# Why doctor doesn't always know best

Marco Van Basten (@MarcoVanB_UK), a constituent, vaper and film maker, interviews Linda McAvan MEP, the European Parliament rapporteur for the Tobacco Products Directive.

I've already given a view on what an incoherent piece of regulation is emerging from the European institutions – a gargantuan dog's breakfast, and McAvan bears some of the responsibility for that. There's a lot in this interview and he does a good job interviewing her. If you want to write to her having seen this, it is lindamcavan@lindamcavanmep.org.uk if you are a Yorkshire and Humber constituent and linda.mcavan@europarl.europa.eu for everyone else. As always, be polite, persuasive, encouraging and give your own views on what you are hearing based on your experience – ask questions and ask for a reply. If you are in the e-cig business she has some critical things to say about your motives, so there are some things you might wish to challenge in what she said.

## Top doctors know everything

I want to focus on her reaction to a Lancet commentary arguing against medicines regulation for e-cigarettes. This was presented to McAvan during the interview at 10 minutes in. She doesn't really engage with the arguments at all but resorts to 'argument from authority' referring to 'top doctors' in the UK who see it differently. I've long wondered how 'top doctors' anywhere manage to form authoritative views on so much outside their training and experience – it seems to be a kind of professional assurance that comes with a white coat. To know that medicines regulation is the right approach to e-cigarettes you would need:

1. Knowledge of legal and policy principles that underpin regulation in the EU – for example, the principles of proportionality, non-discrimination, appropriate legal base, minimum burdens consistent with meeting the policy objective, adequate consultation etc and be sure these had been applied. You might also know of the case law in which medicines regulation was struck down in four cases in the EU. You might want to know why the FDA failed in court with its attempt to regulate e-cigs as drugs.
2. A good understanding of the alternatives to medicines regulation, and what shortcomings, if any these might have and how they might be addressed other

than through medicines regulation.  Also, the balance of costs and risks that these alternatives create.
3. A clear market failure based ‘case for government intervention’ and sound grasp of the type and magnitude of the risks that the regulator is required to manage, and what costs might be justifiable in managing these. At the moment it is hard to detect what is actually so wrong that it needs a draconian regulatory intervention – the only complaints are coming from non-smoking charities, pressure groups and academics, often with mixed motives that do not always involve public health.
4. Insight into the requirements and costs to the supply chain of meeting arbitrary pharmaceutical standards for ‘quality’ – ie the pharma GMP standard and other quality standards (for example could ISO 22716). These cost are revealingly not quantified in the MHRA impact assessment.  It is likely that the supply chain costs and organisational capabilities required will run to tens of millions, not the few hundred thousand often quoted, for the companies involved.
5. Grasp of the potential impact on innovation, product diversity, creativity and the likely impact that would have on the appeal of the e-cigarette category to smokers relative to cigarettes.  It’s hard to assess this but the restraint of commercial freedoms comes at a price. The cautious hand of the regulator has hardly made for competitive NRT products.
6. Some sense of what the medicines regulatory process is trying to achieve.  The regulator says that no products on the market would meet its standard, although many users express themselves very content, to say the least., with products on the market  So what is the thing that justifies the regulator intervening in trade that already exists between satisfied suppliers and users? Why is the regulator’s objective the right one?
7. Feel for the  ‘creative destruction’ economic dynamics of markets and how this raises standards, quality and innovation for the vast majority of products through the interactions of consumers and responsive suppliers in competitive markets.
8. Assessment of how the preferred regulatory regime would work in the 27 other member states and beyond, and how medicines law is applied in practice.  The UK MHRA might be relatively enlightened (‘relative’ is the word here) but the others aren’t necessarily – what effort have top doctors made to understand the consequences of handing such obstructive powers to regulators in such a politicised environment.  In the countries that have banned e-cigs, medicines regulations has been the method of choice.
9. Unintended consequences – the rise of home e-liquid mixing, internet trade etc. that may create more risks than the intended regulation avoids.
I could go on, but let me leave it at that. Not much of this experience is acquired through a career as a cardiovascular surgeon, epidemiologist or smoking cessation counsellor.  That’s not a criticism of those professions, just a reason for

them to be cautious when straying authoritatively into these areas of policy.  My point is that judgements about regulatory arrangements are inherently *economic* in nature – like most of public policy. I worked for a regulator myself once, albeit in a different field, but we were acutely aware of the damage that excessive regulation could do.