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The classification debate shapes policy, regulation, and public health approaches on THR Products

Tobacco Product

- Contains nicotine derived from tobacco
- Used for recreational purposes
- Marketing focuses on lifestyle choices
- Regulated under tobacco control frameworks
- Primary goal: Alternative to smoking

Medicinal Product

- Delivers controlled nicotine doses
- Used for smoking cessation
- Clinical evidence-based approach
- Regulated as pharmaceutical products
- Primary goal: Therapeutic treatment

Beware of the BIAS: Cultural, religious, professional...

Requirements of Regulation for THR Products

- THR (Risk-reduction) products subject to basic testings and responsible to agencies regulating labelling and advertising;
- Prior approval of the Risk-Reduction claim based on scientific evidence presented by the manufacturer that the claim is not false or misleading by regulating agency;
- THR (Risk-Reduction) products subjected to post-marketing epidemiological studies;
- Products continuously subject to current requirements of public health policies;
- Public health regulatory agencies should take steps to assure that consumers are informed about the meaning of statements regarding the contents of a THR (Risk-reduction) product



THR Regulatory Environment: Product Regulation

Nigeria	Kenya	Ghana
THR and RR products, are not effectively regulated in Nigeria. While Nigeria has signed the World Health Organization's Framework Convention on Tobacco Control (FCTC), which aims to reduce tobacco use, the country still lacks specific regulations and guidelines for these products. Currently, the regulation of tobacco harm reduction products in Nigeria is fragmented and unclear, with multiple government agencies involved, including: National Agency for Food and Drug Administration and Control (NAFDAC) Federal Ministry of Health Standards Organization of Nigeria (SON)	 Kenya has implemented a number of policies and regulations to reduce the harm of THR use, including: Tobacco Control Act 2007: This act requires graphic health warnings on e-cigarette packages and bans smoking in public places. Tobacco Control Regulations 2014: These regulations cover aspects such as THR and PREPs product packaging, smoke-free environments, and reducing tobacco industry interference. Tobacco Control Policy: This policy is aligned with the Constitution of Kenya and the Kenya Vision 2030. It also considers the harm PREPs use causes to individuals and society. 	National Tobacco Control Act 2012 disallows the smoking of both tobacco and THR/PREPs in public areas, among other measures. The Tobacco Control Regulations 2016 further established legal measures and restrictions regarding public smoking. Smoking in public places is prohibited and is a punishable offence.

THR Regulatory Environment: Product Classification

Nigeria	Kenya	Ghana
The Nigerian Tobacco Control Act does not effectively differentiate between combustible and non-combustible cigarettes. The current regulations in Nigeria focus on tobacco control in general, without specific provisions that distinguish between combustible and non-combustible products like e-cigarettes.	The Tobacco Control Statutes such as the Tobacco Control Act 2007 and Tobacco Control Regulations have made efforts at distinguishing Smoke and Smoke- free Tobacco products, Combustible and non-combustible tobacco products and cigarettes.	Ghana has made remarkable success in regulating the Manufacture, sales and use of combustible and non-combustible Tobacco products. The Food and Drugs Authority (FDA) has maintained that consumption of non-tobacco harm reducing products (PREPS) such as water pipe tobacco smoking, popularly known as'shisha', is illegal.

THR Regulatory Environment: Product Taxation & Pricing

Nigeria	Kenya	Ghana
The Nigerian government does not apply differential taxes to promote THR products over traditional cigarettes. Ideally, THR products considered health products are taxed like combustible cigarettes. In Nigeria, tobacco products are subject to various taxes, including import tariffs, VAT, excise duties, and other levies. The standard VAT rate in Nigeria is 7.5%. Excise duties on tobacco and alcoholic beverages have increased effective 1 June 2022. This leads to high cost of THR products and restricts availability	Regulatory policies including higher taxes on e-cigarettes, for example, produce significant reductions in smoking, especially among youth and lower-income individuals.	Ghana's THR products are taxed at an ad valorem rate of 175% of the Cost, Insurance, and Freight (CIF) value. This significantly increases the cost of these products, thereby making them less attractive to users.

