

# The national and international regulatory environment in tobacco control

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## Key points

- No country prohibits cigarettes and few regulate their contents
- Most countries regulate conditions of sale (price, place, age, marketing and packaging)
- The Framework Convention on Tobacco Control mandates that countries pursue tobacco control policies, including direct product regulation
- Several countries are beginning to regulate the composition of tobacco products
- The future of global tobacco control appears bright, including the eventual prospect of truly major new product regulations

## Abstract

Despite their lethality, cigarettes are subject to little regulation that directly restricts their contents or their legality. This may change in the near future with the Framework Convention on Tobacco Control (FCTC), the world's first global health treaty, now in force, as well as developments in a few individual countries. Cigarettes are subject to a substantial number of country-specific regulations regarding their conditions of sale: their price (mostly through taxation), the places where they can be consumed (clean indoor air laws), who can smoke them (prohibitions on their use by or sales to minors), how they can be advertised or promoted (if at all), and how they must be packaged (minimum pack sizes, warning labels, plain packaging). Such policies constitute the core of successful tobacco control.

The FCTC has been ratified by 180 countries representing 90% of the world's population. The FCTC requires compliance with numerous provisions relating to the kinds of regulations noted above. The treaty also mandates explicit attention to direct product regulation. Several countries have such authority, at least in limited forms. In the US, for example, the Food and Drug Administration (FDA) now has the legal authority to regulate tobacco products, including their contents. The possibility exists that, in the foreseeable future, a country will mandate product standards that will substantially reduce the appeal of cigarettes and other combusted tobacco products, which are by far the leading sources of the death and disease associated with tobacco.

## Introduction

If a manufacturer attempted to market a new product that killed half of its lifelong users, government would instantly prohibit its sale, with severe penalties for violations. Even if the product's hazards were not known at the time of its introduction, once compelling evidence emerged, government would ban the product. This has happened frequently with products ranging from lawn darts to leaded petrol, from asbestos to DDT, from children's plastic items that contain DEHP to pharmaceuticals with newly discovered serious side-effects.

It has not happened with cigarettes anywhere in the world, with one small and temporary exception.<sup>1</sup> This is despite the fact that, in terms of their death toll, cigarettes are the most lethal product ever marketed. Tobacco product use, and particularly cigarette smoking, accounts for one in every 10 deaths around the world, and twice that number in affluent nations. Unless current patterns of global use are altered, the World Health Organization predicts that tobacco will kill a billion people this century.<sup>3</sup>

The failure of governments to ban cigarettes reflects three factors: (1) historical accident – smoking was widely practised before the dangers were understood, and the vast majority of smokers were addicted; (2) the economic and hence political power of the industry that accompanied widespread product use; and (3) regulatory exception, itself a function of the first two factors. With regard to regulatory exception, in the US, more than a dozen federal health laws would require the banning of cigarettes if cigarettes were not explicitly and singularly exempted in the legislation, or if regulatory authorities had not chosen to overlook the application of the law to this one class of products.<sup>4</sup> Regulatory exception also holds in Australia, where nicotine is identified as a Schedule 7 poison under the Poisons Standard but is explicitly exempted in the context of smoked tobacco products.<sup>5</sup>

Still, national governments do regulate some aspects of cigarette and other tobacco product use. Increasingly, they do so within an international framework – the world's first global health treaty, the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC).<sup>6</sup> I will describe how tobacco products are regulated, both at the national and international level, and speculate briefly on the future of direct product regulation. With the advent of the FCTC and new country-specific governmental regulatory authority, I will note, for example, how certain product regulations could reduce the palatability of smoking, or its addictiveness, sufficiently to dramatically reduce the use of cigarettes.

## Forms of tobacco regulation at the national level

When one thinks of product regulation, one typically focuses on regulation of the product – its composition, legal availability, etc. While no country has yet banned all tobacco products, some countries have banned specific categories. Most notably, 40 countries, including Australia and countries in the European Union, have banned the commercial import and sale of smokeless tobacco.

No country bans cigarettes. Many countries do impose restrictions on the ingredients in cigarettes, however. For example, Brazil bans all flavours and additives in tobacco products. The European Union recently followed suit regarding flavours, including menthol, in their ban. States in Australia ban fruit and confectionary flavours. The US bans artificial or natural flavours, with the exception of menthol. The intent of these policies is to make tobacco products less attractive to children.

Another example of direct product regulation is the requirement that cigarettes be manufactured with a reduced propensity to ignite fires. Cigarettes are the leading cause of fire-related deaths in many countries. In Australia, Canada, Iceland, South Africa, the US and all 28 European Union member states, it is required that cigarettes are 'fire-safer' (with reduced ignition propensity). (For an excellent review of these and other country-specific product regulations, see McNeill et al.<sup>7</sup>).

Most regulation of cigarettes and other tobacco products pertains to conditions of sale. Such regulation has existed for decades and, indeed, constitutes the core of successful tobacco control worldwide. The principal features of tobacco regulation that are in practice in scores of countries are price, place, person, promotion and packaging, outlined below (for detailed references, see Warner<sup>8</sup>).

