Tobacco products directive, e-cigarettes & snus – an update

An update on developments in the European Union and UK. Contains notes on…

- The process – where we are and what next
- The European Parliament
- The European Council
- Summary: you couldn't make it up!
- What next? A compromise amendment on e-cigarettes
- What next? Snus – oral tobacco
- The MHRA – UK medicines regulator

Comments, corrections, insights, gossip, rumours, plots… all very welcome!

The process – where we are and what next

The Tobacco Products Directive is going through a negotiating process known as the 'ordinary legislative procedure' [nice graphic]. Basically, it is a process whereby the European Commision (the civil service for the EU) submits a proposal for legislation (it did this on 19 Dec 2012) to the European Parliament (directly elected representatives, the MEPs) and European Council (representatives of the 27 member state governments). The Parliament and Council debate and amend the Commission's proposal and then try to reach an agreement. The directive passes only if the Parliament and Council can agree. They need to do this before the European elections in May 2014 or the process starts again. No agreement, no directive. The first substantial stage after the Commission proposal – the 'first reading' in the European Parliament – will be in

the week of 10 October 2013. At present, we are in the stage prior to the first reading where the Parliament is scrutinising the Commission's proposal through its committees and the Council is considering it through its working group and ministerial meetings.

The European Parliament

The European Parliament uses a system of committees and *rapporteurs* (someone who examines proposals and leads on an issue) so that the Parliament can scrutinise legislation efficiently. The lead committee on the TPD is the Environment, Public Health and Food Safety committee (known as ENVI) and its rapporteur is Linda McAvan MEP, a British Labour MEP. Other committees also scrutinise the proposal looking at it from different specialised angles – for example, international trade, internal market compatibility, agriculture, industry, and legal affairs – the process is set out in one place, the legislative observatory for this directive. These other committees feed in 'opinions' to the lead committee before the lead committee and rapporteur finalises their 'report' – and that has been happening in the last week. The next big development is that ENVI committee will debate and vote on amendments on 10/11 July, leading to the finalisation of the rapporteur's report. This report from ENVI is then used as a basis for the Parliament's first reading in October. Each committee involved keeps a 'dossier' of documents relevant to the directive – including reports, opinions, drafts, proposed amendments etc. These are linked below. At the time of writing the opinions from all committees are not yet complete or published – I will update as these become available (updated 1 july 2013):

- Environment, Public Health and Food Safety (ENVI) dossier. The key move in this committee was the rapporteur's 'simplified procedure' (amendment 1250) as an alternative to regulation under the medicines directive, though retaining many features of medicines regulation (see my critique of this). Other MEPs have uncritically followed the Commision proposal and seek full medicines regulation for e-cigs (a dreadful idea). But the argument is moving towards the more liberal minded MEPs, who include UK Liberal Democrats and Conservatives, who are pressing for regulation of e-cigarettes as consumer products (along these lines). The question is whether a compromise can be found between those favouring Lind McAvan's 'simplified procedure' and consumer product approach,

and whether that could gain enough support to overcome those determined to misclassify and over-regulate e-cigarettes as medicines.

- Legal Affairs (JURI) dossier. The final opinion is very helpful – it require medicines regulation for e-cigs only where health claims are made and stresses compliance with consumer regulation and proper enforcement, with subsequent review. This would be an excellent amendment to have in the directive. On snus it suggests an exemption for traditional use of oral tobacco.
- Internal market and Consumer Affairs (IMCO) dossier – the IMCO final opinion is unhelpful and incoherent. It retains medicines regulation for products above the low threshold established in the Commission proposal and also specifies in greater detail restrictions on products below the threshold.
- International Trade (INTA) dossier. The final opinion of INTA limits the use of medicines regulation to only those e-cigarette products where a health claim is made – a valuable point – and excludes medicines regulation in any other circumstances. It raises the issue of the WTO Technical Barriers to Trade treaty compliance – ie. not excessively or prescriptively regulating to exclude foreign producers. It also states that the snus ban should be lifted as it is also incompatible with international trade rules.
- Agriculture and Rural Development (AGRI) dossier – the final opinion classifies all non-tobacco nicotine containing products as medicines, proposes regulation instead of a ban for oral tobacco and limits the notification system for novel tobacco products to situations where a health claim is made. It reflects the agenda of Europe's tobacco growers.
- Industry, Research & Energy (ITRE) dossier – the final opinion deletes the entire article 18 related to e-cigs, though without much explanation. It creates an exemption for traditional use of oral tobacco – for example of the loose snus type used in Denmark.

