

REGULATORY UPDATE

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Tobacco products: the new Italian regulatory framework

On 18 January 2016, Legislative Decree no. 6/2016 implementing the Tobacco Products Directive (2014/40/EU) in Italy was published in the Official Journal. Its provisions will enter into force gradually, starting from 20 May 2016.

The Decree lays down a set of rules governing the manufacture, presentation and sale of tobacco and related products (cigarettes, roll your own tobacco, pipe tobacco, cigars, cigarillos, smokeless tobacco, electronic cigarettes and herbal products for smoking).

- Tobacco products The Decree sets the maximum emission levels for cigarettes to be placed on the Italian market and bans tobacco products with characterising flavours (with the specific ingredients of admitted flavours to be determined by a decree of the Italian Ministry of Health). Similarly, tobacco products containing vitamins or other additives which may give the impression that the product has health benefits or presents reduced health risks cannot be placed on the Italian market. In the event of violations of these rules, a fine of between Euro 30,000 and 150,000 can be levied on the manufacturer or the importer and a fine of between Euro 500 and 5,000 on the retailer.
- Labelling and packaging The Decree establishes two sets of warning messages which must appear on the packets of tobacco products. Firstly, each packet and the outside packaging of tobacco products shall carry the

following general warning: "Il fumo uccide – smetti subito" ("Smoking kills – quit now") along with the following information message: "il fumo del tabacco contiene oltre 70 sostanze cancerogene" ("Tobacco smoke contains over 70 substances known to cause cancer"). Both of them shall cover 50 % of the surfaces on which they are printed. In addition, each packet shall carry a combined health warning which contains one of the text warnings listed in Annex I and a corresponding colour photograph specified in Annex II (which contains several shocking pictures). Moreover, the warning shall include the following text: "n. verde 800.554.088 per smettere di fumare" ("toll free number 800.554.088 to quit smoking"). The combined health warning shall cover 65 % of both the external front and back surfaces of the unit packet, as well as of any outside packaging. Tobacco products other than cigarettes, roll your own tobacco, and waterpipe tobacco are exempted from the obligation to carry the information message "Tobacco smoke contains over 70 substances known to cause cancer".

- Advertising Existing restrictions for advertising of tobacco products will extend to e-cigarettes.
- Product presentation 10-packs of cigarettes will be banned: the Decree prescribes that a unit packet of cigarettes shall include at least 20 cigarettes and a unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30 grams. Moreover, the Decree introduces a set of rules concerning the presentation of tobacco products. In particular, labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product.
- Traceability The Decree implements the EU-wide tracking and tracing system established by the Directive for the legal supply chain. To this aim, and starting from 20 May 2019, all unit packets of tobacco products must be

marked with a unique identifier irremovably printed or affixed on the package and containing a set of information regarding the date and place of manufacturing, the name of the importer, etc.

- Tobacco for oral use The sale of tobacco for oral use is prohibited in Italy.
- Novel tobacco products. Manufacturers must notice the Italian Ministries of Health and Finance six months before placing novel tobacco products on the market. A separate decree will establish requisites and procedure to claim the status of reduced health risk to certain novel tobacco products.
- Electronic cigarettes The Decree implements the rules of the Directive concerning e-cigarettes. In particular, electronic cigarette manufacturers, in addition to manufacturing their products in line with the rules on safety, quality and packaging, are required to notify the Ministry of Health before placing new products on the market, and to report annually to the same Ministry on the sales volumes of the products, types of users and their preferences and trends. With regard to the advertising of electronic cigarettes, each unit packet and the outside packaging of electronic cigarettes and refill containers shall carry the message "*Prodotto contenente nicotina, sostanza che crea un'elevata dipendenza. Uso sconsigliato ai non fumatori*" ("This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers").

The Decree also contains a number of specific prescriptions outside the scope of the Directive.

- Cross-border distance sales of tobacco products have been prohibited. This prescription is sanctioned with a fine of between Euros 30,000 and

150,000. The rationale for this prescription is the uncertainty about the age of the buyer.

- The Decree includes a set of measures aimed at protecting the health of minors. In particular, sales to minors of electronic cigarettes and refill containers are banned and violations (along with the sale of tobacco products to minors) will be subject to a fine of between Euros 500 and 3,000, as well as the temporary suspension of the commercial license. The fine is increased up to Euros 8,000 and the suspension of the commercial license can be made permanent in the event of recidivism.
- The Decree has expanded the general smoking ban in indoor public places, prohibiting smoking also in cars in the presence of children and pregnant women as well as in outdoor spaces adjacent to pediatric hospitals and institutions for hospitalization and care, as well as gynecology and obstetrics departments.
- Finally, the Decree has provided that vending machines for the sale of tobacco products or electronic cigarettes equipped with an automatic detection system for the age of the buyer must be subject to regular checks carried out by the competent authority.

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