Tobacco Control in Practice

Article 11:
Packaging and labelling of tobacco products

Case studies of implementation of the WHO Framework Convention on Tobacco Control in the WHO European Region
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Article 11: Packaging and labelling of tobacco products

By Andrew Hayes

Health warnings on tobacco products provide a cost-effective way of reminding tobacco users of the risks they run. Half of all smokers die prematurely as a result of using tobacco. Where better to repeat this information than on the product itself?

"Repeat" is the key word here. Despite knowledge of the dangers of tobacco for more than two generations, every new smoker seems to disregard the inevitable consequences; lulled into a sense of security – or denial – by the efforts of the tobacco industry to portray smoking as perfectly normal.

So the warnings have to be repeated, again and again, in as many imaginative and varied ways as possible. Tobacco packaging provides the opportunity to repeat the message directly to tobacco users.

Article 11 of the The WHO Framework Convention on Tobacco Control (WHO FCTC) requires the introduction of large, rotating health warnings that should cover at least 50% – and must cover at least 30% – of the principal display areas of the packs. Warnings may be in text and/or include pictures or graphics.

Parties to the WHO FCTC are also required to ensure that no "misleading descriptors" appear on tobacco packages. This means that no product should convey the impression of being safer, or less harmful (for instance, by using such terms as "light" or "mild") than any other tobacco product.

As more countries move to ban tobacco advertising (Article 13), tobacco packaging is becoming the last branding and marketing opportunity available to the tobacco industry. Large, graphic warnings not only tell the truth but also diminish any attraction associated with the product. This objective also lies behind the recommendation to consider introducing plain packaging.

Article 11 guidelines? Yes

Timetable for implementation? Within three years of a country’s ratification of the WHO FCTC

Implementation progress within the WHO European Region
In 2008, seven European countries had introduced a strong mix of health warning characteristics (such as medium or large size, on both sides of the pack, using pictures or graphics, rotating etc.). By 2012, this had risen to 16 countries.

Romania

| Population | 21.2 million |
| Prevalence(adults, age-standardized) | Male 37% | Female 17% |
| Total | 27% |
| Selling price (per pack, 20 cigarettes) | Most sold US$ 3.60 |
| Cheapest | US$ 3.30 |
| Date of WHO FCTC ratification | 27 January 2006 |
The story of Romania

During 45 years of communism, Romania did not have any tobacco control laws. In the 1980s, tobacco control advocacy had an unfavourable reputation, as it was seen as a manifestation of communism advocating elimination of the last pleasures and aspiration to the western lifestyle. Despite a long history of pro-smoking policy, Romania became the second country in the WHO European Region to introduce pictorial warnings on cigarette packages.

By Magdalena Ciobanu

Case study questions
What were the favourable conditions within Romania that enabled success?
How can the example of Romania be applied and transferred to other countries?

Country context
Romania is a country in eastern Europe that was a communist country until 1989 and joined the European Union (EU) in 2007. This recent historical past deeply affected both smoking rates and tobacco control policies. The prevalence of smoking increased dramatically after 1989, after the political regime change, allowing Romania to be placed as one of the most smoky European countries (1). In 2002, the tobacco control policies underwent a sudden positive change because, as a mandatory step required for joining the EU, Romania had to transpose the EU legislation into the national legislation.

Beating the odds
The history of smoking and of tobacco control is closely linked to the evolution of the Romanian society and the political context. Tobacco was introduced in the 18th century, through Greek and Turkish channels, initially in the form of water-pipe tobacco. At that time, tobacco symbolized belonging to the high and fortunate class in society. In the 19th century, more young people started to study abroad, particularly in France. Thus, another two societal categories started to smoke: peasants (who smoked hand-rolled tobacco) and the young, educated, wealthy elite, including educated women. Before the Second World War, smoking was perceived as the appendage of the trendsetters, of young students and women who studied abroad and those who were models for the local high society. In contrast, in rural settings, the image of smokers – especially of women – did not carry the same positive image.

