Reduce harm or protect the cigarette industry? Briefing to MEPs for European Parliament public hearing

European Parliament: heading for an own goal?

On Monday 25th February 2013, the European Parliament committee that is scrutinising the proposed EU Tobacco Products Directive holds a public hearing, and take evidence from invited witnesses. The committee is the Environment, Public Health and Food Safety Committee (known as ENVI). This post provides links to the hearing details and my tobacco harm reduction briefing sent to all ENVI committee members in advance of the hearing. *The committee needs to take the harm reduction agenda seriously – if they get it wrong, they will harm health and protect the cigarette industry.*

- ENVI Committee page
- Hearing agenda
- Live stream of hearing (15:00-18:30 Brussels / 14:00-17:30 UK – 25 February 2013)
- CVs and presentations of invited witnesses
- ENVI Committee members

Something missing…? As well as cigarette labeling, packaging and security markings, the proposed directive deals with smokeless tobacco, oral tobacco

(snus), nicotine containing products like e-cigarettes, novel tobacco products (eg. where the tobacco is heated not burnt), and regulation of combustible tobacco smoke emissions (a long-running scandal of EU incompetence, but that's another story). It is therefore taking positions on the main tobacco harm reduction concepts. Market-based, consumer-led, regulation-enabled harm reduction is a vital public health strategy if we are to reduce the World Health Organisation's expected toll of one billion deaths from tobacco in the 21st Century if current trends continue. Yet no-one with any credibility in these important areas has been invited to speak, and none of the presentations deal with the subject. It gets a passing mention by the man from the European cigarette association – but these are alternative to cigarettes!

So in an effiort to redress this lamentable deficit, last week I sent every MEP on the ENVI Committee the following briefing for Monday's meeting.

Tobacco Products Directive – briefing

To: Chair ENVI committee, Rapporteur, ENVI committee Tobacco Products Directive
CC: ENVI Committee members

Dear Mr Groote, Ms McAvan, ENVI members and alternates

My name is Clive Bates, a former director of Action on Smoking and Health (London-based) and long-standing tobacco control advocate. I am sending you this briefing as background for the ENVI committee public hearing on Monday 25th February (15:00 to 18:30). I hope you find it useful and interesting.

Disclosure. I have no competing interests. I have a long history of involvement in tobacco control starting in 1997, previously as director of ASH-UK. I was active during negotiation of the 2001 directive, now under revision, and I was one of the main NGO leaders who helped to bring the WHO FCTC into being in the period up to 2003. I have retained an interest ever since, though I have been working as a civil servant for the last ten years. I am currently setting up a public interest advocacy organisation. Please be assured my sole interest is in reducing the

burden of tobacco-related disease and death in the EU and globally.

Main theme – the directive should promote harm reduction and not protect the cigarette industry

Most attention has been paid to the directive's provisions on labelling and plain packaging. This is an important area of policy, but I believe you will hear views from many others about that. I would like to provide briefing on a different aspect of the proposed directive. Almost all MEPs wish to strengthen the Commission's proposal, and to make sure that it does not benefit the tobacco industry at the expense of the health of Europeans. Unfortunately there are two important areas where the proposal will do more harm than good and will provide implicit support to the tobacco giants. These areas relate to the matter of 'harm reduction' – that is finding much lower risk ways of continuing as a nicotine user other than using the dominant, most harmful method – smoking cigarettes. Even though 700,000 people die in the European Union from tobacco use, 28% of EU citizens continue to smoke despite years of tobacco control efforts. And even the new directive reduce smoking by just 2 percentage points according to the Commission's estimates. This means we have to consider the best health strategies for that substantial number of Europeans who will continue to use nicotine either because they gain advantages form it, or because the are unable or unwilling to give it up. It is possible to quit completely, but quit rates are very low: 3-5% will quit in any year, even though as many as one-third of smokers may try. There are two important strategies available to help those who are unable or unwilling to quit.

