Canadian dawn

written by Clive Bates | 14 March 2015

Vermillion Lakes near Banff

Some good news at last from Canada. The Canadian House of Commons Standing Committee on Health has produced a report, Vaping: Towards A Regulatory Framework for E-cigarettes [report PDF]. Here is my response.

Its first merit is that it has allowed *no-one at all* to express support for the current approach, which basically classifies nicotine-containing e-cigarettes as medicines, requires a medicine marketing authorisation to allow them on the market and so creates a *de facto* prohibition [see guidance to manufacturers and importers]. Fortunately, this prohibition is widely ignored, but it does have the malign effect of inhibiting the development of Canadian vaping businesses and making an ass of the law. The Committee's report is, no doubt, a great relief to Health Canada, which must be embarrassed by its current policy and now has a pretext to rethink.

The Committee commendably took evidence from a range of experts covering the full spectrum of views about vaping and tobacco harm reduction, and has

summarised the divisions of opinion quite well. A close reading reveals the weakness of the opponents of harm reduction and vaping and the strength of evidence presented by the pro-harm reduction witnesses. I submitted written evidence: A disruptive public health technology threatened by excessive regulation (this has since evolved into my more comprehensive briefing).

The main recommendations

In this post I want to provide a short commentary on each of the Committee's fourteen recommendations. I hope the government will consider these issues carefully in its response to the Committee. For ease of reading have emphasised in bold the key text in each recommendation.

> *RECOMMENDATION 1 That the Government of Canada financially support research through existing channels, and that these funds be allocated to independent research on the health effects of electronic cigarettes and related devices, and their impact on the uptake of nicotine products by youth and on other tobacco control efforts.*

Response 1. "More research" is often seen as uncontroversial, but in this case the recommendation comes with a framing bias. It stresses research into health effects of e-cigarettes, impacts on young people and tobacco control efforts. It is framed to assess threat, but not opportunity. The Government of Canada should accept the recommendation to fund research, but approach the issue as a neutral investigator would. Other issues to consider include: defining and meaningfully communicating risks of e-cigarette use in relation to smoking; impact of e-cigarettes on smoking cessation; potential for e-cigarettes to divert risk-taking teens away from smoking; surveillance of use and transitions in use of recreational nicotine; perceptions of users and potential users; technical basis for proportionate and optimal regulation of e-liquid content and vapour product design.

> *RECOMMENDATION 2 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices.*

Response 2. This is very welcome indeed. The Committee calls for regulation to be purpose built and fit for purpose. E-cigarettes are not medicines or tobacco products, and the regulatory regimes for those products attempt to achieve objectives that suit medicines (e.g. precise dosing) and tobacco products (e.g. deterring use and stopping innovation). E-cigarettes are a consumer product that could substantially displace smoking and require specialised regulation – to encourage smokers to switch and make this attractive, while not encouraging new users who would not otherwise have smoked. These objectives are potentially in tension and require careful fine tuning by regulators in a way that maximises the net health benefit to Canadians – most of which would come from displacing smoking.

> *RECOMMENDATION 3 That the Government of Canada consult with the public, provinces/territories and stakeholders with respect to the regulation of electronic cigarettes with a view to protecting the health of Canadians.*

Response 3. The Committee itself made a good start in consulting stakeholders with a broad range of views. It is important that the government does likewise. The European Union Tobacco Products Directive was defined in a closed and secretive process involving no consultation at all. As a result it is poor quality legislation in conflict with good science and likely to be successfully challenged.

> *RECOMMENDATION 4 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices and that this new framework address both electronic cigarettes that contain nicotine and other substances and electronic cigarettes that do not contain nicotine.*

Response 4.That makes sense – but only as long as the regulatory framework is proportionate to risk, encourages the exploitation of health opportunities and supports innovation that deliver products that compete more effectively with cigarettes.

> *RECOMMENDATION 5 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes*

and related devices and that this new framework require that electronic cigarettes be visually distinct from other tobacco products.

