Message 201

Communication from the Commission - TRIS/(2026) 2906

Directive (EU) 2015/1535

Notification: 2026/0223/PL

Forwarding of the response of the Member State notifying a draft (Poland) to of Slovakia.

MSG: 20262906.EN

1. MSG 201 IND 2026 0223 PL EN 06-11-2026 14-10-2026 PL ANSWER 06-11-2026

2. Country: Poland

3A. Department Responsible: Ministerstwo Rozwoju i Technologii, Departament Obrotu Towarami Wrażliwymi i Bezpieczeństwa Technicznego,
Plac Trzech Krzyży 3/5, 00-507 Warszawa, e-mail: notyfikacjaPL@mrit.gov.pl

3B. Originating Department: Ministerstwo Zdrowia
Departament Prawny
ul. Miodowa 15,
00-952 Warszawa
e-mail: kancelaria@mz.gov.pl lub dep-pr@mz.gov.pl

4. Products/Services 2026/0223/PL - S00S - HEALTH, MEDICAL EQUIPMENT

5.

6. Response to the detailed opinion of Slovakia on the provisions of the draft Act amending the Act on the protection of health against the consequences of using tobacco and tobacco products, notified under number 2026/0223/PL.

The Republic of Poland thanks the Slovak Republic for submitting its detailed opinion on the draft Act in question. At the outset, it should be noted that the primary objective of the proposed rules is to ensure a high level of public health protection, in particular the health of children and young people, by limiting the availability and attractiveness of new nicotine products. The protection of public health is a legitimate public policy objective under both European Union law and the settled case law of the Court of Justice of the European Union.

In Poland’s view, the proposed measures do not infringe Articles 34 and 36 of the Treaty on the Functioning of the European Union or the principle of proportionality. Furthermore, restricting the use of ingredients that give nicotine pouches a taste or smell other than tobacco does not in fact eliminate the entire product category. The draft does not provide for a ban on the sale of nicotine pouches as a product category; it merely restricts the placing on the market of products with a taste or smell other than tobacco. Nicotine pouches can therefore still be traded lawfully.

Directive 2014/40/EU does not regulate the market for nicotine pouches, and Member States therefore retain the competence to lay down national rules for this product category. The proposed solution is supported by the available scientific evidence. The World Health Organization points out that characterising flavours increase the attractiveness of nicotine products to young people and contribute to the development of nicotine addiction. Studies show that people aged 13–20 most often choose nicotine pouches with mint and menthol flavours (30.5 %), sweet and candy flavours (29.2 %) and fruit flavours (23.6 %), whereas only a small percentage of users choose tobacco-flavoured products. In Poland’s view, restricting flavours is a targeted measure that is proportionate to the public health objective pursued, as it

reduces the particular attractiveness of these products among young people without removing the entire product category from the market.

Nor does Poland share the view that the proposed ban on placing other nicotine-containing products on the market leads to the unjustified exclusion of products outside the harmonised EU framework. First of all, it should be stressed that the products covered by the proposed Article 7aa do not fall within the material scope of Directive 2014/40/EU. That Directive exclusively regulates tobacco products and related products, and does not cover other products intended for the recreational delivery of nicotine. Consequently, the proposed measure is not subject to assessment under Article 24(3) of Directive 2014/40/EU. For products not covered by EU harmonisation, Member States retain the competence to lay down national rules for placing such products on the market. The proposed regulation is an exercise of that competence. Its aim is to prevent new products for the recreational delivery of nicotine from appearing on the market outside the existing safety control systems. These products are addictive and may pose a particular risk to the health of children, young people and non-smokers, as well as pregnant and breastfeeding women. At the same time, the draft does not impose a total ban on all nicotine-containing products. Express exemptions are provided for medicinal products, medical devices, food and feed that are subject to separate safety assessment and marketing authorisation systems. This means that the measure is neither absolute nor indiscriminate.

It should be stressed that Poland takes the position that nicotine products not covered by Directive 2014/40/EU should be placed on the market only under the pharmaceutical regime, following a positive assessment of registration documentation confirming their safety and efficacy. Nicotine replacement therapy products, such as chewing gum, lozenges and oral sprays, are already available on the market, and their sale requires authorisation by the competent regulatory authority. This means that people who wish to reduce or stop their use of nicotine have access to effective and verified therapeutic products.

Poland has already introduced less restrictive regulatory measures. The State already applies a wide range of instruments restricting trade in nicotine products, including a ban on sales to persons under the age of 18, restrictions on points of sale, a ban on sales from vending machines, mandatory health warnings, reporting and notification requirements, high excise duty and supervisory measures. In particular, the market for nicotine pouches was comprehensively regulated in 2025 by introducing a ban on sales to persons under the age of 18, a ban on sales on the premises of healthcare facilities, schools and sports and recreation facilities, a ban on sales from vending machines and a maximum permitted nicotine concentration. Only after these measures had been implemented was it considered necessary to adopt additional rules on flavours and other nicotine products. The proposed solutions are therefore not a first legislative intervention but a continuation of a gradually developed public health protection system.

The draft should be regarded as consistent from the point of view of public health protection. The different treatment of individual product categories results from their different legal status and level of regulation. Tobacco products and related products are subject to the detailed requirements laid down in Directive 2014/40/EU. By contrast, the products covered by the proposed Article 7aa remain outside the scope of harmonisation and are not subject to comparable requirements concerning safety, composition or notification. Similarly, nicotine-containing medicinal products are subject to rigorous marketing authorisation procedures that include an assessment of efficacy and safety. The regulatory differentiation therefore results from objective differences between individual product categories and cannot be regarded as evidence of inconsistency in the system.

Poland takes the position that the proposed measures are suitable for achieving the objective of protecting public health, as they limit the availability of products that are particularly attractive to young people and of products delivering nicotine outside the existing safety control systems. They are also necessary, as the less restrictive instruments applied so far have not halted the growing popularity of new nicotine products. At the same time, these measures do not go beyond what is necessary to achieve the intended objective, as the draft does not provide for a total ban on all nicotine-containing products or on all nicotine pouches but concerns only selected product categories or specific characteristics of those products.

****

EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu