Comments from the Tobacco Control Community on the RAND Report

1. Background

The European Commission is considering revising its Tobacco Products Directive and has commissioned RAND Europe to help assess the key health, social, and economic impacts of five policy options under consideration. The research uses a variety of qualitative and quantitative methods, including rapid evidence reviews and econometric and health-economic modelling techniques, to assess the economic and health effects of future regulation.

The tobacco and health community was invited to participate in a consultation meeting organised by Directorate General for Health and Consumers as part of the Impact Assessment on the possible revision of the Tobacco Products Directive 2001/37/EC. The meeting took place on **19 October 2010** in Brussels; The intention of this meeting was to have an open discussion and get the tobacco control community's comments on the study "Assessing the Impacts of Revising the Tobacco Products Directive" prepared by RAND Europe¹.

2. Introductory remarks on the Rand Report

The tobacco control community congratulates Rand for the comprehensiveness of their report. Given the diversity and complexity of the different proposed options, the report appears to be a well-researched document based on strong scientific evidence. Nevertheless the tobacco control community expressed a number of key concerns which reflect the challenges of conducting impact assessments using a cost benefit analysis approach and highlight the particular difficulties of providing traditional forms of evidence for interventions that have not yet been implemented in any jurisdiction.

The following points emerged as themes in the discussion:

- → Baseline Scenario
- → Underestimation of healthcare impacts and key concerns regarding the 17 year time lag
- → Effects on employment
- → Issues related to labelling
- → The administrative burden to the industry and retailers
- → Illicit Trade
- → Industry cost relative to their Profits and Revenues
- → Internalisation of tobacco-related costs imposed on governments

Our main points on the Rand report are as follows:

→ The report wrongly predicts that smoking prevalence will continue to decline to 13% in 2027 in the absence of new tobacco control policies.

http://ec.europa.eu/health/tobacco/docs/tobacco_ia_rand_en.pdf

- → The assumption that smoking prevalence will decline without policy intervention is wrong; it significantly decreases the benefits of the described tobacco control policies.
- → The report underestimates the health benefits in terms of morbidity and mortality by assuming that effects of a decrease of prevalence will only become effective after 17 years.
- \rightarrow The report inadequately measures the effects on employment.
- ightarrow Tobacco industry estimates of costs (administrative burden; labelling, etc...) are vastly overestimated.
- → The report insufficiently describes the literature on the effectiveness of standardised/plain packaging.
- \rightarrow Introducing standardised/plain packaging is a very low investment for companies and could be a cost saving exercise.
- → Mandatory pictorial warnings and standardised/plain packaging will facilitate action against illicit/counterfeit trade.
- ightarrow The Industry Costs relative to their Revenue and Profit do not constitute a case for not implementing option 4 at EU level.

3. Baseline Scenario

To establish a baseline scenario and to assess future impacts on morbidity and mortality, RAND developed a forecast of future mortality, morbidity and related healthcare costs, assuming an average time lag of 17 years until reductions in prevalence result in substantive mortality and morbidity impacts (Rand based this forecast on the results shown by Kabir *et al.* (2007)).

- → Based on prevalence data during the period 1985-2007, the report wrongly predicts that smoking prevalence will continue to decline to 13% in 2027 in the absence of new tobacco control policies. The prediction is wrong for two reasons: Firstly, the period 1985-2007 was not a period without tobacco control initiatives. Secondly, evidence suggests that without continuing innovation in policy, smoking prevalence will stop declining, stagnate or even increase.²³
- → Some reduction in prevalence is likely to happen as a result of the requirements of the Tax Directive, but not of the order indicated in the Rand Report. The report assumes overtly that tax rates will continue to rise as they have over recent years.
- → Even if one assumes that that prevalence is falling linearly, RAND are incorrect to assume that the reductions in mortality and morbidity would not be realized completely by 2027 according to the report, no benefits would be felt for 20 years, which is clearly not the case.
- → The incorrect assumption that the smoking prevalence will continue to decline has an impact on all other estimates. The extent of this miscalculation is illustrated by comparing RAND's calculation of the health benefits that would emerge through reductions in smoking prevalence with other estimates.

