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Assessing the impacts of Revising the Tobacco Products Directive

Study to support a DG SANCO Impact Assessment

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Smoking and other forms of tobacco use remain one of the largest avoidable causes of morbidity and premature death in the EU

With more than 650,000 deaths a year – representing more than 15 percent of all deaths in the EU – attributable to smoking, tobacco use is one of the largest avoidable causes of morbidity and premature death in the EU. For more than a decade smoking prevalence in the EU has, however, been declining, reflecting a wider trend of reduction in smoking prevalence that may be observed since the 1980s. Over the past 30 years, smoking has remained more prevalent among men than women in the EU-27, with some of the new Member States reporting the widest gaps between male and female smokers. For young smokers (13 to 15 years old) this situation is somewhat reversed, with slightly more girls than boys smoking.

The negative health impacts of tobacco use are well established and smoking has been linked to several forms of cancer, respiratory diseases, vascular diseases, negative reproductive effects and a wide range of other negative health impacts such as increased risks of cataracts and adverse surgical outcomes related to poor wound healing.

Tobacco-related diseases incur considerable direct and indirect costs for society, including direct healthcare costs and indirect costs such as productivity losses (absenteeism, lost skills, unemployment), welfare provision costs (sickness and unemployment benefits) and fire and other accidents (property losses, wild fires), as well as intangible costs such as pain and suffering that result from loss of life or illnesses brought on by tobacco use. These costs have been estimated to be up to €363 billion in 2000, corresponding to 3.9 percent of EU-27 GDP.

Tobacco manufacturing is dominated by a few large companies, while retail structures are more diverse across Europe

The tobacco industry sector may be roughly categorised into the following activities: tobacco growing, tobacco manufacturing, tobacco wholesale and tobacco retail activities.

Tobacco manufacturing, and in particular the production of manufactured cigarettes, is dominated by a few very large companies in the EU, displaying the characteristics of an oligopolistic market. These companies are Philip Morris International (PMI), British American Tobacco (BAT), Imperial Tobacco and Japan Tobacco International (JTI). Total employment in tobacco manufacturing in Europe was estimated to be 47,000 in 2006, according to Eurostat data. However, overall cigarette manufacturing is a capital-intensive business. According to Eurostat data, gross turnover was in the region of €48 billion in 2006, and tobacco manufacturing is highly profitable.
There are different models of tobacco retailing across the EU, with some Member States having monopoly systems and specific retail outlets while others allow tobacco sales in a wide range of retail outlets. Eurostat reports a total number of 64,000 retail outlets with some 150,000 employees across Europe.

Tobacco product regulation incurs administrative burdens for tobacco manufacturers in the form of labelling and reporting requirements. Based on self-reported data from the tobacco industry, which are likely to be overestimated, the current administrative burden amounts to between €33.2 and €55.4 million per annum.

**Tobacco use generates substantial tax revenues for the Member States but illicit trade undermines national tobacco taxation and other tobacco control measures**

The taxation of tobacco products through excise duties and VAT leads to substantial tax revenues for the Member States in the EU. In 2007 revenues from tobacco consumption accrued to just below €67 billion. Losses due to smuggling have been estimated to amount to €230 million a year in 2007.

**The Tobacco Products Directive is a key instrument of European tobacco control policy**

European tobacco control policies encompass a wide range of policy measures, including restrictions on cross-border advertising, harmonisation of tobacco excise duties, initiatives to reduce exposure to second-hand smoke, recommendations for comprehensive tobacco control policies across Member States and tobacco product regulation.

One of the key instruments is the Tobacco Products Directive (2001/37/EC), which establishes maximum tar, nicotine and carbon monoxide (TNCO) yields for cigarettes, specifies the labelling provisions, bans the use of misleading descriptors – such as ‘mild’, ‘light’ and so on, and bans the marketing of oral tobacco in the EU (except in Sweden). The implementation of the Tobacco Products Directive has been assessed in two reports on its application. These identified emerging issues and areas for further action which DG SANCO is now seeking to address in an upcoming revision of the directive.

