Report of the Forum on E-cigarettes

Smoking and Health Action Foundation/Non-Smokers' Rights Association

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Electronic cigarettes (e-cigarettes), both with and without nicotine, are widely available for sale across Canada. The fact that the train has left the station raises many questions for those in the health community, in particular, what is an appropriate response to this new technology that both serves the needs of smokers and safeguards critical tobacco control gains?

Approximately ninety professionals working in the fields of public health, addictions, and tobacco control primarily from across Ontario met in Toronto on January 30, 2013, to discuss the emergence of e-cigarettes onto the Canadian market and to develop a way forward on this complex issue. Participants shared intelligence regarding the marketing and sale of e-cigarettes; reviewed the evidence regarding the potential risks and benefits of e-cigarettes to the individual and to public health; and discussed the advantages and disadvantages of alternative regulatory approaches.

The Forum presentations covered a wide range of issue and perspectives:

- Overview of the current situation (Melodie Tilson)
- Legal status in Canada (Melodie Tilson)
- Marketing and sales: overview of promotional practices and messaging (Melodie Tilson); research on availability in the E TCAN (Andrea Kruz); Enforcement issues in the SW TCAN (Leila Davis)
- Potential risks to health, safety, tobacco control (Dr. Jean-François Etter)
- Potential benefits to smokers (Dr. Amit Rotem/Dr. Peter Selby; Professor Linda Bauld)
- Regulatory approaches: as a drug/delivery device (Melodie Tilson); as a tobacco product (Melodie Tilson); as a harm reduction product (Professor Linda Bauld)

Overview of the Issue

There is considerable evidence of the burgeoning popularity of e-cigarettes, in Canada and globally. New brands and new products, featuring new and improved technologies, different shapes, sizes, and materials, and a dazzling array of flavours, are regularly coming on the market. Both disposable e-cigarettes and rechargeable models with replaceable or refillable cartridges are available. Other features include adjustable voltage (producing more and better vapour), adjustable smoke volume, longer battery life and more consistent voltage, as well as gimmicks such as sensors and flashlights. The recent acquisition of e-cigarette firms by Big Tobacco is a clear indicator of their popularity.

Two large surveys in the US and the UK show substantial awareness and use of the product. In the US 11% of smokers have ever used e-cigarettes, versus 2% of former smokers and less than 1% of never smokers. The only known Canadian data is from a recent International Tobacco Control four-country study to be published in March. The study found that 40% of Canadian smokers are aware of e-cigarettes and 10% have ever used them. One-third of triers currently use e-cigarettes. Two-thirds of Canadian smokers surveyed believe they are less harmful than cigarettes. Most smokers use e-cigarettes to help them quit (85%) or to cut down (75%), with 70% using them when they can't smoke.

Current Legal Status in Canada

Health Canada has ruled that all electronic products for the administration of inhaled doses of nicotine fall under the *Food and Drugs Act* and thus cannot be imported, marketed, or sold in Canada without being approved as a new drug. As well, the delivery system of an e-cigarette containing nicotine must meet the requirements of the *Medical Devices Regulations*. This ruling has resulted in a regulatory grey zone, whereby nicotine cartridges and liquid (e-juice) are illegal; e-cigarettes with nicotine are illegal; e-cigarettes without nicotine but that make a health claim are illegal; but e-cigarettes without nicotine and with no accompanying health claim are legal. Many distributors and retailers claim their products do not contain nicotine and are therefore legal. Others are openly selling products with nicotine and/or that make health claims such as reduced risk or cessation aid. As well, nicotine is readily available over the internet. Very little enforcement action has been taken by Health Canada, and the complaint process is very onerous.

