

CMS | Romanian law tightens restrictions on sale of tobacco, electronic cigarettes, heated tobacco products and related products



On 28 March 2024, Romania enacted Law No. 64/2024 on amending and supplementing certain laws on tobacco products (“Law 64”), implementing important restrictions on the marketing, sale and packaging of tobacco products, electronic cigarettes, heated tobacco products and related products in Romania. Law 64 introduces the definition of “electronic cigarette”, which previously was only defined in the EU Tobacco Products Directive (2014/40/EU), but not transposed into Romanian legislation. Importantly, Law 64 defines previously unregulated new products, such as “product for smokeless inhalation of tobacco substitutes”, “pouch with nicotine for oral use” and “electronic device for heating products for smokeless inhalation of tobacco substitutes”.

Some changes brought by Law 64, such as the transposition of the EU definition of electronic cigarette into the Romanian framework, have been welcomed. Other changes, however, pose significant practical issues for manufacturers, distributors and retailers.

Restrictions on sales

Firstly, through Law 64, Romania now prohibits the sale to minors (people under 18 years of age) of the following: electronic cigarettes, refill containers for electronic cigarettes, electronic devices for heating tobacco and products for smokeless inhalation of tobacco substitutes, pouches with nicotine for oral use and products for smokeless inhalation of tobacco substitutes (i.e. “**Vaping and Heating Products, Nicotine Pouches and Tobacco Substitutes**”). Before the entry into force of Law 64, Romanian Tobacco Law only prohibited the sale of traditional tobacco products to minors while the sale to minors of electronic cigarettes and heated tobacco products was allowed.

To implement these restrictions, Law 64 requires that a mandatory statement on the prohibition to sell these products to persons under 18 years of age must be included on the health operating permit required for all operators selling these products.

Secondly, Law 64 introduces indirect restrictions on the distance sale of all traditional tobacco products, as well as of Vaping and Heating Products, Nicotine Pouches and Tobacco Substitutes. Mainly, it prohibits the sale of these products through easybox/locker devices. For clarity, Law 64 defines an easybox/locker device as a secure

box/space intended for the storage of parcels to be picked up by the addressee in exchange for a code/words provided by electronic means or at the time of payment. Before Law 64, sale through easybox/locker devices was not regulated at all in the Romanian Tobacco Law.

Infringement of the restrictions on sales to minors and sales through easybox/locker devices is a misdemeanor and sanctioned with a fine of approximately EUR 2,000 and the complementary sanction of suspending the infringer's business activity for 30 days and, in the case of repeated offenses, a fine of approximately EUR 4,000 and the complementary sanction of closing the business's activities.

The sale of Vaping and Heating Products, Nicotine Pouches and Tobacco Substitutes through vending machines is now prohibited. Previously, only the sale through vending machines of traditional tobacco products was prohibited. Infringement of this restriction carries the same sanctions as before Law 64: a fine of approximately EUR 1,000 for the first infringement, and a fine of approximately EUR 2,000 and the suspension of business activities for the second infringement. If there is an additional infringement of the law, the fine will be approximately EUR 3,000 with the complementary sanction of the business activity's closure.

Thirdly, Law 64 introduces several measures aimed at strengthening the protection of minors:

- a prohibition to smoke and use any tobacco products, Vaping and Heating Products, Nicotine Pouches and Tobacco Substitutes in all educational institutions applicable to students of any age;
- an obligation for educational institutions to implement internal regulations for the enforcement of the above prohibition, including obligating the Romanian Education Ministry to establish sanctions to be enforced on students for non-observance of this prohibition.

Amendments to packaging and labeling rules

Furthermore, Law 64 provides that all tobacco products, Vaping and Heating Products, Nicotine Pouches and Tobacco Substitutes, which are sold via courier services must contain the following warning in Romanian on the package: "Warning! This package contains tobacco products and/or products containing nicotine. Please check the age of the customer".

This is an important amendment affecting the packaging of all these products (including traditional tobacco products) since the packaging and labelling of products sold via courier must be adapted to include this statement, while products sold in stores do not need to carry this statement. Law 64 does not provide any details on the size and location of the statement, but it should not interfere with the mandatory health warnings to be included on the package based on the EU Tobacco Product Directive.

Non-compliance with this obligation is a misdemeanor sanctioned with a fine of approximately EUR 2,000 and with the complementary sanction of suspending the business's activity for 30 days. In the case of repeated offenses, the fine will be approximately EUR 4,000 with the complementary sanction of the business's closure. If the infringer is an individual (and not a legal person), the sanction will be a fine ranging between approximately EUR 20 and EUR 100.

