



planning, monitoring & evaluation

Department:
Planning, Monitoring and Evaluation
REPUBLIC OF SOUTH AFRICA

**SOCIO-ECONOMIC IMPACT ASSESSMENT SYSTEM (SEIAS)
ON THE CONTROL OF TOBACCO PRODUCTS AND ELECTRONIC DELIVERY SYSTEMS BILL**

The National Department of Health

FINAL IMPACT ASSESSMENT (PHASE 2)

DATE: 22 March 2018

The Final Impact Assessment [*Proposed Control of Tobacco Products and Electronic Delivery Systems Bill, which will repeal the Tobacco Products Control Act of 1993 (as amended) by Act no. 12 of 1999; Act no 23 of 2007; and Act no 63 of 2008.*]

The Final Impact Assessment provides a more detailed assessment of the ultimately policy/legislative/ regulations/ other proposal. In addition, it identifies **(a)** mechanisms for monitoring, evaluation and modification as required; and **(b)** a system for managing appeals that could emerge around the implementation process.

1. The Problem Statement / Theory of Change

1.1. Summary of the proposal

a) Summary background of the proposal bill

South Africa made significant strides in the fight against tobacco between 1993 and 2010. During that period, several important pieces of legislation were introduced, starting with the Tobacco Products Control Act (TPCA) 83 of 1993 – the main legislation governing tobacco control efforts in the country. It was amended three times over a fifteen-year period with the Tobacco Products Control Amendment Act 12 of 1999 (which came into force on 1 January 2001), the Tobacco Products Control Amendment Act 23 of 2007, and the Tobacco Products Control Amendment Act 63 of 2008, both of which came into force on 21 August 2009.

These efforts, together with sharp increases in the excise tax on tobacco products, led to reductions in smoking prevalence and consumption as well as smoking-attributable deaths. The smoking prevalence for adults decreased from more than 30% in the early 1990s (van Walbeek, 2005) to current levels of around 20% (Southern Africa Labour and Development Research Unit, 2016). The public health benefits of such reductions are very substantial. These interventions have saved hundreds of thousands of people from a premature tobacco-related death. The current process of legislative changes recognises that much more can, and should be done to further reduce smoking prevalence rates in South Africa.

South Africa ratified the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC) on 19th April 2005. Through this treaty, the Government of South Africa has an obligation to protect its citizens from tobacco by implementing strong evidence-based tobacco control interventions. In the past number of years, tobacco control policy in

South Africa has largely stalled, and this is seen in the prevalence statistics. Reddy et al. (2013), using estimates from the South African Global Youth Tobacco Survey (GYTS), for instance, found that smoking rates among girls increased from 10.5% to 12.1% between 2008 and 2011 compared to a decline among boys from 22.8% to 21.7% over the same period. Second-hand smoke exposure is still a concern with 25.7% of youth exposed at home (Peltzer,2011), and even higher exposures among the adult population in restaurants (33.4%) and bars (32.7%) (Ayo-Yusuf et al.,2014). South Africa has also been experiencing a proliferation in non-communicable diseases (NCDs), with smoking, or second-hand exposure to cigarette smoke, being a leading cause of many of them (Chopra et al., 2009; Coovadia et al., 2009; Mayosi et al., 2009). This has resulted in an increased demand for healthcare, specifically related to care for chronic diseases among those least able to pay for the services.

The emergence of electronic nicotine delivery systems (ENDS) and non-nicotine delivery systems (ENNDS), commonly referred to as 'e-cigarettes', is an area of concern. Accurate prevalence statistics for ENDS/ENNDS use are not yet known, but it is estimated that about 3% of smokers in South Africa use ENDS/ENNDS. The ENDS market in the country is growing and several companies are involved in importing the products into the country, mainly via the internet, while manufacturing is dominated by a single industry player. The public health community remains unsure of a clear role of ENDS/ENNDS in the area of tobacco control, but is agreeable on the need for regulation.

In light of the above, three options are proposed to address the tobacco control in the country namely, **Option 1** is to allow the current status quo to remain, hence no changes to the current legislation and tobacco control regulations will remain as is. **Option 2** is the proposed Bill to repeal to the current legislation as is outlined further in the report and **Option 3** is the full implementation of the WHO FCTC Articles and Guidelines. Option 3 will encompass Option 1 (the status quo), plus elements of Option 2, and a number of additional tobacco control interventions. The additional interventions in Option 3 include the following: (1) establishing a National Tobacco Control Coordinating Programme, (2) raising the excise tax on tobacco products to 70% of the retail price, (3) establishing action plans for the implementation of education, communication and training activities, (4) Developing and disseminating appropriate measures to promote cessation of tobacco use and adequate

treatment for tobacco dependence, and (5) developing systems in order to comply with international standards to eliminate illicit trade in cigarettes.

This report focuses on the preferred Option, which is Option 2 and the additional interventions were not assessed in the same way as the interventions that have been proposed under this Option. Maintaining the status quo (option 1) will lead to slower progression towards eliminating the harms from tobacco than Options 2 and 3. Implementing Option 3 has not been considered for purposes of this report.

- In proposing **Option 2**, at least three caveats need consideration, namely (1) the time needed to implement proposed legislation, (2) anticipation of the possible legal ramifications, and (3) addressing the issue of ENDS/ENNDS. The length of time proposed to implement the legislation once the Bill has been passed into law is a maximum of six months. The longer it takes for the legislation to be implemented, the longer it takes for the anticipated benefits to realise. The government could expect a legal challenge from the tobacco industry. Since this has occurred in other countries. The tobacco industry has consistently fought the introduction of tobacco control legislation, particularly in relation to plain/standardized packaging and graphic health warnings. Recently Australia (December 2015), United Kingdom (May 2016) and Uruguay (July 2016) have had strong rulings in favour of public health. These precedents make it easier for other countries to pass strong tobacco legislation, but governments could expect a tobacco industry resistance. With respect to ENDS/ENNDS consideration is needed in developing regulations and ensuring compliance thereof.

