

# **Explanation and measures for the derogation on the use of dental amalgam in the Czech Republic according to Regulation (EU) 2024/1849 of the European Parliament and of the Council of 13 June 2024 amending Regulation (EU) 2017/852 on mercury as regards dental amalgam and other mercury-added products subject to export, import and manufacturing restrictions**

## **Introduction**

Article 10, paragraph 2a of Regulation (EU) 2017/852 on mercury, as revised by Regulation (EU) 2024/1849, stipulates that "from 1 January 2025, dental amalgam shall not be used for dental treatment in the Union, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient." However, under certain conditions, an exemption from this ban is possible until June 30, 2026. To qualify for this exemption, a member state must provide detailed justification and outline measures to ensure compliance with this extended deadline. This information must be notified to the Commission and made public by 31 August 2024. The Czech Republic requires this additional time to adapt to the planned ban on the use of dental amalgam and, as it meets the conditions for this temporary exemption, has acted accordingly to notify the exemption, providing the required information below.

## **Rationale for Temporary Exemption**

In the Czech Republic, dental amalgam has been widely used for dental restorations because it's durable and cost-effective. It's the only material covered by public reimbursement under national law, except for specific groups eligible for reimbursement of mercury-free alternatives (such as individuals under 15, pregnant or breastfeeding women, and fillings on front teeth). The transition period is needed to adjust reimbursement system and reduce the social and economic impacts, making sure that mercury-free alternatives become equally available without lowering the quality of care.

### Adjustment of Public Reimbursement Policy

In the Czech Republic, dental amalgam is currently the only material for dental fillings that is reimbursed at a rate of at least 90% for patients who do not qualify for other reimbursed materials.

Phasing out dental amalgam and transitioning to mercury-free alternatives in the Czech Republic requires comprehensive adaptation of the dental care reimbursement system. Adequate time is necessary to prepare, negotiate, and approve national laws and regulations addressing the specifics of reimbursement decrees and pricing structures. Czech dental care is governed by regulations listed at the end of this document, which will need to be revised to adapt to this new framework.

Switching the reimbursement scheme to totally mercury-free alternatives is predicted to cost about 6 to 8 billion CZK (240 mil - 320 mil EUR). These numbers represent a very conservative estimation, since the Czech Republic does not have data on number of fillings done outside of the reimbursement scheme.

### Alleviating Socio-Economic Impacts

The transition away from fully reimbursed dental amalgam presents significant challenges, particularly as alternative materials are not publicly reimbursed to general population, but only to a specifically defined group of patients. The derogation period is crucial to conscientiously prepare for this change, ensuring fairness, functionality, and accessibility

to dental care. This is especially important for vulnerable populations, including those with lower incomes, disabilities, marginalized communities, and the elderly, who should not face significant financial and health access barriers.

Additionally, the shortage of dentists and the aging demographic of existing practitioners present substantial socio-economic challenges. Many towns and regions experience a scarcity of dental professionals due to the high average age of dentists, with a considerable portion nearing retirement. The sudden prohibition of dental amalgam raises concerns that older dentists, accustomed to its use, may opt to retire rather than adapt to alternative materials. This scenario could exacerbate the existing shortage of dentists, jeopardizing universal access to healthcare. While a gradual decline in amalgam use was anticipated with generational turnover, the timeframe for this transition is longer than a few months.

Adding to these challenges is the fact that using mercury-free alternatives requires approximately twice as much time as repairing the tooth with dental amalgam. This not only drives up costs (in terms of time paid to the dentist and associated practice expenses such as rent, energy use, and instruments) but also puts further strain on the availability of dental care due to a shortage of trained dentists, as mentioned previously.

