

10 reasons not to regulate e-cigarettes as medicines

written by Clive Bates | 12 June 2013

So the MHRA will regulate e-cigarettes as though they are medicines - [press release](#). 10 reasons why is this a bad idea.

1. The real health challenge is to get e-cigarettes to eat into cigarette sales as rapidly as possible, and for as many smokers as possible to switch. This type of regulation works against that. A limited authorised range of dull but perfectly safe medicinalised products that no-one wants to use is worthless and counterproductive.

2. E-cigarettes are not medicines - it is poor policymaking to just hammer them into a regulatory framework designed for something else. They should design something specific to the products, starting with consumer protection legislation, and extending it if needed (the approach taken with cosmetics for example) - see briefing: [Are e-cigarettes medicines?](#)

3. Medicines regulation involves disproportionate costs, compliance burdens and restrictions - none of which apply to cigarettes. So this is a good day for the cigarette makers, and their competition will be weakened. We need regulation to encourage these products to compete with cigarettes, not smother them with red tape. See: [Medicines regulation for e-cigarettes: when caution can kill](#)

4. Medicines regulation will slow down innovation - the lengthy and costly authorisation process does not lend itself to rapid change or the more experimental approach to innovation that works for consumer products (ie. try lots of things and invest in what works or follow changing tastes and buzz).

5. Medicines regulation will reduce the diversity of products available - the process has to be repeated for each product - slow and time consuming and not worth it for niche products. Many products will be deemed unsuitable or will never be put forward in the first place. This is bad because it narrows the potential appeal and removes some of the pleasures vapers find in experimenting with new products. It is likely that regulators will impose counterproductive restrictions to the product design - for example the dozens of frivolous flavours

are part of the appeal as an alternative to smoking - but will the stern suits of the MHRA really approve 'pina colada' flavour?

6. Medicines regulation requires pharmaceutical 'clean room' room manufacturing facilities - this is regulatory overkill, given that most consumer nicotine is delivered in a filthy mix of burning particles of tobacco and hot toxic gases. But the current supply chain is long and extends to China - most factories will not be able to attain this standard, so MHRA will destroy the existing supply chain.

7. They want to substitute their own view of 'efficacy' (what works) for the consumers' view. Markets work by people buying the good products and the poor products failing, not by regulators deciding what works. It would be different if they were making health claims, and could be tested to see if the claim are valid. But the e-cig vendors aren't making any claims. The truth is they don't know what efficacy means with e-cigarettes.

8. What the e-cigarette sector doesn't need is 'boring'. That has been tried and failed with NRT. It needs marketing verve, style and buzz, not the dull deadening hand of bureaucratic approvals. That applies to product design, packing, marketing, sponsorship - the works... the public health challenge is to get as many smokers to switch as possible, not to make perfectly safe products that no-one wants.

9. They will focus on eliminating minute risks but obstruct great potential. There is great danger they will make the products less attractive to smokers who might otherwise switch. So they get the risk down from 99% lower than cigarettes to 99.5%. Big deal... and harmful if it means more people stay smoking as a result. There is no evidence at all of gateway effects - those exist mainly in the imagination of health lobbyists. E-cigs are a major gateway out of smoking, and an alternative to ever smoking.

10. This will give a boost to the home-made and black market - all likely to be more dangerous than a lightly regulated commercial market. So it will fail anyway.