



FDA CIRCULAR

No. _____

SUBJECT: Banning of all Mercury-Containing Thermometers, Sphygmomanometers, Dental Amalgam Capsules and Liquid Mercury for Use in Dental Restorative Purposes

I. BACKGROUND

The government signed the Instrument of Ratification of the Minamata Convention on Mercury on 2 June 2020. The Minamata Convention on Mercury is a global treaty to protect human health and the environment from the adverse effects of mercury”.

Also, on 14 May 2020, Department of Health Administrative Order No.: 2020-0020 entitled “Guidelines on the Phase-out of Mercury use in Dental Restorative Procedures” was issued pursuant to Republic Act 11223 otherwise known as the “Universal Health Care Act” and took effect on 6 June 2020 to adopt a phase-out policy of dental amalgams. Under this policy, the use of dental amalgams / capsules for dental restoration procedures in dental clinics and schools shall no longer be allowed after the phase-out period of three (3) years from the effectivity of the said Order.

On 30 July 2008, Department of Health Administrative Order No.: 2008-0021 entitled “Gradual Phase-out of Mercury in all Philippine Health Care Facilities and Institutions”, was issued to cautiously phased out mercury in all Health Care Facilities and Institutions.

Mercury is known to be highly toxic and can be fatal if inhaled and harmful if absorbed through skin. Elemental and methylmercury are toxic to the central and peripheral nervous systems. The inhalation of mercury vapour can produce harmful effects on the nervous, digestive and immune systems, lungs and kidneys, and may be fatal. The inorganic salts of mercury are corrosive to the skin, eyes and gastrointestinal tract, and may induce kidney toxicity if ingested. Neurological and behavioural disorders may be observed after inhalation, ingestion or dermal exposure of different mercury compounds.

Mercury is used in certain medical devices such as thermometers, sphygmomanometers, gastrointestinal devices and dental amalgams.

The Food and Drug Administration, by virtue of Republic Act No. 9711 also known as the “Food and Drug Administration (FDA) Act of 2009, is mandated to protect public health and safety through effective regulation of medical devices in the country. With this, to ensure that only safe and mercury-free medical devices are available in the local market, this Circular is hereby issued.



II. OBJECTIVES

This Circular aims to totally ban the manufacture, distribution, importation, exportation, sale, offer for sale, donation, transfer, and where applicable, the use, promotion, advertising, or sponsorship of mercury-containing thermometers and sphygmomanometers along with dental amalgam capsules and liquid mercury for use in dental restorative purposes to protect human health from the adverse effects of mercury-containing medical devices.

III. SCOPE

This Circular shall cover establishments that are engaged in the manufacture, distribution, importation, exportation, sale, offer for sale, donation, transfer, and where applicable, the use, promotion, advertising, or sponsorship of mercury-containing thermometers and sphygmomanometers as well as dental amalgam capsules and liquid mercury for use in dental restorative purposes.

This issuance shall not cover medical devices containing mercury that as of the moment do not have effective alternative technology and /or considered gold standard that are used in the laboratory to test the accuracy of similar medical devices. Such similar medical devices are considered alternate to the gold standard mercury containing medical device.

IV. DEFINITION OF TERMS

The terms used in this Circular shall have the meaning as defined in R.A 9711 and its implementing rules and regulations, Administrative Order (AO) No. 2008-0021, AO No. 2020-0020 and related laws and regulations. However, for clarity and for purposes of these guidelines, the following terms are defined as follows:

1. Clinical Mercury Thermometer – a device used to measure oral, rectal, or axillary (armpit) body temperature using the thermal expansion of mercury.
2. Dental Amalgam (commonly known as “silver fillings”) – used to repair decayed or broken teeth generally made up of mercury, silver and tin, with small amount of copper and zinc.
3. Dental Amalgam Capsule – a capsule that contains silver alloy, mercury, a pestle and a plastic bubble.
4. Establishment – refers to a company, corporate or any entity that is engaged in the manufacture, distribution, importation, exportation, sale, offer for sale, donation, transfer, and where applicable, the use, promotion, advertising, or sponsorship of mercury-containing thermometers and sphygmomanometers as well as dental amalgam capsules and liquid mercury for use in dental restorative purposes. Establishment include any individual or any entity that sells or offers for sale the said mercury containing medical devices through digital platforms including social media or through online shopping platforms, but does not include those that are located outside the Philippines.

5. Gold standard - refers to a benchmark that is available under reasonable conditions. It refers to an experiment model that has been thoroughly tested and has a reputation in the field as a reliable method that has already been checked and presents the best accuracy.
6. Liquid Mercury (mercury's unique properties) – a liquid at room temperature that bonds well with the alloy powder, making it an important component of dental amalgam that contributes to its durability.
7. Mercury – any substance containing element mercury, either in its pure form, as metallic salts or organometallic compounds.
8. Mercury Sphygmomanometer – manual device for measuring Blood Pressure (BP), composed of an inflation bulb for controlling the air pressure in the cuff which is attached to a measuring unit and a mercury-infused glass column which displays BP (values in mm Hg)

V. GUIDELINES

1. The manufacture, distribution, importation, exportation, sale, offer for sale, donation, transfer, and where applicable, the use, promotion, advertising, or sponsorship of mercury-containing thermometers and sphygmomanometers are strictly prohibited.
2. Offering for sale and/or sale of mercury-containing thermometers and sphygmomanometers through different digital platforms including social media or through online shopping platforms is strictly prohibited.
3. In accordance with AO 2020-0020, the importation of liquid mercury and dental amalgam capsules for use in dental restorative purposes shall not be allowed.
4. Following AO 2020-0020 and AO 2008-0021, FDA shall not be accepting any application nor shall issue any authorization for the manufacture, distribution, importation, exportation, sale, offer for sale, donation, transfer, and where applicable, the use, promotion, advertising, or sponsorship of liquid mercury and dental amalgams for use in dental restorative purposes, mercury-containing thermometers and sphygmomanometers.
5. Offering for sale and/or sale of second-hand mercury-containing thermometers and sphygmomanometers are likewise strictly prohibited.
6. It shall be the responsibility of the manufacturer, trader, distributor, importer, exporter, wholesaler to conduct inventory of stocks and recall of their products to ensure that all mercury-containing thermometers and sphygmomanometers are removed from the market and ensure that such products are shall no longer be made available to the market.
7. The storage, transport, and disposal of these banned medical devices shall comply with the existing implementing rules and regulations of the Department of Environment and Natural Resources (DENR).

VI. PENALTY CLAUSE

Any establishment found to be in violation of the provisions of this issuance shall be subjected to sanctions and penalties as prescribed under RA 9711 and its IRR.

VII. SEPARABILITY CLAUSE

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions of this Circular shall not be affected.

VIII. TRANSITORY PROVISION

Authorized distributors and retailers of dental amalgam capsules shall be given until June 6, 2023 to exhaust their remaining stocks in the market. After the said date, distribution, offer for sale and sale of the said product shall no longer be allowed.

Whereas, for thermometers and sphygmomanometers containing mercury including liquid mercury shall be given a grace period of thirty (30) days from the effectivity of this Circular to comply with the provisions of this notification.

IX. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and upon acknowledgement of receipt of a copy hereof by the University of the Philippines - Office of the National Administrative Register.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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