

**REPORT**

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# Consultation on Tobacco Addictiveness Reduction Measures

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Berlin, Germany  
15-16 May 2018



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## **Acknowledgements**

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## **Executive Summary**

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A meeting on tobacco addictiveness reduction measures was held in May 2018 in Berlin, Germany, as requested by the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC).

Experts from all WHO regions discussed current and emerging knowledge on the issue and examined the potential positive and negative individual and societal consequences, as well as conditions and challenges to support successful implementation. Although there was no consensus among the participants about the merits or demerits of a nicotine or tobacco addictiveness reduction policy, discussions focused on the elements necessary for a fully informed debate, particularly of combusted tobacco products, for which more evidence is available.

Firstly, the potential individual consequences of nicotine reduction measures for smokers and non-smokers were examined. Experts deemed that the effects for smokers would include reduced consumption of tobacco products and a search for alternative sources of nicotine. However, for non-smokers, these effects would involve, on the one hand, a decreased initiation potential or decreased progression to the use of tobacco products, while on the other hand, it could lead to an increased initiation potential among novices, based on misconceptions about reduced health risk.

Additionally, experts explored the presumed societal consequences for tobacco control of a nicotine reduction strategy. Such an approach may lead to a desired denormalization of smoking, resulting in decreased smoking at local or global levels, environmental benefits due to reduced use of combusted tobacco products and economic benefits from reduced expenditure on tobacco-related diseases, which would improve health system outcomes. Conversely, the presumed negative societal consequences for tobacco control may involve an increase in illicit trade in tobacco products, possibly leading to higher initiation, decreased cessation and an increased rate of relapse by ex-smokers due to competition from low-priced products from illicit trade and other effects undermining tobacco control measures. Furthermore, it could impact on tax revenue, which could be an issue for governments.

Some experts noted that due to the lack of a consensus that a nicotine-reduction strategy would reduce smoking prevalence, any discussion of conditions for successful implementation would be premature. However, it was recognized that countries wishing to consider tobacco addictiveness reduction measures involving the lowering of nicotine content, should consider the policy impact, which will depend on national regulatory context. At the moment, this will suit countries with advanced/comprehensive control measures and extensive resources and knowledge to ensure adequate implementation. As a fundamental prerequisite, participants noted the importance of ensuring that key demand reduction measures under the WHO FCTC, such as those contained in Articles 6, 8, 11, 13 and 14 of the Convention and their implementation guidelines adopted by the COP, be implemented. Further, mandated reductions in nicotine to minimally addictive levels must be part of a comprehensive tobacco control approach, where key demand reduction measures are successfully implemented and a developed capacity for market surveillance and product testing exists. Experts agreed that it was not opportune to develop guidelines on nicotine reduction policies at the current time, in advance of the emergence of country experience that would be valuable in informing such guidelines.

Finally, experts summarized the potential challenges to the implementation of tobacco addictiveness reduction measures under nine headings, so policy-makers can assess the merits of such a strategy in a structured manner. These are: political/regulatory, consumer acceptability, health, capacity, scientific and country specific challenges, as well as legal, economic, agricultural/feasibility and ethical challenges.



# 1. Introduction

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In line with decision FCTC/COP7(14) (1) of the seventh session of the Conference of the Parties (COP7) of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), the Convention Secretariat and WHO convened a face-to-face meeting on the theme of tobacco addictiveness reduction measures from 15–16 May 2018 in Berlin, Germany. This meeting was hosted by the Government of Germany and co-sponsored by the Government of Canada.

The main purpose was to evaluate the current and emerging knowledge base, and to explore the potential benefits and challenges of developing and implementing regulatory interventions to reduce the addictiveness of tobacco products, in particular the conditions that would support or impede success in doing so. These discussions formed the basis of this document, referenced in the WHO's report to the eighth session of the Conference of the Parties (COP8) with document number FCTC/COP/8/8.

The meeting brought together 43 experts<sup>1</sup> from all WHO regions and a range of disciplines, as well as representatives of civil society, to review the feasibility, benefits, risks, negative consequences, and opportunities of addictiveness reduction measures, through the identification of consequences, barriers, exploration of country experience and other relevant topics, including nicotine addictiveness. It was not an objective of the meeting to reach a consensus on any of the issues that were raised, but rather to map them out for discussion.

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<sup>1</sup> A list of the meeting participants can be found in Annex 1.

