" Investigating the Rise of E-cigarettes Across the World from A Regulatory Outlook "

PATEL KRIMA (20BPH056)

RUCHA JANI (20BPH086)

SHREYA RATHOD (20BPH092)

PATEL SHWET (20BPH096)

DHOTRE VISHVA (20BPH110)

BACHELOR OF PHARMACY

UNDER THE GUIDANCE OF

DR. MISARI PATEL

INSTITUTE OF PHARMACY

NIRMA UNIVERSITY

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BACHELOR OF PHARMACY

20BPH056 20BPH086

20BPH092 20BPH096

20BPH110

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"INVESTIGATING THE RISE Of E-CIGARETTES ACROSS THE WORLD FROM A REGULATORY OUTLOOK"

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BACHELOR OF PHARMACY

PATEL KRIMA (20BPH056)

JANI RUCHA (20BPH086)

RATHOD SHREYA (20BPH092)

PATEL SHWET (20BPH096)

DHOTRE VISHVA (20BPH110)

Semester VIII

(PROJECT WORK BP812PW)

UNDER THE GUIDANCE OF

DR. MISARI PATEL

INSTITUTE OF PHARMACY

NIRMA UNIVERSITY

May 2024

DECLARATION

We, **PATEL KRIMA (20BPH056), JANI RUCHA (20BPH086), RATHOD SHREYA (20BPH092), PATEL SHWET (20BPH096), DHOTRE VISHVA (20BPH110)** hereby declare that B.Pharm project work (BP812PW) entitled **"INVESTIGATING THE RISE OF E-CIGARETTES ACROSS THE WORLD FROM A REGULATORY OUTLOOK"** being submitted to Instituteof Pharmacy, Nirma University for the award of degree of B.Pharm was carried by us under the supervision of **Dr. MISARI PATEL** Institute of Pharmacy, Nirma University. The content of this project work, in full or in parts, have not been submitted to any other University for the award of any degree. We also declare that all the information was collected from various primary sources (journals, patents, etc.) has been duly acknowledged in this project report.

Patel Krima (20BPH056),
Jani Rucha (20BPH086),
Rathod Shreya (20BPH092)
Patel Shwet (20BPH096)
Dhotre Vishva (20BPH110)
Institute of Pharmacy,
Nirma University

Date: 14 / 05 / 2024

CERTIFICATE OF SIMILARITY OF WORK

This is to undertake that the B.Pharm. Project work (BP812PW) entitled **"INVESTIGATING THE RISE OF E-CIGARETTES ACROSS THE WORLD FROM A REGULATORY OUTLOOK"** Submitted by **PATEL KRIMA (20BPH056), JANI RUCHA (20BPH086), RATHOD SHREYA (20BPH092), PATEL SHWET (20BPH096), DHOTRE VISHVA (20BPH110),** B.Pharm. Semester VIII is a bonafide review/research work carried out by us at the Institute of Pharmacy,Nirma University under the guidance of **"Dr. MISARI PATEL"**. We are aware about the rules and regulations of the Plagiarism policy of Nirma University, Ahmedabad.

Patel Krima (20BPH056),
Jani Rucha (20BPH086),
Rathod Shreya (20BPH092)
Patel Shwet (20BPH096)
Dhotre Vishva (20BPH110)
Institute of Pharmacy,
Nirma University

14/5

Guide: Dr. MISARI PATEL
Assistant Professor,
Department of Pharmaceutical Analysis,
Institute of Pharmacy Nirma University

Date: 14 / 05 / **2024**

CERTIFICATE

This is to certify that B.Pharm Project Work (BP812PW) entitled **"INVESTIGATING THE RISE OF E-CIGARETTES ACROSS THE WORLD FROM A REGULATORY OUTLOOK"** being submitted by PATEL KRIMA (20BPH056), JANI RUCHA (20BPH086), RATHOD SHREYA (20BPH092), PATEL SHWET (20BPH096), VISHVA DHOTRE (20BPH110) for the award of degree in partial fulfilment of the requirements for the degree of Bachelor of Pharmacy under **Dr. Misari Patel's supervision to our full satisfaction**. The content of thesis in full or in parts,have not been submitted to any other University for the award of any degree.

Misari 14/5

Guide: Dr. MISARI PATEL
Assistant Professor,
Department of Pharmaceutical Analysis,
Institute of Pharmacy Nirma University

Date: 14 / 05 / **2024**

CERTIFICATE

This is to certify that B.Pharm Project Work (BP812PW) entitled **"INVESTIGATING THE RISE OF E-CIGARETTES ACROSS THE WORLD FROM A REGULATORY OUTLOOK"** being submitted by **PATEL KRIMA (20BPH056), JANI RUCHA (20BPH086), RATHOD SHREYA (20BPH092), PATEL SHWET (20BPH096), DHOTRE VISHVA (20BPH110),** to the Institute of Pharmacy, Nirma University for the award of degree in partial fulfilment of the requirements for the degree of Bachelor of Pharmacy under the supervision of (Dr. MISARI PATEL) to fullest satisfaction. The content of thesis in full or in parts, have not been submitted to any other University for the award of any degree.

14/05/24

Dr. GOPAL NATESAN
M.Pharm., Ph.D.,
Director
Institute of Pharmacy
Nirma University

Date: 14 / 05 / **2024**

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LIST OF ABBREVIATIONS

- ENDS- Electronic Nicotine Delivery System
- ASEAN- Association of Southeast Asian Nations
- FDA- Food and Drug Administration
- PMTA- Premarket Tobacco Product Application
- HPHC- Harmful and Potential Harmful Constituents
- NYTS- National Youth Tobacco Survey
- EU- European Union
- EMA- European Medicines Agency
- EEA- European Economic Area
- CDER - Centre for Drug Evaluation and Research
- MRTP- Modified-Risk Tobacco Product
- FDCA- Food, Drug, and Cosmetic Act
- UL- Underwriter Laboratories
- UN- United Nation
- CPSE- Consumer Product Safety Commission
- FCC- Federal Communications Commission
- RoHS- Restriction of (the use of certain) Hazardous Substances
- TGA- Therapeutic Goods Administration
- TGO- Therapeutic Goods Order
- ARTG- Australian Register of Therapeutic Goods
- SAS- Special Access Scheme
- APS- Authorized Prescriber Scheme
- PECA- Prohibition of Electronic Cigarettes Act
- WHO- World Health Organization
- FCTC- Framework Convention on Tobacco Control

