

Question for written answer E-003734/2026
to the Commission
Rule 144
Alexandr Vondra (ECR)

Subject: Consideration of small and medium-sized enterprises in the evaluation of the tobacco control framework

The Commissioner for Health previously promised that the effects on small and medium-sized enterprises (SMEs) would be taken into account when assessing the evaluation criteria for the Tobacco Products Directive¹². However, the published evaluation report only refers to SMEs once and does not include a dedicated SME test, despite a four-year evaluation process³.

The Commission further indicated that simplification for economic operators in the tobacco sector was not considered, as this could conflict with public health objectives. While public health protection is a priority, the ‘better regulation’ principles require balanced consideration of regulatory impacts, including those on SMEs, to ensure that actions are targeted, achieve their objectives and do not add unnecessary costs.

In this context, could the Commission clarify the following:

1. Why were the effects on SMEs not duly taken into account when assessing the evaluation criteria?
2. Does the omission of an SME test indicate that the Commission is disregarding or discriminating against the interests of EU SMEs operating in the tobacco sector?
3. How does the Commission intend to ensure that ‘better regulation’ tools 21, 23, 58 and 59 will be adequately reflected in any future legislative revisions or proposals in this area?

Submitted: 17.9.2026

¹ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1, ELI: <http://data.europa.eu/eli/dir/2014/40/oj>).

² Answer given by Ms Kyriakides on behalf of the European Commission, P-002459/2023(ASW), 2 October 2023, https://www.europarl.europa.eu/doceo/document/P-9-2023-002459-ASW_EN.html.

³ Commission staff working document of 3 April 2026 entitled ‘Evaluation of the Tobacco Products Directive (2014/40/EU), the Tobacco Advertising Directive (2003/33/EC) and other related tobacco control policies across the EU’ (SWD(2026)0112).