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Adaptation of the Greek legislation to the Directive 2014/40/EC of the European Parliament and of the Council of the 3rd April 2014 for the alignment of the legislative, regulatory, and administrative provisions of the member – states related with the manufacture, presentation, and the sale of tobacco products and similar products and the abolition of the Directive 2001/37/ EC (number L 127/1 of the 29.4.2014), as Annex II of such Directive was amended with the Directive 2014/109/EU issued by authority of the Commission of 10th October 2014 for the amendment of Annex II of the Directive 2014/40/EC of the European Parliament and of the Council with the institution of the library of iconographic warnings that must be used for tobacco products, as well as other similar provisions.

THE PRESIDENT OF
THE HELLENIC REPUBLIC

We are issuing the following law voted by the Parliament:

PART A'
GENERAL PROVISIONS

Article 1
Purpose

The purpose of this law is:

1. The adaptation of the Greek legislation to, the Directive 2014/40/EC of the European Parliament and of the Council of the 3rd April 2014 for the alignment of the legislative, regulatory, and administrative provisions of the member – states related with the manufacture, presentation, and the sale of tobacco products and similar products and the abolition of the Directive 2001/37/ EC (number L 127/1 of the 29.4.2014), as Annex II of such Directive was amended with the Directive 2014/109/EU issued by authority of the Commission of 10th October 2014 for the amendment of Annex II of the Directive 2014/40/EC of the European Parliament and of the Council with the institution of the library of iconographic warnings that must be used for tobacco products, as well as other similar provisions.

2. The provisions of this law are applied on the tobacco products, the tobacco received by mouth, the new tobacco products, electronic cigarettes, and replenish containers, as well as the plant tobacco products for smoking.

Article 2
Definitions
(Article 2 of the Directive 2014/40)

For the purposes of this law the following definitions shall apply:

1) "tobacco": leaves and other natural, processed or unprocessed parts of tobacco leaves, including the expanded and reprocessed tobacco.

2) "pipe tobacco": tobacco that may be consumed through combustion process and it is intended exclusively for use with a pipe.

3) "tobacco for rolled cigarettes": tobacco that may be used for the preparation of cigarettes by consumers or by retail stores.

4) "tobacco products" or "smoker products": products that may be consumed and which consist, even partly, of tobacco, either genetically modified or not.

5) "non-smoked tobacco product": tobacco product that is consumed without combustion process, including chewing tobacco, and tobacco taken from the nose, and tobacco taken from the mouth.

6) "chewing tobacco": non-smoking tobacco product intended exclusively for chewing,

7) "tobacco taken from the nose": non-smoked tobacco product that may be consumed through the nose,

8) "tobacco products taken from the mouth": all the tobacco products taken from the mouth, except those that are intended for inhalation or chewing, and which are made either in whole or in part from tobacco, or in powder or in the form of particles or in any combination of these forms, and in particular the products packaged in one-use packets or in porous little packets.

9) "tobacco products for smoking": tobacco products different from the non-smoked tobacco products,

10) "cigarette": a) the cylinders of tobacco that may be smoked as is, and which are not cigars or small cigarettes, b) the cylinders of smoke which can slide into tubes through a simple non-industrial handling are wrapped in cigarette papers,
11) "cigar": a) the tobacco cylinders with an outer jacket from natural tobacco, b) the tobacco cylinders with a chopped tobacco mix and with outer wrapping in the usual color of the cigar, from re-constituted tobacco, which covers the product completely, and where a filter is needed also, but not the mouth piece as well in the case of products with mouthpiece, where the weight per unit, not including the filter or mouthpiece is not less than 2.3 grams nor larger than 10 grams and the perimeter for at least one third of the length is not less than 34 mm,
12) "cigarillo": cigar of maximum weight 3 grams,
13) "tobacco for hookah": tobacco product that can be consumed through a hookah. For the purposes of the present law, the tobacco for hookah shall be considered as tobacco product intended for smoking. If a product can be used through hookah as well as in tobacco for rolled cigarettes, it is considered tobacco for rolled cigarettes,
14) "new tobacco product": tobacco product which, a) does not belong to none of the following categories: cigarette, tobacco for rolled cigarettes, pipe tobacco, tobacco for hookah, cigar, cigarillo, chewing tobacco, tobacco taken from the nose, and tobacco taken from the mouth, and b) circulates in the market after 19 May 2014,
15) "plant product for smoking": product based on plants, herbs or fruits that does not contain tobacco and that can be used through a combustion process,
16) "electronic cigarette": a product that can be used for the consumption of steam 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,
17) "rechargeable container": a vessel containing liquid with a nicotine content, which may be reused in order to recharge the electronic cigarette,
18) "element": tobacco, additive, as well and any substance or element that are present in the final tobacco product or in similar products, including the paper, filter, inks, cartridges and adhesives,
20) "tar": the unprocessed, anhydrous, non-nicotine
19) "nicotine": the nicotinic alkaloids,
smoke condensate,
21) "emissions": substances that are generated when a tobacco product or similar product is used in accordance to its destination, as the substances in the smoke generated or substances generated during the process of use of non-smoked tobacco products,
22) "maximum level" or "maximum level of emissions": the maximum content or emission, including zero, of a substance in a tobacco product, measured in milligrams,
23) "additive" or "additive substance": any substance, with the exception of tobacco, added to a tobacco product in a packaging unit thereof or in every external packaging,
24) "aromatic": an additive that produces an odor and/or flavor,
25) "characteristic aroma/flavor": clearly perceived smell or flavor, different from the aroma and the flavor of tobacco, resulting from an additive or combination of additives, which include but are not limited to, fruits, spices, aromatic plants, alcohol, caramel, menthol or/ and vanilla, and which is felt before or during the consumption of a tobacco product,
26) "addictiveness": the pharmacological ability of a substance to cause addiction, a condition which affects the ability of a person to control their behavior, usually through a sense of reward or relief from withdrawal symptoms or both,
27) "toxicity": the degree in which a substance may cause harmful effects in the human organism, including the effects that appear with time, usually through repeated or continuous consumption or exposure,
28) "material change of conditions": increase of the sales volume per product category by at least 10% in a minimum of five member – states based on the data for sales forwarded in accordance to paragraph 5 of article 5, or increase in the level of appearance of the use in the consumer group under 25 years of age by at least five percentage units in at least five member – states for the corresponding product category on the basis of the Special Report 385 of the Eurobarometer of May 2012 or equivalent appearance studies; at any rate it is considered that there was no substantial change of conditions noted when the sales volume of a product at retail level did not exceed 2.5% of the total sales of tobacco products at the European Union level,
29) "exterior packaging": any packaging in which tobacco products are available or similar products in the market and which includes a packaging unit or a group of packaging units; transparent wrappings are not considered external packaging,
30) "packaging unit": the smallest individual packaging of a tobacco product or similar product available in the market,
31) "pouch": packaging unit of tobacco for rolled cigarettes either in the form of a rectangular case with a cover covering the opening or in the form of a bag with a level bottom,
32) "health warning": a warning concerning the negative effects on human health of a product, or other undesirable side effects of its use including word warnings, combined health warnings, general warnings, and information messages as provided in the law hereby,
33) "combined health warning": health warning consisting of a combination of a word warning and a corresponding photograph or image, as provided in the laws hereby,
34) "cross border distance sales": distance sales of product to consumers, in the context of which the consumer, when ordering the product from a retail store, is located in a

member state different from the member – state or the third country where the said retail store is established; the retail store is considered to be established in a member – state: a) in the case of a physical person: if this physical person has its business domicile in the said member – state, b) in the other cases: if the retail store has in the said member – state is established domicile, its central administration or the place of business, including a branch, dealership, or any other type of facility,
35) "consumer" : every physical person acting for purposes irrelevant to its commercial, business, industrial or professional activity,
36) "age verification system": computer system that verifies electronically and indisputably the age of the consumer in accordance with the national requirements,
37) "manufacturer": every physical or legal person manufacturing the product or which gives the order to design or manufacture a product, and markets this product in the market under its brand or its trademark,
38)"import of tobacco products or similar products": the entry of the said products into the soil of the European Union, unless the products are subject to customs procedure or under suspension regime upon entry into the Union, as well as their release from customs procedure or suspension regime,
39) "tobacco products or similar products importer": the person having the ownership or the right of disposal over tobacco products or similar products that have been imported into the soil of the Union,
40) "circulation in the market": the disposal of products, irrespective of their place of manufacture, to consumers located in the Union, with or without payment, including distance sales; in cases of cross border distance sales, the product is considered as imported in the market in the member – state in which the consumer is located,
41) "retail store": every store that makes available in the market tobacco products, including the disposal of products by a physical person.

PART B'
TOBACCO PRODUCTS

CHAPTER I
INGREDIENTS AND EMISSIONS

Article 3
Maximum emission levels for tar, nicotine, carbon monoxide, and other substances

(Article 3 of Directive 2014/40)

The maximum emission levels of the cigarettes available in the Greek market or manufactured in the member – states ("maximum emission levels") do not exceed:
a) 10 mg of tar per cigarette,
b) 1 mg of nicotine per cigarette,
c) 10 mg of carbon monoxide per cigarette,

Article 4
Measurement methods
(Article 4 of Directive 2014/40)

1. The emissions of tar, nicotine, and carbon monoxide of the cigarettes are measured on the basis of the standard ISO 4387 for tar, the standard ISO 10315 for nicotine, and the standard ISO 8454 for carbon monoxide. The accuracy of the measurements with regard to tar, nicotine, and carbon monoxide is defined in accordance with the standard ISO 8243,
2. The measurements according to paragraph 1 are verified by an accredited laboratory of the General Chemical State Laboratory or other laboratories, which are accredited by the Independent Accreditation Operational Unit of the National System of Quality Infrastructures (NSQI/ESYP) of article 6 of law 4109/2013 (A' 16). Said laboratories must meet the following criteria:
a. They must be established within the Greek territory,
b. They must not belong or not be controlled directly or indirectly by the tobacco industry,
c. They must have a valid Accreditation Certificate related with the methods covering the requirements of the law hereby and which must be based in the relevant harmonized standard concerning the accreditation of laboratories, ELOTEN ISO/IEC 17025 in the fields of application of the above measurements. The as above criteria may be amended in order to meet the applicable national and EU legislation as the case may be.
3. The accredited laboratories notify to the Department of Risk Factors, Social Factors for the Health and Addictions of the Directorate of Mental Health of the Ministry of Health their Accreditation Certificate following its issue by the Independent Operational Accreditation Unit (ESYD) and they are entered in the catalogue of accredited laboratories maintained by the Health Ministry. Every accredited laboratory is required to immediately inform the Health Ministry in case of suspension or revocation of its accreditation by the Independent Operational Accreditation Unit (ESYD). In the case where a laboratory omits to notify immediately the Health Ministry, then this laboratory shall be excluded from any future inclusion into the catalogue of accredited laboratories. The Health Ministry notifies the decision about the exclusion of the laboratory from the catalogue of accredited laboratories to the tobacco products' manufacturers and importers. A catalogue of accredited laboratories is maintained at the Health Ministry. This catalogue and its amendments are notified to the European Commission. Similarly, the measurement methods for cigarette emissions, except the emissions of tar, nicotine, and carbon monoxide, and for the emissions of tobacco products excepts cigarettes are notified.
4. For verification of the measurements of paragraph 1 conducted in the accredited laboratories of the General Chemical State Laboratories the manufacturers and importers of tobacco products pay in advance a

compensation, in accordance with decision no. 3002640/155/6.2.2002 of the Deputy Finance Minister (B' 161).

Article 5
Notification of the ingredients and of the emissions
(Article 5 of the Directive 2014/40)

1. The manufacturers and importers of tobacco products submit to the Department of Risk factors, Social Factors for Health and Addictions of the Directorate of Mental Health of the Health Ministry, in special format, as defined in the executive decision of the European Commission (EC) 2015/2186 (EC L 312 of the 25.11.2015) and constitutes the Annex III of the law hereby, the following information per brand and type:
a) catalogue of all the ingredients and their quantities that are used in the manufacture of tobacco products, in descending order of weight of each ingredient contained in the tobacco products,
b) the emission levels mentioned in article 3,
c) information related with other emissions and their levels, when available.

For products already available in the market, such information is provided until 20 November 2016.

The manufacturers or importers also notify the Health Ministry if the composition of a product is modified in such a way as to affect the information provided by the force of the article hereby.

For a new or modified tobacco product, the information required pursuant to the article hereby shall be submitted prior to the disposal of the said products in the market.

2. The catalogue of ingredients mentioned in item a' of paragraph 1 is accompanied by a statement explaining the reasons for which said ingredients are contained in the relevant tobacco products. Said catalogue also mentions, the status of the ingredients, including whether it has been registered on the basis of the executive decision of the European Commission 2015/2186, the content of which is an integral Annex of the law hereby under item Annex III, of the Regulation (EC) no. 1907/2006 of the European Parliament and of the Council of 18th December 2006, as well as their classification based on the Regulation (EC) no. 1272/2008 of the European Parliament and of the Council of 16th December 2008.

3. The catalogue mentioned in item a' of paragraph 1 is also accompanied by the toxicological data concerning the ingredients prior or after their combustion, as the case maybe, mentioning in particular their effects on the consumers' health and consideration is given, inter alia, to any addictive properties. In addition, for cigarettes and tobacco for rolled cigarettes, the manufacturer or importer submits a technical document that contains a general description of additives that have been used and their properties. Excluding tar, nicotine, and carbon monoxide and the last verse of paragraph 3 of article 4 emissions, the manufacturers and the importers shall mention the measurement methods of emissions that were used and conduct studies, should they be requested by the Health Ministry, by decision of the Ministry, in order to assess the effects of the ingredients on health, considering, inter alia, their toxicity and their addictiveness.

4. The information submitted pursuant to paragraph 1 and the article 6, are published in a special website of the Health Ministry webpage, which properly takes into account the need for the protection of trade secrets, when publishing such information, and the manufacturers and importers define, upon the submission of the information, in accordance with paragraph 1 and article 6, the information they consider to be trade secret.

5. The manufacturers and importers submit to the Department of Risk Factors, Social Factors for Health and Addictions of the Directorate of Mental Health of the Health Ministry the internal and external studies they have available for market surveys and for the preferences of different consumer groups, including the new and current smokers regarding the ingredients and the emissions, as well as brief descriptions of the market surveys that they conduct in the context of the circulation of new products. The manufacturers and importers mention to the Department of Risk Factors, Social Factors for Health and Addictions of the Directorate of Mental Health of the Health Ministry and to the Finance Ministry the data regarding their sales volume per brand and type expressed in number of cigarettes or kilograms, on an annual basis, in the Greek territory, starting on January 1st 2015.

6. All of the data and information provided to the Health and to the Finance Ministries and from the Health Ministry based on the article 6 hereby are submitted in electronic format. Such data are kept electronically and ensure that the European Commission and the other member – states have access to the said information for the purposes of enforcement of the law hereby. The Health Ministry ensures the confidential handling of trade secrets and other confidential information. The manufacturers and the importers are required to define, upon the submission of the information, in accordance with paragraph 1 hereby and article 6, the information they consider to be trade secret.

Article 6
Ranking catalogue of additives and enhanced requirements for submission of notices
(Article 6 of the Directive 2014/40)

1. Apart from the requirements for submission of notices defined in article 5, shall be applied enhanced requirements for submission of notifications on specific additives contained in cigarettes and tobacco for rolled cigarettes and are included in a ranking catalogue for additives based on the executive act of the European Commission. This catalogue includes additives:

a) for which there exist initial indications, research or regulatory adjustments in other jurisdictions where they imply having one of the properties which are defined in items a' through d' of paragraph 2.
b) which are included in the most common additives used by weight or number according to the notifications of ingredients pursuant to paragraphs 1 and 3 of article 5.
2. The manufacturers and importers of cigarettes and tobacco for rolled cigarettes containing an additive included in the ranking catalogue provisioned in paragraph 1 must conduct extensive studies, which should examine for each additive whether:
a) it contributes to the toxicity of addictiveness of the relevant products and whether this has as a result an increase of toxicity or addictiveness in any of the relevant products to a significant or measureable degree,
b) it has as a result a characteristic aroma/ flavor,
c) it facilitates the inhalation or the taking of nicotine
or
d) it leads to the formation of substances that properties carcinogenic, mutagenic, toxic for reproduction (CMR), in their quantities and to what degree this results in the increase of the CMR properties in any of the relevant products to a significant or measureable degree.
3. Said studies take into account the provisioned use of the relevant products and examine in particular emissions arising from the combustion process in which the relevant additive participates. The studies also examine the interaction of said additive with other ingredients contained in the relevant products. The manufacturers or importers that use the same additive in their tobacco products may conduct a joint study when using the said additive in a comparable composition of the product.
4. The manufacturers or importers draft a report for the results of these studies. Said report includes brief description and an overview compiling the available scientific references for the said additive and summarizes the internal data on the effects of the additive. The manufacturers or importers submit such reports to the Health Ministry, as well as to the European Commission, at the latest 18 months once the relevant additive was included in the ranking catalogue, according to paragraph 1. The Health Ministry as well as the European Commission may also request additional information from the manufacturers or the importers about the relevant additive. This information are part of the report. The Health Ministry, by a decision of the Health Minister, and the European Commission may request the conduct of a comparable analysis of these reports through an independent scientific agency, especially regarding their content, methodology, and their conclusions. The information received helps the Health Ministry and the European Commission in making decisions on the basis of article 7 of the law hereby.
5. In the case where a report is drafted for the said additive by another manufacturer or importer, there is exclusion from the obligations of the article hereby of very small, and medium businesses. The class of very Small and Medium Businesses (SMEs) consists of businesses employing less than 250 employees and of which the annual turnover does not exceed 50 million euros or the total of the annual balance sheet does not exceed 43 million euros. In the class of SMEs, as a small business is defined a business employing less than 50 employees and of which the annual turnover or the total of the annual balance sheet does not exceed 10 million euros. In the class of SMEs, a very small business is considered one employing less than ten employees, and of which the annual turnover or the total of the annual balance sheet does not exceed 2 million euros.

Article 7
Regulation of ingredients
(Article 7 of the Directive 2014/40)

1. It is prohibited to dispose in the market the tobacco products having a characteristic aroma/flavor. It is not prohibited to use additives that are necessary for the manufacture of the tobacco products, for example of sugar that replaces the sugar that is lost during the drying process, on condition that the additives in question do not have as a result a product with characteristic aroma/ flavor and do not increase to a significant or measureable degree the addictiveness, the toxicity, or the CMR properties of the tobacco product. The Health Ministry notifies to the European Commission the measures taken each time in accordance with this paragraph.
2. The Health Ministry, by decision of the Health Minister, may initiate a search procedure on whether a tobacco product falls under the field of application of paragraph 1, informing at the same time the European Commission and the other member – states of the European Union.
3. The Health Ministry may consult with an independent advisory committee, made up at European level, prior to instituting measures in accordance with the paragraphs 1 and 2.
4. It is prohibited to dispose in the market tobacco products containing the following additives:
a) vitamins or other additives that create the impression that a tobacco product is beneficial to health or implies reduced risks to the health,
b) caffeine or taurine or other additives and boosting compounds, which considered to give energy and vitality,
c) additives with pigment properties for the emissions,
d) with regard to the tobacco products for smoking, additives that facilitate the intake of the taking of nicotine,
e) additives having CMR properties prior to their combustion.
5. It is prohibited to dispose of in the market tobacco products containing aromatic substances in any of their elements such as filters, cigarette papers, packaging, capsules or any technical characteristics that allow the modification of the smell or the flavor of the relevant tobacco products or the intensity of the smoke generated. The filters, cigarette papers, and the capsules do not contain tobacco or nicotine.

6. The provisions and the terms provisioned by the Regulation (EC) no. 1907/2006 (REACH) shall be applied on the tobacco products as indicated.
7. It is prohibited, based on scientific evidence, to dispose in the market tobacco products containing additives in quantities that increase the toxic or addictive effect or the CMR properties of a tobacco product at the level of consumption to a significant or measureable degree. The Health Ministry notifies to the European Commission the measures that have been taken in accordance with the paragraph hereby.
8. The tobacco products, except cigarettes and tobacco for rolled cigarettes are exempt from the restrictions provisioned in the paragraphs 1 and 5.
9. The Health Ministry may initiate a procedure to assess to what extend a tobacco product has characteristic aroma/ flavor, to what extend there is use of prohibited additives or aromatic agents, and to what extend a tobacco product contains additives in quantities that increase to a significant and measureable degree the toxic or addictive effect or the CMR properties of the relevant tobacco product. The Committee of article 17 paragraph 3 of the law hereby is competent to ascertain the existence of the prohibited ingredients of this article. The Committee takes over following an order of the Health Minister or following a complaint by anyone and submits its relevant proposal to the Health Minister, who, following the concurrent opinion of the Committee prohibits the circulation of products the composition of which in not in line with the provisions of the article hereby.
10. In the case of tobacco products with characteristic aroma/flavor the sales of which at Union level correspond to at least 3% of a specific category of products, the provisions of the article hereby shall be effective as of the 20th May 2020.
11. The article hereby shall not apply on tobacco that is taken orally.

CHAPTER II
LABELING AND PACKAGING

Article 8
General Provisions
(Article 8 of the Directive 2014/40)

1. Every packaging unit of tobacco products and each of the external packaging thereof that is available in the Greek market, bears all of the warnings for health provisioned in the Chapter hereby in the Greek language.
2. The health warnings cover the entire surface of the packaging or of the external packaging intended for these and are not to be commented upon, paraphrased or cited in any form.
3. These health warnings on the packaging unit and on every external packaging are printed in such a way as to not be possible to remove, are permanent and fully visible, as well as that they shall not be hidden in part or in whole no are they interrupted by tax stamps, written price labels, security features, wrappers, covers, boxes or other objects, when the tobacco products are made available in the market. In the packaging units of tobacco products, except cigarettes and tobacco for rolled cigarettes in pouches, the health warnings may be affixed with self-adhesive stickers, on condition that such stickers cannot be removed. The health warnings remain intact with the opening of the packaging unit, except in the packs with a jointed cap, when the health warnings may be torn with the opening of the package, but only in a way that ensures the graphic integrity and the visibility of the text, the photographs, and of the information about rehabilitation from smoking.
4. The health warnings do not hide, nor do they interrupt in any way the tax stamps, the price writing labels, the tracking and tracing signals, or the security features in the packaging units.
5. The dimensions of the health warnings provisioned in the articles 9, 10, 11 and 12 are estimated in relation to the relevant surface when the package is closed.
6. The health warnings are surrounded by a black outline 1mm thick inside the surface intended for the said warnings, with the exception of the health warnings pursuant to article 11.
7. The images of the packaging unit and of every external packaging that are addressed to consumers in the Union are in compliance with the provisions of the Chapter hereby.

Article 9
General warnings and information messages for tobacco products for smoking
(Article 9 of the Directive 2014/40)

1. Each packaging unit and each external packaging of tobacco products for smoking bears the following general warning: "Smoking kills".
2. Each packaging unit and each external packaging of tobacco products for smoking bears the following information message: "Cigarette smoke contains over 70 substances, which are known to cause cancer."
3. On the cigarette packets and on the tobacco for rolled cigarettes in packets or rectangular shape, the general warning appears on the bottom part of one of the side surfaces of the packaging units and the information message appears at the bottom part of the other side surface. These health warnings have a width of at least 20 mm. For the hard packets in the form of case in which the sides surfaces are split in two parts when the packet opens, the general warning and the information message appear in their entirety on the large sections of the said surfaces that are separated. The general warning appears also in the interior of the upper surface, which is visible when the packet is open. The side surfaces of this type of

packet have a height of at least 16 mm. In the tobacco for rolled cigarettes sold in a pouch, the general warning and the information message appear on the surfaces that ensure complete visibility of such health warnings. In the tobacco for rolled cigarettes in cylindrical packets, the general warning appears on the external surface of the cap and the information message on the interior surface of the cap. Both the general warning and the information message shall cover at least 50% of the surface where they are printed.

4. The general warning and the information message mentioned in the paragraphs 1 and 2:

a) are printed in bold black fonts type Helvetica on a white background with the font being optional, on condition that the size of the fonts ensures that the relevant text covers the greatest possible part of the surface intended for the said health warnings, and b) they are aligned at the center of the surface provisioned for these, while in the packets of rectangular shape, as well as in any external packaging these are aligned parallel to the side edge of the packaging unit or of the external packaging.

5. The exact location of the general warning and of the information message regarding the tobacco for rolled cigarettes available in the market in a pouch it is defined by the Executive Decision 2015/1735 (ED) of the European Commission of the 24th September 2015 and it is put into effect as of the effective date of the law hereby, as it is represented in Annex IV of the law hereby.

