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Second Regular Session

HOUSE OF REPRESENTATIVES

H. No. 9456

BY REPRESENTATIVES TAN (A.), BIAZON, SAVELLANO, VILLARICA, OUANO-DIZON, ALONTE, DALIPE, UY (J.), MARIANO-HERNANDEZ, SANCHEZ, GATO, ABUEG-ZALDIVAR, VIOLAGO, NAVA, CELESTE, TIANGCO, GARCIA (J.E.), TUTOR, ERIGUEL, CO (A.N.), REVILLA, ACOP, PADUANO, ARROYO, DELOSO-MONTALLA, RAMOS, HARESCO, RODRIGUEZ, BONDOC, TEJADA, VELOSO, VILLANUEVA (N.), SUAREZ (D.), ORTEGA, SUANSING (E.), PACQUIAO (A.), LOYOLA, ARENAS, GONZALES (A.), CHATTO, TADURAN, ECLEO, EBCAS, NATIVIDAD-NAGAÑO, SAULOG, SUANSING (H.), ESPINA, TY (D.), ACOSTA, DEFENSOR (M.), DE JESUS, SALCEDA, TAMBUNTING, MANGAOANG, NOGRALES (J.J.), MATUGAS, RAMIREZ-SATO, GO (M.), PADIERNOS, NIETO, BARONDA, DAGOOC, GORRICETA, ONG (R.), ESPINO, ESCUDERO, MACAPAGAL ARROYO, DEFENSOR (L.), CRISOLOGO, FORTUN, SUNTAY, LAGON, BASCUG, YU, FUENTEBELLA, SUAREZ (A.), YAP (E.), BAGATSING, ERMITA-BUHAIN, BAUTISTA-BANDIGAN, CUA, CUARESMA, FARIÑAS I (R.C.), GASATAYA, GO (E.C.), BARBA, CABREDO, BORDADO, DIMAPORO (A.), DUJALI, GULLAS, GUYA, LABADLABAD, MACEDA, MARIÑO, TAN (A.S.), VERGARA, ACOSTA-ALBA, FERRER (J.M.), ROMULO, SALO, SANGCOPAN, BROSAS, UMALI (M.V.), ROBES, HOFER AND VELASCO, PER COMMITTEE REPORT NO. 997

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

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 address the devastating consequences of public health emergencies.

SEC. 3. *Definition of Terms.* – As used in this Act:

(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 and amounting to at least One million dollars (US$1 M) and above or its foreign currency equivalent. It shall also cover any of the following arrangements:

(1) *Counterpurchase* – also known as counter exports, this refers to parallel transactions or reciprocal trade, whereby the foreign supplier reciprocally commits to purchase Philippine goods or services, to be exported to the supplier's country or a third country;

(2) *Product Buy Back* – whereby the foreign supplier of the equipment or machinery is paid for with the resultant product(s) or good(s) made or manufactured by such equipment or machinery;

(3) *Offset* – whereby the foreign supplier commits to introduce investments or technology transfer in the Philippines, or assist in establishing new industries or improving existing industries to generate or save foreign exchange or create increased employment, which may or may not be related to the machinery, equipment, products or goods so imported or services procured;

(4) *Trade-for-Debt Swap* – whereby a loan or credit accommodation obtained by a government agency or government-owned or -controlled corporation from a foreign government or creditor which has remained outstanding and unpaid is arranged to be settled in full or partially by way of sales of products, goods or services to be provided by a third party rather than by payment in foreign currency; or

(5) Any form of combination or variation of the above arrangements that results in the inflow to the country of foreign exchange, or savings thereof, investments, training and technology transfer, grants for educational, scientific, technological, environmental and related research programs or projects, which will enhance Philippine industrial or export competitiveness or contribute to the creation of new competitive industries, enhance existing industries or utilization of Philippine services or expertise by foreign clients, or result in the reduction of public debt;

(b) *Device* refers to instruments, apparatus, or contrivances, including their components, parts, and accessories that are authorized by the Food and Drug Administration (FDA), intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; or (2) to affect the structure or any function of the human body;

(c) *Drugs and medicines* refer to any chemical compound or biological substance, other than food, that are authorized by the FDA, intended for use in the treatment, prevention or diagnosis of disease in humans or animals, including:

(1) Any article recognized in the official United States Pharmacopoeia-National Formulary, 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 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 function of the human body or animals;

(4) Any article intended for use as a component of 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) Bioterrorism;

(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 thereof;

(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; and

(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 (DOH) to be known as the Health Procurement and Stockpiling Bureau, hereinafter referred to as the Bureau. It shall serve as the principal agency mandated to undertake a transparent, fair, proactive, and 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 Procurement Service and Logistics Management Division of the DOH. The Secretary of Health shall determine the organizational structure and staffing modifications of the Bureau subject to the approval of the Department of Budget and Management (DBM) in accordance with the existing civil service laws, rules and regulations.