Marketing and Sales

E-cigarettes first came to the attention of the health community in Ontario about two years ago, when they were marketed primarily through the internet and a few non-traditional vehicles. Since then, there has been an explosion in the number and type of venues selling e-cigarettes, including gas stations, convenience stores, pharmacies, and specialty stores. As well, e-cigarettes are being promoted in all the ways that tobacco products were before legislated prohibitions, including TV and radio ads; print ads in newspapers and retail trade journals; point-of-sale signage, product brochures, and countertop displays; price discounting; celebrity endorsements; event sponsorship; branded non-tobacco products; and internet websites, forums, and videos. Promotional messaging is usually focussed on one of the following themes—smoke anywhere, no second-hand smoke, a healthier alternative, an aid to quitting, and a cheaper alternative—and the associated images often portray vaping as sexy, hip, and elitist.

Andrea Kruz, TCAN-East Coordinator, shared research undertaken during the summer of 2012, during which a stratified random sample of retailers in all six area health units was surveyed to assess the extent of e-cigarette sales in the region. An average of 19% of stores sold e-cigarettes, ranging from a low of 15% in Ottawa Public Health (likely due to the high proportion of independent convenience stores in the sample) to a high of 39% in Hastings-Prince Edward County Health Unit. Overall, the highest prevalence of sales was found at chain conveniences stores (58%) and gas stations (44%), with a much higher prevalence in urban areas (38%) than rural (8%).

Leila Davis, Tobacco Enforcement Officer with the London-Middlesex and Elgin-St. Thomas Health Units, estimated that 75% of the 380 tobacco retailers in London sell e-cigarettes, largely because of their high mark-up (30-75%). The health unit has been fielding many calls from workplaces, schools, and restaurants for advice and has been recommending they implement a policy banning the use of e-cigarettes on their premises. Students are using e-cigarettes in the smoking pits and have been selling them from their lockers. Retailers have been seeking clarification on whether they can advertise or sell these products, as well as what constitutes a health claim. Various people charged with smoking where prohibited under the SFOA have claimed in defence that they were using an e-cigarette; in response, enforcement officers have learned to check for hand position, the smell and look of the smoke, and the appearance of the cigarette to defend their charges. Davis recounted the difficulty in completing Health Canada's onerous requirements for submitting a complaint, as well as the futility, since in several cases a few months after illegal products were seized, the vendors had resumed selling.

Potential Risks

Dr. Jean-Francois Etter, professor in the Faculty of Medicine at the University of Geneva and author of many peer-reviewed articles on cessation and a new book on e-cigarettes, gave a detailed presentation on the research to date regarding the risks of e-cigarettes.

- Most e-cigarettes are manufactured in the 200+ factories in the Shenzhen area of China. Only 3 companies control the entire process of manufacturing nicotine for e-cigarettes, from its extraction from tobacco leaves to its distribution (2 in China, 1 in the US).
- 95% of the content of e-cigarettes is propylene glycol or glycerol or a mix of both, plus flavours (tobacco, mint, fruit, coffee are the most popular), aroma transporters, colouring agents, nicotine (on average 18 mg/ml), tobacco impurities, additives, and sometimes vitamins/other medications.
- Tests of liquids and vapours have raised some concerns; however, tests by the US Food and Drug Administration (FDA) showing tobacco-specific nitrosamines (TSNAs) actually found levels similar to levels in nicotine medications (patch, gum).
- There are valid concerns regarding the unknown health effects of *inhaling* the ingredients in e-cigarettes, especially given the strong aspiration required and the fact that daily users may inhale an average of 120-150 puffs/day for months or years. The lack of manufacturing standards results in variable quality and performance within a brand and among brands, leakage, and other problems. Some vials of e-liquid contain toxic amounts of nicotine and/or other chemicals that may be toxic.
- Surveys show that almost all users are current or former smokers who use e-cigarettes with nicotine (97%) to quit smoking, reduce, or prevent relapse. There are very few never smokers, if any, among regular users. A few surveys show some experimentation among adolescents (Paris).
- Some studies show that e-cigarettes can deliver substantial amounts of nicotine, with experienced vapors achieving levels similar to smoking.
- A few small studies show short-term adverse effect on the lung (Vardavas; Gennimata). One death reported in the press was attributed to the use of an e-cigarette (it was 'modified' with oil added). Another case of lipoid pneumonia reversed when e-cigarette use was stopped.
- An unpublished small randomized double-blind study of 300 smokers with no intention of quitting found that 13% of participants using e-cigarette with 7.2 mg nicotine quit smoking, versus 9% using an e-cig with 4.8 mg nicotine versus 4% using an e-cigarette with no nicotine. Approximately 10% of users in all 3 groups cut their cigarette use in half. Reported side effects were minor.
- Second-hand vapour includes propylene glycol, glycerol, aroma transporters (solanone), and nicotine (almost 10x less than with smoking).
- Very few users report using e-cigarette to inhale marijuana, although new vaporisers are on the market for this purpose. There are no reports of e-cigarettes being used to inhale heroin or cocaine; however, it is arguably less harmful to vape these substances than smoke them.
- Based on the research, Dr. Etter has drawn the following conclusions:
  - Prohibition of e-cigarettes is not feasible or desirable, given their potential to save many lives.
  - The regulation of e-cigarettes must balance the risks against the potential public health gains.
  - The risks of e-cigarettes must be compared to those of tobacco use—relative risk is relevant not absolute risk.
  - E-cigarettes do not renormalize smoking. Many vapers prefer not to use e-cigarettes in public, and e-cigarettes most probably help smokers quit smoking.