When Romania became a communist state after the Second World War, everything changed. Although the tobacco trade in Romania has been a state monopoly since 1864, the communists expanded this role. The state controlled tobacco farming, cigarette manufacturing, trade with indigenous and imported tobacco products and even advertising these products. The state established tobacco prices, and the public authorities collected the profit. During the 45 years of communism, Romania became a leader in tobacco farming in the WHO European Region. Numerous cigarette factories appeared across the country, and big tobacco companies were absent from the market. Tobacco control laws did not exist.

The silver line
Advertising and sponsorship for tobacco products were not extensive as in the countries in the western part of the European Region. For example, there were no television or radio ads, no billboards, no events sponsored or grants offered by the multinational tobacco industry and no promotional objects carrying western brands were present. The local brands were somewhat present, but their impact was totally insignificant.

During the communist era, international brands were allowed for sale officially but restricted to special shops for foreigners, and the price was considerably higher than indigenous cigarettes. Regardless of the restrictions, these foreign brands became available on the black market, and well-established networks evolved. As a consequence, the international cigarette brands became an appreciated gift, a symbol of well-being and of belonging to a higher social class, even if there supposedly were no social classes in communism.
Specific to a communist country, these brands were used for small-scale bribes – a pack of Kent opened many doors and bought the benevolence of many, including health professionals. The tradition of offering tobacco products as a gift to physicians clearly contributed to the acceptance of smoking and to the lack of activities and attitudes against smoking, which remains present today. However, in the 1980s, professionals in disease prevention and health education started to present smoking as an enemy for health and recommended tobacco cessation. Some antismoking programmes for preventing and fighting tobacco use were developed in schools and colleges. Despite their positive results, these pioneers of tobacco control advocacy did not have a good reputation because their activities were seen as promoting communism and eliminating one of the last pleasures and manifestations of western lifestyle. Moreover, their educational actions were linked with inspection activities, which were frequently very unpopular and perceived as a contribution to the etiquette of “fascists” and “enemies of the people”.

**Health professionals advocating smoking prevention and cessation were viewed as “freaks” and “former communists”**.

In this context, the explosion of smoking and the reluctance to engage in any tobacco control activity that appeared after the political change in 1989 is understandable. When the state monopoly disappeared, the newly rich started to appear. All the big tobacco companies established offices and factories for manufacturing cigarettes. Cash began to flow to professional tobacco marketing to exploit advertising in a country that had never been exposed to such tactics. Messages linking the American lifestyle to international cigarettes brands were transmitted through every available communication channel. The prices were so incredibly low that everybody could afford a symbol of wealth. Mass media were not at all supportive of tobacco control messages.

The result of this pro-smoking atmosphere generated by the tobacco industry led to the dramatic increase of smoking prevalence from 26% in 1984–1985 (2) to 35% in 2003 (3). This change in rate is mostly due to women smoking, since in 1989 11% of women declared that they smoked daily or occasionally and in 2003 the percentage doubled – 24% of women declared that are using cigarettes on daily or occasionally. Despite increased tobacco control activities in the rest of the world, significant measures against smoking did not reach Romania in the early 1990s. Although a tax earmarked for the Ministry of Health on tobacco products was introduced in 1994, it was never applied because the provisions for implementing this were never published.

The trigger for the introduction of tobacco control measures was the obligation to align national legislation with the EU legislation in the process of joining the EU. Since the European Commission approved the Tobacco Products Directive and Tobacco Advertising Directive in 2001 and 2003, respectively, Romania was required to implement the provisions of the two directives. The first tobacco control laws were passed in 2002 and modified in 2004, establishing new rules for smoking in public places, labelling, packaging and content of tobacco products and for sales, restricting advertising, sponsorship and promotion and establishing a roadmap for increasing taxation. Almost immediately, the entire atmosphere changed: the mass media started to emphasize the negative effects of smoking and the impact of tobacco control advocates increased. The positive social perception of smoking began to change, and smokers became interested in quitting. The price of tobacco increased, and the visible influence of the industry was declining.

