REGULATING TOBACCO PRODUCTS

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Tobacco is a unique consumer product in causing a continuing epidemic of illness and premature death among its users while being used as intended. A strong case can be made that many of the current practices of the tobacco industry are illegal[1]. While the promotion of tobacco products has been increasingly restricted in Australia over the past four decades, the product itself has remained almost untouched by any form of control and very limited collection of information. For example, there is no public information available on the performance characteristics of Australian cigarettes after the Commonwealth's testing regime was abandoned in the early 1990s, it is only as a result of a voluntary agreement between tobacco manufacturers and government in 2000, that some information on additives is disclosed through the Department of Health and Ageing website[2].

At least one company has routinely collected data on engineering and performance characteristics of its own and competitors brands[3] and this sort of information should be publicly available. Efforts need to go beyond collection of information to exercising control in the public interest. No attempt has been made to control what additives are allowed, even though many add to the attractiveness of this inherently toxic product and some have been linked to increased addictiveness. Levels of carbon monoxide, tar and nicotine have long been printed on packets and there is a voluntary agreement to limit these, but it is based on a measurement system that bears no relationship to actual exposures, so it is not only useless but systematically misleading. Indeed, reporting notional tar levels has provided new marketing opportunities for "light" and "mild" brands to consumers who are mostly unaware that the numbers are misleading as an indication of intake or harm.

By contrast foods must meet regulatory requirements set by Food Standards Australia New Zealand for safety, standards in production and manufacturing, disclosure of ingredients and nutritional information and are subject to recall when found to be defective, contaminated or unsafe. There is an average of four to five recalls per months. Imagine how quickly Vegemite would be withdrawn from sale if it were discovered that it killed half of its loyal users prematurely.

Medicines and therapeutic goods must conform to demanding standards prior to being registered for use by the Therapeutic Goods Administration (TGA). Nicotine replacement products designed to assist smokers to quit must meet rigid standards of purity, safety and effectiveness to be licensed for sale. Extensive information about usage, possible side effects and contraindications must be included with the product to inform users and the conditions of sale are strictly regulated, for example by pharmacists or prescription only.

A handful of deaths, birth defects, or cases of illness attributable to a drug can be sufficient for it to be prohibited from sale. The recent Pan Pharmaceuticals disaster may have resulted in some deaths, but lack of quality control in their manufacturing processes was sufficient for their license to be withdrawn by the TGA. For a drug to cause 19,000 deaths a year and still be available in every corner shop, supermarket and pubs would be unthinkable.

Emerging Need for Regulation of Tobacco

The harm done by tobacco would seem to be sufficient reason for a regime to regulate the harm that it causes, but for historical, social and political reasons, this has not happened to date. The reasons for this are complex, but include a focus on reducing or eliminating use without consideration of the possibility, indeed likelihood, that there will always be a market for a mind altering substance such as nicotine. Those working in tobacco control are increasingly concerned about this rump of continuing users. There are also new reasons emerging that may force regulatory action. Much of this has to do with product convergence between tobacco products, foods and therapeutic goods.

- The emergence of tobacco products claimed to be safer to smoke (eg Quest 1,2,3, which are low nicotine cigarettes; Omni and Advance which are reduced carcinogen (some) cigarettes) In some cases, they more closely resemble nicotine replacement products than traditional cigarettes (eg Eclipse and Accord are pseudo cigarettes where the tobacco is heated rather than burned).
- Snuff and chewing tobacco products are currently illegal in Australia. Some of these products cause less harm. Swedish Snus (a moist oral snuff) is often singled out as the most promising candidate for a model harm-reduced tobacco product[4].
- Attempts have been made in some countries to market food-like goods that contain tobacco or nicotine. Examples include a toothpaste with tobacco added and drinks or confectionery containing nicotine. To date these have been prohibited in Australia. If such "foods" containing nicotine or tobacco are not permitted, how can tobacco continue to be freely sold?
- Some nicotine-replacement products increasingly resemble cigarettes. The nicotine inhaler shares many features with cigarettes. The pharmaceutical industry has the capacity to produce new forms of nicotine delivery devices that mimic the features of cigarettes (eg rapid uptake of nicotine, pleasant taste etc), but currently are discouraged from doing so. There is concern that new NRT products that are acceptable to smokers as a satisfying alternative to tobacco may perpetuate tobacco use. However, others have argued that such drug "abuse" would be much safer than smoking and has in fact been proposed by tobacco control advocates (eg Henningfield[5]).

