CLEARING THE AIR, EXPLORING THE INTERNATIONAL PUBLIC POLICY RESPONSE TO THE SYNTHETIC NICOTINE CRISIS: A SCOPING REVIEW

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INTRODUCTION

Introduction:

The alarming global rise of synthetic nicotine use among youth is often fueled by regulatory loopholes that inadvertently allow unrestricted sales and targeted promotion to youth [1,2]. Internationally, narrow legal definitions often exclude synthetic nicotine from existing tobacco regulations, creating unintended gaps in regulatory oversight regarding age restrictions, point of sale, packaging, and advertising [3]. Tobacco companies often exploit these loopholes to expand their markets, ultimately increasing youth access to synthetic nicotine, exposing them to its adverse effects [2,3].

Research Question:

The primary objective of this scoping review is to identify country-level variation in the:

1. Legislative definition and categorization of both naturally containing and synthetically-derived nicotine-containing products.
2. Regulatory levers to control nicotine use: (a) access/sale limitations, (b) taxation/insurance coverage schemes, (c) labeling, promotion and sponsorship restrictions, (d) oversight, administration and enforcement.

METHODS

A cross-jurisdictional scoping review, conducted following the Joanna Briggs Institute methodology and the PRISMA guidelines [4], will include peer-reviewed articles and publicly available grey literature describing legislation or policies related to synthetic nicotine in all Organization for Economic Cooperation and Development (OECD) countries [5]. The review will consider sources available in English, with no restrictions on publication year or study type.

In parallel, a primary source review of legislation and associated regulations will be conducted to provide a comprehensive analysis of the legislative landscape. Legislative analysis of the included OECD countries is currently underway.

Figure 1: Flow diagram outlining methodology of study

Search Strategy: A combination of key words focused on synthetic nicotine', 'nicotine replacement therapies', combined with the terms 'legislation, 'policy', and 'law' in the tobacco laws database, Google Scholar, and the official government websites of included OECD countries

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Screening: This step will be conducted independently by two reviewers.

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Data extraction: This step will utilize categories outlined in Table 1 and will be extracted into excel software.

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Thematic Analysis: This step will follow Clarke et al's methodology [6], and will be employed to identify common regulatory approaches, areas of divergence, and gaps in addressing the needs of disproportionately affected populations.

Table 1: Categories to be used for data extraction step

Definitions	Production	Access	Labeling and Promotion	Administration and Enforcement	Equity, Diversity, and Inclusion
Identifying legal definitions of nicotine, nicotine replacement therapies (NRT), tobacco, and synthetic nicotine.	Identifying the entity and/or industry/industries that manufactures legal product(s).	Identifying the policy instruments that regulate who can access nicotine products and under what circumstances (e.g., age restrictions, points of sale limitations, purchase limitations).	Identifying regulations governing packaging, labelling (i.e., health warnings), marketing, and advertising.	Identifying the government and non-government bodies responsible for regulation enforcement, including identifying the oversight structures, penalty systems, and enforcement resources.	Identifying specific regulations or public policy initiatives aimed at protecting vulnerable populations.

RESULTS: CANADIAN LANDSCAPE

Figure 2: Canadian Landscape: Tobacco and Vaping Products Act and Food and Drugs Act, which regulate tobacco and nicotine

The Tobacco and Vaping Products Act (TVPA) regulates the manufacture, labelling, sale and promotion of tobacco and vaping products. Youth access and appeal are restricted through prohibiting sales to people under the age of 18, certain promotional activities (e.g., lifestyle advertising), and limiting certain flavours appealing to youth.

However, the TVPA does not apply to NRTs, other than vaping products, as they are classified as drugs when authorized for smoking cessation purposes and do not contain tobacco.

Depending on the amount of nicotine contained or delivered by the product, an NRT would be considered a prescription drug or a natural health product. Health Canada regulates NRTs under the Food and Drugs Act (FDA). Under the FDA, there is no restrictions on where and to whom NRT can be sold to, which leaves a large loophole for tobacco companies to market and sell NRT to children and youth.

