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Subject: Fwd: Tobacco Products Directive - views on the way forward

Dear Health Council Working Group

I would like to make a few comments in advance of the next stages of your deliberations on the Tobacco Products Directive (TPD) today and next week.

In summary, the best course of action is to complete the all tobacco parts of the TPD under the Lithuanian presidency, and to insist on a new science-based legislative proposal for nicotine containing products like e-cigarettes. The issue is sufficiently important to justify a high-quality expedited policy-making process, including: evidence-based justification; impact assessment; consultation with users, businesses and public health experts; and proper scrutiny. These are requirements of the treaties and of good policy-making practice. In the interim, more could be done more quickly by purposeful application and enforcement of existing legislation in member states.

1. Views of users. I would like to start with a comment from someone who has switched from smoking to vaping - with great benefits to their health. This is typical of the sentiments expressed by consumers. They are looking to the European institutions to defend their health and welfare from inept and inappropriate regulation. Feelings are very strong:

> *I smoked tobacco for 45 years - the first and only thing that has helped me stop is vaping, which is not smoking. If the EU pass this legislation I will either break the law or go back to tobacco smoking. This is only a "tobacco related product" in the sense that it is helping people like me to give up tobacco. Big pharma and the tobacco industry want control and it looks like unelected bureaucrats in the EU are in their pocket. These proposals are utterly ridiculous and fly in the face of any kind of common sense. We have to hope that the European Parliament continues to treat this garbage with the contempt that it deserves.*

I don't share the view stated above that unelected officials are 'in the pocket' of tobacco or pharmaceutical interests - but I can see why people may think that way. See next section...

2. Unintentionally supporting the cigarette industry. Many features of the proposals will have unintended consequences that strengthen the cigarette-based business model of the tobacco industry and protect the pharmaceutical industry. There is a double negative at work: *tough on e-cigarettes and harm reduction* means *easy on cigarettes and harm*. Specifically, some examples:

- Nicotine density limits set at a low level make it easier to obtain a satisfactory intake of nicotine from smoking rather than vaping (a win for cigarettes). If needed at all, the limit should be set at

50mg/ml to allow for innovation and better products for more addicted smokers. It is not really a sensible quantity to regulate.

- Nicotine caps (e.g. 10mg/unit) can make the e-cigarette products unviable, amounting to a de facto ban, or make it much more convenient to be a smoker than a vaper (a win for cigarettes). There is no need for a cap at all - compliant packaging is the priority.
- Advertising bans give advantages to incumbents and companies with already established distribution channels (a win for cigarettes). A more proportionate approach would regulate advertising with controls of content and placement - perhaps similar to alcohol.
- Flavour bans reduce attractiveness, personalisation and experimentation with e-cigs and are likely to reduce switching and increase relapse to smoking (a win for cigarettes). It is an elementary error to believe that teenagers will be attracted to 'childish' flavours: they are actually trying to emulate adult behaviour.
- Product design standards such as constant dose delivery that do not apply to cigarettes are very burdensome and limiting, but completely unnecessary (a win for cigarettes). Consumers should decide what a good product is, regulators should stick to safety and consumer protection.
- Warnings, leaflets and labelling that are disproportionate to risk create unnecessary fear and do not communicate relative risk in a way that is meaningful to consumers (a win for cigarettes).
- Banning refillable devices blocks off the pathway that many users follow from smoking to entry level cig-a-like to more a more effective vaping device - meaning relapse is more likely (a win for cigarettes)
- Pharmaceutical interests have been active in misleading MEPs about nicotine. A letter from a company full of misinformation and a robust response from three European nicotine experts is (here)

3. Poor analysis underpinning proposals. Much of the analysis that leaks out of the discussions is based on poor understanding of the science. For example:

