Regulation for tobacco harm reduction – four pillars

written by Clive Bates | 29 June 2014



In my last post on regulation I set out some general ideas that I think should guide and constrain the regulation of e-cigarettes. From my presentation at Global Forum on Nicotine in Warsaw, here's a suggested four pillars for regulation of e-cigarettes and other low risk products.

1.To raise the standards of products and industry practice

Rationale: Primarily to increase consumer confidence and to provide appropriate protection of the health and safety of users. I believe there are initially increasing returns to regulation, as some basic standards clear out the poor products and cowboys and do require simple thing like child-proof e-liquid bottles. But the diminishing returns set in as more effort and cost goes into eradicating minor or theoretical risks, and then negative returns as excessive risk aversion makes for unappealing products takes, products of the market because the costs of assurance are too high.

2. To maintain and enhance the appeal of the reduced risk products relative to cigarettes

Rationale: To encourage the greatest number of smokers to switch – retaining

focus on the dominant health effect: the health and welfare improvement to smokers who switch, rather than marginal reductions in risk to vapers. Note that this is not an easy area for regulators, for whom 'pleasure' or 'recreational nicotine use' isn't an easy concept to absorb, and they are likely to instinctively undervalue this, the most important characteristic of reduced risk products – hence the need to identify it as a distinct principle. The perfectly safe product that no-one wants is of no public health value.

3. To promote, rather than inhibit, innovation, diversity and competition in low risk alternatives to smoking

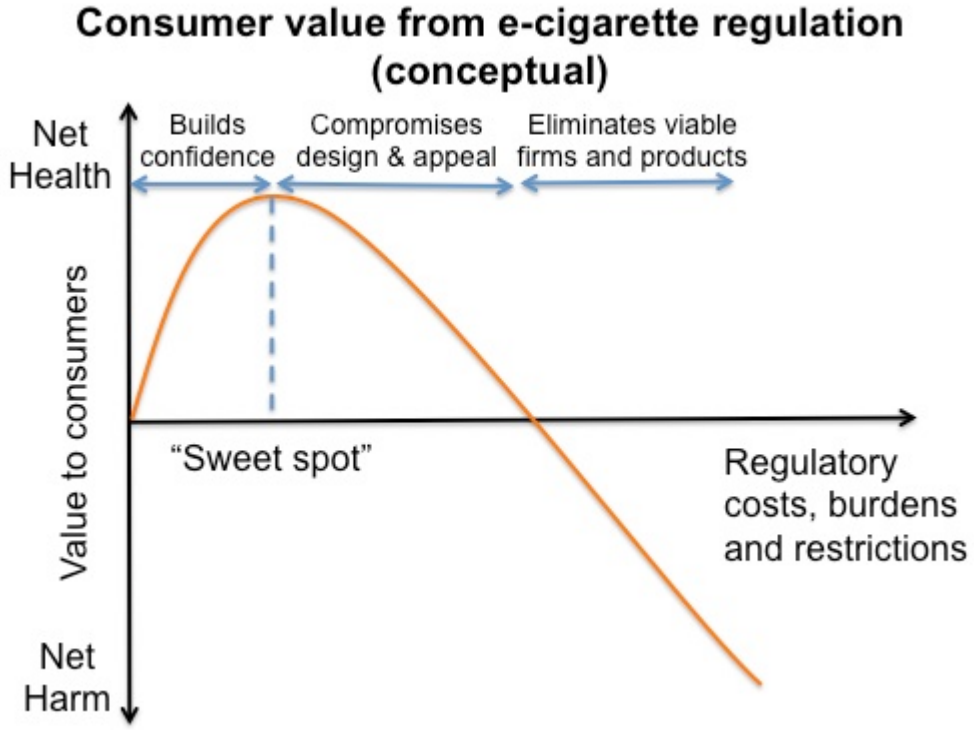
Rationale: So that these products become better alternatives to smoking over time and more smokers find products that suit them. A regulatory regime should clear out cowboys, but not force a contraction to only very large companies offering a few commoditised products. Nor should the effort to regulate e-cigarettes somehow lead to the exclusion of 'heat not burn' tobacco products because they do not meet the same standards. Recent experience suggest that users move on to more personalised options – tanks and mods – and like experimentation.