Comprehensive tobacco control measures as proposed in **Option 2** will support the core national priorities namely, (1) social cohesion and security, (2) economic inclusion, (3) economic growth and (4) environmental sustainability. The National Development Plan (NDP) Vision 2030 operationalises this by incorporating the myriad of multidimensional factors needed for national development (National Planning Commission, 2011). Among these factors, health plays an important role. Tobacco use is listed among the top five risk factors contributing to the country's burden of disease, particularly, non communicable diseases.

b) Problem/s and root causes that the proposal is trying to address

These above mentioned trends demonstrate the need to strengthen current government legislation on tobacco control in order to promote and maintain public health, align with changes in the epidemiological and technological environments, and the World Health Organization Framework Convention on Tobacco Control (WHOFCTC). In light of this, the current Tobacco Products Control Act (TPCA) is being repealed to address key areas pertaining to indoor public areas, display of tobacco products at point of sale, use of electronic devices and the introduction of plain packaging of tobacco products.

The key problems and some of the root causes are listed in the table below.

Identified Problem	Root causes
<p>South Africa has also been experiencing a proliferation in non-communicable diseases (NCDs), with smoking, or second-hand exposure to cigarette smoke, being a leading cause of many of them (Chopra et al., 2009; Coovadia et al., 2009; Mayosi et al., 2009). In 2000 about 44 000 South Africans died prematurely because of smoking-related illnesses (Groenewald et al., 2007).</p>	<p>The country is partially compliant to the WHO FCTC guidelines in terms of indoor smoke free areas. The current Tobacco Products Control Act (TPCA) allows for smoking in 25% of indoor public areas and vending machines are allowed to be placed in these indoor public smoking areas. Smoking in indoor public areas results in Tobacco Smoke pollution (TSP); and exposure to Second Hand Smoke (SHS) which places people at risk of being ill.</p>
<p>The packaging and designs of tobacco products have traditionally served to enhance the advertising of tobacco products an effective tool for the promotion of tobacco use among various target groups. The importance of package and design in product promotion has long been established in the marketing strategy (Pilditch, 1961).</p>	<p>Currently the TPCA does not allow for plain packaging and pictorials. The TPCA allows for:</p> <ul style="list-style-type: none"> • Only text health warning on tobacco products which are not effective. • Brands logos and colours are used as part of the packaging of tobacco products. The Public / youth are therefore attracted by packaging of tobacco products which is used as an advertising and marketing medium. • Descriptors e.g. light, mild and colours are

Identified Problem	Root causes
	<p>used on tobacco products. Tobacco users are misled into believing that products are less harmful because of these descriptors and colours.</p> <p>Plain/standardized packaging of tobacco products, which includes pictorials/ graphics and health warnings will be more effective in making tobacco products less attractive.</p>
<p>Robertson et al., (2014), identified twenty peer-reviewed studies that met their inclusion criteria for a systematic review on the impact of POS tobacco promotion on smoking behaviour. The studies provided evidence of a small to moderate statistically significant effect of POS tobacco displays on increased smoking and smoking susceptibility among the young. This finding was consistent with other cross-sectional studies by Henriksen et al., (2008) and MacKintosh, Moodie & Hastings, (2012), that all found positive associations between exposure to POS tobacco promotion and susceptibility, experimental and current smoking. Furthermore, the remaining studies reviewed by Robertson et al. (2014) reported a positive association between exposure to POS tobacco promotion and smoking or smoking susceptibility.</p>	<p>Currently South Africa is partially compliant to WHO FCTC guidelines on Tobacco Advertising, Promotion and Sponsorship (TAPS), since the TPCA allows for advertising at Point of Sale (POS).</p> <ul style="list-style-type: none"> • South Africa has not introduced a complete ban on the display, advertisement and marketing of tobacco products at retail and wholesale point-of-sale (POS) • Point-of-Sale (POS) used to market or advertise tobacco products which increases tobacco use
<p>ENDS/ENNDS use may act as a potential “gateway” for young people and children to initiate ENDS/ENNDS use and may lead to regular tobacco</p>	<p>Electronic Nicotine Delivery Systems (ENDS), Electronic Non-Nicotine Delivery Systems (ENNDS) and other such devices are not</p>

Identified Problem	Root causes
<p>smoking. For instance, King et al. (2014) investigate whether ENDS/ENNDS increased the desire to smoke in those passively exposed to the vapour. They find that passive exposure to ENDS/ENNDS significantly increases the overall urge to smoke a regular cigarette among young adult smokers. In a different study, Kim et al. (2015) examine the adult smokers' awareness of and receptivity to an ENDS/ENNDS television advertisement and find that it elicits an urge to smoke 75% of the time.</p> <p>A significant portion of ENDS/ENNDS business is conducted on the internet, with some estimates placed at between 30% and 50% of total ENDS/ENNDS sold (Zhu et al., 2014). The ease of setting up such a business online has resulted in the general proliferation of many small businesses dealing in ENDS/ENNDS products across the value chain.</p> <p>The WHO maintains a cautious approach to the issues and advocates for the careful regulation of ENDS/ENNDS in a similar fashion to ordinary cigarettes, taking into account some of the issues outlined above (World Health Organization, 2014).</p>	<p>included into the TPCA.</p> <p>ENDS /ENNDS encourages:</p> <ul style="list-style-type: none"> • Smoking behaviour; • advertizing; • Free sale of products and • Indiscriminate use of devices in public places.

1.2. Description of the intended outcomes of the proposal

Promotion and maintaining public health through:

- Strengthening the current legislation on Tobacco Products Control Act, by repealing the act will address key areas pertaining to indoor public areas, display of tobacco products at point of sale, use of electronic devices and the introduction of plain packaging of tobacco products; and

- Alignment with changes in the epidemiological and technological environments and the World Health Organization Framework Convention on Tobacco Control (WHOFCTC).

