MEPs – 10 things to think about before you vote

On 10/11 July, MEPs of the ENVI committee will take an important step towards finalising the text of a new Tobacco Products Directive. If the preparation and voting goes well thousands of amendments and opinions will be honed into a single coherent legislative text to be presented to the European Parliament plenary in September. The process is a bewilderingly complex negotiation, but the successful MEPs will have a clear view of what they are trying to do and what matters. So I have written to set out 10 things they should really think about before they vote.

To: Linda McAvan MEP, Karl-Heinz Florenz MEP, Frédérique Ries MEP, Martin Callanan MEP, Orerste Rossii MEP, Martina Anderson MEP, Carl Schlyter MEP

CC: ENVI MEPs & substitutes
As you decide how to vote on amendments to the TPD, please consider the following as you decide how to vote.

1. Keep your eye on the prize – e-cigarettes. By far the most important decisions you will take relate to low risk alternatives to smoking – e-cigarettes, smokeless tobacco, and novel non-combustible tobacco products. The measures related to packaging, warnings and cigarette design are at best second order. Even the European Commission believes these will only reduce consumption by 2 percent – equivalent to 0.5 percent reduction in the number of smokers – and that is with a weak evidence base. This is so small it is 'statistical noise'. On the other hand, Sweden has by far the lowest rates of smoking – less than half the EU average – because it is the only country that has widespread use of low-risk

(95-99% lower) alternatives to cigarettes, snus. Some Wall Street analysts believe that e-cigarettes will overtake cigarettes within 10 years – that would be a stunning transformation and major public health success. Even if that sounds optimistic, no other tobacco policy intervention comes remotely close to this scale of transformation – and the wrong regulation would put it at risk.

2. Support rather than obstruct pro-health disruptive technology. E-cigarettes are a true disruptive technology, with amazing revolutionary potential. And the great thing is that they will disrupt the established cigarette business model. But regulating e-cigarettes as medicines will throttle this new industry with costs, regulatory compliance burdens and all manner of restrictions. It will constrain and slow innovation, reduce diversity of products and limit the appeal of the these products to users. The true public health goal here is to let the e-cigarette category compete effectively with the entrenched cigarette oligopoly. Why would the European Parliament send these emerging companies into a ultra competitive market place laden with red tape, unnecessary costs, and a restrictive regime guaranteed to make the product unappealing?

3. Do not vote for regulation of e-cigarettes as medicines.E-cigarettes are not medicines: not in law nor as a matter of common sense. Medicines must have the purpose of treating or preventing disease. E-cigarettes will dramatically reduce smoking if they are a pleasurable and appealing alternative to cigarettes, not a medicalised quitting aid. The effect will be more people stoping smoking and great reductions in harm, but the purpose for the user and the vendor is to have a better way to take the popular and legal recreational drug, nicotine – which is about as harmful as caffeine. If you doubt that medicines regulation will harm the e-cigarette category, ask why the NRT inhalers have failed to capture the imagination of 'vapers'? You can see why by looking at the 'Patient Information Leaflet' for one. Boring, worthy, miserable and unappealing.

4. Do vote for rigorous regulation of e-cigarettes as consumer products. Start by asking what problems regulation is trying to address? What is the problem with e-cigarettes that cannot be addressed in consumer product legislation? The EU is obliged under the treaties (Art 5 TEU Protocol 2) to use the least burdensome form of regulation to achieve the policy objective. So what is it that requires medicines regulation? And how would medicines regulation deal with whatever it is? Consumer product regulations consist of about 15

directives that protect EU citizens from thousands of potentially dangerous products. If standards are needed – have standards. If warnings are needed – have warning labels. Why should these products be barred from the market subject to medical authorisation, when cigarettes are allowed easy universal access?

5. Don't try to ban flavours in e-cigarettes. These products are comprised of only three main ingredients: the drug nicotine; a vaporising substance; and flavours to make them palatable and appealing. Take away the flavours and you might as well ban the product. In fact, all you would do is to create a home mixing 'DIY' market in which people mix their own liquids and use whatever flavours they want. So ban flavours and the effect is to ruin a very promising public health technology produced to good commercial standards, and in doing so to drive users into the more risky practice of mixing their own – and there is nothing you can do to stop that, other than to ensure alternatives are available.

6. Don't misuse children in policy making. It sometimes appears as though any policy, however perverse or evidence-free, can be justified with reference to hypothetical threats to children. Almost everything attempted to stop teenagers smoking directly will fail. This is because teenage smoking is primarily experimentation with adult life, and the key driver of youth smoking is adult smoking. You will hear about 'gateway effects', but this idea exist mostly in the imagination and advocacy literature of campaigners. All the evidence suggest that gateways are out of smoking – and it is possible that products like e-cigarettes could divert kids who would otherwise smoke onto a much less harmful pathway. No discussion of gateways is complete without reference to exit gateways and you can read more about that at: We need to talk about the children – the gateway effect examined.

7. Think again on snus – the ban is negligent and unethical. We know snus is 95-99% less dangerous than cigarettes, and we know it is the reason for much lower levels of smoking in Sweden and Norway – yet there appears to be near consensus that these products should be banned outside Sweden. There is no scientific, ethical or legal basis for a ban, and it has genuinely harmful consequences: see Death by regulation. Ask this: why would the state intervene to deny a person the option to reduce their own risk at their own expense by freely choosing a lower risk alternative to cigarettes, especially as we know this has worked extremely well in Norway and Sweden? It is impossible to justify.