Response 5. This recommendation makes no sense and suffers from very weak justification in the report. It may be that in the initial stages of switching to e-cigarettes, some smokers are self-conscious or wish to appear as they normally do. It is more likely that the appearance of vaping will normalise vaping, than it is likely to normalise a rival product or activity. If smokers choose products like this they are expressing a preference and the case for denying them that choice is not made in the report, nor is the risk that it will reduce the rate of switching and or that it may have the unintended consequence of protecting the cigarette trade. The government should not act on this recommendation based on the un-evidenced hunches of public health activists, but only if there is credible evidence that the visual appearance of e-cigarettes does in fact increase smoking.

RECOMMENDATION 6 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices and that this new framework establish maximum levels of nicotine contained in electronic cigarette liquid or vapour.

Response 6.There is no basis for setting a maximum limit, other than one that is much higher than routinely used in consumer products – say 7% or 70mg/ml. There are several reasons for this:

- When people first switch and are learning their vaping technique, then will often use higher concentrations of nicotine to more closely match the dose they experienced during smoking. The danger of capping the strength is that they never switch or may relapse before they can become properly familiar with vaping using lower nicotine levels.
- More heavily dependent smokers may need stronger nicotine liquids to make the transition to from smoking to vaping – this may exclude or delay certain smokers from switching to vaping
- Higher strength liquids may be integral to future designs and innovations (e.g. for miniaturisation) that would improve the competitiveness of e-cigarettes relative to smoking – there is no basis to needlessly obstruct innovation with an arbitrary technical standard

- There are negligible risks associated with concentrations up to 7% – and these are best managed in the same way that other hazardous substances in the home, such as bleach or medicines, are managed: by effective tamper-resistant packaging.

RECOMMENDATION 7 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices and that this new framework establish standards relating to the safety of all components of electronic cigarettes, and also require manufacturers and importers of electronic cigarettes to disclose information relating to ingredients

Response 7. Safety standards and ingredient disclosure is wise and it is appropriate to set standards requiring pharmaceutical grade nicotine and excipients, and some standards for flavours. What should be avoided however, is excessively burdensome regulation – this will simply wipe out many small businesses, dramatically reduce the variety of products available (especially the vapour, tanks and mods products) and concentrate the market into a few high volume homogenised products manufactured by large companies. The government should aim for proportionality, mindful that excessive regulation will throttle the competitiveness of the e-cigarette category relative to cigarettes, and shape the market in a way that suits Big Tobacco.

RECOMMENDATION 8 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices and that this new framework require that electronic cigarette components be sold in child-resistant packaging, and that all packaging clearly and accurately indicate the concentration of nicotine and contain appropriate safety warnings about the product.

Response 8. Child resistant packaging is an essential safeguard and should be introduced now – and all responsible vendors already do this anyway. One of the adverse effects of Health Canada's irresponsible approach of defining the products as medicines is that it has been unable to regulate the products that are actually sold and consumed in Canada – for example, by insisting on child

resistant packaging. The aim of labelling should be to give consumers concise but actionable information that helps them make well-informed choices. If warnings are used to do this, then they should stress the relative risk with smoking – this being the most important piece of information a consumer needs. It is important that warnings are not simply truthful but misleading statements, but they are defined in way that sets perceptions correctly: this "WARNING: No e-cigarette is safe, but this product presents substantially lower risks to health than cigarettes"", is a better formulation (developed from the Swedish Match MRTP application to FDA for snus).

> *RECOMMENDATION 9 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices and that this new framework prohibit electronic cigarette manufacturers from making unproven health claims*

Response 9. This is a reasonable 'truth in advertising' measure – claims should be true and communicated in a way they are understood properly. The government should avoid two main traps:

1. Assuming that any *health* claim is a *medical* claim and can only be validated through a medicines licensing process. For example, 'low fat' or 'sugar-free' are implicit health claims but not medical claims.
2. Creating an excessively burdensome process for evaluating health claims that means straightforwardly truthful information about health and risk is denied to the public.