## **2. Background papers**

WHO and the Convention Secretariat commissioned experts from all WHO regions, selected to ensure regional and disciplinary diversity, to draft eight background papers centred around the requests by the COP.<sup>2</sup>

- Background paper 1. Feasibility of manufacturing cigarettes/tobacco with reduced addictiveness potential.
- Background paper 2. Behavioural aspects of using cigarettes with reduced addictiveness potential.
- Background paper 3. Potential population and individual health impact of a nicotine/tobacco addictiveness reduction policy.
- Background paper 4. Regulatory approaches and implications of introducing products with reduced addictiveness potential.
- Background paper 5. Exploring factors, other than nicotine, that can contribute to the addictiveness of cigarettes and other tobacco products.
- Background paper 6. Exploring a communication/dissemination strategy to minimize misunderstanding of a nicotine or tobacco addictiveness reduction policy.
- Background paper 7. Socioeconomic consequences and consequences by socioeconomic groups of introducing tobacco products with reduced addictiveness potential.
- Background paper 8. Measuring the effectiveness of an addictiveness reduction policy, pre/post market surveillance and monitoring requirements for implementation.

Prior to the meeting, participants received additional background documents: Decision FCTC/COP7(14) (1) and the Advisory Note on Global Nicotine Reduction Strategy by the WHO Study Group on Tobacco Product Regulation (TobReg) (2) published by WHO in 2015.

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<sup>2</sup>One-page summaries of the background papers are included as Annexes 2-9 of this document. The summaries contain a description of the paper and the main comments made by the participants during discussions.

### **3. Discussion on the tobacco addictiveness reduction strategy**

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Participants considered the following topics, addressing specific COP questions on:

- the potential positive and negative individual and societal consequences of implementing tobacco addictiveness reduction measures, as well as the conditions that would support the successful implementation of tobacco addictiveness reduction measures;
- the challenges to implementation of tobacco addictiveness reduction measures;
- any relevant country experience associated with tobacco addictiveness reduction measures, including nicotine addictiveness; and
- any other related matter that in the opinion of this diverse group should be brought to the attention of COP.

#### **3.1 Assumptions and scope of discussions**

The discussion on the reduction of dependence on tobacco products focused initially on all factors that could contribute to the addictiveness of all tobacco products, including potential dependence reduction measures aimed at reducing or banning certain additives or constituents, such as menthol and sugars (see background paper 5). However, discussions focussed on nicotine reduction, particularly of combusted tobacco products, for which more evidence is available.

Although there was no consensus among participants about the merits or demerits of a nicotine or tobacco addictiveness reduction policy, discussions focused on the elements necessary for a fully informed debate on a nicotine reduction policy.

It was considered that to achieve a reduction of dependence on nicotine entails the reduction of nicotine content in tobacco products below a certain level. Participants recognized that the nicotine content of cigarettes that leads to dependence is likely to vary individually as noted by the WHO Study Group on Tobacco Product Regulation (WHO TobReg) (2). This should be as low as is technically feasible and currently would appear to be 0.4 mg nicotine per gram of cigarette tobacco filler.

The discussion proceeded under the assumption that a nicotine reduction policy would not allow coexistence of reduced nicotine and regular nicotine tobacco products within the same category and would require successful implementation and enforcement. To do so, mandated reductions in nicotine to minimally addictive levels must be part of comprehensive tobacco control approach where key demand reduction measures are successfully implemented and a developed capacity for market surveillance and product testing exists.

There is currently no country experience from which to derive lessons in reducing tobacco addictiveness. Only the United States Food and Drug Administration (FDA) has issued an advanced notice of proposed rule-making to implement a rule on the maximum level of nicotine in combusted cigarettes.

## **4. Potential positive and negative individual and societal consequences of implementing tobacco addictiveness measures**

In deliberating the positive and negative individual and societal consequences of implementing the use of reduced nicotine tobacco product measures designed to reduce addiction to tobacco products, participants mapped out the following individual responses or alternative behavioural paths that are possible, but of unequal and sometimes unknown probability, and which may be positive or negative depending on the regulatory context.

### **4.1 For smokers**

1. Reduced consumption of tobacco products, hopefully leading to cessation and therefore obtaining its associated gains.
2. Seeking alternative sources of nicotine because smokers would not be able to legally obtain high nicotine cigarettes:
  - i. use of available nicotine products in the market, such as Electronic Nicotine Delivery Systems (ENDS) or medicinal sources of nicotine;
  - ii. use of combusted tobacco products containing nicotine from alternative sources, such as cross-border purchases or the illicit trade, which could prevent some smokers from completely quitting.

### **4.2 For non-smokers**

1. Decreased initiation potential or decreased progression to the use of tobacco products for experimental smokers.
2. Increased initiation potential by novices, based on misconceptions about reduced health risk.

