Written evidence submitted by Medic Pro Limited (ECG0075)

Executive Summary
- E-liquid Ingredients: Gaps in research into toxicity, addictive properties and interactions
- Clinical trial data is required to determine which types of product are more likely lead to smoking cessation
- Variations in the regulations exist between member states
- Brexit: the interests of UK-based e-cigarette industry services should be protected
- Rules on advertising and marketing largely ineffective
- Short-fill e-liquids: a work-around to the strict rules of the TPD and safety issues

Brief Introduction about Medic Pro
1. Medic Pro is a regulatory affairs consultancy that help e-cigarette and pharmaceutical businesses comply with regulations.

2. We have been working in the e-cigarette industry since 2015. We have provided regulatory support to a wide range of e-cigarette companies: 3 large Chinese manufacturers, 2 UK-based e-liquid manufacturers, independent retailers, a high-end U.S device brand and multiple EU-based brands.

3. Our background in pharmaceutical regulation – the foundation of e-cigarette regulation - underpins are expertise in advising on e-cigarette regulation.

Reason for submitting evidence
4. Our day-to-day work involves helping e-cigarette businesses to comply with the Tobacco Products Directive (‘TPD’) and corresponding national legislation. Through our work, we have gained an invaluable insight into the e-cigarette industry including:
   - the impact of the regulations on business,
   - how businesses are adapting to the new rules,
   - other important insights

5. Medic Pro is an independent company. We have no affiliation with any business or association in the e-cigarette, tobacco or pharmaceutical industry.

On Health
The impact on human health of e-cigarettes—themselves and relative to ‘conventional’ smoking—and any gaps in the science knowledge-base in this area.

6. We understand there are gaps in the science knowledge-base. Our research – via literature searches of scientific databases - suggests there is very little information on the toxicology of ingredients including the chemistry and toxicity of emissions and addictive properties of many ingredients.
7. There is also little information on the interactions that occur between ingredients in e-liquid formulations. In fact, many e-liquid manufacturers rely on these interactions – through a manufacturing process known as ‘steeping’ – to help manufacturers develop more palatable flavours. Shelf life testing on e-liquids is a tool that would help to identify these interactions in e-liquid formulations.

The benefits and risks of e-cigarettes as a ‘stop smoking’ tool, any gaps in the knowledge-base on this, and whether any approaches are needed to tackle e-cigarette addiction.

8. Although there is substantial anecdotal evidence that e-cigarettes help with smoking cessation, robust clinical data is lacking. Furthermore, given the wide variety of e-cigarette products on sale (types of devices and e-liquid flavours), clinical research should specifically identify which product characteristics are more likely to result in smoking cessation. It is likely that some types of product with certain product characteristics are more effective than others for smoking cessation. These types of products should be identified and be subjected to less stringent advertising and marketing rules than other product types.

The uptake of e-cigarettes among young people and evidence on whether e-cigarettes play a role in ‘re-normalising’ smoking.

No comment.

**Recommendation for action:**

- Conduct more research on the chemistry and toxicity of emissions and additive properties of ingredients.
- Businesses should be encouraged to conduct shelf life testing on e-liquid product range.
- Conduct more clinical research into types of product and smoking cessation efficacy.

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**On Regulation**

*Whether there is any regulatory variation between the EU and UK, and across UK nations, and the implications of Brexit on regulation in this area.*

**Variation between EU and UK**

9. There are a number of regulatory variations between UK and EU states. They relate to the following: cross-border sales, notification fees, Health Warning, requirements for nicotine-free products, leaflet/labelling requirements.
10. We have expanded on two regulatory variations in particular:

11. **Tank size limit of refillable e-cigarettes:** The TPD restricts tank size of refillable e-cigarettes to 2ml. The UK has transposed this rule into local legislation whereas Germany has not. Our research shows that Germany is the only country that has omitted the tank size limit on refillable e-cigarettes.

12. **Health Warning on refill containers and carton:** Where refill containers are sold in cartons, some Member States stipulate the Health Warning should appear on the carton and as well as the refill container itself while other States, including the UK, allow for the Warning to appear on the carton only.

**Implications of Brexit on regulation**

13. Provided the UK’s manufacturing and e-cigarette standards are in line with those in Europe and internationally, we do not envisage a significant impact. However, non-UK e-cigarette businesses – particularly the Chinese manufactures - may feel more comfortable sending products to be tested in an EU-based laboratory instead of one in the UK. In light of this, it should be made clear to international businesses that using services – including consultancy and testing services - in the UK will be acceptable to health authorities in the EU.

**The effectiveness of regulation on the advertising and marketing of e-cigarettes.**

14. Our research into e-cigarette advertising and marketing shows that few businesses comply with all the advertising and marketing rules on e-cigarette. Digital marketing through Internet social media is still very prominent despite certain advertising and marketing restrictions.

**The impact to date of the Tobacco and Related Products Regulations on the vaping industry and on the prevalence of e-cigarettes.**

15. Initially, certain regulations – particularly the limit on refill container size (10ml) and notification requirements – impacted on a manufacturer’s product range. However, we have seen the emergence of ‘short-fill’ e-liquid products. Short-fills are nicotine-free refills typically sold in 60ml bottles that are under-filled by the manufacturer to allow room for the decanting of nicotine-containing e-liquid into the bottle after sale by the consumer. A consumer can purchase the short-fill with a flavour-free nicotine-containing e-liquid – known as a ‘nicotine shot’ - and combine the two to make a nicotine e-liquid refill.

16. Because short-fills do not contain nicotine, the rules and restrictions of the TPD do not apply and in our experience, businesses are moving from a TPD range to a short-fill and nicotine shot range which takes advantage of the associated benefits.

**The safety of e-cigarette devices, and any safety regulation requirements.**
17. No comment.

**Recommendation for action:**
- The emergence of short-fills and their safety should be a topic for discussion.

**On Financial**

*The economic impact of the UK’s e-cigarette industry.*

18. Although the implementation of TPD regulations initially increased compliance costs of manufacturers and impacted on the range of products, our research - with particular reference to e-liquids - suggests that short-fills will slowly replace the TPD range, and as such, we will see a return to the status quo (before the TPD). With particular reference to this development, we expect good growth for the e-cigarette industry.

*The public finances implications of e-cigarettes, including how the rise in e-cigarette consumption could affect NHS costs.*

19. No comment.

**Recommendation for action:**
None.

**On Government Policy**

*Views on whether Government policy and regulation has kept up with the full range of ‘smoking’ and novel tobacco products (such as ‘heat not burn’) that are becoming available to the public, and if it takes account of their likely impact on human health.*

20. Clinical data on e-cigarettes (including heat-no-burn) and their efficacy in smoking cessation is emerging periodically. In our opinion, government policy and regulation does largely reflect the data to date but they should be updated in accordance with new scientific data accordingly.

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