ASH response to the consultation on the age of sale of nicotine inhaling products

ASH (UK) is a health charity set up by the Royal College of Physicians in 1971 working towards the elimination of harm caused by tobacco. ASH receives core funding from the British Heart Foundation and Cancer Research UK and has received project funding for work to support government tobacco strategy for England from the Department of Health (DH). ASH does not have any direct or indirect links to, or receive funding from, the tobacco industry other than a small number of shares in BAT and Imperial Tobacco to enable us to vote and ask questions at the Annual General Meetings (we don't accept tobacco company dividends).

This consultation response is endorsed by 39 other organisations, listed below, all of whom have also confirmed that they do not have any direct or indirect links to, or receive funding from, the tobacco industry. The only exceptions are some local authorities which have confirmed that any dealings they have with the tobacco industry conform with Article 5.3 of the FCTC. In addition, some local authorities' pension funds have investments in the tobacco industry although any benefit from this investment does not accrue to the council but to its employees and does not have a direct impact on the development of policy by councils.

Organisations endorsing ASH's response to this consultation:

ASH Scotland

Association of Respiratory Nurse Specialists

Asthma UK

Blackpool Council

Bristol City Council

Bristol Health & Wellbeing Board

British Dental Health Foundation

British Heart Foundation

British Lung Foundation

British Thoracic Society

Chartered Institute of Environmental Health

Devon County Council

Diabetes UK

Dudley Council

Dudley Health & Wellbeing Board

Hull City Council

Liverpool Community Health NHS Trust

London borough of Haringey

North Lincolnshire Smokefree Alliance

Nottinghamshire Strategic Tobacco Alliance

Rochdale Tobacco Free Alliance

Rotherham Tobacco Control Alliance

Royal College of Nursing

Royal College of Radiologists

Royal Society for Public Health

Shropshire Council

Somerset County Council

Smokefree Devon Alliance

Smokefree Lincs. Alliance

Smoke Free Northumberland Alliance

Smokefree Yorkshire and the Humber

Solutions4Health

South Gloucestershire Council

Tobacco-free Leicestershire & Rutland

Tobacco Free Luton

Tobacco Free Futures

The Big Life Group

University Hospitals of Leicester

Warrington Borough Council Public Health Team

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'. 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 electronic cigarettes.

We believe this is appropriate and proportionate. Electronic 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."* [Counotte, D. et al. (2011). "Development of the motivational system during adolescence, and its sensitivity to disruption by nicotine" in Developmental Cognitive Neuroscience; 2011; 1 (2011), pp.430-443.]
- 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 tobacco 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 support implementation which is straightforward, fair and consistent, 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 support implementation which is straightforward, fair and consistent.

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).

We have now updated the information to give data for 2014. 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 electronic 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 electronic 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. It should be noted too that the evidence from the ASH survey is consistent with that from other youth surveys in the UK for example the Smoking Drinking and Drug Use survey, the Welsh CHETS survey and the Scottish SALSUS survey.
(ASH. Use of Electronic Cigarettes in Great Britain. October 2014.)

In addition the Smoking Drinking and Drug Use survey from England which 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 evidence against the gateway effect, it is impossible to be certain that we will not see this or that a very few individuals do transition

from electronic cigarettes to tobacco cigarettes. 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.

Given the low level of regular use by under 18s there is unlikely to be a significant impact on current underage users.

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?

We are concerned that there is confusion about the relative risks of electronic cigarettes compared to smoking, not just amongst the general public but also amongst health professionals. See for example an article in the Daily Telegraph on 27th August 2014 headlined *'I thought my e-cigarette was a miracle. Turns out, I was smoking the equivalent of 40-a-day'* The author of the article in question says she was given this impression by her doctor.

Such confusion also exists for nicotine products per se. Many smokers wrongly believe that it is nicotine rather than tobacco smoke that harms them and so worry that pure nicotine products are potentially harmful. Half of smokers in the UK mistakenly think that nicotine is the chemical which causes most of the cancer contracted by smokers.
(Siahpush M, McNeill A, Hammond D, Fong GT. Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke: results from the 2002 International Tobacco Control (ITC) Four Country Survey. Tobacco Control, Jun 2006; 15: iii65 - iii70).

Many health professionals are also unclear about the relative risks of tobacco and nicotine. In one study, a substantial proportion of GPs incorrectly asserted that nicotine in cigarettes causes CVD (51%), strokes (49%) and lung cancer (41%)
(Bobak A. Perceived safety of nicotine replacement products among general practitioners and current smokers in the UK: impact on utilization. Presented at the UK National Smoking Cessation Conference, 9th June 2005.)

This confusion could be exacerbated by the adoption of an age of sale of 18 which, because it is the same age as for cigarettes risks giving the erroneous message that electronic cigarettes are just as harmful as smoked tobacco.

To summarise *"Smokers smoke for nicotine but are killed by smoke, and despite uncertainty over the potential hazard to health from the nicotine vapour produced by e-cigarettes, any such hazard is evidently minimal in relation to that arising from inhaling tobacco smoke"* (Britton J, Bogdanovica I, Ashcroft R, McNeill A. Electronic cigarettes, smoking and population health. Clinical Medicine. Royal College of Physicians. 2014.) In addition the Cochrane Collaboration has recently published a review which finds emerging evidence that smokers who use electronic cigarettes can stop or reduce their smoking. (McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. Cochrane Database of Systematic Reviews 2014, Issue 12. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub2.)

It is therefore crucial that at the same time that the regulations are introduced the DH 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. (NICE Tobacco: Harm reduction approaches to smoking. Public Health Guidance PH45, 2013)

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 distributers, including our assessment of any loss of profits.

The ASH Smokefree Youth survey for 2014 cited in the answer to Q5 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 the electronic cigarette trade association, ECITA, has told DH that they support age of sale controls for electronic cigarettes. From a cursory examination of the ECITA website as at 2nd January 2015 they currently have 27 members. Although this is only a minority of manufacturers and importers it represents many of those most concerned that there should 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."* 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."* (NFRN Public Affairs Manifesto 2015)

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 Q7.

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.