



**NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY
DEPARTMENT OF PUBLIC HEALTH**

Information on the registration process for electronic cigarettes, refillable liquids and smoking imitation devices in Hungary

Please note that under current legislation in Hungary, electronic cigarettes, refill containers, cartridges, electronic devices imitating smoking can't be marketed with flavouring. Accordingly, please do not submit a notification for such products in Hungary.

Legal background to the prohibition of flavouring:

According to the **Government Decree 39/2013. (II. 14)** Section 19/B (1), *on the Production, Placing on the Market and Control of Tobacco Products, on Combined Warnings, and the Detailed Provisions on the Application of Healthcare Penalties*, (hereinafter: Gov. Decree) electronic cigarettes and refill containers **can be placed on the market only without any flavour.**

Furthermore, according to Section 19/C (1) of the Gov. Decree, electronic devices imitating smoking and nicotine-free refill containers may be placed on the market and distributed only if the following conditions are met the liquid held inside may not contain nicotine (hereinafter referred to as "nicotine-free liquid"), the nicotine-free liquid may not contain any flavoring.

Kit-Pack distribution in Hungary:

Pursuant to Section 15/D (10) of Act CXXXIV of 2012 *on the Reduction of Underage Smoking and the Retail Sale of Tobacco Products*, **the sale of Kit-Packs, i.e. electronic cigarettes, refill bottles or cartridges packaged together, is prohibited in Hungary.**

"§ 1 (1) The following may be carried on in Hungary only in compliance with this Act

- a) tobacco products,*
- b) cigarette tubes and cigarette papers,*
- c) tobacco leaf filler,*
- d) electronic cigarettes,*
- e) refill bottles, cartridges, nicotine-free refill container, nicotine-free cartridges,*
- f) electronic device imitating smoking,*
- g) smoking-substitute nicotine-containing product,*
- h) novel tobacco product accessory; and*

i) herbal product for smoking

retail sale of tobacco products for smoking purposes.

(....)

*According to the Section 15/D (10) of Act CXXXIV of 2012, a retailer of tobacco products may not, in the course of his business, sell without consideration tobacco product supplements as defined in paragraph (1) of Section 1. **It shall be prohibited to sell the product listed in paragraph (1) of Section 1 together with any other product listed in paragraph (1) of Section 1, or with any product complementary to tobacco products, by means of a lottery or other similar game or by any other means of encouraging consumption.***"

General provisions on notification:

The Section 7/D (1) of the Act XLII of 1999 on the Protection of Non-Smokers and Certain Regulations on the Consumption and Distribution of Tobacco Products (hereinafter: NSA). provides:

„Manufacturers, importers and Hungarian distributors of electronic cigarettes, refill containers, cartridges, electronic devices imitating smoking, nicotine-free refill containers, nicotine-free cartridges and smoking-substitute nicotine-containing products shall submit a notification to the government body in charge of the healthcare system of any such products which they intend to place on the market at least six months in advance..”

According to Section 19/A (1) of the Gov. Decree, the notification shall be submitted to the National Centre for Public Health and Pharmacy (hereinafter: NNGYK) through the common entry gate (EU-CEG) provided for in Commission Implementing Decision (EU) 2015/2183, in Hungarian or English, subject to data content requirements provided for in Commission Implementing Decision (EU) 2015/2183.

According to the Section 19/A (2) of the Gov. Decree, the notification referred to in Subsection (1) shall contain the following information:

- a) the name and contact details of the manufacturer, importer, distributor in Hungary, the submission identifier, the electronic cigarette identification number;
- b) a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;
- c) toxicological data regarding the product’s ingredients and emissions, primarily their effects on the health of consumers when inhaled and taking into account any addictive effect they may have;
- d) information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;
- e) a description of the components of the product, including the opening and refill mechanism of the electronic cigarette or refill containers;
- f) a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements set out in the relevant legislation; and
- g) a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

When any change is made in the product affecting the information referred to in Subsection (2) a new notification shall be submitted.

Administrative service fees for registration and notification of changes:

According to the Section 7/D. (4) of NSA, the Subsections (1) and (3) the **notifier shall be liable to pay an administrative service fee** to the NNGYK, as well as **for notified products for which the NNGYK has issued a certificate**, by 31 March of the reference year. From the year following the notification the administrative service fee shall serve to maintain the notification

According to Ministerial Decree 30/2016. (X. 3.) *on the administrative service fees for the notification of the placing on the market of electronic cigarettes, refillable bottles and electronic devices imitating smoking and related changes*, the administrative service fees payable are:

Product	Fee
I.1. electronic cigarette placing on the market per brand name and per intensity	570 000 Ft
I.2. refill containers, cartridges placing on the market per brand name and per intensity	570 000 Ft
I.3. electronic devices imitating smoking, nicotine-free refill containers, nicotine-free cartridges a placing on the market per brand name	570 000 Ft
I.4. change notification for electronic cigarettes per brand name and per intensity	367 200 Ft
I.5. change notification for refill containers, cartridges per brand name and per intensity	367 200 Ft
I.6. change notification for electronic devices imitating smoking, nicotine-free refill containers, nicotine-free cartridges per brand name	367 200 Ft

For faster processing, please send the proof of payment of the fee to the NNGYK via e-mail kozegeszseg@nngyk.gov.hu with a reference to the name of the product and the number of the product ID.

Data reporting obligations:

According to the Section 19/D. (1) of the Gov. Decree manufacturers and importers of electronic cigarettes, electronic devices imitating smoking and refill containers are required to submit, annually, through the common entry gate, by 31 March of the year following the given year:

- a) data on sales volumes, by brand name and type of the product;
- b) information on the preferences of various consumer groups, including young people, non-smokers and the main types of smokers;
- c) the mode of sale of the products; and
- d) executive summaries of any market surveys carried out in respect of Paragraphs a)-c), including an English translation.

The reporting period is from 1 January to 31 December of the year preceding the year in which the lists are submitted.

The managing authority name, postal and e-mail address, telephone number and opening hours of the managing authority

Nemzeti Népegészségügyi és Gyógyszerészeti Központ

1097 Budapest, Albert Flórián út 2-6.

Mailing address: Nemzeti Népegészségügyi és Gyógyszerészeti Központ Közegészségügyi Főosztály

1437 Budapest, Pf: 839.

Telefon: 06 1/476-1220

E-mail: kozegeszseg@nngyk.gov.hu

Office Gate: NNKKOZEG, KRID azonosító: 369732197

Customer reception by prior arrangement by telephone.