**From challenge to success**

In this context, 2006 appeared to be crucial for future tobacco control development, because the politicians understood how smoking adversely affects the economy and health. Sustained by the political goal of joining the EU, the Minister of Finance agreed with the Minister of Health’s proposal to introduce a fixed tax for health on all tobacco products (€0.20 per pack), to be used for health programmes and tobacco control activities. The Minister of Health, driven by the deep understanding of the negative effects of smoking on the present and future generations and despite the aggressive opposition of the industry, obtained approval to implement the most severe legislative health measures possible at that time: pictorial health warnings on all tobacco products (for smoking), restricting smoking in public places and restricting advertising, mandatory disclosure of all ingredients used in tobacco products, free treatment for tobacco dependence and educational programmes in schools and colleges at the national scale.

Finally, despite historical roots and traditions and public opinion favouring smoking, in July 2008, Romania became the second country in the WHO European Region to implement pictorial warnings. The country demonstrated that complex and efficient tobacco control measures can be introduced in a short period of time when there is political leadership to adopt and implement legislative measures. From a historical peak of 36% in 2003, the prevalence of daily smoking
decreased by almost one third in less than eight years to 22% in 2011.

**Getting it on the agenda**

Directive 2001/37/EC regulates the labelling of tobacco products in the EU. In the process of joining the EU, Romania had to transpose this directive into the national law regarding tobacco control. Thus, in 2002, Law No. 349/2002 on preventing and combating the effects of the use of tobacco products was passed (4).

Once the European Commission finished the rules for the use of colour photographs or other illustrations on tobacco packages (5), it provided enough information to obtain the approval of the Minister of Health to introduce the rules for using the images on tobacco packages sold in Romania. Thus, in 2004 the first health ministerial order on the use of images on tobacco packages appeared (6). In 2005, the political context changed. Tobacco control was on the agenda of the new government because of the process of joining the EU and also because Romania ratified the WHO FCTC that same year.

The Stability Pact for South Eastern Europe and the corresponding South-eastern Europe Health Network significantly contributed to this change through the project Strengthening Tobacco Control in South-eastern Europe. Although the goal was to ratify the WHO FCTC, the project facilitated communicating the elements of a comprehensive tobacco control policy to decision-makers and the interaction between members of the government, including finance, agriculture, foreign affairs and internal affairs ministries. In this way, the awareness of stakeholders about the need for a comprehensive tobacco control policy was increased. Once political support was obtained, the next steps fell into place: the Minister of Health understood the usefulness of proper warning labelling on tobacco products, since the EU’s technical regulations for pictorial warnings (7) were finished in 2006 and the first international studies about the effectiveness of pictures were published, he approved the use of pictorial warnings through a ministerial order in March 2007 (8).

Being an economist, the Minister of Health quickly understood the value: putting images on the tobacco packages is the most cost-effective information and education measure because every user and potential user is informed about the dangers of using the product and the tobacco industry pays the printing costs. The final regulation published in November 2007 included cartons of cigarettes.

In January 2008, the tobacco control law was modified to set the implementation date for cigarettes (1 July 2008) and for all the other tobacco products (1 January 2009). The transition period needed for finishing the stocks had to end by 1 July 2009 for all tobacco products. As of 1 July 2009, all tobacco products intended for smoking had to be labelled with pictorial health warnings.

Only eight months elapsed between finalizing regulation and implementing pictorial warnings.

**EU regulations and decisions at the country level**

The use of colour photographs or other illustrations is not mandatory at the EU level and is a decision of every country. However, the European Commission has established rules for use (5).

**Article 5.3.** Where Member States require additional warnings in the form of colour photographs or other illustrations, these shall be in accordance with the above-mentioned rules.

This article of the directive was transposed into Romania’s legislation as follows.

**Article 6.2h.** The use of images or drawings that illustrate the health effects of smoking shall be established according to the European Community regulations through a health ministerial order.

**Taking action**

Commission decision 2003/641/EC on the use of colour photographs (5) stipulates that “Member States may choose the source documents best adapted to consumers in their countries”. A public consultation was launched to select the proper images that are appropriate for the context of Romania. Time and financial restrictions did not allow for a consultation that accounted for all subpopulations within Romania. Instead, the selection was the result of a combination of public consultation through the Internet, consultation with nongovernmental organizations that worked towards tighter tobacco control, medical and social
The story of Romania

Ministerial order on pictorial warnings
The Ministerial order included general technical details (e.g. images, margins and rules of rotating images) and technical specifications for printing (e.g. colour, fonts and alignment).