1.3. Description of the groups that will benefit from the proposal, and the groups that will face the cost.

A number of groups were identified that are likely to be negatively affected by the proposed legislation. For the sake of brevity and because there are significant overlaps in how the proposed legislation is likely to affect each of them, we have combined them into six groups. The nature of the impact of the proposed legislation will be discussed below. The six broad groups that are expected to bear the cost of the legislation are the following:

Groups that will benefit	How will they benefit?
<p>Public, Owners and/or managers of work-places i.e public and private sector (includes poorest of the poor, youth and women)</p>	<p>The main beneficiaries of the proposed legislation will be the people (poorest of the poor, youth and women) of South Africa. The aim of the legislation is to advance public health and the literature clearly indicates that plain packaging, POS restrictions and 100% smoke-free policies advance public health by encouraging behaviour change that reduces smoking prevalence and tobacco consumption. Since the causal linkage between tobacco use and tobacco-related morbidity and premature mortality is undisputed, a decrease in tobacco use will result in a lower burden of death and disease.</p> <p>In 2000 about 44 000 South Africans died prematurely because of smoking-related illnesses (Groenald et al., 2007). The needless pain and suffering of the people who died, and the emotional suffering of their loved ones, are very real costs, even though they typically do not appear in some economic magnitude like the GDP. Other than these intangible costs, tobacco imposes a large tangible cost on society. People who get ill and die because of tobacco forego income, and impose direct costs (e.g. medicine and premature funeral expenses) on their families. They have to be looked after by family members or outsiders, which implies an opportunity cost. Breadwinners who become ill are unable to care for their families.</p> <p>Spending money on tobacco implies a significant opportunity cost for individual households. Most households in South Africa are severely income constrained. Money spent on tobacco needs to be taken from somewhere else. Although there are no published studies on the opportunity costs of tobacco use at the international level, a rapidly expanding international literature indicates that expenditures on children, especially education and foodstuffs like milk, are most typically compromised by tobacco purchases (John, 2008; Pu et al., 2008; John, Ross & Blecher, 2012; Chelwa, Grieve; Walbeek, 2014). To the extent that the proposed legislation will encourage</p>

Groups that will benefit	How will they benefit?
	<p>smokers to quit smoking or non-smokers to not initiate smoking, it will contribute to better economic outcomes at the household level.</p>
<p>Government</p>	<p>Tobacco imposes a significant burden on the health care system. The vast majority of South Africans make use of the public health care system, provided by the National Department of Health, which is ultimately funded by taxpayers. For a large number of South Africans, the cost of treating tobacco related diseases is borne by the already overburdened public health care system. Treatment for tobacco-related diseases is expensive and implies that the limited resources in the public hospitals are being diverted away from other patients, or from other primary health care programmes.</p> <p>Reducing tobacco prevalence implies that the burden on the public health care system will be reduced. While the benefits from reduced smoking on the public health care system are very real, they take time to manifest. This follows because of the long lag between the onset of smoking and the onset of illness. In reverse, a decrease in smoking prevalence today, will not result in a discernible decrease in smoking related morbidity and mortality next year, but will play itself out over a number of years</p>

Groups that will bear the cost or lose	How will they incur the cost or lose?
Manufacturers and distributors of cigarettes and other tobacco products	<p>Plain/Standardized Packaging will impose two kinds of costs on the tobacco industry: (1) a reduction in sales, and (2) costs of compliance with the Plain/Standardized Packaging legislation. Cigarette consumption in South Africa has been decreasing for more than two decades, and, till about 2010, the tobacco industry was able to mitigate the decrease in sales volumes by increasing the net-of-tax price (Linegar and van Walbeek, 2016). According to BATSA, the cost of compliance for the introduction of Plain Packaging will be about R2.4 billion over two years.</p> <p>While BAT is also strongly opposed to POS display bans, 100% smoke-free policies, the banning of vending machines, and the regulation of ENDS/ENNDS as tobacco products, it seems unlikely that the tobacco industry would have to incur any implementation costs associated with these policies. In fact, the tobacco industry might make a modest saving because currently they pay the retail outlets to advertise tobacco products at the POS through, for instance, supplying the money mats and paying the retailers for having them at the POS. This marketing expenditure will fall away as the POS display bans become effective. Presumably the tobacco industry's opposition to these interventions is based on the fear that these interventions will reduce the sales of cigarettes. Ultimately that is the aim of the proposed legislation.</p>
Companies in the hospitality industry, including restaurants, bars and pubs;	When the Tobacco Product Control Amendment Act of 1999 was debated, the hospitality industry was strongly opposed to the smoking ban. Whereas initially the legislation aimed to create 100% smoke-free public places, the lobbying by the tobacco and hospitality industries resulted in the compromise that an establishment could

Groups that will bear the cost or lose	How will they incur the cost or lose?
	<p>dedicate up to 25% of its floor space to smokers, subject to some constraints (e.g. separate air ventilation, warnings on the doors, etc.). Many hospitality establishments incurred substantial costs to comply with this concession. The Amendment Act of 1999 did not prescribe that establishments must accommodate smokers by providing a smoking section.</p> <p>To the extent that the proposed smoke-free regulations will result in hospitality establishments that have dedicated smoking sections being frequented less by smokers (and not more by non-smokers), this would result in a decrease in turnover in such establishments. Based on empirical ex post studies in other parts of the world and South Africa, the hospitality sector as a whole is unlikely to be negatively affected. However, there may be some establishments that cater for a disproportionately high percentage of smoking customers, who may experience a fall in revenue.</p> <p>The fact that establishments have incurred costs in the past to create smoking sections is irrelevant from an economic perspective. The proposed smoke-free legislation does not require hospitality establishments to remove the smoking sections. It simply requires them to not use them as a smoking section any more. Based on testimony from a public health advocate, going smoke-free may yield a financial benefit in the cleaning costs of the smoking section would be reduced and because it may result in a higher overall occupancy rate, especially if the smoking section is currently underutilised.</p>

