

Consultation questions about the proposed regulations and assessment of impact on business

ASH Wales is the only public health charity in Wales whose work is exclusively dedicated to tackling the harm that tobacco causes to communities. Further information about our work can be found at <http://www.ashwales.org.uk/>

We are engaged in a wide range of activities including:

- Advocating for tobacco control public health policy
- Undertaking tobacco control research projects
- Training young people and those who work with young people to provide factual information about the health, economic and environmental effects of smoking
- Engaging young people and professionals working with young people through the ASH Wales Filter project
- Bringing health information and advice to the heart of the community

We also oversee the Wales Tobacco or Health Network (a network of over 300 individual members) and the Wales Tobacco Control Alliance (an alliance of 35 voluntary and professional bodies in Wales), providing forums for sharing knowledge and best practice.

ASH Wales does not have any direct or indirect links to, or receive funding from, the tobacco industry.

1. Do you have any comments regarding the definition of nicotine inhaling products proposed in the regulations?

We support the definition of 'nicotine inhaling products' as 'any device intended to enable nicotine to be inhaled through a mouth piece'. This definition not only covers all e-cigarette devices and their refills but is also future-proofed to cover any novel devices designed to enable nicotine to be inhaled in addition to e-cigarettes.

We believe this is appropriate and proportionate. E-cigarettes are a specific type of nicotine-inhaling product. The product category is evolving and new technologies are developing so it is crucial that the definition be future-proofed. All nicotine inhaling products need to be included because:

- Inhaled nicotine products which have not been licenced as medicines are intended for recreational use which distinguishes them from licenced NRT products. Although as yet there is no evidence of widespread regular use amongst children and young people, experimentation has grown rapidly, trends in use are unpredictable and can change rapidly, and there is widespread concern about youth oriented marketing of these products.
- There is evidence (albeit much of it from animal models) that adolescence is a critical period of high sensitivity to the effects of nicotine. This is consistent with the evidence that few people who do not start smoking during adolescence later go on to do so. Therefore there is indirect evidence that regular nicotine use in adolescence might heighten the risk of subsequent nicotine dependence. In addition there are potentially irreversible consequences to the adolescent brain from nicotine use. Counotte, whose research is included in the Impact Assessment, concluded that *“nicotine exposure during adolescence can disrupt brain development bearing long-term consequences on executive cognitive function in adulthood.”*¹
- There is still insufficient evidence about the extent to which the vapour is absorbed through the lungs as opposed to the mouth in such products and what the long-term impact of lung absorption may be. The younger the age of uptake of inhaled nicotine products the greater the number of potential years of exposure so this is of particular concern with under 18s, who are not yet established smokers.
- Inhaled nicotine products have the potential to be faster acting than current licenced nicotine products which are absorbed primarily through the skin, mouth and oral mucosa, and therefore to be more addictive than current licenced NRT products.

2. Do you have any comments regarding the proposals for nicotine inhaling products that are medicines or medical devices?

We support the proposals that there should be exemptions for products that are authorised as medicines for use in smoking cessation or harm reduction by the MHRA either on prescription or on general sale, e.g. the Nicorette inhalator. It is for the MHRA to decide on the basis of the evidence whether or not such products can be sold over the counter to children under the age of 18. The MHRA has already decided that Voke, a novel inhaled nicotine product which has received marketing authorisation but is yet to be brought to market, can only be sold to those aged eighteen and under on prescription.

3. Do you have any comments regarding the enforcement arrangements proposed in the regulations, or any views or evidence on enforcement costs?

We support the enforcement arrangements set out in the regulations. They are consistent with the enforcement arrangements for tobacco products which will make them simpler and easier to implement, so making for better regulation.

4. Do you have any comments on the proposal to extend the current proxy purchase offence for tobacco to cover nicotine inhaling products?

We support the extension of the current proxy purchase offence for tobacco to cover nicotine inhaling products. This is consistent with the proposals for tobacco products which will make it simpler and easier to implement.

5. Do you have any additional evidence on the use of e-cigarettes by under 18s as a gateway in or out of smoking? For example, how a minimum age of sale for e-cigarettes would impact on current users aged under 18?

The Impact Assessment quotes ASH data on e-cigarette use in young people for 2013, which was included in a PHE publication (see point 16).

ASH have updated the information to give data for 2014. ² In 2013, just over two thirds (67%) of 11-18 year olds and 83% of 16-18 year olds had heard of electronic cigarettes. By March 2014, this had risen to 84% of 11-18 year olds and 90% of 16-18 year olds. Overall, of those children who were aware of e-cigarettes, the number of 11-18 year olds who have ever tried an electronic cigarette increased from 5% in 2013 to 8% in 2014. However, use is closely linked with smoking behaviour. Among children, sustained use is rare and generally confined to children who currently or have previously smoked. Eight percent (13% among 16-18 year olds) had tried electronic cigarettes at least once or twice. Two percent reported using them monthly or weekly. Among children who reported ever using electronic cigarettes, 33% had used them in the last month. Of those who had heard of e-cigarettes and had never smoked a cigarette, 98% reported never having tried electronic cigarettes and 2% reported having tried them “once or twice”. This provides good evidence that there is no regular use of electronic cigarettes among children who have never smoked or who have only tried smoking once. Furthermore, a 2014 ASH Wales survey of young people found less than 3% of never-smokers reported having tried an e-cigarette once or a few times, with e-cigarette usage and experimentation concentrated among smokers and experimenters. ³ It should be noted too that the evidence from these ASH surveys is consistent with that from other youth surveys in the UK for example the Smoking Drinking and Drug Use survey, ⁴ the Welsh CHETS survey ⁵ and the Scottish SALSUS survey. ⁶