Article 10
Combined health warnings on tobacco products for smoking
(Article 10 of the Directive 2014/40)

1. Each packaging unit and each external packaging of tobacco products for smoking bears combined health warnings. The combined health warnings:

a) contain word alerts that are given in Annex I and a corresponding colored image that is defined in the image library of the Annex II,

b) include the website www.moh.gov.gr ("Rehabilitation Information: www.moh.gov.gr ") to provide information for rehabilitation from smoking that are intended to inform consumers regarding available support programs for those who wish to quit smoking,

c) cover 65% of the external front as well as of the rear surface of the packaging unit, as well as every external packaging. The cylindrical packets bear two combined health warnings at equal distance between one another, with each one covering 65% of the corresponding half of the surface curve,

d) have the same worded warning and the corresponding color image on both sides of the packaging units and each external packaging,

e) they appear on the upper end of the packaging unit and every other external packaging and they are placed in the same direction with all of the other information written in the said surface of the packaging. A transitional exception is provided from the said requirement about the location of the combined health warning as follows:

aa') wherever the tax stamp (tax strip) or the national identity sign that is used for tax purposes is affixed on the upper end of a packaging unit from cardboard, the combined health warning that must appear on the rear surface is placed exactly under the tax stamp or the national identity sign,

bb') when a packaging unit is made from soft material, a rectangular space is allowed of a height that does not exceed 13 mm between the upper end of the packet and the upper end of the combined health warnings, which must be allocated for the tax stamp (tax stamp strip), or the national identification sign used for tax purposes.

The exceptions mentioned in the items aa' and bb' apply for a period of three (3) years following the effective date of the law hereby. No trademarks or logos shall be placed over the health warnings,

f) they are reproduced according to the format, arrangement, design and proportions that are defined by the European Commission,

g) in the case of cigarettes packaging unit, they have the following dimensions:

aa) height: at least 44 mm
bb) width: at least 5.2 mm

2. The combined health warnings are combined in three sets as these are set out in Annex II, and each set is used as follows:

Set A': from the start of effect of the law hereby to the 31.12.2017
Set B': from 1.1.2018 to 31.12.2018
Set C': from 1.1.2019 to 31.12.2019

and it is alternated annually, following the same order. Every combined health warning made available for use in a specific year appears if possible in equal numbers on every brand of tobacco products.

3. The Executive Decision (ED) no. 2015/1842 of the European Commission of 9th October 2015 sets out the technical specifications regarding the arrangement, the design, and the shape of the combined health warnings, as it is represented in the Annex V of the law hereby.

Article 11
Labeling of tobacco products for smoking except cigarettes, tobacco for rolled cigarettes, and tobacco for hookah
(Article 11 of the Directive 2014/40)

1. In addition the general warning pursuant to paragraph 1 of article 9, each packaging unit and each external packaging of the tobacco products for smoking except cigarettes, tobacco for rolled cigarettes and tobacco for hookah bears one of the verbal warnings given in Annex I. The general warning pursuant to paragraph 1 of article 9 includes reference to the support services for smoking rehabilitation, which is mentioned in item b of paragraph 1 of article 10. The general warning appears on the most visible surface of the packaging unit and each external

packaging. Each verbal wording appears, as much as possible, in equal number on each brand of these products. The verbal warnings appear on the next more visible surface of the packaging unit and every external packaging. In the packaging units of case type, the next more visible surface is the one shown when the packet is opened.
2. The general warning pursuant to paragraph 1 covers 30% of the relevant surface of the packaging unit and of each external packaging.
C3) The verbal warning pursuant to paragraph 1 covers 40% of the relevant surface of the packaging unit and of each external packaging.
4. When the health warnings mentioned in paragraph 1 must appear on a surface that exceeds 150 cm^2, the warnings cover an area of 45 cm^2.
5. The health warnings mentioned in paragraph 1 meet the requirements defined in paragraph 4 of article 9. The text of the health warnings is parallel to the main text on the surface intended for these warnings. The health warnings are surrounded by a black outline of thickness at least 3 and at most 4 mm. Said outline appears outside the surface intended for the health warnings.

Article 12
Labelling of non-smoked tobacco products
(Article 12 of the Directive 2014/40)

1. Each packaging unit and every external packaging of the non-smoked tobacco products bears the following health warning: "This tobacco product is harmful to your health and it is addictive."
2. The health warning mentioned in paragraph 1 meets the requirements defined in the article 9, paragraph 4. The text of the warnings is parallel to the main text in the surface intended for these warnings. In addition: a) it appears on the two larger surfaces of the packaging unit and every external packaging, b) covers 30% of the surfaces of the packaging unit and every external packaging.

Article 13
Product presentation
(Article 13 of the Directive 2014/40)

1. The labelling of the packaging units and every external packaging, as well as the tobacco product itself do not include any element or characteristic which:
a) promotes the tobacco product or encourages its consumption creating the wrong impression concerning its characteristics, its effects on health, the risks or the emissions; the labelling does not include information related with the content in nicotine, tar, or carbon monoxide of the tobacco product,
b) suggests that a specific tobacco product is less harmful than others or tends to reduce the effects of certain harmful ingredients of tobacco or it has revitalizing properties, properties that provide energy or therapeutic, rejuvenating, physical or biological properties or it offers other benefits for health or to social behavior,
c) refers to taste, smell, aromatic substances or other additives or points out their absence,
d) is similar to food product or to cosmetics,
e) suggests that a specific tobacco product has an improved biodegradability or other environmental benefits.
2. The packaging units and every external packaging do not suggest financial benefits having printed coupons, offering discount or free distribution or including offers of they type "two for the price of one" or similar offers.
3. The prohibited details and characteristics pursuant to paragraphs 1 and 2 may include texts, symbols, names, trademarks, images or other signs, without being exhausted to these.

Article 14
Appearance and content of the packaging units
(Article 14 of the Directive 2014/40)

1. The cigarette packaging units have a rectangular shape. The tobacco packaging units for rolled cigarettes have a rectangular shape or cylindrical or pouch shape. The cigarette packaging units contain at least 20 cigarettes. The tobacco for rolled cigarettes packaging units contain tobacco weighing at least 30 gr.
2. The cigarette packaging units may consist of cardboard or of soft material and they do not have an opening that can be closed again or resealed after the first opening, except the packets with joint cap and the case type packets. In the packets with joint cap and in the case packets to cap is jointed only with the rear part of the packaging unit.

CHAPTER III
TOBACCO TAKEN ORALLY AND NEW PRODUCTS

Article 15
Tobacco taken orally
(Article 17 of the Directive 2014/40)

It is prohibited to circulate in the market tobacco taken orally.

Article 16
Cross-border distance sales of electronic cigarettes and refill containers
(Article 18 and 20 par. 6 of the Directive 2014/40)

1. The cross-border distance sales from abroad to Greece of electronic cigarettes and refill containers is prohibited. Nevertheless, the cross-border distance sales from Greece to abroad of electronic cigarettes and refill containers is allowed on condition that the member – states in the

market of which these products will be made available have not restricted the said cross-border sales.

2. Retail stores that desire to sell to consumers in another member – state of the European Union electronic cigarettes and refill containers must: a) use a consumer age verification system according to which the consumer has, at the moment of sale, the required age for the purchase and consumption of the product, which is valid in the member – state of the European Union in which the products are going to be available in the market, b) to be entered in a special registry maintained at the Department of General Security of Products of the Directorate of Quality Policy of the General Directorate for Enforcement of Regulations, Infrastructures and Control of the General Secretariat of Industry of the Ministry of Economy, Development, and Tourism, in order to enter in a similar registry maintained in the member – state of the European Union in the market of which the products will be made available.

3. The entry in the special registry maintained in the Department of General Security of Products of the Directorate of Quality Policy of the General Directorate for Enforcement of Regulations, Infrastructures and Control of the General Secretariat of Industry of the Ministry of Economy, Development, and Tourism includes the following information:

a) name or company name and permanent address of the business location of the company,

b) the start date of the export activity of the company through internet services,

c) address of the website or websites used for said activity and any relevant information to locate the website.

The Department of General Security of Products of the Directorate of Quality Policy of the General Directorate for Enforcement of Regulations, Infrastructures and Control of the General Secretariat of Industry of the Ministry of Economy, Development, and Tourism issues a registration certificate of the as above retail stores in the registry of the paragraphs 2 and 3. Having this certificate is necessary for the legal disposal of these products abroad with the reservation of the paragraph 1.