Groups that will bear the cost or lose	How will they incur the cost or lose?
Retailers, including supermarkets, forecourt retailers and small retail stores	<p>Two large retailers were consulted, especially about the POS display bans. The feeling from both groups was that they were not concerned about POS restrictions. They expect to lose some revenue for allowing the tobacco companies to place the money mats and other marketing material at the POS, but this was not seen as a major issue. Retailers were not concerned that the POS restrictions and the Plain Packaging would reduce their turnover, because what is not spent on cigarettes is probably spent elsewhere in the shop.</p> <p>The retail margin on cigarettes is low, amongst others because cigarettes are a Known Value Brand. That means that retailers have the perception that their price competitiveness vis-à-vis other retailers is monitored by customers' heuristic that cigarette prices are representative of prices in that shop in general.</p> <p>This forces the retail margin down. Large retailers are confident that sales that might potentially be lost at the cigarette kiosk will be made up in the form of sales of other products in the rest of the shop. The retailers did not foresee any impact on employment.</p> <p>We did not speak to the forecourt retailers, despite a serious attempt to contact them, and we did not have contact with representatives of small retail stores or the informal retail sector.</p>
Cigarette vending machine manufacturers, operators and importers	<p>A tiny percentage of cigarettes sold in South Africa is sold through vending machines. Cigarette vending has been in decline for a long time. There has been very little investment in the form of vending machines in the past number of years. The proposed ban on cigarette vending machines will have no impact on cigarette vending machine manufacturers and importers, because there has not been a demand for these machines for some years.</p>

Groups that will bear the cost or lose	How will they incur the cost or lose?
	<p>Some vendors have diversified into other products, such as sweets and soft drinks.</p> <p>The ban on vending machines will imply the death knell for vending companies that vend only cigarettes and will hurt the more diversified vending companies (to the extent that they depend on cigarettes). There will be some job losses, probably in the order of a few hundred. It seems that the vending operators have been expecting this legislation for a number of years, which explains their lack of investment in machines. The capital stock is ageing and has probably been fully depreciated and amortised. The vending machine operators request that (1) they be compensated for the loss of their equipment as a result of the vending machine ban, and (2) be given enough warning time to switch out of the market. To the extent that the cigarette vending machines can be converted to vending machines of other products, the impact of the vending machine can be mitigated.</p>
<p>ENDS/ENNDS manufacturers, importers, retailers and wholesalers</p>	<p>The use of ENDS/ENNDS has increased dramatically in the past four or five years, both in South Africa and in other parts of the world. The product is currently being manufactured and sold in a legislative vacuum. In South Africa the manufacture and distribution of ENDS/ENNDS is dominated by one company, even though the market is apparently quite accessible for other players as well. The dominant company, and the ENDS/ENNDS industry more generally, are at pains to explain that they are different from the tobacco industry. They want to see themselves as part of the solution, rather than as part of the problem. They emphasise the possible public health benefits to be derived from ENDS/ENNDS, especially for people that are unable to quit smoking cigarettes.</p>

Groups that will bear the cost or lose	How will they incur the cost or lose?
	<p>It is likely that regulation of ENDS/ENNDS will significantly reduce the growth in the ENDS/ENNDS market. It seems unlikely that there will be a decrease in ENDS/ENNDS use, since the intention of the legislation is not to ban the use of the product. However, relative to the rocketing growth in the past few years, the legislation may slow down ENDS/ENNDS sales. This in turn will have detrimental consequences for the manufacturers, importers, wholesalers and retailers of these products, not necessarily in absolute terms, but relative to past trends and possibly expectations.</p>

1.4. Description of the behaviour that must be changed, main mechanisms to achieve the necessary changes.

Groups inside Government	Behaviour that must be changed (Current Behaviour)	Main mechanism to achieve the necessary changes
Government	<p>Main issue - No legal frameworks:</p> <ul style="list-style-type: none"> • Smoking in indoor public places • ENDS / ENNDS used in all spaces (vapour & smoking behaviour promotion) • Not adequately aligning with changes in the epidemiological and technological environments and the World Health Organization Framework Convention on Tobacco Control (WHOFCTC). 	<p>Development of regulations for:</p> <ul style="list-style-type: none"> • 100% Smoke free indoor public places • ENDS / ENNDS

Groups outside Government	Behaviour that must be changed (Current Behaviour)	Main mechanism to achieve the necessary changes
Tobacco industry	<p>Main issue - No legal frameworks:</p> <ul style="list-style-type: none"> • Vending machines easily accessible • POS display, product packaging and ENDS/ ENNDS promoting tobacco use 	<p>Development of regulations for</p> <ul style="list-style-type: none"> • 100% Smoke free indoor public places • ENDS / ENNDS
Hospitality industry	<p>Main issue - No legal frameworks:</p> <ul style="list-style-type: none"> • Smoking taking place in 25% indoor smoking areas • Indiscriminate use of ENDS / ENNDS in public places 	<p>Development of regulations for</p> <ul style="list-style-type: none"> • 100% Smoke free indoor public places • ENDS / ENNDS
Public	<p>Main issue - No legal frameworks:</p> <ul style="list-style-type: none"> • Smoking taking place in 25% indoor smoking areas • Indiscriminate use of ENDS / ENNDS in public places • Youth attracted to purchase at point of sale • Public response to deceptive descriptors 	<p>Development of regulations for</p> <ul style="list-style-type: none"> • 100% Smoke free indoor public places • ENDS / ENNDS • Public awareness and education

1.5. Report on consultations on the proposal with the affected government agencies, business and other groupings.

In addition to the literature review, interviews were held with various stakeholders who are knowledgeable about tobacco and tobacco control in the South African context, as well as with representatives from industries which are likely to be affected by the proposed legislative measures.

