



FDA CIRCULAR
No. 2022-003

10 JUN 2022

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

I. BACKGROUND/RATIONALE

According to the World Health Organization Fact Sheets on Mercury and Health, mercury is considered as one of the top ten chemicals or groups of chemicals of major public health concern. Exposure to mercury even small amounts may cause serious health problems and is a threat to the development of the child in utero and early in life. Mercury may have toxic effects on the nervous, digestive and immune systems, and on lungs, kidneys, skin and eyes.

Mercury is used in a wide variety of medical devices such as thermometers, sphygmomanometers, gastrointestinal devices and dental amalgams. Considering this fact, mercury exposure is possible to all the users of the aforementioned devices.

With the recognition that mercury is a threat to public health, the United Nations Environment Programme (UNEP) Governing Council agreed in 2009 to the elaboration of a legally binding instrument on mercury. To support this global treaty, the Minamata Convention on Mercury entered into force on August 2017 which is a global treaty that aims to protect human health and the environment from the anthropogenic emissions and releases of mercury and mercury compounds. In support, the government of the Philippines signed the Instrument of Ratification of the Minamata Convention on Mercury on 02 June 2020. The Food and Drug Administration (FDA), being the agency mandated to regulate medical devices decided that it is imperative for the FDA to sustain the government's effort in phasing out mercury-added products by issuing a policy to further strengthen the Ratification of the Minamata Convention on Mercury.

Paragraph 1 of Article 4 on Mercury-added products of the Minamata Convention provides that the manufacture, import or export of mercury-added products listed in Part I of Annex A after the phase-out date specified for those products shall not be allowed by the Party or the country bound by the Convention. Such list includes thermometer and sphygmomanometer whose phase out date was stated to be 2020.

Moreover, Paragraph 3 of the aforementioned Article on Mercury-added products of the Minamata Convention cited that each Party shall take measures to phase down the use of dental amalgam taking into account the country's domestic circumstances and relevant international guidance.



In line with the above-mentioned global treaty on mercury in which the Philippines signed in October 2013, the Department of Health (DOH) has implemented measures or strategies to reduce the use of mercury-added products.

On 14 May 2020, DOH Administrative Order (AO) 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 06 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. To date, the result of the implementation of AO 2020-0020 is the exclusion of dental amalgam and its capsules as well as liquid mercury from the list of registrable medical devices in the Philippines.

Prior to the issuance of AO No. 2020-0020, DOH has already issued AO No. 2008-0021 entitled “Gradual Phase-out of Mercury in all Philippine Health Care Facilities and Institutions” on 30 July 2008 to cautiously phase out mercury in all health care facilities and institutions. Meanwhile, BAN Toxics, a non-government environmental organization based in the Philippines, conducted a research and produced a paper on the “Situation Assessment of Mercury-Containing Medical Measuring Devices in the Philippines” that contained data collection and analysis results based on the implementation of the abovementioned AO which have been eventually reviewed and approved by their project implementing agency, the Asian Institute for Technology, Regional Resource Center for Asia and the Pacific as well as their partners at the Hazardous Waste Management Section. Also, it was presented and approved at the National Stakeholder Workshop held on 06 September 2021. (*Please refer to Annex 1*). Based on their data, the implementation of the aforesaid AO was successful. However, we cannot neglect the fact that in the period from 2010 to 2020, there are still hospitals that purchased mercury-added medical devices.

Despite the policies that have been implemented in today’s era when internet is accessible, the promotion, advertisement, sale and offer for sale of mercury-added medical devices has become widespread on various digital platforms including social media or through online shopping platforms. The policies issued do not address the online sale of mercury-added medical devices.

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. To address the current issues arising from the rampant sale of mercury-added medical devices through various digital platforms and to totally ban such devices in the country, this Circular is hereby issued.

II. OBJECTIVES

This Circular aims to totally ban the manufacture, importation, exportation, distribution, sale, offer for sale, donation, transfer, and where applicable, the use, promotion, advertising, or sponsorship of mercury-added 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-added 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-added 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 (IRR), 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:

- A. Clinical Mercury Thermometer – a device used to measure oral, rectal, or axillary (armpit) body temperature using the thermal expansion of mercury.
- B. 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.
- C. Dental Amalgam Capsule – a capsule that contains silver alloy, mercury, a pestle and a plastic bubble.
- D. 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 includes 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.
- E. 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.
- F. 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.
- G. Mercury – any substance containing the element mercury, either in its pure form, as metallic salts or organometallic compounds.