- While some smokers may become addicted to the nicotine in e-cigarettes, addiction to e-cigarettes is weaker and less dangerous than to tobacco cigarettes and can be treated.
- E-cigarette use does not interfere with a smoker's decision to quit, given the evidence that many users not intending to quit did so after using an e-cigarette.
- Adolescents may be tempted to experiment with e-cigarettes (novelty appeal, flavours); however, no teen addiction to e-cigarettes has ever been reported. No study to date supports e-cigarette use as a gateway to smoking, and fruit-flavoured nicotine gum has not proven a gateway to smoking.
- It is unknown whether e-cigarette use where smoking is prohibited will undermine smoking bans by encouraging smokers to light up; however, by helping smokers quit or temporarily abstain from smoking, e-cigarettes may aid the implementation of smoke-free laws.
- Children should not be exposed to second-hand vapour. Some substances emitted are toxic, although concentrations are very low and often below permitted thresholds. Second-hand vapour is far less toxic than second-hand tobacco smoke.
- E-liquids should be regulated, and bottles of e-liquid should be child-proof or replaced by cartridges containing less than 1 ml of liquid.

Potential Benefits

Dr. Amit Rotem a Fellow with the Centre for Addiction and Mental Health, in collaboration with Dr. Peter Selby, addressed the potential benefits of e-cigarettes from the perspective of addictions specialists.

- Although the propylene glycol in e-cigarettes is a known irritant, it is also considered safe for oral consumption and is used as a solvent in medications.
- While much attention has been paid to a small FDA study showing TSNAs in e-cigarettes, the levels are comparable to those in NRTs.
- Some studies show that e-cigarettes can deliver nicotine effectively and significantly reduce cravings more rapidly than a nicotine inhaler but much less effectively/rapidly than a cigarette.
- The reduction in desire to smoke in the first 10 minutes of e-cigarette use appears to be independent of nicotine absorption and may be due to satisfying the addiction to smoking behaviours; however, imitating the act of smoking may serve to perpetuate a smoker's addiction rather than help them to quit.
- More research is needed: prospective randomized controlled trials of e-cigarettes v. approved cessation medications and of e-cigarettes with nicotine v. with no nicotine; retrospective clinical trials of e-cigarettes v. cigarettes; and studies of e-cigarettes and specialized populations.
- Dr. Selby expressed consternation over the lack of harm reduction in tobacco control compared to other addictions (e.g., supervised methadone injection facilities); in tobacco control 'we are stuck between cessation and cigarettes with nothing in between'. When questioned, Dr. Selby said he could not recommend e-cigarettes to his patients given the lack of evidence proving that they are safe to use long-term; instead, he questions the motivation behind the patient's desire to try e-cigarettes and then examines the pros and cons of e-cigarettes with them, including the known and unknown risks as well as the relative risks compared to smoking.

