Discussion paper on harm reduction and electronic cigarettes

Purpose of this paper

1. This paper provides a background to the evolution of harm reduction and electronic cigarettes in the UK to inform a discussion about what we might be able to say in the Smoking Still Kills report, our new strategy report due to be published in 2015. ASH believes that sustaining the public health consensus on harm reduction as set out in Beyond Smoking Kills in 2008 and backed by the publication of NICE guidance in 2013 is essential.

2. Sustaining consensus will not necessarily be easy, as there are a wide variety of opinions about electronic cigarettes both at individual and at organisational level. It is important to understand the history and philosophy behind the opposition and the uneasiness even some supporters have for 'harm reduction', so the paper goes into some detail on this.

3. We need to examine carefully what we can reach agreement on, stretching from principles via regulatory objectives to specific regulatory options. I believe that we can and must gain agreement on principles, that we may be able to gain agreement on regulatory objectives, but that it may not yet be possible to gain consensus on a list of specific regulatory proposals in our report.

4. Indeed given the evolving evidence base it may be more appropriate to let agreement over regulatory measures evolve over time rather than try to set it in stone in a report. The one specific regulatory option so far that has general acceptance on all sides of the debate is the need to prohibit sales to minors. But, for example, there is a diversity of opinion about whether or not electronic cigarettes should come under smokefree laws.

5. While this paper reflects on the evidence base it is largely an exploration of policy issues and key principles. The RCP and the academic community will focus on the evolving evidence base and the RCP is planning to update its 2007 report on tobacco harm reduction which will be very useful. There are references to further sources for evidence throughout this document.

Current Situation

6. The current situation with little or no regulation of electronic cigarettes other than the basic consumer protection laws provided by the General Product Safety Directive of the EU has allowed electronic cigarette sales to grow rapidly from their UK launch in

2008 with some evidence of benefit to smokers who have used them to switch or quit.

7. However, this situation will be replaced by 2016 by regulation under the EU Tobacco Product Directive or medicines licensing. Our goal is to ensure that regulation evolves in such a way as to maximise the benefit, to smokers, and minimise the risks, of uptake amongst youth and non-smokers. As we develop our approaches dialogue across the public health community will be key.

8. Recently we've seen the licensing by the MHRA of a novel nicotine inhaler which will, in coming months, be put on sale by a tobacco company, BAT. Before too long we are likely to see a more traditional electronic cigarette get a medicines licence. The revised CAP advertising code has now been published; the WHO FCTC Conference of the Parties has come out with a decision recommending that governments prohibit or regulate electronic cigarettes; and development of the regulations implementing the EU Tobacco Products Directive will take place during 2015 for implementation in 2016. These are the events we know about, plus there will inevitably be others as yet unknown.

9. In conclusion this is a fast moving area – and much could influence the policy process between now and 2016. Taking the time now to think through the core principles the public health community agrees on in relation to harm reduction and electronic cigarettes will help us to navigate the uncertainties of the future.

Principles of harm reduction

10. Those committed to eliminating the harm caused by smoking line up along the continuum of belief about the risks and benefits of electronic cigarettes. It's important that we all acknowledge the need to adjust our opinions in the light of the emerging evidence. However, what would be helpful is to have a clear idea of what we hope to achieve and what are the principles and objectives which should underpin a tobacco harm reduction approach and the evolving regulatory framework.

11. Set out below are the principles agreed by the Framework Convention Alliance and set out in its briefing paper for the sixth session of the WHO Framework Convention on Tobacco Control[1]:

    - The global burden of death and disease from tobacco is primarily caused by smoking.
    - While quitting tobacco use is paramount, quitting nicotine use altogether is the best option.
    - For those unable to quit, switching to alternative sources of nicotine that are less harmful than tobacco can reduce, often very substantially, the harm smoking causes to the individual.
    - The benefits of such an approach would be maximized if uptake were limited to existing smokers who are unable to quit.
    - The risks of such an approach would be minimized by limiting uptake by never-smokers, in particular amongst young people, and by taking measures to protect

[1] Framework Convention Alliance. Policy briefing: Electronic Nicotine Delivery Systems. October 2014.

non-users and discourage long-term dual use.
- There could be negative unintended consequences from over-regulation just as there could be from under-regulation.
- The involvement of tobacco companies in the production and marketing of electronic cigarettes is a matter of particular concern as there is an irreconcilable conflict of interest between those profiting from the sale of tobacco and public health.