THR Regulatory Environment: Product Access & Availability

Nigeria	Kenya	Ghana
THR and reduced-risk products are typically available through licensed retailers, and there could be age restrictions to prevent minors from purchasing them. However, there is uncontrolled sale and marketing of e-cigarettes and vaping products, resulting in inadequate surveillance and enforcement and unregulated quality and safety of products.	Kenya has also taken steps to reduce the availability of THR and PREPs products, by promoting Smoke-free workplace laws and banning smoking in public places and transport systems. There is also high clampdowns on illicit tobacco trade.	Ghana has also taken steps to reduce the availability of THR and PREPs, by promoting Smoke-free workplace laws and banning smoking in public places and transport systems. There is also high clampdowns on illicit tobacco trade.

THR Regulatory Environment: Product Affordability

Nigeria	Kenya	Ghana
E-cigarettes and vapes are indeed relatively expensive in Nigeria compared to traditional cigarettes. The prices of e-cigarettes and vaping products in Nigeria can be a significant barrier for smokers looking to switch to these less harmful alternatives. For instance, a 10 ml e-juice container costs \$10 (N3,600), while pod cartridges cost \$38 (N14,000). This cost disparity between e-cigarettes and traditional cigarettes, which are sold for \$1.25 (N450) on average, contributes to the continued popularity of smoking over vaping in Nigeria.	The cost of PREPs such as vapes and e-cigarettes is considered expensive comparative to the cost of tobacco products. This has to an extent made the affordability of these products unattractive. It is further considered as a status symbol, given the disparity in prices.	The cost of THR and PREPs such as vapes and e-cigarettes is considered expensive comparative to the cost of tobacco products. This has also made the affordability of these products unattractive.

THR Regulatory Environment: Product Education & Awareness

Nigeria	Kenya	Ghana
In Nigeria, there are low levels of awareness and education regarding non-combustible cigarettes, particularly among the youth and young adults.	Kenya has a complete ban policy on advertisement of combustible and non-combustible tobacco products. Unfortunately, kenya has made little in-roads into defining or prevention of use of PREPs, leading to an increased attraction and use of these productions in the notion that they are non-combustible, thus harmless.	Ghana has a complete ban policy on advertisement of non-combustible tobacco products. Though not fully implemented, the awareness on the negative consequences of PREPs and THR are continuously done through public enlightenment programs.

THR Regulatory Environment: Data, Research & Monitoring

Nigeria	Kenya	Ghana
There are low levels of research and monitoring of THR products. Surveillance systems may be required to enhance the monitoring of THR-product use trends.	There is a low level of research and monitoring of THR products, leading to poor enlightenment policies.	There is a low level of research and monitoring of THR products, leading to poor enlightenment policies.

THR Regulatory Environment: Product Advertising Regulation

Nigeria	Kenya	Ghana
The advertising regulations for THR products such as e-cigarettes, snus, and vapes in Nigeria are governed by the National Tobacco Control Act (NTCA) 2015, which prohibits tobacco advertising, promotion, and sponsorship, except for specific communication channels.	The law prohibits virtually all forms of advertising and promotion of tobacco products. As well as THR and PREPs. Although sponsorship by the tobacco industry is not completely prohibited, publicity of the sponsorship is prohibited.	The law prohibits virtually all forms of advertising and promotion of THR products. Although sponsorship by the tobacco industry is not completely prohibited, publicity of the sponsorship is prohibited.

THR Regulatory Environment: Enforcement

Nigeria	Kenya	Ghana
The lack of specific regulations for e-cigarettes allows the tobacco industry to freely market these products, potentially leading to unintended consequences due to their novelty, flavours, and addictive nicotine content.	Tobacco industry have increased the marketability of THR and PREPs and non-combustible tobacco products due to the sparse literature and laws that govern and regulate these products.	

Conclusion

The classification debate shapes policy, regulation, and public health approaches on THR Products

