MEPs – do you really want to vote for this?

Time to do the right thing

Hundreds of politicians, civil servants, ministers and lobbyists have been busy on the tobacco products directive for more than a year. Is the result of all that work a credit or embarrassment to the European Union? MEPs vote on it today. My letter to say they should drop article 18. I sent variations to MEPs in the each of the main political groups.

> *Dear Member*
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> *On Wednesday 26 February, you will be able to vote on the revised tobacco products directive, which the institutions appear determined to agree at first reading. I understand that you will be denied the opportunity to vote on separate articles and that the plenary will not be allowed to consider amendments at first reading, so your ability to reflect the views of your constituents will have been highly restricted. You will be presented with a text on a 'take it or leave it' basis. You may have the opportunity to ask for the directive to be returned to the ENVI committee for further development. If that arises, I suggest you take it as the directive is highly flawed in its current form.*

The directive in its current form will cause more harm to health than it prevents, and it will place unjustified restrictions on an industry that could present an important alternative to the 28 percent of European adults who smoke tobacco. All this in what is supposed to be an internal market measure.

There is a growing recognition that tobacco harm reduction through well regulated markets for e-cigarettes and smokeless or non-combustible tobacco as alternatives to cigarettes could have great potential to reduce smoking and related death and disease in the European Union. However, the post-trilogue text of the revised Tobacco Products Directive is, regrettably, obstructive and damaging to this approach and as such, it will cause net harm to health. The main concerns are as follows:

1. Measures that we know will cause harm. There is no logic or scientific basis for imposing a limit to liquid nicotine strength of 20mg/ml – about 25-30% of users use liquids stronger than this, and there is no health or internal market basis for preventing the trade in these products. The stronger liquids are important to heavier smokers and to people as they make their first switch into e-cigarettes. The result of this limit will be less switching and more relapse to smoking. The result of that: more disease and premature death. Further harms are likely to arise from a black market forming in stronger liquids – this will of course be uncontrolled and outside any regulatory regime. Measures that restrict the free movement of goods are justifiable under the internal market legal base if they protect health, but not if they increase harm.

2. Measures that will perversely protect the cigarette market. The directive bans most forms of e-cigarette advertising, treating e-cigarettes in the same way as tobacco. This will have the highly undesirable effect of protecting the cigarette market from competition from much safer products. It will impede free movement of goods, inhibit innovation and limit the appeal relative to smoking. The justification for banning tobacco advertising rests on the reality that smoking kills over half a million Europeans annually (see recital 3 in 2003/33/EC). No such justification exists for e-cigarettes, which are actually reducing death and disease by reducing smoking. The advertising provisions blatantly fail the 'proportionality' test of the EU treaties and therefore are likely to be unlawful. A regime more like that used for alcohol advertising would be proportionate (eg. these UK codes for non-broadcast and broadcast media.), but not outright bans. Similar concerns apply to excessively large and bold

warnings and packaging leaflets.

3. Measures with no justification that obstruct the spread of real world success. *No-one in the Council, Parliament or Commission has so far produced a single credible reason for the ban on oral tobacco in Article 15 or responded to our rigorous critique of the Commission's case. This is especially troubling, given the excellent tobacco-related health outcomes that have emerged in Sweden and Norway and are clearly attributable to snus use displacing smoking. Further, the new text contains a mechanism to allow novel inhaled or chewed tobacco products into the internal market under Article 17, but this is not open to snus, the one product we know has been effective in reducing disease. The responsible expert community regards this as the unthinking continuation of a 25 year error – it has no scientific, ethical or legal basis.*

4. Measures that introduce arbitrary clashes with other EU legislation. The directive creates a new approach to handling potentially dangerous substances – by limiting nicotine container size, apparently with the aim of keeping the volume of contents below an (incorrectly) estimated lethal dose. In doing so, it is more likely to have created an increased choking hazard than protected anyone at all. The European Union has a well established approach to handling hazardous substances through the 1272/2008 Classification, Labelling and Packaging (CLP) Regulation, and that is all that is needed for nicotine liquids. Imagine if we controlled the risks from household bleach or drain cleaner by reducing the container size to a few millilitres?

5. Measures that should be included but are missing. It would have been useful to have some standards, or at least a standard-setting regime, for the purity of e-liquids and operational parameters of e-cigarettes. These would build confidence in the products and bring about efficient standardisation, but the opportunity to do something constructive and useful has been missed in the intense negotiation over pointless restrictions.

6. Shoddy drafting and improper undemocratic amendments. While the Parliament was acting on the basis that no plenary amendments were possible after the ENVI committee met, the directive has actually been substantively amended in the lawyer-linguist process (see complaint from Martin Callanan MEP). This amendment partially, but not fully, prevents a legal mess arising from shoddy drafting. A wide range of flavours is integral to the e-cigarette and smokeless tobacco market and it is good news that flavours will be allowed

under the directive for these products. However, convoluted drafting created a legal fiasco. Vendors would have been able to sell flavoured products but unable to say what the flavour actually is on the packaging. This is has been corrected for e-cigarettes but remains an embarrassing anomaly for flavoured smokeless tobacco products. For MEPs who care about proper process, it is unacceptable to make substantive amendments through the lawyer-linguist drafting process – please see this letter from .

7. No consultation. E-cigarettes and related products are used by 8-10 millions Europeans, now involve thousands businesses and are the subject of intense research efforts in the expert community. It simply is not credible to produce 4,500 words of new regulation in a closed and insular process between October and December 2013 with no consultation with these stakeholders. Not only has that led to poorly designed regulation, but it violates obligations set out in the EU treaties, which require consultation on legislative proposals (see Article 11 TFEU, Article 2 Protocol 2). On what basis can the EU legislature simply ignore these obligations and proceed with poor regulation regardless?

8. Flawed science, inadequate analysis. For EU legislation to be good for public health, and therefore to have a firm legal base, it needs to be based on sound science and analysis. To the extent that science has been used to justify the proposals, it has drawn stinging criticism from the scientists whose work has been cited. See: Scientific errors in the Tobacco Products Directive – a letter sent by scientists to the European Union and follow-up. The supporting analysis for this part of the directive is completely inadequate: there is no impact assessment or credible justification for the measures. The little there is (a one page fact sheet) has been dismissed by experts as a set of scientifically baseless assertions. Again, the treaties require proper justification and comprehensive impact assessment and none has been done (Article 5, Protocol 2). On what basis is this legislation proceeding?

9. The rest of it does very little. All this harmful, disproportionate and unlawful legislation might actually be worth enduing if the rest of the directive had some substantive evidence-based public health measures in it to compensate. But it doesn't. It is mostly just peripheral tinkering and harassment, which even the European Commission says would only reduce consumption by 2 percent in 5 years: far far less that the likely impact of e-cigarettes in future.

I wish I could say that this is all that is wrong, but there are further issues regarding excessive technical requirements, information demands that have no purpose, and discriminatory burdens placed on e-cigarette makers that are not placed on cigarettes vendors.

The key measures in the directive from a public health perspective relate to reduced risk alternatives to smoking, and in agreeing to this you will be maintaining a ban on the product that has the best results in Europe by far and imposing a poorly designed, unscientific, regulatory framework for e-cigarettes negotiated in haste behind closed doors without consultation and in contradiction to the views of the most experienced scientists in the field.

It is disappointing to see agreement in the European legislature to so much that will be harmful to health and that so clearly violates the treaties. I hope you will use whatever influence you have to challenge this third rate legislation and to help develop a credible regulatory framework that will stand the test of time and be an example to other jurisdictions rather than an embarrassment to the European Union.

Yours sincerely

Clive Bates