**DG SANCO considers changes in five areas of the regulation**

DG SANCO is thus currently considering revising the directive in five areas of tobacco product regulation:

1. Adjusting the scope of the directive by including further tobacco products and paraphernalia.
2. Changes to the labelling requirements for producers.
3. Introducing reporting and registration requirements and market control fees.
4. Defining the ingredients of tobacco products.
5. Revising the sales arrangements for tobacco products.

For each of these areas of change, DG SANCO is presently considering a number of measures to strengthen current regulation, and has clustered these into five policy options. These options may be described as follows:

**Option 1**: No change.

**Option 2**: No binding measures.
Option 3: Minimum revision of the directive, bringing it in line with scientific and international developments.

Option 4: Revision of the directive, bringing it in line with scientific and international developments and strengthening the protection of vulnerable groups.

Option 5: Revision of the directive with the objective of strengthening product regulation and full implementation of the polluter pays principle.

This study will inform a full impact assessment by DG SANCO

Against this background, DG SANCO commissioned RAND Europe to provide support for assessing the impacts of these five policy options. This report serves as an input to DG SANCO’s own impact assessment exercise. By taking into account the possible health, economic and social impacts of these policy options, RAND Europe weighs their costs and benefits and supports the identification of a preferred policy option to meet DG SANCO’s objectives of achieving a high level of health protection and ensuring good functioning of the internal market. This report does follow the impact assessment guidelines of the European Commission (EC) as far as feasible; it, however, does not constitute a full impact assessment.

A variety of methods to assess possible impacts of European action has been used in this study

This study uses a variety of research methods and techniques of analysis to arrive at an assessment of the different social and economic impacts of the options currently being considered by DG SANCO. It is primarily based on analysis of existing literature and data sources, but additional primary data have also been gathered to inform the assessment of the administrative burden and compliance costs for industry. The key methods used are as follows:

1. Targeted literature reviews of both the health and economic impact of different measures of tobacco product regulation, including labelling and health warnings, changes in sales arrangement, more stringent regulation of ingredients and additives and reporting requirements.

2. The analysis of statistical data available based on official data sources, including data from the World Health Organization (WHO), Organisation for Economic Cooperation and Development (OECD), Eurostat and Eurobarometer.

3. Primary data gathering, using key informant interviews and questionnaires with tobacco manufactures and retailer associations, on the administrative burden and compliance cost of tobacco product regulation. These data were analysed using a methodology inspired by the standard cost model.

4. Two quantitative models were developed and used to forecast future mortality and morbidity rates, and healthcare costs, and to model the macroeconomic impacts of reductions in smoking prevalence.

5. A cost consequence framework and scoring mechanism to compare the different options and to identify their different impacts was also used.
With the strengths and limitations of these options in mind and taking into account the timeframe and scope of this research project, RAND Europe assessed the potential impacts of the options considered.

**Stakeholder consultation**  
As part of the development of this research, key stakeholders were consulted in an informal consultation exercise, preceding the formal consultation to be conducted by DG SANCO as the legislative proposal is developed. The key objective of the stakeholder consultation was to provide input for this research project at an early stage and to ensure that the project team could obtain the best available information. The engagement with stakeholders had two key components:

1. Discussion of an interim report, with stakeholders having the opportunity to provide comments and feedback during a series of workshops, and to provide written comments for the research team.

2. An administrative burden measurement exercise with tobacco manufacturers and retailers, consisting of key informant interviews and the distribution of a cost questionnaire to a number of businesses and their umbrella organisations.

**This study reviewed evidence and assessed measures in five areas of change**  
To assess the options suggested by DG SANCO, RAND Europe reviewed evidence in five areas of change to arrive at a balanced and reasoned assessment of the potential impacts of the different measures considered by DG SANCO.

