



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

MAY 14 2020

ADMINISTRATIVE ORDER

No. 2020 - 0020

SUBJECT: Guidelines on the Phase – Out of Mercury Use in Dental Restorative Procedures

I. BACKGROUND / RATIONALE

With the enactment of RA 11223 also known as the Universal Healthcare Law, the Department of Health is committed to ensure that every Filipino citizen is entitled to healthy living, working and schooling conditions and access to comprehensive set of health services.

The World Health Organization (WHO) reported that dental caries is a major public health problem where 60-90% of school children and nearly 100% of adults have dental cavities globally. Although the Department of Health and other concerned stakeholders have consolidated efforts to promote oral health and prevent dental caries, dental restorations are still necessary in most people.

While dental amalgam is still used in several countries including the Philippines, concerns were raised on the potential health and environmental impacts of mercury use due to its bio accumulative and persistent properties.

In October, 2013, the Philippines signed the global-legally-binding treaty on mercury. The Minamata Convention on Mercury provides controls and reductions across a range of products, process and industries where mercury is used, released or emitted.

In line with this, the Department of Health in coordination with concerned government agencies shall adopt a **phase-out** policy of dental amalgams.

II. OBJECTIVES

This Order aims to provide the guidelines on the phase-out of mercury use in dental restorative procedures. Specifically, it seeks to:

1. Provide a comprehensive policy direction in the phase-out of dental amalgams in the country.
2. Develop guidelines for the phase – out of the importation, manufacture, distribution/offer for sale and use of dental amalgams in the country.
3. Establish health and safety guidelines in the handling, use and disposal of dental amalgams among dental workers and students including patients.

4. Educate and promote awareness among consumers and other concerned stakeholders on dental restorative materials.
5. Identify measures to strengthen strategies on dental carries prevention and oral health promotion.

III. SCOPE

These guidelines shall cover the phasing-out on the importation, distribution, manufacture, storage, transport, handling, use (including dental schools and research) and disposal of dental amalgams in the Philippines.

IV. DEFINITION OF TERMS

1. Alternative dental restorative materials - refers to materials used as alternates for dental amalgam.
2. Dental amalgam (commonly known as "silver fillings") – is used to repair decayed or broken teeth generally made up of mercury, silver and tin, with small amounts of copper and zinc.
3. Dental amalgam capsule – a capsule that contains silver alloy, mercury, a pestle and a plastic bubble.
4. Distributor/importer/exporter – means any establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets.
5. Exposure – amount of chemical that is available for absorption into the body through possible routes of entry into the body (i.e. inhalation, ingestion and skin absorption).
6. Importation - means the entry of products or substances into the Philippines (through the seaports or airports of entry) after having been properly cleared through or still remaining under customs control, the product or substance of which is intended for direct consumption, merchandising, warehousing, or for further processing.
7. Manufacturer – in relation to a health product, means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulation, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.
8. Oral health – shall mean being free of chronic mouth and facial pain, oral and throat cancer, oral sores, birth defects such as cleft lip and palate, periodontal (gum) disease, tooth decay and tooth loss and other diseases and disorders that affects the mouth and oral cavity.


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9. **Precautionary principle approach** - is a strategy for approaching issues of potential harm when extensive scientific knowledge on the matter is lacking.
10. **Registration** – the process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer and where applicable the use, testing, promotion, advertisement, and and/or sponsorship of health products.
11. **Retailer** – any establishment, which sells or offers to sell any health product directly to the public.
12. **Treatment, Storage and Disposal (TSD) Facility** – means the facility where hazardous wastes are transported, stored, treated, recycled, reprocessed, or disposed of.
13. **Waste generator** – means a person who generates or produces hazardous waste through any institutional, commercial, industrial or trade activities.
14. **Waste transporter** – a person, corporation or juridical person registered to transport hazardous wastes.
15. **Waste treater** – means a person, corporation or juridical person registered to treat, store, recycle or dispose hazardous wastes.