The Council

There was a significant development on 21 June. The ministerial meeting of the Council agreed its 'General Approach'. This is best thought of as an opening negotiating position of the European Council, and is in the form of the

amendments they would like to see to the Commission's original proposal of 19 Dec 2012. They expose this 'general approach' before the Parliament has its first reading (in October) so that areas of potential agreement are more visible. It is also an opportunity for the Irish Presidency to chalk up a diplomatic win – securing agreement on the approach. The Presidency now moves to the government of Lithuania, which intends to prioritise the TPD.

On e-cigarettes, the Council position follows the Commission proposal, but does three main things differently:

- Retains the idea of a nicotine threshold, but halves the thresholds to 1mg of nicotine and 2mg/ml nicotine density, and abandons the bizarre one related to blood plasma.
- Gives more time to secure a medicines marketing authorisation. *Nicotine-containing products referred to in Article 18(1) and which are placed on the market before [entry into force + 24 months], may continue to be marketed until [entry into force + 36 months].* If entry into force is, say, May 2014. Then this means e-cigs on the market by May 2016 have until May 2017 to acquire a marketing authorisation. This is good. It is also a setback for the MHRA, which placed great emphasis on regulating e-cigs by 2016.
- Adds a more foreboding warning to products below the threshold: "*This product contains nicotine which is an addictive substance and can damage your health*". Of course these products are very unlikely to be addictive given how low the threshold is.

On smokeless tobacco, the main Council position is the outcome of a sordid trade-off. Snus will remained banned outside Sweden, but the lucky Swedes will be allowed to keep flavourings in snus available in Sweden. Flavourings, such as bergamot or juniper, are integral to the appeal of snus to people who would otherwise smoke – so the Council has in effect threatened to diminish the harm reduction potential, and then dropped the threat in return for Sweden's subordination over lifting the ban. There is a danger that the directive will ban acidity regulating additives that assist with the delivery of nicotine through smokeless tobacco, and so make them less viable as an alternative nicotine delivery system to cigarettes – more smoking will be the result. In addition the warnings on smokeless tobacco are to be made more misleading and much larger – now printed twice instead of once. I have written more about the approach to

snus in: *Negligence in tobacco policy*.

On novel tobacco products, for example products in the pipeline that heat rather than burn tobacco. For these, the Council sticks with the Commission position on Article 17 – a *notification* regime. I think this is right – they could hardly make something more dangerous than cigarettes.

Summary: you couldn't make it up!

It's hard to express just how incoherent the product regulation measures in the proposed tobacco products directive really are. But here we go…. The least dangerous, most promising, fastest growing products (e-cigs) are to be barred from the market unless authorised as medicines, which they aren't, and subject to an onerous regulatory regime increasing cost, limiting choice and appeal, holding back innovation and generally making the products less competitive relative to cigarettes. If someone wants to bring a low risk nicotine product to market, they should just make sure it is a novel *tobacco* product – they just have to let the authorities have some information about it. That is unless the tobacco product in question is snus, the least dangerous tobacco product in existence, in which case it is banned completely everywhere but Sweden, where it has delivered a spectacular public health success. This is banned because it is put in the mouth and sucked not chewed, even though it is less toxic that many forms of chewing tobacco. Cigarettes can be put on the market pretty well at will, as long as they meet some irrelevant tests for 'yields', the results of which are no longer to be printed on packs because they are misleading. Except the 5 percent of cigs that are flavoured, mostly with menthol. They will be banned. We have no reason to believe they are more or less toxic than other cigarettes, it's just that different people like them and these different people are to be protected by switching to unflavoured cigarettes. Something will be done with additives, but no-one really knows what or what effects, good or bad, whatever is done will have on smoking behaviour – less addictive nicotine might mean more exposure to smoke. Who knows?