5. The destination member – states of the electronic cigarettes and the refill containers may require from the retail stores to assign a physical person as the one in charge, in order to verify, before the disposal of the products in the destination member – state market that the products for the cross-border disposal comply with the requirements of the law hereby. Also, the electronic cigarettes and refill containers retails stores submit to the competent authorities of the destination member – states of the products for disposal a description of the details and the operation of the age verification system they have pursuant to paragraph 2 case a'.

6. The personal data processing of the consumers by the retail stores is carried out in accordance with law 2472/1997 (A' 50). The electronic cigarettes and refill containers retail stores conducting cross-border sales abroad do not reveal the personal data of the consumers of their products abroad neither to the manufacturers of electronic cigarettes and refill containers, nor to the companies belonging to the group with these manufacturers, nor to any other third party. The consumers' personal data are neither used nor transferred for any other purposes beyond the specific cross – border market. The same applies also in the case that the retail store belongs to the manufacturer of electronic cigarettes and refill containers.

Article 17
Notification – licensing of new tobacco products (Article 19 of the Directive 2014/40/EC)

1. The manufacturers and importers of new tobacco products are required to submit a notification to the Health Ministry for each such product that they intend to circulate in the Greek market. The notification is submitted in electronic format six (6) months prior to the provisioned disposal in the market and it is accompanied by a detailed description of the relevant new tobacco product, as well as by its instructions for use and the information provisioned by the article 6 regarding the ingredients and the emissions. The manufacturers and the importers submitting notification for a new tobacco product shall also provide:

a) the available scientific studies for toxicity, risk of addiction, and attractiveness of the new tobacco product, especially with regard to its ingredients and emissions,

b) the available studies, the summary descriptions thereof and the market surveys related with the preferences of different consumer groups, including the new and the current smokers,

c) other available and relevant information, among which is also the risk/ benefit analysis of the product, its expected consequences on the stop of tobacco consumption, its expected consequences at the start of the tobacco consumption and their projected effects on the consumers.

2. The manufacturers and importers of new tobacco products are required to forward any new and updated information related with the studies, the research, and other information mentioned in the items a' through c' of paragraph 1. The Health Ministry may require the manufacturers or the importers of new tobacco products to carry out additional testing or to submit supplementary information. The Health Ministry shall make available to the disposal of the European Union all of the information received by the force of the article hereby.

3. A five-member committee is created for the evaluation of new tobacco products, which consists of one (1) representative of the Health Ministry and his deputy, one (1) representative of the Finance Ministry and his deputy, one (1) representative of the Ministry of Economy, Development, and Tourism and his deputy, one (1) representative of the National Medicines Organization (EOF) and his deputy, and one (1) representative of the Greek Pulmonary Society and his deputy. In order to

establish the committee, the Finance Ministry, the Ministry of Economy, Development, and Tourism, EOF, and the Greek Pulmonary Society appoint their representatives by a document addressed to the Health Minister. The Health Minister, once he appoints the representatives of his Ministry establishes a committee by his decision. In the case that the National Medicines Organization (EOF) and the Greek Society do not appoint representatives, then the Health Minister shall appoint two additional persons, that is one EOF employee and one lung specialist – Director of the National Health System (ESY), or a pulmonologist Faculty Member from a University Hospital. The term of office of the committee members is two years.

4. The manufacturers and importers of new tobacco products are required, at least four (4) months before a new tobacco product is released in circulation to file a technical envelope with the Committee of paragraph 3, or, in the case where the Committee of paragraph 3 has not been established, with the Health Minister. The envelope is filed in writing and electronically and comprises the following:

a) what is mentioned in paragraph 1,

b) the evidence of full compliance of all the ingredients and of their electronic details with the relevant security standards and maintenance of all the relevant regulatory requirements,

c) a complete qualitative and quantitative record of all the ingredients and their emissions,

d) description of the technical characteristics of the devices and their electronic details,

e) draft instructions of use and labelling,

f) toxicological studies and physico-chemical tests involving the ingredients of the new tobacco products and their emissions, according to which the substances contained, and the substances that are released during the operation of the products that fall under the field of application of the law hereby do not pose any risk to health in the sense of the EC regulations 1907/2006 and 1272/2008. The toxicological studies are conducted in accordance with the Principles of Proper Laboratory Practice (PLP) and according to the Regulation (EC) 440/2008 (EEL 142/). The laboratories where the toxicological studies are conducted are accredited according to the Proper Laboratory Practice Principles and the laboratories where the physico-chemical tests are conducted are accredited according to the standard EN ISO 17025.

g) description of the production process and of the quality assurance measures, which must be taken,

h) report of safety assessment of the devices,

i) solemn statement of compliance to the specifications of the law hereby whether it is about a new tobacco product falling under the definition of non-smoked tobacco product, or the definition of tobacco product for smoking,

j) epidemiological or/and clinical studies that have been conducted in accordance with the principles of proper clinical practice as long as they involve the product under licensing,

k) receipt of payment of deposit 1,000 euros for the review of the technical envelope, as defined in the article 25.

The scientific data that are notified with the technical envelope are covered by industrial and commercial secrecy.

5. If, within thirty (30) days from the filing of the technical envelope, the Committee finds that the technical envelope is not complete, or that it is not evident from the data submitted that the legal requirements for licensing are not met, invites the interested party to supplement or correct the data of the envelope by setting a relevant deadline for them.

6. Each member of the Committee reviews the data of the envelope falling under the competence of the Ministry they represent and drafts, along with the other members of the Committee, a joint opinion (concurrent opinion) to the Health Minister for licensing or not of the product, within a term of three (3) months from the filing of the envelope in accordance with what is set out in paragraph 4 hereby. For the acceptance or the rejection of the request for license a decision by the Health Minister is issued, who takes into account the concurrent opinion of the Committee.

7. If the Committee issues opinion in favour of rejecting the request due to idle lapse of the term of paragraph 5, the license request is required to be rejected.

8. If the opinion is not drafted within the three-month term of paragraph 6, the Committee is required to justify specifically and substantiate by its document addressed to the Health Minister its inability to exercise its competence to render an opinion. The Health Minister, once he considers as reasonable the justification of the Committee, he may extend the term for opinion rendering for one (1) more month. In the case where this last deadline lapses idle, then the new tobacco product is placed, legally in circulation without the relevant license. If, belatedly, there is a negative opinion drafted, the Health Minister is required by his decision to prohibit the circulation of the product.

9. The licensing involves exclusively the product as it is outlined in the technical envelope filed and covers only the manufacturer and the importer, to whom it was granted. Any planned modification on the product to be licensed product must be notified to the Committee of paragraph 3. The latter decides on whether the planned modifications are so significant in order to require a new evaluation and licensing of the new product.

10. If, during the review, inspection, or sampling conducted by the supervisory authorities there are material modifications found on the licensed product, for which the Health Ministry was not notified, according to paragraph 9, the license for release may be revoked.

11. The manufacturer and the importer of an already licensed new tobacco product are required to immediately notify the Health Ministry in case of appearance of any undesired ingredient on any user of their products. In this case the Committee of paragraph 3 takes over, and there is immediate activation of the procedure of the paragraphs 3 through 9, which is applied appropriately.
12. The new tobacco products released in the market must observe the specifications of the law hereby. The induction of these products under the provisions hereby depends on whether the said products fall under the definition of a non-smoked tobacco product, or tobacco product for smoking.

