Folkhälsomyndigheten
PUBLIC HEALTH AGENCY OF SWEDEN

Form – Notification of deficiencies

Notification type

Notification of tobacco free nicotine products that are not safe, are not of good quality, or are otherwise not in conformity with the Act on Tobacco Free Nicotine Products.

Legal requirements

A manufacturer, importer, or distributor of tobacco free nicotine products who considers or has reason to believe that a product is not safe, or is not of good quality, or otherwise not in conformity with the Act on Tobacco Free Nicotine Products or issued rule, must immediately:

- take the corrective action necessary to bring the product concerned into conformity with the Act on Tobacco Free Nicotine Products,
- withdraw the product, or
- to recall it.

If a corrective action is taken the manufacturer, importer or distributor are also required to immediately inform the Public Health Agency of Sweden about the details of the deficiencies and of the corrective action taken, and of the results of such corrective action.

This applies under Section 16 of the Act (2022:1257) on Tobacco Free Nicotine Products.

If you have any questions, please send them to info@folkhalsomyndigheten.se.

Processing of personal data

If applicable, the Public Health Agency of Sweden stores and processes personal data when processing a notification in accordance with Section 16 of the Act (2022:1257) on Tobacco Free Nicotine Products. The legal ground is Article 6.1 (e) General Data Protection Regulation (GDPR). Our website contains more information about how we process your personal data and the rights you have as an individual:
How the Public Health Agency of Sweden processes personal data

Processor

Company:	Folkhälsomyndigheten
Company registration number:	202100-6545
Postal address:	Folkhälsomyndigheten SE-171 82 Solna Sweden
Phone:	+46 (0)10-205 20 00
E-mail address:	info@folkhalsomyndigheten.se

Manufacturer, importer or distributor details

Please state if you are a manufacturer, importer or a distributor:

◯ **Manufacturer** ◯ **Importer** ◯ **Distributor**

Registered Name

VAT Number (If applicable)

Postal address

Postal code (or Zip), Town/City

Country

E-mail address

Description of the product

Type of product (Enter type of product)

Brand name (Enter the products brand name etc.)

Contact details of the company that manufactured or imported the product
(Provide information if it is not you that manufactured or imported the product)

◯ *Manufacturer* ◯ *Importer*

Registered Name

VAT Number (If applicable)

Postal address

Postal code (or Zip), Town/City

E-mail address

Country (If other than Sweden)

Describe the product's deficiencies

Describe the deficiencies associated with the product. If applicable, attach pictures and documentation that describes the deficiencies.

Describe why the product is not safe

Describe why the product is not of good quality

Describe why the product is not in conformity with the Act on Tobacco Free Nicotine Products or issued rules

Describe the corrective action taken

Describe the corrective action taken that were necessary to bring the product into conformity with the Act on Tobacco Free Nicotine Products, or for the product to be withdrawn or recalled.

Describe the results of the corrective action taken

Signature

Date

Name

Please submit the form to info@folkhalsomyndigheten.se