The tobacco market is a classic case of market failure. Consumers cannot rationally judge the harms of use (not surprising as the experts can't either), therefore they make consumer choices on things like satisfaction. To date the most satisfying products have been the most harmful (partly because of that attractiveness). If public policy is to be serious and consistent about trying to reduce as far as possible the harms from tobacco use, then regulation of all aspects of the tobacco market, including the product, is essential.

If Tobacco Itself is to be Regulated How Should it be Done?

The simplest alternative would be to give the power to regulate the composition and manufacturing of tobacco products to one of the existing regulatory bodies. Several attempts have been made to extend the powers of the US Food and Drug Administration to cover tobacco, so far without success. In Australia there is no equivalent body that covers both food and drugs, so responsibility would need to be given to either the TGA or Food Standards Australia New Zealand. This would cause both bodies some concern in that tobacco is clearly not like the products they currently regulate. Tobacco is almost the opposite of a therapeutic substance such as those that the TGA has responsibility for, although it has some similarities to the "alternative" herbal medicines they also regulate. Similarly, tobacco is not a food like any other, since it is clearly not a part of the nutritional intake and is lethal for long-term users. If these conflicts were considered to be too problematic, a new body might be created specifically to regulate tobacco. In any case, manufacturers would need to be licensed and regularly inspected to ensure they were compliant. The ultimate sanction would be to suspend their license.

What Should be Regulated?

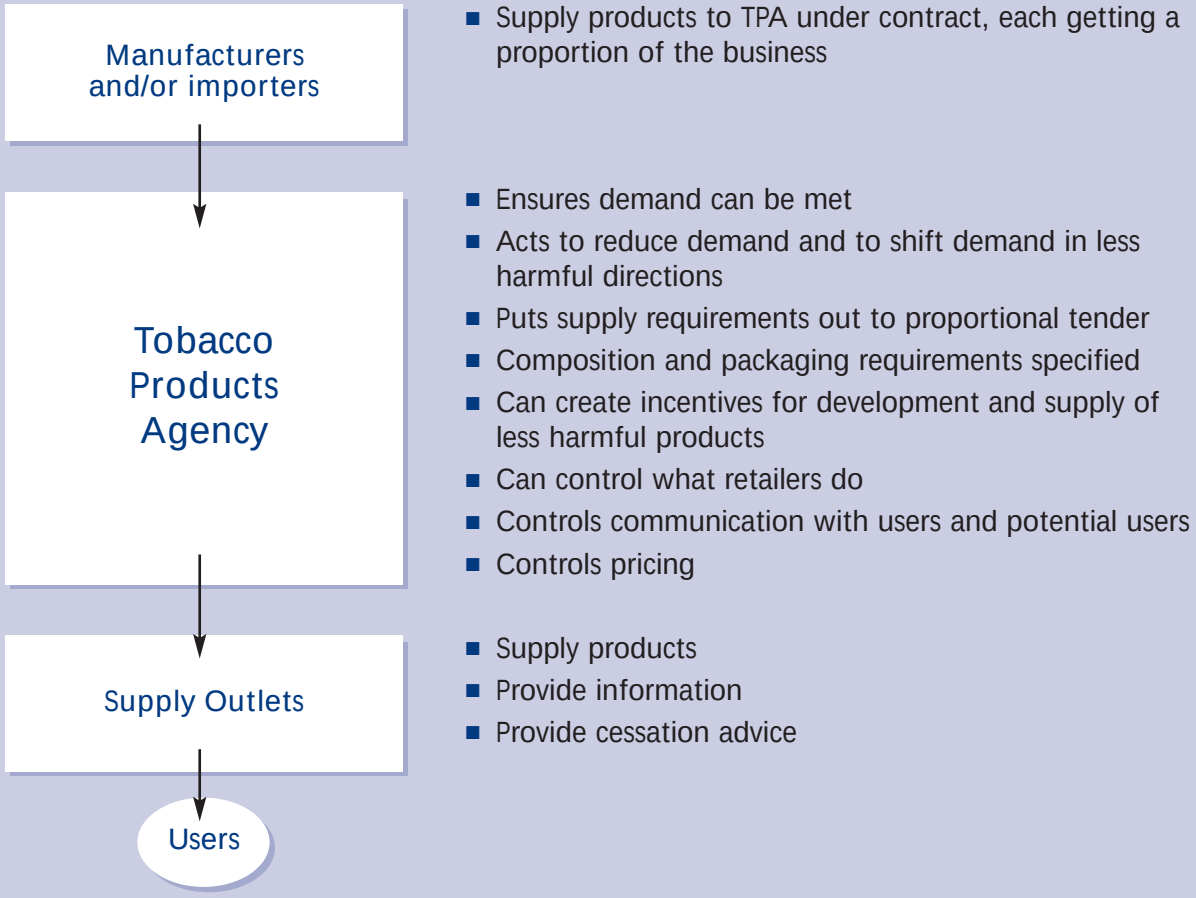
The aim of any regulation must be to reduce the harm caused by the use of tobacco. This can be achieved by some combination of:

- Limiting the level of toxicity of the product, for example by regulating maximum levels of at least some of the main agents known to be harmful such as tobacco-specific nitrosamines, polycyclic aromatic hydrocarbons, hydrogen cyanide, acrolein and heavy metals[6].
- Controlling the level of addictiveness, for example by controlling allowable nicotine levels (although there may be a problem if smokers compensate by increasing the number smoked to achieve desired levels of nicotine uptake).
- Making the product less palatable, for example by removing additives designed to mask harsh taste or add attractive aroma.

The approach needs the best possible science. As our current understanding is limited, it is imperative that regulation allows the flexibility to change to better methods as the science develops. Over time, the levels of toxicity, addictiveness and palatability parameters could be reduced. Yet internationally little has been done. Only two places have implemented any serious regulation of tobacco products. New York State and Canada have both recently moved to ensure that cigarettes are self-extinguishing: that is they go out after a short time if not actively puffed. This has been aimed at preventing death and injury through fires started by cigarettes, rather than preventing harm to the smoker. While a worthwhile move, it is peripheral to the main game.

Regulation is not a panacea. It can be expensive and cumbersome and can even hinder desirable innovations. To the extent that manufacturers' interests are in conflict with regulators, they are duty-bound (to their shareholders) to seek ways to circumvent or sidestep regulation in order to maximise their profits. In doing this they often try to reduce the regulators' effectiveness. The regulatory body can be captured by the industry players through relationships that are either too close or through outright corruption. Regulators can be subject to political control or influence, or starved of resources to do their job properly. Regulation is always under pressure to be minimised or wound back where it conflicts with free-market values.

