

Personal Perspectives

Tobacco product regulation: what can be achieved?

*T. Yoshida, Quality and Safety of Medicines,
World Health Organization, Geneva*

Few people would question the evidence now available that smoking tobacco is both addictive and harmful to health. Ample proof has been provided to support the linkage between smoking and increased incidence of serious health problems, notably lung cancer and cardiovascular diseases (1). Tobacco now kills over 4 million people annually. By 2030, it will kill 10 million people, out of which 7 in 10 will be in developing countries.

This public recognition has led many governments to implement legal and/or administrative measures to reduce tobacco smoking. Some countries have already achieved tangible results in reduction of both smoking rates and associated health problems. However, there is still an ongoing debate among countries concerning the interpretation of the harmfulness of tobacco smoking and the measures needed for effective reduction of smoking.

Faced with this situation, public health administrators of WHO Member States have urged governments to intensify their efforts to reduce tobacco smoking. Concerted international action will be needed to help governments achieve this objective and the World Health Assembly has resolved that WHO should develop a Framework Convention on Tobacco Control (FCTC) (2). WHO has already begun a formal process of intergovernmental negotiations for this purpose.

The FCTC will be supplemented by several protocols, each containing specific control measures related to a particular field. As a package, it is expected to provide a legal instrument for a comprehensive set of tobacco control measures to be implemented globally in a stepwise manner. The flexibility required for implementation is provided through the accession procedure which allows governments to ratify the FCTC and different protocols separately at different times depending on progress made.

Against this background, tobacco product regulation is increasingly viewed as one of the potential areas for international control under the FCTC. Needless to say, product regulation is applied widely in the pharmaceuticals sector. The topic therefore attracted the attention of many drug regulators in April 1999, and the Ninth International Conference of Drug Regulatory Authorities (ICDRA) devoted one plenary session to discussion of this issue.

More recently, tobacco product regulation was discussed at two WHO meetings — the Conference on the Regulation of Tobacco and Tobacco Dependence Treatment Products, held in Helsinki, 18–19 October 1999 and the International Conference on Advancing Knowledge on Regulating Tobacco Products, held in Oslo, 9–11 February 2000. In addition, the European Commission (EC) has announced a proposal to update a directive calling for the harmonization of the laws and regulations of its Member States regarding the manufacture, presentation and sale of tobacco products. Although formal reports of the WHO conferences mentioned above are not published yet, highlights of these events are discussed below.

Public health goals of tobacco regulation

The public health goal of tobacco product regulation should be to reduce the health risks due to smoking. However, it is not immediately clear how action to reduce the amount of risk to an individual smoker would justify action taken on behalf of the community as a whole. If there is a difference between the two, it may be necessary to evaluate the risk to the entire population rather than the risk to individual smokers. This was the consensus reached after some debate at the Oslo Conference, which agreed that the objective of tobacco product regulation should be to prevent the initiation of tobacco use and thereafter aim for a substantial and sustained reduction in tobacco-related morbidity and mortality among smokers.

Harm reduction is not a well-defined concept. In the context of discussions on illegal drug problems surrounding heroin and cocaine abuse, the ambiguous use of the expression "harm reduction" has created much confusion leading to confrontational

debates. The controversy has mainly been a consequence of the implicit acceptance of illegal drug use. For this reason, the United Nations Commission on Narcotic Drugs, the international policy-making body for drug abuse control, did not accept "harm reduction" as a substitute for demand reduction. Since tobacco is not an internationally agreed illegal drug, such a controversy was not anticipated in the discussion of "harm reduction" concerning tobacco smoking.

Contrary to expectations, there were numerous debates on the question of whether "safer cigarettes" are a good thing from a public health point of view or not. The answer is not so simple as one may think. Firstly, the meaning of "safe cigarettes" would have to be clarified.

