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GOVERNMENT GAZETTE OF THE HELLENIC REPUBLIC

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LAW No. 4600

Modernization and Reform of the Institutional Framework for Private Clinics, the Establishment of a National Public Health Organization, the Establishment of a National Institute for Neoplasias and other provisions.

THE PRESIDENT OF THE HELLENIC REPUBLIC

We hereby issue the following law that was adopted by the House of Parliament:

[.....]

CHAPTER C' PROVISIONS ON TOBACCO PRODUCTS

Article 96 Amendments to Law 4419/2016 (A' 174) on Electronic Cigarette

The following amendments are made to Law 4419/2016 (A' 174):

- 1. In Article 1, case 14 the following subparagraph is added worded as follows:

 By decision of the Minister of Health, the hereinabove mentioned concept may also include the devices the use of which is a prerequisite and is exclusively associated to the use of the new tobacco products, and the terms and conditions for the promotion and disposal thereof to be defined more particularly.
- 2. Article 2, case 16 is substituted as follows:
 - "16. "electronic cigarette": a product that can be used for the consumption of steam containing nicotine or steam that not containing nicotine with a mouthpiece or element of the said product, including the container, the vessel and the device without container or vessel. Electronic cigarettes may be rechargeable through a refilling container/cartridge and vessel, or rechargeable with disposable containers".
- 3. Article 2, case 17 is substituted as follows:

 "17. "rechargeable container": a vessel containing liquid, regardless of the fact that may be with a nicotine content or not, which may be reused in order to recharge the electronic cigarette."

- 4. In Article 2, cases 17a and 17b are added as follows:
 - "17a. "nicotine liquid": liquid containing nicotine and intended for vaping through an electronic cigarette,";
 - 17b. "non-nicotine liquid" liquid not containing nicotine and intended for vaping through an electronic cigarette,".
- 5. In Article 2, case 42 is added as follows:
 - "42) "tobacco substitute": any product not containing tobacco is not a herbal product for smoking or an electronic cigarette and may be similar to the intended use therewith.".
- 6. In Article 2, case 43 is added as follows:
 - "43) "related products": the tobacco substitutes, the electronic cigarette, the herbal product for smoking, as well as any other product the use of which is associated to the exclusive use of one of the above."
- 7. In Article 3, the words "or manufactured in the member states" are substituted by the words "or manufactured in Greece".
- 8. In Article 4, paragraph 5 is added as follows:
 - "5. The measurements stated in this article may be carried out also by laboratories that are established in the territory of other member states of the Union, provided that these have been accredited and are respectively supervised by the competent National Authorities of these states and are not owned or controlled, directly or indirectly, by the tobacco industry."
- 9. The text of Article 15 is numbered as paragraph 1 and paragraph 2 is added to this Article as follows:
 - "2. The placing on the market of chewing tobacco, snuff tobacco and tobacco substitutes is prohibited.".
- 10. At the end of paragraph 1, Article 17 the following subparagraph is added worded as follows:
 - "The notification of the devices of the new tobacco products is to be carried out on the basis of the Commission's existing implementing acts at the time, in accordance with paragraph 5, Article 5 of the Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014."
- 11. In Article 17, paragraph 13 is added as follows:
 - "13. Regarding the packaging of the devices of the new tobacco products, unless these are jointly packaged with the products themselves:
 - a) the provisions of sub-cases aa' and ff' of case a' of paragraph 4, Article 18 apply;
 - b) this (common packaging) includes a recommendation in Greek to keep the product away from children;
 - c) it does not include any elements or characteristics referred to in Article 13. If the device is placed on the market in a common package with the product itself, this shall be considered as the product's packaging.".
- 12. The last subparagraph of paragraph 1 of Article 18, is substituted as follows: "The law hereby is not applied on electronic cigarettes and their refill containers that are subject to licensing requirement of the joint decision no. Δ.ΥΓ3α/Γ.Π.32221/2013 of the Ministers of Development, Competitiveness, Infrastructure and Networks and Health (B' 1049) or the requirements of the DY8d/G.R./fin. 130648/2009 joint decision of the Ministers of Economy and Finance, Development, Health and Social Solidarity (B' 2198)."
- 13. Case d' of paragraph 2 of Article 18 is substituted as follows:

- "d) regarding the electronic cigarettes and refill containers with nicotine liquid, information related with the dosage and taking of nicotine, when the product is consumed under normal or reasonably predictable conditions."
- 14. The last subparagraph of paragraph 6 of Article 18 is substituted as follows:

"The Health Ministry monitors the developments of the market related with electronic cigarettes, as well as refill containers, including any data proving that their use by youths and non-smokers leads to nicotine addiction and ultimately in the traditional consumption of tobacco."

