

**National Institute for Health and Clinical Excellence**

**Public Health Guidance – Tobacco Harm Reduction  
 Consultation on the Draft Guidance from 24<sup>th</sup> October 2012 – 19<sup>th</sup> December 2012  
 Comments to be received no later than 5pm on 19<sup>th</sup> December 2012**

**Stakeholder Comments**

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<b>Organisation:</b>		<b>Philip Morris Limited</b>
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General		Philip Morris Limited and its parent company, Philip Morris International (PMI), agree that the best way to reduce the harm of tobacco use is to prevent initiation and encourage cessation. However, despite the well-known health effects of tobacco use, many people continue to smoke and use other tobacco products. While rates of smoking have continued to decline over the past decade, 21 per cent of adults in England still smoke, and smoking prevalence has fallen little since 2007. (HM GOVERNMENT, A SMOKEFREE FUTURE: A COMPREHENSIVE TOBACCO CONTROL STRATEGY FOR ENGLAND (2010).) Tobacco harm reduction policies should therefore complement prevention and cessation objectives.
General		We agree with the draft guidance's recognition that not everyone intends to or is able to stop smoking. We think it is important that these people should have access to scientifically substantiated and regulated reduced harm products as alternatives to conventional tobacco products.
Introduction: Scope and purpose of this draft guidance - What is this guidance about?	1	We note that products containing tobacco are outside the scope of the draft guidance. As a number of public health authorities and tobacco control advocates have expressed, "smokers have a right to be able to obtain and choose from a range of safer nicotine products, and they have a right to accurate and unbiased information to guide that choice." (Royal College of Physicians Tobacco Advisory Group, HARM REDUCTION IN NICOTINE ADDICTION: HELPING PEOPLE WHO CAN'T QUIT, 223 (2007).)
Introduction: Scope and purpose of this draft guidance - What	1	A growing number of academics and public health experts have called upon governments and public health institutions to recognise that tobacco products that eliminate combustion could

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is this guidance about?		reduce the harm caused by tobacco use. (Phillips, C. V., & Heavner, K. K. "Smokeless Tobacco: The Epidemiology and Politics of Harm," 14 BIOMARKERS 79-84 (2009); Phillips, C.V., Guenzel, B., & Bergen, P. "Deconstructing Anti-Harm-Reduction Metaphors; Mortality Risk from Falls and Other Traumatic Injuries Compared to Smokeless Tobacco Use," 3 HARM REDUCTION JOURNAL (2006), art no. 15.) Consequently, excluding tobacco products from the scope of the guidance and future policies on tobacco harm reduction is inconsistent with the objectives of the guidance and the desire to develop effective tobacco harm options for the NHS and members of the public. In assessing the effectiveness of reduced harm products, Government should focus on scientific evidence of harm reduction rather than whether the products contain tobacco or not.
Introduction: Scope and purpose of this draft guidance - What is this guidance about?	1	Nicotine replacement therapies (NRTs), used with or without counselling, have not meaningfully improved smokers' long-term chances of successfully quitting smoking. (HM Government, A SMOKEFREE FUTURE: A COMPREHENSIVE TOBACCO CONTROL STRATEGY FOR ENGLAND, 11 (2010) (noting that fewer than 3% of smokers succeed in quitting each year). <i>See, e.g.</i> , Alpert, H., Connolly, G. and Biener, L., "A Prospective Cohort Study Challenging the Effectiveness of Population-Based Medical/Intervention for Smoking Cessation," TOBACCO CONTROL (2012); <i>see also</i> Ferguson, J. et al, "Effect of Offering Different Levels of Support and Free Nicotine Replacement Therapy via an English National Telephone Quitline: Randomised Controlled Trial," BMJ 344:e1696 (March 23, 2012).)
Introduction: Scope and purpose of this draft guidance - What	1	There is increasing recognition—including amongst representatives of the Royal College of Physicians and the UK Centre for Tobacco Control Studies—that smokers who are

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is this guidance about?		unwilling or unable to quit should have access to and should be encouraged to use reduced harm alternatives to conventional cigarettes. (HM Government, A SMOKEFREE FUTURE: A COMPREHENSIVE TOBACCO CONTROL STRATEGY FOR ENGLAND (2010); Royal College of Physicians Tobacco Advisory Group, HARM REDUCTION IN NICOTINE ADDICTION: HELPING PEOPLE WHO CAN'T QUIT, 223 (2007).)