What next? Proposed compromise amendment on e-cig regulation

The ENVI committee has its important meeting on 10/11 July. This will settle the

rapporteur's report, which will then go to the plenary of the European Parliament on 10 October. We are aiming to find some common ground between all those now concerned about over-regulation of e-cigarettes. These are the main things we need to press for:

1. Compromise amendment: given that quite a lot of MEPs want almost all e-cigs under medicines regulation and this is the position of the Council and Commission, we are trying to find an acceptable compromise amongst all those who recognise how damaging this would be to the category. So this compromise amendment aims to find some middle ground. It borrows from the approach that is taken to regulating cosmetics – vendors are required to prepare an independently audited 'compliance report' of product information that shows they comply with the main safety and consumer protection regulation in force. In effect, this is trying to find a middle way between the rapporteur's 'simplified procedure' [info on this] and the more liberal approach [info on this], which is favoured by many in the vaping community and backed by Liberal Democrat and Conservatives in the Parliament. If the product dossier wasn't up to scratch or shows that the products are not compliant they would be taken off the market.

2. Flavours: several MEPs, including the rapporteur Linda McAvan MEP, think it makes sense to ban flavours in e-cigarettes. We really need to persuade them this would be a terrible error – needlessly limiting the category to tobacco flavours , reducing its appeal to smokers and removing the option to migrate away from tobacco altogether as the user's experience evolves.

3. Timetable: it is important to give plenty of time for any significant changes. If a light touch regulatory regime comes in, it could be done more quickly. If they insist on medicines regulation it needs to be 36 to 48 months after entry into force.

4. Review. The Commission proposal was a botch job – medicines regulation is no more than a convenient but inappropriate and legally shaky basis for regulating what is clearly not a medicine – and there are at least 10 reasons why it would be a bad idea. As was the case with cosmetics, it is necessary to design a specific regime that aligns with the purpose, technology, benefits and risks or the real-world product – not just smash a square peg into a regulatory round hole. This doesn't have to happen at once – providing the products are *safe enough,* the regulatory regime can be developed to be proportionate and light touch.

What next? Snus – oral tobacco

We will keep making it clear that Sweden has the lowest smoking rate in the EU by some distance and it is for one reason only – snus. We want anyone who want to or needs to take nicotine to be able to take it in an almost harmless form. I am not optimistic that the European Parliament will agree to lift the ban on snus and replace it with regulation of ingredient, which is beyond doubt what should happen. The contrast between the regulation of novel tobacco products (ie. notification) and regulation of snus (ie a ban) is obviously absurd and indefensible. I suspect it will end in court. However, there are some details to take care of:

- Lift the ban… we should never stop saying this, whatever the negligence of the the public health community, politicians and bureaucrats.
- Flavours – there should be no ban on flavours in smokeless tobacco. These are much more integral to smokeless low risk products than cigarettes – it would make the lower risk product much less attractivce relative to cigarettes, potentially reversing gains made in Sweden and elsewhere.
- Additives – we do not want bans on additives that reduce the effectiveness of smokeless tobacco at delivery of nicotine – and so become a less credible alternative to smoking, potentially reversing harm reduction gains made in Sweden and elsewhere.
- Member state discretion – member states should be able to allow the product, in effect have the same opt out that Sweden has – especially where oral tobacco has a long tradition, for example in Denmark and several other North European states.