Based on the alternative behavioural paths described, the potential consequences at population level would depend on the likelihood of the different paths. In other words, the likelihood that each individual smoker and non-smoker may adopt specific behavioural paths and therefore lead to different population consequences is a subject for empirical studies. Such research would need to explore the various factors and how they could maximize the policy's potential benefits or positive consequences and minimize the risks or negative consequences. Possible outcomes include those listed below.

### **4.3 Presumed positive societal consequences for tobacco control**

1. Denormalization of smoking, leading to decreased smoking at local or global levels. Ultimately the reduction of smoking prevalence would reduce mortality and morbidity from tobacco-attributable diseases and conditions.
2. Some environmental benefits due to reduced use of combusted tobacco products.
3. Economic benefits from reduced expenditure on tobacco related diseases, which would improve health system outcomes.

### **4.4 Presumed negative societal consequences for tobacco control**

Consideration should be given to effects ranging from insignificant smoking prevalence changes to its increase due to the factors below.

1. A primary concern is an increased illicit trade in tobacco products, possibly leading to higher initiation, decreased cessation and an increased relapse by ex-smokers due to competition from low-priced products from illicit trade and other effects undermining tobacco control measures. Furthermore, it could impact on tax revenue, which is an issue for governments.
2. Less likely concerns, include:
  - i. misconceptions about the harm of reduced addictiveness products and possible renormalization of smoking, especially for those who have quit;
  - ii. creating opportunities for the tobacco industry to exploit the policy by misleading consumers about the risk or addictiveness of these and other products, and thus preventing the possible effectiveness of the policy;
  - iii. the tobacco industry reinventing itself through alternative products; and
  - iv. the tobacco industry lobbying against tobacco control measures in general and promoting its products in advance of the implementation of the reduced nicotine policy.

## **5. Conditions that would support successful implementation of tobacco addictiveness reduction measures and other tobacco addictiveness reduction-related matters relevant to COP**

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Some participants noted that due to the lack of a general consensus that a nicotine-reduction strategy would reduce smoking prevalence, any discussion of conditions for successful implementation would be premature. However, it was recognized that countries considering implementation of tobacco addictiveness reduction measures involving the reduction of nicotine content, should take into account that policy impact will depend on the certain issues set out below as well as the national regulatory context.

The policy is more suited at the moment to countries with advanced/comprehensive control measures and extensive resources and knowledge to ensure adequate implementation. As a fundamental prerequisite, participants noted the importance of ensuring that key WHO FCTC policy measures to reduce demand, such as provisions and guidelines in relation to Articles 6, 8, 11, 13 and 14, be implemented.

Participants also noted that such a policy should be assessed within the context of a comprehensive tobacco control programme, requiring a comprehensive regulatory strategy for implementation, with certain preconditions in line with the recommendations of the WHO Study Group on Tobacco Product Regulation. The study group recommended that “mandated reductions in nicotine to minimally addictive levels in cigarettes must be part of comprehensive tobacco control, including increased taxes on cigarettes, comprehensive smoking bans, anti-smoking educational campaigns and graphic warning labels or plain packaging”, (2) and that, “a strategy to reduce the addictiveness of tobacco is not recommended in the absence of developed capacity for market surveillance and product testing. Countries without adequate infrastructure to ensure a comprehensive approach to nicotine reduction should carefully consider increasing that capacity before implementing such a strategy” (2).

The (study group) participants identified the following which might be relevant to the COP, or merit further discussion

- The need for careful deliberation and analysis of the country-specific situation and return-on-investment of various measures, particularly for countries initially implementing the policy in isolation. Although there is substantially more evidence that nicotine reduction will have an effect on smoking behaviour than for any other constituent, countries could consider less stringent measures, including the regulation of additives, for example a reduction of sugar, which requires further evidence of its possible impact on dependence reduction or elimination of cooling agents like menthol, which facilitate inhalation.
- The need for a comprehensive regulatory strategy to implement, monitor and enforce such a policy and to perform regulatory testing, which would include the following.
  - Full implementation of the partial guidelines on Articles 9 and 10 of the WHO FCTC.
  - Building adequate regulatory capacity for the development and implementation of the proposed policy and ensuring pre- and post-market surveillance and enforcement.
  - The need to ponder both sides of the ethical debate on reduction of dependence. On the one hand, there are ethical considerations related to the persistent sale of highly addictive, highly toxic tobacco products. On the other hand, there are ethical issues with regards to the challenges that nicotine reduction measures would pose to highly addicted smokers. This includes contemplating the institution of suitable support mechanisms to assist smokers wanting to switch to potentially lower-risk nicotine products or full cessation.
  - The need for a suitable national communication strategy in each country aimed at both policy-makers and the general population to counter the tobacco industry's non-feasibility and non-effectiveness argument. The strategy should have clear messages to the public which articulate the purpose and rationale behind such a policy to avoid confusion, and to anticipate attempts to subvert the policy.
  - The need to foster further country-specific scientific evidence to assess the suitability and potential impact of tobacco addictiveness reduction measures. This includes the need for a coordinated

approach amongst regulators at international and national levels to build the required evidence and formulate best practice based on reliable and robust evidence.