The DOH shall ensure an effective and efficient monitoring system for the proper implementation of the procurement and stockpiling of drugs and medicines, vaccines, devices, and materials.

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

(a) Formulate plans, policies, and programs on procurement management;

(b) Undertake the procurement process in accordance with the Government Procurement Reform Act;

(c) Advise the Secretary of Health on matters pertaining to the procurement of goods and services, infrastructure and consultancy services;

(d) Manage the Bureau's response activities during a public health emergency;

(e) Conduct procurement monitoring visits to DOH field offices;

(f) Provide technical assistance to DOH field offices on procurement matters;

(g) 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;

(h) Maintain a buffer supply of strategic and critical drugs, medicines, vaccines, devices, and materials to ensure the availability of these items;

(i) Facilitate the provision of potentially life-saving pharmaceuticals, vaccines, devices, and materials in times of public health emergencies;

(j) Act as supply-chain manager to ensure the rotation and replenishment of stocks, and a steady, available, fresh and adequate supply of drugs and medicines, vaccines, devices, and materials, which are essential in responding to public health emergencies;

(k) Acquire, release, and properly dispose drugs and medicines, vaccines, devices, and materials, as directed by the Secretary of Health;

(l) Require all suppliers to monitor their stocks and production capacity and notify possible supply disruptions at least six (6) months in advance;

(m) Conduct regular analysis and communicate any impending shortage 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 to avoid supply shortage in the country;

(p) Maintain a publicly accessible inventory database of the available commodities and stocks of all items included in the proposed stockpile, including the expiration dates of relevant stocks and their purchase prices;

(q) Spearhead the crafting of a multi-sector National Drug and Device Security Program geared towards the country's self-reliance in producing drugs and medicines, vaccines, devices, and materials; and

(r) Ensure adequate provision of the appropriate storage and containment facilities in strategic areas of the country that properly comply with requirements for room temperature and humidity, refrigeration and non-exposure to heat, sunlight, rain and moisture.

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 meet public health needs.

SEC. 8. *Industrial Collaboration Program.* – The DOH shall implement an Industrial Collaboration Program wherein it shall maintain and develop institutional linkages or partnerships with government and nongovernment institutions, including the DBM, Department of National, Defense, Department of the 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, FDA, 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, management, distribution, and utilization of drugs and medicines, vaccines, devices, and materials in the stockpile.

SEC. 9. *Establishment of Medical Stockpiling Fund and Tax Exemptions.* – All donations, contributions, grants, bequests, or gifts, in cash or in kind, received from various sources, shall be placed into a fund, to be known as the Medical Stockpiling Fund. This Fund shall be expended to support the National Drug and Device Security Program in accordance with existing budgeting, accounting and auditing rules and regulations.

The DOH may solicit and receive grants, bequests, endowments, donations and contributions which shall form part of the Fund. Said grants, bequests, endowments, donations and

contributions used actually, directly and exclusively for the purpose of the Fund shall be exempt from donor's tax and the same shall be considered as allowable deduction from gross income for purposes of computing the taxable income of the donor, in accordance with Section 34 (H)(2)(a) of the National Internal Revenue Code of 1997, as amended. 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 the sale of donated commodities shall be deposited with the National Treasury and recorded as a special account in the General Fund and shall be made 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 Secretary of 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 Chairpersons of the House Committee on Appropriations and the Senate Committee on Finance, and the Chairperson of 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 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 information regarding:

(a) Foreign and domestic purchases of stockpiled drugs and medicines, vaccines, devices, and materials;

(b) Acquisition and disposal of stockpiled drugs and medicines, vaccines, devices, and materials; and

(c) Such other pertinent information on the implementation of this Act.

SEC. 11. ***Appropriations.*** – The amount for the initial implementation of this Act shall be charged against the current year's appropriation of the DOH. Thereafter, the funding of which shall be included in the annual General Appropriations Act.

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. ***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. ***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. 15. ***Effectivity.*** – This Act shall take effect fifteen (15) days after its publication in the *Official Gazette* or in a newspaper of general circulation.

Approved,