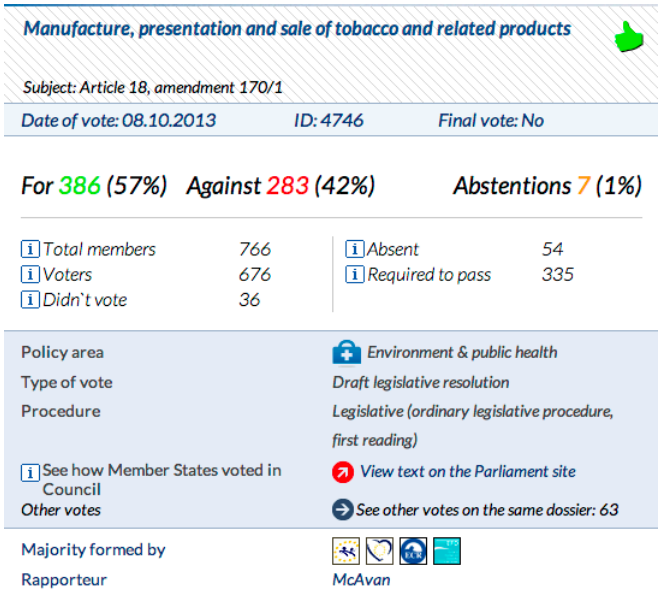
Tobacco products directive: after the insurrection – what next?

written by Clive Bates | 16 October 2013



Jump straight to what should happen next.

Summary – a quick read

On 8th October in Strasbourg, the European Parliament voted on a raft of measures to regulate tobacco and nicotine products. The headlines were the following [also see Telegraph summary]:

- a ban on menthol and other flavoured cigarettes from 2022
- warnings covering 65% of packs (30% now – campaigners are pushing for 75% and the right to go further)
- a ban on selling cigarettes in packs of less than 20
- no ban on 'slim' cigarettes
- a ban on most additives in tobacco products
- a continuation of the ban on snus outside Sweden in the face of all evidence

The most important decision by far was **a rejection of the proposal to regulate e-cigarettes as medicines**. In its place was a proposal to apply aspects of tobacco regulation and other restrictions (this was amendment 170). Neither

medical or tobacco approach is really appropriate: these products are not used as medicines or for treating anything, and they are not tobacco products – not least because they have a tiny fraction of the known risks of cigarettes. It is only the high health risks that justify restrictive tobacco control measures such as banning tobacco advertising. This is a great victory for people-power and for the MEPs who have taken the trouble to understand and support this incredibly important public health development, but it isn't yet the best approach to regulating e-cigarettes.

What we need for the new nicotine market: regulation fit for purpose. What we need now is regulation that is fit for purpose, proportional to risk and designed for non-tobacco nicotine containing products used as alternative to smoking. E-cigarettes are far too important for public health to just force them into ill-fitting, costly, burdensome and restrictive regulation designed for something else. It is far from clear that a rapid negotiation between Parliament and Council between now and Christmas will achieve the right regulation. It is unlikely to allow for adequate impact assessment for unintended consequences, proper consultation with stakeholders or for good risked-based policy design that is proportionate, non-discriminatory and legally robust.

Best way forward: a new proposal from the Commission. Council and Parliament should use the directive *to invite the Commission to develop options for purpose-built regulation for nicotine containing products*. This could include setting standards for e-cigarette performance and safety (to do what it originally proposed in 2010), defining accountability and responsibilities, a disclosure and notification regime, creating schedules for prohibited ingredients, defining limits for contaminants etc. It need not be completed in one go, but a basic framework established that is designed around what the products really are and how they are used (as has been done for cosmetics and food supplements for example). It could also emphasise immediate enforcement of the existing consumer protection framework and the responsibility of member states where they have competence, such as for age restrictions and marketing controls (for example of the type that most members states apply to alcohol).

