OBJECTIVE: This document is written to specifically address the issues and concerns held by public health officials, local government health departments and ministers regarding alternative nicotine consumption methods, their use and place within the tobacco harm reduction policies and process and specifically addresses Electronic Nicotine Delivery systems/Electronic Liquid Vapouriser systems (ENDs/ELVs) and the people who that utilise liquid nicotine diluent (vapers).

This is a collaborative effort and there is unanimous agreement on the contents of this document by the alternative nicotine consumer organisations in Australia, India, Malaysia, New Zealand, Philippines and Thailand who are members of the the International Network of Nicotine Consumer Organisations (INNCO) in the Asia Pacific region.

None of the organisations involved in this effort and document have any vested interest(s) in the tobacco, pharmaceutical, alternative nicotine products industries.

INTRODUCTION: First and foremost, we believe that **Harm Reduction is a Human Right** and the exclusion of vapers from the process of policy creation and implementation - internationally and locally within our own countries is in direct opposition to what is outlined on the human right to health embodied in Article 12 of the International Covenant on Economic, Social and Cultural Rights, this article contends that international law supports a harm reduction approach to tobacco control. *The Framework Convention on Tobacco Control (FCTC) fails to acknowledge the harm reduction strategies necessary to help those incapable of breaking their dependence on tobacco as is shown by the static rates of smoking cessation through "suggested methods" throughout the global base of signatories to the charter.*

The article specifies that "*the work of the parties needs to be about 'emphasizing the special contribution of nongovernmental organizations and other members of civil society not affiliated with the tobacco industry, including health professional bodies, women's, youth, environmental and consumer groups, and academic and health care institutions, to tobacco control efforts nationally and internationally and the vital importance of their participation in national and international tobacco control efforts*.'"[1]

Harm reduction, in this context needs to also be inclusive of all who may benefit from reduced harm/risk products such as all current combustible tobacco users, governmental health ministers and policy makers as well as the general public to clear any misconceptions and misinformation that has been disseminated. Harm reduction involves everyone and the language and locus of harm reduction needs to be inclusive of everyone.

Dr. David Abrams, a professor of social and behavioral sciences at NYU College of Global Public Health, said studies show the alternative approach reduces mortality. "Harm minimization is a pragmatic approach that can complement proven current tobacco control efforts of prevention and cessation," researchers write in the study. "Its primary goal is to move the whole population of smokers of toxic combusted tobacco products to exclusive use of much safer products as quickly and as early as possible in their individual smoking careers." [2]

[1] World Health Assembly Resolution 56.1. (n.d.). Retrieved January 08, 2018, from http://www.who.int/tobacco/framework/final_text/en/index2.html

[2] Abrams, D. B., Glasser, A. M., Pearson, J. L., Villanti, A. C., Collins, L. K., & Niaura, R. S. (2018). Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives. *Annual Review of Public Health, 39*(1). doi:10.1146/annurev-publhealth-040617-013849

Harm Reduction is a Human Right:

ENDs/ELVs are not tobacco products nor are they a novel construct of tobacco companies. This technology was created by and for the consumers as a means of harm reduction and it has only been recently that tobacco companies have chosen to create and market their own version of the technologies.[3]

The health issues with the use combustible tobacco are NOT present in the use of ENDs/ELVs that utilise liquid nicotine diluent, and that for those for whom the "approved methods of NRT" have not worked, they have been a means to an end in terms of individual tobacco harm reduction, as the **science shows now that it is not the nicotine nor the aerosol of ENDs/ELVs that causes health harm**, it is the tar from combustion of tobacco.[4]

For those for whom traditional Nicotine Replacement Therapies (NRT) have failed, the individual choice to seek and utilise alternative harm reduction methods and the reasoning behind doing so was clearly outlined by Meier and Shelley when they noted *"**Harm reduction can involve the use of novel, purportedly less hazardous tobacco products. By dissociating nicotine from the ancillary carbon monoxide and myriad carcinogens of smoking, these tobacco harm-reduction products may allow the individual smoker to retain addictive behaviors while limiting their concomitant harms. These less hazardous products, while not offering the preferred benefits of abstaining from tobacco entirely, might nevertheless become a viable strategy for buttressing individual autonomy in controlling health outcomes.**"*[5]