Professor Linda Bauld, Chair of the UK National Institute for Health and Clinical Excellence (NICE) Working Group on Tobacco Harm Reduction, gave a presentation on the evidence that informed the NICE recommendations on e-cigarettes.

- Each year, one-third of smokers in the UK attempt to quit, but the vast majority are unsuccessful. People in lower SES groups have higher smoking rates and make as many quit attempts but are not as successful as those in higher income groups.
- Only 5-7% of smokers use cessation services, and existing NRTs are unattractive to most smokers.
- New research in the UK shows many smokers reduce their cigarette consumption first before attempting to quit and most who do so eventually quit.
- Current use of e-cigarettes among smokers is 9% and ever use is 22% (2012); both rates have tripled since 2010, reflecting a major increase in availability in 2011.
- A rolling smoker cohort study shows a month-by-month increase in use of e-cigarettes for any purpose, with e-cigarette use replacing use of licensed NRTs for quit attempts.
- Testing shows that some brands of e-cigarette (Voke) delivered a spike in plasma nicotine in 13-15 minutes, compared to 3 minutes for a cigarette and up to 30 minutes for the nicotine inhaler.
- Several studies by Goniewicz and colleagues show that exposure to all tobacco smoke toxicants was significantly reduced after switching to e-cigarettes.
- A large survey of smokers found that more than 50% cite the cost savings and potential as a quit aid as the main advantages of e-cigarettes.

Regulatory Approaches

The World Health Organization (WHO) Study Group on Tobacco Product Regulation (TobReg) in its 2009 report summed up the difficulty in regulating e-cigarettes:

> "[Electronic Nicotine Delivery Systems (ENDS)] pose a significant challenge to regulation, as they may fall outside the scope of domestic regulatory regimes for tobacco products. Nevertheless, their popularity and the fact that they are marketed as alternatives to cigarette smoking indicate the need to characterize them, regulate them and establish appropriate educational programmes to limit their use."

WHO TobReg recommends that ENDS be regulated as drugs; if this is not possible, then they should be subjected to the same restrictions as tobacco products to ensure they do not undermine key requirements of the *Framework Convention on Tobacco Control*, the global tobacco control treaty.

There are various possible options for the regulation of e-cigarettes:

- As a drug/device (the status quo in Canada)
  - No jurisdiction has authorized e-cigarettes as a drug.
  - Various jurisdictions regulate e-cigarettes as a drug and thus they are effectively prohibited—Australia, Belgium, Germany, New Zealand, Norway, Turkey, EU (draft directive).
- As a tobacco product
  - As a result of an industry challenge and subsequent ruling by the US federal Court of Appeals, tobacco-derived products, which include nicotine-containing products such as e-cigarettes, must be regulated as tobacco products.
  - However, e-cigarettes that make a therapeutic claim are to be regulated as drugs.
- As a harm reduction aid
  - E-cigarettes are part of New Zealand's 20-year plan to phase out the use of cigarettes.
  - Has been proposed by the UK's NICE harm reduction committee.

- As a consumer product
  - Consumer protection laws could be used to require minimum product safety and manufacturing standards.
  - The EU draft tobacco product directive proposes that e-cigarettes below a specified nicotine level (4 mg/ml) be regulated as consumer products with mandated health warnings.
- Banned
  - Several countries have banned e-cigarettes, including Uruguay.
  - Singapore and Seychelles prohibit imitation tobacco products, which includes e-cigarettes.

Regulation as a drug/device

PROs

- Recommended by WHO and the chosen approach of most countries.
- Mandates a rigorous approval process, which assures the quality and safety of the approved products.
- Protects the public from unproven claims that e-cigarettes support cessation, by requiring scientifically rigorous evidence that they are effective in helping smokers cut down and/or quit.
- Protects regulated NRTs and other cessation medications from unfair competition, by subjecting a new product containing nicotine to the same requirements as existing non-tobacco nicotine products.
- Recognizes that nicotine is a dangerous drug, and protects youth from potential addiction to an attractive new nicotine product.