V. IMPLEMENTING GUIDELINES

A. Proper Use / Storage

1. The use of dental amalgams under this Order shall be specific for dental restoration, use in dental schools and research purposes only. The distribution, use, handling, retail and re-sale of dental amalgam capsules shall not be used for purposes other than which is allowed under this Order.
2. Dental amalgam capsules in combined, pre-dosed encapsulated form containing at most 50% mercury by weight, for single use only, shall be allowed for use of government dental units, the local dental schools and private industrial dental clinics during the phase - out period only.
3. Dental amalgam filling shall not be given to pregnant women, children under the age of fourteen (14), breastfeeding mothers and persons with compromised renal and immune systems in consonance with the precautionary principle approach.
4. Distributors/importers/exporters, manufacturers, retailers, waste generators and users (dental practitioners, dental schools and researchers) shall phase-out dental amalgam in accordance with this Order.

5. The importation of liquid mercury and dental amalgam capsules for use in dental restorative purposes shall not be allowed upon the effectivity of this Order.
6. The Food and Drug Administration (FDA) shall regulate dental amalgam capsules in combined, pre-dosed encapsulated form, for single use only in accordance with an agreed timeline and supply reduction guidelines within the prescribed period.
7. Under this Order, the phase-out period shall be within three (3) years from effectivity after which the use of dental amalgam in the country shall no longer be allowed.

B. Proper Disposal

1. The management of dental amalgams in dental clinics and dental schools shall be collected, stored and disposed in accordance with the existing rules and regulations of the Environmental Management Bureau (EMB) of the Department of Environment and Natural Resources (DENR) on the disposal of hazardous waste.
2. The waste shall be collected and disposed of through an accredited waste transporter and TSD facility.

C. Institutional Mechanism

1. Strengthening of the operational structure for the implementation of the guidelines on the importation, handling, use and disposal of dental amalgams shall be achieved within the existing public health programs at different levels of governance through multi-sectoral cooperation / collaboration.
2. A reporting mechanism shall be developed through the Inter-Agency Committee on Environmental Health (IACEH) Chemical Safety and Health Sector to discuss issues and concerns of relevant stakeholders on the implementation of this Order. An Inter-Agency Technical Working Group (IATWG) shall be created for monitoring and evaluation of the implementation of the provisions of this Order during the phase out period.
3. Consumer Protection Groups, Civil Society Organizations (CSOs) and the academe may provide assistance to government agencies in the dissemination and implementation of this Order.

D. Capacity Building

1. Health and safety trainings /seminars on the handling, use and disposal of dental amalgams shall be developed and conducted to educate dental health workers, dental school students and patients.
2. Dentists and dental students who are intending to use dental amalgam capsules shall be protected from unnecessary exposure to mercury through training and the proper use of Personal Protective Equipment.



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VI. ROLES AND RESPONSIBILITIES

1. The Department of Health (DOH) shall:
 - a. Strengthen the National Oral Health Program;
 - b. Phase-out the use of dental amalgams in all health care facilities in accordance with the set timelines;
 - c. Develop and conduct training programs on the health effects of mercury and use of mercury – free alternatives for DOH healthcare personnel;
 - d. Raise public awareness on the effects of mercury to human health and environment through the Health Promotion and Communication Service (HPCS); and
 - e. Integrate the existing funds and/or earmark funds for the implementation of this Order.
2. The Food and Drug Administration (FDA) shall:
 - a. Issue an advisory on the phase – out of dental amalgams;
 - b. Stop the registration of dental amalgams during the phase out period;
 - c. Perform post – market surveillance of dental amalgams in the market; and
 - d. Issue regulatory actions to distributors, retailers, importers, exporters, who sell dental amalgams after the phase – out period.
3. The Department of Environment and Natural Resources-Environmental Management Bureau (DENR-EMB) shall:
 - a. Issue an advisory on the proper storage and disposal of dental amalgams;
 - b. Prescribe regulation and licensing requirements for the storage and disposal of dental amalgams; and
 - c. Conduct monitoring to ensure that the disposal of dental amalgams shall be in accordance with the existing policies and guidelines.
4. The Department of Labor and Employment (DOLE) shall prescribe the rules and regulations for occupational safety and health standards for dental clinics.
5. The Department of Finance – Bureau of Custom (DOF-BOC) shall:
 - a. Implement the ban on the importation of dental amalgam in the country;
 - b. Provide a report on the volume of importation of mercury and dental amalgam capsules that have entered the country; and
 - c. Enforce this Order and other proposed guidelines, as necessary, regarding the importation of mercury in the Philippines during the phase – out period.
6. The Department of the Interior and Local Government (DILG) shall:
 - a. Issue and disseminate this Order and other guidelines/memoranda to the Local Government Units relative to this Order; and
 - b. Serve as the oversight body to the LGUs responsible for monitoring their compliance to these guidelines and other issuances pertinent to this Order.
7. The Department of Trade and Industry – Bureau of Philippine Standards (DTI-BPS) in cooperation with the Department of Health, shall issue standards needed for alternative dental restorative materials as Philippine National Standards.