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² All Party Parliamentary Group on Smoking and Health. Inquiry into the effectiveness and cost-effectiveness of tobacco control: Submission to the 2010 Spending Review and Public Health White Paper Consultation process. 2010

³ Beyond Smoking Kills: Protecting children, reducing inequalities. London, ASH, 2008.

- → RAND calculate that reducing prevalence by 0.5% would save 900 lives annually across the whole of Europe and prevent 9.300 cases of lung cancer, aerodigestive cancer and CPD, but only from 2027 onwards (i.e. 17 years after policy implementation) (p 47). These figures can be compared with the following examples:
 - o Work by Lewis et al $(2005)^4$ on the no. of lives saved by reducing smoking prevalence in the UK alone suggests that reducing the prevalence of smoking by 1 percentage point each year for 10 years would prevent 69,049 deaths in those aged between 35 and 74 years during that period alone.
 - Naidoo et al (2000)⁵ estimate that 1% reduction in smoking prevalence per annum would lead to reduced admissions from myocardial infarction of over 20,000 per year and from stroke of over 10,000 per year. (i.e. these reductions in morbidity occur annually in the UK alone).
 - Unal et al (2005)⁶ estimate that a reduction in smoking prevalence from 26% to 21% over a 10 year period (i.e. a 0.5% absolute reduction each year) would prevent 8,880 deaths from coronary heart disease in a year by the end of that period in the UK alone. (i.e. 8,800 deaths prevented from cardiovascular disease in the UK alone, compared with 900 deaths estimated by RAND across the whole of the EU after 17 years)

It is noteworthy that the above models have been subject to peer review and are therefore likely to provide far more accurate estimate of benefit from smoking reduction than those presented in the RAND report.

4. Underestimation of health impacts

The health benefits of the various potential interventions have been significantly underestimated and as a result, give a very inaccurate picture. The authors of the report note that they provide a conservative estimate of health impacts because they halve the relative risks used (p 15) and outline other reasons why their model is likely to underestimate health benefits (p 20). However, they fail to recognise additional reasons why their model will provide a serious underestimate.

- → The model assumes an average time lag of 17 years between reductions in prevalence and health benefits (p 11). Indeed the report states that tobacco regulation will "have a noticeable impact on mortality, morbidity and costs only several decades into the future" (p 11, emphasis added). These assumptions are wholly inconsistent with existing evidence and will seriously underestimate any health impacts:
- → The model applied does not include reproductive/ maternal effects including impacts on the foetus which have both short and long term health and thus cost implications (see for example Royal College of Physicians 2010).

⁴ Lewis S, Arnott D, Godfrey C, and Britton J. Public health measures to reduce smoking prevalence in the UK: how many lives could be saved? Tob Control. 2005 August; 14(4): 251–254. doi: 10.1136/tc.2005.011064 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1748066/

⁵ Naidoo B, Stevens W, McPherson K. Modelling the short term consequences of smoking cessation in England on the hospitalisation rates for acute myocardial infarction and stroke. Tobacco Control 2000;9:397-400.

⁶ Unal B, Critchley J, Capewell S. Small changes in cardiovascular risk factors could halve coronary heart disease mortality. J Clinical Epidemiol 2005; 58: 733-40.

