Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

27 August 2021

DEPARTMENT CIRCULAR
No. 2021 - 0376

FOR: **ALL CENTERS FOR HEALTH DEVELOPMENT, NATIONAL DRUG POLICY COMPLIANCE OFFICES, LEAGUES OF CITIES, PROVINCES AND MUNICIPALITIES, PROFESSIONAL HEALTH SOCIETIES, DIRECTORS OF BUREAUS AND REGIONAL OFFICES, BARMM MINISTER OF HEALTH, CHIEFS OF MEDICAL CENTERS AND SANITARIES, AND OTHER CONCERNED**

SUBJECT: **Interim Requirements for the Health Technology Assessment (HTA) of Medical Devices**

By virtue of Republic Act 11223, otherwise known as the Universal Health Care (UHC) Act, health technology assessment (HTA) shall be institutionalized as a fair and transparent priority-setting mechanism to provide financing and coverage recommendations on health technologies to be funded by the Department of Health (DOH) and the Philippine Health Insurance Corporation (PhilHealth).

In accordance with the mandate of the Health Technology Assessment Council (HTAC) to ascertain the safety and quality of health technologies, proponents shall submit a Certificate of Product Registration (CPR), Certificate of Product Notification (CPN), or appropriate certification issued by the Philippine Food and Drug Administration (FDA).

For medical devices that are not yet covered by the mandatory registration or notification, the HTAC shall require the proponents of medical devices to submit the following interim requirements in the absence of the CPR or CPN:

1. Certificate of License To Operate (LTO) as a medical device establishment issued by the FDA; and,
2. Any of the appropriate product approval:
   a. Certificate of Medical Device Notification (CMDN) pursuant to FDA Circulars 2020-001, 2020-001-A, and 2021-002 (for all Class A medical devices and non-registrable Class B, C, and D medical devices);
   b. Certificate of Medical Device Registration (CMDR) for registrable medical devices pursuant to FDA Circular 2020-001-A (for Classes B, C, and D);
   c. Equivalent CPR/marketing authorization from National Regulatory Agencies (NRA) with mature and established medical device regulation, either from the country of origin or other countries where the same product and manufacturer are registered/notified.
3. Manufacturers must also submit proof of independent validation or validation results of a third-party trial/study.

Verification of registered/notified medical devices (including in-vitro medical devices) shall be viewed at www.fda.gov.ph via the verification portal. Request for product verification of those products that are not included in the FDA verification portal, but with presented FDA issued CPR or CPN shall be forwarded to cdrrhr@fda.gov.ph or cdrrhr.lrd@fda.gov.ph.

After completing the appropriate regulatory requirements, applications of COVID-19 health technologies and products for government procurement shall be endorsed to the Disease Prevention and Control Bureau (DPCB) for initial screening and prioritization prior to HTA.

For your information and guidance.

By Authority of the Secretary of Health:

GERARDO V. BAYUGO, MD, MPH, CESO I
Undersecretary of Health
Health Regulation Team

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Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

25 August 2021

GERARDO V. BAYUGO, MD., MPH, CESO I
Undersecretary of Health
Health Regulation Team
Department of Health
Manila

Dear Usec Bayugo:

This refers the draft Department Circular on the Interim Requirements for the Health Technology Assessment (HTA) of Medical Devices.

The Food and Drug Administration concurs with the attached drat Department specifically on the required authorization to be submitted to HTAC and the verification procedure of these authorization.

Thank you.

Very truly yours,

ROLANDO ENRIQUE D. DOMINGO, MD
Director General