Amending the Tobacco Products Directive – how to fix the harm reduction agenda

Key votes in July and September – everything still to play for.

We're getting closer to serious position-taking and the first decisions in the European Parliament. So here is a post with my suggestions for amendments to the directive and some information for anyone interested in following what is going on in the process.

The most important thing is the 'harm reduction' agenda – finding ways to decouple taking the not-very-harmful drug nicotine from the very harmful way of taking it by smoking cigarettes – mainly through low-risk alternatives nicotine products such as smokeless tobacco or e-cigarettes. Huge health and well-being benefits would flow from a substantial switch.

What's wrong with the proposed Tobacco Products Directive?

In several important areas, the proposal is crudely weighted against much lower-

risk alternatives to smoking and therefore implicitly favours cigarettes, smoking, and more disease. A good directive would be about proportionate and non-discriminatory regulation of nicotine in the internal market to enable the low risk products to compete to help people move off the most dangerous nicotine products of all, cigarettes. In fact, the Directive is a chaotic and counter-productive setback that in total favours cigarettes.

Yes, but what's wrong with the proposal? Well…. it bans the safest tobacco product, despite it making Sweden the best country in Europe by far for tobacco outcomes. It carelessly mis-classifies almost all e-cigarettes as medicines and is likely to drive out many of the innovative firms in the market by wrapping them in red tape, loading on high costs, and imposing restrictions for no benefit that couldn't be more easily achieved. A ban on flavours hits the lower risk smokeless products much harder than cigarettes (only 5% of cigarettes use flavours, but 70% of smokeless products do). It places arbitrary bureaucratic obstacles in the way of potential new designs for low-risk 'heat-not-burn' tobacco products that don't apply to cigarettes. It imposes warnings that ignore 100-fold differences in risk and thereby mislead consumers. It goes even further by making it illegal to be truthful about relative risk. It does nothing to reduce or even sensibly measure the toxic emissions from combustible products – despite 15 years of knowledge that the current regime is a misleading distraction. And it doesn't do what most experts advise: set up a coherent framework for managing the legal widely-used recreational drug nicotine with the least harm and greatest consent possible.

Amendment briefings

These are my summaries and text proposals of the main weaknesses in the Commission's proposal from the point of view of someone hoping to get better health results by extending the range and availability of much lower risk nicotine products than cigarettes. I have focussed on these issue and not discussed other issues like standardised packaging, anti-fraud measures or distance selling.

Consolidated version

These are in MS Word format and the overview is reproduced later in this post. These may be updated as we discuss with MEPs and fellow travellers. For more background on e-cigarettes and good words to quote, I recommend the European Parliament Library briefing: *Electronic Cigarettes*.

Taking action

It's easy to feel that decisions are made 'somewhere else' remote and unaccountable. But that isn't actually right – MEPs, MPs and Ministers represent you and do respond to your views. And MEPs especially need to feel people in their home countries are interested in what they are doing. My advice in an earlier post – *EU draft Tobacco Products Directive: who to write to and what to say (a short guide)* – still applies, but we have more information now. The basic rule is that genuine views, presented with calm conviction, expressed politely and based in real life experience really count and do change what politicians do. And I mean that as a good thing about politics.

How to write. So if you want to have your say: writetothem.com is the fastest way to get to your MEP or MP (UK). Ask your MP to take it up your points with the the Department of Health. For visitors from other member states, look for MEPs that directly represent you. Also, focus on MEPs on the following committees: ENVI, IMCO, ITRE, JURI and INTA – each has a different angle and ENVI is in the lead.

But what to say? No-one should ever feel as though the process has advanced to a level of detail and complexity that they are no longer qualified to comment. The trick is not to try to impersonate a lawyer or scientist – but to say what you think should be done in normal language. It's up to you to say what you think, but I hope the briefings above are useful. And I'd certainly welcome comments (especially disagreements) on any of them.

Process of agreeing the Tobacco Products Directive in the European Union

Does the process seem incredibly convoluted to you? Well that's because it is! The legislative process is the 'Ordinary legislative Procedure' (the flowchart is the easiest to follow). This is a process of negotiation that happens initially *within*

the European Council (member state representatives and ministers) and European Parliament (elected politicians) – that phase ends at 'first reading'. There is then an attempt to get agreement *between* Parliament and Council. I mention the Council to emphasise that domestic politicians are very important – we don't hear much about the Council and they work in secret, but they are important and they are connection back to domestic UK politics, Westminster and your MP.

So where are we in the process? the Commission proposal was made on 19 December 2012. The first reading in the Parliament plenary will likely be 8 October 2013. The ENVI Committee is leading for the European Parliament and will vote on 10 July. Committees are producing opinions and proposing amendments through May and June. We are entering a hot phase in the process. The European Parliament is quite transparent – you can follow it all via the European Parliament's *Legislative Observatory*. Basically, if the Parliament and Council agree easily, then it will go through quickly. Otherwise it can stall of be killed off. Remember that the European elections are in May 2014, so many want this to proceed to completion before that to chalk up a win. So there will be a temptation to cut things out, rather than add new good ides in. Under those circumstances difficult issues tend to get 'parked' in the future – usually a review or something – rather than worked out now. So its a choice between calling for what you want, and calling for the Commission to go off and do more work

Calendar

View main dates in a calendar using this site or via or your browser – please let me know of other developments or any mistakes in this.

Responsibilities in the European Parliament

There are several MEPs that have particular responsibilities for the directive. The European Parliament is organised into committees that scrutinise legislation from a particular angle (public health, single market, agriculture, trade etc). Each committee has a 'rapporteur' that leads on the issue, and 'shadow rapporteurs' that represent each political group. To see a list of committees involved, rapporteurs and shadows for each political group, and draft reports and opinions produced so far – click here. Make your views known to them via your own MEP.