- → The model seriously underestimates morbidity from smoking: the authors estimate morbidity for 3 conditions only – ca lung, ca oesophagus and COPD. For the 1st two of these conditions, mortality rates are so high there is little benefit in estimating morbidity in addition to mortality.
- → By contrast, morbidity from other conditions e.g. cardiovascular, cerebrovascular and peripheral vascular disease) would be far higher as smokers live for years with these conditions. The applied model therefore represents a gross underestimate of the morbidity from smoking (see footnote to Naidoo et al on page 3)
- → The model does not include morbidity or mortality from second-hand smoke, yet growing evidence suggests this will be substantial (see for example Jamrozik 2005⁷) and reductions in smoking prevalence and cigarette consumption will inevitably lead to some, albeit likely relatively small, reductions in exposure.
- → The Rand Report does not offer any sensible rationale for halving the relative risks used in the model (p 15). These relative risks come from large cohort studies and are therefore accurate. Therefore, no reason exists to halve them, particularly given that for other reasons the model already underestimates the health benefits.
- → **Key concerns regarding the 17 year time lag**: The Rand Report appears to be confusing the following issues:
 - o the lag between onset of smoking and the increase in lung cancer at a population level (which is a few decades) (Lopez et al 1994⁸)
 - o the lag between quitting/reductions in prevalence and reductions in lung cancer which is far shorter (IARC 2007⁹).
 - o the impacts of young people no longer taking up smoking (which will be seen years into the future)
 - the impact of current smokers quitting. The benefits of the latter will be seen far quicker, and the benefits of quitting at a young age are substantial, as shown clearly in Doll et al2004¹⁰. These issues also appear to be confused (penultimate paragraph p 20).
- ightarrow As the authors acknowledge, smoking causes numerous diseases and the reversal in risk following quitting varies between these diseases. The risks of cancers generally take longer

http://www.bmj.com/content/330/7495/812.full?view=long&pmid=15741188

⁷ Jamrozik K. Estimate of deaths attributable to passive smoking among UK adults: database analysis. *BMJ* 2005; 330: 812 doi: 10.1136/bmj.38370.496632.8F

⁸ Lopez A, Collishaw N, Piha T. A descriptive model of the tobacco epidemic in developed countries. Tobacco Control 1994;3: 242-7 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1759359/pdf/v003p00242.pdf

⁹ IARC. IARC Handbooks of Cancer Prevention. Volume 11. Reversal of Risk After Quitting. Lyon: International Agency for Research on Cancer, 2007.

¹⁰ Doll R, Peto R, Boreham J, Sutherland I. Mortality in relation to smoking: 50 years' observations on male British doctors. *BMJ* 2004; 328: 1519 doi: 10.1136/bmj.38142.554479.AE (Published 22 June 2004)

to reverse than those of other diseases but 17 years is way too long a delay even for lung cancer (IARC 2007¹¹).

→ Although the authors cite Doll et al (2004) in the table on p 13, they instead appear to use a single paper (Kabir et al) to justify their decision to use a 17 year delay. Kabir et al look only at lung cancer mortality in Massachusetts following implementation of the Massachusetts Tobacco Control Program. Kabir et al do not attempt to formally assess the time lag between behaviour change and health benefit and indeed do not even provide trend data on smoking prevalence with which to explore this delay. Instead they comment that "it is relatively early for the [Massachusetts Tobacco Control Program] to have a substantial impact", going on to note that this is consistent with the tobacco control programme in California showing a 6% decline in lung cancer within a decade (Barnoya & Glantz 2004¹²). i.e. even the paper the authors use to justify a 17 year delay indicates that declines in risk of lung cancer occur far more quickly than this.

The Doll et al paper which is based on the UK Doctors Study¹³ suggests that the benefits of quitting occur from the point of quitting and that if quitting occurs at young age, mortality rapidly returns to levels seen in never-smokers. The most comprehensive work with which to assess the timescale over which the varied risks of smoking reverse is a 2007 IARC handbook which reviews the international evidence in this area (IARC 2007). This shows that:

- \rightarrow For lung cancer: lower lung cancer risks are apparent within 5 to 9 years of quitting and the reduction in risk becomes progressively greater over time (p 10).
- \rightarrow For coronary heart disease: a risk reduction in the order of 35% is seen within the 1st 2 to 4 years of quitting and the reduction in risk continues to increase over time.
- \rightarrow For cerebrovascular disease: similar pattern to coronary heart disease.
- \rightarrow For COPD: the symptoms reduce within months of quitting.