In addition the Smoking Drinking and Drug Use survey from England found that the proportion of 11-15 year old smokers in 2013 were the lowest since records began in 1982 (1% of 13 year olds and 8% of 15 year olds) and continued to fall from 2009/10 onwards.

However, while at population level there is currently no evidence in support of the gateway effect, it is impossible to be certain that we will not see this in the future. Furthermore this is a rapidly evolving market which could change over time. Because of the potential risks (see answer to question 1 above) it is therefore appropriate to introduce age restrictions, but they should be reviewed in the light of the emerging evidence base.

6. Do you have any additional evidence that restricting the sale of nicotine inhaling products would contribute to reducing health inequalities and/or help us fulfil our duties under the Equality Act 2010?

More research is required to determine whether restricting the sale of nicotine inhaling products would contribute to reducing health inequalities. There is confusion about the relative risks of electronic cigarettes compared to smoking, not just amongst the general public but also amongst health professionals. It is very important to get the correct balance between discouraging non-smoking children under the age of 18 from using electronic cigarettes whilst at the same time not discouraging adults who do smoke from using electronic cigarettes as a smoking cessation aid.

It is therefore crucial that at the same time that the regulations are introduced, the Welsh Government also promote better understanding of the relative harm of electronic cigarettes and other nicotine products including those authorised as medicines and their potential benefit to smokers.

7. Do you have any information or evidence that would inform the consultation-stage impact assessment? We particularly welcome any evidence or information which would improve any of the assumptions or estimates we have made in terms of the impact on retailers, manufacturers and distributors, including our assessment of any loss of profits.

The ASH Smokefree Youth survey for 2014 cited in the answer to question 5 should be used to update the calculations in the Impact Assessment of lost profit to retailers.

However, it would be completely inappropriate for the decision on whether to proceed with the regulations to be made on the basis of whether or not there would be lost profits to retailers. Manufacturers and importers have already put a voluntary age restriction on these products because of the potential harm they could cause to young people. Such profits therefore only accrue from irresponsible sales to minors to the benefit of manufacturers, importers and retailers acting contrary to best practice. These regulations are supported by the DH, by the health community, by parliamentarians, and by manufacturers, importers and retailers of

these products, because they are appropriate, would set a level playing field and bring clarity to the market.

The Impact Assessment states that ECITA the electronic cigarette trade association has told DH that they support age of sale controls for e-cigarettes. From a cursory examination of the ECITA website as at 8th January 2015 they currently have 25 members. ⁷ Although this is only a minority of manufacturers and importers it represents many of those most concerned that there be effective regulation of the market to the benefit of manufacturers, importers, retailers and consumers.

Such restrictions are also supported by key trade bodies acting for small retailers. For example the Association of Convenience Stores (ACS) Chief Executive said at the launch of the DH consultation, *“The vast majority of our members already have a voluntary age restriction on these products in place, but this consultation will provide important clarity for all responsible retailers who sell these products and ensure that they have the support of legislation.”* ⁸ The National Federation of Newsagents says, *“The ban on selling e-cigarettes to under 18s was also welcomed by the Federation. Our members were already advised by us to apply the current age restrictions on tobacco to e-cigarettes, however enshrining this in legislation will certainly make it easier for a retailer to refuse a sale.”* ⁹

In Wales, Local Authorities are already taking steps to regulate the sale of electronic cigarettes to under 18s. For instance, in Pembrokeshire two-thirds of retailers which stock electronic cigarettes have signed up to a voluntary scheme prohibiting their sale to children under 18. In addition, out of the one-third of retailers not signed up to the ‘E-cigarette Responsible Retailer’ scheme in Pembrokeshire, the majority are national retailers who already have a similar arrangement in place. ¹⁰

8. Do you have any information or evidence that would improve any of the assumptions we have made in terms of the impact of these proposed regulations on small and micro businesses?

See answer to question 7.

9. Is there anything else you wish to tell us that you think would improve the draft regulations?

We recommend the addition of regulations to prohibit of the sale of nicotine-inhaling devices from self-service vending machines. It is already the case that sales of tobacco via self-service vending machines is prohibited. Prohibiting such sales is appropriate for all products with age of sale restrictions to ensure that the restrictions are effectively enforced.

There should be a review period built in to the regulations given that we are still at the early stages of development of the market for electronic cigarettes and the regulations should be reviewed in the light of the emerging evidence base.

References

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6. Scottish Government. *Scottish Schools Adolescent Lifestyle and Substance Use Survey 2013*. November 2014.

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10. <http://www.pembrokeshire.gov.uk/content.asp?nav=101,2212&id=31069> – accessed 08/01/2015.