Amending the Tobacco Products Directive: the harm reduction agenda overview

This document focuses primarily on tobacco harm reduction. It is concerned with those parts of the proposed Tobacco Products Directive that regulate products that present substantially lower health risk than cigarettes. It does not discuss cigarette packaging, cigarette additives and labelling, distance selling or anti-fraud measures.

Scale of the challenge and trends

The WHO anticipates one billion premature deaths from tobacco on current trends would arise this century, and there are already 700,000 deaths per year in the EU. Tobacco use is widespread and growing around the world – there are approximately 1.45 billion smokers in the world today, and if current trends continue, that number is expected to increase to 1.6 billion by the year 2025. Despite years of action at all levels, 28% of EU citizens still smoke. But the European Commission's estimate of the impact of the proposed directive is that it will reduce consumption by just 2% (equivalent to about a half percent fall in smoking prevalence). That response lacks the ambition and the bold leadership needed to make deep and rapid inroads into one

Fast-acting health and welfare gains

The harm reduction approach addresses the health risks to those who cannot or do not wish to give up using nicotine. The fastest way to address the health consequences of smoking is to decouple use of the drug nicotine from the poisonous smoke that is conventionally used to deliver it to the body. Nicotine itself is addictive, but has only minor direct health impacts – similar to caffeine. The illnesses associated with smoking are caused by inhalation of *smoke* – hot gases and smouldering particles of burning tobacco – deep into the lungs. Smokeless tobacco, e-cigarettes and future novel tobacco and nicotine products may provide a satisfying 'hit' of nicotine, but without the toxic burden of the smoke and much lower health risks – 90-99% lower. Health and welfare benefits begin within days of a smoker switching to a lower risk product.

A flawed directive for both the single market and for health

The legal base for the directive makes it a measure to improve the functioning of the internal market, with the objective of free movement of goods but ensuring a high level of health protection. As both an internal market and a health measure, the Commission's proposal is very poorly designed. It is important to recognise that the products regulated by the directive have very pronounced differences in risk to the user. Smokeless tobacco like Swedish snus is at least 90% less dangerous than smoking (probably 95-99%). E-cigarettes are likely to be around 99%) less dangerous. A credible internal market directive would promote competition between high-risk and low-risk products in a way that reflected the health advantages of the low-risk products. In fact the directive does the opposite: it adds disproportionate burdens, costs and restrictions to the lower risk products, and in effect shelters high-risk cigarettes from competition.

In all the main areas of harm reduction product policy, there are serious flaws in the Commission's proposal. Each has the effect of providing competitive advantage to the cigarette category, and therefore increases harm.

1. E-cigarettes and other nicotine containing products

E-cigarettes and other non-tobacco nicotine containing products have astonishing potential to disrupt the business model of the established tobacco industry. But rather than encourage this, the directive subjects them to disproportionate and discriminatory regulation by misclassifying the vast majority as medicines, thus increasing costs and compliance burdens, imposing restrictions, and driving out innovation and potentially destroying the existing supply chains. The right approach is to draw on the highly developed body of existing consumer protection legislation and regulate them as consumer products, and only as medicines where the vendor claims the product is for the treatment or prevention of disease. See briefing: *Amending the Tobacco Products Directive: E-cigarettes and Other Nicotine Containing Products*.

2. Smokeless tobacco

Despite the obvious and large public health success of Sweden's experience with smokeless tobacco, the least dangerous form of tobacco (oral tobacco or 'snus') is banned and a ban on characterising flavours in smokeless tobacco provides more competitive advantage to cigarettes. There is no case for such an arbitrary and counterproductive ban on any known scientific, ethical or legal grounds. The right approach is to lift the arbitrary ban on oral tobacco and regulate the toxicity of all smokeless tobacco products, as recommended by the WHO's expert panel. See briefing: *Amending the Tobacco Products Directive: Smokeless Tobacco*.

3. Novel tobacco products

New products that would heat tobacco to vaporise nicotine, rather than burn it, hold out the prospect of very significantly lower risks than smoking. However, the Commission introduces the option of an 'authorisation' process for these, and the ENVI rapporteur would make authorisation mandatory. Neither can say what the authorisation criteria would be, and it is hard to imagine what they could be. So this simply opens up a promising harm reduction development to arbitrary decision-making, adds political risk and would achieve nothing. The right approach is to retain a notification system, but allow member states to withdraw novel tobacco products only if they believe them to be more dangerous than cigarettes. See briefing: *Amending the Tobacco Products Directive: Novel Tobacco Products*.

4. Cigarettes and combustible tobacco emissions

For several decades cigarette emissions have been characterised by 'yields' measured by smoking machines using a standardised smoking regime. In fact, these yields provide no useful information on health risks because real people adjust their smoking patterns to get the nicotine they want. With the assistance of legislators, these numbers have for years mislead smokers about into believing 'light' products pose a lower risk to health. Elements of this system are inappropriately retained, but the main weakness is a failure to include any emissions standards that would be meaningful and useful. The right approach is to introduce standards that reduce toxic exposure rather than mislead consumers. See briefing: *Amending the Tobacco Products Directive: Cigarette and*

Combustible Tobacco Emissions.

5. Coherent nicotine regulation

The proposed directive is a muddle of incoherent and counter-productive regulatory interventions, largely unsupported by evidence or principle. Most of the proposal weakens the harm reduction agenda, providing implicit competitive protection to the cigarette category and thereby likely to induce more harm than would otherwise be the case. A thorough review of nicotine regulatory policy is recommended. This is overdue and should have been done by the Commission before publishing the current proposal. See briefing: *Amending the Tobacco Products Directive: Coherent Nicotine Regulation.*