**Scope of the Tobacco Products Directive**  
Recent years have seen a diversification of tobacco products in use, such as roll-your-own cigarettes (RYO) and water pipes, and the emergence of new forms of product such as electronic cigarettes. Evidence shows that consumers do not have good knowledge about the harmfulness of these products and underestimate the health risks of their use. In the case of electronic cigarettes, very little is currently known about health impacts, and in many Member States they are not adequately regulated. Extending tobacco regulation to these products – as well as to paraphernalia such as rolling paper, water pipes, pipes, and so on – may help to increase consumer awareness and have positive health effects, but there is very little evidence available on the health impacts of regulating such products. Extending the scope of the Tobacco Products Directive would affect the producers of paraphernalia and electronic cigarettes, but given the limited information available on these business sectors, measuring this impact is fraught with difficulty.

**Labelling and packaging**  
There is a large and clear body of evidence showing that health warnings on tobacco products increase consumers’ knowledge about the health consequences of tobacco use, and contribute to changing attitudes towards tobacco and consumers’ smoking behaviour. In general pictorial warnings are more effective than textual warnings; and the larger the warnings, the more effective they tend to be. There are, however, difficulties in observing this individual-level effect at the population level using prevalence rates. Generic or plain packaging has been shown to reduce the attractiveness of cigarette packages and to direct the attention of the consumer to the more prominent health warnings on the pack, and is thus likely to strengthen further the positive impact of health warnings. There is strong
evidence that quantitative TNCO measurement and labelling does not accurately represent the yields smokers are exposed to and that smokers wrongly interpret cigarettes with lower yields as less damaging for their health. Very limited information is available on the effect of additional inserts for tobacco packages.

Labelling and packaging are likely to result in administrative burden for tobacco manufacturers; these are, however, to a large extent one-off costs for adapting the label and can be further reduced by synchronising labelling changes due to regulation with labelling changes that would have occurred anyway (e.g. changes in text and pictorial warning contents). Thus the longer the transition period of introducing labelling changes, the lower the costs. Changes in the packaging regime may impact on brand values, but there is little evidence of such an effect.

Registration and market control fees
Improving the current unsatisfactory situation of ingredient reporting by having mandatory reporting formats may lead to better data about the composition of tobacco products becoming available, and subsequently to better consumer information and potentially better regulation. Using market control fees or a general liability principle to transfer healthcare costs to tobacco manufacturers has not been previously attempted, but it would be likely to have the same effect as a substantial rise in tobacco duty, leading to large positive health effects and savings in healthcare costs but also to reduced revenues and employment in the tobacco industry.

Ingredients
A substantial body of literature assesses the harmfulness, and in particular the carcinogenic nature, of specific tobacco ingredients, but little is known about the health effects a regulation or ban of these ingredients would have on tobacco consumers. Tightening the yield limits for manufactured cigarettes will not necessarily lead to better health outcomes as studies have shown that smokers compensate for lower (nicotine) yields by smoking more intensely or more.

Sales arrangements
Restricting or banning the promotion of tobacco products in retail outlets, and restricting or banning the display of tobacco products at the point of sale (PoS), have been shown to remove smoking cues and reduce triggers for unplanned tobacco purchases in stores. This effect is thought to be particularly strong among adolescents and young people, who are thought to be more susceptible to such displays and promotions. However, the literature does not provide any estimates of the effect of removing such displays and promotions on smoking prevalence. Vending machines are often considered an easily accessible source of tobacco products for adolescents. The literature shows that (technical) solutions to restrict access to vending machines do not necessarily succeed in effectively restricting youth access, and therefore that banning vending machines altogether might be more effective to curb youth consumption of tobacco. However, adolescents often use a wide range of sources in order to access tobacco products – such as older-looking or older friends and acquaintances – and therefore although banning vending machines may have some impacts on youth tobacco purchasing, it would not prevent them from accessing tobacco products altogether.
The effect of package size is very mixed in nature, with both positive and negative effects observed. Small packages lower the barrier for purchasing tobacco, making it more feasible for people on tight budgets, including children and adolescents, to purchase tobacco. Therefore enlarging packages raises the barriers for purchase. At the same time, it has been observed that smokers regulate their intake by packs rather than by individual cigarettes and therefore bigger packs may incite smokers to increase their cigarette consumption.

