Global Approaches to E-cigarette Regulation

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Outline

• Explain the state of global e-cigarette regulation by describing:

  • The **policy domains** addressed by nations
  • How nations have **classified** the product
  • The various **regulatory mechanisms** taken by nations
  • Country **case studies**
Global Policy Scan: Approach

Reviewed policies for 123 countries included in WHO 2014 report, OECD, web searches

Communicated with health ministries and/or in-country tobacco control experts, reviewed government websites & WHO/EU reports

Obtained polices from government websites and in-country experts

61 countries with active e-cigarette policies
Policy Scan: Identification Schema

90 countries: WHO report

12 high-income countries: OECD

21 countries: web searches

123 countries reviewed for e-cigarette policies

62 countries excluded

61 countries with active e-cigarette policies
Which policy domains have been addressed?
Regulatory Domains

- **Sale**: minimum age for purchase; medical authorization
- **Use**: restrictions or bans in enclosed public spaces/transportation
- **Tax**
- **Advertising, promotion and sponsorship**: nicotine content may be relevant, classification as medicines
Sale

• 17 countries have a minimum age for purchase
  18 years: Costa Rica, Czech Republic, Ecuador, Fiji, France, Italy, Malaysia, Malta, New Zealand, Norway, Slovakia, Spain, Togo, United Kingdom and Viet Nam; 19 years: the Republic of Korea; 21 years: in Honduras

• 20 countries restrict the sale of e-cigarettes with nicotine
  Australia, Austria, Belgium, Canada, Costa Rica, Czech Republic, Denmark, Estonia, Fiji, Finland, France, Hungary, Jamaica, Japan, Malaysia, New Zealand, Norway, Philippines, Portugal and Switzerland

• Sale of all types of e-cigarettes is banned in 24 countries
  Argentina, Bahrain, Brazil, Brunei Darussalam, Cambodia, Colombia, Greece, Jordan, Lebanon, Lithuania, Mauritius, Mexico, Nicaragua, Panama, Qatar, Saudi Arabia, Seychelles, Singapore, Suriname, Thailand, Turkey, United Arab Emirates, Uruguay and Venezuela
Use

• 3 countries ban the use of e-cigarettes
  *Cambodia, Jordan and the United Arab Emirates*

• 14 countries ban the use of e-cigarettes in enclosed public spaces (bars, restaurants & other workplaces)
  *Bahrain, Belgium, Colombia, Croatia, Ecuador, Greece, Honduras, Malta, Nepal, Nicaragua, Panama, Philippines, Republic of Korea and Turkey*

• 8 countries restrict the use of e-cigarettes in certain enclosed public spaces
  *Brunei Darussalam, Costa Rica, Fiji, Slovakia, Spain, Togo, Ukraine and Viet Nam*

• 18 countries prohibit use on public transportation
  *Bahrain, Belgium, Colombia, Ecuador, Fiji, Greece, Honduras, Malta, Nepal, Nicaragua, Panama, Republic of Korea, Slovakia, Spain, Togo, Turkey, Ukraine and Viet Nam*
Tax

• Togo taxes e-cigarettes to a maximum of 45 percent

• Republic of Korea applies a special health tax to e-cigarettes proportional to USD 1.65 per mL nicotine liquid
Advertising, Promotion, Sponsorship

- Of the 47 countries that ban or restrict sale, 31 prohibit or restrict the advertising, promotion or sponsorship of e-cigarettes in their policies
  - Argentina, Australia, Austria, Bahrain, Belgium, Brazil, Canada, Colombia, Costa Rica, Czech Republic, Denmark, Estonia, Fiji, Finland, France, Greece, Hungary, Japan, Jordan, Mexico, New Zealand, Norway, Panama, Portugal, Qatar, Saudi Arabia, Seychelles, Turkey, United Arab Emirates, Uruguay, Venezuela

- Some countries contend that TAPS bans are inherent within their bans on sale
  - Argentina, Australia

- 12 countries have explicit bans or restrictions on e-cigarette advertising, promotion or sponsorship
  - Croatia, Ecuador, Honduras, Malta, Nepal, Netherlands, Republic of Korea, Slovakia, Spain, Togo, United Kingdom, Viet Nam
How are e-cigarettes being regulated?
Regulatory Mechanisms

61 countries with regulations:

- Interpretation of existing legislation
- Amendments to existing legislation
- New law, decree, resolution, circular, notification
- Multiple approaches

Most countries are using existing laws to regulate e-cigarettes

Many countries have outright banned e-cigarettes through decrees or decisions
Product Classification

- Tobacco products – imitation, derivative, and substitute
- Medicinal/pharmaceutical products
- Consumer products
- E-cigarettes/Electronic nicotine delivery systems (ENDS)
- Poisons

Classification of the product relates to regulatory approach
Country Case Studies
E-cigarette regulation across countries varies with regard to regulatory mechanism, approach, and policy domains covered.
Australia

• A law classifies nicotine as a restricted poison if it is not used for therapeutic purposes