Benefits of this approach: good policy, good politics, rapid progress of tobacco measures, no downsides. A new legislative proposal specifically for nicotine containing products would allow for better policy-making, proper engagement and consultation with the industry, users and public health experts

and (we believe) a better political solution. There is no problem demanding an emergency solution by Christmas, and huge numbers of lives are at stake in finding the balance between products that are *safe enough*, and products that are *attractive enough* to appeal to smokers. It would allow the rest of the tobacco directive to proceed to a rapid satisfactory conclusion and avoid the risk that controversy over e-cigarettes will derail the whole directive and play into the hands of the tobacco industry or pharmaceutical interests. This is the Right-Thing-To-Do. If it is not possible to do this for some reason, then we will have to press for improvements to AM170… but going back to medicines regulation, either explicitly or by stealth, should no longer be on the table. The UK government having pushed it, should now lead on an alternative strategy that respects the Parliament's decision by assessing options and consulting with all stakeholders.

Cautionary note: I have decided to focus on what should should happen to secure the best public health outcome – *not necessarily what will happen*. Once we know more about the starting positions of the negotiators and how strongly they hold those views it will be possible to judge more precisely how this will proceed. Please remember, the snus ban tells us that evidence, analysis and even concern for human life are not always that influential in way the EU makes policy.

In more detail…

The numbers

E-cigarettes. On 8 October, the European Parliament rejected the approach of regulating e-cigarettes as medicines (amendment 71) by a majority of 64… 362 against to 298 for (see voting for amendment 71) and voted in favour of a mixture of restrictions (amendment 170) instead by a majority of 104 … 386 for to 282 against. (see voting for amendment 170). The enemies of public health (the Greens) tried a sabotaging trick which was to require a separate vote on whether to allow flavours in e-cigarettes (ie a separate vote on 3.h of amendment 170 "*flavourings are allowed in the products*"). The Greens were hoping this would be defeated, but it was passed – though more narrowly: 342-317 than the rest of the amednment – see voting. You can use the links on voting to explore who voted for what, who rebelled from their party lines etc.

Snus. The vote to lift the ban on snus was lost 207 to 453 (see voting), with a solid majority of MEPs backing the unethical, unscientific and lethal ban favoured by anti-health 'public health' advocates and negligent governments, even though the case to lift the ban it is really straightforward. Fortunately, the Commission's cynical ban on flavours in snus was removed – this would have been very damaging as these products rely more on added flavours than the flavours that come from burning tobacco.

The result is mixed

The result is that the Parliament now has an agreed approach to e-cigarettes that rejects medicines regulation, in favour of regulations drawn up within the directive, as set out in amendment 170. These draw on tobacco regulation. The amendment is most significant for what it rejects and the process of negotiation this now triggers. However, the amendment text is a compromise and is not as good as it should be and is disproportionate and arbitrarily restrictive in places. It's two main weaknesses are:

- **Advertising ban.** The application to e-cigs of the ban on cross border tobacco advertising 2003/33/EC and ban on advertising, sponsorship and product placement in audiovisual services 2010/13/EU are counterproductive. Remember it is *good* for public health to advertise e-cigarettes because this will drive more smokers to try them, understand them and keep using them instead of smoking. Note that some experts do not believe the advertising ban would be that significant given the internet strength of the industry – I think that is optimistic. A final thought – the application of these advertising restrictions under a single market directive would be almost certainly struck down by the European Court of Justice once the directive was in force.
- **An arbitrary nicotine density limit of 30mg/ml.** This falls in the upper-middle of the range of products available on the market today, and would tend to rule out liquids that appeal to the heaviest nicotine users. That would be counterproductive and discriminatory. Why make it more difficult to access the liquids that give a nicotine hit more comparable to cigarettes and therefore are attractive to the heavier smokers – and hence those more at risk from smoking related disease. It would create an arbitrary and discriminatory dividing line through the market, with no

justification whatsoever.

There are other aspects of tobacco control policy that have been included in the amendment that are undesirable when applied to low risk alternatives to cigarettes: – excessively large warnings out of proportion to risk, unnecessary bans on cross-border distance sales that inhibit the internal market, unnecessary additive restrictions that may reduce technical options to compete with cigarettes in nicotine delivery and a lot of unnecessary costly bureaucracy and burdens that will serve no useful purpose but slow down the development of these products. However, medicines regulation only would have been much worse (I don't want to rehearse the case again: see here and here).

