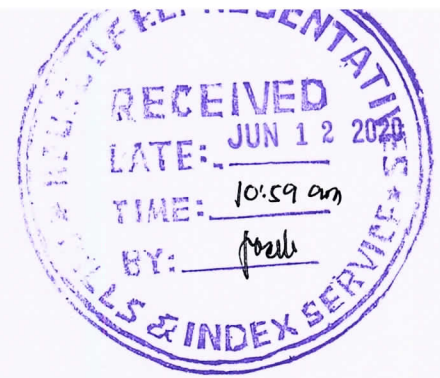


Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 6995



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

AN ACT

PROVIDING FOR THE STOCKPILING OF STRATEGIC AND CRITICAL DRUGS AND MEDICINES, VACCINES, DEVICES, AND MATERIALS FOR PUBLIC HEALTH EMERGENCIES, CREATING FOR THE PURPOSE THE HEALTH PROCUREMENT AND STOCKPILING BUREAU UNDER THE DEPARTMENT OF HEALTH, AND APPROPRIATING FUNDS THEREFOR

EXPLANATORY NOTE

The report by the Global Preparedness Monitoring Board (GPMB), an independent monitoring and advocacy body that aims to assess the world's ability to protect itself from health emergencies and identify critical gaps to preparedness across multiple perspectives, warns that humankind is stumbling toward the 21st-century equivalent of the 1918 influenza pandemic, which affected one-third of the world's population and killed approximately 50 million people.

Based on the report, only one third of countries, as of 2018, have the capacities required under the International Health Regulations (IHR) and that the great majority of national health systems would be unable to handle a large influx of patients infected with a respiratory pathogen capable of easy transmissibility and high mortality.

As pointed out in the Joint External Evaluation (JEE) Mission report, the Philippines, due to its location, is one of the most natural-disaster prone countries in the world and in the past decade the country has faced challenges in making solid progress in infectious disease control. Given this situation, the country's preparedness in times of public health emergencies is significantly necessary such as during pandemics and natural disasters.

One case in point that caught the country and the world flat footed is the current COVID-19 situation, which affected the global and local production and distribution of pharmaceuticals and medical devices as well as the supply of raw materials, active pharmaceutical ingredients, excipients, packaging materials as well as finished medical products needed to combat COVID-19 and other diseases of public health. This is after India and China, two of the biggest country suppliers of active ingredients and finished generic products, were both severely affected by the pandemic. To make things worse, some countries like France, Germany, Turkey, Russia, and India have imposed limits on export of medicines and medical supplies/equipment such as facemasks, shields, and ventilators to mitigate critical shortages in their countries. The European Union has also imposed a block-wide export ban on some medical protective equipment in order to keep adequate supplies within the region in the face of scarcity in supply amid the increasing demand.

This bill aims to protect public health by addressing the problem of access to critical drugs and medicines, vaccines, devices, and materials in times of public health emergencies by mandating the procurement and stockpiling of critical and strategic pharmaceuticals and medical devices as well as the supply of raw materials.

It is hoped that through this proposal, problems on the lack of access to strategic and critical drugs and medicines, vaccines, devices, and materials in times of national need may now be adequately addressed.

Hence, immediate passage of this bill is earnestly being sought.

ANGELINA "HELEN" D.L. TAN, M.D.
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 “Health Procurement and Stockpiling 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. The State also mandates the adoption of an integrated and comprehensive approach to health development.

Towards this end, it shall protect public health and safety by preventing and controlling the spread of diseases and other health hazards through the stockpiling of essential and critical drugs and medicines, vaccines, devices, and materials to effectively and swiftly confront the devastating consequences of public health emergencies.

SEC. 3. *Definition of Terms.* –

(a) *Countertrade* refers to a supplemental trade tool in connection with transactions involving the importation or procurement of foreign capital equipment, machinery, products, goods and services of at least US\$1 million and above or its foreign currency equivalent;

(b) *Device* means instruments, apparatus, or contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; or (2) to affect the structure or any function of the body of man or animals;

(c) *Drugs and medicines* refer to any chemical compound or biological substance, other than food, intended for use in the treatment, prevention or diagnosis of disease in humans or animals, including but not limited to:

(1) any article recognized in the official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippine Pharmacopoeia, Philippine National Drug Formulary, British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Indian Pharmacopoeia, any national compendium or any supplement to any of them;

(2) any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) any article other than food intended to affect the structure or any function of the human body or animals;

(4) any article intended for use as a component of any articles specified in clauses (1), (2), and (3) not including devices or their components, parts, or accessories; and

(5) herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine which are:

(i) recognized in the Philippine National Drug Formulary;

(ii) intended for use in the treatment or cure or mitigation of disease symptoms, injury or body defects in humans;

(iii) other than food, intended to affect the structure or any function of the human body;