ABSTRACT

E-cigarettes, frequently referred to as vapes, have become increasingly popular among younger audiences, partly because of the wide variety of flavors they provide. Although they were initially intended to be a healthier replacement to traditional tobacco cigarettes, their growing acceptance has caused a number of social and health problems for users. As an outcome, several nations have implemented regulations into effect to address these issues. Originally designed as a substitute for traditional smoking, e-cigarettes are appealing due to their broad range of flavours, attracting a significant number of buyers from youngsters. But this rise in popularity hasn't come without consequences; users have experienced a number of social and physical difficulties as a result. Consequently, governments all over the world have taken measures to control the use of e-cigarettes This review sheds light on the different strategies adopted by regulatory bodies through investigating the intricate regulatory environment surrounding e-cigarettes in various countries. The need for regulatory action to decrease the risks associated with e-cigarettes increased along with their demand. Government agencies have responded to this by introducing regulations meant to reduce their use, especially among vulnerable groups like children. Several countries have established strict policies with the goal of regulating the promotion, sale, and use of electronic cigarettes, recognizing the urgency to tackle the growing public health issues associated with them. These rules cover a broad spectrum of topics, such as limitations on advertising, age verification procedures, and flavour restrictions. These steps are meant to protect the general public's health and lessen the adverse consequences of e-cigarette use. In addition, the regulatory framework keeps changing as a result of new information coming to the forefront and changing social perceptions of e-cigarettes. The constant communication between public health professionals, regulatory bodies, and interested parties emphasises how dynamic the regulation of e-cigarettes is. Governments work to achieve a balance in the vaping industry within consumer preference and public health demands by continuously reviewing and improving these regulations.

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CHAPTER-1 INTRODUCTION

Electronic Nicotine Delivery System (ENDS) represents quickly evolving category of tobacco products that go by various names, such as tank systems, vapes, mods, e-cigarettes, and e-cigs.

They may be designed to resemble traditional pipes, cigars, or cigarettes that burn.

A few of these devices look similar to pens or flash disks from USB while larger devices, such as tank systems or mods, bear little or no resemblance to cigarettes.

These devices can be disposable, meaning they are used just once before being thrown away, or they can be reusable.

Figure 1: Different types of vapes

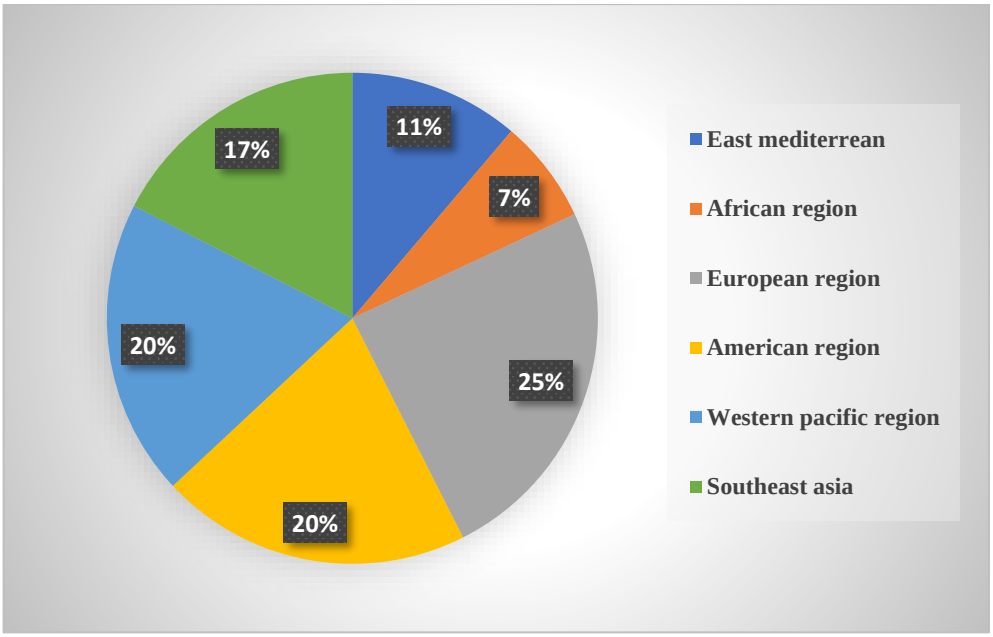

Figure 2: Estimate of vapers worldwide in 2021

The above graph depicts the number of vapers in different continents in the year 2021.

As consumer items, medical devices, tobacco products, poison, or as e-cigarettes/ENDS themselves, e-cigarettes were subject to regulations. Manufacturing, distribution, importation, sale, promotion, health warnings, and other related activities were all included in the extensive scope of the regulations.

About twenty-five countries forbade the selling of electronic cigarettes, and four of those were members of the Association of Southeast Asian Nations (ASEAN).

The ASEAN is made up of ten countries in Southeast Asia: Vietnam, Singapore, Thailand, Laos, Malaysia, Myanmar, Philippines, Cambodia, Indonesia and Bhutan. Ten percent of the world's smokers reside in this region, which makes it of special study interest to us. In addition, the ten countries' collective tobacco control efforts, despite their diverse cultural and socioeconomic backgrounds, are remarkable.(*Usa*, n.d.)

1.1 VAPE: AN EFFECTIVE ALTERNATIVE?

To help individuals quit smoking and provide an alternative method of delivering nicotine, The "e-cig," or electronic cigarette, was first patented in 2003.

Since their release, e-cigarette use has increased significantly, mainly in North America. Over the past 20 years, e-cigarettes have grown in popularity while the number of Americans who smoke tobacco cigarettes has continued to decline. In the United States, tobacco cigarettes were smoked by 25.9% of men and 22.1% of women aged 18 years or older in 1998. By 2017, that number had dropped to 16% of men and 12.3% of women. At the moment, there is no data known to us that suggests whether this drop in numbers is due to E-cigarettes or whether the subjects have actually quit smoking.

Although e-cigarette vapor is said to produce a less toxic aerosol cloud than traditional tobacco smoke, it still contains toxins from nicotine, additional flavorings, and metallic contaminants.

The FDA believed that by permitting e-cigarettes, adult addicts would be forced to use them, which would lower the number of traditional cigarettes consumed.

Although there are many claims regarding how well e-cigarettes work to help people who are addicted quit smoking, the devices themselves can lead to addiction. The amount of nicotine in e-cigarettes is still strong enough to cause addiction and nicotine intoxication, despite the makers' claims that their products contain less nicotine than traditional cigarettes.

Since they do not inhale cigarette smoke after they stop smoking, people who are addicted to nicotine still experience the same effects or even worsening of their addiction.

