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## **Preface**

The Scientific Advisory Committee on Tobacco Product Regulation (SACTob), established by the World Health Organization, held its first meeting in October 2000. The committee is composed of national and international scientific experts on product regulation, smoking cessation and laboratory analysis. SACTob advises WHO about scientifically sound recommendations to Member States addressing the most effective and evidence-based means to achieve a co-ordinated regulatory framework for tobacco products. The work of the committee is based on recent leading edge research on tobacco product issues and aims to fill the regulatory gaps in tobacco control.

The present recommendation was finalized by SACTob during its Fourth Meeting in 4-6 February 2002 held at Oslo, Norway.

# **SACTob Position Statement on Nicotine and Its Regulation in Tobacco and Non-Tobacco Products.**

## **Background**

Over the past two decades a wealth of research findings have pointed to nicotine as the key pharmacological factor underlying tobacco use. The 1988 report of the US Surgeon General identified cigarette smoking as nicotine addiction (1); the Royal College of Physicians similarly concluded that nicotine is an addictive drug on par with heroin and cocaine, and that the primary purpose of smoking tobacco is to deliver a dose of nicotine rapidly to the brain (2). The Diagnostic and Statistical Manual of Mental Disorders [D.S.M-IV] classifies nicotine-related disorders into the sub-categories of dependence [305.10] and withdrawal [292.0] which may develop with the use of all forms of tobacco (3). The effects of tobacco and nicotine to produce dependence and withdrawal are also identified by the International Statistical Classification of Diseases and Related Health Problems [I.C.D-10] as a disease in the category [T 65.2] ‘Toxic effect of other and unspecified substances’ (4).

While nicotine is acknowledged to be the primary reinforcer of smoking (5,6), and nicotine-free cigarettes have consistently failed in the marketplace (7), exposure to nicotine in itself is believed not to be responsible for more than a minor portion of tobacco related disease (8). Rather, harmful gases and particulates, which can be thought of as contaminants of the cigarette as a nicotine delivery device (9), cause the great majority of smoking related diseases and their specific role in the reinforcing effects of smoking is not well understood.

Despite their toxicity, tobacco products have enjoyed an unprecedented degree of freedom from the regulations that apply to food and drug products and to consumer products generally (10,11). Paradoxically, pure nicotine products designed to aid smokers trying to quit (12), are subject to stringent regulation and are required to meet the same standards of safety and product information as any other pharmaceutical preparation (13,14,15,16).

It is theoretically possible that changes in cigarette design could lower exposure of smokers to the harmful constituents in smoke, but efforts to do so through so called “low-yield” cigarettes have failed (2, 17). Smokers self-dose for nicotine, and they smoke more intensively or smoke more cigarettes per day to obtain the dose that will give them satisfaction (9, 15, 16, 17, 18). Most so called “low-yield” cigarettes are designed such that these changes in smoking behaviour return the delivery of nicotine and other smoke constituents to levels similar to those of so called “full flavour” or “high –yield” cigarettes (19). Dependence on nicotine is a biological force that drives such behaviour (1,2,20).

Proposals for more effective nicotine regulation have ranged from reducing nicotine availability from cigarettes to the point where they are no longer reinforcing (6,21) to restricting unwanted particulate and gas phase components while accepting a laissez faire approach to nicotine (7, 22, 23, 24). A common thread is the recognition of the need to level the regulatory playing field, as between consumer and pharmaceutical nicotine products (14, 25, 26), as well as the need to ensure that the future market for nicotine does not continue to be dominated by the most contaminated product, the cigarette (27).

**Based on the existing science, SACTob makes the following recommendations:**

1. The present situation in which the most toxic form of nicotine delivery is the least regulated, is unacceptable from a public health perspective.
2. Because nicotine appears to be responsible for a small proportion of tobacco-caused diseases relative to other tobacco constituents and emissions, there is considerable scope for developments that reduce the risks experienced by users of tobacco, but without undermining efforts to prevent initiation to tobacco use and promote cessation among established users.
3. In the absence of firm contrary data, those responsible for public policy decisions are justified in using the conservative assumptions that smokers' preferences for a nicotine dose are persistent over time and are not influenced by changes in the product used and that smokers will compensate for reductions in yield to maintain a relatively consistent dose of nicotine.
4. A broad and comprehensive regulatory framework is required to enable policy options for controlling nicotine to move forward in ways that minimise the risks.

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