PART C'
ELECTRONIC CIGARETTES AND PLANT PRODUCTS FOR SMOKING

Article 18
Electronic cigarettes
(Article 20 of the Directive 2014/40/EC)

1. The electronic cigarettes and refill containers become available in the market only when they observe the provisions hereby and the other provisions of the legislation in place. The law hereby is not applied on electronic cigarettes and their refill containers that are subject to licensing requirement of the joint decision no. 31637/2004 of the Ministers of Economy and Finance, Health and Social Solidarity (B' 1176) 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).
2. The manufacturers and importers of electronic cigarettes and refill containers file notice with the Department of Risk Factors, Social Factors for Health and Addictions of the Directorate of Mental Health of the Health Ministry for any relevant products that they intend to put into the market. The notice is filed electronically six (6) months prior to the provisioned disposal in the market in common format, as defined by the decision 2015/2183 executive decision of the European Commission of the 24th November 2015, as this is represented in the Annex VI of the law hereby. With regard to electronic cigarettes and refill containers that are already circulating in the market upon the start of the effect of the law hereby, the notice is filed within six (6) months from the start of effect of the law hereby. A new notice is filed for each material modification of the product. Depending on whether the product is electronic cigarette or refill container, the notice contains the following information: a) the name and contact details of the manufacturer, the legal or physical person responsible within the Union and, as the case may be, of the importer in the Union, b) list of all the ingredients contained in the product and of all the emissions from its use, per brand and type, including these quantities, c) toxicological data involving the said ingredients and emissions of the products, among others when they are heated, mentioning specifically their effects on the health of the consumers when inhaled, and taking also into account, inter alia, any addiction effects, d) information related with the dosage and taking of nicotine, when the product is consumed under normal or reasonably predictable conditions, e) description of the ingredients of the product, including, as the case may be, the mechanism of opening and refill of the electronic cigarette or the refill container, f) description of the production process, inter alia if it includes production in series, and statement that the production process meets the requirements of the article hereby, g) statement that the manufacturer and the importer have complete responsibility for the quality and safety of the product when made available in the market and it is used under normal or reasonably predictable conditions. When it is considered that the information submitted is incomplete, the relevant information supplementation may be requested by the competent Department of Risk Factors, Social Factors for Health and Addictions of the Directorate of Mental Health of the Health Ministry.
3. The electronic cigarettes and the refill containers must meet the following specifications: a) the liquid containing nicotine is made available in the market only in special refill containers, the volume of which does not exceed 10 ml, in disposable electronic cigarettes or disposable vials, and the volume of the vials or containers does not exceed 2 ml, b) the liquid containing nicotine does not contain nicotine that exceeds 20 mg/ml, c) the liquid containing nicotine does not contain the additives given in the paragraph 4 of article 7, d) for the manufacture of the liquid containing nicotine only highly pure ingredients are used. Substances different from the ingredients of item b' of the fifth verse of the paragraph 2 exist only at the level of traces in the liquid containing nicotine, when such traces cannot be avoided technically during the manufacture, e) excluding nicotine, only ingredients that are not harmful to the human health are used in the liquid containing nicotine in heated form or not, f) the electronic cigarettes dispense the nicotine dosages in constant levels under normal conditions of use, g) the electronic cigarettes and the refill containers are protected from children and cannot be tampered with, they are protected from breaking and leakage and have a mechanism that ensures refill without leakage.
4. The electronic cigarettes and the refill containers must also meet the following specifications:
a) The packaging units of electronic cigarettes and refill containers contain an information leaflet (also in Greek) with information involving: aa) instructions for use and storage of the product, as well as reference that the use of the product is not recommended to young people non-smokers, bb) the counter indications, cc) the warnings for specific risk groups, dd) any harmful effects, ee) the risk of addiction and the toxicity, ff) the contact details of the manufacturer or the importer and of the legal or physical person to contact within the Union.

b) the packaging units and all external packaging of electronic cigarettes and refill containers: aa) include a list of all the ingredients contained in the product in descending order of weight and mention the nicotine content of the product and the administration per dosage, the receiving batch number, and a recommendation in Greek for the product to be kept away from children, bb) with the reservation of item aa) of the item hereby, they do not include details or characteristics mentioned in the article 13, except the items a' and c' of the paragraph 1 of articles 13 related with the information involving the content in nicotine and concerning the aromatic materials, cc) have the following health warning:

"The product contains nicotine which is extremely addictive substance."

c) the health warnings observe the requirements defined in the paragraph 2 of article 12.

5. In relation to the electronic cigarettes and refill containers the following restrictions shall apply:

a) commercial communication on the internet, the press and other print media with the purpose or a direct or indirect result the promotion of electronic cigarettes and refill containers are prohibited, excluding the print media intended exclusively for professionals in the trade of electronic cigarettes or refill containers and of the print media printed and circulating in third countries, where the print media in question are not intended primarily for the market of the Union,

b) the commercial communication in television and radio with the purpose or with direct or indirect result the promotion of electronic cigarettes and refill containers are prohibited,

c) any form of public or private contribution to radio and television programs with the purpose or a direct or indirect result the promotion of electronic cigarettes and refill containers is prohibited,

d) any form of public or private contribution to any event, activity, or person with the purpose or the direct or indirect result the promotion of electronic cigarettes and refill containers, which is carried out in more than one member – states or in which participate more than one member – states or has cross-border effects in another way is prohibited,

e) all audiovisual commercial communications on which is applied the Presidential Decree 109/2010 (A' 190) for electronic cigarettes and refill containers are prohibited.

6. The manufacturers and importers of electronic cigarettes and refill containers submit to the Department of Risk Factors, Social Factors for Health and Addictions of the Directorate of Mental Health of the Health Ministry and the Finance Ministry, annually: a) overall data on the sales volumes, per brand and type of the product, b) information on the preferences of different consumer groups, including also youth, non-smokers, and the major kinds of the current users, c) the sale method of the products, and d) brief descriptions of any market surveys carried out related with the above, including their translation in English. 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.

7. In a website of the Health Ministry is published information that has been taken in accordance with paragraph 2, in observation of the provisions regarding commercial secrecy. The Health Ministry, 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. The Health Ministry ensures the confidential handling of the commercial secrecy and of the other confidential information.

8. The manufacturers, the importers and the distributors of electronic cigarettes and refill containers create and maintain a system of collecting information related with possible harmful consequences of these products on the human health. If any of the said financial undertakings considers, or deems reasonably that electronic cigarettes or the refill containers within their possession and are intended for disposal in the market or/ and are available in the market, are not safe or of good quality, or they fail to comply otherwise with the provisions of the law hereby, the said financial undertaking takes the necessary corrective measures immediately in order to ensure for compliance with the provisions hereby, the withdrawal or the recall of the product, as the case may be. In these cases, the financial undertaking is required to immediately inform the market supervisory authorities, as these are defined in the article 23, as the case may be. Also, the financial undertaking is required to inform the supervisory authorities of the member – states, where the product is available or is going to be available, providing specific details related with the risk for human health and safety, any corrective measure that has been taken and the results of the said measures. The Health Ministry may also request additional information from the financial undertaking, especially in relation to the aspects of safety and quality or elated with any harmful consequences of the electronic cigarettes or the refill containers.

9. Regarding the electronic cigarettes and the refill containers that meet the requirements of the article hereby, when the Health Ministry finds or has grounds top believe that specific electronic cigarettes or refill containers, or a type of electronic cigarettes or refill containers may pose a serious risk on human health, it may, by decision of the Health Minister, restrict its circulation in the market temporarily. The Health Ministry notifies without neglect 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.

Article 19
Plant products for smoking
(Article 21 of the Directive 2014/40/EC)

1. Each packaging unit and every external packaging of plant products for smoking includes the following health warning:
"Smoking this product is harmful to your health".
2. The health warning is printed on the front and rear external surface of the packaging unit and in every external packaging.
3. The health warning complies with the requirements defined in the paragraph 4 of article 9. It covers 30% of the surface of the corresponding side of the packaging unit and every external packaging.
4. The packaging units and all of the external packaging of plant products for smoking do not include any of the details or characteristics that are defined in the items a', b' and d' of the paragraph 1 of article 13 and do not mention that the product does not contain additives or aromatic agents.

Article 20
Notification of ingredients of plant products for smoking
(Article 22 of the Directive 2014/40/EC)

1. The manufacturers and importers of plant products for smoking submit to the Department of Risk Factors, Social Factors for Health and Addictions of the Directorate of Mental Health of the Health Ministry a list of all the ingredients and their quantities that are used in the manufacture of these products per brand and type. The manufacturers or importers also notify the Health Ministry when the composition of a product is modified in such a way as to affect the information that are submitted by the force of the article hereby. The information required according to the article hereby is submitted prior to the disposal of a new or modified plant product for smoking in the market.
2. The Health Ministry website at www.moh.gov.gr has published the information that is to be submitted according to paragraph 1, observing the provisions on commercial secrecy, in the case that the said information is published. The financial undertakings determine exactly which information they consider to be commercial secret.