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Introduction: Scope and purpose of this draft guidance - What is this guidance about?	1	<p>Although a range of nicotine-containing products may fall within the scope of the current draft guidance, the Institute should anticipate that other novel products, including tobacco-containing products, could also play an important role in harm reduction. Although tobacco-containing products are outside the scope of the current draft guidance, the Institute should continue to assess and consider expanding the scope of the guidance.</p> <p>For example, PMI is developing a range of products which have the potential to reduce risk in adult smokers who switch to them from conventional cigarettes. These products include both non-tobacco-containing platforms within the scope of the guidance and tobacco-containing platforms outside its scope. PMI's approach is to eliminate combustion and limit or eliminate pyrolysis while still providing adult smokers with products that they will accept as substitutes for conventional cigarettes. PMI believes that such products have the potential to significantly benefit public health, given that they are likely to be more acceptable substitutes for conventional cigarettes to a much wider group of smokers than current alternatives, because they come closer to replicating the sensory experience and ritual of conventional cigarettes without generating many of the harmful compounds found in cigarette smoke. Allowing such products to be marketed could achieve greater levels of harm reduction than would otherwise be achieved with the products currently contemplated by the draft guidance.</p>

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Introduction: Scope and purpose of this draft guidance - What is this guidance about?	1	Reduced harm nicotine-containing products and tobacco-containing products should be regulated, based on robust scientific evidence. For example, PMI is rigorously assessing the tobacco-containing products it is developing by conducting physical and chemical analysis of the product aerosol, <i>in vitro</i> and <i>in vivo</i> toxicological assays, and short- and long-term clinical research, with the objective of substantiating that using the products instead of conventional cigarettes reduces the risks associated with smoking and, in fact, achieves short- and long-term indicators in line with smoking cessation. PMI's product design takes place within a structured quality management environment, and manufacturing processes are well documented and include controls of critical quality attributes in order to consistently deliver a product with predefined characteristics.
Draft Recommendations – Using nicotine without tobacco	7	We agree that nicotine-containing products have a role to play in harm reduction, especially where the nicotine-containing product delivers nicotine in a quantity and manner that is acceptable to smokers but without exposing smokers to many harmful or potentially harmful smoke constituents. As described above, we believe that scientifically substantiated tobacco-containing products can also play a role and should be considered in the scope of this consultation and in harm reduction policies.

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Draft Recommendations – Using nicotine without tobacco	7	Nicotine-containing products will only be effective substitutes for cigarettes if they are accepted by adult smokers. (Cobb, C., Weaver, M., Eissenberg, T., "Evaluating the Acute Effects of Oral, Non-Combustible Potential Reduced Exposure Products Marketed to Smokers," 19 TOBACCO CONTROL 367-73 (2010); see also Le Houezec, J., Mcneill, A., and Britton, J., "Tobacco, Nicotine and Harm Reduction," 30(2) DRUG & ALCOHOL REVIEW 119-23 (2011).) Many NRTs and other nicotine-containing products fail to replicate the sensory experience and ritual of smoking; as a result, many smokers do not accept them. An additional limitation of existing products is "the fact that no available licensed nicotine-containing product mimics the pharmacokinetic nicotine delivery characteristics of the cigarette." (UK Centre for Tobacco Control Studies, Response to Consultation "MLX 364: Regulation of Nicotine Containing Products," available at: <a href="http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con102949.pdf">http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con102949.pdf</a> .)

