



## **European Regulatory Framework for Nicotine Containing Pouches**

This document sets out a voluntary, industry-led self-regulatory framework for nicotine pouches, and constitutes a basis for common industry engagement in the European Union and in Member States.

As responsible manufacturers, in addition to marketing the nicotine pouches in compliance with all applicable laws we commit to applying the requirements set out in this document at all times.

The target consumers for nicotine pouches are adult users of tobacco products or other forms of non-medicinal nicotine products, who are looking for alternatives.

### **1. Definition**

A 'nicotine pouch' is a pre-portioned, tobacco-free consumer product that contains nicotine compounds, flavourings and other ingredients, that releases nicotine and flavours by placing the pouch in the mouth<sup>1</sup> resulting in nicotine uptake via the oral mucosa.

### **2. Age limit**

Nicotine pouches should not be sold or marketed to people under 18 years of age (or the legal age of purchase for nicotine products in the jurisdiction, where higher).

### **3. Nicotine ceiling**

Nicotine content should not exceed 20mg per pouch.

### **4. Ingredient standards**

The nicotine used in nicotine pouches shall meet standards equivalent to those of nicotine used in pharmaceutical products (pharmaceutical grade and quality according to USP/EP).

All other ingredients shall meet standards equivalent to those applicable to food products.

### **5. Labelling**

- a. Health warning:** the unit packaging and outer consumer packaging shall carry the following text - "This product contains nicotine which is a highly addictive substance"
- b. Health warning placement:** the health warning shall be placed on the side or the base of the unit packaging and outer consumer packaging and shall be clear and visible.

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<sup>1</sup> This definition does not apply to products that are subject to an authorization requirement under Directive 2001/83/EC (Community code relating to medicinal products for human use) or to the requirements set out in Directive 93/42/EEC (Medical Device Directive). In addition, the definition neither apply to products that are subject to the requirements set out under Directive 2014/40/EU (Tobacco Products Directive) nor to the Regulation laying down the general principles and requirements of food law (EC 178/2002).



- c. Consumer information:** all unit packaging for nicotine pouches shall contain information about
- i. the ingredients of the product,
  - ii. the nicotine content of the nicotine pouch,
  - iii. the weight of the nicotine pouch,
  - iv. the manufacturing and best before date(s), and
  - v. contact information for the manufacturer and/or distributor.
- d. Age restriction:** Unit packaging and outer consumer packaging shall carry a logo or text indicating that the product is for adult consumption only.

## **6. Product descriptors**

Neither the labelling of any packaging, nor the nicotine pouch itself shall include any element or feature that

- is deceptive or misleading,
- suggests that nicotine pouches have vitalising, energetic, healing, rejuvenating, natural, organic properties or has health benefits,
- resembles a food or a cosmetic product,
- can be linked with youth culture or depict situations, environments or objects that are typical of the world of children and youth (such as comic or cartoon characters, toys or sweets), or
- suggests that nicotine pouches have environmental advantages.

## **7. Marketing communications**

All marketing communication must comply with applicable laws and regulations, including those relating to general product safety, consumer protection and marketing.

All marketing shall be directed at persons above the age of 18 (e.g. in respect of choice of media, placing, execution, manner, and the overall impression).

Marketing must be honest, accurate and transparent. All marketing and sales activities must respect applicable local culture and practices prevailing in the country where the activities will occur.

The products must not be positioned or marketed as medicinal products. Marketing communication must not include any medicinal claims.

The target consumers for nicotine pouches are adult users of tobacco products or other forms of non-medicinal nicotine products, who are looking for alternatives.



Marketing in any channel of communication should not:

- Appeal particularly to people under 18 years of age (or the legal age of purchase for nicotine products in the jurisdiction, where higher), including through
  - the selection of media in which the marketing appears,
  - the context in which the marketing appears,
  - reflecting or inviting and association with youth culture,
  - featuring or portraying real or fictitious characters who are likely to appeal particularly to underage users, or
  - by depicting people using nicotine pouches (or playing another significant role) behaving in an adolescent or juvenile manner.
- Encourage non-nicotine users to use nicotine pouches.
- Include misleading information about product's ingredients.

All consumer advertising must carry clearly visible information/logo that the product is not for people under the age of 18 (or the legal age of purchase for nicotine products in the jurisdiction, where higher).

People featured in marketing communication shall be adult, both in age and appearance.

Consumer-facing marketing activities should only be done by people with adult appearance, in an adult setting.

Age of the recipients of product samples shall be verified before samples are distributed.

## **8. Implementation**

To ensure the spirit of the document is fully applied throughout the supply chain, and to prevent the underage use of nicotine pouches, we are committed to educating, informing, and cooperating with retailers, distributors and public officials.