With regard to the harm to individual smokers, there is broad consensus that most of the health risks associated with tobacco smoking are due to the intake of a large number of chemical substances resulting from the combustion and heat decomposition of tobacco constituents and additives as well as the paper used to roll cigarettes. Nicotine itself is not regarded as the main culprit but is responsible for addiction (dependence-producing capacity). Tar and the nonvolatile constituents of tobacco smoke contain most of the harmful chemical substances in the smoke, particularly those associated with lung cancer. Carbon monoxide is considered to be responsible for cardiovascular disease as well as low-birth-weight babies and foetal abnormalities. Based on these facts, it has been concluded that the health risks associated with tobacco smoking can be reduced by decreasing tar levels, nicotine contents and carbon monoxide yields in cigarettes. The proposed European Union (EU) directive is a direct translation of this concept into a concrete EU-wide anti-smoking policy.

EU directive on tobacco product regulation

Past EU directives were progressively aimed at reducing the permissible tar yield of cigarettes, and the current ceiling is set at 12 mg/cigarette. The new directive proposed by the Commission of the European Communities in 1999 (3), if adopted, will lower this limit to 10 mg/cigarette. Likewise, it would set the ceiling on the nicotine yield in cigarettes at 1 mg/cigarette. The limit of carbon monoxide yield would be 10 mg/cigarette. The effective date of the directive will be 31 December 2003 (or 3 years from the date of adoption). The measurement systems proposed for each of these ceilings are

those set down by the International Standards Organization (ISO). With regard to labelling, the existing provisions require that yields of tar and nicotine be shown on cigarette packaging and that warning messages to alert consumers be printed on all tobacco product packaging. The proposed directive would additionally require that the carbon monoxide yield be indicated on cigarette packaging, in addition to improved clarity and presentation of warning messages (e.g. "Smoking kills"). The use of terms which convey the impression that a particular product is less harmful than others (e.g. "low tar") will be prohibited, unless expressly approved by the national authorities.

With regard to non-tobacco ingredients, including additives, manufacturers or importers of tobacco products would be required to submit to the authorities not only the list of such ingredients and the reasons for their inclusion but any toxicity data they may have to demonstrate their safety when used as intended in their tobacco products. The directive also requires a ban on the marketing of tobacco for oral use in the EU except in Sweden, where its use is traditionally allowed.

Reduction in tar yield

Questions have been raised concerning the usefulness of the reduction in tar level per cigarette. Doubts exist concerning the linkage between the tar yield as measured by the ISO method and the amount of tar actually absorbed by the body of the smoker.

However, it was noted that the ISO methods currently in use, which employ a smoking machine, were not designed to measure the biological impact of tobacco products. Unlike the smoking machine, smokers can and do modify the way they smoke in order to change the subjective effects of smoking. This practice has been shown to have a significant influence on the amount and composition of tar taken into the lungs of the smoker. Therefore, there is no assurance that the amount of tar per cigarette measured by the ISO method will demonstrate the amount of toxic substances absorbed by the biological system of the smoker when smoking a cigarette. Secondly, experts have pointed out that so-called "low tar" or "light" cigarettes did not actually lead to any significant reduction in the incidence of health problems associated with smoking (4). This is due to the "compensation mechanism", which is the tendency of nicotine-dependent smokers to adjust their smoking patterns according to the quantity of nicotine actually absorbed into the body.

Thus, if the "low tar" cigarette also contains less nicotine, the smoker might simply smoke more cigarettes so that there may be no real reduction in the total amount of the tar that has entered the body. The question would be equally valid for the yield of carbon monoxide. Furthermore, it was pointed out that the perception of "low tar" or increased safety may reduce the motivation to quit smoking.

Reduction in nicotine level

The question raised about the usefulness of reducing the nicotine content per cigarette is related again to the "compensation mechanism". If nicotine-dependent smokers smoke more cigarettes to compensate for the reduced nicotine, the total intake of tar will increase. On the other hand, experimental and casual smokers who are not dependent on nicotine yet would have a smaller risk of developing nicotine dependence. In theory, therefore, there is likely to be a turning point below which the reduction in the risk of developing nicotine dependence in non-dependent smokers would outweigh the increase in the risk of tar intake in nicotine-dependent smokers.