What next?

What happens next is negotiation between Parliament and Council (member states governments) to see if they can reach a common position – a process call the Trilogue. I've explained the full process in an earlier posting, so will not repeat here. But basically the text goes back and forth between Parliament and Council until they agree on every single word – either by compromising, fudging or taking things out. (if you want to know *everything*, use this guide) This process gets underway quickly with first of four Trilogue meetings scheduled for 23rd October. I understand they want to complete the process by Christmas – partly because of concern that the next presidency, Greece, is pro-tobacco (I think this is quite insulting to the Greeks by the way – they are as good as anyone at playing a chairing role without bias). The Trilogue negotiations will aim to generate amendments acceptable to the negotiators from both sides. These would be put to the Council at its first reading (possibly in December). If they are agreed by the Council (likely to be), the Council's amended text passes back to the European Parliament for its approval. At that point the Parliament can accept the Council's revised text in full, and the directive is adopted. If it rejects it or amends it, the process continues and further negotiations start. *There will be a great deal of pressure to settle on the amendments agreed by the Council following negotiations with the Parliament's negotiating team so the deal is done*.

What attitude will the negotiators adopt?

They need to understand what happened and why. The progress of the negotiations really depends on the reaction of the negotiators on both sides to the

Parliament's rejection of medicines regulation for e-cigs and what else they think is important. The right thing to do is to pause and understand what happened and why. Why were so many MEPs persuaded to vote against the position of the Commission, many governments and the rapporteur? I think they have been persuaded that applying ill-fitting, excessive and restrictive medicines regulation to a low risk alternative to cigarettes is counterproductive, harmful to health and damaging to an emerging disruptive industry (see my critique of rapporteur's position on e-cigs). Vapers articulated that case in thousands of communications with MEPs, the media and other interested parties. It wasn't just weight of campaigning either, but also that the views expressed were authentic and strongly personal. *But most importantly, they were right – their arguments convinced MEPs because they are convincing*. If vapers continue to make the case eloquently, patiently and in large numbers, the is no reason why governments will not eventually understand and listen.

Government's should not just plough on. So a good government would now show some humility, and reflect that they might have got this wrong. It wouldn't be the first time. Remember the Department of Health and MHRA tried to ban e-cigs in 2010, and were overcome by the unexpected response of hundreds of vapers then. The danger is that civil servants see the European Parliament's vote as just an obstacle to overcome so they can continue undaunted. We can only hope cooler heads with better political judgement will grip this unfolding mess and start to adopt the approach we've seen from the Conservative and Liberal Democrat politicians in Brussels. When a centre-right, liberally minded, instinctively deregulating government sees an editorial (*Smoke without fire*) in its heartland newspaper, the Daily Telegraph, bluntly challenging its inept regulatory meddling, you might hope some alarm bells will ring in No 10.

Who's involved…?

Parliament. The cast list in the negotiations isn't very reassuring. It is mostly filled with people who voted against the position the Parliament actually adopted on e-cigs. The Parliament's side will have:

- Matthias Groote (S&D – voted against) in the chair,
- Linda McAvan (against, of course) in the lead.

The ENVI shadow rapporteurs are also in the delegation, and include:

- Karl Heinz Florenz (voted against and in defiance of his group, the EPP);
- Carl Schlyter (Green anti-corporate conspiracy theorist – against);
- Frédérique Ries (supportive in ALDE but in favour of heavy restrictions);
- Martin Callanan (British Conservative ECR – supportive);
- Martina Anderson (Nationalist – against);
- Giancario Scottà (EFD right winger – EFD including UKIP appeared confused during the voting).

Presidency. The Lithuanian Presidency will play a crucial role in seeking a compromise in the negotiations, and making sure that at least a qualified majority of the Council will support the negotiated outcome. For this directive, the Lithuanian Presidency is led by health minister Vytenis Andriukaitis. Lithuania appears to have fixed itself to the Irish – and the health minister's speech could have been the words of the Irish presidency. More on who is involved on the Council side when we know.