- The need for adequate control of the illicit tobacco trade.

Other topics raised included political conditions which could be influenced by the scientific consensus, feasibility, country experience and country co-operation, and the possibility/ability to produce suitable tobacco strains in sufficient quantities and in a manner that will prevent unintended consequences, such as a negative impact on the agricultural sector (for example employment) and public health consequences. Therefore, it is relevant to gather information and learn from country experience(s), as well as to promote collaboration among countries with an interest in implementing a strategy to reduce the dependence from combusted tobacco products. Such real-life experience could be crucial to the successful implementation of a nicotine reduction policy, although it is recognized that many regulatory questions remain unanswered at this stage.

## **6. The challenges to implementation of tobacco addictiveness reduction measures**

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Participants summarized the previous discussion on the potential challenges to the implementation of a tobacco addictiveness reduction policy at country level under nine headings.

1. Political/regulatory challenges – such as adequate political support, risk of going first and possibly failing, length of time for implementation, risk of a negative impact on tax revenue, need for regional treaties to regulate trade of new products, need of country strategy for policy, risk of distraction from other policies (opportunity costs) and social acceptance of new products.
2. Behavioural/acceptability challenges – such as consumer acceptance of products and the need to develop a communication strategy.
3. Health challenges – smokers could try to maintain the same levels of nicotine which they are accustomed to getting from other sources, including illicitly traded highly toxic conventional tobacco products and tampered products. This may lead to unforeseen behavioural implications, unanticipated market effects, and in some cases, unexpected health effects.
4. Capacity challenges – such as the requirements for a suitable country strategy and infrastructure for the policy, potential for distraction from other policies in terms of opportunity costs,<sup>3</sup> the need for clarity over the rules governing the process of transitioning to manufacturing of addictiveness reduction products, potential increased costs in general, need for capacity and know-how, and lack of monitoring capacity.
5. Scientific and country specific evidence challenges – which include the choice of approach to reducing addictiveness, translation of research into real life, the definition of the addictiveness term, classification of products with reduced addictiveness potential, lack of country-specific evidence and lack of product specific evidence.

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<sup>3</sup>The cost of tobacco product regulation is sometimes wrongly assumed to be higher than it really is. Therefore, opportunity costs should be calculated realistically and always consider potential additional sources of funding from tobacco control, such as charging costs to tobacco companies or manufacturers.

6. Legal challenges – such as the response of the tobacco industry to such a policy, the role of regional treaties and trade agreements, constant industry innovation to reinvent itself.
7. Economic challenges – such as the potential increase of illicit trade of conventional tobacco products, possible decrease in tax revenue, lack of coordination and differentiated regulatory treatment between neighbouring countries which may lead to cross-border illicit trade.
8. Agricultural/feasibility challenges – given the complexity and magnitude of intervention requiring adequate growing and production capacity, which could impede the timely implementation of tobacco addictiveness reduction measures. Furthermore, this may involve genetic engineering of tobacco plants which may be the subject of differing legislation in different countries, in the light of the environmental impact and consumer perception of genetically modified organisms (GMOs).
9. Ethical challenges – such as the possible impact on highly addicted smokers affected by tobacco addictiveness reduction, particularly if alternative lower-risk nicotine products were not readily available.

## **7. Outputs and next steps**

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As requested by COP7 and in accordance with COP Decision FCTC/COP7(14), current and emerging knowledge on tobacco addictiveness reduction measures were discussed at a face-to-face meeting, which focused primarily on the COP request to examine the potential positive and negative individual and societal consequences, the conditions to support successful implementation, and the challenges to implementation. Participants noted the limited evidence on the countrywide effects of implementing the policy and the complexity of the issues to be considered by policy-makers. At this point, rather than trying to reach a consensus on possible measures, participants preferred to map out the potential topics that policy-makers should bear in mind to ensure a methodical and structured discussion when reviewing new evidence and contemplating the possibility of implementing such a policy. Participants also agreed that it was not opportune to develop international guidelines on the nicotine reduction policy at the current time, in advance of the necessary country experience that would be valuable in informing such guidelines.

Participants proposed that authors review the commissioned papers according to the recommendations received during the meeting and once finalized, submit them to a peer-reviewed journal for publication.