The MHRA – the UK medicines regulator

There was a lot of hype for the MHRA announcement about regulation of e-cigarettes by 2016 and full documentation. But closer examination reveals something of a climb-down by the MHRA. All the announcement does is to say that they will regulate e-cigarettes in line with the forthcoming EU directive. They said they support the European Commission proposal and that the Commission had said they expect mandatory medicines regulation from 2016. However, within a few days, the Council 'general approach' position had shifted to 2017 (see above for detail). When the MHRA says we should trust it with this

category as a disruptive alternative to smoking, it is worth recalling that in 2010 it wanted all unlicensed e-cigarettes taken off the market within 21 days. So some seven years later, they may get their way… but that will depend on whether the directive is agreed at all, and if it is agreed, whether it applies medicines regulation to e-cigarettes. A couple of other interesting things in the announcement:

1. A paper on 'proportional regulation' – this reveals the MHRA's thinking about what they are now calling 'right touch' regulation – an account of what is needed to secure a marketing authorisation for e-cigs and how the product would be regulated once on the market. Some 'highlights' (disclaimer: please read the full document if you are professionally involved).

- Efficacy: the applicant would need to run trials to show the products deliver a certain dose of nicotine to the body, probably with reference to an inhaled NRT product.
- Quality: pharma grade ingredients would be required and production facilities would need to reach the pharmaceutical Good Manufacturing Practice standard, which must be inspected by an EU approved inspector. In depth information would have to be provided on every aspect of the manufacturing process, ingredients and raw materials.
- Availability: they would be generally available 'general sales list'. In many EU countries licensed medicines can only be sold in pharmacies.
- Risk management: the applicant would have to set up a surveillance system to check for use by under-18s, non-smokers and ex-smokers and how the product is being used.
- Packaging: packaging, branding and names would need regulatory approval.
- Advertising: adverts would need prior approval by the regulator. Note this is more onerous than for alcohol advertising.

2. An impact assessment to back the UK government support for medicines regulation. Gives costs of up to £2,288,000 (present value) or £266,000 annualised cost of a marketing authorisation per product. However, for inexplicable reasons they haven't included the cost of upgrading manufacturing facilities to pharmaceutical 'clean room' standards – this is a potentially huge cost. Also notes the effect of licensing on electronic nicotine delivery systems (ENDS):

> *Licensing ENDS is likely to erect a barrier to entry into the market, thus limiting the competition and innovation that would otherwise have driven prices downwards. By itself this would represent a reduction in consumer welfare but if additionally it means that fewer smokers switch to ENDS than otherwise have been the case, then it is possible that the health losses would be significant.*

Er… that's rather important isn't it? And innovation isn't just about money – it's about better products, niche products and product diversity.

3. A Q&A. Mostly predictable – but two interesting questions. The first is one that wasn't asked: *what happens if the EU directive is not agreed?* The second is Q25, which asks: *Why is the MHRA leaving unlicensed medicines on the market if there are no guarantees on safety, quality and efficacy?*

> *Existing electronic cigarettes on the market, and other NCPs that make no medicinal claim, will not require a medicine licence until the European Commission's revised Tobacco Products Directive is transposed into UK law. The European Commission has said it expects the new legislation to be adopted in 2014 and for it to come into effect in the UK from 2016. This will allow time for manufacturers to ensure that their products meet the safety, quality and efficacy requirements of a medicine if they wish to continue to market their product.*

Hmmm… the problem with this is that the definitions of a medicine are exactly the same in EU and UK law (the latter is governed by the former). So if they aren't medicines in UK law if no claim is made, they aren't medicines in EU law either. The EU institutions can't just insist on that a directive applies if the products in question fall outside the definitions in the directive – something the courts have repeatedly found in Europe. The reason for this is that *e-cigarettes are not medicines*… this fact is inescapable, and until it is recognised they will be going up a regulatory blind ally.