POLICY VACUUM
A TOBACCO INDUSTRY FAIT ACCOMPLI?

NGPs and The Policy Dilemma in Pakistan

Waseem Iftikhar Janjua
Syed Ali Wasif Naqvi

SDPI
Sustainable Development Policy Institute

The Union
International Union Against Tuberculosis and Lung Disease
Health solutions for the poor
Contents

Acronyms .................................................................................................................................................. 3
About the Project ........................................................................................................................................ 5
NGPs and Policy Dilemma in Pakistan ........................................................................................................ 6
  Introduction ............................................................................................................................................... 6
  Understanding the NGPs .......................................................................................................................... 7
Policy Gaps and Vacuum in Pakistan ........................................................................................................ 9
Exploitation by the TI ................................................................................................................................ 10
Recommendations & Conclusion ............................................................................................................... 12
<table>
<thead>
<tr>
<th>Acronyms</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANDS: Alternative Nicotine Delivery Systems</td>
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<td>ENDS: Electronic Nicotine Delivery Systems</td>
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<td>ENNDS: Electronic Non-Nicotine Delivery systems</td>
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<td>FCTC: Framework Convention on Tobacco Control</td>
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<td>HnB: Heat no Burn.</td>
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<td>HTPs: Heated Tobacco Products.</td>
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<td>GoP: Government of Pakistan.</td>
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<td>LMICs: Low-and-Middle-Income Countries.</td>
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<td>MoNHSR&amp;C: Ministry of National Health Services Regulation and Coordination.</td>
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<td>MPOWER: (Six components of World Health Organization, these are the measures complementing Framework Convention on Tobacco Control). M refers to Monitoring the tobacco use and prevention policies pertaining to the tobacco usage, P is to ‘Protect’ the people from harmful tobacco smoke. Similarly, O refers to ‘Offering’ the help to quit smoking, Warning about the harmful dangers of the tobacco use is the next component. ‘E’ has been catered to ‘Enforce’ the ban on the tobacco advertising, including promotion and sponsorship of events etc. and finally ‘R’ refers to ‘Raising’ the taxes on all tobacco products.</td>
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<td>MRTPs: Modified Risk Tobacco Products.</td>
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<td>NGPs: Next Generation Products.</td>
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<td>PREPs: Potentially Reduced-Exposure Products</td>
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<td>SRO: Statutory Regulatory Order</td>
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<td>TCC: Tobacco Control Cell.</td>
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<td>TI: Tobacco Industry.</td>
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1 Currently five ANDS are available in the market gum, patch, nasal spray, oral inhaler, and sublingual tablets.
WHO: World Health Organization.
About the Project

Sustainable Development Policy Institute (SDPI), through Bloomberg Tobacco Control Initiative and in collaboration with The Union is conducting tobacco control project in Pakistan. The project objectivises to assist the Ministry of National Health in developing Pakistan’s strategic policy direction and guideline on GHW/PHW, Smokeless Tobacco Control (SLTC), and Next Generation Products (NGPs) including E-cigarettes, ENDS, ENNDS, ANDS and HnBs. The project also looks forward to collating the evidence on gaps in existing TC framework in line with MPWER commitments by Pakistan. Finally, the project will also facilitate the national and provincial governments in sustainable TC initiatives through system strengthening and capacity building of the stakeholders, in post-COVID-19 environment. This study develops an understanding of the rapidly expanding NGPs market and foresees it becoming out of control before a realization at the national policy level takes the charge. Foregoing in view, this study aspires to highlight the significance of the policy development on the tobacco products and makes policy recommendations for banning the NGPs in Pakistan. It is also an effort to strengthen the need for a multi-sectoral and comprehensive tobacco control regime and policies in Pakistan. The recommendations will be shared with the policy makers and legislative framework.
NGPs and Policy Dilemma in Pakistan