Use of ENDs/ELVs by Youth - The "Gateway Theory":

The right to harm reduction should **extend to all users who currently use combustible tobacco, including youth.** Nicotine dependence in youth develops rapidly and **over 50% of those youth who smoke daily are already nicotine dependent.**[6] Allowing access to medicalised NRT (in some countries from the age of 12) and not allowing access to this technology is questionable. In saying that, we believe that youth, under the age of 16/18 (depending upon jurisdictional law) should have access to the technology with parental permission. The available evidence does not support the "gateway hypothesis" that ENDs/ELVs encourages nicotine addiction or uptake by youth.[7] The focus instead needs to be **harm reduction by allowing youth already using combustible tobacco access to ENDs/ELVs** instead of a *perceived* risk of "Gateway Theory" that youth who vape will eventually move onto combustible smoking.

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[3] Historical Timeline of Electronic Cigarettes. (2017, November 14). Retrieved January 09, 2018, from http://casaa.org/historical-timeline-of-electronic-cigarettes/

[4] Polosa, R., Cibella, F., Caponnetto, P., Maglia, M., Prosperini, U., Russo, C., & Tashkin, D. (2017, November 17). Health impact of E-cigarettes: a prospective 3.5-year study of regular daily users who have never smoked. Retrieved January 08, 2018, from https://www.nature.com/articles/s41598-017-14043-2

[5] Meier, B. M., & Shelley, D. (2006). The Fourth Pillar of the Framework Convention on Tobacco Control: Harm Reduction and the International Human Right to Health. Retrieved January 08, 2018, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1564445/. Accessed 9 Jan 18.

[6] Use of electronic cigarettes among children in Great Britain. Action on Smoking and Health, UK, 2015 Contract No.: Fact sheet 34. Available at http://www.ash.org.uk/information/facts-and-stats/fact-sheets (accessed August 2016)

[7] Bauld L, MacKintosh AM, Ford A, McNeill A. E-Cigarette Uptake Amongst UK Youth: Experimentation, but Little or No Regular Use in Non-smokers. Nicotine Tob Res. 2016;18(1):102-3.

Researchers from the University of Stirling and Public Health England collaborated for a study looking at teen vaping trends in the United Kingdom to address the "Gateway Theory". The study found roughly 10 to 20 percent of teens ages 11 to 16 have tried a vaping device at least once, however, only 3 percent used them regularly. Daily users among this age group were overwhelmingly found to already smoke. **Only 0.1 percent to 0.5 percent of teens who have never smoked are regular users of a vape device.**[4] ,[5] Similar results were found in the Population Assessment of Tobacco and Health (PATH) Study out of the United States, which is a national longitudinal study of tobacco use and how it affects the health of people in the United States.[8]

Nicotine is not the Enemy:

There have been many "public health" announcements and media campaigns put out by various interests in the region (and worldwide) promoting and promulgating the many misconceptions surrounding liquid nicotine diluent such as what is used with the devices.

For years the pharmaceutical industry has invested millions of dollars in research, development and marketing of Nicotine Replacement Therapies (NRT) to be utilised by combustible tobacco smokers to "kick the habit". This same pharmaceutical grade nicotine is **exactly** what is used by reputable e liquid manufacturers for use in ENDs/ELVs.