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Recommendation 1 – Raising awareness of nicotine-containing products to reduce the harm from smoking	9	<p>PMI supports this recommendation's recognition that significant efforts need to be made to raise adult smokers' awareness and understanding of alternative, less harmful products in order to reduce the harm from smoking. Many smokers have been unwilling to accept NRTs as real substitutes for conventional cigarettes, for a range of reasons. (See Le Houezec, J., McNeill, A., and Britton, J., "Tobacco, Nicotine and Harm Reduction," 30(2) DRUG &amp; ALCOHOL REVIEW 119-23 (2011); Royal College of Physicians Tobacco Advisory Group, HARM REDUCTION IN NICOTINE ADDICTION: HELPING PEOPLE WHO CAN'T QUIT (2007).) Beyond nicotine levels, discussed previously, additional impediments include "ignorance of the relative health hazards of medicinal and smoked nicotine, the high cost of medicinal nicotine products, [and] the limited availability and attractiveness of medicinal products." (UK Centre for Tobacco Control Studies, Response to Consultation "MLX 364: Regulation of Nicotine Containing Products," available at: <a href="http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con102949.pdf">http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con102949.pdf</a>.)</p> <p>Similar impediments would need to be overcome for tobacco-containing reduced harm products. The draft guidance has identified much of the key information that adult smokers should receive, and in particular PMI agrees with the need to remind or inform the public that "most health problems are almost entirely caused by other [constituents in cigarette smoke], not by the nicotine."</p>
Recommendation 1 – Raising awareness of nicotine-containing	9	Many smokers do not understand that nicotine plays little, if any, role in causing smoking-related disease. (Weinstein, N., Slovic, P., Gibson, G., "Accuracy and Optimism in Smokers' Beliefs

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products to reduce the harm from smoking		<p>About Quitting," 6 NICOTINE AND TOBACCO RESEARCH Suppl. 375-80 (2004.) Despite the availability of NRTs for over 25 years and high awareness of these products, one third of adult smokers in the UK are concerned that NRTs are just as harmful as cigarettes. (Borland, R., McNeill, A., O'Connor, R., Cummings, M., "Trends in Beliefs About the Harmfulness and Use of Stop-Smoking Medications and Smokeless Tobacco Products Among Cigarettes Smokers: Findings from the ITC Four-Country Survey," 8 HARM REDUCTION JOURNAL, art. 21 (2011).) In a survey by Ferguson, 69% of the participants did not know that NRTs are not as dangerous as cigarettes. (Ferguson, S., Gitchell, S., Shiffman, S., Sembower, M., "Providing Accurate Safety Information May Increase a Smoker's Willingness to Use Nicotine Replacement Therapy as Part of a Quit Attempt," 36 ADDICTIVE BEHAVIORS 713-16 (2011).)</p> <p>There is significant confusion about the role of nicotine in tobacco-related harm. (Borland, R., McNeill, A., O'Connor, R., Cummings, M. "Trends in Beliefs about the Harmfulness and Use of Stop-Smoking Medications and Smokeless Tobacco Products Among Cigarettes Smokers: Findings from the ITC Four-Country Survey," 8 HARM REDUCTION JOURNAL, art. 21 (2011).) Cummings demonstrated that 67% of people think nicotine is the main cause of tobacco-related cancers (Cummings, K., Hyland, A., Giovino, G., Hastrup, J., Bauer, J., Bansal, M., "Are Smokers Adequately Informed About the Health Risks of Smoking and Medicinal Nicotine?," 6 NICOTINE AND TOBACCO RESEARCH Suppl. 333-40 (2004).), and Borelli found this is the case in 59% of nurses. (Borrelli, B., Novak, S., "Nurses' Knowledge About the Risk of Light Cigarettes and Other Tobacco 'Harm Reduction' Strategies," 9 NICOTINE &amp; TOBACCO RESEARCH 653-61 (2007).)</p>