Further supportive evidence suggesting that the cardiovascular risks from tobacco smoke quickly reverses comes from more recent evaluations of the implementation of smokefree legislation in numerous jurisdictions. These evaluations show that benefits from reductions in smoke exposure are seen immediately, i.e. within days of quitting, consistent with in vitro and in vivo evidence in this area

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¹¹ IARC. IARC Handbooks of Cancer Prevention. Volume 11. Reversal of Risk After Quitting. Lyon: International Agency for Research on Cancer, 2007.

¹² Barnoya J and Glantz S. Association of the California tobacco control program with declines in lung cancer incidence. *Cancer Causes* Control 2004: 15:689-695

¹³ http://www.bmj.com/content/328/7455/1519.full.pdf+html

(Lightwood & Glantz 2009¹⁴; Meyers et al, 2009¹⁵; Institute of Medicine 2009¹⁶; IARC 2009¹⁷; Bartecchi et al 2006¹⁸; Khuder et al 2007; Sargent et al 2004¹⁹; Juster et al 2007²⁰; Vasselli et al 2008²¹; Pell et al 2008²²; Edwards et al 2006²³, Sims et al 2010²⁴).

5. Effects on employment

The baseline scenario predicts a fall in employment as a consequence of changes in consumption and prevalence trends. Rand forecasts prevalence trends and estimated changes to industry employment, revenues and tax revenues in relation to changes in prevalence. We dispute this assumption:

→ The report fails to say that a reduction in sales does not mean that jobs will be lost. The tobacco manufacturing is not a labour intensive sector, but a capital intensive sector and a reduction in tobacco sales would be beneficial for employment. If consumers don't spend their money on tobacco, they will buy other products in other sectors which are more labour intensive and news jobs will be created in those other sectors.

¹⁴ Lightwood JM, Glantz SA. Declines in Acute Myocardial Infarction After Smoke-Free Laws and Individual Risk Attributable to Secondhand Smoke. *Circulation* 2009;120:1373-79.

¹⁵ Meyers DG, Neuberger JS, He J. Cardiovascular Effect of Bans on Smoking in Public Places: A Systematic Review and Meta-Analysis. *J Am Coll Cardiol* 2009;54(14):1249-55.

¹⁶ Institute of Medicine. Secondhand Smoke Exposure and Cardiovascular Effects: IARC. Chapter 7: Reductions in exposure to secondhand smoke and effects on health due to restrictions on smoking. *IARC Handbook of Cancer Prevention, Tobacco Control: Evaluating the Effectiveness of Smoke-free Policies*. Lyon, France: WHO, IARC 2009

¹⁷ IARC Handbook of Cancer Prevention, Tobacco Control: Evaluating the Effectiveness of Smoke-free Policies. Lyon, France: WHO, IARC, 2009.

¹⁸ Bartecchi C, Alsever RN, Nevin-Woods C, Thomas WM, Estacio RO, Bartelson BB, et al. Reduction in the Incidence of Acute Myocardial Infarction Associated With a Citywide Smoking Ordinance. *Circulation* Khuder SA, Milz S, Jordan T, Price J, Silvestri K, Butler P. The impact of a smoking ban on hospital admissions for coronary heart disease. *Preventive Medicine* 2007;45(1):3-8.

¹⁹ Sargent RP, Shepard RM, Glantz SA. Reduced incidence of admissions for myocardial infarction associated with public smoking ban: before and after study. *BMJ* 2004;328(7446):977-80.

²⁰ Juster HR, Loomis BR, Hinman TM, Farrelly MC, Hyland A, Bauer UE, et al. Declines in Hospital Admissions for Acute Myocardial Infarction in New York State After Implementation of a Comprehensive Smoking Ban. *Am J Public Health* 2007;97(11):2035-39.

