

## **Order regarding the approval of the national plan of measures for the phasing out of use of dental amalgam**

Seeing the Approval Report no. .... from ..... .. of the Directorate General of Health Care and Public Health within the Ministry of Health and address of the College of Dentists in Romania no. 1243 of July 2, 2019 registered at the Ministry of Health with no. 35570/TMB147 of July 2, 2019, taking into account the provisions of art. 10 of the Regulation (EU) 2017/852 of the Parliament European and Council of May 17, 2017 on mercury and repealing a Regulation (EC) no. 1102/2008 regarding the obligation of the Member States to elaborate by July 1, a national plan regarding the measures they intend to take implements to gradually reduce the use of dental amalgam, pursuant to the provisions of art. 7 paragraph (4) of the Government Decision no. 144/2010 regarding organization and functioning of the Ministry of Health, as subsequently amended and supplemented, the Minister of Health issues the following

### **ORDER**

Art. 1 The National Plan of measures for the gradual elimination of the use is approved of the dental amalgam, provided in the annex which forms an integral part of this order.

Art. 2 The public health departments of the county and of the municipality of Bucharest as well

the sanitary units involved will comply with the provisions of this order.

Art. 3 This order is published in the Official Gazette of Romania, Part I.

**HEALTH MINISTER**

**SORINA PINTEA**

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**Structure**

**date**

**application**

**opinion**

**date**

**obtaining**

**opinion**

**Signature**

**INITIATIVE STRUCTURE**

**The General Directorate of Medical Assistance and Public Health**

**General Manager Amalia ȘERBAN**

**Deputy General Manager Costin ILIUȚĂ**

**ADVISORY STRUCTURES**

**General Directorate of Legal and Human Resources**

**General Manager Dana Constanța EFTIMIE**

**Directorate of Relations with the Press European Affairs and International Relations**

**General Manager Oana GRIGORE**

**State Sanitary Inspection**

**Director Dr Maria Mioara Comana**

**State Secretary**

**Cristian Vasile GRASU**

**General secretary**

**Ana Maria CIOBANU**

The person responsible for the project development: Horațiu Marcu, Senior Advisor,  
021.3072.665,

[horatiu.marcu@ms.ro](mailto:horatiu.marcu@ms.ro)

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ANNEX

**National plan of measures for the gradual elimination of the use of dental amalgam**

1. The use of dental amalgam in the treatment of milk teeth is prohibited in children under 18 years and in pregnant or breastfeeding women, unless this is considered strictly necessary by the dentist, for reasons related to specific medical needs of the patient, in accordance with the provisions of art.10 of Regulation 2017/852;
2. In the case of dental emergencies, removal of the dental amalgam will be possible in all dental medicine offices. The College of Dentists in Romania will organize a registry of emergency dental offices and of the offices that use amalgam in dental work.
3. The use of bulk amalgam by dentists shall be prohibited in accordance with the provisions of art.10 of Regulation 2017/852;
4. The use, in accordance with the provisions of art.10 of Regulation 2017/852; of the amalgam for dental purposes will only be done in a predetermined encapsulated form.
5. The legal representatives of the dental medicine offices in which amalgam is used dental, in which fillings based on amalgam are removed or teeth that are extracted contain such seals, ensure that they are equipped with amalgam separators which retain and collect amalgam particles; as of January 1, 2021, all amalgam separators in use must provide at least one retention level 95% of the amalgam particles. Amalgam separators and capsules are considered which comply with European or other national standards or international, which provide an equivalent level of quality and retention meet the requirements of Regulation (EU) 2017/852 of the European Parliament and of the Council of May 17, 2017 regarding mercury and repealing Regulation (EC) no. 1102/2008, in accordance with the provisions of art.10 of Regulation 2017/85;
6. The disposal of dental amalgam waste in the environment is prohibited; dentists will concluded contracts with specialized companies to ensure that dental amalgam wastes they are handled and collected by entities authorized for management and neutralization them, in accordance with the provisions of art.10 of Regulation 2017/852;
7. Ministry of Health, in collaboration with the College of Dentists in Romania organizes public information activities (through press, television, radio, articles, brochures, posters, etc.) regarding dental amalgam, for awareness, by population, of the environmental risks of mercury, as one of the most important measures to completely stop the use of amalgam.
8. Ministry of Health, in collaboration with the College of Dental Doctors of Romania through the measures of prophylaxis of dental caries and the promotion of health reduce the need for restoration and minimizing the use of dental amalgam.

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9. Patients will complete the informed consent form provided in the Order

to the Minister of Public Health no. 482/2007 regarding the approval of the Methodological Norms of application of Title XV "Civil liability of the medical personnel and the product supplier and medical, health and pharmaceutical services" from Law no. 95/2006 regarding the reform in the field of health with subsequent modifications and completions, before application dental amalgam.

10. The college of dentists provides through the programs of continuous medical education informing current and future dentists about the impact of dental amalgam on the environment thus constituting a major source of pollution with mercury in air, water and earth.

11. Ministry of Health in collaboration with the College of Dentists in Romania promotes the use of mercury - free therapeutic alternatives that are both effective cost and clinical view for dental restorations.

12 The College of Dentists organizes meetings for education and training of future specialists regarding the use of restoration alternatives mercury-free dentistry and promoting best dental management practices, which involves the removal of the smallest amount of healthy dental tissue (amalgam requires removal of healthy dental tissue to a greater extent than mercury-free alternatives).

13. The College of Dentists of Romania will promote the use in dental offices of mercury-free quality materials for dental restorations.