- Extremely naive figures are used to assert equivalence between e-liquid volumes and cigarettes. It is important to distinguish between two quantities: nicotine in the liquid/vapour and nicotine absorbed - they are very different in both cigarettes and e-cigarettes. Calculations presented by the Commission misunderstand this: 5 minute use of an e-cigarette with 20mg/ml liquid does not equate to smoking a 1mg yield cigarette. The yield is an *absorption* measure - it would more likely take 30 minutes to achieve the nicotine equivalent of cigarette smoking through vaping. One of the critical weaknesses of e-cigarettes is their inability to compete with nicotine delivery of cigarettes - a regulator that further weakens them is doing no-one any good.
- Fears are raised of nicotine overdose - this is impossible other than with industrial strength liquids (eg. >300mg/ml) never found on the market. There are numerous misunderstanding about the accident potential with nicotine liquids (see this recent assessment by Professor Bernd Mayer showing that many claims date back to flawed 19th Century experiments and that the generally assumed risks are 10-20x overstated)
- The assertion that 'nicotine is highly addictive' is incorrect and incomplete: it is addictive when delivered in a way that causes it to 'spike' rapidly in blood plasma - ie. through pulmonary delivery. It is the cigarette that makes it especially addictive. NRT and e-cigarettes are not as addictive as cigarettes.
- The recitals contain wild allegations about e-cigarettes for which there is no supporting evidence. There are no signs of harmful gateway effects, let alone anything that justifies banning advertising or other restrictions and it is important to recognise that a much safer and less addictive product creates many desirable gateways (diverting young people from smoking, substituting for smoking or assisting in quitting completely - see here). The experience of snus - where gateway fears were raised to justify a ban but all the gateways are in fact beneficial - should be a cautionary tale for EU legislators as many have died as a result of this 21-year error (see expert views on this).
- There is minimal use by children and even where surveys have found children using e-cigarettes it is most likely to be *displacing* smoking (as with the heavily spun US CDC survey - see critique).

4. Consumers and most of the industry want well crafted protective regulation - but these proposals do not deliver. Most of those directly involved want to see the EU and member states establish a stable and proportionate regulatory regime and to deal decisively with any rogue products or vendors. The directive proposals under discussion would not do this. For example, what is is needed is:

- a set of standards for e-liquids (e.g. a requirement to use pharmaceutical grade nicotine and excipients and overall purity standards)
- operating standards for devices (e.g. maximum temperatures, what happens when they run dry).
- testing protocols that reflect the range of real-world use.

At this stage a process that would develop such standards and testing protocols is essential. This is the normal way to regulate: set reasonable proportionate standards; expect the industry to comply, which it will; adopt a risk-based approach to inspection and compliance. I have set out some ideas for a broad regulatory framework in paragraph 8 below.

5. Medicines regulation is now a distraction. The arguments against regulating e-cigarettes as medicines have been well rehearsed (e.g. here), but are more familiar to the Parliament than to the Council, which appears determined to work around the Parliament's position either by making the alternative to medicine regulation impracticable or by using Article 24. This is now a *distraction* from achieving a proper regulatory grip on e-cigarettes. The medicines approach has been repeatedly struck down in member state courts, the Parliament's Legal Affairs Committee found it to be disproportionate, and there is solid evidence that a challenge is likely and likely to succeed. There are even rumours that the Council Legal Service believes there is no legal base for regulating e-cigarettes as medicines. What is needed now is regulation that is fit for purpose and designed for e-cigarettes - not something designed for medicines or tobacco products.

6. The wrong way to make new policy. The most serious concern about the trilogue process is that it is a very unsatisfactory way to make new policy for important products that could provide benefits to millions and pose little risk in themselves. Trilogue works best when it is used to close differences in well-developed positions that are conceptually similar but not identical. Such a closed process is poorly suited to defining new policy. The trilogue process lacks four fundamentals of EU policymaking - and these are *requirements* under the treaties: (see more on this here):

- ***Evidence based justification*** - especially to justify departure from the principle of free movement of goods on health grounds. The evidence base for the proposed measures is poor to non-existent.
- ***Impact assessment and options appraisal*** - there has been no attempt to gauge the impact these proposal on users and businesses, or the wider population, including for unintended consequences - such as closing businesses, black market support or more smoking.
- ***Consultation*** - it is extraordinary to see the legislature defining entirely new measures with consulting the millions of users, thousands of businesses and dozens of experts with a legitimate point of view. It is not surprising that the EU can seem high handed and remote when this happens.
- ***Scrutiny*** - national parliaments scrutinised the Commission proposal and some may have scrutinised the Council General Approach. But since the Parliament's very welcome intervention, the proposal has changed beyond recognition and expanded to five times the length.