## **References**

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1. Decision FCTC/COP7(14), Conference of the Parties to the WHO Framework Convention on Tobacco Control, seventh session. Geneva: World Health Organization; 2016 ([http://www.who.int/fctc/cop/cop7/FCTC\\_COP7\(14\)\\_EN.pdf](http://www.who.int/fctc/cop/cop7/FCTC_COP7(14)_EN.pdf)).
2. Advisory note: global nicotine reduction strategy: WHO Study Group on Tobacco Product Regulation. Geneva: World Health Organization; 2015.

## **Annex 1**

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<sup>2</sup> An intern within the Department of Prevention of Noncommunicable Diseases from 1 March 2018 – 30 August 2018.

## **Annex 2.**

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### **Summary of background paper 1**

#### **– Feasibility of manufacturing cigarettes/tobacco with reduced addictiveness potential<sup>1</sup>**

Background paper 1 explores the feasibility of manufacturing less addictive tobacco products. The paper addresses some important questions on nicotine reduction, such as what level of nicotine can be regarded as non- or minimally addictive and is unlikely to provoke compensatory smoking or other undesired effects. Other questions considered include whether it is feasible to reduce nicotine sufficiently in tobacco either by traditional agricultural practice, genetic engineering or by technical modifications, and whether low or reduced nicotine free tobacco can maintain a sufficiently high appeal to be voluntarily used by addicted smokers.

Setting standards for the levels of nicotine above which addiction is likely and below which addiction is less likely is vital in the development of reduced nicotine cigarettes. Although a clear threshold has not been defined yet and individual differences in sensitivity to nicotine should be accounted for, various studies indicate that decreasing nicotine content to 0.4 mg/g would minimize the risk for dependence. This article provides an overview of agricultural practices, including genetic manipulation, and tobacco product manufacturing techniques, such as supercritical extraction, that have been developed and used by tobacco manufacturers to remove nicotine from tobacco leaves. Most of the available techniques are successful in reducing nicotine levels – genetic manipulation and superficial extraction can reduce nicotine levels to 0.4 mg/g in tobacco – but differ in their effectiveness and their possible unintended consequences e.g. flavour or increased amounts of certain toxicants. However, in almost all cases the resulting tobacco leads to a less satisfactory smoking experience. In general, the rationales to reduce nicotine are very well founded and feasible from a technical perspective. However, the high dependence potential of cigarettes is also affected by multiple factors of product design and manufacture that might provide further options to reduce addictiveness.

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<sup>1</sup> Prepared by R. Talhout, F. Henkler-Stephani, E. Pieper, A. Havermans; reviewed by H. Bozukov.

Even though producing cigarettes with nicotine levels low enough to limit addiction is possible, there are many unanswered questions concerning user acceptability of the product and legal issues. Genetic modifications that affect single and specific mechanisms are generally thought to have the fewest unintended consequences, thus resulting in a flavour quite similar to regular cigarettes. However, genetic modification may also lead to issues in countries with strict legislation. Monitoring nicotine levels can be challenging in some countries, and other tobacco additives besides nicotine may influence addictiveness of cigarettes, such as sugar levels and menthol. Furthermore, little is known about the cost implications, possibilities for exploitation by manufacturers, and timing and feasibility of large-scale production of reduced nicotine tobacco by any of the techniques described.

## **Annex 3.**

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### **Summary of background paper 2**

#### **– Behavioural aspects of using cigarettes with reduced addictiveness potential<sup>1</sup>**

Background paper 2 considers the behavioural implications and the impact on the market and population of introducing tobacco products with reduced addictiveness potential. The paper addresses positive and negative behavioural implications and unintended consequences among specific target groups, manipulation of products, potential use of other sources of nicotine, and the possible effects on initiation, cessation and relapse.

A central reason for reducing nicotine is to prevent youth and young adults from becoming smokers. To prevent continued use among youth and minors who initiate smoking, reduced nicotine cigarettes should produce fewer positive effects than regular conventional cigarettes. Data from controlled clinical trials show that smokers randomized to receive cigarettes low in nicotine smoked fewer cigarettes, had low compensatory smoking behaviour, were less dependent and had an increase in quit attempts and abstinence from smoking. However, a potentially important unintended consequence of reducing nicotine is that consumers could perceive low nicotine products as safer. Manufacturers could attempt to maintain the addictiveness of cigarettes by altering the content or design of the product. Other concerns about nicotine reduction relate to consumer responses such as hoarding of normal nicotine content cigarettes, product tampering, and increased demand for illicit market normal nicotine cigarettes.