1. E-cigarettes (Nicotine Containing Products)

The benefits. E-cigarette sales have been growing at an extremely high rate from a small base, and there are many eloquent testimonies from "vapers" detailing how important these products are to them. What lies behind this success is that they are an effective alternative to cigarettes for nicotine users, but with very low health risks. They work because they deliver a satisfying "hit" of nicotine. This is very different from the function of NRT medicines, which deliver a slower

background dose of nicotine to help relieve cravings during an effort to quit smoking and nicotine use completely. This is a fundamental difference: e-cigarettes are alternatives to cigarettes with a number of desirable characteristics for users: much lower long term health risks, immediate benefits in well-being and quality of life, no second hand smoke impact on others, minimal fire risk, less mess and so on. NRT on the other hand is designed to help with the side-effects of nicotine withdrawal, and is properly considered a medicine. E-cigarettes create the possibility of a fundamental challenge to the business model of the major tobacco companies and a complete change in the nicotine market, with potential to avoid millions of the one billion deaths the WHO estimates for the toll of tobacco in the 21st Century. Europe should be leading in this transformation.

The risks. E-cigarettes should not be assumed risk free, but given what is in them they are likely to be very low risk relative to cigarettes – two orders of magnitude (about 99%) less hazardous would be a reasonable assumption based on what is known already. The most serious risk arises not from use, but accidental ingestion of nicotine e-liquids – and can be mitigated with tamper proof packaging. They can contain residual contaminants or nitrosamines – but so do NRTs and many foods. The concentrations are at levels so low as to be of little concern These risks are likely to be small and manageable compared to what we know of the burning hot tar particulates and toxic gases taken into the lungs through cigarette smoke.

The threshold used in the proposed directive. E-cigarette users, like smokers, control the dose of nicotine they receive by the number and strength of puffs they take (this is another important difference with most NRT and the reason why simplistic comparison with NRT doses should be avoided). The more concentrated the nicotine in the vapour, the easier it is for a highly dependent nicotine user to get their required dose without excessive puffing. So nicotine e-liquids come in a range of concentrations from zero (nicotine free) to 48mg/ml or more with the typical users using about 18mg/ml. The threshold of 4mg/ml established in the Commission proposal Article 18.1 would not be suitable for well over 90% of those using e-cigarettes as alternative to smoking. Article 18 of the proposed directive thus classes most e-cigarettes and liquids as medicines to be regulated under the provisions of the medicines directive 2001/83/EC. The key issue is whether this system of regulation is appropriate, proportionate and fair when applied to e-cigarettes.

- Appropriate? Medicines regulation should apply to medicines, and e-

cigarettes are not medicines. These products are consumer alternatives to cigarettes – they provide nicotine in a much less harmful way than cigarettes, why should they face high regulatory burdens? They are not a variant on NRT and the manufacturers do not make health claims. The appropriate regulatory framework is consumer protection legislation, which is highly developed and fit for purpose in the EU. It keeps EU consumers safe from hundreds of potentially dangerous items, including products that use electricity, flame, food, cosmetics and toxic substances. The EU is perfectly able to create regulation that fits the characteristics of the product.

- Proportionate? The medicines directive imposes substantial compliance burdens, costs and restrictions. These include conducting clinical trials, risk-benefit analysis, pharmaco-vigilance clean-room manufacturing and numerous requirements regarding packaging, labelling and marketing (see Article 8 of the 2001/83/EC). The approval process is slow and cumbersome, and would be required for each product variant. Important feature of e-cigarettes such as the wide range of flavours may be ruled unacceptable. Consumer protection legislation has a lighter touch and can guarantee a high standard of safety. Many existing e-cigarette companies will have to withdraw and leave the market to tobacco or pharmaceutical companies, or more likely, to the black market.
- Fair? Applying medicines regulation to e-cigarettes when this cannot conceivably be applied to cigarettes creates a regulatory imbalance between e-cigarettes and cigarettes that favours the cigarette makers. The effect is to make cigarettes more competitive relative to much lower risk alternative products. This will increase harm and will damage the prospects of a transformation in the market for nicotine.

Expert Opinion. I would like to provide two quotes for you to consider from Professor Jean-François Etter, an authority on e-cigarettes, Head of the tobacco group at Institute of Social and Preventative Medicine, University of Geneva. He says in his Jan 2013 book, *The Electronic cigarette – an alternative to tobacco?*

> *The risk-averse regulation of nicotine causes thousands of deaths annually, because it artificially strengthens the position of tobacco, blocks safer products and innovations, obstructs the marketing of nicotine medications, builds high barriers of entry in the nicotine market, and otherwise distorts the market*

> *economy. The current legislation benefits mainly the tobacco and pharmaceutical industries, by eliminating competitors for nicotine supply.*

… and states that the proposed EU directive would "essentially kill the e-cigarette market":