²¹ Vasselli S PP, Gaelone D, Spizzichion L, De Campora E, Gnavt R, Saitto C, Binkin N, Laurendi G, Reduction incidence of myocardial infarction associated with a national legislative ban on smoking. *Minerva Cardioangiol* 2008.

²² Pell JP, Haw S, Cobbe S, Newby DE, Pell ACH, Fischbacher C, et al. Smoke-free Legislation and Hospitalizations for Acute Coronary Syndrome. *NEJM* 2008;359(5):482-91.

²³ Edwards E BC, O'Dea D, Gifford H, Glover M, Laugesen M, Thomson G, Waa A, Wilson N, Woodward A. After the smoke has Cleared: Evaluation of the Impact of a New Smokefree Law. Wellington: New Zealand Ministry of Health, 2006.

²⁴ Sims M, Maxwell R, Bauld L, <u>Gilmore A</u>. The short-term impact of smokefree legislation in England: a retrospective analysis on hospital admissions for myocardial infarction. *British Medical Journal*. BMJ 2010;340:c2161

- → The tobacco companies are already reducing their employment due to efficiency savings. Company annual reports illustrate this issue as do reports on closures of cigarettes factories²⁵.
- → The loss of employment/revenue in the retail sector can be explained by other factors, in particular the increasing sale of tobacco products in supermarkets, which is due to competition and not to tobacco prevalence.
- → The retailers' market is very different across the EU. For instance, the tobacconists in France need a license, whilst the Belgian newsagents, supermarkets and corner shops do not.
- → The Rand report treats retailers as a uniform group. A study conducted by Deloitte analysed many different types of convenience stores (retailers) in Australia (which is only one jurisdiction). It is reasonable to assume that there would be different types of tobacco retailers between and within the EU Member States.
- → In order to help the Commission conduct its own impact assessment, retailers should provide a breakdown of their sales to validate their responses to the questionnaire.

6. Issues related to Chapter 8

- → This chapter gives an appropriate overview of the literature, although the RAND report does not mention all published and unpublished plain packaging research conducted in Europe (such as Moodie, Hastings & Ford, 2009).
- → The RAND report quantified the impact of Option 3 as a 0.5% decrease in consumption. The health impacts of option 3 (mandatory pictorial warnings) and 4 (75% pictorial warnings plus generic packaging) have been modelled as identical although the text acknowledges that for option 4, these will be "the lower boundary of the expected effect". We believe it would be more helpful to model a more realistic impact of option 4 rather than just a lower boundary estimate. It is reasonable to assume that option 4 and 5 would have a much bigger health impact.
- → Sambrook international describes a five-stage process or "dimension of effectiveness" that may lead to behaviour change in consumers (p 128) (1-Attention, 2-Reading/comprehension, 3- Recall, 4- Judgement and 5- Behaviour compliance). The RAND report only investigates the evidence presented in the literature on step 5 (behaviour compliance). However, irrespective of sample type or study location, research consistently shows that large pictorial warning on plain packs: a) make the health warning more salient; b) reduce customer appeal and c) provide a more realistic indicator of harm. It is reasonable to assume that the consumer's perception of how dangerous and hazardous tobacco products are (step 4 Judgement) will lead to behaviour change in consumers. Furthermore, in countries where quitline information is on cigarette packs along with graphic health warning, there is a great increase in smokers calling such helplines (p 135).

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²⁵ http://www.forbes.com/feeds/afx/2005/07/13/afx2136445.html).

→ The discussions regarding the "effectiveness" of large graphic warnings and standardized packaging is reminiscent to those on advertising of tobacco products. Although it is difficult to isolate one type of behaviour and one factor, there is clear evidence that pictorial warnings reduce the attractiveness of tobacco products and have an impact on taking up smoking.