Studies of reduced nicotine cigarettes suggest that reducing the level of nicotine in the product will render it less reinforcing and less addictive. These changes may both decrease the probability that naïve youth will become regular smokers and increase the probability that current smokers will quit. There are limitations in current clinical studies that may not be representative of the population or generalizable to other countries, and improving these studies will build a body of evidence for reducing addictiveness. Future surveillance

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<sup>1</sup> Prepared by E. C. Donny; reviewed by B. Khoorshid Riaz.

studies are necessary to assess their use, cessation/withdrawal, and effects on certain groups, such as dosing and side effects for those with psychiatric conditions. Extending the standard to other combusted tobacco products that effectively substitute for cigarettes may be critical to realizing the potential benefits of nicotine reduction. Products that are known to function as behavioural substitutes for cigarettes and are highly toxic themselves, should be considered for inclusion in any standard. Reducing nicotine in cigarettes and other combusted products may increase demand for illicit products. Consequently, markets with non-combusted alternative sources of nicotine may provide more favourable conditions for a nicotine reduction strategy.

## **Annex 4.**

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### **Summary of background paper 3**

#### **– Potential population and individual health impact of nicotine/tobacco addictiveness reduction policy<sup>1</sup>**

Background paper 3 explores potential health impact of an addictiveness reduction policy, such as short- and long-term health impact at the individual and population levels. Additionally, this paper addresses the implications on health services programmes, including raising awareness without promotion to unintended target groups and costs associated with training health service providers, and the potential reduction in the overall health risks of most smokers. As the policy has not been introduced in any jurisdiction and there is no country experience, participants agreed that it would be difficult to base health impact on real life data. However, the use of good simulation models which could provide useful information on the possible health impact of a nicotine/tobacco addictiveness reduction policy was suggested in the meeting. Experts also strongly stated that such simulations will need to consider possible scenarios in various settings including low- and middle-income countries. Further, it is to be noted that as recommended by the WHO Study Group on Tobacco Product Regulation, the ultimate health benefits of a nicotine reduction strategy for individual smokers will require complete cessation of intake of all combusted tobacco.

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<sup>1</sup> Prepared by J. Gyapong, H. M. Mamudu, W. Agbenyikey; reviewed by P. T. Phuong.

## **Annex 5.**

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### **Summary of background paper 4**

#### **– Regulatory approaches and implications of introducing products with reduced addictiveness potential<sup>1</sup>**

Background paper 4 examines the regulatory approaches to implementing a nicotine product standard for cigarettes, potential barriers for implementation, and recommendations to overcome these barriers.

When lowering the level of nicotine in cigarettes, an immediate reduction approach is associated with a greater and more rapid overall reduction in smoke exposure, decrease in dependence and a higher number of abstinence days compared to gradual reduction. However, this approach may also lead to greater short-term discomfort among smokers, which would potentially lead them to seek nicotine from other sources. Several measures can be implemented to mitigate any negative impact from reducing nicotine in cigarettes, which include: i) making access to nicotine replacement therapies or other widely available and less costly pharmacological products; ii) for some countries, providing other alternative sources of nicotine, which are less toxic than combusted products (e.g., ENDS); and iii) controlling illicit markets. Comprehensive tobacco control (e.g. maintaining or increasing taxes), education about the effects of nicotine, laboratory testing to monitor any attempts to alter cigarettes, and surveillance to determine prevalence of use and monitor unintended consequences would support a nicotine reduction approach.

The majority of the studies on reduced nicotine content cigarettes have been conducted in the United States of America, therefore the generalizability of the study results to other countries, particularly in middle- and low-income countries, are uncertain. More studies outside of the United States of America are necessary, considering that cigarettes are not always the most used tobacco products in these countries. The practical implications of introducing nicotine reduction measures need to be explored, as well as political concerns about legislation on tobacco products targeted for nicotine reduction.

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<sup>1</sup> Prepared by D. Hatsukami, D. Xu; reviewed by L. J.-e. Lee.

As the illicit market is a problem across borders, coordinating policy across countries would be beneficial. Relatively little is known about the economic burden for industry, farmers and governments associated with the implementation of nicotine regulation, including the provisions of Article 15 of the WHO FCTC. Additionally, how long-term smokers will use reduced nicotine cigarettes and the long-term consequences of implementing this policy are unknown. It is important to note that the focus should be on reducing smoking prevalence and not only the number of cigarettes smoked.

## **Annex 6.**

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### **Summary of background paper 5**

#### **– Exploring factors, other than nicotine, that can contribute to the addictiveness of cigarettes and other tobacco products<sup>1</sup>**

Background paper 5 considers substances other than nicotine that might have addictiveness properties and potential manipulation of products to influence product addictiveness. It includes a systematic review of 106 studies, where menthol was the most widely studied additive. All experimental pre-clinical studies and most human studies reported a positive association between menthol and addictiveness. Menthol adversely impacts quitting behaviour and tobacco cessation, leading to increased dependence potential. Further, higher dependence levels amongst menthol smokers were found in certain subgroups such as adolescents, women, and African-Americans.