> *In the European Union, a proposal to change the Directive regulating tobacco product was announced in December 2012. In this proposal, cartridges that contain more than 2 mg nicotine, e-liquids that contain more than 4 mg nicotine per ml, or e-cigarettes that result in blood nicotine concentrations of more than 4 ng/ml (nanograms per milliliter, a very low level, similar to level observed in non-smokers exposed to light levels of passive smoking) will need to be approved as medicinal products. If implemented in this form, this directive would essentially kill the e-cigarette market, and therefore have seriously adverse effects on public health.*

Questions that should be asked:

- What consideration has been made of the option to regulate e-cigarettes using proportionate consumer protection legislation? This could include CE markings, specific decisions or directives under the General Product Safety Regulations and related consumer protection law.
- Has any assessment been made of the advantage that the directive would confer on cigarette makers and what impact this would have on health?
- What effect would medical regulation have on the e-cigarette industry and its products – would the diversity of firms and brands decline? Would its growth rate slow? Would new firms enter, and if so in all members states, including those where cigarettes are cheap?
- Would black markets in unregulated products emerge?
- Would more e-cigarette users start making their own e-liquids (a dangerous practice)?

Solution: use the substantial body of consumer protection legislation to ensure these products are safe, work as intended and are properly described – the EU already has legislation to protect consumers from thousands of products that are potentially risky. If vendors want to make health claims, they should opt in to medicines regulation, and seek a marketing authorisation having proved the

therapeutic claim is backed by evidence..

More information, including referenced sources and detailed recommendations is available here: *Medicines regulation for e-cigarettes: when caution can kill*

2. Oral tobacco (snus) and other smokeless tobacco

The benefits. Paradoxically, one of the greatest public health successes in Europe is down to tobacco. Sweden is the only EU member state where snus can be sold and is widely used as an alternative to smoking, mainly by men. As a result, Sweden has the lowest smoking rates in the EU (13% compared to 28% EU average and 23% in the next lowest country). Because low-nitrosamine smokeless tobacco is at least 95% less hazardous than cigarettes, Sweden also has the lowest rates of smoking related disease – cancer, cardiovascular disease and lung damage. There has been extensive research done on Sweden's experience and it shows that snus has been used as an alternative to cigarettes and as a way of quitting altogether. No evidence has shown any sign that snus increases the number of tobacco users – it is a gateway exit from smoking, not an entrance. Despite this harm reduction success story oral tobacco is banned outside Sweden (and Norway in the EEA). For the cigarette makers, Sweden is the worst market in Europe by far.

Risks. The risks are much lower than for smoking because there are no products of combustion, burning organic material, hot particulates and toxic gases, taken deeply into the lungs – the redueced risk is inherent in the physics and chemistry. I enclose a graphic PDF illustrating this based on cancer data. There are possible residual cardiovascular risks and cancer risks associated with snus – but regulatory standards can reduce or maybe eliminate these. The UK Royal College of Physicians said in 2007:

> *Low nitrosamine smokeless tobacco products may have a positive role to play in a coordinated and regulated harm reduction strategy which maximises public health benefit and protects against commercial market exploitation.*

Expert opinion. Despite what some Brussels-based lobbyists claim, there is no public health expert consensus in favour of a ban on oral tobacco. On the

contrary, 15 international experts* in the field wrote to Commissioner Dalli in 2011 to propose replacing the ban on the lowest-risk tobacco product with consistent regulation of purity, additives and labelling of all smokeless tobaccos. I attach the letter. This approach is also more widely supported: for example it is recommended by the WHO TobReg advisory committee, the UK Royal College of Physicians and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA – an agency of the European Union). This agency points out:

> *The most promising strategy for reducing harm to tobacco smokers is to encourage smokers who are unable or unwilling to quit to switch to pharmaceutical nicotine or low nitrosamine smokeless tobacco products.*

The WHO TobReg committee recommended the following regulatory approach for all smokeless tobacco.

- *All products that deliver nicotine for human consumption should be regulated.*
- *Smokeless tobacco products should be regulated by controlling the contents of the products.*
- *The metric for measuring toxicants in smokeless tobacco should be the amount per gram of dry weight of tobacco.*
- *Initially, upper limits should be set for two nitrosamines N-nitrosonornicotine (NNN) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), and one polycyclic aromatic hydrocarbon, benzo[a]pyrene.*
- *The combined concentration of NNN plus NNK in smokeless tobacco should be limited to 2 µg/g dry weight of tobacco.*
- *The concentration of benzo[a]pyrene in smokeless tobacco should be limited to 5 ng/g dry weight of tobacco.*

Something like this standard, or the existing German standard, could form the basis for a European regulatory framework where any smokeless tobacco is permitted. It is likely that a number of existing smokeless tobacco products that are sold in the EU would need to be withdrawn if this standard was imposed.