The government should be able to establish a number of factual statements that apply to products that comply with its regulatory framework. If well done and communicated effectively, these may obviate the need for many vendors to make health claims. The government should be wary of e-cigarette manufacturers making claims relative to each other – creating a market in meaningless toxicological data or making trivial difference in risks between competitors appear to be an important selling point.

> *RECOMMENDATION 10 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes*

and related devices and that this new framework prohibit the sale of electronic cigarettes or other electronic nicotine delivery systems to persons under the age of 18.

Response 10. This is reasonable and probably necessary as a 'license to operate'. However, there are Canadians aged under 18 who smoke and it is beneficial to health if they switch to e-cigarettes. Where there is harm, there is no reason to delay harm reduction to age 18. Given that many under-18s do in practice source cigarettes it is likely they would have access to e-cigarettes if they wanted them.

RECOMMENDATION 11 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices and that this new framework prohibit the use of electronic cigarettes and other electronic nicotine delivery systems in federally regulated public spaces

Response 11. Though 'federally regulated public spaces' represent a small share of the public places in Canada, the issue here is the signalling and norm-setting influence of the federal government. These are all the public spaces the federal Government of Canada has the power to regulate (most public spaces in Canada are regulated by the Provinces and Territories). Several activists called for vaping to be banned wherever smoking is banned, even though there is no realistic prospect that vaping will be any worse than a nuisance, rather than a cause of harm, to non-users. The use of blanket prohibitions should be reserved for situations where there there is reason to suppose that there will be material harm to others. In the absence of that, a much better policy is to let the owners and operators of public spaces decide a policy that meets the needs of users – vapers and non-vapers. While it might make sense to prohibit vaping in official buildings etc, it would be wrong to generalise that to everywhere and at all times. Issues to consider:

- Being able to vape indoors is an important dimension of the value proposition of e-cigarettes, and to deny this will reduce the appeal of switching and may cause some relapse. It is nota policy that is precautionary when the overall health impacts or considered.
- It has the effect of driving vapers into the same physical spaces as

smokers and agains may be a cause of relapse to smoking.

- In certain premises allowing vaping allows for more humane treatment of nicotine users than the bans on smoking – for example in mental health facilities, prisons, hospitals, transportation etc.
- Certain commercial premises (bars, cafés, clubs, specialist vape shops, sports stadiums) may wish to cater for vapers – either as a speciality, at certain times on in separate parts of the premises. There is no reason to stop them and they should be free to pursue that trade unless there is a real reason to prevent them.

The role of government should be to help owners and operators determine the optimum policy by laying out the issues and providing reliable information on risks, benefits and unintended consequences.

> *RECOMMENDATION 12 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices and that this new framework restrict advertising and promotional activities for these products*

Response 12. To maximise the health gains from vaping, manufacturers need to appeal to smokers, build brands, communicate innovations and create some excitement about their products. These are consumer products that, if successful, will displace smoking and disrupt the cigarette trade – and advertising will aid that disruption (and excessive restrictions on advertising will obstruct it and protect the cigarette trade). Some advertising restrictions are justified and desirable. The UK Committee on Advertising Practice produced a set of well designed controls that could form a model for any jurisdiction – see section 22 of the non-broadcast code and section 33 of the broadcast code introduced in October 2014 (press release). The approach of banning most e-cigarette advertising outright is absurdly disproportionate – the case for banning tobacco advertising rests on smoking killing one in two of its long term users. No such justification applies to e-cigarettes – which are likely to have a net negative death toll (health protective) because they function as an alternative to smoking.

> *RECOMMENDATION 13 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act,*

new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices and that this new framework prohibit cross-branding practices, which can involve tobacco industry logos being used on electronic cigarettes.