CONs

- Amounts to a ban on e-cigarettes with nicotine in the short- to medium-term, until one or more manufacturers goes through the lengthy and costly process of getting approval as a drug.
- Fails to address the current situation whereby e-cigarettes (ostensibly without nicotine) are widely available, intensely promoted, used where smoking is banned, and sold to minors
- Hinders meaningful enforcement, since (a) it is not possible to distinguish between the legal (no nicotine) and illegal (with nicotine) product without testing and (b) Health Canada does not regard e-cigarettes as a serious risk compared to other drugs.
- If fully enforced, smokers would be denied access to a product that is much safer than cigarettes.
- It could result in restrictions that make the product unattractive to smokers. (UK data shows that e-cigarettes are popular because they look/feel like cigarettes.)

Regulation as a tobacco product

PROs

- Ends the current perverse situation whereby the most hazardous nicotine product—cigarettes—is the least regulated.
- Ensures e-cigarettes remain available to smokers, while minimizing the risks of undermining tobacco control.
- Safeguards many critical tobacco control gains, including the denormalization of smoking, and helps prevent youth uptake, by ensuring that an imitation tobacco product is subject to the same

restrictions as tobacco products—retail display ban; public place and workplace smoking ban; ban on most forms of promotion; ban on sales to minors.

- Permits the application of other requirements under the federal *Tobacco Act*—health warnings; ban on flavourings; provision of sales/marketing information; prohibition on discounting; prohibition against brand elements on non-tobacco products, etc.
- Reinforces the perception of e-cigarettes as a consumer product.
- Helps maintain the affordability of e-cigarettes, since regulation as a drug will increase the cost to manufacturers and stifle competition.
- Permits greater product innovation and more attractive packaging (which increase acceptability to users).
- Simplifies enforcement by not distinguishing between products based on nicotine content or health claim.

CONs

- Likely requires a legislative amendment to include e-cigarettes with and without nicotine under the federal *Tobacco Act* (perhaps as an imitation tobacco product).
- Requires government commitment to the provision of relative risk information (difficult to do).
- Does not ensure a high standard of quality, safety, efficacy.
- May undermine the promotion of e-cigarettes as a quit aid (they would be seen as tobacco products); they would not be covered as a cessation aid by health insurance.
- Does not differentiate between tobacco products based on their level of risk.

Regulation as a Harm Reduction Product

PROs

- Serves to promote the use of a (likely) much less harmful nicotine product.
- Ensures that meaningful information is provided to the public regarding the relative risk of use of various nicotine products.

CONs

- Amounts to government endorsement of e-cigarettes without rigorous evidence regarding their safety and efficacy.
- Does not differentiate between proven and unproven cessation aids.
- Provides a marketing advantage to e-cigarettes over pharmaceutical cessation aids that have had to undergo a higher level of scientific scrutiny and that must adhere to more legislated restrictions.

Linda Bauld, Chair of the UK National Institute for Health and Clinical Excellence (NICE) Working Group on Tobacco Harm Reduction, explained the thinking behind and process that will likely result in e-cigarettes being regulated in the UK as tobacco harm reduction products.

- UK NICE issued draft guidance on tobacco harm reduction in October 2012, a world first:
  - Recommends substituting the nicotine in tobacco with nicotine from less harmful products, either temporarily or indefinitely and as a partial or complete substitute for tobacco.