Officials. The Committee of Permanent representatives an a health working group will manage agreement within the Council.

How it might play out…?

The problem for negotiators is that medicines regulation is quite binary – the products either are, or are not, regulated as medicines. Limits, targets or obligations be varied, tweaked or qualified in negotiations… That is not so easy with medicines regulation: it is a 'half-pregnant' problem. The Council's informal position ('General Approach') favours medicines regulation, the Parliament rejects it. So how can they come to agreement?

Here are four possible outcomes… (there may be more)

1. Set up a 'who blinks first' contest. The negotiators could present the Parliament with a compromise requiring medicines regulation for e-cigs in return for some of the other things the Parliament says it wants. It would then in effect 'dare' the Parliament to reject it and be blamed as tools of Big Tobacco if it did. This would show the negotiators (on both sides) have learned nothing and just see the Parliament as an obstacle to steer around. I think this is unlikely for two reasons:

(1) how could the negotiators agree to that approach when the EP has

rejected it, and what role would ALDE, ECR, EPP delegations play in allowing this to happen, as they voted against medicines regulation?

(2) what would Parliament value so highly that they could accept it as a concession from the Council as a reason to change its mind on e-cigs? Parliament and Council are aligned on warning size and it is *Parliament* insisting on delays on banning cigarette flavours and refusing to ban slims – the things that seem to have annoyed the health lobby.

2. Accommodates and improve. Council could reopen its apparent unity on medicines regulation and looks for a compromise and makes some workable improvements to AM 170. **The issue is that AM 170 is too restrictive already to strike the best balance for public health** – especially on advertising. Tt is *good* for public health to advertise e-cigarettes because this will drive more smokers to try them, understand them and keep using them instead of smoking. So we would have to hope that the Council amended AM170 to create a workable proportionate, non-discriminatory regulatory framework. I am sceptical that this is how it would go in practice – I think they are more likely to try to 'strengthen' the provisions (in doing so strengthen the protection of cigarettes from competition).

3. Collaborate and sabotage. More cynically, and with the aid of collaborators from Parliament, they could propose further changes to AM170 make it so restrictive that it becomes *de facto* medicines regulation – simply by adding further restrictions which make the legislation unworkable and mean that applying for a medicine license is the only way to operate a business. Those tactics are poor politics and policy. They don't address *why* the proposal for medicines regulation failed to convince the parliament. But they create the danger of a rejection by the European Parliament, which will likely object to having its views sidelined in this way, or subsequent legal challenges.

4. Purpose-built and fit-for-purpose regulation. They recognise that the binary division between medicines and non-medicines is irreconcilable in the time available and may derail the settlement on the rest of the directive. They agree to give the Commission a mandate to bring new proposals for NCPs into the next Parliament after May 2014, and put some sensible protections in place in the interim. In many ways this would be preferable. The 'problem' is not so serious (in fact there isn't a problem) that it needs an immediate regulatory response, and

they were proposing a 3-year lead-in for medicines regulation anyway. The idea of having specific standards for regulating e-cigs isn't new or contentious. In 2010, the Commission proposed and consulted on the following option for revising the tobacco products directive:

> *An extension of the scope of the Directive could be envisaged to include novel forms of oral tobacco, herbal cigarettes, and electronic nicotine delivery systems, insofar as they are not already covered by other EU legislation (food, pharmaceutical). Specific safety and quality requirements would be developed for ENDS. (emphasis added)*

Setting safety and quality requirements is a proportionate response and does not require medicines regulation. Going back to the approach the Commission actually consulted on in 2010 would be a good outcome in many ways.

What should happen next?