Health Canada approved the product "Zonnic", a nicotine replacement therapy produced by Imperial Tobacco, under the FDA. Given that Zonnic does not contain tobacco and because the pouches contain less than 4 mg of nicotine each and are not inhaled, they were not regulated by the TVPA, allowing them to be marketed and sold directly to children and youth when they entered the Canadian market in July 2023. The exploitation of this regulatory loophole prompted a series of actions by the Canadian Government (see Figure 3).

RESULTS: CANADIAN DEFINITIONS

Tobacco product means a product made in whole or in part of tobacco, including tobacco leaves. It includes papers, tubes and filters intended for use with that product, a device, other than a water pipe, that is necessary for the use of that product and the parts that may be used with the device.

Nicotine replacement therapy (natural health product) means a natural health product, other than a homeopathic medicine, that **(a)** contains nicotine or its salts; and **(b)** is for administration in the oral cavity.

Nicotine (pharmaceutical grade nicotine) for human use, except: (a). in natural substances; (b) in the form of a chewing gum containing 4 milligrams or less of nicotine per dosage unit; (c) in the form of a transdermal patch with a delivery rate of 22 milligrams or less of nicotine per day; (d) in a form to be administered into the oral cavity by means of a non-active device (one that operates on energy generated by the human body or by gravity) that delivers 4 milligrams or less of nicotine per dose for buccal absorption; (e) in the form of a lozenge containing 4 milligrams or less of nicotine per dosage unit

Figure 3: Timeline of the regulatory actions by the Canadian Government in the midst of the sale of the Zonnic nicotine pouches to children and adolescents

April 1997: Tobacco vaping products act assented → June 2009: Natural health products regulations under food and drug → July 2023: Zonic pouches enter the market → March 20th 2024: Statement from the Minister of Health on nicotine replacement therapies → March 20th 2024: Public advisory; Only use authorized nicotine pouches as directed, and do not use unauthorized nicotine pouches → August 28, 2024: Supplementary Rules Respecting Nicotine Replacement Therapies Order (see Table 2).

Table 2: Data Extracted from Canada's Minister of Health- Food and Drugs Act: Supplementary Rules Respecting Nicotine Replacement Therapies

Labelling, Packing, and Promotion Restrictions		Access and Sale	
Packaging	**Flavours**	**Age**	**Place of Sale**
A person must **not** sell a nicotine replacement therapy if its label or package displays statements or graphic design elements, including brand elements, for which there are reasonable grounds to believe that they could be **appealing to young persons, (young person: under 18 years) [7].**	A person must **not** manufacture or sell a nicotine replacement therapy that is in a dosage form set out in the List if it contains the flavour of a **confectionery, dessert, soft drink or energy drink.** A person must not manufacture or sell a nicotine replacement therapy that is in a dosage form not set out in the List if it contains a flavour other than mint, menthol or a combination of mint and menthol [7].	A statement, in both official languages, indicating an intended use by individuals **18 years of age or older must be shown on the outer label** of a nicotine replacement therapy or, if there is no outer label, on the inner label [7].	No person shall furnish a tobacco product or vaping product to a young person in a public place or in a place to which the public has access. **No person shall send or deliver a tobacco product or vaping product to a young person [7].**

CONCLUSION

Legal definitions of nicotine varied across jurisdictions; synthetic nicotine was inconsistently categorized as a product regulated by tobacco laws [8-13]. Within Canada, current legislation under the Tobacco and Vaping Products Act applies only to "*products derived from the tobacco leaf*", excluding synthetic nicotine as a product regulated by this Act [13]. Many synthetic nicotine products within Canada are regulated as nicotine replacement therapies (NRT) under Natural Health Product regulations; this loophole inadvertently allows unintentional access to pediatric populations [13].

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