  - Less harmful nicotine-containing products include licensed NRTs; they could also include electronic cigarettes since they may be licensed in the future.
  - One product, "Voke" by BAT Nicoventures, is almost ready to be licensed (looks and feels like a cigarette but no LED light on tip and no second-hand vapour produced). If Voke is licensed, other companies will likely be given a couple of years to comply.
  - Some NRTs are now licensed for helping smokers cut down. The health benefits of cutting down are unclear, except that it pushes people along the continuum toward quitting.
- The final guidance will be issued in May 2013 in conjunction with the decision by the UK Medicines Healthcare Regulation Authority (MHRA) on the regulation of e-cigarettes. MHRA is expected to regulate e-cigarettes as a drug, but under fast-tracked, 'light touch' regulation:
  - E-cigarettes won't have to prove that they are as effective as current NRT, since they would be licensed for harm reduction not cessation.
  - Safety profile/efficacy of e-cigarettes is very similar to the nicotine inhaler; therefore, MHRA could 'cross-refer' to the evidence on the inhaler.
  - There is a huge public demand for e-cigarettes, with the public consultation on e-cigarettes receiving the highest response ever.
  - Post-market surveillance will be done to understand how e-cigarettes are prescribed by the National Health Service and to monitor youth uptake.
  - Licensing can be overturned as a result of future research findings.
- An economic model developed to assess a wide range of potential harm reduction approaches found that all interventions (except temporary abstinence with no support) were highly cost effective.
  - Only when a nicotine-containing product is provided for more than 5-10 years and the quit rate is less than 6% do the costs to the health system potentially outweigh the benefits.
- The NICE recommendation to include e-cigarettes in its tobacco harm reduction approach is controversial within the UK health community, in particular related to disagreements over:
  - Nicotine addiction
  - Communication and understanding of risks
  - Population versus individual harms
  - Ethics of tobacco industry involvement (BAT has the first product going through the MHRA process).

Recommendations and Conclusions

The Forum provided an opportunity for a wide-ranging dialogue in which a variety of opinions were voiced. There was discussion over whether e-cigarettes should be mandated to be unattractive and/or to not resemble cigarettes. Professor Bauld pointed out that UK data indicates that e-cigarettes are used almost exclusively by current smokers and recent quitters and that if they didn't look like cigarettes, they would likely be less accepted by this population. There was widespread agreement (not consensus) that e-cigarettes are likely much less harmful to the individual than cigarettes and have significant potential to help smokers cut down and quit. For this reason, the Lung Association representative cautioned colleagues against taking a strictly negative stance against e-cigarettes, citing the public backlash against their NNSW news release. On the flipside was concern over possible greater harm to the population if e-cigarettes prove to be a gateway to youth smoking initiation and the possible health consequences of long-term deep inhalation of propylene glycol and other e-cigarette constituents.

Several recommendations gave rise to rapid consensus:

- Participants agreed to continue monitoring the marketing and sales of e-cigarettes and to send photos and information updates to the Smoking and Health Action Foundation (Melodie Tilson), who will maintain a watching brief on the issue.
- The status quo, whereby e-cigarettes fall under a stringent regulatory regime on paper only, does not serve the interests of smokers who might benefit from a non-combustible imitation tobacco product or tobacco control/population health.
- More complaints will have to be lodged with Health Canada officials before the department will be convinced that the issue merits greater attention/action. The current complaint process is onerous and bureaucratic. However, even sending in letters of complaint (as opposed to answering the thirty or so questions) will likely have an impact if enough are received. The issue will likely also have to be brought to the attention of politicians.
- More and higher quality research is urgently needed, including large, randomized controlled trials of e-cigarette use and its impact on tobacco use behaviours; studies of absolute health risks (of long-term use in particular) and health risks relative to cigarette use; and studies of attitudes toward and use of e-cigarettes by Canadian youth and young adults. Questions should be added to the Youth Smoking Survey.

Several people emphasized that there are far more important tobacco control problems that demand greater attention and resources, such as the widespread availability of cheap contraband tobacco. Numerous participants, however, agreed that we can't continue to stick our head in the sand, waiting for definitive evidence or hoping the problem will go away. There was strong support for requiring e-cigarettes to be subject to the same controls as tobacco products, including bans on use in public places and workplaces, prohibitions on sales to minors, and bans on retail display and other forms of promotion. In addition, there was agreement that whatever measures are implemented to address e-cigarettes need to be broad enough to cover other new products on the horizon.