7. The right thing to do. The most appropriate course now is as follows:

i) Complete the Tobacco Products Directive for tobacco products - all but Article 18 - in December under the Lithuanian presidency.

ii) In the interim ensure members states purposefully apply and enforce the existing body of safety and consumer protection legislation and expect the industry to comply and raise its own standards.

This would deliver immediate benefits and should prompt the industry into raising its own game. For example it should be assumed that the general safety requirement means use of pharma grade nicotine and excipients and food grade flavourings - and there are other standards that could be applied from now.

iii) Bring forward and expedite a new science-based legislative proposal with a proper legislative process, involving: evidence based justification, impact assessment, consultation and scrutiny as discussed above. This should conclude rapidly, and be implemented quickly. The EU legislature, Commission and members states have much greater knowledge of these products than only one year ago.

8. Develop an health-optimising regulatory framework. To give some idea of of what should be included, I have listed elements below - this should be designed carefully and implemented at EU and member state level as appropriate. It should develop over time and include:

1. Advertising. Limits on advertising content and placement roughly comparable to controls on alcohol advertising - not a complete ban - with appropriate role to member states for advertising that does not cross borders. The aim of this policy should be to discourage advertising that appeals to children, but encourage smokers to switch.

2. Age restrictions. A ban on sales to persons under age of 18 - likely to be a member state issue.

3. Testing and notification regime - covering testing of liquids and vapours for harmful and potentially harmful substances. There is a similar requirement in Article 17 of the revised tobacco products directive for novel tobacco products - the testing demands should be no greater than these.

4. Product standards - e-liquid purity. Limits to contaminants or purity standards for e-liquids (eg covering carbonyls, volatile organic compounds, nitrosamines and heavy metals), with requirements to use pharmaceutical grade excipients and nicotine, and food grade flavourings.

5. Product standards - liquid ingredients. A negative list of prohibited flavours where there is evidence of harm either to the user or where there are signs of disproportionate or deliberate appeal to children (this can only be determined *ex-poste* - once products are on the market) and other additives (eg. stimulants, vitamins) set out in a schedule with a mechanism to update in the light of advancing knowledge.

6. Product standards - devices. Standards could be set for maximum operating temperature and behaviour when liquid levels are low - and other relevant design parameter to assure safe operation or to limit changes to the chemistry of vapour. These could be developed as CEN/ISO standards for vaping devices with CE markings for consumer information. There is no reason to prevent refillable devices - if superior products can be made with cartridges.

7. Packaging. Safe packaging for e-liquids (comparable with bleach) and compliance with the Classification, Labelling and Packaging Regulation where appropriate. This is a better safeguard than limiting total nicotine in a container.

8. Labelling. Warnings and other communication proportionate to risk and recognising significant potential benefits to smokers who switch. Consumer information should be helpful to consumers and be even handed about risks and benefits. This should also include traceability requirements to allow for product recalls.

9. Accountability arrangements - designation of a responsible person(s) in manufacturers, importers and distributors to discharge regulatory obligations.

10. Product file and safety assessment - a dossier on the product characteristics, tests done etc. and assessment of risks and measures taken to mitigate.

11. Surveillance. Members states should conduct or support independent surveillance of the evolving nicotine market - this is preferable to each vendor doing it, though members states should recover costs.

12. Technical committee and delegated powers - advisory machinery as appropriate to advise on standards and update in the light of advancing knowledge

13. Rapid implementation - aiming to have this in force as soon after 2017 as possible - it does not all have to be complete out the outset if there are powers to amend.

I must emphasise that this framework is indicative. The disciplines of proper policy-making, consulting users, businesses and experts is the right way to reach the most appropriate framework.

I hope these views are of interest - please do contact me if I can be of further assistance.

Disclosure: I have no competing interests - my interest is exclusively in the public health outcome. (Note: transparency register entry 810709012348-60)

Yours sincerely,

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