8. The Department of Science and Technology (DOST) in coordination with Department of Health and the Philippine Dental Association, shall lead the research and development efforts on mercury – free alternatives such as resin composites to dental amalgam, conduct further studies on its safety profile and durability, and encourage the search for new and better alternative materials.
9. The Department of Education (DepEd) shall develop and implement strategies to prevent dental caries and dental diseases, promote oral health and the use of mercury free alternatives for dental restorative procedures in school children.
10. The Commission on Higher Education (CHED) shall standardize the teaching and training on the use of alternatives to dental amalgam in the dentistry curriculum in collaboration with the Philippine Association of Dental Colleges (PADC).
11. The Professional Regulation Commission (PRC) shall review and revise the licensure examination for dentist, particularly the practical phase to replace dental amalgam with composite restoration and other available alternatives, under the Board of Dentistry, during the phase - out period.
12. The Philippine Dental Association (PDA) shall:
 - a. Develop clinical guidelines and best practices for the safe use, handling and disposal of dental restorative materials in collaboration with government agencies;
 - b. Formulate best practice guidelines on the use, handling, storage and disposal of alternatives to dental amalgam; and
 - c. Disseminate information materials to patients on oral health programmes and safety of dental restorative materials.
13. The Civil Society Organizations shall:
 - a. Support the campaign of the government on the phase – out of dental amalgam;
 - b. Conduct awareness campaigns on the effects of mercury on health as well as the environmental and health benefits of the phase – out of dental amalgam.

VII. TRANSITORY PROVISION

1. Immediately upon the effectivity of this Order, the following shall be implemented:
 - a. Ban on the importation of liquid mercury for use in dental restorative procedures and dental amalgam and its capsules;
 - b. Ban on the use of dental amalgams and its capsules for children fourteen (14) years old and below, pregnant women and nursing mothers.
2. The ban on the use of existing dental amalgams / capsules for dental restoration procedures in dental clinics and schools shall be carried out after three years from the effectivity of this Order.
3. Proper storage and disposal of all dental amalgam capsules in the country through an accredited TSD facility shall be completed no later than the phase-out period of three (3) years.



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VIII. BUDGET AND FINANCING

The concerned national agencies shall allocate a corresponding yearly budget for the implementation of this Order.

IX. SEPARABILITY CLAUSE

In the event that any provision or part of this order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain and effective.

X. PENALTY CLAUSE

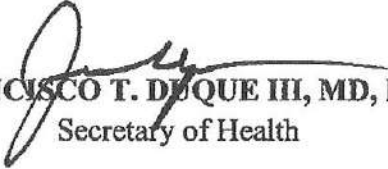
Any person or entity that violates any of the provisions of these guidelines shall be subject to applicable fines and penalties as provided for in Republic Act 9711 "Food and Drug Administration Act of 2009", Republic Act No. 7394 "Consumer Act of the Philippines", and Republic Act No. 6969 "Toxic Substances and Hazardous Wastes and Nuclear Wastes Control Act of 1990" and its corresponding implementing rules and regulations and other existing pertinent laws, rules and regulations.

XI. REPEALING CLAUSE

Provisions of Administrative Order No. 2008-0021 and other issuances or parts thereof that are inconsistent with the provisions of this Administrative Order are hereby repealed, amended or modified accordingly.

XII. EFFECTIVITY

This order shall take effect fifteen (15) days after posting in the official website, publication in a newspaper of general circulation and submission of a copy hereof to the Office of the National Registry of the University of the Philippines Law Center.


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Secretary of Health