Article 21
Cooperation and compliance
(Article 23 of the Directive 2014/40/EC)

1. The manufacturers and importers of tobacco and similar products provide the Health Ministry and the other competent authorities of the article 23 hereby, as well as to the European Commission, within the defined deadlines, complete and accurate information that are requested in accordance with the provisions of the law hereby. The requirement to provide the required information burdens primarily the manufacturer, if the manufacturer is established in the Union. The requirement to provide the information requested burdens primarily the importer, if the manufacturer is established outside the Union and the importer is established in the Union. The obligation to provide the requested information burdens jointly the manufacturer and the importer, if both are established in the Union.
2. The tobacco products and similar products shall not become available in the market if not compliant with the provisions hereby. Tobacco products and similar products shall not become available in the market if the notification obligations provisioned by the provisions of the law hereby are not observed.
3. The national competent authorities cooperate with each other, with the authorities of the member – states of the European Union and with the European Commission in order to ensure the proper application and enforcement of the provisions of the law hereby and exchange all of the necessary information with the view to their application in a uniform fashion.

Article 22
Free circulation
(Article 24 of the Directive 2014/40/EC)

1. The competent authorities do not prohibit or restrict the disposal in the market of tobacco products or similar products that comply with the provisions hereby and with the reservation of the paragraphs 2 and 3.
2. Further requirements may be instituted by decision of the Health Minister applicable to all of the products that are available in the Greek market, related with the standardization of the packaging of tobacco products, when this is justified for the purposes of public health, taking into consideration the high level of protection of human health achieved through the provisions of the law hereby. The said measures must be according to the principle of proportionality and they cannot constitute means of arbitrary discrimination or covert restriction on the trade between the member-states. These measures are notified to the European Union along with the justification regarding their maintenance or their institution.
3. It is possible to prohibit by decision of the Health Minister, taking also into account the high level of protection of the human health achieved through the provisions hereby, a certain category of tobacco products or similar products, when the restriction is justified by the need for the protection of public health. These decisions of the Health Minister are notified to the European Commission accompanied by a clarification of the reasons for being instituted. The Commission, within six (6) months from the date of acceptance of the notification provisioned in the paragraph hereby, approves or rejects the national provisions. If the decision is not made by the European Commission within the 6-month term it is

considered that the national provisions have been approved.

Article 23
Competent Authorities
(Article 26 of the Directive 2014/40/EC)

1. Competent National Authority to exercise the duties resulting from the provisions of the law hereby is the Health Ministry (Department of Risk Factors, Social Factors for Health and Addictions of the Directorate of Mental Health of the Health Ministry) in collaboration with the General Secretariat of Industry of the Ministry of Economy, Development, and Tourism, the Directorate of Energy, Industrial, and Chemical Products and the Regional Chemical Services of the General Chemical State Laboratory, as well as the General Directorate of Customs and Special Consumption Taxes (SCT/EFK) and the Customs of the General Secretariat of Public Revenues of the Finance Ministry. The competent Authorities see to the application of the provisions of the law hereby, coordinate and control the actions of the familiar services under their supervision.
2. Competent authorities of market supervision are appointed to be the Health Services of the Local Government Organizations 2nd degree, the Trade Services of the Regional Units of the Country, the customs and the regional Chemical Services of the General Chemical State Laboratory. The market supervisory authorities conduct controls, inspections, sampling and implement control programs in the market, when required, for the evaluation of the application of the provisions of the law hereby. The controls, inspections, and sampling in the market and in the production, packaging, storage, and distribution areas are conducted as the case may be and by reason of competence by the above competent market supervisory authorities either individually or by mixed teams.
3. The General Chemical State Laboratory is competent to carry out the physical-chemical control and the control of classification, labelling and packaging of the products that fall under the provisions of the law hereby. The controls, sampling, examinations, examinations by appeal and any other relevant topic regarding samples are conducted in accordance with the provisions of the decision no. 1100/1987 of Finance Minister (B' 788, Coding and compiling of the provisions of the Code of Foods and Drinks by a system of mobile sheets of Objects) and the provisions of Law 4177/2013 (A' 173) with the reservation of other special and provisions as the case may be.
4. To control the electronic cigarettes device, the relevant labelling, the battery of the refill mechanism of electronic cigarettes that fall under the provisions of the no Z2/2810/`14.12.2004 decision of the Ministers of Interior, Public Administration and Decentralization, Economy and Finance, Development, Health and Social Solidarity, Justice, Transportation and Communications (B' 1885) is taken over by the competent service of the General Secretariat of Industry, Directorate of Quality Policy of the Ministry of Economy, Development, and Tourism. More specifically, for the electrical and other electric materials concerning the electronic cigarette (charger of the electronic cigarette either sold as integral piece of the device or individually) is taken over by the service of the General Secretariat of Industry (Directorate of Technical Industrial Legislation) of the Ministry of Economy, Development and Tourism, under the competence of which fall the provisions of the legislation for electrical materials intended to be used within certain voltage limits in accordance with the decision no., Fin. 51157/DTIL 1129/17.5.2016 of the Minister of Economy, Development and Tourism – Environment and Energy (B' 1425).
5. The Competent Authorities and Control Agents for the enforcement of the provisions of the article 24 paragraphs 1 and 2 are the agencies of article 5 of Law 3730/2008 (A' 262). The relevant procedure is regulated by the number G.R. fin. 104720/2010 of the Ministers of Interior, Decentralization and Electronic Governance, Finance, Labor and Social Security, Health and Social Solidarity, Protection of the Citizen, Culture and Tourism (B' 1315), by the no. Y1/G.R./fin. 93828/2011 (B' 2026) decision, of the Ministers of Finance, Health and Social Solidarity, by the no. Y1/G.R./fin. 76017/29.7.2002, decision of the Minister of Health and Welfare (B' 1001).
6. The Control Sector of Public Health and Mental Health of the Corps of Health and Welfare Services Inspectors (C.H.W.S.I.) investigates the relevant complaints for violations, collaborates according to its competence with the other review Authorities, verifies violations and imposes fines for the proper application of the provisions hereby.
7. For the application of the provisions of the law hereby, the market supervisory authorities, as well as the control agencies for the application of the provisions of article 24 paragraphs 1 and 2, during the execution of their work and following their request, they are assisted by the local police and other authorities, which are required to respond.
8. The competent authorities conduct special and sudden inspections and sampling in order to ascertain the degree of compliance with the requirements of the provisions hereby and the control agents of the article hereby draft monthly reports with detailed data related with the results of the controls and the finding of violations and send these under the responsibility of the Director of the service, under which fall the control agents that found the violation to the competent Department of Risk Factors, Social Factors for Health and Addictions of the Directorate of Mental Health of the Health Ministry as well as the competent service of the Finance Ministry.

Article 24
Sanctions
(Article 21 of the Directive 2014/40/EC)

1. For the sale and advertisement of tobacco products, new tobacco products, electronic cigarette and plant products for smoking shall apply the provisions of article 2 of the law 3730/2008 (A' 262) and the provisions 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' 315). Also, on the tobacco products, the new tobacco products, the electronic cigarette and plant products for smoking, shall apply the provisions of no. Y1/G.R., fin. 81348/2005 of the decision of the Ministers of Interior, Public Administration and Decentralization, Economy and Finance, Health and Social Solidarity, Minister of the State (B' 1075).
2. For the use of tobacco products, new tobacco products, the electronic cigarette and plant products for smoking shall apply the provisions of article 3 of the Law 3730/2008 (A' 262) and the provisions of article 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). Also, on the tobacco products, new tobacco products, electronic cigarette and on the plant products for smoking shall apply the provisions of the no. Y1/G.R./fin., 76017/2002 decision of the Minister of Health and Welfare (B' 001) and the provisions of the no. Y1/G.R./fin., 93828/2011 decision of the Ministers of Finance, Health and Social Solidarity (B' 2026).
3. 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 in violation of the articles 5, 6 and 7 of the law hereby and in case of false notification in violation of the articles 5, 6 and 7 of the law hereby there will be imposing, by decision of the Health Minister, a fine of four hundred (400) euros per product. By a joint ministerial decision of the Ministers of Health and Finance the amounts of the above fines may be readjusted. Said fines are collected according to the Public Revenues Collection Code (PRCC/K.E.D.E., law decree 354/1974, A;' 90) and are revenues of the State Budget which may cover expenditures for the implementation of public health programs and more specifically programs to manage the use of tobacco products and of other similar products, and in general the addictions. The above amounts after they appear in the revenues (Budget, they are entered as credits in the budget of the Health Ministry (CIR/KAE 5117 S.T. 15-210). The Health Minister, in the case of violation of the provisions hereby, taking into account the nature and the gravity of the violation as well as its consequences on public health, may disclose, through the printed and electronic mass media, and the internet in any other expedient way whatsoever any sanctions that are imposed.
4. In case of violation of the obligations of the articles 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 paragraphs 1, 2 and 11, paragraphs 1 through 6 and 21 of the law hereby, there will be imposing, by decision of the Health Minister of the fines provisioned in the article 3 paragraph 1 case D 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).
5. In the case where the electrical or electric materials of the electronic cigarette is not complying with the requirements of the technical industrial legislation, according to the articles 22 through 31 of Law 4072/2012 (A' 86) and with Annex IV of law 4072/2012 (A' 86), shall apply the provisions of article 32 of law 4072/2012 (A' 86). In the case that the electrical material of the electronic cigarette fails to comply to the provisios of the no. Fin. 51157/DTIL 1129/20.5.2016 decision of the Ministers of Economy, Development and Tourism – Environment and Energy (B' 1425) related with the availability in the market of electrical material intended to be used within certain voltage limits, shall apply the provisions of article 23 of the no. Fin 51157/DTIL 1129/20.5.2016 decision of the Ministers of Economy, Development and Tourism – Environment and Energy (B' 1425).