12. The Framework Convention Alliance is a coalition of more than 350 non-government organisations from over 100 high, middle and low income countries, whose mission is to help strengthen the WHO FCTC and support its full and accelerated implementation worldwide. The Alliance is the most influential voice for civil society at the FCTC Conference of the Parties. These principles are set out in a briefing paper which was developed by consensus. I was very involved in their development and strongly support them as I hope the SFAC will be able to do too.

13. One of the criticisms made of electronic cigarettes is that those interested in harm reduction have lost the essential focus which needs to be on eliminating tobacco use. What these principles make very explicit is that harm reduction is only one element of a strategy with exactly that overarching aim.

14. The risk of over-regulation, as set out in the principles, is an area that has received less attention than the discussion of under-regulation. It is worth pointing out that long-term smokers in middle age are the group at most immediate risk of premature death from smoking-related disease[2], and therefore are the group most in need of interventions that will help them to quit. To quote Richard Peto, *"… Thus, using widely practicable ways of helping large numbers of young people not to become smokers could avoid hundreds of millions of tobacco-related deaths in the middle and second half of the twenty-first century, but not before. In contrast, widely practicable ways of helping large numbers of adult smokers to quit (preferably before middle age, but also in middle age) might avoid one or two hundred million tobacco-related deaths in the first half of this century."*

Goals of the tobacco control movement and how this impacts on attitudes to harm reduction

15. The tobacco control movement has not just been dedicated to its primary goal of eliminating the harm caused by tobacco. There have been two subsidiary goals, which are to eliminate nicotine addiction and to destroy the tobacco industry, seen as uniquely evil because of its behaviour over the last century in promoting uptake of smoking in full knowledge of the deadly nature of the products it produces.

16. Historically these three goals were not in conflict and the major tools in reduction in the supply and demand for tobacco were equally valid for all three objectives. However, by the end of the last century it became increasingly clear that while population smoking rates had been declining over many years, some groups, in particular the poor, the disadvantaged and those with mental health problems, for

[2] Peto, R. Future worldwide health effects of current smoking patterns. In: IARC Monographs on the Carcinogenic risk to humans. Vol 83: Tobacco smoke and involuntary smoking. IARC, 2002. http://monographs.iarc.fr/ENG/Monographs/vol83/mono83-5.pdf

example, were being left behind. And that these were groups with the highest levels of nicotine addiction who find it hardest to quit.

17. In response to this a debate started within the tobacco control community about the need for a harm reduction approach in order to enable smokers unable to quit to have access to alternative less harmful forms of nicotine. This required a reassessment of the first subsidiary goal, to eliminate nicotine addiction, and an acceptance that while quitting completely is always the best option, for some smokers it may not be possible, and in these cases an alternative was needed. The UK has been in the forefront of this analysis and debate.[3]

18. One of the first major debates around the promotion of an alternative 'safer' product was about a product called snus. Snus is a relatively low risk tobacco product banned in Europe since the 1980s following an active campaign by the public health community against an American oral snuff called Skoal Bandits which was being manufactured in Scotland and promoted to youth.

19. Although banned in Europe it is still legal in Sweden, which had an exemption from the ban, because of widespread traditional use of the product. The widespread use of snus by Swedish men (estimated at 30% of Swedish male ex-smokers), displacing tobacco smoking, is responsible for the incidence of tobacco-related mortality in men being significantly lower in Sweden than any other European country.

20. While the debate on snus didn't find consensus in the UK, it did prompt the exploration of an alternative approach to harm reduction based on medicinal nicotine. ASH, Department of Health, MHRA, NICE, the Royal College of Physicians, the UK Centre for Tobacco and Alcohol Studies and others have for some years been discussing and developing an approach along these lines.