Relevant respondents were identified through a stakeholder-mapping process: participants were selected based on their interest or involvement in each of the key areas in which the legislative measures are being proposed. Each identified stakeholder was sent a letter requesting an interview and the ETCP conducted semi-structured interviews with those who responded to the request to be interviewed. This provided interview respondents with the opportunity to comment on any aspects of the proposed legislative measures, based on their preference and interest.

Industry bodies and other interested parties in the tobacco industry were contacted and requested to participate in the interview process. Interview responses were obtained from eleven interested parties out of the thirteen contacted and requested permission to record each of the interviews. Following each meeting, a summary of the key issues raised by interview respondents regarding the relevant proposed legislative measures was compiled.

Given the interest of the tobacco industry in the proposed legislation, and the desire to include all stakeholders and interested parties' views into this SEIA report, the tobacco industry was included in this process.

The following organisations were interviewed:

- Tobacco Alcohol and Gambling (TAG) Advisory Advocacy and Action Group
- British American Tobacco South Africa (BATSA)
- The Tobacco Institute of Southern Africa (TISA)
- Priority Cost Effective Lessons for Systems Strengthening (PRICLESS)
- National Council Against Smoking (NCAS)
- Fuel Retailer Association (FRA) Of Southern Africa
- Pick 'n Pay
- Shoprite Checkers Group

- Electronic Cigarette Association of Southern Africa (EASA)
- Federated Hospitality Association of South Africa (FEDHASA)
- Vending Association of Southern Africa (VASA)

In addition to their espousal of views regarding the economic and social consequences of each of the proposed legislative measures, both BATSA and public health advocates provided some general considerations regarding the legislative measures holistically, which are considered in turn below.

BATSA is of the view that the proposed legislative measures are not a necessary or proportionate means to enhancing public health in South Africa.¹ BATSA suggests that there exist less costly and less restrictive measures which government should consider to achieve its public health objectives. Particularly, BATSA indicated its support for efforts to reduce the risks associated with the use of tobacco products through youth education, retail access prevention and ID programs, and creating a regulatory framework which supports tobacco harm reduction, including reduced-risk products.

Public health advocates drew attention to the fact that a comprehensive approach to tobacco control such as that entailed in the proposed legislative measures would address some of the development challenges currently faced by South Africa. This is because policies geared toward reducing the consumption of tobacco products will help to create a virtuous cycle where, in the medium-to-long run, better health outcomes will improve the economic development of the country.

It is also expected that social development will be both supported and enhanced through the elimination of tobacco-attributable inequities. To this end, it was noted that more poor people die from diseases than rich people. Therefore, any reduction in smoking by the poor *reduces* the broader mortality gap between the rich and the poor.

Table 2. Consultations (THIS TABLE WILL TO BE UPDATED AS CONSULTATIONS ARE HELD)

Affected Stakeholders	What do they see as main <u>benefits, costs and risks?</u>	Do they <u>support or oppose</u> the proposal?	What <u>measures / amendments</u> do they propose?	Have these measures / amendments been <u>incorporated</u> in your proposal?
1. Government Departments and Agencies (Name them)	<p>Standardised / Plain Packaging Health Risks: use of Misleading descriptors; packaging used as a marketing tool to attract users. Benefits: Greater health awareness and less attractive packages to discourage use.</p>	Proposal supported.	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Yes
	<p>100% smoke free indoor public places Benefits: No pollution; Clean air; Less cleaning and damage to premises</p>	Proposal supported.	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Yes
	<p>ENNDS /ENNDS</p>	Proposal supported	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Yes
	<p>Display at Point of Sale (POS)</p>	Proposal supported	<ul style="list-style-type: none"> • Request for ban on advertising to cover film, television and stage productions 	<ul style="list-style-type: none"> • Yes

Affected Stakeholders	What do they see as main <u>benefits, costs and risks?</u>	Do they <u>support or oppose</u> the proposal?	What <u>measures / amendments</u> do they propose?	Have these measures / amendments been <u>incorporated</u> in your proposal?
	General inputs		<ul style="list-style-type: none"> • strengthen public awareness programmes through innovative social engineering mechanisms • Review pricing strategies to reduce demand, especially by youth 	<ul style="list-style-type: none"> • Yes

TABLE 3 SUMMARY OF CONSULTATION WITH BUSINESS AND KEY ORGANISATIONS LISTED IN 1.5

Proposed Legislative amendment	Positive Economic Consequences	Negative Economic Consequences	Positive Social/Other Consequences	Negative Social/Other Consequences
Standardised packaging	<ul style="list-style-type: none"> • Reduced Economic burden of tobacco-related death and disease • Simple and inexpensive to implement 	<ul style="list-style-type: none"> • Increase in illicit trade • Additional costs for retailers and cigarette manufacturers • Reduction in the profitability of retailers 	<ul style="list-style-type: none"> • Improved Health outcomes • Reduced environmental harm associated with tobacco use • Promotion of health equality 	<ul style="list-style-type: none"> • Efficiency losses by retailers because of increased time to find products in-store • Security risk for retailers • Not effective (does not influence smoking behaviour) • Lower cigarette prices, and undermines public health objective • Increases the burden on law enforcement and regulatory bodies • Illicit cigarettes are of poorer quality and thus pose a further health risk to consumers
100% smoke free indoor public places	<ul style="list-style-type: none"> • Not costly for government or business to implement and no anticipated loss of jobs • Induced economic benefits for small business owners in particular 	<ul style="list-style-type: none"> • More cost for businesses, which have already incurred costs to comply with existing legislation • Loss of business and employment, disproportionately so for smaller venues • Enforcement will be costly 	<ul style="list-style-type: none"> • Ensures the law is not subject to interpretation • Ensures equal access to health for predominantly low and semi-skilled workers in the hospitality sector • Positive public health outcomes, with accompanying economic benefits 	<ul style="list-style-type: none"> • Negative environmental/aesthetic impact • Puts physical safety of smokers at risk • Complications regarding implementation (people being legally prevented from smoking) • Likely that compliance will be monitored in an unfair manner