Little is known about the total extent of cross-border (internet) sales of tobacco products, but it has been shown elsewhere that cross-border trade may undermine national tobacco control policies, in particular different excise duty rates but also underage sales regulation.

Some of the suggested changes to sales regulation – such as banning the promotion and display of tobacco products – would have substantial economic impacts, mostly on tobacco retailers. They would need to make changes to their stores and sale processes as well as losing advertising revenues from tobacco manufacturers. These costs might have a knock-on effect on price and thus consumption of tobacco products. Packaging changes would involve compliance cost for manufacturers, but could also lead to long-term savings if they lead to a reduction in product lines.

**Baseline scenario and the no-change option**

To assess the impacts of changes to the Tobacco Products Directive and to assess the impacts of the ‘no-change’ policy option, RAND Europe developed a baseline scenario. The baseline scenario assumes that past trends in prevalence and health impacts will continue into the future. There are two main elements in the baseline scenario: a forecast of future prevalence, and a forecast of future mortality and morbidity. Derived from these two forecasts are impacts on healthcare costs and tax revenues on the tobacco industry.

Even in the absence of stricter tobacco product regulation, we forecast prevalence will fall across EU over the next decades. This result is based on a strong trend in prevalence reduction over the last decade or so, which has seen a considerable extent of tobacco control policy being implemented in the EU, and the scenario may thus overestimate the reduction in prevalence if regulatory activity in fields such as taxation and smoke-free environments is not maintained at the current level.

Based on falling prevalence, the baseline scenario forecasts a continuing fall in employment in the tobacco manufacturing and tobacco retail sectors. In all but one of the different forecasts available, tax revenues are likely to increase despite changes in prevalence, assuming the relationship between consumption and tax revenues remains the same as in previous years.

For assessing future health impacts we assumed an average time lag of health impacts of 17 years. Thus the baseline scenario will be dominated by past changes in prevalence and the effects of current policy will only be felt well into the 2020s. Male mortality and morbidity rates will therefore decline across the EU until 2027, while female rates will increase until 2027. Overall, we estimate a total of 342,000 tobacco-related deaths in 2027, direct healthcare costs of €36 billion and indirect costs of €43 billion.
RAND Europe assessed economic and health impacts of five different policy options

RAND Europe assessed the economic and health impacts of five different policy options. While smoking tobacco also has environmental effects, these were not considered central to this assessment.

Option 1
The baseline scenario describes the no-change option. In this case, even in the absence of tighter tobacco product regulation, smoking prevalence and tobacco-related morbidity, mortality and healthcare costs are likely to fall until 2027, accompanied by reduced employment and economic activity in the tobacco industry sector. This option would, however, not address the obvious shortcomings of the current directive. These include difficulties in dealing with new and emerging products, and unsatisfactory ingredient reporting and information and consumer awareness of the harmfulness of tobacco products other than manufactured cigarettes. The administrative burden arising from continuing reporting requirements would continue to be incurred by the tobacco industry, and is estimated to be at around €1 million to €10 million for cigarette manufacturers, and between €0.3 million and €1.7 million for cigar manufacturers.

Option 2
The impact assessment guidelines encourage EC services also to explore non-binding measures as an alternative to binding legislation. In the case of tobacco product regulation, where a range of binding legislation is already in place, such an approach is likely to encounter difficulties as the current legislative framework could not be amended or changed. In terms of effectiveness, experience with previous non-binding measures – such as harmonised reporting formats and laboratory cooperation – have not proved very successful. Against this background, no detailed list of non-binding measures has been developed by DG SANCO to be assessed in this study; nevertheless we should like to explore potential health and economic impacts briefly.

In terms of achieving positive health impacts, some impacts could be achieved by Member States implementing stricter measures on their own, as is already the case for the introduction of pictorial warnings, displays bans and restrictions or bans on vending machines. Other measures such as introducing large pictorial warnings or plain packaging would only be possible after a change in regulations. This might lead to more diverse tobacco product regulation in the areas where the current Tobacco Products Directive allows further measures by Member States, and to no change in the areas where a revision of the directive would be required. Thus, overall health impacts would be likely to be lower than in scenarios where a revision of the current directive is implemented.