7. The administrative burden to the industry and retailers are dramatically overestimated.

- → The administrative burden estimates presented in the report are mainly based on sources from individual companies or industry and retailers organisations, which have an interest to exaggerate the costs. The rand report acknowledges that these industry estimations should be used with caution. (see page 151)
- → The potential additional administrative burden associated with different measures is estimated on the basis of hypothetical scenarios and no historical data are available.
- → For example the costs to retailers of point of sale prohibition are based on the hypothetical calculations by retailers groups which give rise to an estimate of 5,000 euros per shop on average (p.207). However, this does not take into account actual data collected by retailers groups subsequently from Ireland which found much lower costs. The Association of Convenience Stores (ACS) in its response to the UK DH stated that shop refitting could cost as much as £4,965 per shop. For A survey of the actual costs carried out by the same trade body following implementation of the legislation in Ireland found the average shop refitting costs paid by retailers to be just £300, less than a tenth the hypothetical amount it included in its consultation response. For a survey of the actual costs carried out by the same trade body following implementation of the legislation in Ireland found the average shop refitting costs paid by retailers to be just £300, less than a tenth the hypothetical amount it included in its consultation response.
- → Several estimates are based on overall cost estimations of the industry in which no detailed cost break-down was disclosed, which decreases the precision and reliability of the estimates.
- → Several per company estimates showed large discrepancies between companies, which are not substantiated owing to lack of detailed cost break-down.
- → The manufacturing industry is motivated to disclose cost figures that are higher than they actually are in order to reduce the probability of additional regulation being enacted.
- → The tobacco manufacturers' self-reported data on labelling were 5 to 10 times higher than those of direct comparators available (e.g. food labelling), which strengthens the suspicion that some of the administrative burden data are overstated.
- → The labelling costs for the manufacturer are linked with the number of stock keeping units (SKU's) Stock keeping unit is an item which is unique because of some characteristics (such as brand, size, colour, model) Uniform labelling requirements, prohibiting promotional pictures and standardized packaging would have the benefit of enabling economies of scale for tobacco manufacturers.

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²⁶ Department of Health. Consultation on proposed tobacco control regulations for England (under the Health Bill 2009). October 2009.

²⁷ ACS The implementation of the tobacco display ban in the Republic of Ireland 2008

- → The assessment that the implementation costs to manufacturers of bigger pictorial health warnings (50%, 75 or 100% of the both sides of the packs) would cost three times more than the actual warnings is without justification.
- → Introducing plain packaging would represent a low investment for the manufacturers. Cigarette packages are printed on paper rolls which are introduced to the cigarette packaging machines. A new package is the replacement of a paper roll with the old cigarette packages by a paper roll with the new cigarette packages. The main cost for new labels is the cost of the new make up of the package, estimated at €2000 to 4000 in the case of food labelling. The pictures on the packs are provided by the authorities which reduces again the costs. The colours on the rest of the packaging are restricted in the case of plain packaging, which reduces again the costs.
- → The cigarette industry has been characterized as an oligopoly²⁸ in which the firms clearly recognize their mutual interdependence. Economic histories indicate that the cigarette firms have, for long periods, been able to price cigarettes above competitive levels, notwithstanding infrequent episodes of more intense price competition and product innovation. In April this year two of the major manufacturers, Imperial and Gallaher (now owned by Japan Tobacco International) together with a number of retailers, were fined heavily for under competition law in the UK for price fixing.²⁹
- → The tobacco industry argues that standardised packaging would decrease the competition between products and would be against internal market principles. However, the argument can be made that standardised packaging would stimulate competition between tobacco products. It would potentially allow more room for smaller manufacturers to enter the market.