Response 13. This risk should be already addressed in any legislation that controls tobacco advertising, sponsorship and promotion. Usually this means subjecting a non-tobacco product carrying a tobacco product brand to the same restrictions (e.g. on advertising) as the tobacco product. It does not usually extend to preventing the brand or trademarks being used on non-tobacco products altogether – though this is the case in Canada. The rise of e-cigarettes may challenge that restriction: it is not self-evidently harmful to have e-cigarette products branded with tobacco brands. For example a *Marlboro* vapour product may appeal to *Marlboro* smokers and provide a pathway to safer products for committed *Marlboro* smokers. There is no ethical reason to prevent the *Marlboro* range extending into products that are much less harmful alternatives to cigarettes – as long as they are subject to the same marketing restrictions as tobacco products if they have the *Marlboro* brand. (Note: I have no information suggesting that any of those owning *Marlboro* brand ownership have plans to do expand the *Marlboro* franchise in this way – this is an illustrative example).

RECOMMENDATION 14 That the Government of Canada work with all affected stakeholders to establish a new legislative framework (under the Tobacco Act, new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices and that this new framework prohibit the use of flavourings in electronic cigarette liquids that are specifically designed to appeal to youth, such as candy flavourings

Response 14. The evidence for this measure is non-existent and it is pure assertion based on a naive understanding of adolescent motivation. Teenagers are generally experimenting with adult risk behaviours – why would they wish to emphasise their childishness. The one study that has actually looks at this (Shiffman et al The impact of flavor descriptors on nonsmoking teens' and adult smokers' interest in electronic cigarettes. Nicotine Tobacco Research, Jan 2015 release) found negligible interest in flavours among teenage non-smokers (averaging 0.41 on a scale of interest from 0-10) and to the extent they showed

any preferences at all the most interest was in ‘Single Malt Scotch’ and ‘Classic Tobacco’ flavours – though the differences in interest were small and not statistically significant. The key point about flavours is that they are a major qualitative difference to smoking and many smokers evolve away from tobacco flavours as they gradually leave smoking behind. Banning certain flavours because of baseless hypothetical concerns risks harming smokers and vapers.

Conclusion

The Committee has done Canadians (and the rest of us) a great service. It hopefully means Canada will now go ahead and develop a world class regulatory framework. It has several advantages over those that have gone before, and I am optimistic:

- It is not bound by the rigidities and bureaucratic overkill of having to use tobacco or medicine legislation such as the US Family Smoking Prevention and Tobacco Control Act that will cause untold damage in the United States.
- It will have an inclusive process open to stakeholders, unlike the ridiculous secretive and amateurish evidence-free policy-making among that went on in Brussels as the European Union Tobacco Products directive was negotiated in a 3-month haggle.
- It will have the benefit of the evolving evidence base which is telling an increasingly positive story about e-cigarettes and harm reduction – despite much contrived hype to the contrary.
- It has has better technical resources and expertise than most countries and is used to being a leader rather than laggard – this is a good opportunity to seize back the initiative
- The stakeholder landscape in Canada has a sufficient mass of science- and ethics-driven experts and advocates, knowledgeable users and credible businesses that arguments will be debated on their merits.

What next? The most important development that can happen now is that the government responds constructively, and affirms its determination to be led by evidence and principle, and with full stakeholder participation. It should embrace the opportunity offered by the Committee to have a thorough rethink, not simply accept Committee recommendations uncritically. In response to the report, the

government should develop:

- A *process* for evidence-gathering and stakeholder engagement that would enable it to respond to the Committee's first three general recommendations
- A conceptual regulatory framework for managing risks and exploiting opportunities arise from tobacco harm reduction
- For each recommendation, an assessment of evidence tending to support the recommendation or equivalent best practice
- For each recommendation, an assessment of the evidence tending to oppose the recommendation
- A careful assessment of likely or possible unintended consequences – for example regulatory measures that protect the cigarette trade
- An impact assessment detailing what it expects to be the costs, benefits and risks associated with the proposed regulatory framework