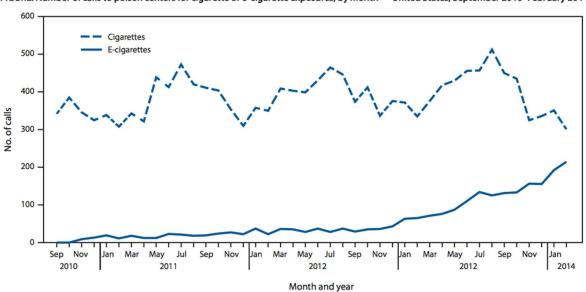


FIGURE. Number of calls to poison centers for cigarette or e-cigarette exposures, by month — United States, September 2010–February 2014

Figure 4 – Poison incidents relating to cigarettes and e-cigarettes.

Source: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm

#### B. Harms of flavourings and other vehicle compounds.

E-cigarettes contain many flavourings that are approved for oral ingestion but certainly not for inhalation. Further, the superheated environment alters these to toxins, and higher levels of toxins equal to or greater than those seen in cigarette smoking can be produced. In particular, the carcinogen formaldehyde and other aldehydes may be created in these superheated aerosols.

## C. Harms of heavy metal exposures

The heating coil for the e-cigarettes can decay or flake and cause toxic heavy metals to be included in solution or as a particle in the aerosol. These include nickel, chromium and aluminium. All are known carcinogens which should not be inhaled.

Australia is leading the way in research into the health effects of e-cigarettes and personal vaporisers. Cellular and molecular scientists are beginning to identify tissue damage and impaired cellular function caused by both e-cigarettes and personal vaporisers.

Early data investigating the *in vitro* effects of e-cigarettes has found that immune cells (macrophages) which normally reside in the small and distal airways of the lungs in order to protect from infection, are less able to detect and digest pathogenic bacteria when they have been exposed to an e-liquid and/or nicotine. This **South Australian study found e-cigarette components contributed to suppressed immune cell function and immune response, potentially contributing to chronic lung inflammation [2].** 

Recently published animal data have found e-cigarette exposure causes decreased lung function in the areas of the lung where gas exchange occurs (parenchyma). This West Australian study demonstrated that exposure to e-cigarette aerosol during adolescence and early adulthood is not harmless to the lungs, and can result in significant impairments in lung function [3].

Animal studies are also being used to investigate the effect maternal e-cigarette smoking and personal vaporisers have on offspring, and how these products interact with allergic airways. These studies found that e-cigarette vapour containing nicotine caused more inflammation and reduced flexibility of the offspring's airways, compared to vapour with did not contain nicotine. This study from New South Wales suggests that maternal e-cigarettes and personal vaporiser use enhances and worsens allergic asthma in offspring [4].

Case-studies on the effects of e-cigarettes and personal vaporisers are beginning to emerge. In October last year, there was a case of **respiratory bronchiolitis interstitial lung disease in a 33-year-old male**. This individual had a history of a mixed germ cell tumour and was vaping 10-15 times a day alongside smoking traditional cigarettes. After three months of this regimen, multiple new areas of interstitial lung damage were identified. These areas of damage resolved after ceasing the use of a personal vaporiser. **This Queensland case is the first identifying personal vaporiser use associated with rapid lung damage** [5]. This case bring evidence against e-cigarette smoking and personal vaporisers being used for smoking cessation.

When considering the broader effect e-cigarette smoking and personal vaporisers may have on the whole lung, we must consider Chronic Obstructive Pulmonary Disease (COPD). **COPD is the 5**<sup>th</sup> leading cause of death in Australia and was responsible for 66,250 hospitalisations in 2014-15 [26]. The main cause of COPD is tobacco smoking. However, COPD is also caused by inhalation of irritants such as dust, air pollution, smoke and fumes. Research has shown undiluted e-cigarette aerosol particles<sup>2</sup> are

<sup>&</sup>lt;sup>2</sup> Particles have diameters of average in the 250-450nm range and particle number concentrations in the 10<sup>9</sup> particles/cm³ range.

comparable to those observed for tobacco burning cigarette smoke and may have a similar potential to penetrate and deposit in the lung tissue [27].

There is a potential myriad of other health effects on the developing lung. The gamut of lung injury which may develop from the use of e-cigarette smoking and personal vaporisers, alone or alongside traditional cigarettes, may be more numerous and develop more rapidly than previously thought. The current lack of quality control over the contents of e-cigarettes and personal vaporisers makes it unclear as to the impact of these products over the longer term.