Table 1: E-cigarettes authorized by FDA as of Jan 2024

MANUFACTURE	PRODUCT NAME
RJ Reynolds Vapor Company	Vuse Solo Power Unit
	Vuse Ciro Cartridge Original 1.5%
	Vuse Ciro Power Unit (1)
	Vuse Ciro Power Unit (2)
	Vuse Replacement Cartridge Original 4.8% G1
	Vuse Replacement Cartridge Original 4.8% G2
	Vuse Vibe Tank Original 3.0%
	Vuse Vibe Power Unit (1)
	Vuse Vibe Power Unit (2)
Logic Technology Development LLC	Logic Pro Capsule Tank System (1)
	Logic Pro Capsule Tank System (2)
	Logic Power Tobacco e-Liquid Package
	Logic Regular Cartridge/Capsule Package
	Logic Power Rechargeable Kit

	Logic Vapeleaf Cartridge/Capsule Package
	Logic Pro Tobacco e-Liquid Package
	Logic Vapeleaf Tobacco Vapor System
NJOY LLC	NJOY ACE POD Classic Tobacco 2.4%
	NJOY ACE POD Classic Tobacco 5%
	NJOY ACE POD Rich Tobacco 5%
	NJOY DAILY Rich Tobacco 4.5%
	NJOY DAILY EXTRA Rich Tobacco 6%
	NJOY DAILY Rich Tobacco 4.5%
	NJOY DAILY EXTRA Rich Tobacco 6%

1.2 CHEMICAL CONSTITUENTS

Studies have indicated that e-cigarettes labelled as nicotine-free still contain small amounts of nicotine. In addition, as the e-liquid heats up, more dangerous compounds are produced. Since the Food and Drug Administration (FDA) has not established any standards for the products or begun to review any of the ingredients, e-cigarette contents and effects vary.

Table2: Chemical constituents of e-cigarettes

NICOTINE	A highly addictive drug that impairs the development of the adolescent brain
PROPYLENE GLYCOL	A typical food additive that is also used to create paint thinner, antifreeze, and artificial smoke for fog machines.
CARCINOGENS	Substances like formaldehyde and acetaldehyde that are known to cause cancer
ACROLEIN	The herbicide acrolein, is mainly used to eradicate weeds results in permanent lung damage.
DIACETYL	A chemical that causes bronchiolitis obliterans, also known as "popcorn lung".
DIETHYLENE GLYCOL	A hazardous chemical found in antifreeze that is connected to lung disease
HEAVY METALS	Heavy metals, including Lead, Tin, and Nickel

CADMIUM	A hazardous metal present in regular cigarettes that can lead to illness and breathing problems
BENZENE	A volatile organic compound (VOC) present in vehicle exhaust is benzene.
ULTRAFINE PARTICLES	Ultrafine particles can be inhaled deep into the lungs

1.3 WORKING OF E-CIGARETTES

E-cigarettes usually comprises of 4 primary elements:

Figure 3: Flowchart showing different parts of e-cigarettes

The battery-operated heating element of the e-cigarette activates when the user takes a puff. The e-liquid stored within the cartridge is then heated as a result, turning it into an aerosol or vapor. The desired flavor and nicotine delivery are then inhaled by the user through the mouthpiece, free of the combustion and smoke associated with conventional tobacco products.

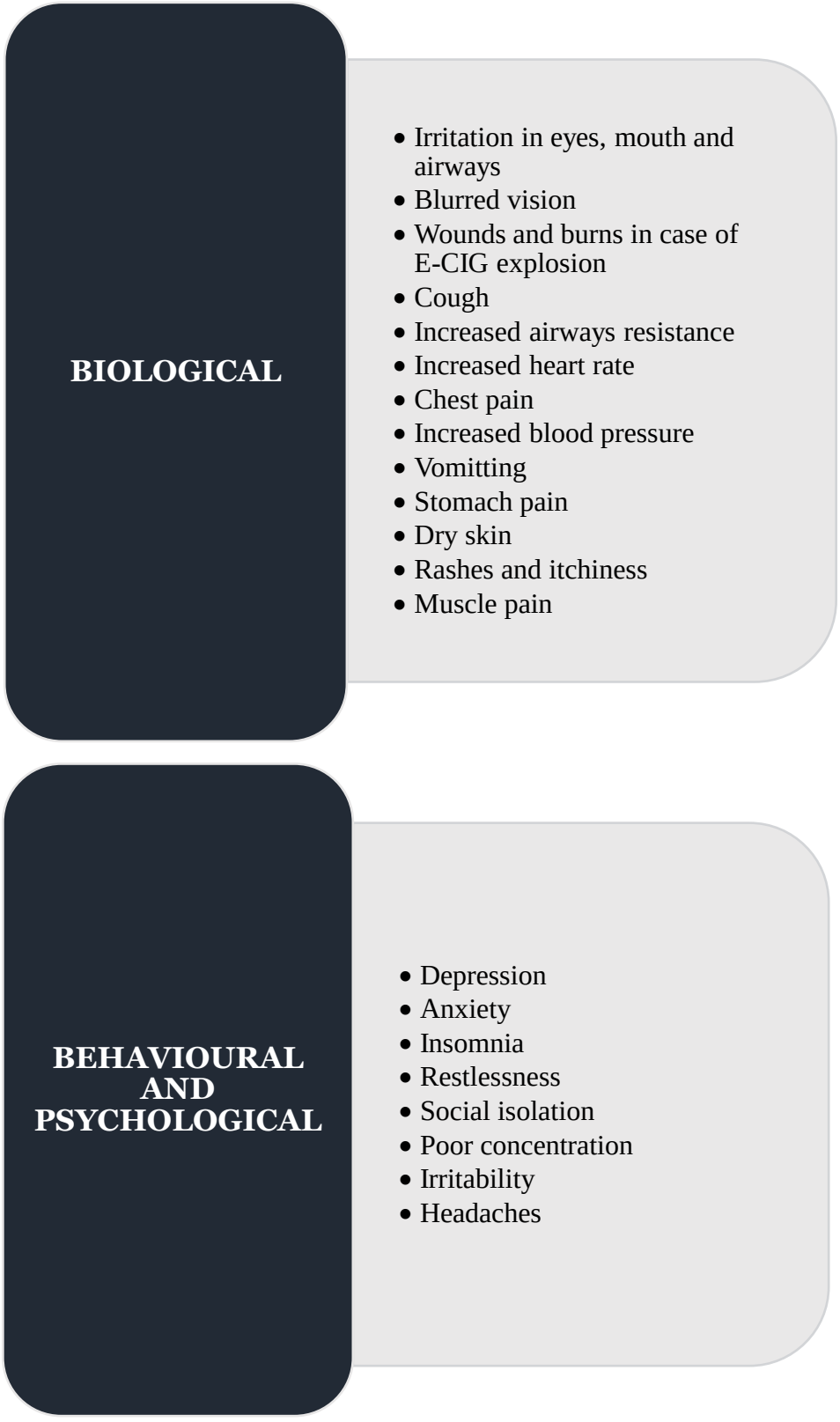

Figure 4: Flowchart showing different side effects of vapes

1.4 FDA's FIRST VAPE AUTHORIZATION [A CASE STUDY]

The FDA granted marketing authorizations for the first time for R.J. Reynolds Vapour Company's e-cigarette product, Vuse, on October 12, 2021.