What other cases do you know where the EU bans a safer product but leaves an alternative 20-100 times more dangerous on the market? There are none. The effect of the ban is to support the cigarette trade and cause more harm to health by denying people better choices – all supposedly in the name of the internal market.

8. Don't legislate in haste. Devising a regulatory framework is a painstaking and precise process – but worthwhile when it works. Poorly drafted incomplete 'simplified procedures' will not prove to be simple in practice and would need many additional provisions to make a robust procedure: The road to hell is paved with good intentions. Given that there is no crisis engulfing e-cigarettes (or snus) it is best to ensure that the regulatory job is done properly. Making the existing consumer protection framework apply to e-cigarettes is all that is needed for now.

9. Learn from other systems of regulation. Regulatory systems and standards evolve. The directives covering cosmetics began in the 1970 and were substantially updated in 2009. The regulation 1223/2009 for cosmetics has many useful features – safety assessment, full disclosure, named responsible persons, quality standards, labelling, traceability, banned substance schedules, a special ISO standard for manufacturing practice (ISO 22716:2007) etc – these elements and others could be fashioned into a comprehensive framework for regulating nicotine products, including tobacco based products. That need not happen overnight – but could come out of a Commission review, options appraisal and extensive consultation – something that has not happened with the proposal to regulate as medicines. For now, all that is needed is for member states to apply and enforce the existing consumer protection legislation.

10. Listen to the users. The people who this directive really matters to are existing or future smokers – 28 percent of EU adults at present. Can anyone find any who think that e-cigarettes are medicines, that the users are patients, or that the vendors of e-cigarettes are health care providers? I am unable to find such people. Many health campaigners will have told you that medicines regulation is the right approach. But experience as a chest physician, epidemiologist or smoking adviser is a poor qualification for making judgements on risk based regulation, product innovation, smoker's preferences, fast moving consumer goods markets etc. The vaping community knows from

first hand experience how this works and why it matters. They do not want these products regulated as medicines.

Retrieved comments

6 comments to Private: MEPs – 10 things to think about before you vote
Electronic Cigarettes. – Page 121
July 4, 2013 at 7:15 pm · Reply · Edit
[…] […]

Mark Harburn
July 4, 2013 at 8:37 pm · Reply · Edit
Don't forget the average cost per quitter on NRT with a 95%+ failure rate is £381. This is nearly a years worth of electronic cigarette usage for most people. It's estimated that without medicinal license interference and market forces that those that want to quit with electronic cigarettes is anywhere upto 50% just using market forces.

Mark Harburn
July 4, 2013 at 8:39 pm · Reply · Edit
Source for above comment: https://catalogue.ic.nhs.uk/publications/public-health/smoking/nhs-stop-smok-serv-eng-apr-2011-mar-2012/stat-stop-smok-serv-eng-apr-11-mar-12-rep.pdf

Benji
July 4, 2013 at 9:19 pm · Reply · Edit
Thank you Mr Bates for this exceptional written letter that sums up the majority of electronic cigarette users views. Hopefully the receivers of this letter will take it seriously and consider all the eloquently worded points outlined and take action based on their mandate, to legislate for the benefit of the public, not for company profits and election votes.

Thanks again.

Zillatron
July 4, 2013 at 9:52 pm · Reply · Edit
Thank you!

Mark Entwistle
July 6, 2013 at 12:29 am · Reply · Edit
From the Website of Linda Mcavan,

Double standard?

Linda has hit back at UKIP deputy leader Paul Nuttall for his suggestion that EU regulation of Tobacco is like regulating what time we go to bed.
Nuttall, the outspoken UKIP MEP for the North West made a number of claims in relation to the EU's new draft tobacco laws which have been developed in the hope of making smoking less attractive to young people.
He told the press that attempts to make packaging less attractive would actually increase consumption and of plans to ban menthol cigarettes, Nuttall said; 'If people want to smoke menthol cigarettes, let them. What will the EU do next? Regulate what time we go to bed?'
Linda McAvan is leading on tobacco regulation for MEPs across Europe and has called Nuttall's comments incredibly short-sighted and irresponsible.
Linda said; "In Yorkshire alone, 13,710 children aged between 11-15 are regular smokers and the devastating reality is that around half of regular smokers will die from a smoking related disease. If UKIP want to use every opportunity to make outlandish claims about the EU then that's their prerogative, but myself and colleagues in Europe are not prepared to let this number of young and preventable deaths go unchallenged."
"Tobacco should look like tobacco and taste like tobacco, not like sweets. If the taste isn't pleasant to young smokers then we would hope to see less and less young people regularly smoking."
Jean King, Cancer Research UK's director of tobacco control, said: "We wholeheartedly back the move to remove flavouring from cigarettes. Making them taste like mint, chocolate, vanilla and cherry is designed to improve the taste of smoking and make it easier to inhale the toxic and carcinogenic tobacco fumes, particularly for young people just starting to smoke. Reducing the appeal of tobacco will help to reduce the number of young people who are drawn into this lethal addiction."
Menthol cigarettes, which have already been banned in Brazil, were identified as a risk when scientists discovered that menthol acted as a local anaesthetic, which reduced coughing due to inhalation of irritating smoke, and allowed smokers to inhale more deeply (and more frequently) increasing the risks associated with

smoking.
“Given the evidence, menthol in cigarettes is not as trivial as Mr. Nuttall is trying to suggest with his flippant comments.” Linda added.
The Tobacco Products Directive will be voted on by MEPs in September, before being approved by governments later in the year.