Date of first appearance
- July 2008 – for cigarette packages
- January 2009 – other tobacco products

Accepted time period
- 1 year for cigarette packages
- 6 months for other tobacco products

Responsibility for inspection
In Romania, the inspectors from the Ministry of Health and from the National Authority of Consumer Protection are responsible for supervising the enforcement of the tobacco law. Each year, they establish an annual plan for all enforcement activities, including tobacco control, and have to respond to all individual notifications and information about non-compliance. The penalties are: fines (Leu 10 000–50 000), seizure and destruction of the packs.

The battle is not over
According to the law about transparency in decision-making, the project of every legislative measure has to be put on the Internet for public debate. The tobacco industry used the tactic of delaying approval of the regulation. Some arguments used by the industry and also present in some mass media included:

- the lack of evidence for effectiveness of pictorial health warnings, with smokers supposedly not being influenced by the pictures;
- the images are too scary and could frighten children;
- it is premature to use approved pictograms by the EU – “Why should we be the first ones to verify or implement this measure?”; and
- “if the measure works and the number of smokers decreases then that will affect the economy and the budget.”

During a public consultation, the tobacco industry made false claims about the effectiveness of graphic warnings and potential threats to the economy.

As the Minister of Health was very determined to implement the measure, the next industry tactic was to delay implementation and to enhance the time period to synchronize the text to the pictures. However, the key factor that prevented a delay was the existence of well-defined technical specifications for using the images on different formats of tobacco packages.

Favourable conditions
The support of the international tobacco control community was very important in exchanging knowledge and resources and obtaining immediate assistance to counteract the arguments against pictorial warnings. More importantly, the environment within Romania was very favourable and the momentum was strong.

Political support
The political support and trust given by the Minister of Health and his expert panel were instrumental, since only one other country in the WHO European Region had implemented such a measure. The economics background of the Minister of Health quickly allowed him to recognize the great economic toll tobacco has on a country and the benefit of reducing tobacco consumption through pictorial warnings. Political support can be obtained more easily in the context of a broader tobacco control policy that links the pictorial warnings with other social and economic measures such as the introduction of subsidized (total or partial) smoking-cessation treatment and a tax earmarked for health and education in schools and universities.

Solid evidence base
Getting correct information to the politicians about the real targets of pictorial warnings (such as non-smokers, occasional smokers and less severely addicted smokers) is essential to counteract the lies of the tobacco industry. A solid file with the evidence-informed positive effects of introducing such pictorial warnings in other countries is essential to convince...
the policy-makers about the high cost–effectiveness of this measure.

Ratification of the WHO FCTC
The ratification of the WHO FCTC focused attention on the importance of a comprehensive national policy rather than voluntary agreements or heterogeneous measures. The need for ratifying and implementing the WHO FCTC could aid tobacco control advocates in convincing politicians to decide to implement pictorial warnings.

Joining the EU
The overarching political context associated with the major objective of joining the EU generated the interest to modify the entire national legislation. In addition, experts from the European Commission established unique technical guidelines for applying the pictorial warnings, eliminating the scientific and financial burden of creating rules for technical implementation.

Context in south-eastern Europe
The local tobacco control context resulting from the project Strengthening Tobacco Control in South-eastern Europe brought knowledge and facilitated communication between government institutions.

Mass media
With a few exceptions, the mass media presented the public health arguments neutrally and correctly. The subject of tobacco control was present in all mass-media channels and received prime and repeated broadcast slots.

Evaluation
Extensive evaluation was conducted before pictorial warnings were implemented and at two times afterwards: at 4 months, in October 2008 (early effects) and at 16 months, in October 2009 (late effects). The results demonstrated that the tobacco industry’s arguments against pictorial warnings on tobacco products proved to be incorrect.