• Non-nicotine e-cigarettes are classified as legal consumer products

• Sale and marketing are prohibited, though according to a statement import for personal reasons may be permitted under certain instances; advertising, promotion and sponsorship are inherently prohibited
Republic of Korea

• Nicotine-containing e-cigarettes are classified as tobacco products and thus their sale is banned to minors (under 19) according to an act

• Use is banned in public places and transport with the exception of designated smoking areas

• Nicotine-containing e-cigarettes can only be featured a maximum of 10 times per magazine per year.*

• There is a special health tax, proportional to 1,799 won/mL nicotine liquid (Tobacco Business Act)

• Non-nicotine containing e-cigarettes are considered consumer goods
Singapore

- E-cigarettes are classified by the tobacco control act as imitation tobacco products; this bans their sale, distribution and importation
Togo

• The tobacco control law classifies e-cigarettes as “derivative products”

• The law forbids provision to minors (under 18), advertising and promotion, and prohibits smoking in public places/transport outside of designated areas

• E-cigarettes are subject to duties/fees and are not eligible for tax exemptions; they are taxed at a ceiling of 45 percent
United Kingdom:
A unique approach
UK Context

• 2005: UK Medicines and Healthcare products Regulatory Agency (MHRA) adopted principle that any risks associated with NRT are substantially outweighed by dangers of continued smoking

• Harm reduction advocated by Royal College of Physicians, Action on Smoking and Health

• 2010: MHRA allows harm reduction indication

• 2011: National tobacco control plan – “develop new approaches to encourage tobacco users who cannot quit to switch to safer sources of nicotine”

• MHRA: NRTs not like other pharmaceuticals – continued smoking, not placebo, is the relevant comparator

• 2015 Public Health England report: e-cigarettes are 95% less harmful than cigarettes
UK Policy Approach

- E-cigarettes are governed by general product safety regulations.

- However, manufacturers can apply for a medicinal license through the Medicines and Healthcare products Regulatory Agency (MHRA).

- In 2016, any unlicensed e-cigarette will be governed by European Union’s Tobacco Products Directive (TPD), with full compliance necessary by 2017.
MHRA Medicinal License (2010)

- “Light-touch” medicines regulation
- Available on prescription and general sale
- Can make health claims
- Age of sale according to license
- Advertising permitted, similar to other nicotine-containing products
- No upper limit on nicotine concentration
- Flavors allowed but need approval
- Currently, one product has applied (BAT product)
Advertisements expected to:

• Be socially responsible
• Not promote any tobacco brand design, imagery or logo
• Make clear e-cigarettes are not tobacco products
• Not undermine quit tobacco messaging
• Not contain health or medicinal claims without licensing
Age of Sale (2015)

On October 1, 2015 it became illegal to sell e-cigarettes to or buy for someone under 18 years of age in the UK
Final Thoughts

It may not be the case that one approach works for all; factors that may be important include:

- Country’s goals & approaches to tobacco control and cessation
- Country’s regulatory system/structure and its capacity to implement and enforce policies
- Political influences, including lobbying, values, governing party
- State of the tobacco epidemic and e-cigarette use patterns
- Availability of e-cigarette products/product types in the market
- Timing/time since e-cigarettes emerged as product category
- Pricing (including tax), affordability, price relative to tobacco products
- Tobacco & e-cigarette industry behaviors
- Marketing practices, including social media, and marketing restrictions
Country Laws Regulating E-cigarettes

This report provides a description of select country-level laws that regulate the sale, use, advertising, promotion, taxation and/or classification of e-cigarettes. We reviewed 123 countries for regulations on e-cigarettes: 90 from a World Health Organization (WHO) report on e-cigarette policies, 12 high-income (OECD) countries that were not in the WHO report and 21 additional countries. This report features summaries and a searchable database that describe the policy domains, product classifications and regulatory mechanisms employed by countries to regulate e-cigarettes.

Summary

- Web searches of government websites and media reports yielded 71 countries that have national/federal laws regulating the sale, advertisement, promotion, sponsorship, taxation, use and classification of e-cigarettes.
- Fifty-five countries have bans or laws that prohibit or restrict the sale of e-
Country Comparison Database

Use this form to filter countries based on Policy Domains and Product Classifications. You may choose any combination of terms from either list.

Policy Domains
- Child Safety
- Distribution
- Importation
- Manufacture
- N/A
- Sale
- Smoke-free
- TAPS
- Taxation

Product Classifications
- Consumer Goods
- Commodity
- Poison
- Other
- Hazardous substance
- Chemical mixture
- Chemical product
- Electrical appliance
- ENDS/E-cigarette

Argentina
A ruling bans the sale, advertisement, distribution and importation of e-cigarettes. A decree classified these as tobacco products, thus use is inherently prohibited in enclosed public spaces/transport by the national tobacco control law.

Australia
A law classifies nicotine as a restricted poison if it is not used for therapeutic purposes. Non-nicotine e-cigarettes are classified as legal consumer products.
A CENTURY OF SAVING LIVES
MILLIONS AT A TIME

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