- H. 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

- A. The manufacture, distribution, importation, exportation, sale, offer for sale, donation, transfer, and where applicable, the use, promotion, advertising, or sponsorship of mercury-added thermometers and sphygmomanometers are strictly prohibited.
- B. Offering for sale and/or sale of mercury-added thermometers and sphygmomanometers through different digital platforms including social media or through online shopping platforms is strictly prohibited.
- C. The importation, distribution, sale or offer for sale of liquid mercury and dental amalgam capsules for use in dental restorative purposes shall not be allowed.
- D. 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-added thermometers and sphygmomanometers.
- E. Offering for sale and/or sale of second-hand mercury-added thermometers and sphygmomanometers are likewise strictly prohibited.
- F. 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-added thermometers and sphygmomanometers are removed from the market and ensure that such products shall no longer be made available to the market.
- G. 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

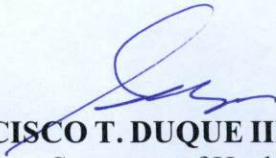
Any establishment found to be in violation of the provisions of this issuance shall be subjected to sanctions and penalties as prescribed under RA 9711 and its IRR.

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. EFFECTIVITY

This Circular shall take effect fifteen (15) days following its publication in the Official Gazette or in a newspaper of general circulation and upon filing three (3) certified true copies with the University of the Philippines Law Center – Office of the National Administrative Register



FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

DTN: 20201030152202

The table below shows the purchase history of mercury-containing medical devices from hospitals for the year 2010-2020 that were conducted by BAN Toxics as part of the "Situation Assessment of Mercury-Containing Medical Measuring Devices in the Philippines"

Name of Hospital	Mercury-Containing Desk Sphygs. Purchased (2010 – 2020)										
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Zamboanga Del Sur Medical Center	100	100	100	100	0	0	0	0	0	0	0
Tuguegarao City People's General Hospital	20	20	20	40	10	10	10	10	10	10	10
Las Pinas City Medical Center	5	10	8	9	8	7	7	5	10	6	9
Nodado General Hospital	10	5	5	6	5	10	3	0	0	0	0
Ipil Doctors Hospital	0	0	0	0	0	5	6	6	8	6	6
Bayugan City Doctors Hospital	5	5	5	10	0	0	0	0	0	0	0
Olivarez General Hospital	8	4	6	4	0	0	0	0	0	0	0
Zamboanga City Medical Center	5	5	5	5	0	0	0	0	0	0	0
Wellserved Infirmary And Drugstore Inc	3	1	1	1	2	1	2	0	0	0	0
Aravat Doctors Hospital	0	0	0	10	0	0	0	0	0	0	0
Aguas Z Maternity And General Hospital	3	0	1	0	1	1	0	1	0	0	0
Statelab Clinics & Diagnostic Center, Inc.	1	1	1	1	1	0	0	0	0	0	0
Lady Of Lourdes Hospital And Colleges Of Cavbiga Inc	0	0	0	0	0	0	1	0	0	0	1
Lph-San Pedro District Hospital	2	0	0	0	0	0	0	0	0	0	0
Baron Yee Hospital	1	0	0	0	0	0	0	0	0	0	0
Zamboanga Puericulture Maternity Lying-In Hospital	1	0	0	0	0	0	0	0	0	0	0
St George Clinical Laboratory Services	1	0	0	0	0	0	0	0	0	0	0

Name of Hospital	Mercury-Containing Standing Sphygs. Purchased (2010 – 2020)										
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Aparri Provincial Hospital	10	10	10	10	10	10	10	10	10	10	10
Nodado General Hospital	15	12	10	8	15	6	5	0	0	0	0
Corazon Locsin Montelibano Memorial Regional Hospital	0	0	4	0	12	0	40	4	0	0	10
Las Pinas City Medical Center	5	3	6	5	5	4	7	6	8	5	5
Zamboanga Del Sur Medical Center	10	10	10	10	10	0	0	0	0	0	0
Tuguegarao City People's General Hospital	10	10	10	0	0	0	0	0	0	0	0
Donsol District Hospital	2	2	3	2	1	2	4	2	3	4	2
Zamboanga City Medical Center	5	5	5	5	0	0	0	0	0	0	0
St. Victoria Hospital	0	0	0	0	0	0	0	9	9	0	0
Pines City Doctors' Hospital	0	0	0	0	0	0	0	0	0	0	15
Olivarez General Hospital	4	2	5	2	0	0	0	0	0	0	0
Our Mother Of Piat Medical Maternity & Lying In Clinic	1	1	1	1	1	1	1	1	1	1	1
Statelab Clinics & Diagnostic Center, Inc.	2	2	2	2	2	0	0	0	0	0	0
The Medical City South Luzon (Formerly: Southern Luzon Hospital And Medical Center, Inc.)	0	0	0	0	0	0	1	1	2	1	0
San Joaquin Mother And Child Hospital	0	0	0	0	0	0	0	0	0	2	0
Minglanilla District Hospital	0	0	0	0	0	0	0	2	0	0	0
Wellserved Infirmary And Drugstore Inc	0	0	1	0	0	0	1	0	0	0	0
The Medical City @ Waltermart Makati	1	0	0	0	0	0	0	0	0	0	0
LPH-San Pedro District Hospital	1	0	0	0	0	0	0	0	0	0	0