Questions that should be asked:

- What role has snus played in the low rates of smoking in Sweden and Norway? (13% and 16% respectively, compared to the EU average of 28% as recorded by Eurobarometer)?
- How much smaller is the cigarette market in Sweden because of snus/oral tobacco? (note oral tobacco also contributes to 'denormalising' smoking because it is much less visible)
- What is the relative risk of low nitrosamine smokeless tobacco use and smoking?
- Which other countries have cultural familiarity with smokeless tobacco and could benefit from harm reduction based on smokeless tobacco?
- Is there any evidence that snus increases tobacco use, smoking or disease? (there is none)
- What are the ethics of banning a product that is much less risky than cigarette use, and therefore preventing addicted smokers switching?
- What are the precedents for banning a much safer alternative to the most harmful dominant market leader – cigarettes?
- What is the legal basis for banning oral tobacco but leaving very high risk cigarettes and other high-nitrosamine smokeless tobacco that is more harmful on the market? (it is disproportonate, discriminatory and does nothing to help the single market operate with a high level health protection)
- What is the case for protecting the cigarette market from competition from lower risk smokeless tobacco?
- Can any NGOs point to a reasoned case for banning oral tobacco? (no credible justification has so far been forthcoming)

Solution: it is unlikely that there is sufficient political will to lift the ban on oral tobacco and to regulate all smokeless products, even though is the best scientific, ethical and legal option. A more realistic approach may be to allow each member state to decide whether it should be banned or permitted, according to its cultural preferences and views on harm reduction. This could be a rebalancing of competency between EU and member states that would be beneficial to health. Where member states do allow it, they could harmonise product standards with a high level of health protection.

More information, including sources here: *Death by regulation: the EU ban on low risk oral tobacco* and this data

Other issues: when low risk alternatives to cigarettes are regulated heavily, the regulatory balance tips in favour of smoking. So great care should be taken not to make smokeless tobacco or e-cigarette products less attractive relative to cigarettes – for example by severely restricting characterising flavours, which are more important in non-combustible nicotine products than they are in cigarettes (which have the flavours created by smoke). Similarly, warnings on packs should not just deter people from using low risk alternatives to smoking, but also inform smokers that there are benefits from switching to these.

*Note: List of experts signing the letter (attached):
Tony Axell, Senior Consultant, Dept. of Maxillofacial Surgery, Halland Hospital Halmstad, Halmstad, Sweden.
Ron Borland, Professor, The Cancer Council Victoria, Australia
John Britton, Professor of Epidemiology, University of Nottingham. UK.
Karl Fagerström, Principal Investigator, Fagerström Consulting, Helsingborg, Sweden.
Jonathan Foulds , Professor of Public Health Sciences & Psychiatry, Penn State University, College of Medicine Cancer Institute, Cancer Control Program. Hershey, PA, USA.
Coral Gartner, Professor, The University of Queensland Centre for Clinical Research, Brisbane, Australia.
John Hughes, Professor, Dept of Psychiatry, University of Vermont, Burlington, VT, USA.
Martin Jarvis, Emeritus Professor of Health Psychology, University College, London. UK.
Lynn Kozlowski, Professor, School of Public Health and Health Professions, State University of New York. NY, USA.
Michael Kunze, Univ.Prof., Institute of Social Medicine, ECDC (European Centre for Disease Prevention and Control), Centre of Public Health, Medical University Vienna, Austria.
Jacques Le Houezec, Consultant in Public Health, Tobacco dependence, Rennes, France
Karl E Lund, Research Director, Norwegian Institute for Alcohol and Drug Research, Oslo, Norway.
Ann McNeill, Professor of Health Policy & Promotion, University of Nottingham.UK.
Lars Ramström, Principal Investigator, Institute for Tobacco

Studies,Stockholm,Sweden.
David Sweanor, Adjunct Professor, Faculty of Law, University of Ottawa, Canada.

Please do not hesitate to contact me if you would like further information or have a different views of these issues.