15. The second subparagraph of paragraph 7 of Article 18 is substituted as follows:

"The Health Ministry, regarding the electronic cigarettes and refill containers, following a request, places all of the information that has been obtained in accordance with the article hereby at the disposal of the European Commission and the other member - states.".

16. At the end of paragraph 9 of Article 18, the following subparagraph is added worded as follows:

"Regarding the electronic cigarettes and refill containers with nicotine liquid, the Ministry of Health shall, without neglect, inform the European Commission and the competent authorities of the other member – states regarding the measures that have been taken and notifies any support data for the temporary measure."

17. Article 18a is added as follows:

"Article 18a

Regulations on components and packaging of the electronic cigarettes and refill containers with non-nicotine liquid

Regarding the electronic cigarettes and the refill containers with non-nicotine liquid the following apply: a) the provisions of paragraph 2 of Article 18; b) the provisions of cases c', d' e' and g' of paragraph 3 of Article 18; c) the provisions of paragraph 4 of Article 18, except sub-case cc' of paragraph b'; d) the packaging units and every external packaging of electronic cigarettes and refill containers includes the following health warning:

"This product may be harmful to your health"

These health warnings meet the requirements stipulated in paragraph 2 of Article 12"

18. Article 18b is added as follows:

"Regulations on the circulation of electronic cigarettes and refill containers with non-nicotine liquid

- 1. For the electronic cigarettes and refill containers with non-nicotine liquid the provisions of paragraphs 5, 8 and 9 of Article 18, as well as Article 16 shall apply.
 - a) The non-nicotine liquid is marketed only in special refill containers and in disposable electronic cigarettes or vials.
 - b) The separate sale and disposal to the end consumer of ingredients, including perfumes, intended for the do-it-yourself of refill liquids for electronic cigarette. The above prohibition exempts those ingredients that are available for use other than the consumption of electronic cigarette refill liquid.
 - c) Electronic cigarettes and refill containers with non-nicotine liquid that doe not meet the requirements of paragraph 1 are prohibited to be placed on the market.".
- 19. Paragraph 4 of Article 24 is substituted as follows:
 - "4. In case of violation of the obligations of Articles 8 through 16, Article 17 paragraphs

- 1, 2, 11 and 13, Article 18 paragraphs 1 through 6 and paragraph 8, Articles 18a and 18b, as well as Articles 19 and 21, there will be imposing, by decision of the Minister of Health, of the fines provisioned in case D' of paragraph 1 of Article 3 of the no. G.R., fin. 104720/2010 decision of the Ministers of Interior, Decentralization and Electronic Governance, Finance, Labor and Social Security, Health and Social Solidarity, Citizen Protection, Culture and Tourism (B' 1315)".
- 20. The first subparagraph of paragraph 3 of Article 24 is substituted as follows: "In case of failure to observe the obligation of notification of the articles 5, 6, and 7 of the law hereby, in case of incomplete notification or false notification in violation of the articles 5, 6 and 7 and Article 20, paragraph 1 of the law hereby there will be imposing, by decision of the Health Minister, a fine of four hundred (400) euros per product.".
- 21. In Article 25, paragraph 4 is added as follows:

 "4. By a joint decision of the Ministers of Health and Finance, the amount of the fees referred to in paragraphs 1 and 2 is readjusted, and any other matter relating to the
- 22. The provision of paragraph 2 of Article 15 and the provisions of paragraph 13 of Article 17 and Article 18b shall enter into force six (6) months after the entry into force of this.

Article 97

Amendment of Law 3730/2008 (A' 262) on advertising and marketing prohibitions

The following amendments are made to Law 3730/2008 (A' 262):

method of calculation and payment thereof is regulated.".

- 1. Case c' of paragraph 1 of Article 2 is substituted as follows:
 - "c) the manufacturing, display, trading and sale of items with the external appearance of tobacco and related products, as stipulated in Article 2 of Law 4419/2016.".
- 2. Paragraph 2 of Article 2 is substituted as follows:
 - "2. The circulation of products which are intended for the cessation of use of tobacco and related products is prohibited, except for those that are subject to licensing under joint decision no. DYG3a/G.R.32221/2013 of the Ministers of Development, Competitiveness, Infrastructure and Networks and Health (B' 1049) or the requirements of the joint decision no. DY8d/G.R./fin. 130648/2009 of the Ministers of Economy and Finance, Development, Health and Social Solidarity (B' 2198). Any accompanying indication in tobacco or related products packaging, as well as in any type of advertising displays or entries, according to which the use thereof imposes a reduced risk for health."

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