Additionally, the identified evidence suggests that minor alkaloids present in tobacco, particularly at doses higher than delivered in cigarettes, could possibly contribute to some of the dependence potential of tobacco products. As the chemical structure of alkaloids is similar to nicotine, they act in a similar way, but the issue requires further research. Sugars added in high quantities to most tobacco products give rise to numerous aldehydes, such as acetaldehyde, in tobacco smoke. Acetaldehyde is self-administered by animals and is potentially addictive. Most studies suggested that monoamine oxidase (MAO) inhibitors increased abuse liability and may increase the reinforcing value of low doses of nicotine. Thus, the potential role of these substances in very low nicotine content products will require further research.

Overall, this systematic review identified evidence supporting the potential role of non-nicotinic factors in increasing the dependence potential of tobacco products. However, varied methods for testing the addictiveness of substances have been used which need standardization and require further validation. Also, there are no human or longitudinal studies to determine the importance of these factors, or what impact they will have in addictiveness long-term. Determining dose is critical, as well as determining how

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<sup>1</sup> Prepared by S. Jhanjee, E. Akl, L. Bou Karroum, R. Gupta; reviewed by L. Ayo Yusuf.

the tobacco industry can manipulate these factors, as some of these factors could have reported doses that are below the threshold that affects behaviour. Additionally, there is a need to undertake research on understanding the roles of flavour additives other than menthol for their contribution to the addictiveness of tobacco products. Importantly, this paper determines other substances that could increase addictiveness and raises questions on what substance should be the focus for regulation. Policy may not be limited to nicotine reduction only as it may not be feasible for every country.

## **Annex 7.**

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### **Summary of background paper 6**

#### **– Exploring a communication/dissemination strategy to minimize misunderstanding of a nicotine or tobacco addictiveness reduction policy<sup>1</sup>**

Background paper 6 provides an overview of what is known about the public's perception of nicotine and addiction, and how available evidence could inform a communications campaign adopted as part of a tobacco products addictiveness reduction policy recommendation.

Communication surrounding nicotine and addiction has been influenced by both the tobacco industry, which until a decade ago denied that nicotine was addictive, and the lack of initiatives promoting lower levels of nicotine as a strategy to support quitting. Multiple national and international surveys have shown that healthcare professionals receive little-to-no education related to tobacco dependence treatment, including education on nicotine addictiveness, withdrawal and available therapies. A communication strategy to support an addictiveness reduction policy would need to educate health professionals and involve key stakeholders – consumers (i.e. smokers and ex-smokers), health professionals, policy-makers, media, opinion leaders – in all stages of policy development and implementation. Importantly, communication would ensure that the message uncouples overall tobacco harm from nicotine content and addresses the misperception that reduced addictiveness tobacco products are less carcinogenic. It would further have to ensure that the target audience is clear, the campaign is evaluated, and that investments on communications campaign are cost effective. A communication strategy requires political and resources commitment, and an evaluation to assess impact will be key.

A communication strategy needs to convey information about country-specific products to consumers and ensure that it is not an advertising campaign that would drive consumers to use reduced addictiveness tobacco products. Identifying media coverage on the topic of addictiveness and nicotine, and

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<sup>1</sup> Prepared by S. Bialous, B. Freeman; reviewed by D. Arnott.

how best to influence it going forward, are necessary steps. Future research could shed light on the reasons why people support these policies and how such rationale could guide the communication strategy development. Research should also explore the informational needs of politicians and policy-makers to ensure that proper resources are allocated and that any policy to reduce the addictiveness of tobacco occurs within a broader framework of tobacco control measures.

## **Annex 8.**

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### **Summary of background paper 7**

#### **– Socioeconomic consequences and consequences by socioeconomic groups of introducing tobacco products with reduced addictiveness potential<sup>1</sup>**

Background paper 7 reviews the existing evidence on differential acceptability of tobacco products with reduced addictiveness potential by socioeconomic groups and the evidence on differential behaviours or health effects they may have, which could ultimately determine economic feasibility.