Introduction
Health systems around the globe are traditionally structured at national level and the policies disseminated to the lower tiers of governance. After the institution of the 18th Constitutional Amendment in Pakistan, multiple governance sectors, including health, were devolved to the provinces. However, many structural impediments continued to hinder the uninterrupted functioning at provincial level, not to mention issues causing inevitable temporary reversal to federal level (Khan et al. 2014). Nishtar (2011) has argued in favour of retaining health-related policy and governance issues at the national level. Tobacco control is a vital issue, notwithstanding the politics of tobacco, the policy needs to accrue from the Ministry of National Health Services Regulation and Coordination (MoNHSR&C) for further dissemination and implementation. Owing to structural inadequacies, devolution of power, political reluctance, and many other inhibitions, the tobacco control policies get delayed, and in most cases are absent, becoming a major driver of health inequalities. Tobacco Industry (TI) finds the appropriacy in policy vacuum and exploits these gaps very conveniently (Janjua and Naqvi 2020).

Tobacco continues to be the leading cause of preventable deaths and incurs enormous health burden on economies, especially in Low-and-Middle-Income-Countries (LMICs), which, Rezaei et al. (2016) contend, has been estimated to be as high as 15% of the health budget in some countries. The tobacco control policies rest on two significant pillars; first, preventing the initiation of smoking, and second, smoking cessation. The focus of national policies in Pakistan has been on the former, with minimal to no policies focusing on the latter. There is a constant struggle between the tobacco control regime on the one hand and tobacco industry exploiting all possible gaps on the other. Realizing the policy vacuum in the cessation domain, Tobacco Industry (TI) is seamlessly
indoctrinating the youth/smokers and is introducing Next Generation Products (NGPs) as a “alternative” or “harm reduction” aid making hefty profits at the cost of the health (Hatsukami and Carroll 2020).

The policy vacuum in NGPs is confounding those who are in genuine need of help to quit, as well as encouraging the TI to make rapid progress and profits in a short span of time. Foregoing, this study inquires the issues related to policy gaps, making recommendations to overcome the vacuum, emphasizing the need to promote proactive and protective regulation and legislation rather than curative and preventive policies.

**Understanding the NGPs**

The US Institute of Medicine referred to the products with reduction in exposure to one or more tobacco toxicants as “potentially reduced-exposure products” or PREPs (Stratton et al., 2001), which was replaced by the Food and Drugs Administration as the “modified risk-tobacco products (MRTPs). The Union (2020) has defined ENDS, HTPs, Novel, Alternative, Emerging and NGPs as the hybrid products that contain both tobacco and nicotine solutions, and their rapid emergence has blurred the difference among the tobacco products. For example, Electronic Nicotine Delivery Systems (ENDS) is the umbrella term used for the electronic smoking products and includes e-cigarettes, vapes, vape pens, etc. (Iftikhar and Naqvi, 2019-2020). ENDS are the devices that heat the liquid containing nicotine to create an inhalable aerosol. The products vary in shape, size, function, and price, ranging between low-cost disposable devices to large refillable tanks. E-Cigarettes also vary with regard to nicotine dosage, flavours, emissions, design, battery voltage, and unit circuitry (Margham et al. 2016; Talih et al. 2014). Additionally, the open systems in E-Cigarettes contain a refillable tank whereas the closed systems are
either disposable or a prefilled cartridges can be added to such devices (Chen et al. 2016). Juul, Vype and Blu are some of the examples.

Similarly, as per WHO (2020), the Heated Tobacco Products (HTPs) or Heat-no-Burn (HnB) products use a device to heat the tobacco and other chemicals to produce the aerosol. They have been available in the market since 1980. These are the specially designed cigarette-pods or plugs such as ‘heat sticks’ or ‘neo sticks’, which are designed to heat the tobacco to 250 to 300 degrees Celsius (compared to the conventional cigarette burning at 900 degrees), besides producing many toxicants (Bitzer et al. 2020). Lil Hybrid (Korean tobacco & Ginseng Corporation), Ploom Tech (Japan Tobacco International, and Glo iFuse (British American Tobacco) are some of the examples of these hybrid products. Similarly, Velo, Lyft, Dryft, Zyn, Paz, ZoneX, On!, Spirit, etc. are the chewable non-nicotine and nicotine pouches falling in the NGP categories. The container holds small bite-size pouches which can be placed in the mouth just like the snus or chewing tobacco.