(iv) in finished or ready-to-use dosage form; and

(v) intended for use as a component of any of the articles specified in clauses (i), (ii), (iii), and (iv);

(d) *Materials* refer to essential medical and/or life-saving supplies needed in times of pandemics such as face masks, body bags, personal protective equipment, and similar supplies or equipment;

(e) *Public health emergency* refers to an occurrence or imminent threat of an illness or health condition that:

(1) Is caused by any of the following:

(i) Bio terrorism;

(ii) Appearance of a novel or previously controlled or eradicated infectious agent or biological toxin;

(iii) A natural disaster;

(iv) A chemical attack or accidental release;

(v) A nuclear attack or accident; or

(vi) An attack or accidental release of radioactive materials; and

(2) Poses a high probability of any of the following:

(i) A large number of deaths in the affected population;

(ii) A large number of serious injuries or long-term disabilities in the affected population;

(iii) Widespread exposure to an infectious or toxic agent that poses a significant risk of substantial harm to a large number of people in the affected population;

(iv) International exposure to an infectious or toxic agent that poses a significant risk to the health of citizens of other countries; or

(v) Trade and travel restrictions;

(f) *Stockpiling* refers to an inventory of health commodities and materials or those physical reserve of definite quantities of commodities or materials that are stored in government warehouses or on government-owned properties that are intended for all essential health uses in times of emergencies.

SEC. 4. *Creation of a Health Procurement and Stockpiling Bureau.* - There is hereby created a body under the Department of Health to be known as the Health Procurement and Stockpiling Bureau (HPSB), hereinafter referred to as the Bureau. It shall serve as the principal agency mandated to undertake a transparent, fair, proactive, innovative procurement service for the DOH and to stockpile, conserve, and facilitate the release of adequate amounts of potentially life-saving pharmaceuticals, vaccines, devices, and materials in times of public health emergencies.

SEC. 5. *Organization.* - The Bureau shall absorb the existing Procurement Service of the DOH. It shall be headed by a Director and shall be provided with adequate personnel complement and all necessary material means and resources.

Subject to the approval of the Department of Budget and Management (DBM), the Secretary of Health shall determine the organizational structure of the Bureau and create new divisions or units as may be necessary

and appoint officers and employees in accordance with the civil service laws, rules and regulations.

SEC. 6. *Functions and Responsibilities.* – The Bureau shall perform the following functions and responsibilities:

- (a) Formulates plans/policies/programs on procurement management;
- (b) Undertake the procurement process to provide the logistical requirements;
- (c) Conduct procurement monitoring visits to DOH field offices;
- (d) Provide technical assistance to DOH field offices on procurement matters;
- (e) Identify, in consultation with appropriate agencies, strategic and critical drugs and medicines, vaccines, devices, and materials needed for public health emergencies that have the distinct capability of being stockpiled in strategic and secure areas of the country;
- (f) Serve as a national supplement of drugs and medicines, vaccines, devices, and materials to state supplies acting as a stopgap buffer when the immediate supply of adequate amounts of drugs and medicines, vaccines, devices, and materials may not be immediately available;
- (g) Ensure rotation, replenishment, and freshness of stocks and that there exists at all times steady, available and adequate supply of drugs and medicines, vaccines, devices, and materials, which are essential in responding to public health emergencies;
- (h) Facilitate the provision of potentially life-saving pharmaceuticals, vaccines, devices, and materials in times of public health emergencies.
- (i) Act as supply-chain manager in the stockpiling of strategic and critical drugs and medicines, vaccines, devices, and materials;
- (j) Acquire and release drugs and medicines, vaccines, devices, and materials, as directed by the Secretary of Health, in the interest of the public in response or in preparation of any conceived public health emergency.
- (k) Dispose drugs and medicines, vaccines, devices, and materials as required for purposes of addressing public health emergencies;
- (l) Require all suppliers to monitor their stocks and production capacity and notify supply disruptions at least six (6) months in advance;
- (m) Regular analysis and communication of impending shortages ahead of time;
- (n) Facilitate the creation of a conducive environment to encourage pharmaceutical and device self-sufficiency for medical supplies needed by the country by forging public-private collaboration with institutions, sectors and the industry, which could bolster government efforts to achieve pharmaceutical and device self-sufficiency;
- (o) Make an in-depth study on drugs and medicines, vaccines, devices, and materials supply shortage in the country; and
- (p) Spearhead the crafting of a multi-sector national drug and device security program towards the country's self-reliance in producing drugs and medicines, vaccines, devices, and materials.