Figure 1: The Regulated Market Model



Recently, Borland[7] has suggested looking more closely at the patterns of incentives and has suggested restructuring the industry to better align industry incentives with the public interest. Under this approach, which Borland calls a Regulated Market Model, tobacco companies would retain the rights to manufacture tobacco products, but instead of marketing direct to users, they would have only one customer – a Tobacco Products Agency (TPA). The TPA would in turn sell to wholesalers and retail outlets. Smokers would purchase their products from retail outlets in much the same way as they do now. The charter of the TPA would be specifically to reduce the harm caused by tobacco. To pursue this goal it would have powers to:

- Meet demand from customers but act to reduce it over time;
- Call for tenders for supply of products from manufacturers or importers;
- Specify product composition, including limits to toxicity, addictiveness and palatability;
- Create incentives for the development of less harmful products;
- Control communication with users, through advertising, promotions and branding (or the lack of it);
- Control pricing; and
- Use marketing, price or other mechanisms to shift demand in the direction of less harmful products.

The Regulated Market Model is depicted in Figure 1.

Over time, the TPA would move to reduce the toxicity of tobacco products as rapidly as consumer preferences allowed. It could introduce new products conditional on them not having unacceptable interest to new users and, when viable alternatives existed, phase out the more harmful products. As a result of its direct relationship with manufacturers, it would engender a collaborative, rather than antagonistic relationship. Profitability for tobacco companies would be tied to their performance in meeting the needs of the TPA.

With its power over packaging and promotion, it might be expected that the TPA would move to eliminate the value added by branding by supplying product in generic packaging, together with a system of educating users to ensure they are more fully informed of the health consequences of the products and ways to reduce or eliminate risk.

Competition between manufacturers would be preserved, but the industry's ability to produce innovation would be harnessed in the interests of harm reduction rather than maximising sales and profit. In such a system there would be incentives to provide information on product composition and performance to promote their competitive edge to the TPA. The TPA would need to have expertise in product design and toxicology, which at present, is mostly held by manufacturers. In this way, the TPA would act as the ideal fully informed customer, able to assess the risk and rewards of products supplied in the interest of its ultimate smoking customers and the community in general.

A body such as the TPA is subject to some of the same problems of being captured by the industry it seeks to regulate such as political interference or neglect. Ensuring independence, transparency and accountability will need to be a high priority in the establishment of the TPA to reduce this potential.

The adoption of the Regulated Market Model is likely to be difficult. There are few precedents for such a powerful body, although it does have some similarities with the monopolistic export or marketing bodies for agricultural products that have existed for grains, dairy products and fruit and vegetables. It also bears considerable similarity to alcohol marketers in some US states, most of Canada and in Scandinavia. Governments may be unwilling to be associated with the production and sale of tobacco products and the health problems that it entails. Tobacco control advocates may have no doubt that the size of the problem justifies such an unusual solution, but policy makers may not be so convinced. There is no natural constituency to advocate for such a solution beyond the public health groups and perhaps the victims of big tobacco. The industry would no doubt oppose its adoption with all the resources it can muster.

Given these obstacles, it would be unrealistic to expect a TPA to be established in the near future. The trigger for adopting such a model is most likely to be a major crisis, such as the escalation of litigation against tobacco companies or retailers that threatens their very existence. Such a crisis is far from unimaginable, given the rapid increase in the number and extent of successful cases being brought to courts throughout the world.

Conclusions

Tobacco products are in dire need of control to reverse the continuing epidemic of tobacco related diseases that they have unleashed globally in the last century. To date, tobacco products have been regulated only in respect of how they can be promoted and to whom. The time has come to seriously address the need to regulate the product itself to make it less harmful.

Two plausible mechanisms to do this have been discussed. The first is regulation by an existing body such as the Therapeutic Goods Administration or Food Standards Australia New Zealand. If the inherent contradictions of either of these bodies taking on the task are seen as being too great, a new regulatory body may need to be created.

The second alternative is a more radical one and would involve interposing a Tobacco Products Agency between the current manufacturers and the distributors, retailers and smokers. The TPA would have an explicit charter to reduce harm by controlling the product through tender specifications, how it is packaged and how it is marketed. This is likely to be a more effective way of reducing harm, but faces more obstacles in being adopted.

Regulation of the product is the missing plank in comprehensive tobacco control. It's time for governments to start thinking seriously about it.

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