As mentioned above, most of the LMICs continue to focus on the prevention of smoking initiation, albeit with little success. For example, in Pakistan, more than one thousand children between the ages from 6 to 15 years start smoking every day (Ahmed et al. 2008). Very little efforts are under way to help cessation, establishment of cessation helpline at the MoNHSR&C (TSFC, 2019), one such case in point. TI in Pakistan has a long history of identifying regulatory snags, distracting public attention away from core issues and profiting out of every opportunity.

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2Toxicants are produced in all combustible as well as non-combustible/chewing tobacco products.
Policy Gaps and Vacuum in Pakistan

Pakistan has been a signatory to the WHO Framework Convention on Tobacco Control FCTC for the past almost 17 years. The report by WHO claims that at least one of the MPOWER policies is preventing almost 5 billion. To meet the MPOWER policies Pakistan has comprehensive set of laws and regulations in place. However, enforcement has been a challenge in Pakistan (See, for example Janjua, 2019, Janjua and Naqvi, 2019, Janjua and Naqvi, 2020, Naqvi and Janjua, 2019, Iftikhar and Naqvi, 2019-2020). Moreover, almost all of the policies have exclusively focused on the combustible manufactured cigarettes. Smokeless tobacco products (such as naswar/snuss/Gutka etc.) and more prominently the NGPs have been completely absent from the policy. Local as well as global scholarships, and FCTC points to the need for enactment of regulatory actions controlling smokeless tobacco products (Khan et al. 2017; Siddiqi et al 2016; Savitz et al. 2006; Mehrotra et al. 2019). The first decision regarding the NGPs was taken by the conference of parties of the FCTC during 2018, which differentiated the cigarette sticks from the HnB/HTPs devices (Gruszczynski and Melillo2020). Literature pivots this distinction on the core concept of FCTC, which is the complete elimination of tobacco and smoking pandemic. HnBs and many other vaping products, smokeless tobacco products, etc. have since long been promoted by the TI as the MRTPs and PREPs which cause less harm – and therefore promoted to the customers as safer alternative, despite no clear scientific evidence to support these claims. Instead of saving the smokers from harmful effects and preventing the young children (and adults) from initiating smoking, these products continue to gain popularity as “recued risk products”. Moreover, as highlighted by Gruszczynski and Melillo (2020), dichotomy was created by the FCTC in defining waterpipes as well, in which the waterpipe per se has been referred to as “apparatus”, therefore delinking it from the tobacco products used in the waterpipe. This segregation provided the policy gap at the point of sale, where the apparatus could be
promoted and sold in flashy/golden colours and designs, while restrictions were to apply only on the tobacco products. Turkey has been applauded to became the first country whose labelling laws explicitly requires the health warning to be placed on the waterpipe, hookah bottles and waterpipes tobacco packages (See, for example, Lempert and Glantz, 2018; Jawad et al. 2015).

In Pakistan, the issue of policy vacuum and gaps (in existing policy) is complicating the situation and the preventive environment is becoming hazier because of the inclusion of “economic factor” in the NGPs. As per the 2021-22 budget announced by the Government of Pakistan, Federal Excise Duty (FED) has been enhanced from 65% to 100% for all imported tobacco products (Budget 2020-21, 2020). Ironically the E-Cigarettes/Vape products have been added to this list, making them legal to be imported. However, the legal Vendors’ license and other requirements are not very well pronounced nor being implemented. Consequently, a mushrooming of Vape Stores and Hubs in the twin cities of Rawalpindi and Islamabad, besides other provincial capitals and major towns, is a natural outcome.