More diverse national tobacco control regulations would, however, certainly have a negative impact on tobacco manufacturers across Europe. More diverse regulation increases the cost of compliance as more national particularities have to be taken into account. This includes, for example, a search for relevant information on regulation and adapting products to meet national requirements, and has the potential to undermine the functioning of the single European market.
Option 3
Option 3 is the first ‘legislative option’, combining measures in all areas of change. It has been designed as a minimum revision to the directive, bringing it into line with scientific and international developments. Our assessment starts with the health impact.

Health impact
Analysing this option, the strongest health impact may be expected from the introduction of mandatory pictorial warnings, which according to a UK impact assessment could reduce prevalence by at least 0.5 percent, saving 900 lives and preventing 9,300 cases of lung cancer, aerodigestive cancer and chronic obstructive pulmonary disease (COPD) annually from 2027, with related savings in healthcare costs.

Especially targeted at adolescent smokers are the measures relating to underage sales, vending machines and the promotion of tobacco products in retail stores. For all these measures positive health impacts, albeit not quantifiable, may be expected as these measures have been shown to influence purchasing decisions. The overall scope of the impacts will, however, remain limited as many Member States have implemented similar measures already and the changes would mean a further institutionalisation of common practice in the Member States. For example, all but two Member States have already instituted a minimum purchasing age of 18 years.

Introducing a minimum package size is also a measure designed to protect adolescent smokers. The reasoning here is that larger packets are more expensive, and would be less likely to be bought by cash-strapped youths. Evidence of the impact of this measure is, however, very mixed because bigger pack sizes have been shown to increase tobacco consumption. Therefore we do not expect positive, population-wide health effects from this measure.

Changes in the labelling of tobacco yields will without a doubt benefit consumers as it has been shown that quantitative yield information confuses consumers about the relative harmfulness of different tobacco products. This has to be set against the evidence that lower yield cigarettes are as harmful as high-yield cigarettes, given that smokers compensate for lower yield cigarettes by either smoking more intensely or smoking more cigarettes in order to obtain the dose of nicotine they require. We do not expect additional measurement methods and a further reduction of yields to have substantial health impacts. This is somewhat different for the ban on carcinogenic ingredients, which could reduce the presence of high-risk additives and ingredients currently used in tobacco products. However, there is not sufficient knowledge about this, and there is no common list of these ingredients that could be used to determine the most harmful ingredients and thus those whose reduction would be most likely to produce a positive impact on the health of consumers.

The primary benefit of extending the scope of the directive to paraphernalia and other non-tobacco nicotine products would be to increase consumers’ awareness of the risks of these products. Smokers of roll-your-own cigarettes (RYO), pipes and water pipes often believe that these products are less harmful than manufactured cigarettes when in fact there is evidence to the contrary. There are, however, difficulties regarding how far the current regulations could meaningfully be applied to the other product categories.
This leads us to a set of measures contained in Option 3, concerning the reporting and registration of tobacco products. While these measures do not have direct health impacts, they are set out to develop the (scientific) infrastructure to improve both scientific and regulatory knowledge about tobacco products, as well as to increase the information available to consumers and thus bring about clear long-term benefit.

**Economic impact**

For all options changes in prevalence, either directly induced by policies such as labelling or a result of increasing costs to industry, have the most wide-ranging economic impacts. For Option 3 we expect a decline in prevalence of 0.5 percent through labelling measures. Prevalence changes are likely to have an impact on industry revenue and profits (€200m and €35m) and on employment (−0.5 for manufacturers, retailers (−2.9 percent to −1.3 percent) and wholesalers (−1.5 percent to 0.1 percent).

Tax revenues may fluctuate in the range of −€350 million reduction or an increase of €1.1 billion if current trends of increased revenues continue. Prevalence changes resulting from new labelling requirements will save direct healthcare costs in the region of €91 million, and indirect costs of mortality and morbidity of €108 million.