4. To protect against unwanted or unintended consequences

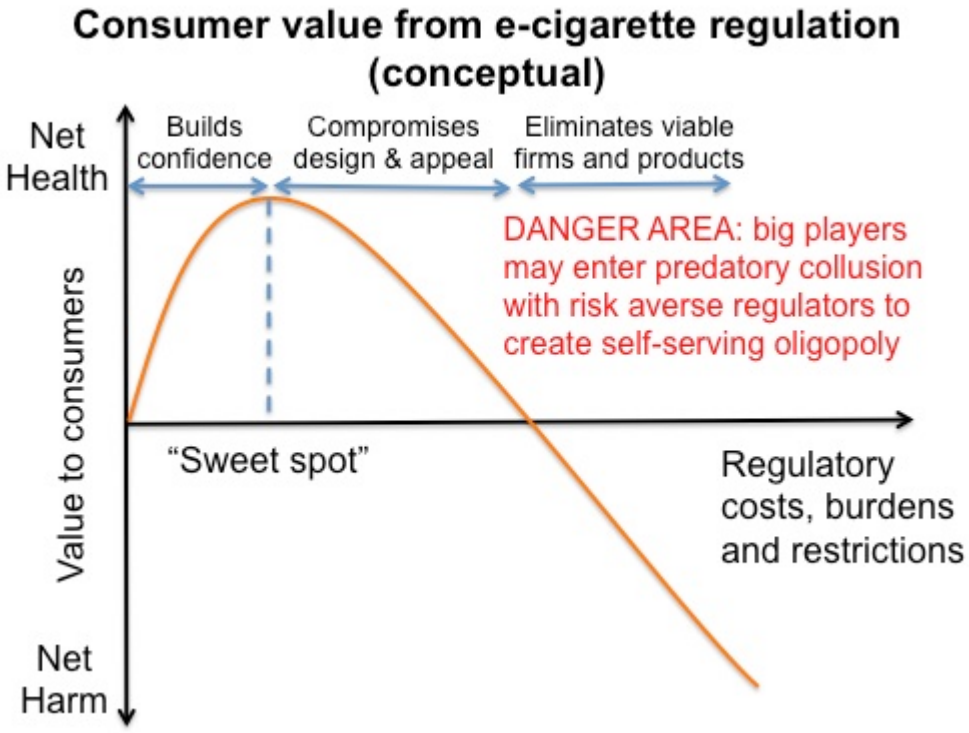
Rationale: Avoiding practices or products that would tend to increase smoking, but recognising that regulators control product specifications and business practices, not the behaviour of users (see discussion on regulating population effects). Note that vague concepts like 'renormalising smoking' or 'undermining tobacco control' are only relevant if they mean smoking increases, compared to what would happen otherwise. Because the individual risk is so much lower than smoking, the starting point should be to permissive by default and monitor for adverse developments and only control these products on the basis of population effects when there is evidence supporting a harmful population effect.

Risk based trade-offs. These objectives may be in tension, for example marginal reductions in risk may reduce appeal of the product by forcing unwanted design limitations. Very burdensome regulation may reduce certain risks but also reduce the diversity of products available and firms operating in the market, reducing choice and innovation. Excessive focus on preventing use of e-cigs by youth may

leave more young people smoking or reduce the number of adults who switch. Regulators need to make optimising trade-offs within a risk-based framework that recognises opportunities to reduce smoking as well as potential risks arising from vaping. It should be evident from this that the right level of regulation is not 'as much as possible' and the right level of safety for an e-cigarette is not as safe as possible if it means the design is comprised to the point where the appeal to smokers is lost. Nor should standards be set so high and information demands be so great that they wipe out large swathes of the industry, currently selling perfectly acceptable products, liked by consumers with adequate safety and consumer protection – albeit with scope for improvement. I've tried to capture this idea in the graphic below:



A further point… this graphic illustrates the potential for mischief in regulation: the tacit collusion between regulators and large players to raise regulatory barriers to entry. It might be unintentional or even well-meaning on the part of the bigger players, but the effect can be predatory in terms of its impact on the market as a whole:


Consumer value from e-cigarette regulation (conceptual)
Net Health
Builds confidence
Compromises design & appeal
Eliminates viable firms and products
DANGER AREA: big players may enter predatory collusion with risk averse regulators to create self-serving oligopoly
Value to consumers
"Sweet spot"
Regulatory costs, burdens and restrictions
Net Harm