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Recommendation 1 – Raising awareness of nicotine-containing products to reduce the harm from smoking	9	Public health communications have not always differentiated nicotine from the harmful substances in cigarette smoke, potentially making it difficult for smokers themselves to differentiate less harmful products from cigarettes. Clarifying the role of nicotine in cigarettes may, in turn, make it easier to explain the role and properties of nicotine, and may aid in addressing concerns surrounding reduced harm products.
Recommendation 1 – Raising awareness of nicotine-containing products to reduce the harm from smoking	9	It can be challenging to communicate about the relative risk of a less harmful product compared to a conventional cigarette, while still communicating that cessation is the best way for a person to reduce the risk of smoking-related disease. Qualitative and quantitative research methods can be used to develop and validate balanced messages that are correctly understood by consumers.
Recommendation 1 – Raising awareness of nicotine-containing products to reduce the harm from smoking	9	Effective risk/benefit communications about reduced harm products must play a crucial role in helping adult smokers understand and ultimately accept such products instead of conventional cigarettes. Adult smokers need clear, non-misleading information about the benefits of using a reduced harm product instead of conventional cigarettes. This should include communication on and in packaging as well as in marketing materials.

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Recommendation 1 – Raising awareness of nicotine-containing products to reduce the harm from smoking	9	We recommend revising the statement that “most health problems are almost entirely caused by other components in cigarettes and not by the nicotine.” Strictly speaking, the health problems are caused by inhaling cigarette smoke (and its combustion and pyrolysis products), not by the components of the cigarettes themselves. We therefore suggest that this text should read: “most health problems are almost entirely caused by other components in cigarette <b>smoke</b> and not by the nicotine.”
Recommendation 5 – Behavioural support for harm reduction	13-15	Although Recommendation 8 addresses the harm reduction potential of e-cigarettes and other currently unlicensed nicotine-containing products, we would suggest that the same potential should be recognised in Recommendation 5. Adult smokers who do not want to use NRTs, or who have not gained any benefit from them, should be made aware of the potential benefits of unlicensed nicotine-containing products. For the same reasons, and although outside the scope of the draft guidance, we believe that adult smokers should also be aware of the potential health benefits of switching to <i>tobacco</i> containing products provided those products have been substantiated as less harmful than conventional cigarettes. (See Lawson, E., “Tobacco Harm Reduction: Thinking the Unthinkable,” 62 BRITISH JOURNAL OF GENERAL PRACTICE 314 (2012).)

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Recommendation 15 – Point-of-sale promotion of licensed nicotine-containing products,  Recommendation 16 – Information on licensed nicotine-containing products	22-23	We support the view that less harmful products need to be visible, available to and understood by adult smokers in order to support harm reduction. Although Recommendations 15 and 16 focus on access and information about licenced nicotine-containing products, the same rationale would apply equally to other nicotine-containing products and even to novel tobacco products, so long as those products have been substantiated by scientific evidence as reduced harm products.
Public Health Need and Practice – Reducing Cigarette Consumption	26	We believe that tobacco products which are scientifically substantiated to be less harmful and which are acceptable to smokers as substitutes for conventional cigarettes, can play an important role in reducing the harm caused by smoking tobacco. While the Institute's current recommended action of encouraging the commercialization of less harmful alternatives is a substantial step forward for harm reduction, we respectfully suggest it could be improved by expanding its scope to include reduced harm tobacco products. Because they closely mirror the taste and feel of conventional tobacco products, reduced harm tobacco products that do not combust have the potential to provide smokers with the most effective harm reduction alternatives.

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Recommendations for Research	35	Given the recognised uncertainty about the safety and quality of unlicensed nicotine-containing products—something that MHRA is currently reviewing—we would suggest further research into currently unregulated nicotine-containing products.  In particular, we recommend that e-cigarettes and other unlicensed nicotine-containing products should be subject to quality control standards, ingredient disclosure requirements, and the requirement that any express or implied claim should be scientifically substantiated and not misleading
Recommendations for Research	35	PMI recommends research to support robust regulatory standards for assessing whether nicotine-containing products and novel tobacco-containing products could offer benefits for individuals who switch to those products from cigarettes and the population as a whole.
Appendix D Gaps in the Evidence	97	Data on the acceptability of reduced harm alternatives to cigarettes, and the extent to which products that more closely match the taste, ritual and nicotine kinetic aspects of conventional cigarettes are more accepted by adult smokers as substitutes for conventional cigarettes, would also be desirable.