New definitions introduced for the first time

Law 64 amends the Romanian Tobacco Law by introducing new definitions:

1. **“pouch with nicotine for oral use”** is defined as “a nicotine-containing non-tobacco product which is used for the oral consumption of nicotine in powder or particulate form or in any combination of those forms”;
2. **“product for smokeless inhalation of tobacco substitutes”** is defined as “a new product that does not contain tobacco but is based on a tobacco substitute substrate (including herbal products, herbs, fruits), which is heated to produce an emission containing or not containing nicotine and other chemicals, which is then inhaled by the users”;
3. **“electronic device for heating tobacco and products for smokeless inhalation of tobacco substitutes”** is defined as a “device used for heated tobacco products or products intended for smokeless inhalation of tobacco substitutes”;
4. **“electronic cigarette”**, which refers to “a product that can be used for consumption of vapours that contains or not nicotine, via a mouth piece or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges”;
5. **“refill container”** which refers to “a container of a liquid that contains or not nicotine and that that can be used to refill an electronic cigarette”.

Several observations can be made regarding these new definitions.

Firstly, the notions of “electronic cigarette” and “electronic device for heating tobacco” are introduced to fill a gap in the legislation since the Romanian Tobacco Law already contained provisions on electronic cigarettes and heating tobacco products, but there was no definition for these products.

At the same time, the definition of “refill containers” amends the existing definition in order to align it with the newly introduced definition of electronic cigarettes.

One of the purposes of Law 64, as mentioned in the Statement of Reasons accompanying this Law, is to transpose the definitions of these device that were omitted in the previous transposition of European legislation. The definition for electronic cigarettes in Law 64, however, departs from the definition in the EU Tobacco Products Directive. While the Tobacco Directive refers to products that can be used for the consumption of nicotine-containing vapour only, the definition in Law 64 also includes products that can be used for consumption of vapours that do not contain nicotine.

This means that all provisions for electronic cigarettes in the Romanian Tobacco Law and related applicable legislation should also apply to electronic cigarettes that do not contain nicotine, which contrasts with the EU Tobacco Products Directive that does not regulate these types of products.

Nevertheless, the Romanian Tobacco Law establishes certain requirements that electronic cigarettes and refill containers must comply with when placed on the market, which are only related to liquids that contain nicotine (e.g. the requirements that the nicotine level in the nicotine-containing liquid must not exceed 20 mg/ml, no ingredients that pose a risk to human health should be used in nicotine-containing liquids, except for nicotine, and that the nicotine-containing liquid must not contain certain additives). Electronic cigarettes that do not contain nicotine remain out of the scope of regulation in terms of the ingredients and the maximum volume of refill containers, cartridges and tanks.

Law 64 also enacted a new definition for refill containers as “a container of a liquid that contains or not nicotine and that that can be used to refill an electronic cigarette”, which is in line with the definition of the electronic cigarette. It did not, however, repeal the definition already existing in the Romanian Tobacco Law, which provides that refill containers are defined as “a container of nicotine-containing liquid that can be used to refill an electronic cigarette”. Both definitions are now present in the Romanian Tobacco Law.

Secondly, the notions of “pouch with nicotine for oral use” “product for smokeless inhalation of tobacco substitutes” and “electronic device for heating products for smokeless inhalation of tobacco substitutes” are completely new in Romanian legislation, and were introduced to clarify the meaning of the provisions of Law 64. The Tobacco Law’s provisions that transpose the EU Tobacco Directive, however, do not deal with these products and the exact regulatory framework applicable to these products still must be determined.

Regarding these new definitions, while an “electronic device for heating tobacco” refers to a novel tobacco product (i.e. heated tobacco products), already defined in the Romanian Tobacco Law, all the other notions (including “electronic device for smokeless inhalation of tobacco substitutes”) refer to non-tobacco products. All newly defined notions, however, should be considered non-tobacco products since they do not qualify as tobacco products or novel tobacco products.

In relation to pouches with nicotine for oral use, Law 64 prohibits the placing on the market of pouches with nicotine for oral use exceeding 20 mg/pouch. Non-compliance with this prohibition is considered a misdemeanor and is sanctioned with a fine of between approximately EUR 15,000 and EUR 20,000 with the complementary sanction of banning the non-compliant products from the market. The other products defined by Law 64, including electronic devices for heating tobacco and products for smokeless inhalation of tobacco substitutes and products for smokeless inhalation of tobacco substitutes, are not expressly regulated in the Romanian Tobacco Law. They are only mentioned in the prohibitions introduced by Law 64 (i.e. the sale to minors through vending machines and easybox/locker devices).

Final remarks

Finally, as per the Statement of Reasons, the amendments introduced by Law 64 arose out of the need to reduce the exposure of minors to products that can affect their health, such as tobacco. Law 64 also covers gaps in the previous transposition of European legislation by including in the Romanian Tobacco Law definitions provided in the Tobacco Directive that were omitted in the initial transposition.

While some of the amendments were necessary, others require clarifications. New amendments for consistency and a more complete regulation of the new products defined in Law 64, particularly electronic cigarettes that do not contain nicotine, would be welcome.

For more information on Romania’s transposition on the EU Tobacco Products Directive, contact these CMS experts: Anna Morogai or Carmen Turcu.