21. In 2008 ASH published, Beyond Smoking Kills, it included a chapter on alternatives to smoking. The majority of the public health community, including the major health charities, the medical royal colleges and public health organisations such as the Faculty of Public Health, the Association of Directors of Public Health, and the Chartered Institute of Environmental Health signed up to a 'harm reduction' approach to smoking, the evidence base for which had been provided in the previous year's seminal report 'Harm Reduction in Nicotine Addiction' by the Royal College of Physicians.[4]

22. The core principle remained that quitting is always the best option, however, it was accepted that for smokers unable to quit, and in particular for the most disadvantaged smokers in society, '*the promotion of wider access to pure nicotine products as an alternative to smoking is an important means of tackling health inequalities.'* The report called on government to *'[d]evelop a strategy and an appropriate regulatory structure to improve the acceptability, attractiveness and accessibility of pure nicotine products for use as an alternative to smoking for those who are currently unable or unwilling to quit'.*

[3] Royal College of Physicians of London Tobacco Advisory Group. Protecting smokers, saving lives: the case for a tobacco and nicotine regulatory authority. London: RCP; 2002.
[4] Royal College of Physicians of London. Tobacco Advisory Group. Harm reduction in nicotine addiction: helping people who can't quit. London: RCP; 2007.

Evolution of policy since Beyond Smoking Kills and impact of electronic cigarettes

23. In 2008 when the report was launched, electronic cigarettes had only recently been launched in the UK market, the term 'electronic cigarette' was not in common parlance, usage was still negligible and the products were widely believed in the public health community to be ineffective and an unlikely competitor to cigarettes. Hardly surprising as the cost of the product recently launched in the UK in May 2008 and referred to in our report, was £79 for the equivalent in nicotine dose of less than a packet of twenty cigarettes.[5]

24. Even in 2010 and 2011 when first the Labour Government[6] and then the successor Coalition Government[7] took on board the BSK recommendation in their tobacco strategies, electronic cigarettes still did not merit a mention. Both governments focused on the principle with the current government strategy stating only that, *"We will work in collaboration with the public health community to consider what more can be done to help tobacco users who cannot quit, or who are unwilling to, to substitute alternative safer sources of nicotine, such as NRT, for tobacco."* There was also a commitment to the development of NICE guidance on such an approach.

MHRA licencing of nicotine

25. There was a growing understanding of the relative risks of smoking and alternative nicotine sources by the medicines regulator, the MHRA from 2005 on. The remit of the MHRA includes as one of its three key aims, *"Improving public health by encouraging and facilitating developments in products that will benefit people."* [8] In line with this remit over the last decade the organisation has revised the way that it licences medicinal nicotine products taking into account that it is now widely accepted that there are no circumstances in which it is safer to smoke than to use NRT.[9] The licence indications included[10]:
    - Adolescents of 12 years and over;
    - Pregnant women – although they should be encouraged to stop smoking without NRT if possible;
    - Smokers with cardiovascular disease – although for those with the severest forms, NRT should be initiated under medical supervision;
    - Combination therapy (use of more than one product at once);
    - Cutting down as a "stepping stone" to quitting completely for smokers unable to stop abruptly;
    - Temporary abstinence; and
    - All nicotine replacement therapy medicines can be made available for general sale over the counter and are not limited only to pharmacies.

[5] http://www.gizmag.com/supersmoker-electronic-cigarette-uk/9379/
[6] Department of Health. A smokefree Future. February 2010.
[7] Department of Health. Healthy Lives, Healthy People: A tobacco control plan for England. March 2011
[8] http://www.mhra.gov.uk/Aboutus/Whoweare/
[9] http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON065626
[10] http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087732

26. The biggest single step, however, was taken in 2010 when the MHRA licensed NRT for harm reduction including long-term partial or complete substitution of smoking.[11] By that time electronic cigarettes were established in the market and their use was beginning to take off, around 8% of smokers had tried them. The MHRA recognised that by licensing NRT for long-term use electronic cigarettes potentially came within the regulatory remit and so they consulted on whether or not they should be required to have a medicines authorisation before being sold.

27. ASH, the RCP and others recommended that this should not happen overnight as it risked forcing users back to smoking and these responses were backed up by large numbers of responses from electronic cigarette users making the same point. The MHRA therefore decided to allow electronic cigarettes to remain on the market while they carried out more research.