Article 25
Deposits – Proportional Fees
(Articles 5, 6, 7, 19, 20 of Directive 2014/40/EC)

1. For the acceptance, storage, handling, analysis and the disclosure of information that are submitted according to article 5 and the paragraph 2 of article 18 a deposit is set out totaling 50 euros per product for the manufacturers and importers. Said deposits are collected according to the Public Revenues Collection Code (PRCC/K.E.D.E., law decree 354/1974, A' 90) and are State Budget revenues, from which can be covered expenditures for the implementation of public health programs and more specifically management programs of the use of tobacco products and other similar products and addictions in general. The above amounts after their appearance in the state budget expenditures are entered as credits on the budget of the Health Ministry (SIR/KAE 5117 TX 15-210).
2. For the evaluation of the reports of manufacturers or importers through the conduct of a comparative analysis of such reports by an independent scientific organization according to the paragraph 4 of the article 6, as well as for the assessment as to how much a tobacco product has characteristic aroma/flavor, how much use is there of prohibited additives or aromatic agents and how much a tobacco product contains additives in quantities that increase significantly and to a measureable degree the toxic or addictive effect or the CMR properties of the relevant tobacco product, in accordance with paragraph 9 of article 7, the manufacturers and the importers of the said product shall pay a deposit the total of which and its collection and payment procedure, as well as any possible readjustment thereof is determined by decisions of the Health Minister.

3. The deposit of case ja' of paragraph 4 of the article 17 hereby is to be collected in the collection code CIR/KAE 3471 (Deposits due to any cause).

Article 26
Transitional Provision
(Article 30 of the Directive 2014/40/EC)

The following products are allowed to be available in the market until 28.2.2017 that are not consistent with the provisions hereby:

a) tobacco products that are produced or put in free circulation and are labelled in accordance with the no. Y1/G.R., fin. 266/2.1.2003 joint decision of the Ministers of Health and Welfare and Agriculture (B' 8), prior to the start of effect of the law hereby,

b) the electronic cigarettes or the refill containers produced or placed in open circulation prior to the 20.11.2016,

c) the plant products for smoking that are produced or placed into open circulation prior to the start of effect of the law hereby.

Article 27
Abolition
(Article 31 of the Directive 2014/40/EC)

From the start of effect of the law hereby shall be abolished the no. Y1/G.R., fin. 266/2.1.2003 joint decision of the Ministers of Health and Welfare, and Agriculture (B' 8), as well as the no." Y1c/G.R., fin., 40097/23.4.2003, joint decision of the Ministers of Health and Welfare and Agriculture (B' 540) and every other general or special provision that contradicts the provisions of the law hereby or regulates differently the issues governed by such law.

Article 28
Annexes

The following Annexes I, II, III, IV, V and VI are attached and constitute integral part of the document hereby.

Article 29

The first verse of par. 1 of the article 41 of the Law 4058/2012 (A' 63), as replaced with par. 1 of article 182 of Law 4261/2014 (A' 107) and is valid, is replaced as follows:

"The hospitals of the National Health System (ESY), the Health Centers of island, mountain and distant areas, the Center for Disease Control and Prevention, Organization Against Narcotics, the Therapy Center for Dependent Individuals, and Health Units SA by decision of their Board of Directors, may, in order to cover their needs in staff for their appropriate operation, when their staff is not sufficient, collaborate with physicians of all specialties, psychologists, social workers, sociologists, nurses and special therapists former dependent who have completed successfully a therapeutic program of the approved Organizations or Agencies of Law 4139/2013 (A' 74), with a status of these issuing a receipt of services rendered for the services that they render.**"**

Article 30

From par. 2 of article 54 of Law 4272/2014 (A' 145), as amended with the case a' of par. 7 of the article 52 of the Law 4410/2016 (A' 141), the phrase: "… if the post has not been announced…" is eliminated. Also the phrase"… which expires on the 30.9.2016…" is replaced by the phrase: "which expires until the 30.9.2016".

Article 31
Start of effect – Application

The effect of the law hereby shall commence from its publication in the Government Gazette, unless it is defined otherwise in its partial provisions.

Annex I

List of verbal warnings
(mentioned in the article 10 and in the article 11 par. 1)

1. Smoking causes 9 out of the 10 lung cancers
2. Smoking causes mouth and pharyngeal cancer
3. Smoking destroys the lungs
4. Smoking causes heart attack
5. Smoking causes strokes and disability
6. Smoking causes stenosis and blockage of the arteries
7. Smoking increases the risk of blindness
8. Smoking destroys the teeth and gums
9. Smoking can kill your unborn child
10. Smoke harms your children, your family and your friends
11. The children of smokers are more likely to start smoking
12. Stop smoking, continue to live for your loved ones
13. Smoking reduces fertility
14. Smoking increases the risk of sexual impotence

ANNEX II

Library of Images

(which is mentioned in article 11 par. 1)

Set 1:

Smoking causes 9 out of 10 Lung cancers

Smoking causes cancer of the mouth and of the pharynx

Smoking destroys the lungs

Smoking causes heart attack

Smoking causes strokes and disability

Smoking causes arterial stenosis and blockage

Smoking increases the risk Of blindness

Smoking destroys the teeth and gums

Smoking may kill your unborn child

Your smoke harms your children, your family, your friends

The children of smokers are more likely to start smoking

Stop smoking, keep living for your loved ones

Smoking reduces fertility

Smoking increases the risk of sexual impotence

Set 2:

Smoking causes 9 out of 10 Lung cancers

Smoking causes cancer of the mouth and of the pharynx

Smoking destroys the lungs

Smoking causes heart attack

Smoking causes strokes and disability

Smoking causes arterial stenosis and blockage

Smoking increases the risk Of blindness

Smoking destroys the teeth and gums

Smoking may kill your unborn child

Your smoke harms your children, your family, your friends

The children of smokers are more likely to start smoking

Stop smoking, keep living for your loved ones

Smoking reduces fertility

Smoking increases the risk of sexual impotence

Set 3:

Smoking causes 9 out of 10 Lung cancers

Smoking causes cancer of the mouth and of the pharynx

Smoking destroys the lungs

Smoking causes heart attack

Smoking causes strokes and disability

Smoking causes arterial stenosis and blockage

Smoking increases the risk Of blindness

Smoking destroys the teeth and gums

Smoking may kill your unborn child

Your smoke harms your children, your family, your friends

The children of smokers are more likely to start smoking

Stop smoking, keep living for your loved ones

Smoking reduces fertility

Smoking increases the risk of sexual impotence

. . .

We order the publication of the document hereby in the Government Gazette and the execution thereof as law of the State.

Athens, 16 September 2016
The President of the Republic
PROKOPIOS B. PAVLOPOULOS

The Ministers

Economy, Development and Tourism
GEORGE STATHAKIS

Deputy minister of Economy, Development and Tourism
THEODORA TZAKRI

Health
ANDREAS XANTHOS

Deputy Minister of Health
PAVLOS POLAKIS

Finance
EUCLIDES TSAKALOTOS

Deputy Minister of Finance
TRIFONAS ALEXIADIS

Agricultural Development and Food
EVANGELOS APOSTOLOU

Validated and the Great Seal of the State was affixed

Athens, 19 September 2016
The Minister of Justice
NIKOLAOS PARASKEVOPOULOS