## Device Injury

Device-related injuries are mostly burns or shrapnel injuries caused by exploding devices (Figure 5). These are the direct result of a lack of effective regulation and add further support to the call to ban these devices except for those which are regulated for cessation use through the TGA.

There are now dozens of cases reported in medical journals of burns and other injury related to lithium-ion battery powered device malfunction [28]. Explosive malfunction cause three complications: **blast injury, thermal burn from the device and superheated vaping liquid, and corrosive burn from lithium.** 

Broadly, device-related injuries can be grouped into those when the device is not in use, most commonly when in a trouser pocket, and when in use near or in the mouth. Explosions in the vicinity of the mouth during use are potentially catastrophic. Reported consequence include major dental injury, injury to soft tissues in the mouth and pharynx and even fractures of C1/C2 vertebrae [29].

Burn injuries are becoming so frequent that a classification system has been proposed. Burns have most commonly been reported in the thigh area. Whereas first aid for thermal burn generally is based on water application, this may worsen the situation with lithium burn. The total burn area averages less than 10% but may include the external genitalia - an area that represents particular challenges for burns surgery and of course important long-term physical and psychological harms for the (generally) young person affected.

By way of contrast, several billion doses of asthma sprays are used in Australia each year and none of these events are seen.



Figure 5 - Injuries from exploding e-cigarette device [30]

Pictures A and B demonstrate injury from burns after a lithium-ion battery explosion in a pocket. Picture C shows a burn and blast injury to the face after an e-cigarette device exploded during use, which led to traumatic tattooing of the right cheek. Picture D shows a wound from an e-cigarette explosion, with a rim of discoloration characteristic of an alkali chemical burn. Source: <a href="http://www.nejm.org/doi/full/10.1056/NEJMc1608478#t=article">http://www.nejm.org/doi/full/10.1056/NEJMc1608478#t=article</a>

# TOR 3: International approaches to legislating and regulating the use of E-cigarettes and personal vaporisers

Australia is a world leader in reducing tobacco use and we must do nothing to jeopardise this. Additionally, in 2016 more than 3 in 10 Australians suffer from one or more chronic respiratory conditions (21). COPD is a leading cause of mortality and hospital costs. We should avoid taking measures that will further exacerbate this situation.

Our current approach to e-cigarette and personal vaporiser use is far more lenient than those of Singapore and Brazil which have total bans. The UK is leading the argument for e-cigarettes and personal vaporisers as harm reduction. However, care needs to be taken in adopting such an approach in Australia as the nature of cigarette smoking and success in reducing quit rates is markedly different. In the UK, 17% of adults continue to smoke, whilst in Australia we have seen a steady decline in smoking prevalence, with a daily smoking rate now at 12.8% in adults [15]. Furthermore, the prevalence of cigarette smoking in kids (aged 12-17) is now lower than ever and we must ensure that we do not jeopardise this success [15].

Our approach is entirely consistent with the precautionary principle being urged in many jurisdictions. A recent Editorial in the Lancet argued "What is needed from the scientific community and policy makers

in this difficult area of electronic nicotine delivery systems is an open mind for providing and examining much more and longer-term evidence to answer these questions objectively absent of hidden agendas. A lifelong attention to lung health needs both quick action where it is needed and the judicious application of the precautionary principle." [31]

In Australia, we have a high acceptance of regulatory approaches to restricting smoking. If e-cigarettes and personal vaporisers play any part in normalising smoking activity then they need to be strongly regulated, and would need the safeguards from overuse that would come with requiring a prescription from a medical practitioner. We note that the major tobacco companies now have a significant holding in e-cigarettes and personal vaporisers. At the present time, there is insufficient evidence that e-cigarettes and personal vaporisers do not normalise smoking activity, and evidence is mounting to suggest uptake of these devices for social image [13].

## TOR 4: The appropriate regulatory framework for E-cigarettes and personal vaporisers in Australia

The current situation is variable across states, resulting in inconsistent approaches and potentially inconsistent protection from e-cigarettes and personal vaporisers.

E-cigarettes and personal vaporisers have no role to play on the open market, except potentially as another cessation aid that is effectively regulated by the TGA.

TGA regulation will obviously be an expensive undertaking to prove that e-cigarettes and personal vaporisers are safe and effective smoking cessation aids, but this remains the level of rigour to ensure the equipment and ingredients are manufactured and sold to the standard required to protect the lungs of Australians using them. The safety and efficacy standards required by the TGA would be sufficient to determine if the benefits of e-cigarettes and personal vaporisers were effective and worth the known risks and potential future risks from certain levels of use. This regulation would bring appropriate control and health monitoring to e-cigarettes and personal vaporiser users.