8. Illicit Trade

- → The tobacco industry constantly uses illicit trade as a way to disclaim the effectiveness of tobacco control measures. Their comments cannot be taken seriously in this context.
- → The tobacco industry claims that "plain packaging will stimulate the counterfeiting of tobacco products, by making it easier and cheaper to copy their packaging and by increasing the burden on enforcement agencies". They add that "there is a strong likelihood that plain packaging will increase the demand for branded black market cigarettes." "30"
- → Standardized/plain packaging cannot be dissociated from mandatory pictorial warnings. Since plain or standardised packaging would always be implemented with mandatory pictorial warnings, the counterfeiting and piracy arguments cannot be sustained.

²⁸ http://www.ftc.gov/reports/tobacco/tobacco9909.shtm

²⁹ Office of Fair Trading press release. OFT imposes £225m fine against certain tobacco manufacturers and retailers over retail pricing practices16 April 2010. http://www.oft.gov.uk/news-and-updates/press/2010/39-10

³⁰ See http://www.plain-packaging.com/CounterfeitCigarettes (last accessed on March 10, 2010).

- → Mandatory pictorial warnings would actually make counterfeiting and piracy more difficult, and would thus support the actions already undertaken by the EU in that field.
- → The application of holograms and unique markings on the pack are ways to prevent counterfeiting, not the presence of logos which have never proved to be an obstacle to counterfeiting and piracy.
- → The tobacco industry claims ignore a new phenomenon in cigarette illicit trade, which are the cheap whites: cigarettes which are legally manufactured, but mainly or only destined for the illegal market. Jin Ling, for instance, is legally manufactured in Russia, not available on the legal retail market, but is the second most seized cigarette brand in the EU in 2008. The absence of large pictorial warnings on cigarettes packs facilitates the illicit trade of those tobacco products. Jin Ling cigarettes look like Camel and taste like Camel. If Camel had large pictorial warnings (80%) on the front and back of the pack, Jin Ling would not be able to benefit from the similarity with the camel pack and would be more easily identifiable.

9. Industry Costs relative to their Revenue and Profit

The RAND report estimates the global cost to the industry of a range of measures. These costs are given as those resulting from increased administrative burden (labelling and reporting overhead) and those resulting from reduced sales (revenue and profit reduction). The costs are summarised in tables 12.4 (option 4) and 12.6 (option 5) of the report.

- ightarrow The (overestimated) costs reported by the tobacco industry as quantified by RAND amount to:
 - Option 4: 3-6% of annual profits and 0.5-1% of annual revenues
 - Option 5: 29-32% of annual profits and 4-5% of annual revenues
- → The costs stated above relative to the enormous revenues and profit of the tobacco industry does not constitute a case for not implementing option 4 at EU level.

10. Internalisation of costs imposed on governments

- → The big jump in costs between option 4 and option 5 is of course due to the fact that option 5 requires the health cost to be paid in some way by the industry.
- → The RAND report cites a health cost per cigarette, based on data for 2003 in Germany, of 0.146 euro (It also cites a "revised" figure of 0.17 somewhere else in the report. This means 3 Euros per cigarette packs. This figure is underestimated and does not take into account the full costs. A recent calculation conducted by Prof. M. Adams and Dr. T. Effertz³¹ estimates indirect costs of € 24.89 billion in Germany (2009). The indirect costs account for nearly twice the estimates of € 13.54 billion used in the German study cited as the source for the RAND

³¹ Deutsches Krebsforschungszentrum (Hrsg.): Die Kosten des Rauchens für Gesundheitswesen und Volkswirtschaft in Deutschland, Heidelberg, 2009. Available at

http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/AdWfP/AdWfP Die Kosten des Rauchens.pdf

calculations (Neubauer 2006). The difference between both calculations is due to the fact that the Neubauer calculations only covered indirect costs linked to paid work (work days lost and early retirement) but did not include mortality or morbidity costs related to non-market activities. The externality cost per pack would be at least 4.6 euros. As neither methodology includes estimates on "value of life", they can be considered as very conservative in nature and underestimate the real costs of smoking.

