

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
Second Regular Session

HOUSE BILL NO. 8660



Introduced by: Hon. Angelina "Helen" D.L. Tan, M.D.

AN ACT
EXEMPTING ESSENTIAL AND CRITICAL MEDICINES AND VACCINES FROM
CERTAIN PROVISIONS OF REPUBLIC ACT NO. 11223, OTHERWISE KNOWN
AS THE UNIVERSAL HEALTHCARE LAW, DURING PUBLIC HEALTH
EMERGENCIES

EXPLANATORY NOTE

Republic Act No. 11223, or the Universal Healthcare Law, provides for the health technology assessment process, a priority setting mechanism that shall be recommendatory to the Department of Health (DOH) and Philippine Health Insurance Corporation (PhilHealth) for the development of policies and programs, regulation, and the determination of a range of entitlements such as drugs, medicines, pharmaceutical products, and other devices, procedures and services. The law further provides that a positive recommendation from the Health Technology Assessment Council (HTAC) is needed before the DOH and PhilHealth can invest in any health technology or develop any benefit package. One of the criteria that the HTAC must observe prior to making recommendations is that such a pharmaceutical product has undergone Phase IV clinical trial, and systematic review and meta-analysis must be readily available.

However, public health emergencies such as the COVID-19 pandemic require the State to act faster than what regular procedures allow in order to expedite the procurement of life-saving medicines and vaccines. Given the very short time frame that may be available to develop and produce these medicines and vaccines, manufacturers may not be able to go through the full process of clinical trials. For example, some COVID-19 vaccines have released preliminary data and are on Phase III clinical trials, which will take another two (2) to (5) years of further data gathering before reaching Phase IV. All available COVID-19 vaccines have not reached Phase IV clinical trials. This limits the recommendatory power of the HTAC, and hinders the country's procurement efforts.

To this end, this bill seeks to exempt essential and critical medicines and vaccines from the minimum requirement of undergoing Phase IV Clinical Trial as a criterion for safety and effectiveness and allow recommendations based on the most readily available data such as preliminary data for phase III clinical trial for a limited period in absence of a completed

phase III and Phase IV clinical trials, during public health emergencies provided that these essential and critical medicines and vaccines have been issued an Emergency Use Authority.

In view of the foregoing, the immediate passage of this bill is earnestly sought.



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4th District, Quezon

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Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

Section 1. Short Title. – This Act shall be known as the “*Agarang Lunas Laban sa Krisis Pangkalusugan Act*”.

Sec. 2. Declaration of Policy. – It is the policy of the State to protect and promote the right to health of the people and instill health consciousness among them.

Pursuant to this and the objectives of universal healthcare as provided in Republic Act No. 11223 or the Universal Healthcare Law, the State recognizes the importance of the health assessment technology process as a fair and transparent priority setting mechanism, adhering to the principles of ethical soundness, inclusiveness and preferential regard for the underserved, evidence-based and scientific defensibility, transparency and accountability, efficiency, enforceability and availability of remedies, and due process.

The State acknowledges that public health emergencies such as the COVID-19 pandemic necessitate the need for emergency processes in order to expedite the procurement of life-saving medicines and vaccines. To this end, the State shall take proactive measures to fast-track the acquisition of medication and vaccines during public health emergencies, while

maintaining due regard for scientific evidence and consensus, quality healthcare, and the safety of all Filipinos.

Sec. 3. *Exemption of Essential and Critical Medicines and Vaccines from Phase IV Clinical Trials.* – Notwithstanding any law to the contrary, and upon the declaration of the President of a State of Public Health Emergency as provided in Republic Act No. 11332, the requirement of undergoing Phase IV Clinical Trials as a criterion for safety and effectiveness observed in the Health Technology Assessment (HTA) process provided under R.A 11223, shall be waived. The use of preliminary data on Phase III clinical trials and recommendations from the World Health Organization, in the absence of a completed Phase III and Phase IV clinical trials may be allowed as basis in HTA recommendations in times of public health emergencies, *Provided That*, the essential and critical medicine or vaccine manufacturer has been issued an Emergency Use Authorization by the Food and Drug Administration (FDA); *Provided further*, That this authority shall expire five (5) years from the declaration of State of Public Health Emergency, or until such time that the President, upon the recommendation of the Department of Health (DOH), declares the cessation of the Public Health Emergency.

“Essential and critical medicines” under this Act shall refer to those medicines and vaccines that satisfy the priority health care needs of the population as determined by the Department of Health for a specific declared public health emergency.

Sec. 4. *Separability Clause.* – If any provision of this Act is declared unconstitutional or otherwise invalid, the validity of the other provisions shall not be affected thereby.

Sec. 5. *Repealing Clause.* – All other laws, decrees, orders, rules and regulations, other issuances, or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

Sec. 6. *Effectivity.* – This Act shall take effect immediately upon its publication in a newspaper of general circulation or in the *Official Gazette*.

Approved,