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Ms Florika FINK-HOOIJER
Director-General for Environment
European Commission

Ms Sandra GALLINA
Director-General for Health and Food Safety
European Commission

Number: 170-1/2021-2711-30 Date: 19 August 2024

Subject: The notification about the derogation in accordance with Article 10,

paragraph 2a of Regulation (EU) 2017/852 on mercury, as amended by

Regulation (EU) 2024/1849

Dear Ms Florika FINK-HOOIJER, Dear Ms Sandra GALLINA,

I am officially notifying the European Commission of Slovenia's intention to make use of a derogation for the use of dental amalgam until 30 June 2026. This request is made in accordance with Article 10, paragraph 2a of Regulation (EU) 2017/852 on mercury, as amended by Regulation (EU) 2024/1849.

Slovenia has carefully evaluated the implications of phasing out dental amalgam by 1 January 2025 and concluded that it is not feasible within this timeframe. Dental amalgam is the only material fully reimbursed under national law for patients not eligible for other reimbursed dental filling materials. Persons with low incomes would be socioeconomically disproportionately impacted if they were required to finance non-amalgam alternatives on their own.

In accordance with health insurance regulations, adult patients in Slovenia are currently eligible for white fillings in the visible sector (including canines) and for amalgam fillings in the posterior sector. Children up to the age of 15, pregnant women, and nursing mothers are entitled to white fillings in the posterior sector as well. In 2023, approximately 553,000 amalgam fillings were administered.

To achieve the out of dental amalgam on such a scale, up to 50 additional teams in primary dental care will be needed, representing up to €7.5 million in additional annual funds. The estimated additional funds required for higher material costs amount to €8.6 million annually, bringing the total additional funds needed annually to €16.1 million.

At the same time, we will comprehensively round off our efforts in dentistry with five fundamental measures:

- 1. Restricting the use of amalgam in dentistry.
- 2. Prevention of dental caries and promotion of oral health.
- 3. Promoting the use of effective alternative solutions without mercury and limiting the use of amalgam in encapsulated form.

- 4. Promoting research and development of high-quality mercury-free materials.
- 5. Educate and train dental staff and students in the use of alternative materials and promote best management practices and the use of best environmental practices in dental facilities to reduce the release of mercury and mercury compounds into water and soil.

The following adjustments will be made to eliminate the use of amalgam in dentistry from July 1, 2026:

- Amendments to health insurance regulations.
- Amendments to the Financial Plan of the Health Insurance Institute of Slovenia for the year 2026 and the General Agreement for the year 2026 to ensure adequate financial and staffing conditions.
- Raising awareness among dentists and patients about the changes to their rights according to the adopted plan to phase out the use of amalgam.

Considering the aforementioned challenges due to staffing and financial constraints, Slovenia cannot provide additional resources to achieve the phase out of dental amalgam by 1 January 2025. This could socioeconomically disproportionately impact individuals with low incomes if they were required to finance non-amalgam alternatives on their own.

This document is also published on the Ministry of Health's website: https://www.gov.si/teme/izvajanje-zdravstvene-dejavnosti/.

We trust that the European Commission will acknowledge our notification, including the explanations and proposed measures presented herein. Should you require any further information, additional data, or clarification, please do not hesitate to contact us.

Thank you for your attention to this matter.

With regards,

dr. Valentina Prevolnik Rupel minister