Unfortunately, no studies are available to enable an estimation of where this break-off nicotine level in cigarettes would be. Although some studies and industry reports have addressed "threshold levels" of nicotine the authors have studied "the lowest addictive level of nicotine" rather than the turning point level in terms of public health risk-benefit ratio (5). If it were close to the level specified by the EU directive (1 mg/cigarette), any further reduction would be a public health gain. Should it be much lower than this level, a gradual reduction in nicotine levels per cigarette would increase the overall public health problems associated with smoking.

Recommendations and discussion

What is recommended? In general, both the Helsinki and Oslo Conferences were supportive of the EU policy outlined in the new directive, with the exception of the two questions mentioned above. On these contentious issues, the Oslo Conference adopted the following recommendations:

1. Discontinue harm reduction strategies based on naive interpretation of tar and nicotine yield measurements.

This means abandoning the strategy of seeking lower nominal tar yields and instead finding approaches that genuinely reduce harm to nicotine users.

2. Remove tar and nicotine measures derived from ISO methods from packages.

From a public health point of view, it will be valuable to see how the policy-makers of the European Union respond to these recommendations.

Other recommendations adopted by the Oslo Conference but not mentioned in the EU directive, include the proposal that product regulation should be applied to all forms of tobacco and nicotine products. This would require a unified regulatory framework for nicotine delivery products, including tobacco products, products for treating tobacco dependence, and novel nicotine delivery devices, whether or not these are based on tobacco products.

A required condition for the successful implementation of this recommendation would be the existence of a national agency mandated to regulate the marketing of all nicotine-containing products, regardless of their usage. Currently, it is common to find diverse laws, often implemented by various governmental agencies, which regulate the marketing of different consumer products containing the same chemical substance. However, the idea of having a single agency regulating all nicotine-containing products did receive some international attention at the Ninth ICDRA held in Berlin in April 1999, when the representative of the US Food and Drug Administration (FDA) presented the FDA tobacco regulations, promulgated on the basis of the agency's legal interpretation that nicotine in tobacco is a "drug" as defined by the US Food, Drug and Cosmetic Act. This focus on such a solution seems to have lost support as a result of a Supreme Court ruling, in March 2000, that the FDA did not have such authority.

Setting legal questions aside, it is clear that several key questions remain unanswered. It was therefore important for the Oslo Conference to urge further research, listing the following as priority areas.

- Research to evaluate the benefits and/or hazards of reducing nicotine and other possible addictive constituents in tobacco products over time. Particular attention should be given in research to determining whether a threshold exists for addiction.
- Research to develop better measures, including biomarkers, to assess the health impact of the use of "less harmful" tobacco products in order to drive

future regulatory action. For exposure, a composite measure of toxicity is needed. In addition, the unintended consequences of consuming such products should be investigated.

- Expand behavioural research on how “cigarettes affect smokers” and how the population (of smokers and nonsmokers) responds to claims about new products and to new packaging rules.
- Research to determine whether regulators should encourage the development of substantially less harmful nicotine delivery devices.
- Research to determine whether countries should forbid addition of all new additives and explicitly address the possibility of reducing the use of additives that make tobacco products more attractive and/or taste better.
- Research to evaluate how regulatory approaches developed for cigarettes could be adapted to cover all forms of tobacco use.

References

1. Tobacco or Health, WHA 39.14. *WHO Handbook of Resolutions*, Volume II, 1.16.19.
2. International framework convention for tobacco control, WHA49.17. *WHO Handbook of Resolutions*, Volume III, 1.11.4.
3. Proposal for a Directive of the European Parliament and of the Council adopting measures for the harmonization and approximation of the laws, regulations or administrative provisions of the Member States regarding the manufacture, presentation and sale of tobacco products. Commission of the European Community, COM 594 (1999).
4. Bates, C. The future of tobacco product regulation and labelling in Europe: implications for the forthcoming European Union directive. *Tobacco Control*, **8**: 225–235 (1999).
5. Hurt, R.D., Robertson, C.R. Prying open the door to the tobacco industry's secrets about nicotine. *Journal of the American Medical Association*, **280**: 1173–1181(1999).