Influence of pictorial warnings
Pictorial health warnings provide more specific knowledge about the health risks of smoking. Smokers were asked to give three examples of warnings from tobacco packs, to measure what they remember as well as a proxy of what they consider to be relevant for their health. Before pictorial warnings were introduced, the most memorable warnings to smokers were very general, demonstrating a lack of knowledge about the specific diseases caused by smoking. Only 12% responded “Smoking causes cancer” as their first example of recalling warnings. In contrast, early after implementation, the first identified warnings were the images about lung cancer (20%) and throat cancer (11%). New adverse health effects were mentioned such as babies being affected (8%) and harm to teeth (6%). Much later after implementation, more people remembered the new images: 14% mentioned throat cancer and 11% harm to teeth as the first example of the effects of smoking. Lung cancer remained at the top of the list (18%).

Before and after pictorial warnings are implemented

Before pictorial warnings
General knowledge about smoking effects:
- “Smoking seriously damages health” (35%)
- “Smoking can kill” (31%)

After pictorial warnings
More specific knowledge about:
- Lung cancer
- Throat cancer
- Babies are affected
- Harm to teeth
- Intention to quit

In the Eurobarometer 2009 conducted in December 2008 (six months after pictorial warnings were implemented), 61% of Romanian respondents said that adding a colour picture illustrating the health effects of smoking is more effective when added to a text-only warning (10). This is further supported by gauging the intention to quit and actual quit attempts.

The intention to quit smoking is enhanced. Smokers were asked whether they thought about quitting smoking because of the health warnings. Before pictorial warnings, 14% strongly agreed. Early after pictorial warnings were implemented, the percentage increased to 22%. However, after one year, the percentage decreased to 17%, illustrating the importance of rotating the images. In a recent national telephone poll of adults, 39% of interviewed smokers declared that they thought about quitting smoking in the last 30 days because of pictorial health warnings (11).

Further, before the pictorial warnings, 21% of smokers tried to quit. In the early stages after pictorial warnings were implemented, 28% tried to quit, and 14% tried to quit in the late stage. Since heavy smokers can face severe nicotine withdrawal symptoms...
and thus are less likely to quit because of an image, this data could suggest that occasional smokers are most severely influenced by images in their decision to quit. As one of the new health warnings contains the quitline number, the impact of pictorial warnings could also be evaluated by an increase of the number of calls received. This number increased significantly after 1 July 2008, but this cannot solely be attributed to pictorial warnings and could be partly explained by an intensive national outdoor advertising campaign in September 2008 promoting the quitline number and the launch of the smoking-cessation services. Fig. 1 shows the trend in the number of calls in 2008–2009 and the various tobacco control events taking place in that period of time. After March 2009, the number of calls remained relatively stable, varying between 150 and 300 calls per month, influenced by various activities such as campaigns (for World No Tobacco Day and the national no tobacco day), articles and interviews in mass media.

Prevalence
The prevalence of daily smoking decreased from 31% in 2009 to 28% in 2008 (12). In 2008 and 2009, many tobacco control measures were implemented in conjunction with the pictorial warnings. Thus, we cannot attribute the decreasing prevalence solely to the appearance of images on tobacco packs, although this made an important contribution. Nevertheless, the decreased prevalence is evidence to counteract the false statement that it is too early to measure any change, since it is never too soon to protect population against smoking by implementing all evidence-informed measures.

Public support and preventive measures
Nonsmokers are more influenced by pictorial warnings than smokers. In the Eurobarometer 2009, 58% of nonsmokers and 48% of smokers in Romania considered that adding a colour picture illustrating the health effects of smoking to the text-only health warning is very or somewhat effective, with similar findings in Belgium and the United Kingdom, the other first two EU countries to implement pictorial warnings. This is a very important result because it demonstrates the public support, even among smokers,

Fig. 1. Total calls to the quitline in Romania, 2008–2009

![Fig. 1. Total calls to the quitline in Romania, 2008–2009](image-url)
and the potential of pictorial warnings to reduce the uptake of tobacco use.

**Attractiveness of packages**
The attractiveness of packages was significantly reduced. Fewer smokers declared that they are indifferent to the labelling of tobacco products (from 38% before pictorial warnings to 32% after one year). The rest of the smokers surveyed reported various feelings when they look at a package of cigarettes.

- **Disgust and loathing for packs:** 21% of smokers reported such feelings before pictorial warnings. Early after implementation, the percentage increased to 35%; the trend remained even after one year of implementation at 43%. Since disgust is a measure of the lack of attractiveness and since young people are the group of smokers most influenced by the image of the product, these results support the implementation of pictorial warnings as an efficient measure for preventing smoking and for decreasing occasional smoking.