NICE guidance on Tobacco Harm Reduction

28. NICE developed guidance on tobacco harm reduction[12] which recognised that although quitting is always the best option for smokers that there are other ways of reducing the harm from smoking, even though this may involve continued use of nicotine. This guidance is about helping people, particularly those who are highly dependent on nicotine, who:
    - may not be able (or do not want) to stop smoking in one step
    - may want to stop smoking, without necessarily giving up nicotine
    - may not be ready to stop smoking, but want to reduce the amount they smoke.

29. The NICE guidance took two years to develop having spent considerable time and resource examining the evidence before being published in June 2013. It recommends harm-reduction approaches which include temporary or long-term use of licensed nicotine-containing products. While dual use of nicotine products while smoking was not found to be beneficial in and of itself, the evidence showed that dual users were more likely to go on to quit which was beneficial.

30. The group developing the guidance thought long and hard about whether it could recommend the use of unlicensed products such as electronic cigarettes. In the end it did not, recognising that it would not be appropriate for NICE to do so given that these products had not met regulatory standards and were of uncertain quality and efficacy. However, the NICE group did recognise that users who had found them effective should not be discouraged from using them and that using them was better than smoking. [13]

31. While the NICE guidance was still under development the draft EU Tobacco Products Directive was published in December 2012[14] which required medicines regulation for all electronic cigarettes except those with very low levels of nicotine.[15]

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[11] MHRA information on nicotine containing products web page with links.
[12] http://www.nice.org.uk/guidance/PH45
[13] Hope, J. Cut down if you can't quit: Doctors concede that some smokers just can't stop - and that gum and patches are safe alternative. Daily Mail. 5 June, 2013.
[14] http://europa.eu/rapid/press-release_IP-12-1391_en.htm
[15] http://ec.europa.eu/health/tobacco/docs/com_2012_788_en.pdf

32. The MHRA position also published in May 2013 supported medicines regulation for electronic cigarettes but prohibition of unlicensed products was held up until the EU Tobacco Products Directive came into effect.

33. However, by this time the price of electronic cigarettes had plummeted making them competitive with cigarettes and their popularity soared. An active campaign by electronic cigarette users and others led to the Directive being revised to allow for nicotine products up to 20 mg/ml to come under the Directive rather than be licensed as medicines. The Directive has now passed by the EU and will come into effect in May 2016.

34. Electronic cigarettes are now widely recognised as 'disruptive technology' which some investment analysts are predicting could overtake cigarette sales in the next decade.[16] The tobacco industry has recognised the potential threat to their current business model and moved in with the result that many in the public health community – supportive of harm reduction in principle - have understandably become very alarmed. Some organisations which were supportive of tobacco harm reduction have now become much more cautious about the potential risks of such an approach.

35. In England, Public Health England has now begun to take a leadership role and held a national symposium in March on the issue, and is continuing to work to ensure that the public health profession takes a considered view.[17]

36. The regulatory position that we have ended up with in Europe with electronic cigarettes under 20 mg/ml of nicotine coming under the TPD while those above or unable to meet other requirements of the TPD only allowed on the market if they have received marketing authorisation as medicines is problematic. If medicines regulation cannot be made flexible enough there is a risk that products that are working to help users quit smoking are forced off the market and that their users will revert to smoking.

37. In the US the Food and Drugs Administration has consulted on how it should regulate e-cigarettes. The consultation finished on the 8th August and given the threat of legal action it could well take a year before the final regulations are issued. From the draft regulations the US is likely to end up with a similar twin track approach to the UK and Europe. [18]

38. We have now seen the first medicinally licensed alternative nicotine product, a nicotine inhaler called Voke. This will be brought to market by a tobacco company; British American Tobacco. BAT has also made public that it is taking a more traditional electronic cigarette through the licensing process, but as yet it is not clear whether any other companies will follow suit.

Committee on Advertising Practice: rules on advertising electronic cigarettes

[16] http://www.cnbc.com/id/100991511#.
[17] https://publichealthmatters.blog.gov.uk/2014/05/21/e-cigarettes-and-harm-reduction-where-are-we-now-and-what-next/
[18] FDA proposed deeming regulation published 25th April 2014

39. In summary the new rules, published on 9th October 2014, state that[19]:
    - Ads must not be likely to appeal particularly to people under 18, especially by reflecting or being associated with youth culture.
    - People shown using e-cigarettes or playing a significant role must neither be, nor seem to be, under 25.
    - Ads must not be directed at people under 18 through the selection of media or the context in which they appear.
    - Ads must not encourage non-smokers or non-nicotine users to use e-cigarettes.
    - Ads must make clear that the product is an e-cigarette and not a tobacco product.