Data from the Premarket Tobacco Product Application (PMTA) submitted by RRJ Reynolds Vapour Company showed that the tobacco-flavoured products it offers could help current smokers reduce or stop smoking completely.Participants in the manufacturer's study were exposed to fewer unpleasant and potentially hazardous constituents (HPHCs) from the aerosols in the Vuse Solo product than those who smoked regular cigarettes. Compared to regular cigarettes, the aerosols of the e cigarettes contained notably less harmful substances, according to a toxicology report.

Vuse is the brand that almost 10% of Students in high school who use e-cigarettes claimed that theyalways use, based on the 2021 National Youth Tobacco Survey (NYTS) in the US. Based on this data, the FDA acknowledged thatthe youthis more prone to make use of non-tobacco flavorede cigarette products and are less likely to use tobacco flavoured ENDS products before changing to traditional cigarettes. Young people are more inclined to use fruit, candy, or mint-flavoured ENDS products than tobacco-flavoured ones, according to the NYTS survey data, which suggests that their risk of shifting to traditional cigarettes is low. Since the authorised items flavoured with tobacco will have a decreased appeal to childrenand and be more advantageous for adults who have previously smoked conventional cigarettes,this data supported the FDA's decision to approve Vuse marketing.

The FDA rejected Reynolds' requests on October 12, 2023, to permanently remove its best-selling menthol products from the market. The FDA pointed out Reynolds' failure to comply with federal regulations requiring e-cigarettes to offer a greater health benefit than a risk. The FDA stated that in the case of the Vuse vapes, the potential for helping traditional smokers stop outweighed the risks of attracting young people to the popular menthol and flavoured products.

Products flavoured with tobacco by the company are not covered by the ruling.

A recent study of children studying in middle and high school revealed that Vuse vapes were a popular choice among those who used e-cigarettes. Antismoking

groups and others have urged the FDA to more strictly regulate the e-cigarette market

CHAPTER-2 LITERATURE REVIEW

2.1 EUROPEAN MEDICINES AGENCY [EMA]

Within the European Union (EU), the European Medicines Agency (EMA) is a decentralized organization that is in charge of overseeing, monitoring, and evaluating medical products from a scientific standpoint. Since its founding in 1995, the European Medicines Agency (EMA) has worked to ensure that medicines meet the safety, efficacy, and quality requirements necessary to meet the healthcare needs of the approximately 450 million people who live in EU member states and the European Economic Area (EEA). The EMA was given the fundamental responsibility of making sure that all medications that are sold on the market adhere to strict scientific standards ever since its founding. This entails supervising their advancement, evaluating their security and effectiveness, and tracking their effectiveness after approval. By doing this, the EMA greatly enhances public health protection and millions of people's well-being.(Tarasenko, elena et al)

2.1.1 Criteria for quality and safety:

- Regarding the volume and quantity of nicotine allowed in e-cigarette cartridges, tanks, and nicotine liquid containers, the EU Directive lays out precise requirements. These rules place restrictions on the amount of nicotine that can be found in order to protect users. Moreover, tamper-evident, child-resistant, and having a refill mechanism that stops spills are just a few of the safety features that e-cigarettes must have.
- Apart from safety features, e-cigarettes need to meet certain regulations about the purity of substances used in manufacturing. By using only premium ingredients, this guarantees the overall safety and effectiveness of these products. Furthermore, the directive stresses uniformity in the delivery of nicotine, specifying that every kind of e-cigarette shall deliver the same quantity of nicotine when used for the same(*Tobacco_infograph2_en*, n.d.)

2.1.2 Criteria for Packaging and Labelling:

E-cigarettes must have health warnings on them to alert the users about the fact that they contain nicotine and are not recommended for use by non-smokers. A list of the product's ingredients, details on how much nicotine is in it, and a leaflet outlining usage guidelines as well as details on potential risks, adverse effects, toxicity, and addictiveness must all be included in the packaging. It is prohibited to include promotional elements on e-cigarette packaging, and it is also unlawful to advertise and promote e-cigarettes internationally.

2.1.3 Implementing Legislation:

- In support of Article 20 of the Directive, the European Commission has sanctioned two implementing acts and commissioned a study focused on e-cigarettes. These initiatives are designed to bolster regulatory oversight and ensure compliance with prescribed guidelines within the electronic cigarette industry.
- The Commission Implementing Decision (EU) 2015/2183, ratified on November 24, 2015, plays a pivotal role in this endeavor. This decision establishes a standardized notification format for refillable containers and electronic cigarettes. By introducing a uniform format, this decision aims to promote consistency and clarity in regulatory submissions, thereby simplifying the notification process for manufacturers and importers.
- Furthermore, the Commission Implementing Decision (EU) 2016/586, dated April 14, 2016, delineates technical specifications for the refill mechanism of electronic cigarettes. This decision outlines specific requirements and standards pertaining to the design and functionality of refill mechanisms. By setting forth clear guidelines, this decision aims to enhance user safety and mitigate potential risks associated with refilling electronic cigarettes.
- Overall, these implementing acts, along with the commissioned study, represent concerted efforts by the European Commission to reinforce regulatory oversight and ensure adherence to established protocols within the e-cigarette sector. Through these measures, the Commission endeavors to promote consumer safety and uphold the integrity of the electronic cigarette market within the European Union.(Saitta et al., 2014)

2.1.4 Product Regulation:

The Directive sets rules for the manufacture, marking, and sale of tobacco products and related items. These consist of rolling your own tobacco, pipe tobacco, electronic cigarettes, smokeless tobacco, cigars, cigarillos, and herbal smoking items.
Specifically, the directive:

- Prohibits the use of roll-your-own tobacco products and cigarettes with unique flavors.
- Requires reporting from the tobacco industry to the EU about the ingredients in tobacco products.
- Bans the use of tobacco products and related goods without providing health advice. Health warnings (text, image, and information on quitting) must cover 65% of the front and back of packaging for cigarettes and roll-your-own tobacco.
- Restricts the size of some tobacco products' packaging and establishes minimum requirements for warnings.
- Bans fraudulent and promotional content on e-cigarettes, herbal products, and tobacco products.
- Launches tracking and tracing across the EU to fight the illegal tobacco product trade.
- Permits EU nations to forbid the online selling of tobacco and associated goods.
- Specifies requirements for electronic cigarettes in terms of safety, quality, and notification.
- Requires manufacturers and importers to notify member states of any new tobacco products they plan to release for sale.(O'Leary,Renée et al)

2.2 FOOD AND DRUG ADMINISTRATION (USA)

The Food and Drug Administration is responsible for ensuring the safety, efficacy, and security of biological products, medical devices, and pharmaceuticals for humans and animals in order to protect the public's health.
It additionally ensures that the nation's radiation-emitting items, cosmetics, and food supplies are all safe. To protect the general public's health and avoid tobacco usage in the youth, FDA also regulates the manufacturing, advertising, and retailing of tobacco goods.

ENDS products have been available for sale for some time, but FDA could not regulate them until August 2016, when the "Deeming Rule" came into force. This rule gave FDA regulatory authority over all ENDS, including cigars, e-cigarettes, roll-your-own tobacco, hookah (waterpipe) tobacco, pipe tobacco, smokeless tobacco, and nicotine gels.

The FDA is in charge of this regulation under the Family Smoking Prevention and Tobacco Control Act of 2009.
The FDA controls the production, importation, labelling, packaging, sale, distribution, advertising, and promotion of ENDS and their constituent parts. This includes cartridges, flavors, specific batteries, e-liquid vials, software, and even e-liquids. The FDA does not control ENDS accessories like vape cases or chains.

The legal age to purchase tobacco products is 21 years according to the law. this law came into force on 20th December 2019. Retailers are not allowed to offer any tobacco product, including cigarettes and ENDS, to customers under 21 years. There are no exceptions to the law; it applies to all stores and retailers.(Litt, Mark D et al)

2.2.1 The Real Cost Campaign:

The Real Cost campaign is an FDA-awarded public education program that prevents youth from starting and maintaining the use of tobacco products. The purpose of these campaigns is to raise awareness among youth about the dangers and negative impacts of smoking and vaping on their health.

The "The Real Cost" campaign aims to reach youth by using a combination of marketing and advertising strategies through teen-relevant communication channels. It was developed based on thorough studies.

2.2.2 For Manufacturer:

The FDA controls the production, import, labelling, packaging, sale, distribution, advertising, and promotion of ENDS, including their parts and components but not their accessories.

ENDS parts and components that are subject to regulation includes:

- E-liquids
- Flavorings for ENDS
- A glass or plastic vial container of e-liquid
- Programmable software
- Digital display or lights to adjust settings
- Cartridges
- Atomizer
- Tank systems
- Mouthpieces
- Certain batteries

FDA's Centre for Drug Evaluation and Research (CDER) supervises products marketed for therapeutic purposes or to help in quitting smoking. The FDA released a rule that explains which products are classified as drugs, devices, or tobacco products depending on how they are made or derived from tobacco.

How to comply FDA’s tobacco regulations:

- Register the company and send in a list of goods, product labels, and ads.
- Provide data and pay the user fees.
- Provide a list of ingredients.
- Choose one of the three paths to apply for the promotion of an innovative tobacco product.

- Provide in quantities containing dangerous and possibly dangerous ingredients.
- Provide tobacco-related health records.
- Provide a warning strategy for smokeless tobacco and cigars.
- Ensure that advertisements and packages have the necessary warning statements.
- Apply for a modified-risk tobacco product (MRTP).

2.2.3 For Retailers:

A voluntary education program called "This is our watch" provides tobacco retailers with tools to help them better comprehend and abide by FDA tobacco regulations.(U.S. E-Cigarette Regulation: A 50-State Review, n.d.)

Rules for sales of ENDS:

- Whenever someone under the age of 27 tries to purchase e-liquids, e-cigarettes, or other ENDS,a picture ID must be checked.
- Sell e-liquids, e-cigarettes, and other ENDS products only to clients who are at least 21 years old.
- If you are not in a place limited to adults, and don't sell e-cigarettes, e-liquids, or other ENDS through vending machines.
- It is NOT acceptable to provide free samples of e-cigarettes, e-liquids, or other ENDS to customers, along with any of their parts or components.
- It is strictly prohibited to market or provide e-cigarettes, e-liquids, or any other ENDS for which the container does not bear a health warning notice.
- Promotion for e-liquids, e-cigarettes, or other ENDS should not be displayed without a health warning.(Gades, Mari S et al)

2.2.4 Getting Around American Laws Regarding E-Liquid and E-Cigarettes:

There are several rules and specifications that must be followed when importing, producing, and selling electronic cigarettes and liquid in the US. “The Food, Drug, and Cosmetic Act” (FDCA), “UL Standards”, labelling specifications, paperwork, and other topics are all covered in this guide.

- **Mentioned Products:**
  - Refillable e-liquid tanks
  - E-cigarette pens
  - Rechargeable e pipes
  - Reusable e pipes
  - Vaporizers

2.2.5 Food, Drug, And Cosmetic Act (FDCA)

- Quantities of harmful and potentially harmful constituents’ submission: It is mandatory for domestic producers, importers, and distributors to use the FDA web portal to report any harmful ingredients found in e-cigarettes.

  The submission must be completed six months in advance of the final guidance's estimated publication date, or nine months in the case of small manufacturers.(Ryan David Kennedy, Ayodeji Awopegba)
- The Food, Drug, and Cosmetic Act (FDCA) laws are strictly enforced by the FDA to guarantee the safety of Electronic Nicotine Delivery System (ENDS) goods, such as E-cigarettes and E-liquids. Ensuring the protection of the public's health from possible dangers connected with these items requires a strong commitment to enforcement.
- Warning Statements: During the electronic submission procedure, one must additionally provide warning plans that have been authorized by the FDA or other warning plans for approval.
- Examples of FDA-approved warnings are as follows:
  - “WARNING”: This product may cause mouth cancer.
  - “WARNING”:This product is not a safe substitute for cigarettes

- "WARNING": Tooth loss and gum disease may result from using this product.

- The FDA also sets restrictions on the font, text, size, placement, and formatting.