For industry the economic impact of Options 3 to 5 arises out of the administrative burden for manufacturers and compliance costs for retailers. A number of measures in Option 3 are likely to result in administrative burden as they require changes to the packaging and labelling of tobacco products. These occur primarily as one-off costs for the change of a label; ongoing costs seem to be low. It is important to note that these costs are not simple to calculate. The maximum cost incurred by industry will be that of the most comprehensive labelling change.

In this option the costs would range between one-off costs of €101.8 million and €198.8 million, and only marginally increased ongoing costs. Indeed, introducing qualitative TNCO labelling may increase annual running costs by between €4.8 million and €9.8 million a year only. Adjustments to the reporting and registration requirements will cause additional administrative burden, but are overall relatively low. The introduction of standardised electronic reporting may even reduce the burden for tobacco manufacturers.

Owing to the large number of businesses, retailers face the most substantial economic cost in adapting to measures proposed in this option. The one-off costs for retailers have been estimated to be between €44.1 million and €394.2 million and ongoing compliance costs to be up to €70.8 million a year. Another cost for retailers will be that of the introduction of age restrictions for vending machines. However, these will be relatively low (up to €48m) as many Member States already have such measures in place.

Costs that could not be quantified, owing to uncertainty in the required action as well as a lack of data, include the costs for reformulating products because of changed ingredient regulation and the introduction of minimum package sizes.

**Option 4**

Option 4 is the second option that involves changes to the legislative framework. The suggested measures have been in particular designed to bring the directive into line with scientific and international development and strengthen the protection of vulnerable
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...groups, particularly adolescents. Again we started by looking at the health impact of this option.

Health impact
In this option even stronger labelling requirements are suggested, with the mandatory introduction of pictorial warnings covering 75 percent of the pack in combination with generic or plain packaging. These two measures are likely to have an even stronger impact on prevalence rate, so the conservatively estimated 0.5 percent reduction in prevalence – leading to reduced mortality of 900 lives and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually from 2027 with related savings in healthcare costs – will be the lower boundary of the expected effect.

Measures targeted at protecting adolescents from smoking are further strengthened in this option, with a complete ban on vending machines for adolescents – which would solve the enforcement problems related to age restrictions on vending machines and could lead to small reductions in youth smoking. It has, however, to be stated that this effect will be far less effective in reducing the current percentage of youths using vending machines as they are likely to compensate at least partially by using other sources of supply such as older-looking – or older – friends and acquaintances.

A ban on cross-border internet sales of tobacco products may help Member States to enforce their wider tobacco control policies, in particular taxes and age restrictions. Overall, internet purchases of tobacco products constitute only a very small proportion of tobacco purchases; therefore we do not expect this to have a measurable health effect.

Widening the definition of ingredients to cover the tobacco leaf, as well as introducing higher market control fees to cover the costs of ingredient work, would contribute to a better understanding of the harmfulness of specific ingredients, including the tobacco leaf, but health impacts would be achieved in the long term only if further action is taken on the basis of this information.

Finally, this option contains a measure to decrease continuously the yield limits of tobacco products. As discussed earlier, given the evidence that smokers compensate for lower yield cigarettes by smoking more intensely or more, there is little evidence that such measures would produce positive health impacts on consumers.

The economic impacts of Option 4 are only slightly higher than those for Option 3, with slightly increased costs for manufacturers and retailers, and with the same effect on smoking prevalence.

Economic impact
The economic impacts of Option 4 are only slightly higher than those for Option 3, primarily in the form of increased costs for manufacturers and retailers, and the same effect on smoking prevalence.

For Option 4 we thus expect a decline in prevalence of 0.5 percent through labelling measures. Prevalence changes are likely to have an impact on industry revenue and profits (€200m and €35m) and on employment (–0.5 for manufacturers, –2.9 percent to –1.3 percent for retailers and –1.5 percent to 0.1 percent for wholesalers).
Tax revenues may fluctuate in the range of €350 million reduction or an increase in €1.1 billion if current trends of increased revenues continue. Prevalence changes resulting from new labelling requirements will save direct healthcare costs in the region of €91 million, and indirect costs of mortality and morbidity of €108 million.