Name of Hospital	Mercury-Containing Thermometers Purchased (2010 – 2020)										
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Zamboanga Puericulture Maternity Lying-In Hospital	1,200	1,000	0	0	0	0	0	0	0	0	0
Zamboanga Del Sur Medical Center	200	200	200	100	100	0	0	0	0	0	0
Ospital Ning Angeles	500	0	0	0	0	0	0	0	0	0	0
Lph-San Pedro District Hospital	100	100	100	100	100	0	0	0	0	0	0
Urdaneta District Hospital	150	100	80	0	0	0	0	0	0	0	0
Zamboanga City Medical Center	70	50	30	30	0	0	0	0	0	0	0
Nodado General Hospital	30	25	25	20	30	20	25	0	0	0	0
Seamen's Hospital Iloilo	120	0	0	0	0	0	0	0	0	0	0
Sto Rosario Hospital Inc.	120	0	0	0	0	0	0	0	0	0	0
Tuguegarao City People's General Hospital	50	40	30	0	0	0	0	0	0	0	0
Minglanilla District Hospital	20	20	20	20	20	20	0	0	0	0	0
Aguas Z Maternity And General Hospital	15	10	12	15	18	15	8	10	0	0	0
Ipil Doctors Hospital	10	10	9	8	10	10	8	10	8	10	8
Adventist Hospital Santiago City, Inc.	0	0	0	0	0	0	0	0	12	12	12
Trinity Woman And Child Center "The Birthplace"	10	6	8	0	0	0	0	0	0	0	0
Lyceum Of Aparri Hospital	0	0	0	0	0	0	0	0	0	0	24
Dr. Marcelo M. Chan Memorial Hospital, Inc.	5	5	5	5	0	0	0	0	0	0	0
Olivarez General Hospital	4	3	6	7	0	0	0	0	0	0	0

Dr Danilo V Mallari Medical Clinic	1	1	1	1	1	1	1	2	2	2	2
The Medical City South Luzon (Formerly: Southern Luzon Hospital And Medical Center, Inc.)	14	0	0	0	0	0	0	0	0	0	0
Primelab Inc.	1	1	1	1	1	1	1	1	1	2	3
Fort Del Pilar Station Hospital	0	0	0	0	0	0	0	3	3	3	3
Wellserved Infirmary And Drugstore Inc	0	1	2	2	1	1	1	2	2	0	0
United Doctors Hospital Of Kidapawan Inc	10	0	0	0	0	0	0	0	0	0	0
Statelab Clinics & Diagnostic Center, Inc.	2	2	2	2	2	0	0	0	0	0	0
The Medical City @ Waltermart Makati	2	1	1	1	1	1	1	0	0	0	0
New World Diagnostics, Inc. - Las Piñas Branch	0	0	0	0	0	8	0	0	0	0	0
St. Joseph Infirmary	2	0	1	1	2	1	0	0	0	0	0
Corazon Locsin Montelibano Memorial Regional Hospital	5	0	0	0	0	0	0	0	0	0	0
Surallah Community Hospital	2	2	0	0	0	0	0	0	0	0	0
Cuison Hospital Incorporated	2	0	0	0	0	0	0	0	0	0	0
St George Clinical Laboratory Services	2	0	0	0	0	0	0	0	0	0	0
Blessed Heart Diagnostics And Multispecialty Clinic	0	0	0	0	0	2	0	0	0	0	0
Bloodworks Lab Inc	0	0	2	0	0	0	0	0	0	0	0
New World Diagnostics, Inc - Ongpin Branch	0	0	0	0	0	0	0	0	1	0	0
New World Diagnostics Inc.-Baliuag Branch	0	0	0	0	0	0	0	0	0	0	1

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