2.2.6 Child Nicotine Poisoning Prevention Act

- "The Child Nicotine Poisoning Prevention Act" is enforced by the CPSC because of the toxicity of nicotine and the possible negative effects it may have on children. Its goal is to avoid unintentional child poisoning by regulating the packaging of nicotine containers.

- The statute mandates that liquid nicotine containers have a label that says "child-resistant packaging" on them. Any cautions regarding nicotine exposure must also be included on the box.

- Except for liquid nicotine containers, the Act states that neither other tobacco products nor substitute e-cigarette devices are subject to its regulatory authority.(Sunday Azagba, Lingpeng Shan)

2.2.7 Underwriter Laboratories (UL)

- UL established UL 8139 as a voluntary standard to address the risks associated with lithium batteries in e-cigarettes. UL 8139 covers the battery, charging, heating, and electrical systems of electronic cigarettes.
- It can be used as a guide by importers and manufacturers to guarantee product safety during the design phase. Note that the UL 8139 does not cover e-liquid.
- The following is covered by the standard:
    - Mechanical stress testing
    - Environmental Resilience
    - Accidental activation
    - Battery management system evaluation
    - Compatibility with interconnected systems

- For manufacturers and importers, the test is an essential tool that helps them avoid any risks associated with lithium batteries in advance. They may successfully reduce the possibility of catastrophic damages and guarantee the safe handling and delivery of their products by carrying out these tests with diligence, protecting both customers and the environment.(F. Andersson, P. Karlson)

States	State Law Definition	Product Packaging	Youth Access/Other Retail Restrictions	Retail License or Permit Required	Smoke-Free Restrictions
California	Yes.	Cartridges and refill solutions for e-cigarettes need to be marketed in packaging that is childproof.	It is illegal to sell electronic cigarettes to anyone younger than 21 (active-duty military members must be at least 18 years old).	Yes.	Electronic cigarettes are illegal in any location where smoking is prohibited, including workplaces, family day care institutions, and foster and group homes.
New York	No	Liquid nicotine must be sold in a child-resistant bottle.	The Sale/distribution of e-cigarettes or liquid nicotine to persons under age 18 is prohibited.	No	E-cigarette use is restricted similar to smoking on Niagara Frontier Transportation Authority property.
New Jersey	No	Sales of liquid nicotine must occur in child-resistant packaging.	The sale or distribution of electronic smoking devices to those under the age of 21 is illegal.	No	The use of electronic smoking devices is included in the definition of "smoking" and is forbidden in the same environments, such as indoor public places, businesses, and schools.
Florida	No	N/A	The sale and distribution of nicotine dispensing devices or nicotine	No	It is forbidden to use nicotine-dispensing devices or electronic cigarettes in Sixth Judicial

			products to those under the age of 18 is illegal.		Circle courthouses or within 50 feet of their entrances.
Wyoming	Yes.	It is required that liquid nicotine be sold in child-resistant bottles.	It is illegal to sell or distribute liquid nicotine or e-cigarettes to anyone less than 18 years old.	No	E-cigarette usage is forbidden on Niagara Border Transportation Authority property in the same way that smoking is.
Texas	No	If liquid nicotine is offered as an e-cigarette accessory and is not intended for customer opening, it must be sold in a child-resistant container that has been prefilled and sealed by the producer.	E-cigarette sales and distribution to those younger than 18 are restricted.	No	E-cigarette usage is restricted in specific locations like hospitals, schools, elevators, libraries, museums, and on some buses, airplanes, and trains.

Figure 5: Restrictions in different states

2.2.8 Other Regulations:

- **UN 38.3:** Lithium batteries are found in most e-cigarettes. You have to adhere to UN 38.3 requirements before sending your lithium battery product to the United States. These requirements include,
    - "UN 3090": Lithium metal batteries
    - "UN 3480": Lithium-ion batteries
    - "UN 3091": Lithium metal batteries contained, or packed with equipment
    - "UN 3481": Lithium-ion batteries contained, or packed with equipment

  There are two options available to you in order to guarantee compliance: either obtain a UN 38.3 test report from your supplier, or arrange for independent laboratory testing via respectable organizations such as SGS, TUV, or Intertek. If you skip this important step, your freight forwarder may reject your shipment for safety reasons, which might result in setbacks, financial consequences, and damage to your image. It is critical to stress that following safety procedures and legal requirements is essential to protecting both the well-being of customers and your company.(F. Andersson, P. Karlson)
- **CPSC Battery Standards:** The Consumer Product Safety Commission (CPSC) advises that your battery product follow applicable requirements to avoid potential dangers like electrical shock, fire shock, or overheating that are connected to lithium batteries. Among these criteria include,
    - UL 1642 – Standard for Safety for Lithium Batteries
    - ANSI/NEMA C18 – Safety Standards for Primary, Secondary and Lithium Batteries.(Richtel)
- **FCC Part 15:** "FCC Part 15", which regulates interference in the frequency spectrum and telecommunications infrastructure, may apply to e-cigarettes that generate radio waves or operate at frequencies of 9 kHz or above.
- **RoHS:** Lead, mercury, nickel, and cadmium are just a few of the heavy metals that are regulated by the RoHS regulation, which restricts the use of certain materials in electronic equipment. This rule forbids the importation of e-cigarettes that contain certain compounds in amounts that are forbidden.(Mikolajczak, M. White)
- **Country of Origin:** For e-cigarettes imported into the United States, the country-of-origin label must be present. As a result, you must permanently and prominently label the product's and its packaging's country of origin.these are a few instances,

- Constructed in the USA
- Crafted in China(Ryan David Kennedy, Ayodeji Awopegba)

2.3 THERAPEUTIC GOOD ADMINISTRATION [TGA]

Within the Department of Health, the Therapeutic Goods Administration (TGA) is a crucial regulatory body that oversees the administration of therapeutic goods in Australia. With a broad range of duties, the TGA carefully oversees and controls every aspect of the lifecycle of pharmaceuticals, including the processes involved in manufacturing, distribution, import, export, and production. This oversight guarantees the protection and improvement of public health across the country and is not only thorough but also timely and efficient in its execution. The TGA is essential to guarantee the efficacy, safety, and quality of therapeutic goods available to the Australian public because of its strict regulations and evaluation processes. By adhering to these guidelines, the TGA carries out its responsibility to safeguard people's welfarewhile encouraging community-based improvements in healthcare.(Therapeutic Goods Administration, 2021)

Guidance for the Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 and related matters

2.3.1 TGO 110 Product Standard:

Approved by Section 10 of the Therapeutic Goods Act 1989, the Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021, or TGO 110, was created. The Australian Register of Therapeutic Goods (ARTG) does not list vaping products that contain nicotine, but they are distributed, imported, or exported from Australia. This regulatory framework lays out the necessary requirements guaranteeing the quality and safety of these products. TGO 110 is a critical step in creating baseline standards that cover things like production procedures, ingredient quality, labelling specifications, and packaging guidelines in order to protect consumers from the health hazards that unregistered nicotine vaping products may pose. Regulation TGO 110 expands regulatory supervision to include goods that aren't registered with the ARTG,promoting consumer confidence in the vaping industry and improving public health protection. The regulatory authorities' proactive approach towards addressing new health concerns and ensuring responsible marketing and distribution of nicotine vaping products in Australia is reflected in this order.