### Price

A robust body of international research demonstrates that raising the price of cigarettes substantially is the single quickest way to achieve a significant decrease in smoking. A 10% increase in cigarette price produces a 3–5% decrease in the quantity of cigarettes smoked, possibly more in low- and middle-income countries. About half of the decrease reflects smokers quitting, the other half decreasing daily consumption but continuing to smoke. The impact of price is two to three times larger among young people than adults. Low-income smokers are more price responsive than high-income smokers. Raising the price of cigarettes, typically by raising a country's cigarette excise tax, is thus a highly effective tobacco control policy in general, and also specifically reduces youth smoking and reduces disparities by socioeconomic status in smoking-related disease and death.

i In 2010 the Parliament of Bhutan enacted The Tobacco Control Act of Bhutan,<sup>1</sup> which banned the cultivation, harvesting, production and sale of tobacco and tobacco products in the kingdom, although use was permitted in some circumstances (e.g. in private areas of hotels). Since then, authorities have reduced restrictions, penalties and enforcement of the law, with a 2014 legislative action restoring sale (but not tobacco growing or product manufacture).<sup>2</sup>

## Place

The other tobacco control policy with a large impact is mandating smoke-free workplaces, including restaurants and bars. At least three-dozen countries have adopted such laws. In several countries, including Australia, Canada and the US, smoke-free policies are made at the state or provincial level. A large body of literature demonstrates that smoke-free workplace policies:

- Dramatically reduce worker exposure to second-hand smoke (by 80–95%)
- Increase quitting (by nearly 4%, similar to the effect of a sizable tax increase)
- Decrease the number of cigarettes smoked per day by continuing smokers (by three cigarettes)
- Do not harm business in hospitality industry enterprises
- Reduce some business costs
- Most importantly, reduce myocardial infarctions (by 10–15%).

In many countries that lack comprehensive smoke-free workplace laws, smoking is prohibited in numerous public places, ranging from government office buildings to sports venues. In the most recent development, several countries, as well as Australian and US states, are prohibiting smoking in motor vehicles in which a child is present.

## Person

Most countries prohibit tobacco product use by or sale to minors. There is little evidence to indicate that such policies deter youth smoking, although high rates of compliance with sales-to-minors laws, often driven by serious enforcement, can reduce smoking by children.

Tasmania is considering a policy that would permanently prohibit the sale of tobacco products to anyone born after 2000. This 'smoke-free generation' concept<sup>9</sup> thus stands as the first of a series of tobacco 'endgame' proposals<sup>10</sup> that might eventually be adopted by a government.

## Promotion

Cigarette marketing increases the size of the market, attracting new (young) customers and discouraging adult smokers from quitting. A complete ban on all forms of advertising and promotion would likely reduce smoking by about 6% compared with no restrictions. That may not sound like much, but 6% of a huge problem would represent a substantial contribution to public health.

Restrictions on advertising and marketing vary widely by country, commonly including bans on advertising through broadcast media. Many countries impose restrictions in print media, outdoor media (billboards) and, increasingly, at the point of sale. Some countries prohibit retail display of tobacco products, and many prohibit sports sponsorship and other nonadvertising forms of promotion.

## Packaging

Cigarettes come in packages of varying sizes throughout the world. A relatively recent restriction in several countries involves prohibiting packs of fewer than 20 cigarettes (a policy in Australia and the US), and many countries prohibit the sale of 'loosies', cigarettes sold individually by street vendors.

Almost all countries require health warning labels on cigarette packs. Most of the limited research on conventional warning labels, dating from the 1960s, has found little or no effect. In part, this was due to the often minuscule size of the labels, their placement in obscure locations (e.g. the side of the pack), their sometimes faint-coloured print (gold on a white background on some packs in the US), and the weakness or generality of their messages.

More recently, numerous countries are requiring graphic warning labels that must occupy at least 50% of the front and back of the pack, and include graphic depictions of the damage that smoking inflicts, in addition to text-based warnings. As of late 2014, 77 countries and territories had adopted graphic warning labels. Six countries now require that the graphic warning labels cover 75% or more of the pack, led by Thailand (82.5%), Australia (80%) and Uruguay (80%). Early research suggests that graphic warning labels may reduce smoking.<sup>11</sup>

The newest innovation in cigarette packaging policy – and indeed in tobacco control policy overall – is plain packaging, the requirement that all packs of cigarettes be of the same unappealing background colour and use a single font of a given size to present the brand's name. This approach eliminates the use of colours, pack designs and distinctive, market-enhancing brand logos to promote a given brand. To date, Australia is the only country to have implemented plain packaging. Recently, the UK and Ireland announced that they would follow suit. Several other countries are also actively considering the policy.