The best option is to do the job properly – the 4th option above – withdraw the parts of the directive that deal with e-cigarettes. It needs a new Commission proposal and a proper procedure followed to develop new legislation. Advantages of this approach:

> **Expedites the rest of the directive**. It would allow the tobacco control aspects of the directive to proceed rapidly to completion and allow negotiations to focus on effective policies for the most dangerous products. It would avoid the risk that controversy over e-cigarettes will derail the whole directive and play into the hands of the tobacco industry. Options for expediting introduction of new regulations for e-cigarette could be examined. If they are less onerous and build on existing good practice they could be introduced more quickly than mandatory medicines regulation.
>
> **Allows for good policy-making.** It avoids creation of poorly designed legislation. What seems like a good trade-off in the negotiating room may create harmful and unintended consequences in the real world. That is why policy-making is usually 'deliberative' (ie. involves those affected) and allows negotiation to concentrate on detail rather than major design features. This would enable the Commission to propose measures that would provide:

'specific safety and quality requirements' to supplement existing consumer protection legislation; a safety regime including responsible persons and a product safety file; a proportionate disclosure and notification regime; establish accountability and responsibility arrangements; impose advertising controls as necessary (with properly shared competence with member states). I have discussed the type of regulation that might emerge by comparison with cosmetics regulation.

Good politics. E-cigarette politics are changing, and not to the advantage of incumbent positions. Users are getting more confident in their arguments, with a stronger sense of mission and more effective in social media campaigning – and they are growing rapidly in number. They will see the forthcoming European election as an opportunity. The e-cigarette industry is getting better at making its technical case and investment analysts are increasingly clear on the harmful impacts impacts of regulation on this emerging sector. The media and commentariat is coming to understand the benefits of these products (not least as they increasingly have personal experience or understand through friends, family and colleagues) and we have seen significant editorial hostile to medicines regulation. MEPs who have opposed or ignored vapers could make this conciliatory gesture in the run up to the 2014 election and some may be spared local activism.

Avoid unintended consequences. A proper policy-making process would allow the EU institutions to assess impacts and test options. In contrast, those negotiating compromises during the Trilogue will not be able to assess impacts in the time available with the expertise they have.

Allows proper consultation. Community rules require consultation – *no consultation* has been done on the application of medicines regulation to e-cigarettes or for that matter on the AM 170 proposals, some of which could be regarded as disproportionate and may lead to subsequent court action if not addressed now. The obligation to consult interested parties originates from Article 11.3 of the Treaty on European Union (TEU) which states:

> *3. The European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent.*

Legally sound proposal. Those who think that getting back to medicines regulation would be the ideal outcome have to remember the proposal is very vulnerable to legal challenge A new proposal allows for the member states to assess recent case law, examine the Opinion of the Parliament's Legal Affairs Committee, look at recent legal analysis for the e-cigarette industry (ECITA, TVECA)

If I were in the institutions, I'd want a bit of time to rethink. So this option has some attractions instead of just trying to bludgeon through the idea they first thought of. It's too early to tell how this will play – but I hope that government's will try to understand what has happened and why. However, it's politics and egos don't always allow for that.

How to negotiate?

Be straightforward about the right thing to do. The most effective approach for concerned citizens is to say what they think and mean it, rather than to be too involved in second guessing the negotiations and proposing trade-offs. The negotiators do take account of the pressures they are feeling and arguments that they find persuasive. So I think the line I would take with anyone (government, Commission, MEP) with a hand in the negotiations would be:

- Don't try to go back to mandatory medicines regulation. Parliament has rejected it, you will put the whole directive in danger, and it will ultimately fail in court anyway – so it really is a distraction now.
- We would be best served by a new proposal for regulation that is purpose-built and fit-for-purpose. The optimum health result is achieved by allowing these products to compete effectively with cigarettes, not by closing them down.
- Some regulation is very desirable: for example standards for quality, safety assessments and a product file, designation of responsible persons, notification of ingredients and controls on marketing at EU or member state level as appropriate.
- If you can't do that, please find a more proportionate approach to e-cigarette advertising than a blanket ban and allow member states to control advertising until some need for harmonisation becomes apparent.
- If you want to improve the Parliament's proposal remove the 30mg/ml threshold or raise it to at least 50mg/ml
- Keep the other measures under review in case they turn out to be having

a negative effect and protecting cigarettes.