Keeping in mind that what causes harm in tobacco is the combustion of leaf tobacco and the chemical reactions of the additives that form the negative health effects of tobacco and potentiate the effects of the naturally occurring nicotine in leaf tobacco.[9] Combustion is the main health harm from smoking as that creates the chemical reactions and tar that not only affect the user, but also indirectly those who are in the presence of a user who is actively smoking. None of those harms are present with the use of ENDs/ELVs.[10]

[8] Population Assessment of Tobacco and Health (PATH) Study [United States] Restricted-Use Files (ICPSR 36231). (n.d.). Retrieved January 09, 2018, from http://www.icpsr.umich.edu/icpsrweb/NAHDAP/studies/3623

[9] Alpert, H. R., Agaku, I. T., & Connolly, G. N. (2016, July 01). A study of pyrazines in cigarettes and how additives might be used to enhance tobacco addiction. January 09, 2018, http://dx.doi.org/10.1136/tobaccocontrol-2014-051943

[10] Goniewicz ML, Knysak J, Gawron M et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control. 2014;23(2):133-9

SUMMARY:

- **ENDs/ELVs that utilise liquid nicotine diluent are NOT tobacco products**, nor should they be considered the same as combustible tobacco as it relates to policy and taxation as **they do not carry** the same health risks and harms as combustible tobacco.[11]

- Nicotine dependence in youth develops rapidly and over 50% of those youth who **smoke** daily are already nicotine dependent.[12]

- The use of ENDs/ELVs by adults (and youth) does **not** lead to combustible tobacco use and access to the products should not be restricted because of a misperception of any "Gateway" theory.[4] ,[5]

- Independent (of tobacco and pharmaceutical links) researchers focused on harm reduction say efforts to misrepresent the health impacts of vaping risks undoing the progress made on improving public health.

- Nicotine is no more addictive than that of the caffeine contained in coffee and tea.[13]

- Nicotine is **not** a carcinogen and does not cause respiratory disease and has only minor cardiovascular effects.[14]

- The nicotine used in ENDs/ELVs, while it may contain small amounts of other chemicals including volatile organic compounds, carbonyls, aldehydes, tobacco-specific nitrosamines (TSNAs) and metal particles, research indicates that they are present at much lower levels than in cigarette smoke.[15]

- In normal conditions of use, toxin levels in inhaled ENDs/ELVs aerosol are below prescribed threshold limit values for occupational exposure, in which case significant long-term harm is unlikely.[16]

- An individual's right to health is recognized as a fundamental international human right. Founded upon the non-derogable right to life, the Universal Declaration on Human Rights (UDHR) affirms that "[e]veryone has the right to a standard of living adequate for the health and well-being of himself and his family, including … medical care and necessary social services…."[17]

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[11] Goniewicz ML, Knysak J, Gawron M et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control. 2014;23(2):133-9

[12] Use of electronic cigarettes among children in Great Britain. Action on Smoking and Health, UK, 2015 Contract No.: Fact sheet 34. Available at http://www.ash.org.uk/information/facts-and-stats/fact-sheets (accessed August 2016)

[13] Schipper EM, de Graaff LC, Koch BC et al. A new challenge: suicide attempt using nicotine fillings for electronic cigarettes. Br J Clin Pharmacol. 2014;78(6):1469-71

[14] Bell K, Keane H. All gates lead to smoking: the 'gateway theory', e-cigarettes and the remaking of nicotine. Soc Sci Med. 2014;119:45-52.

[15] Zwar N, Bell J, Peters M, Christie M, Mendelsohn C. Nicotine and nicotine replacement therapy – the facts. Australian Pharmacist. 2006;25(12):969-73

[16] Goniewicz ML, Knysak J, Gawron M et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control. 2014;23(2):133-9

[17] 1948. Universal Declaration of Human Rights. G.A. Res. 217A(III), U.N. GAOR, 3d Sess. U.N. Doc. A/810.

CONCLUSION:

Harm Reduction *is* a human right and individual autonomy towards the utilisation of ENDs/ELVs needs to be promoted and supported as part of wider Tobacco Harm Reduction policies and procedures within WHO FCTC and its signatory countries/states.

Submitted and Authorised by the Asia Pacific Regional Organisations of INNCO:

1 February 2018