- → Given the 745 billion cigarettes which the "big four" report were selling in 2009, gives a total health cost of 745 * 0.146 = 109 billion Euros due to those sales based on RAND, but should be at least 160 billion Euros.
- → The RAND figures imply (using the revenue and profit figures above) that the health cost to the EU of the cigarettes sold there in 2009 are 2.4 times the industries revenues and 16.2 times its profits for the same year.
- → The estimated health costs (3 Euros per pack by RAND but at least 4.6 Euros) would not be covered by the tax on tobacco products in most countries, which includes both excise duty and VAT, as they greatly exceed the excise duty in most countries. In any case, taxes are not set only to cover externalities nor are they earmarked but for general contribution to the costs of necessary services. RAND rightly proposes that these extra externality costs be paid by the industry as a levy.
- → The Health and Consumer Protection Directorate of the European Commission published a study paper on "The contribution of health to the economy in the European Union"³². The study also estimates the total social cost of smoking.
- → The Aspect Report³³ provides a conservative (and out dated) cost of smoking estimate for Europe, which ranges between €105.83 billion and €130.31 billion, or between €228 and €281 per capita.
- → The above studies are all conservative and out dated but nonetheless represent (at the very least) 1% of the GDP, a sum equivalent to the entire European budget.
- → Smoking also impacts heavily on employers in terms of lost productivity associated with, for example, long-term disability, absenteeism due to sickness, and smoking breaks. There are a number of studies that have generated estimates for the extent of lost productivity. These have recently been reviewed by Parrott et al (2000). One (conservative) estimate for 'excess' sickness absence among smokers in the UK is 0.9 days per annum. Also, time spent by smoking employees in smoking breaks has been estimated at 2.5 hours per week. Based on such statistics and taking into account wage rates, estimated costs to employers in terms of lost productivity may lie between GBP 700 (EUR 1 000) and GBP 1 000 (EUR 1 430) per smoking employee per year. There are also costs to government revenues. In the UK a recent

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³² http://ec.europa.eu/health/archive/ph overview/documents/health economy en.pdf

³³ Chapter 2: http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/tobacco_fr_en.pdf

economic analysis found that the annual revenue costs to government of current levels of smoking prevalence of 21% were £3.3 billion in health costs, £1.9 billion in reduced tax revenue from premature mortality, £1.5 billion in reduced tax revenue from workplace absenteeism and £3.2 billion in increased disability payments due to poor health.²

→ The costs of tobacco go far beyond the medical expenditure and productivity impact: It is estimated that 20 % of all rubbish collected is cigarette butts (Mackay and Eriksen 2002). The annual cost of fires caused by smoking in the EU is also significant.

11. Final remarks:

The EU tobacco control community considers Impact Assessments an important tool to help take decisions. However, we would like to remind decision makers that Impact Assessments should not replace the objective of the Tobacco Product Directive nor the decision-making itself. The overwhelming importance placed on economic impacts means that other impacts have to be equally quantified and monetised. This triggers the question: How much is a life worth? Balancing the interests of economic competitiveness of individual economic actors with health or environmental outcomes means monetising the price of a life or of the environment, which would hugely increase the estimate of the externality costs of the tobacco industry

The above figures highlight the importance of taking a broad perspective in relation to the consequences of (ill) health. The European Commission recently adopted a Communication on Smarter Regulation³⁴ which set out plans to further improve the quality and relevance of EU legislation. The Communication specifies that "regulation has a positive and necessary role to play. The crisis has highlighted the need to address incomplete, ineffective, and underperforming regulatory measures and, in many cases, to do so urgently...". We hope that our contribution will contribute to a favourable impact assessment that will allow the Commission to bring forward a proposal for a revised Directive requiring, at the very least, large mandatory graphic warnings and standardised/plain packaging and a ban on ingredients.

³⁴ http://ec.europa.eu/governance/better_regulation/documents/com_2010_0543_en.pdf