Objectives of TGO 110:

- Provide accurate information about the contents of the unregistered nicotine vaping product that the person is inhaling to consumers and health professionals.
- Reduce the potential hazards of inadvertently coming into contact with and/or consuming nicotine vaping products, especially for kids, as these incidents can have fatal consequences.(al)

Nicotine vaping products captured by TGO 110:

- TGO 110's regulations exclusively cover unregistered vaping products that are supplied, imported, or exported from Australia.
- Products obtained from Australia through the Special Access Scheme (SAS) or Authorized Prescriber Scheme (APS).
- Extemporaneously compounded product
- Products supplied as part of a clinical trial

- **TGO 110 does not apply to:**

- Any vaping products containing nicotine that may be registered in the ARTG in the future.
- Vaping products are brought into Australia by tourists using the Traveler's Exemption or by visiting medical teams who are accompanying a patient with a life-threatening illness.
- Nicotine replacement therapies that do not fall under the Schedule 4 prescription-only product category, like patches, gum, lozenges, mouth spray, and inhalators
- Other nicotine-containing products that are not approved, like snuff, chewing tobacco, and "heat not burn" tobacco products
- Non-nicotine vaping products, like flavor refills that don't contain nicotine but can be combined with nicotine

- **Overview of TGO 110 requirements**

  According to TGO 110, information about unregistered nicotine vaping products must be provided on their "label" (which can be found on the product's container, main pack, or information sheet), as well as on their packaging, ingredients, and records that Australian product sponsors are required to keep.

  Products that consumers directly import from foreign suppliers through the Personal Importation Scheme are exempt from TGO 110's requirements regarding packaging and labelling.(Litt, Mark D et al)

2.3.2 Personal Importation Scheme

- Under the Personal Importation Scheme, anyone can import unregistered nicotine vaping products for themselves or members of their immediate family as long as they have a valid prescription, which can be obtained through the Authorised Prescriber Scheme (APS) or the Special Access Scheme (SAS). According to Item 1 of Schedule 5 to the Therapeutic Goods Regulations 1990, this allowance allows the importation of up to three months' worth of these products. This plan takes into account situations in which patients choose to fill their prescriptions online from foreign suppliers.
- This implies that people who possess a valid prescription from a licenced healthcare provider can purchase their necessary nicotine vaping products from foreign suppliers. The patient and their immediate family members are also eligible for the allowance.The programme guarantees the legal and convenient access to nicotine vaping products for those with medical requirements by permitting personal importation under specific conditions. This framework takes into account the changing nature of healthcare delivery, which includes the use of online channels to obtain necessary prescription drugs.
- The programme also supports patient autonomy and access to options for treatment while upholding safety regulations and standards.

Requirements that apply:

- Products that contain active ingredients other than nicotine and certain substances that can lead to health risks when inhaled are prohibited from being added to these products.
- The limit of nicotine base form concentration is 100 mg/mL.

Requirements that do not apply:

- Nicotine vaping products imported via the Personal Importation Scheme and not registered are exempt from TGO 110's requirements regarding labelling, packaging, and record-keeping.
- Imported nicotine vaping products that are not registered and are obtained through the Personal Importation Scheme are not subject to TGO 110's labelling, packaging, and record-keeping requirements.

2.3.3 Labelling of Nicotine Vaping Products:

- Unregistered nicotine vaping products must have thorough labelling with particular components meant to educate customers and guarantee their safety.
- Ingredient List: An ingredient list with an extensive description of the main ingredients must be displayed on the label. The name of the active ingredient, an indication of flavor (either by using the term 'flavor' or a descriptive mention), and a detailed list of all other excipient ingredients are included.
- Nicotine concentration: The concentration of products containing nicotine base and the concentration of goods containing nicotine salt both should be stated in milligrams per milliliter (mg/mL).
- Warning Statements: Following warning statements should be present on the label-
  - "KEEP OUT OF REACH OF CHILDREN"- This is to prevent the access of e-cigarettes to minors.
  - "Avoid contact with eyes"- To minimize the potential risk of eye injury
  - "Avoid contact with skin"- A cautionary statement advising the users to

prevent the direct contact between the products with the skin in order to avoid skin irritation or any other adverse reactions.(Foulds J, Veldheer S, Berg A)

2.3.4 Ingredients in Nicotine Vaping Products:

- TGO 110 provides specific regulations regarding the components that must be used in unregistered nicotine vaping products; these guidelines cover both active and excipient ingredients. These strict guidelines are intended to maintain the vaping industry's high standards for quality and safety.
- Significantly, goods imported via the Personal Importation Scheme are subject to these ingredient regulations. It's important to note, though, that foreign suppliers of these goods are exempt from these regulations.
- Consumers must understand that certain products are exempted from these ingredient requirements if they have a PMTA (Pre-Market Tobacco Application) marketing order from the FDA and comply with all of its requirements. Before issuing a PMTA marketing order, the FDA thoroughly assesses the ingredients in these products, taking into account scientific data to ensure their suitability for protecting the public's health.
- One of the most important requirements is that nicotine concentrations must be within a particular range in order to guarantee accuracy and consistency. In order to uphold safety standards, limits are also placed on the concentration of nicotine base and comparable base forms in nicotine salt products.
- Moreover, TGO 110 forbids the addition of specific materials to nicotine vaping products because of the possible health hazards that arise from inhaling them. These prohibited ingredients include:
    - Acetoin
    - Benzaldehyde
    - Diethylene glycol
    - Diacetyl
    - Cinnamaldehyde
    - Ethylene glycol
    - Vitamin E acetate

- Pentane-2,3-dione

- This extensive framework demonstrates the dedication to preserving public health by controlling the ingredients in vaping products that contain nicotine. TGO 110 seeks to promote consumer safety and well-being by limiting potential risks associated with these products through the establishment of explicit guidelines and restrictions.(Goods Administration, 2021)

2.4 RESTRICTIONS IN INDIA

THE PROHIBITION OF ELECTRONIC CIGARETTES ACT [P.E.C.A], 2019 - PRODUCTION, MANUFACTURE, IMPORT, EXPORT, TRANSPORT, SALE, DISTRIBUTION, STORAGE AND ADVERTISEMENT.