- **Fear or being scared:** from the initial 26% before pictorial warnings were implemented, the percentage of smokers confirming moderate or strong fear increased to 31% in the early stage and to 32% in the late stage.

- **Anxiety and concern:** the percentage of smokers reporting such feelings did not change much. From an initial 33%, the value decreased very slightly to 32% (early stage) and then increased very slightly to 33% (late stage). All these values are within the statistical error of the poll. This could be an indication that anxiety subsides and can potentially be replaced with a feeling of empowerment to elicit behaviour change.

Common allegations by the tobacco industry are listed below and evaluated within Romania’s context.

**Avoidance behaviour**
Smokers were asked whether lighting a cigarette was accompanied by various gestures.

- **Avoiding looking at the pack:** this avoidance behaviour is the most frequent gesture, both before and after the introduction of pictorial warnings, as the frequency increased from 13% to 30%.

- **Covering the health warnings:** the percentage of smokers adopting this behaviour increased over time, from 5% before the pictorial warnings to 24% (early stage) and 27% (late stage). The act of using a cigarette case or box to avoid the warnings increased, from 2% to 9% (early) and 8% (late), demonstrating that pictorial health warnings produce discomfort to some smokers.

The total number remains small, and this is an important counterargument.

- **Asking for packs with less-harmful pictures:** before pictorial warnings were implemented, only 2% of smokers asked for a specific pack of cigarettes at the point of sale. At 4 and 16 months after the implementation, the rate increased to 16% and 19%, respectively. Moreover, the percentage of smokers recognizing the preference for a pack without warnings increased from 8% (before) to 29% (early stage) and 35% (late stage). These data demonstrate that pictorial warnings are effective in reaching smokers and can be the first step for changing behaviour and attitudes.

**No loss in revenue**
Despite the tobacco industry’s allegations of revenue loss (13), the price of a pack of cigarettes increased in the first months after pictorial warnings were implemented, even though taxation was not modified. The tobacco industry increased the price of cigarettes in the first five months after pictorial warnings were implemented. The prices of two popular brands were raised by 5% and 5.5% respectively between July and October 2008.

**The tobacco industry raised their prices when the pictorial warnings were implemented.**

In January 2009, the excise tax increased, but the price of cigarettes increased in advance, in December 2008, by at least 3%. Even though the tobacco industry could present other reasons for the increased price, the trends in prices in the absence of any changes in taxes and regardless of the manufacturer could be considered a relevant argument for the economic benefits of pictorial warnings. It has been demonstrated that increasing the price of tobacco products reduces the smoking prevalence and increases tax revenue.

**No smuggling**
The use of images on tobacco packs is not an incentive for smuggling. On the contrary, the images could help the authorities identify the counterfeit or smuggled products. The public data about the magnitude and causes of smuggling come from the tobacco industry’s studies. They emphasize the impact of the price of tobacco packages on smuggling and not of their labelling. Just a few months after 1 July 2009, all the packs of cigarettes were clearly labelled with pictorial warnings. In conclusion, the industry’s argument that they need more time to implement the measure...
(often at least 12 months) was just another way to delay implementation.

**Conclusion**

During 45 years of communism, Romania did not have any tobacco control laws. In the 1980s, tobacco control advocacy did not have a good reputation, as this was considered to be a manifestation of communism advocating the elimination of the last pleasures and manifestations of the western lifestyle. Despite a long history of pro-smoking policy, Romania became the second country in the WHO European Region to introduce pictorial warnings.

The battle was not easy. However, the support of the international tobacco control community was very important for exchanging knowledge and resources and acquiring immediate assistance to counteract the arguments against pictorial warnings. More importantly, the environment within Romania was very favourable and the momentum was strong.

**Checklist for success**

- Organize a public consultation to counteract the arguments presented by the tobacco industry
- Consider useful and cost-effective media, such as Internet consultation through web sites, forums and social media
- Establish the technical details for applying pictorial warnings before the regulation is made public to limit the tobacco industry’s possibility to influence health policy
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The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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