When introducing tobacco products with reduced addictiveness potential, socioeconomic factors can be important due to the accessibility/affordability and the differential impact they may have in terms of smoking behaviour or health outcomes on different groups. Distribution and marketing costs may have an important influence on the economic viability of the introduction of these products, especially if they are only available at high prices, in which case certain groups (e.g., low-income individuals, young and retired people) will find them inaccessible. Given accessibility and affordability, if these products are more appealing to some groups due to factors such as palatability or better smell and they are linked to, for instance, higher probabilities of quitting regular tobacco products or a lower probability of initiation of regular tobacco product consumption, their introduction will have direct socioeconomic consequences on health outcomes. It is also possible that indirect consequences will be present, given the link between smoking and socioeconomic factors, such as poverty or health and education-related expenditures. However, little is known about the economic feasibility of marketing these products, as they have rarely been marketed. Further, most clinical trials have been conducted on very low nicotine cigarettes and these have samples of individuals of different ages, sex, ethnicities, with very few of them reporting differential behaviours by socioeconomic group. Studies have also shown that some groups believe that nicotine is related to smoking-related cancers. Such misconceptions will need to be addressed by raising awareness and running educational campaigns to educate these groups.

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<sup>1</sup> Prepared by G. Paraje, V. H. Herrera Ballesteros; reviewed by J-P. Tassin.

Determining the goal (e.g. cessation or reduction of tobacco) of introducing tobacco products with reduced addictiveness potential would be important since there will not be a universal solution, and research and evaluation of these products should be performed in countries with comprehensive tobacco bans first. Economic issues would exist from different perspectives (e.g. tobacco growers versus tobacco industry versus government), and affordability would be an issue. Discussing taxation would be important in the socioeconomic context, as these products are harmful and need to be taxed, yet taxation should vary from relative to conventional cigarettes and be high enough to discourage use among vulnerable groups. The description of the literature found on socioeconomic aspects related to the use of reduced addictiveness tobacco products shows that there is not enough evidence to assess what would be the impact in an actual market. Understanding what will happen in the illicit market will be an important socioeconomic consequence as well. Future research should include experiments and trials on socio-economic dimensions that could inform policy-makers about how specific groups would react to the introduction of tobacco products with reduced addictiveness potential.

The authors indicated that given that there is no evidence of the economic consequences of the speed at which nicotine reduction should be introduced and recommended a cautious approach.

## **Annex 9.**

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### **Summary of background paper 8**

#### **– Measuring the effectiveness of an addictiveness reduction policy, pre/post market surveillance, and monitoring requirements for implementation<sup>1</sup>**

Background paper 8 explores various short- and long-term indicators that may be relevant to evaluating the effectiveness of an addictiveness reduction policy for combusted cigarettes. This paper also discussed the existing mechanisms by which each of these indicators may be surveilled and operational considerations, including the potential timelines and cost implications, associated with such a policy.

Measures and methods were identified to evaluate the effectiveness of an addictiveness reduction policy, including: tobacco product testing; tobacco product sales; tobacco use behaviours; biological indicators of tobacco-related disease; and tobacco-related financial burden. Evaluation of these indicators will be a large undertaking utilizing many types of data, including household surveys, health insurance claims data, scanner-based purchasing behaviour data. Importantly, evaluations of an addictiveness reduction policy should not be limited to assessing compliance within the intended effects of a regulation (e.g. only evaluating use behaviours related to combusted cigarettes). Rather, they should also study the broader effects (e.g. evaluating use behaviours related to a wider spectrum of tobacco products), as well as unintended effects of responses, such as tobacco industry innovation, manipulation of product content or design features, that may interfere with the impact of regulation. Additionally, timelines for evaluating these indicators are likely to vary based on availability of the data and a prolonged natural time course for some indicators to manifest (e.g. development of tobacco-related diseases). Regarding cost implications, it is likely unavoidable that implementation will incur costs. However, these costs may be offset by the benefits, such as improved population health and anticipated healthcare expenditure savings.

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<sup>1</sup> Prepared by L. Pacek, M. M. Elhabiby; reviewed by D. Kiptui.

Despite an accumulating evidence base suggesting that a nationwide addictiveness reduction policy would have broad beneficial effects, a number of research questions remain unanswered. For example, an additional indicator of effectiveness of an addictiveness reduction policy could include the emergence of a black market for normal nicotine content cigarettes, a measure needed for inclusion at baseline of surveillance studies. However, the size, nature, and harm of the black market are difficult to predict and would likely be related to how the policy is implemented, the resources dedicated to enforcement and the availability of alternative nicotine containing products. There will be implementation challenges that differ by country and evaluation of any policy will depend on resources available and the costs versus the benefits of the measure. Additionally, the use of technology, such as social media and texting, could be useful to monitor consumers over time. Another important behavioural aspect to monitor is access to cessation services. Whilst it would be important to evaluate the effectiveness of tobacco addictiveness reduction measures, there is no consensus or internationally agreed approaches to evaluate the effectiveness of such measures, specifically if there is an adequate minimum standard required and or a gold standard for an addictiveness reduction policy.

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