Proposed Legislative amendment	Positive Economic Consequences	Negative Economic Consequences	Positive Social/Other Consequences	Negative Social/Other Consequences
Display at Point of sale (POS)	<ul style="list-style-type: none"> Financial burden on retailers can be mitigated and no employment losses for large retailers 	<ul style="list-style-type: none"> Will inhibit competition between tobacco manufacturers on dimensions other than price Decreased profitability of retailers Employment losses for small retailers and informal traders Incentivizes illicit trade in tobacco products 	<ul style="list-style-type: none"> Positive public health outcomes, with accompanying economic benefits Prevention of marketing, especially to young people Closes last promotional activity of tobacco companies 	<ul style="list-style-type: none"> Poses an inconvenience and heightened security risk for retailers Will be difficult to monitor compliance in a fair manner – puts bigger retailers at an unfair disadvantage relative to informal sellers of tobacco products Difficult to enforce
Tobacco vending machines	<ul style="list-style-type: none"> Financial implications can be mitigated through product diversification The industry is currently small and employs few people, so no huge job losses 	<ul style="list-style-type: none"> Employment losses, profit losses and business closures 	<ul style="list-style-type: none"> Removes one of the final vestiges of cigarette advertising Prevents access of youth to cigarettes and supports those who have quit 	<ul style="list-style-type: none"> Argued to be unfair to vending whilst still allowing retailers to sell cigarettes at kiosks

Table 3 presents a summary of the key views espoused regarding the economic, social and other consequences that stakeholders identified in relation to each of the proposed legislative measures. The discussion on ENDS/ENNDS is not included here as the interviews primarily focused on whether or not ENDS/ENNDS should be regulated in the same manner as tobacco products and thus did not fit the framework of the discussion surrounding the other proposed legislative measures.

1.6. Description of the possible disputes arising out of the implementation of the proposal, and system for settling and appealing them.

The government should expect a legal challenge from the tobacco industry. Throughout the world, the tobacco industry has consistently fought the introduction of tobacco control legislation. The fight has been particularly fierce in relation to plain/standardized packaging and graphic health warnings. Anticipated legal disputes from the tobacco industry will be handled by the Cluster: Legal Services within the national Department of Health.

2. Impact Assessment

2.1. Describe the costs and benefits of implementing the proposal

TABLE 4

Group	Implementation Costs	Costs of changing behaviour	Costs/Benefits from achieving desired outcome	Comments
NDOH and Provincial Health Departments	Staff, Educational and awareness campaigns; equipment	<ul style="list-style-type: none"> • Public awareness and education programmes • Social Reengineering programme • Monitoring and Enforcement 	<ul style="list-style-type: none"> • Compliance with the amendments • Reduced public responses to misleading descriptors and packaging • Reduced health and economic burden of tobacco-related death and disease • Not costly for government to implement • Improved health outcomes • Reduced 	

TABLE 4

Group	Implementation Costs	Costs of changing behaviour	Costs/Benefits from achieving desired outcome	Comments
			environmental harm associated with tobacco use <ul style="list-style-type: none"> • Promotion of health and prevention of marketing, especially to young people • Closes last promotional activity of tobacco companies quality	
Tobacco Industry: Manufacturers and Retailers	<ul style="list-style-type: none"> • No need to renovate structures previously dedicated for smoking zones • Vending machines - Financial implications can be mitigated through product diversification. The industry is currently small and employs few people, so no huge job losses 	<ul style="list-style-type: none"> • Standardised packaging & POS - Initial additional costs for and reduction in the profitability, later stabilises • Financial burden on retailers can be mitigated and no employment losses for large retailers 		

TABLE 4				
Group	Implementation Costs	Costs of changing behaviour	Costs/Benefits from achieving desired outcome	Comments
Hospitality Industry		<ul style="list-style-type: none"> Adapting from designated smoking to 100% no smoking will incur less dry cleaning and cleaning costs 	<ul style="list-style-type: none"> Positive environmental/aesthetic impact 	
Tobacco industry		<ul style="list-style-type: none"> Negative environmental/aesthetic impact Puts physical safety of smokers at risk Complications regarding implementation (people being legally prevented from smoking) Likely that compliance will be monitored in an unfair manner 		

2.2. Description of the changes required in budgets and staffing in government in order to implement the proposal.

Tobacco control monitoring and compliance forms part of the functions of the Environmental Health Officer's work and additional staff maybe required to strengthen control efforts at ports of entry and within local authorities.

2.3. Describe how the proposal minimises implementation and compliance costs.

The proposed **Option 2** will minimise implementation steps for both the government and the tobacco industry:

TABLE 5	
Government	Tobacco Industry
<p>Plain Packaging:</p> <ul style="list-style-type: none"> • Clear and simple regulations, therefore minimizing time for inspection and compliance. • Graphic health warnings on the packages will create awareness on the harms of tobacco use. • Initial implementation costs on strengthening Information, Education and Communication. <p>100% Smoke Free Indoor Public Places:</p> <ul style="list-style-type: none"> • Clear and simple regulations, therefore minimizing time for inspection and compliance. • Initial implementation costs for strengthening Information, Education and Communication, but later stabilises. • No structural costs for implementation. <p>Display at Point of Sale (POS):</p> <ul style="list-style-type: none"> • Clear and simple regulations, therefore minimizing time for inspection and compliance • Initial implementation costs for strengthening Information, Education and Communication, but later stabilises • No structural implementation costs. <p>ENDS and ENNDS:</p> <ul style="list-style-type: none"> • Clear and simple regulations, therefore minimizing time for inspection and compliance • Initial implementation costs for strengthening Information, Education and Communication, but later stabilises 	<p>Plain Packaging:</p> <ul style="list-style-type: none"> • Initial packaging costs to be carried by the industry <p>100% Smoke Free Indoor Public Places; ENDS and ENNDS; POS:</p> <ul style="list-style-type: none"> • Clear regulations therefore minimal confusion in enforcing compliance • No compliance costs (e.g structural renovations)

3. Managing Risk

3.1. Description of the main risks to the achievement of the desired ends of the bill or to the national priorities (aims) that could arise from adoption of the proposal.