**Exploitation by the TI**

The dwindling cigarettes sales across the globe and understanding of ill-effects of smoking exacerbating COVID-19 have caused serious drop in sales and profits (Münzel et al. 2020). Despite the known and scientifically proven health detriments, and no known benefits of the NGPs, TI has been running promotional events, campaigns, paid advertisements, and social media advocacies to attract youths, reassuring health benefits of these products during COVID-19 pandemic (Ramamurthi et al. 2020). The Bureau of Investigative Journalism in a study claimed that TI has specifically been targeting the youth (Chapman 2021a). Relatedly, the countries where the enforcement is weakest have been the easiest targets of TI, and the two countries topping the list in this regard are
Kenya and Pakistan (Davies and Chapman 2021). The advertisements on the social media, YouTube channels, Instagram and Facebook have received estimated $1 billion funding campaign to run the ads promoting British American Tobacco products Velo and Lyft (Davies and Chapman 2021).

It is important to note that with an ongoing project Tobacco Smoke Free Cities, the Ministry of National Health issued an SRO 72(1)/2020 on 30th Jan 2020, banning all online advertising of the tobacco products and point of sale advertising and display of the tobacco products (GoP, 2020). As per WHO (2017), almost all of the NGPs including E-cigarettes and nicotine pouches are extracted from tobacco and are injurious to lungs, dangerous to health and need to be regulated. Defying the SRO 72(1)/2020, and flouting the laws of the land, British American Tobacco Company is busy polluting the minds of the youth in Pakistan, being a soft, unmonitored and under-enforced tobacco market (Chapman, 2021a; Davies and Chapman 2021). To curb similar tactics, very recently USFDA ordered four major TI manufacturers to share their online/social media advertisement practices (Hunt 2021). British American Tobacco has been operating in Pakistan for decades and has been flouting the laws for an equal duration. Hiring of the social media influencers, producing scores of YouTube videos\(^3\), promoting their nicotine pouch products, and other NGPs, has facilitated flooding of the market due to youth attraction and affordability. Chapman (2021a) argues that the main aim of the campaign has been to present these products as “cool” and have been presented in “glossy youth focused advertising campaign”. Moreover, social media influencers have been paid heavily to promote these products on Instagram. Facebook and Instagram banned promoting NGPs (E-Cigarettes, nicotine pouches and HTPs/HnBs etc.), and weapons

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\(^3\) British American Tobacco also launched Velo Sound Station, promoting their product through the youth singing and enjoying Velo pouches, can be viewed at https://www.youtube.com/channel/UCj2pTe8EOi0zS-iNXkc-fKA.
through influencers since 2019 (Graham 2019). TI, however, continues to flout the international as well as local/national regulations in Pakistan.

TI is also sponsoring music and sports events, including F1 e-sports tournament that was streamed live on the YouTube and was easily accessible to the children to watch not to mention the youth (Chapman 2021a). The TI distributed international free samples of NGPs to the Pakistani youth and children, attracting smokers and non-smokers alike (Chapman 2021b).

International TI is generally targeted for flouting the domestic laws, as they generally do not make such ingresses in the Western and their home countries. However, the domestic tobacco industry is no less defiant of the laws. In one such widely covered event, at the height of the COVID-19, a local Senator manufactured cigarettes and labelled the product “Senate House”. The packings were designed without any GHW/PHW, (ironically) containing the “Government of Pakistan” emblem on the top and Senate House written below. The free samples were distributed among the members of parliament in the state lodges (Haider 2020). This act alone broke scores of domestic laws as well as international obligations – however the event went unnoticed as far as the regulatory and policy circles are concerned.

Such disturbing situation needs immediate and stern policy intervention, not only to control the spread of tobacco products, but also to limit and end the import and ingress of NGPs. Some recommendations are being made here for consideration by the stakeholders and policy circles, which will help Pakistan meet the national and international obligations in tobacco control regime.