On December 5, 2019, the President granted assent to this Act of Parliament. It will be considered to have taken effect on September 18, 2019.

To protect the public's health and prevent harm to individuals, the Act forbids the production, manufacturing, import, export, transport, sale, distribution, storage, and advertising of electronic cigarettes.

In case of any violation of section 4, which prohibits the production, manufacturing, import, export, transport, sale, distribution, and advertisement of electronic cigarettes, the offender faces a maximum sentence of one year in prison, a fine of one lakh rupees, or both. In the event of a second or subsequent offense, the penalty increases to five lakh rupees and one lakh rupees in prison.

Individuals who violate the terms of section 5, which prohibits the storage of electronic cigarettes, may face imprisonment for up to six months or a monetary penalty of up to fifty thousand rupees, or both.

If a corporation commits an offense under this Act, everyone who was in charge of the company's business at the time of the offense and is responsible to the company for its conduct will be considered guilty of the offense and will face suitable legal proceedings and punishment. As long as the person can demonstrate that the crime was committed without his knowledge or that he took all reasonable precautions to stop it from being committed, nothing in this subsection will subject him to the penalties specified in this Act.

Despite subsection (1), if a company commits an offense under this Act and it is established that a director, manager, secretary, or other officer of the company acknowledged committing the offense, knew about it, or was negligent in some other

way, then the director, manager, secretary, or other officer will also be considered to have committed the offense and will be subject to legal action and punishment. The late Dr. G. Narayana Raju, the Legislative Secretary to the Government of India, passed and signed this act.

2.5 Overview of E-Cigarettes In Restricted Countries

Throughout the world, many countries have made restrictions on different subjects for e-cigarettes. Many countries like China, Bhutan, Israel, USA, Greece, South Korea etc. have put restrictions.(Amalia, Beladenta et al)

Further this can be seen in the table given below.

Table 3: Overview of restrictions in Asian countries(Amalia, Beladenta et al)

States	**State law definition**	**Product packaging**	**Youth access/other retail restrictions**	**Retail license or permit required**	**Smoke-free restrictions**	**Advertisements restriction**	**Flavors restrictions**
Bhutan	No	No	No	Yes	Mostly ll indoor and outdoor places in transportation publicly have restriction. Even restriction on places where smoking is prohibited.	Yes	No
China	Yes	The front and back of the packaging must	Cannot be sold to children below	No	Restricted on places where children are present	Yes	Cocoa extract, vanilla tincture, pepper

		contain 35% of the text only health warnings and should be rotated annually.	age 18		like kindergarten, schools.		mint oil and lemon oil flavors have restriction.
Jordan	Yes	Packaging must contain front and back with 30% warning	Restricted to persons under age 0f 18.	No	Have restrictions on many places but does not have specific rules for all indoor and public places	Yes	No
USA	Yes	E-cigarettes cartridges and solution filling must be child proof.	Restrictions under age of 21	Yes	Use is restricted where prohibition is their but it doesn't have any specific rules for specific location.	No	Restrictions in all flavors other than menthol.

					The use is prohibited for schools.		
Canada	Yes	Prohibits the products with the packaging which contains nicotine concentration above 20mg/ml.	Products can't be sold to person below 18 years.	Yes	Banned to indoor and workplaces.	Yes	Tobacco, mint, menthol, mixed flavours, sweeteners, and the majority of tastes are all prohibited.

CHAPTER 3 ALTERNATIVES AVAILABLE TO E-CIGARETTES

As the negative effects of e-cigarettes increased with time nicotine replacement therapies were designed. These therapies work by controlling the amount of nicotine and hence reducing the adverse effects caused due to smoking of these e-cigarettes.

FDA has approved several nicotine replacement therapies such as:

Table 4: FDA approved nicotine replacement therapies

ALTERNATIVES	MODE OF ACTION
NICOTINE NASAL SPRAY	Nicotine is administered in the body through nasal route which helps with sudden cravings
NICOTINE INHALER	Rapid onset of action
NICOTINE PATCH	Small amount of nicotine is steadily released into the patient's bloodstream which results in reduction of withdrawal symptoms
NICOTINE GUM	It is an oral dosage form which releases nicotine in small amounts into the lining of mouth it also decreases withdrawal symptoms
NICOTINE LOZENGES	It has rapid delivery of nicotine into the mouth tissues

CHAPTER 4 CURRENT SCENARIOS

On 26th February 2024 FDA fined 20 retailers for illegal selling of unauthorized Elf-Bar e-cigarettes which is a popular youth brand. This was done as these retailers were not able to meet the instructions already provided in the warning letters issued to them by FDA. This led to them being fined of $20,678 for each violation per retailer.

FDA issued warning letters to five online e-cigarettes retailers for selling of unauthorized e-cigarettes. These letters were issued on 28th February 2024.

CHAPTER 5. CONCLUSION

The regulatory landscape associated with vaping products exhibits notable regional variations, underscoring the absence of a united global structure. While the European Medicines Agency (EMA) works to uniformly enforce regulations among its member states in Europe, the United States has fragmented regulations with inconsistencies between federal and state laws. Therapeutic Goods Administration (TGA) of Australia has a distinct methodology of its own. Although vaping is legally prohibited by India's 2019 Act, enforcement of the law is challenging, which has created a flourishing black market and online sales.These inconsistent regulatory surroundings highlight the need for a comprehensive worldwide effort directed by an organisation such as the World Health Organisation (WHO), similar to the Framework Convention on Tobacco Control (FCTC). An initiative like this might tackle illegal sales, prioritize youth education, standardise regulations, and stop illegal imports. Any regulatory structure, though, needs to be harmonious. Stringent laws are required to stop youth initiation and protect public health, but access for smokers looking for alternatives to quit smoking must also be guaranteed. Innovative technologies that monitor consumption and facilitate gradual reduction, such as metered vapes, demonstrate potential in this context. Moreover, taxes can support public health objectives while limiting potential drawbacks by acting as a revenue source and an inhibitor to excessive consumption. In a nutshell it is critical to address the complicated issues surrounding vaping regulation through a globally coordinated effort. This strategy should take into account the complexities of regulation, taxation, and technological developments in the vaping sector, with a focus on public health, safeguarding the youth, and accessibility to harm reduction resources.

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