It is also worth noting, that despite the hype around the UK approach, EU regulations require nicotine containing e-cigarettes to restrict refillable tank capacity, be registered as a medicine in strengths over 20mg/ml, bans additives including colouring, caffeine and taurine, packaging is to be tamper-evident and childproof tanks are required.

Regulation of e-cigarettes and personal vaporisers as medicinal products should ensure:

- 1) Nicotine content is known and documented
- 2) All ingredients and concentrations are listed on the label, including specifying compounds used for flavouring, not just the common name of the flavour, e.g. "apple flavouring"
- 3) Quality standards for the liquid and for the device are applied and audited, and
- 4) A warning statement about the impact on health should be on every product.

Until such time as long term randomised controlled studies are conducted with a homogenous product class, it is not possible to determine the safety and efficacy of e-cigarettes and personal vaporisers. If e-cigarettes are not banned, clinical trial research into harms and benefits of e-cigarettes as a means of smoking cessation support must be supported.

We do not support these products being available other than for smoking cessation. However, should this not be achieved, the application of tobacco control supply related legislation such as sale to minors and smoke-free laws should be applied. E-cigarettes and personal vaporisers are currently easily

obtainable from retailers to under 18s in many states and from online stores. Nationally consistent child protection measures must be set in place, specifically:

- 1) Tamper-proof and kid-safe packaging
- 2) Restriction on sales to under 18s
- 3) Prohibit use in car with under 18s on board
- 4) Prohibition from indoor areas i.e. cafes, restaurants, and areas where children could be present, such as playgrounds

The existing regulations are confusing and require change. The manufacture of devices and products is unregulated and nicotine remains easy to import. Retailer education in such a complex regulatory environment would be highly resource intensive and is unlikely to be successful given the complexities of existing regulations.

#### Conclusion

Globally, e-cigarettes and personal vaporisers are being marketed as a harmless life choice, without any cautionary labels or health warnings. However, emerging evidence has shown that the use of e-cigarettes and personal vaporisers can deliver an unregulated cocktail of harmful chemicals which contain variable concentrations of nicotine, directly to the lungs.

Australia cannot afford to see increases in lung disease (such as COPD) from healthcare and cost perspectives. The TSANZ and LFA strongly advocate for independent, long-term studies on health outcomes as part of the commitment to achieving a smoke-free future and reducing the preventable lifelong health burden of chronic respiratory disease.

Governments did not have the opportunity to prevent cigarette smoking and its enormous contribution to death and disease, but we have that opportunity with e-cigarettes and personal vaporisers. There is no good public health claim for an unregulated approach to e-cigarettes and personal vaporisers. **There is a strong case for a total ban on these products.** If these products are to be allowed, they must be regulated under the TGA and further independent, academic research and clinical trials are required to develop our knowledge about these products.

