

Question for written answer E-004584/2025
to the Commission
Rule 144
Christine Anderson (ESN)

Subject: Toothpastes with fluoro-calcium-phosphosilicate as an active ingredient and the potential regulatory burdens in the EU internal market

The toothpaste BioMin F uses fluoro-calcium-phosphosilicate (FCPS) as an active ingredient and is supported by independent studies for its ability to reduce dentine hypersensitivity and promote enamel remineralisation¹.

However, the manufacturer reports that supply in the EU has been ‘temporarily disrupted ... due to regulatory updates’².

In view of this:

1. Has the Commission received communications or reports from Member States, manufacturers or notified bodies indicating that BioMin F (or products based on FCPS) have been refused market access, withdrawn, or had their classification changed in the EU because of regulatory burdens?
2. What measures has the Commission taken (or plans to take) to assess whether the regulatory transition under the medical device regulation³ (or other legislation) is having unintended effects on the availability of innovative oral-care medical devices in the internal market?
3. Have any Member States reported safety concerns, market-surveillance actions or national restrictions relating to products containing FCPS, and if so, what were the outcomes?

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¹ <https://researchopenworld.com/efficacy-of-a-biomin-f-toothpaste-compared-to-conventional-toothpastes-in-remineralisation-and-dentine-hypersensitivity-an-overview/>.

² <https://biomin.co.uk/stockists>.

³ OJ L 117, 5.5.2017, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.