

➤ Law No. 21,642 on electronic cigarettes was published

On January 4th, 2024, Law No. 21,642 which "amends Law No. 19,419 to prohibit the sale of electronic cigarettes to minors; assimilates electronic nicotine delivery systems, similar nicotine-free mechanisms and heated tobacco products to tobacco products; and regulates alternative devices with or without nicotine" (hereinafter the "Law"), was published in the Official Gazette, highlighting the following aspects:

- 1 The concepts of "Electronic Nicotine Delivery Systems" ("ENDS")^[1] and "Electronic Non-Nicotine Delivery Systems" ("ENNDS") are defined by the Law, which, in principle, could only use vaping liquids.
- 2 ENNDS for therapeutic use are expressly recognized as electronic systems for the delivery or administration of therapeutic active ingredients, in liquid or herbal format, and whose sale (e., the sale of the drug or product containing the active ingredient) will be subject to medical prescription.
- 3 Both ENDS and ENNDS are assimilated to tobacco products, setting forth a "common regulation", regarding which the following stands out:
 - a A regulation will set forth the restrictions and warnings limiting its direct and indirect advertising, including its liquids, accessories and other elements associated with these products' trademarks. Notwithstanding the latter, it is expressly allowed to provide information on the general characteristics of therapeutic ENNDS, "*such as indications, dosage, adverse effects, contraindications and, in general, all necessary information for its correct use*".
 - b All companies whose products are regulated by the Law are subject to the obligation of notifying the Ministry of Health of donations executed by the same, as well as the expenses incurred under agreements with public institutions, sports and community organizations, academic and cultural entities, and non-governmental organizations.
 - c It is prohibited to offer, deliver or sell the products regulated by the Law to minors under 18, including accessories and vape liquids. Likewise, other limitations on the commercialization of these products are established, such as the prohibition to include them in vending machines, selling them inside or near certain premises, offering direct or indirect compensation for their purchase and donating them, among others.
 - d The labeling of these products must include a warning regarding the damages or effects to human health associated with their consumption or exposure to smoke or aerosols generated by them, including their accessories.
 - e It is mandatory to inform the Ministry of Health, on an annual basis, of the quality and quantity of constituents, additives, and substances used for the treatment of ENDS/ENNDS and their vape liquids; which must not correspond to prohibited additives or additives not previously informed to the Ministry, and must comply with the established concentration limits, if applicable.
 - f It is prohibited to use ENDS/ENNDS in the same places as tobacco products (g., closed spaces of the premises mentioned by Law No. 19,419, public transportation, sports facilities and stadiums –except in spaces that are specially designated for this purpose–, among others),

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except for therapeutical ENNDS, provided there is an imperative medical necessity, and that the user carries their medical prescription indicating its use.

- g** It is mandatory to display warnings prohibiting the use of ENDS/ENNDS in places of public access.
 - h** It is prohibited to induce minors to consume tobacco products, ENDS/ENNDS or their accessories, as well as using means that take advantage of their credulity, and to use commercial hooks through elements attractive to children in order to gain sales.
- 4** The sanctioning regimen of infringements associated with Law No. 19,419 is modified, transitioning from Local Police Courts to an administrative sanctioning procedure (“*sumario sanitario*”) as per Title X of the Sanitary Code, notwithstanding the fines established under article 16 of Law No. 19,419 are maintained (*g.*, ranges from 1 to 1,000 Monthly Tax Units –from 73 to 73,000 USD, approximately– for the conducts expressly indicated therein and which may be directed against both individuals or legal entities).
- 5** The Law adds a new “Title II” specially dedicated to ENDS/ENNDS and its vaping liquids, regulating aspects associated with its packaging and the mandatory mentions to include in its labeling, and setting forth the obligation of including a manual with mandatory information for vaping liquids, which cannot exceed 46 mg/ml of nicotine. It is forbidden to suggest that an ENDS/ENNDS or vaping liquid is less harmful than others, or that it has a positive effect on health or lifestyle.

The Law will enter into force at the time of publication in the Official Gazette of the modification to Decree No. 5/2022 of the Ministry of Health –that regulated the sanitary warnings that shall be included in the packages of tobacco products, ENDS/ENNDS and accessories–, which shall be enacted within a 12-month deadline, from the publication of the Law in the Official Gazette.

[1] It is important to remember that, based on a determination of the sanitary control regimen contained in Exempt Resolution No. 2994/2010, the Public Health Institute (“ISP”) resolved to classify as pharmaceutical products all “electronic cigarettes” containing nicotine, including its cartridges, components and any other device formulated with nicotine.

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