## References

- 1. Drummond, M.B. and D. Upson, *Electronic cigarettes. Potential harms and benefits*. Annals of the American Thoracic Society, 2014. **11**(2): p. 236-242.
- 2. Ween, M., P. Reynolds, and S. Hodge, *Hidden dangers of E-cigarettes: Airway macrophage dysfunction and altered inflammatory response*. 2016, Eur Respiratory Soc.
- 3. Larcombe, A.N., et al., *The effects of electronic cigarette aerosol exposure on inflammation and lung function in mice*. American Journal of Physiology-Lung Cellular and Molecular Physiology, 2017: p. ajplung. 00203.2016.
- 4. McAlinden, K.D., et al., Maternal E-cigarette Vaping Enhances Development Of Allergic Asthma In The Offspring, in D98. INSIGHTS INTO ENVIRONMENTAL EXPOSURES IN ASTHMA, COPD, AND CONSTRICTIVE BRONCHIOLITIS. 2017, Am Thoracic Soc. p. A7333-A7333.
- 5. Flower, M., et al., Respiratory bronchiolitis-associated interstitial lung disease secondary to electronic nicotine delivery system use confirmed with open lung biopsy. Respirology case reports, 2017. **5**(3).
- 6. Manigrasso, M., et al., *Aerosol deposition doses in the human respiratory tree of electronic cigarette smokers.* Environmental Pollution, 2015. **196**: p. 257-267.
- 7. Borgas, D., et al., *Cigarette Smoke Disrupted Lung Endothelial Barrier Integrity and Increased Susceptibility to Acute Lung Injury via Histone Deacetylase 6.* American journal of respiratory cell and molecular biology, 2016. **54**(5): p. 683-696.
- 8. Mayer, B., How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. Archives of toxicology, 2014. **88**(1): p. 5.
- 9. Vardavas, C.I., et al., Short-term pulmonary effects of using an electronic cigarette: impact on respiratory flow resistance, impedance, and exhaled nitric oxide. Chest Journal, 2012. **141**(6): p. 1400-1406.
- 10. Gualano, M.R., et al., *Electronic cigarettes: assessing the efficacy and the adverse effects through a systematic review of published studies.* Journal of Public Health, 2014. **37**(3): p. 488-497.
- 11. Hartmann-Boyce, J., et al., *Can electronic cigarettes help people stop smoking, and are they safe to use for this purpose.* Cochrane Collaboration, 2016.
- 12. Nagelhout, G.E., et al., *E-cigarette advertisements, and associations with the use of e-cigarettes and disapproval or quitting of smoking: Findings from the International Tobacco Control (ITC) Netherlands Survey.* International Journal of Drug Policy, 2016. **29**: p. 73-79.
- 13. Ayers, J.W., et al., Why do people use electronic nicotine delivery systems (electronic cigarettes)? A content analysis of Twitter, 2012-2015. PloS one, 2017. **12**(3): p. e0170702.
- 14. Soneji, S., et al., Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-analysis. JAMA Pediatrics, 2017.
- 15. *Tobacco Control key facts and figures*. 29 June 2016 03 July 2017].
- 16. Grana, R., N. Benowitz, and S.A. Glantz, *Background paper on e-cigarettes (electronic nicotine delivery systems)*. 2013.
- 17. Pepper, J.K. and N.T. Brewer, *Electronic nicotine delivery system (electronic cigarette) awareness, use, reactions and beliefs: a systematic review.* Tobacco control, 2014. **23**(5): p. 375-384.

- 18. Murthy, V.H., *E-Cigarette Use Among Youth and Young Adults: A Major Public Health Concern.* JAMA pediatrics, 2017. **171**(3): p. 209-210.
- 19. Wills, T.A., et al., *Longitudinal study of e-cigarette use and onset of cigarette smoking among high school students in Hawaii.* Tobacco Control, 2016: p. tobaccocontrol-2015-052705.
- 20. Youth, E.-C.U.A., U.D.o. Health, and H. Services, *A Report of the Surgeon General—Executive Summary.* Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
- 21. Chun, L.F., et al., *Pulmonary Toxicity of E-cigarettes*. American Journal of Physiology-Lung Cellular and Molecular Physiology, 2017: p. ajplung. 00071.2017.
- Wang, M.P., et al., *Electronic cigarette use and respiratory symptoms in Chinese adolescents in Hong Kong.* JAMA pediatrics, 2016. **170**(1): p. 89-91.
- 23. Cho, J.H. and S.Y. Paik, Association between electronic cigarette use and asthma among high school students in South Korea. PloS one, 2016. **11**(3): p. e0151022.
- 24. Durmowicz, E.L., *The impact of electronic cigarettes on the paediatric population.* Tobacco control, 2014. **23**(suppl 2): p. ii41-ii46.
- 25. Chatham-Stephens, K., et al., *Notes from the field: calls to poison centers for exposures to electronic cigarettes—United States, September 2010–February 2014.* MMWR Morb Mortal Wkly Rep, 2014. **63**(13): p. 292-293.
- 26. AIHW, *Admitted patient care 2014–15: Australian hospital statistics*. 2016: http://www.aihw.gov.au/publication-detail/?id=60129554702.
- 27. Ingebrethsen, B.J., S.K. Cole, and S.L. Alderman, *Electronic cigarette aerosol particle size distribution measurements*. Inhalation toxicology, 2012. **24**(14): p. 976-984.
- 28. Nicoll, K., et al., *Thigh burns from exploding e-cigarette lithium ion batteries: first case series.* Burns, 2016. **42**(4): p. e42-e46.
- 29. Norii, T. and A. Plate, *Electronic cigarette explosion resulting in a C1 and C2 fracture: a case report.* The Journal of emergency medicine, 2017. **52**(1): p. 86-88.
- 30. Brownson, E.G., et al., *Explosion injuries from e-cigarettes*. New England journal of medicine, 2016. **375**(14): p. 1400-1402.
- 31. The lung: a magnificent organ that needs lifelong attention. Lancet, 2016. **387**(10030): p. 1789.