Conclusion and Recommendations

As mentioned above, many tobacco control policies have been reactionary, and lack implementation. TI is taking full advantage of the situation and continues to make
ingresses, flout laws, and make violations with impunity. Although tobacco control has been progressing with enormous efforts from the MNHSR&C and civil society with support from international partners such as Bloomberg Philanthropies, The Union etc. there is a serious policy void as far as NGPs are concerned. TI continues to exploit the gaps in existing policies. For such an effort, tobacco control regime needs to support a broad-based multi-sectoral policy which could ensure regulation of all tobacco products, and possible banning of NGPs, putting an end to the rampant expansion and youth addiction. Following recommendations are, therefore, being made:

1. The final goal of the tobacco control efforts is complete ban on all tobacco products and NGPs, however, TI continues to exploit the gaps in existing policies and the policy vacuum. There is an urgent need to plug these gaps and develop a comprehensive multi-sectoral policy. NGPs need special focus in the policy to restrict and prohibit the rapid ingress in the society.

2. Youths and children have always been the focus of the TI promotion campaigns. To replace aging and dead customers, TI continues to tactfully recruit the youth, who would continue to buy the tobacco products for many decades from now. In Pakistan, there is an urgent need to start mass media and social media campaigns to discredit TI narratives and attractive campaigns. It is important for Pakistan to have the healthy youth to increase economic productivity, and this is possible by preventing youth from becoming easy prey to TI. Simultaneously, the TI continues to target the poor, uneducated and marginalized groups in rural areas through its traditional tobacco products. Its activities and promotional drives in rural and far-flung areas needs to be monitored as well.

3. NGPs also tend to be promoted by the TI as the replacement therapy. Nicotine craving is considered a critical factor in quitting, albeit with no clear scientific evidence (cf DiFranza and Wellman, 2005; Kozlowski and Wilkinson 1987).
However, these studies increasingly reported, the nicotine replacement users tend to become dual (tobacco as well as nicotine replacement) addicts (Czoli et al. 2017; Sweeney et al. 2001; Alberg et al. 2005). There is a requirement to keep this aspect in mind during admittance policy formulation.

4. TI has been innovative to add popular flavours in NGPs to make them more appealing for the youth and new starters (Hoffman et al. 2016). Flavours act as “silent aspect of tobacco marketing” (Camenga et al. 2018) motivating and promoting agents. Ban on flavours has been scientifically observed to have a positive impact on reduction in smoking (Courtemanche et al. 2017). This aspect needs special attention in the policy formulation process, as similar issues also existed, but ban (for example, on sheesha products) worked very well in the past. Pakistan must consider outrightly banning the NGPs from the market.

5. The permission to import cigars or other NGPs has economic implications and needs serious policy regulation beyond the import duty imposed by the government. TI and the importers have clearly demonstrated the import of tobacco products and other NGPs rampantly. As mentioned above, the enforcement is a weak link in tobacco control regime. There is an urgent need to strengthen the regulatory efforts targeting the import of all tobacco products and NGPs to prevent the youth addiction and rapid flooding of the market with these unregulated products.

6. Despite existing ban on advertising, British American Tobacco has been recruiting social media influencers and running YouTube channels to promote their products. Immediate and comprehensive ban is necessary to prevent promotion and marketing of NGPs, should we hope to prevent our youth from addiction to these products.
7. Article 12 of the FCTC necessitates public awareness and communication through multiple channels to educate the masses (WHO 2004). Policy formulation always focuses on promoting laws which have positive health outcomes. For example, in the Western countries, the stringent laws prevent the TI a freedom of operation as compared to the LMICs (Doku 2010). Policy formulation must focus on the domestic health and prioritize well-being. Although, the tobacco control laws exist, what is worrisome is the ingress of NGPs and the speed with which these have been promoted and marketed to the youth, necessitating an urgency in policy formulation. This paper has highlighted the issue of NGPs in the absence of regulatory policies and argued that these products continue to endanger the health of our youth through nicotine addiction. E-cigarettes and other NGPs attract the youth who may otherwise are not regular smokers. Singh et al. (2020) posited that between 2017 and 2018, past 30-day use of nicotine e-cigarettes among high school seniors nearly doubled, from 11% to 21%, which is the largest recorded increase for any adolescent use in more than four decades in the USA. No research has been done on this issue in Pakistan, however, the likely trend will be revealing for many health and tobacco policy advocates.
References


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