Contact. It is not over. If you are a vaper with a view, have a public health interest or are involved in the business, you should keep up the activity on social media that reaches MPs and MEPs and keep writing to politicians. The key players now are **member state governments** – that means health ministries and parliamentarians. In the UK I suggest you write to:

- The new Minister for Public Health, Jane Ellison MP [via here and @janeellisonmp]
- Secretary of State for Health, Rt Hon Jeremy Hunt MP [via here and @jeremy_hunt]
- If you have a business interest, write to Rt Hon Dr Vince Cable MP, Secretary of State for Business, Innovation and Skills or RT Hon Michael Fallon MP Minister for Business and Enterprise [here and @vincecable & @bisgovuk]
- Your own Member of Parliament – and ask them to take up the issue with Jane Ellison, Jeremy Hunt, Vince Cable or Michael Fallon [via www.writetothem.com]
- MEPs involved in negotiations (see above)
- Presidency: Mr. Vytenis Andriukaitis, Minister of Health, Republic of Lithuania. Vilnius str. 33, LT-01506 Vilnius, Lithuania ministerija@sam.lt or Vytenis.Andriukaitis@lrs.lt (please take care with this – no ranting!)

Usual guidelines apply: polite, personal, to the point and drawing on your own experience and views. Politicians are tired of mass letter-writing.

Options for UK government...

So far, the UK government is sticking to its medicines mantra, which is disappointingly narrow-minded. In practice, the Parliament's decision probably means that every member state will now need to revisit its position on regulating these products in order to know where to it can meet the Parliament and where it has red lines, or whether it just wants to stick with its existing position. The Council can't enter a negotiation simply reiterating its position of banning almost all products containing nicotine unless they are classed as medicines. So I think there are six things that could move the process forward inside the UK

government (and similar for other member states).

1. Do not stubbornly pursue medicines regulation. Time for a rethink and open minds. Ministers should pay attention to this issue, not just leave it to officials. They should try to understand more about what happened and why, and notice how the media is swinging on it (see for example: Economist, Telegraph, Times). The Permanent Representation needs to go into the Trilogue with a fresh approach looking at the government's broader interests, not just lip-syncing instructions from MHRA to continue banging its head against against the wall of arguments.

2. Look at all options. Ask the Department of Health (*not MHRA*, which only has one approach) to put all the various regulatory options on the table and to test them in the light of knowledge gained since 2010. They need to know what they would do if they cannot regulate these products as medicines. This should include supporting a new Commission proposal. I would advise the formation of a multi-stakeholder group with representatives of different views within public health (there are pro- and anti-harm reduction views), a variety users and the different types of firms in the industry.

3 New impact assessment. Insist that a much better impact assessment is now prepared for the government's preferred policy (this remains medicines regulation). This should examine reality-based impacts on the industry and products in greater detail. Government has been proceeding on the basis this form of regulation would be 'light touch'. Medicines regulation isn't and cannot be light touch (see our report: *Costs and Burdens of Medicines Regulation)*. An outline impact assessment and risk-benefit analysis should be completed for other options.

4. Robust scrutiny. The government has built machinery to make sure excessive or inappropriate regulation doesn't needlessly sink promising businesses. Ask the Regulatory Policy Committee to examine this issue again (it has already found the policy-making unsatisfactory – see 2010 scrutiny), once a new IA has been done. Alternatively, apply a Red Tape Challenge using the Disruptive Business theme – if the situation of regulating e-cigs as medicines doesn't qualify, it's hard to imagine what would.

5. Consultation. Hold a proper consultation for those affected – the small

businesses and users have been roundly ignored and dismissed throughout. There has been *no consultation* on the government's preferred option so far, bar the attempt to use medicines regulation to ban these products in 2010. There was certainly no consultation on finding an effective way to make it work.

6. Take independent legal advice. Take legal advice on the lawfulness of the proposed regulatory approach at EU level – it is likely that medicines regulation via an EU ban on non-licensed nicotine products would be struck down as unlawful. The Chair of the Parliament's Legal Affairs Committee said as much in the debate and in his committee's opinion, there have now been five successful challenges in courts in the member states and and the e-cig industry has Counsel's opinion from a former ECJ Advocate General arguing that it is unlawful.