Labelling costs for industry may be expected to stay the same between options as they already include the costs incurred for a substantial redesign of labels. However, the cost for retailers of implementing restriction on the display of tobacco products is potentially substantial.

In this option there are, however, important cost impacts that could not be quantified. The first are the costs of introducing a comprehensive ban of vending machines across Europe, which is very likely to be substantial in terms of sunk costs but which could be reduced by a long transition period. The second important cost that could not be quantified concerns tobacco manufacturers’ brand equity, which would be substantially reduced if plain packaging is introduced and if other possibilities for maintaining brands, such as in-store advertising, are banned as well.

**Option 5**

In Option 5 a further strengthening of the directive is foreseen, with the objective of strengthening product regulation and fully implementing the polluter pays principle.

**Health impact**

Option 5 is again characterised by a further tightening of the labelling requirements, with pictorial health warnings covering most of the package surface of a plain tobacco pack. Compared to the other options, this is likely to have the largest health impact and is likely to exceed the conservative estimate we used in the quantitative estimation. For this option pictorial warnings are very large and there is no possibility of branding and other distracting designs. The success of producing inserts is less certain. There is only sparse evidence of the effectiveness of this measure and information, if provided in a text-heavy format, may be less effective in reaching less literate smokers.

The largest health effects of all options may, however, be expected through the two different approaches to internalising the external costs of smoking through fees or through making cigarette manufacturers liable for the external costs engendered by tobacco consumption. If the currently approximate €100 billion in indirect costs is passed on to tobacco manufacturers, this will have a substantial impact on the price of tobacco products and thus on the prevalence of tobacco use. Our calculation estimated a 25 percent reduction in prevalence, which would result in a reduction of around 45,000 in smoking-related deaths and 46,000 fewer cases of lung cancer, aerodigestive cancer and COPD per annum by 2027.

The complete ban of tobacco promotion and displays in store is likely to have a positive impact on adolescent smoking and to a lesser extent also on adult smokers – in particular on those attempting to quit or stay quit – as all smoking cues would be removed from stores. As the implementation of this measure is connected to considerable costs, this would have an additional impact on the price of tobacco products, which could lead to further reductions in prevalence, estimated at 0.12 percent, and result in 200 fewer deaths and 2,200 fewer cases of lung cancer, aerodigestive cancer and COPD annually by 2027.
From the introduction of a minimum package size we do not expect population-wide health effects as there is conflicting evidence on the health impact of such a measure.

Further measures in this final option concern the infrastructure to collect and analyse ingredients, which could have long-term positive health impacts.

*Economic impact*

Without a doubt Option 5 would have the most substantial economic impact, both in terms of costs for industry and in terms of potential economic benefits such as saved healthcare costs. This is because of the idea of transferring healthcare costs to the tobacco manufacturers, who would in turn be required to increase the price of their products, leading to an overall reduction in prevalence.

Using the data available, we would expect a 25 percent reduction in prevalence, with a related reduction in revenues of €10 billion, reduction in profits of €1.7 billion, and reduced employment for manufacturers of between 13 percent and 17 percent, of 15–22 percent for wholesalers and of 50–70 percent for retailers.

Lost tax revenues would constitute around €15 billion (a reduction of around 24 percent), while direct healthcare costs of €4.5 billion and indirect costs of €5 billion to €6 billion could be saved annually.

We expect the impacts of labelling costs and changes in prevalence related to these to be along the same lines as for the other two regulatory options, but with higher one-off and ongoing costs for banning the display of tobacco products in retail stores. These have been estimated as set-up costs of between €321 million and €2,297 million, with ongoing costs of around the same level.

In addition to these impacts, other important unquantified impacts include the cost of setting up an EC laboratory to conduct ingredient work, which is likely to be transferred to industry through fees.