## International product regulation

Although there is no current international regulation of tobacco products, an international device is fostering tobacco control around the globe. The FCTC represents WHO's first use of its long-standing authority to develop global health treaties. The World Health Assembly unanimously approved the treaty in 2003, and formal adoption followed late the next year when the 40th nation ratified the treaty. Today, 180 countries, representing almost 90% of the world's population, have ratified the treaty. Argentina, Switzerland and the US are among the 16 eligible countries that have not ratified.<sup>6</sup>

A framework convention establishes a series of general principles that are adopted by the parties (ratifying countries). The parties meet periodically to negotiate the details to translate general principles into

specific treaty requirements. Six such meetings have taken place since 2006. Policies covered by the treaty include increasing tax and price; protecting nonsmokers from second-hand smoke exposure; regulating the contents of tobacco products; imposing packaging and labelling requirements; restricting advertising, promotion and sponsorship; providing treatment support for cessation; prohibiting sales to minors; and curtailing illicit trade (cigarettes are the world's most widely smuggled legal product).<sup>6</sup>

In many countries, public health advocates and health authorities are using their countries' ratification of the FCTC to push for more substantial tobacco control regulation. Although it is not possible to establish a causal relationship between FCTC-promoted tobacco control and changes in smoking, since 2008 the volume of cigarettes sold globally, which had been rising steadily, flattened out at 5.8 trillion cigarettes per year. In 2013, it decreased for the first time.<sup>12</sup> Global smoking prevalence is falling at a rate of approximately 1% per year.<sup>13</sup> Of course, that encouraging statistic reflects a combination of larger annual decreases in smoking in the world's developed nations, and increases in smoking in developing countries. According to WHO, 80% of the world's smokers reside in low- and middle-income countries.<sup>3</sup>

## The future of tobacco product regulation

This is a good time for global tobacco control. Innovative and effective policy measures, such as graphic warning labels and smoke-free workplaces, are spreading rapidly throughout the world. The FCTC provides an ongoing motivation to do more and to do better. Cigarette consumption has levelled off globally and may be in decline, and smoking prevalence is falling.

Predicting the future of tobacco control is something of a fool's errand. Just over a decade ago, few would have predicted that, by 2015, three dozen countries would have prohibited smoking in all workplaces, including all restaurants and bars, and that they would have been led in 2004 by pub-loving Ireland. Almost no-one would have predicted that global cigarette consumption would have levelled off.

Observation of recent general trends and specific developments encourages optimistic speculation that governments will become more involved in direct tobacco product regulation. The FCTC calls for it, and, in theory, its 180 member countries will have to comply. Some such regulation has occurred for years – for example, most European countries ban smokeless tobacco products, as do other countries. Australia has effectively banned open-market sale of electronic cigarettes by virtue of its requirement that all 'clean' nicotine products be registered as medicines. Effective from May 2016 in the European Union, electronic cigarettes

containing up to 20 mg/mL of nicotine will come under the European Union's Tobacco Products Directive. In the UK, e-cigarettes that contain more than 20 mg/mL of nicotine will fall under the authority of the Medicines and Healthcare products Regulatory Agency, meaning that they will require approval for sale as over-the-counter medicines, similar to the treatment of nicotine replacement therapy products.

In 2009, US legislation granted the FDA broad and deep, if not complete, authority to regulate tobacco products. Specifically, the law grants the FDA the authority to establish product standards. In theory, the FDA could thus require increases in the pH of tobacco product smoke, thereby greatly reducing its palatability for inhalation; or reduction in nicotine yields in cigarettes and other combusted tobacco products to nonaddicting levels. The latter<sup>14</sup> has attracted a great deal of attention within the US tobacco control community and in federal agencies that deal with tobacco and public health. If combusted tobacco products were to be rendered nonaddicting, the future of the cigarette in the US would likely be bleak.

Given the politics involved, no-one should anticipate rapid development of such a policy. The FDA can and will develop many other less controversial product regulations; a few have been established already.<sup>15</sup> The point is simply that, for the first time in US history, a government agency has explicit authority to regulate tobacco products, and not merely the conditions of their sale. The implications for the future of smoking could be profound, both within the US and eventually throughout the world.

## Conclusion

We are a long way from the demise of smoking and the enormous toll it exacts. Tobacco kills six million people every year, most of them in low- and middle-income countries. Short of dramatic and unanticipated changes, that figure will rise to more than eight million by 2030.<sup>3</sup> Nevertheless, the future of tobacco control in its various guises appears bright, particularly with regard to product regulation. Supported by a global framework that is now international law, we should expect to see many individual nations pursuing increasingly aggressive tobacco control measures.

Direct regulation of the contents of tobacco products in a manner that will dramatically reduce the attractiveness or addictiveness of smoking seems a bit further off into the future. But product regulation is one of the provisions mandated by the FCTC. Developments in countries like Australia, the UK and the US suggest that this future may not prove to be so distant after all. It may well be hastened by continuing developments in core strengths of tobacco control, including evidence-based policy interventions, research and advocacy.

## Competing interests

None declared.

## Author contributions

KE Warner conceived, researched, drafted, and revised the manuscript.

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