40. ASH was pleased that the prohibition on marketing communications that promote associations with tobacco and tobacco brands was strengthened. We are also pleased that all radio ads will require central copy clearance, which is already in effect the case for TV ads.

41. However, we were disappointed that celebrity endorsement and free samples are not prohibited as we had proposed and believe that the impact of this decision needs to be monitored carefully. ASH strongly supported the decision to review the rules after 12 months as we believe that electronic cigarette advertising regulation needs to keep pace with changes in the market. If any electronic cigarette advertisements are of concern to those in the public health community, the opportunity is there to make formal complaints via the ASA complaints procedure[20] and any such complaints can also be fed into the review process.

WHO Framework Convention on Tobacco Control

42. In August the WHO published a report on ENDS (electronic nicotine delivery systems, more commonly known as electronic cigarettes) for discussion by the WHO Framework Convention on Tobacco Control Conference of the Parties meeting in October. Parties to the WHO FCTC were asked to note the report and '*provide further guidance'*.[21] This report gained a great deal of publicity, headlines such as '*WHO urges stiff regulatory curbs on e-cigarettes'*.[22] It is worth noting that the report is more nuanced than the media coverage has been. Paragraph 2 states, *"ENDS, therefore, represent an evolving frontier, filled with promise and threat for tobacco control."*

43. The Framework Convention Alliance (FCA)[23] developed a consensus position in advance of the COP on the principles which should underpin any regulatory system. In the case of e-cigarettes, the FCA was not convinced the evidence base or national experience exists to definitively recommend, at the global level, a detailed list of specific approaches to many of the complicated regulatory issues these products raise.[1]

44. The COP agreed with the FCA that global guidelines are not yet feasible but did invite *"Parties to consider prohibiting or regulating ENDS/ENNDS[24], including as*

[19] CAP and BCAP. New rules for the marketing of e-cigarettes. October 2014.
[20] ASA complaints procedure. http://www.asa.org.uk/Consumers/How-to-complain.aspx
[21] Electronic nicotine delivery systems: Report by WHO.
[22] http://www.reuters.com/article/2014/08/26/us-health-who-ecigarettes-idUSKBN0GQ0PF20140826
[23] The Framework Convention Alliance (FCA) is a coalition of nearly 500 civil society organisations in over 100 countries dedicated to the development and implementation of the WHO FCTC.
[24] electronic non-nicotine delivery systems (ENNDS)

tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health". In addition WHO has been asked to prepare a further report on electronic cigarettes for the seventh session of the Conference of the Parties with an update on the evidence of the health impacts, potential role in quitting tobacco usage, methods to measure contents and emissions of these products, impact on tobacco control efforts and policy options.

Conclusions

45. So far the UK has been in the forefront of tobacco harm reduction policy development globally and the SFAC has played a role in ensuring that is the case. This will continue to be a priority in coming years if we are to ensure that policies in this area continue to evolve in order to maximise the potential benefits as well as minimise the potential risks. Set out below is the draft principles as endorsed by the Framework Convention Alliance, which ASH hopes we can all endorse.

Principles to guide policy on tobacco harm reduction and electronic cigarettes:

1. The global burden of death and disease from tobacco is primarily caused by smoking.
2. While quitting tobacco use is paramount, quitting nicotine use altogether is the best option.
3. For those unable to quit, switching to alternative sources of nicotine that are less harmful than tobacco can reduce, often very substantially, the harm smoking causes to the individual.
4. The benefits of such an approach would be maximized if uptake were limited to existing smokers who are unable to quit.
5. The risks of such an approach would be minimized by limiting uptake by never-smokers, in particular amongst young people, and by taking measures to protect non-users and discourage long-term dual use.
6. There could be negative unintended consequences from over-regulation just as there could be from under-regulation.
7. The involvement of tobacco companies in the production and marketing of electronic cigarettes is a matter of particular concern as there is an irreconcilable conflict of interest between those profiting from the sale of tobacco and public health.

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