SEC. 7. *Sources.* – Consistent with the country's obligations under international treaties and agreements, drugs and medicines, vaccines, devices, and materials may be obtained from domestic or foreign sources and the procurement thereof shall be open to all eligible suppliers, manufacturers and distributors. However, in the interest of availability, efficiency, and timely delivery of drugs and medicines, vaccines, devices, and materials, the Bureau shall encourage the development of domestic sources to ensure steady, available and adequate supply of such drugs and medicines, vaccines, devices, and materials that are essential in responding to public health emergencies, and in such manner as may be allowed by law, to include countertrade and industrial cooperation to augment stockpiling and availability of critical materials by:

(a) Purchasing, or making a commitment to purchase, either directly or through countertrade, strategic and critical drugs and medicines, vaccines, devices, and materials of domestic origin when such are needed for the stockpile;

(b) Contracting with domestic facilities, or making a commitment to contract with domestic facilities, for the processing or refining of strategic and critical drugs and medicines, vaccines, devices, and materials in the stockpile when processing or refining is necessary to convert such into a form more suitable for storage and subsequent disposition;

(c) Identifying existing domestic facilities and domestically produced strategic and critical drugs and medicines, vaccines, devices, and materials to meet the requirements of public health and essential civilian industries in times of public health emergency when existing domestic sources of supply are either insufficient or vulnerable to single points of failure; and

(d) Contracting with domestic facilities to recycle strategic and critical devices and materials, thereby increasing domestic supplies when such devices and materials would otherwise be insufficient to support public health needs.

SEC. 8. *Institutional Linkages.* – The DOH shall maintain and develop institutional linkages or partnerships with government and non-government institutions including, but not limited to, the Department of National Defense, Department of Interior and Local Government, Department of Social Welfare and Development, Department of Finance, Department of Trade and Industry, National Disaster Risk Reduction and Management Council, Food and Drug Administration, Bureau of Customs, Philippine Council for Health Research and Development, Philippine International Trading Corporation, Government Procurement Policy Board, the price negotiation board as provided under Section 28 (b) of Republic Act No. 11223, otherwise known as the “Universal Health Care Act”, World Health Organization, Philippine Red Cross, and other pertinent institutions, concerning the procurement, distribution and utilization of drugs and medicines, vaccines, devices, and materials in the stockpile.

SEC. 9. *Establishment of Medical Stockpiling Fund.* – There is hereby established a Medical Stockpiling Fund to support the national drug and device security program. The DOH shall manage the Fund in accordance with existing budgeting, accounting and auditing rules and regulations and shall make a quarterly report to the Office of the President and Congress on the disbursement of the Fund.

The DOH may solicit and receive donations which shall form part of the Fund and such donations shall be exempt from income and or donor’s tax and all other taxes, fees and charges imposed by the government. Likewise, fund raising activities may be conducted by the DOH and the proceeds of which shall accrue to the Fund and shall be exempt from any and all taxes.

Receipts from donations, whether in cash or in kind, shall be accounted for by the DOH in accordance with accounting and auditing rules and regulations. The receipts from cash donations and proceeds from sale of donated commodities shall be deposited with the National Treasury and recorded as a special account in the General Fund and shall be available to the DOH through a special budget pursuant to Section 35, Chapter 5, Book VI of Executive Order No. 292. The cash value of the donations shall be deemed automatically appropriated for the purpose specified by the donor. Donations with a term not exceeding one (1) year shall be treated as trust receipts.

The DOH shall submit the quarterly reports of all donations received, whether in cash or in kind, and expenditures or disbursements thereon with electronic signature to the DBM, through the Unified Reporting System, and to the Speaker of the House of the Representatives, the President of the Senate of the Philippines, the House Committee on Appropriations, the Senate Committee on Finance and the Commission on Audit, by posting such reports on the DOH website for a period of three (3) years. The Secretary of Health shall send written notice to the said offices when said reports have been posted on its website which shall be considered the date of submission.

SEC. 10. *Report to Congress.* – The DOH shall submit an annual report to the Congress of the Philippines, through the Committee on Health of the House of Representatives and the Committee on Health and Demography of the Senate on or before February 15 of each year, detailing its operations under this Act which shall include:

(a) information with respect to foreign and domestic purchases of stockpiled drugs and medicines, vaccines, devices, and materials;

(b) information with respect to the acquisition and disposal of stockpiled drugs and medicines, vaccines, devices, and materials;

(c) such other pertinent information regarding the implementation of this Act.

SEC. 11. *Appropriations.* - The amount necessary to carry out the provisions of this Act shall be included in the General Appropriations Act of the year following its enactment into law and thereafter.

SEC. 12. *Implementing Rules and Regulations.* - The Secretary of Health, in consultation with appropriate government agencies, shall promulgate the necessary rules and regulations for the implementation of this Act within sixty (60) days from its effectivity.

SEC. 13. *Repealing Clause.* - All laws, executive orders, presidential decrees, presidential proclamations, letters of instruction, rules and regulations or part, thereof which are inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SEC. 13. *Separability Clause.* - If any provision of this Act is declared unconstitutional or invalid, other parts or provisions hereof not affected thereby shall continue to be in full force and effect.

SEC. 14. *Effectivity.* - This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in two (2) newspapers of general circulation in the Philippines.

Approved,