### **Measures to achieve the end of dental amalgam use in the Czech Republic by 30 June 2026**

The Czech Republic will put in place suitable actions to ensure a seamless shift to the updated dental care reimbursement system, aligning with the ban on dental amalgam use. To uphold its pledge to discontinue dental amalgam use by this deadline, the Czech Republic will enact the following measures:

1. Adapt current health care system to prohibition of amalgam use: Establish a comprehensive reimbursement framework to ensure that mercury-free dental materials are covered by public health insurance, making them accessible and affordable for all patients (novelization of Act No. 48/1997 Coll. on Public Health Insurance).
2. Negotiate and approve amendments to national laws and reimbursement regulations: Collaborate with relevant stakeholders to amend existing national laws and reimbursement regulations to support the transition to mercury-free dental materials, ensuring legal and financial structures are updated.
3. Launch a public awareness campaign: Inform citizens about the forthcoming changes in reimbursement policies and the availability of mercury-free alternatives through a targeted public awareness campaign. Highlight the health and environmental benefits of these alternatives and provide information on their use and effectiveness.
4. Prepare and execute prevention campaigns: Develop and implement prevention campaigns focused on educating the public about oral health practices. Emphasize the importance of preventive care to reduce the need for dental fillings and promote the benefits of using mercury-free materials.
5. Offer training for dental professionals: Provide comprehensive training programs including hands-on workshops, educational materials, and support networks.
6. Conduct a thorough assessment of labour market impacts: Evaluate the potential effects on the dental labour market, including job displacement or changes in demand for certain skills. Develop strategies to support workers through retraining programs and ensure the continued availability of high-quality dental care services.
7. Implement a monitoring and evaluation system: Establish a system to monitor and evaluate the impact of these measures. This system should track progress, identify

challenges, and ensure compliance with the phase-out date. Feedback from dental professionals and patients will be collected to identify and address any emerging issues promptly.

## **Summary**

The derogation for the use of dental amalgam in the Czech Republic until 30 June 2026 is crucial for ensuring a smooth transition towards mercury-free alternatives. The rationale behind this derogation lies in the need to mitigate socio-economic impacts and ensure continued access to affordable dental care, particularly for vulnerable populations. To address this transition effectively, a series of measures will be implemented.

It's essential for Czech citizens to understand that these measures are aimed at safeguarding their health and ensuring environmental sustainability. By embracing mercury-free alternatives, we are not only protecting our well-being but also contributing to a healthier planet for future generations.

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## **Regulations Governing Czech Dental Care**

Act No. 48/1997 on Public Health Insurance, as amended: This Act defines what is and isn't covered by health insurance, including conditions for coverage. It outlines the basic rules for negotiating contracts between health service providers and health insurance companies regarding the provision and reimbursement of covered services. Additionally, it details the annual procedure for negotiating reimbursement amounts, known as the conciliation procedure. Annex 1 lists services that are either not covered or covered only under specific conditions, while Annex 4 specifies the dental products covered by health insurance and the terms of their reimbursement.

Act No. 372/2011 on Health Services and Conditions of their Provision, as amended: This Act outlines the fundamental principles governing the provision of health services, including the rights and responsibilities of both health service providers and patients. It also addresses the maintenance and management of medical records.

Act No. 95/2004 on the conditions of acquisition and recognition of professional competence and specialized competence to practice the medical profession of a doctor, dentist, and pharmacist, as amended: This Act specifically regulates the professional competence required to practice as a dentist.

Decree No. 315/2022 on the determination of point values, the amount of reimbursement for covered services, and regulatory limitations for 2023 (the reimbursement decree): Dental procedures are governed by Annex No. 11 of this decree. The conditions and reimbursement rates specified in the decree apply by default, unless otherwise negotiated between the health insurer and the service provider. However, deviations from these conditions and rates may occur through mutual agreement between the parties, as evidenced by addenda to the contract for service provision and reimbursement.

Ministry of Health Pricing Regulation No. 1/2024/CAU dated 3 November 2023: This regulation establishes the maximum prices for dental services covered by health insurance. While health insurers and providers may agree on prices different from those specified in the reimbursement decree, they must adhere to the maximum prices set by the Ministry of Health. Notably, the maximum prices for reimbursed dental services outlined in this regulation for 2023 are approximately 30% higher than those specified in the reimbursement decree.