Table 8: Potential risks and how to mitigate them

TABLE 6	
Identified risks	Mitigation measures
Potential loss of revenue in form of taxes in the short term as the Bill is aiming to raise cessation rates and improve public health.	Economic growth from increased productivity from those who would have given up smoking and now have the money to spend on other products and services such as education. Border controls be strengthened to prevent illicit tobacco trade (Plain Packaging).
Anticipated Resistance by the Industry (Tobacco and Hospitality)	Strengthen information, education and communication on the harms of tobacco use in the population.
Possible litigations against the NDOH	Address litigation through Legal Services.

3.2. Description of the mechanisms included in the proposal for monitoring implementation, evaluating the outcomes, and modifying the implementation process if required.

Tobacco Control complex and involves many sectors in government, outside of health. Although the National Department of Health takes the leading role in ensuring and protecting public health, other government departments play a key role in implementing and ensuring compliance with the TPC Bill. The key government departments that are directly involved are listed in the Table 7 below.

TABLE 7

Proposed Legislative Measures	Implementation Role of NDOH	Implementation Role of Key Government Departments
<p>100% Smoke Free Indoor Public Places</p>	<p>Health Promoters are responsible for education and awareness activities, and the Environmental Health officers are responsible for monitoring compliance with regulations, including ports of entry.</p> <p>The NDOH builds capacity of key service providers on:</p> <ul style="list-style-type: none"> • Tobacco legislation and awareness on harmful effects of tobacco • Smoking Cessation • Monitoring of Compliance on the Products/ legislation 	<p>Dept. Justice: Responsible for fines for offences</p> <p>SAPS Enforcement of the law /Prosecution</p> <p>Dept. Education: Provide learners with education on Tobacco Control /Protection from exposure to tobacco smoke; Education, communication, training and awareness programs in schools; encourage research in academic Institutions.</p> <p>Dept. Trade and Industry: Develop Policies that protect health in terms of bilateral agreements Permission/ Certification/ licensing of the products;</p> <p>Dept. Public Service Administration: Protect employees from exposure to tobacco smoke Develop and implement the policies that protect the workers from tobacco use and second hand smoke; Participate in the development of Smoking Cessation mechanisms for workers; Advocate for supplementary funding with the medical Aids for Nicotine replacement therapy for cessation programmes; Conduct Research on smoking and absenteeism rates, hours of duty wasted in smoking breaks, etc among employees.</p>

		<p>Correctional Services: Protection of Inmates from Tobacco Use and the Harmful effects; Protection of inmates from the second hand smoke in prisons; Implement Smoking Cessation programmes; Ban sale of tobacco products in prisons.</p> <p>Dept. Finance(National Treasury): Implement Price and taxation measures to reduce the demand for tobacco, Develop policies on Tobacco Taxation; Collect revenue: Conduct relevant Research</p> <p>SARS (Custom & Excise): Import / Export control; Manage and control Illicit trade of tobacco products (e.g smuggling, illicit manufacturing and counterfeits)</p> <p>Dept. Agriculture: Support economically viable alternative activities for tobacco farmers; Protect the environment and the health of farmers and farm workers in respect of tobacco cultivation and manufacture ; Regulate Tobacco farming; Regulate the import and Export of raw tobacco products;</p> <p>Dept. Environmental Health: Protect the environment and the health of persons in relation to the environment with respect to tobacco cultivation and manufacture (FCTC Article 18); Protect the environment with policies on tobacco use.</p>
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Display at Point of Sale (POS)		SAPS: Same as row 1 Dept. Trade and Industry: Same as row 1
Plain / Standardized Packaging		SAPS: Same as row 1 Dept. Trade and Industry: Same as row 1 Dept. Finance (SARS): Price and taxation measures to reduce the demand for tobacco (FCTC Article 6)
ENDS and ENNDS		SAPS: Same as row 1 Trade and Industry: Same as row 1 Dept. Finance (Treasury): Same as row 1

a) Transition period for implementation of the TPC Bill

In implementing **Option 2**, a number of factors will need to be considered as the interventions are introduced. These include the following, but may not be exhaustive, the amount of time for transition from the current legislation to the legislation; and possible legal ramifications (e.g. Uruguay, Australia, UK).

The amount of time proposed for transition to the legislation once the Bill has been passed into law is **6 months**. This may seem an abrupt move, prima facie, but in reality is not. The amount of time it takes between introduction of the Bill, public debate and a final bill and eventually passing in parliament may take 18-24 months. During this time the anticipated gains already described in the preceding sections will be postponed. Any further delays in implementation, would thus unnecessarily stall gains even longer.

b) Anticipation of the legal ramifications

The tobacco industry has consistently fought the introduction of tobacco control legislation across the globe. Several countries, including South Africa, have been embroiled in legal battles brought on them by the tobacco industry, challenging proposed tobacco control

legislation, especially in relation to standardized /plain packaging and graphic health warnings. Recently however, countries such as Australia (December, 2015), United Kingdom (May 2016) and Uruguay (July 2016) have had rulings in favour of public health. However, these legal battles merely portend the route that countries willing to strengthen their tobacco control legislation may have to take in the future. The government thus needs to anticipate litigation at various levels from different stakeholders aggrieved by the proposed interventions.

c) Compliance with legislation

Implementation and compliance to this proposed Bill will require the full cooperation of manufacturers and retailers. Businesses that sell tobacco products are liable and must ensure that they conform to the law. Adequate information dissemination efforts will need to be undertaken to create a greater understanding of the legislation and implementation thereof. Business entities can also play a very significant role in the monitoring and evaluation by providing regular input on various indicators relevant to understanding both the levels of implementation and compliance. ENDS and ENNDS present a potential risk to reduce the effectiveness of decades of tobacco control interventions, hence a specific framework needs to be defined to regulate ENDS/ENNDS. This would involve identifying aspects of ENDS/ENNDS use that can be regulated and enforced. Possible areas to be regulated, include use in indoor public spaces; advertising and sale to minors; packaging and labelling of e-cigarettes and flavouring; child-proofing of e-liquid vials; and labels of unsubstantiated health benefits, potential harms and contents of vials. Further research is being conducted on the efficacy of these systems.

d) Lobby Groups and support services to promote legislation implementation and compliance

Various advocacy and lobby groups play a potentially important role in sensitizing businesses and the general public on the contents of the proposed Bill and its implications. This would enhance public acceptability and support of the proposed Bill.

Additional support services such as the smoking quit-line service may need to be adequately prepared for the potential upsurge of responses to the legislation. This with other behavioural support services may increase, once the legislation is in place.

e) The Public and Consumers as advocates for tobacco control and compliance with legislation

Public health initiatives are intended at maximising the good health of the public, i.e. reducing the potential for unintended harm and increasing the potential benefits to all. It is therefore important to incorporate public comments and concerns about the proposed legislation in order to gain acceptability. In addition, consumers and the general public can help monitor the levels of compliance of the various interventions. This will require the Government to ensure that there is adequate information about the legislation, its intentions and its requirements. Public health legislation relies on public support to be effective and is important for the TPC Bill.

4. Summary

4.1. Summary of the impact of the proposal on the main national priorities

TABLE 8	
Priority	Impact
Social cohesion	<ul style="list-style-type: none"> • Aligns the country’s tobacco control efforts with the WHO FCTC, while remaining constitutionally compliant; • Public support for this regulation will increase as citizens feel their right to health is being addressed, encouraging social cohesion; • Wide public support will lead to enforcement by citizens in compliance with the law, enhancing social cohesion;
Security (Safety, financial, food, energy etc.)	<ul style="list-style-type: none"> • Increased taxes on cigarettes over the years have made smoking an expensive habit, particularly for the poor. Among those who have been able to reduce their consumption their financial security has improved; • Reduced cigarette consumption indirectly contributes to better nutrition and education as income previously used for cigarettes is freed for other household uses such as food and education. • Reduction of health bill on government constrained fiscal environment

TABLE 8	
Priority	Impact
Economic growth and investment	<ul style="list-style-type: none"> • Reducing cigarette consumption will lead to reduced smoking-related morbidity and mortality, consequently contributing to higher productivity and economic growth. • Reduced smoking prevalence and cigarette consumption will redirect expenditure from cigarettes to other potentially more useful commodities and/or services.
Economic inclusion (employment creation and equality)	<ul style="list-style-type: none"> • Reduced smoking will likely have additional impacts in reducing the inequalities of the health burden across socioeconomic, gender and age categories. • Anticipated reductions in smoking-related illnesses will lead to healthier citizens more capable of engaging in viable economic activities. • Farmers currently engaged in tobacco leaf production will likely need to engage in alternative farming, which in the short-run may incur transition costs, but that may be more economically beneficial in the long-run.
Environmental sustainability	<ul style="list-style-type: none"> • Reduced consumption will decrease the likelihood of forest fires and other types of fires linked to cigarette use; • Reduced pollution can be expected from reductions in the number of cigarette butts. Cigarette butts are not bio-degradable and pose a health and environmental risk; <ul style="list-style-type: none"> Tobacco farming also depletes soil nutrients faster than food and other cash crops, thus requiring potentially environmentally unfriendly means of fertilizing existing land and or finding land for tobacco farming.

4.2. Identification of the social and economic groups that would **benefit most** and that would **bear the most cost**.

Main Beneficiaries
<p>Public</p> <p>Good health benefits</p> <p>Lower risk of ill health, healthy workforce and improved economy.</p>

Main Cost Bearers
<p>Manufacturers</p> <p>Initial packaging costs</p> <p>Hospitality / Retailers and Employers</p> <p>Development of no smoking signs and price lists for retailers</p> <p>Government</p> <p>Campaigns, quit-lines, support structures as part of relevant line function costs</p>

4.3. Summary and Conclusion

Continued and strengthened mass media communication and education and awareness campaigns, a national quit-line and support services for tobacco users to quit will mitigate risks and offer support to the public in general and enhance healthy lifestyle practices and well being.

	Reduce costs	Maximise benefits	Mitigate risks
100% Smoke free indoor public places	Reducing cleaning and ventilation costs in current smoking places	Cleaner air and increased smoke free space . Less complaints from non-smokers	<ul style="list-style-type: none"> • Economic growth from increased productivity from those who would have given up smoking and now have the money to spend on other products and services such as education. • Strengthen Border controls to prevent illicit trade (Plain Packaging). • Strengthen information, education and communication on the harms of tobacco use in the population
Display at point of Sale (POS)	Industry marketing and advertising costs reduced.	No attraction for users and non-users	
Plain / Standardized Packaging	Initial cost increase to industry for plain packaging, thereafter, Industry marketing and advertising costs reduced.	Greater awareness and publicity of health risks	
ENNDS/ENDS	Industry marketing and advertising costs reduced.	Minimise exposure to vapour No attraction for users and non users	

	Reduce costs	Maximise benefits	Mitigate risks
			<ul style="list-style-type: none"> Address litigation through Legal services

4.4. Identification of areas where additional research would improve understanding of the costs, benefits and/ or risks of the Bill

The use of combustible cigarettes be reviewed on a regular basis. However, aspects such as taxation and ENDS/ENNDS require more research to determine the impact it would have on reducing demand for the product, particularly among current smokers, and the likelihood of switching to them.

For the purpose of building SEIAS body of knowledge please complete the following:

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