

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City, Metro Manila

20th Congress
Second Regular Session

House Bill No. 10680



Introduced by **REPRESENTATIVE EMIGDIO P. TANJUATCO III**

EXPLANATORY NOTE

The COVID-19 pandemic exposed the vulnerability of the Philippine healthcare system to disruptions in global pharmaceutical supply chains. During the initial wave of the pandemic, border closures, export restrictions, and logistical bottlenecks significantly constrained the country's ability to import essential medicines, placing public health at risk.

While existing laws promote access to affordable medicines (e.g. Cheaper Medicines Act), the current regulatory framework relies heavily on administrative issuances of the Food and Drug Administration (FDA) to safeguard medicine quality and ensure supply continuity. At the same time, domestic pharmaceutical manufacturers incur substantial fixed costs to comply with Good Manufacturing Practice (GMP) standards, while import-dependent products may enter the market with uneven quality oversight. This imbalance undermines medicine security, public trust, and long-term industrial resilience.

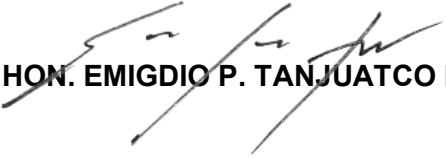
Local pharmaceutical manufacturing occupies a distinct and strategic role in the national health system. Unlike purely distribution-based or import-based models, local manufacturing directly supports medicine security by maintaining domestic production capacity, enabling closer regulatory oversight, sustaining technical and skilled employment, and strengthening the country's ability to respond to public health emergencies and external supply disruptions. For this reason, local pharmaceutical manufacturing should be recognized not merely as an ordinary commercial activity, but as a strategic capability necessary to safeguard public health and national resilience.

This bill seeks to establish a statutory medicine security Framework that balances access, availability, affordability, safety, and quality, while strengthening local pharmaceutical manufacturing as a strategic component of national health security. It does not prohibit imports nor confer automatic incentives. The bill also does not discriminate between multinational and local industry players in the market. Instead, it ensures that all medicines, whether locally produced or imported, are subject to equivalent, science-based quality standards.

The measure aligns fully with the CREATE Act, the CREATE MORE Act, and the Strategic Investment Priority Plan by recognizing pharmaceutical manufacturing as a strategic investment activity subject to existing incentive regimes. It further strengthens regulatory enforcement through statutory FDA-BOC coordination, risk-based traceability, and enhanced oversight of online pharmaceutical sales.

Ultimately, this bill aims to protect Filipino patients, promote fair competition, and ensure that the availability of affordable medicines is never achieved at the expense of quality, safety, and national resilience.

Immediate passage of this bill is earnestly sought.



HON. EMIGDIO P. TANJUATCO III

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Introduced by **REPRESENTATIVE EMIGDIO P. TANJUATCO III**

AN ACT
ESTABLISHING A NATIONAL MEDICINE SECURITY FRAMEWORK,
STRENGTHENING LOCAL PHARMACEUTICAL MANUFACTURING AS A
STRATEGIC INVESTMENT, ENSURING THE QUALITY, SAFETY, AND
AFFORDABILITY OF MEDICINES, AND FOR OTHER PURPOSES

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 ***“Medicine Security Act.”***

SECTION 2. Declaration of Policy. – It is hereby declared the policy of the State to protect and promote the right to health by ensuring medicine security, defined as the sustained availability, accessibility, quality, safety, and affordability of medicines through resilient, transparent, and well-regulated supply chains. In furtherance thereof, the State recognizes local pharmaceutical manufacturing as an industry with a distinct contribution to strategic investment and development necessary to safeguard public health, ensure supply continuity, and strengthen the country’s preparedness for public health emergencies and external supply disruptions.

The State recognizes that excessive dependence on import-dependent pharmaceutical supply chains exposes the country to significant public health risks during pandemics, global emergencies, trade disruptions, and geopolitical shocks. Accordingly, the State shall:

- (a) Strengthen local pharmaceutical manufacturing as a pillar of national health security, industrial development, and economic resilience;
- (b) Ensure that all medicines offered in the Philippine market, whether locally manufactured or imported, comply with uniform, science-based, and verifiable standards of quality, safety, and efficacy;
- (c) Promote fair competition, consumer choice, and transparency in the manufacture, importation, marketing, and distribution of medicines;

(d) Encourage pharmaceutical investments in a manner fully consistent with Republic Act No. 11534, Republic Act No. 12066, the Strategic Investment Priority Plan (SIPP), and related investment laws;

(e) Strengthen regulatory enforcement against counterfeit, substandard, falsified, and unregistered medicines, including those sold through digital and online platforms; and

(f) Harmonize public health objectives with the State's obligations under international trade agreements.

SECTION 3. Scope and Application. – This Act shall apply to all entities engaged in the manufacture, importation, registration, distribution, marketing, sale, and dispensing of pharmaceutical products in the Philippines, without prejudice to existing powers of the Food and Drug Administration (FDA), the Department of Health (DOH), the Department of Trade and Industry (DTI), and other relevant agencies.

SECTION 4. Definition of Terms. – As used in this Act:

(a) **Active Pharmaceutical Ingredient or API** refers to any substance or mixture of substances intended to be used in the manufacture of a medicine and which, when used in such manufacture, becomes an active ingredient of the medicine intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the human body;

(b) **Advanced Manufacturing** refers to the use of innovative, technology-enabled, or high-value pharmaceutical production methods, platforms, processes, facilities, or systems, including continuous manufacturing, biotechnology-based manufacturing, vaccine manufacturing, biologics manufacturing, sterile manufacturing, high-containment manufacturing, digital quality systems, process automation, and other technologies as may be identified by the Inter-Agency Committee on Medicine Security;

(c) **Certificate of Product Registration or CPR** refers to the authorization issued by the FDA allowing the manufacture, importation, distribution, sale, offer for sale, or use of a specific medicine or pharmaceutical product in the Philippines, subject to applicable laws, rules, and regulations;

(d) **Critical Pharmaceutical Inputs** refer to active pharmaceutical ingredients, intermediates, excipients, primary and secondary packaging materials, laboratory supplies, reference standards, reagents, production materials, quality testing materials, and other inputs necessary for the development, manufacture, testing, release, storage, or distribution of medicines, as may be identified by the DOH, FDA or the Inter-agency Committee on Medicine Security;

(e) **Essential Medicines** refer to medicines identified by the DOH and FDA as significantly critical and absolutely necessary to addressing priority public health needs, including those which may be identified under the National Pharmaceutical Manufacturing and Resilience Strategy;

(f) **Equivalent Locally Manufactured Medicine** refers to a locally manufactured medicine that is duly registered with the Food and Drug Administration and is comparable to an imported or other reference medicine in terms of active ingredient, strength, dosage form, route of

administration, therapeutic use, quality, safety, efficacy, regulatory status, required delivery specifications, and, where applicable, therapeutic equivalence or interchangeability as determined under applicable laws, rules, and regulations;

(g) **Foreign Manufacturing Site** refers to any facility located outside Philippine territory that is engaged in the manufacture, processing, formulation, filling, finishing, packaging, testing, release, or other production-related activity involving a medicine or pharmaceutical product intended for importation, distribution, sale, or use in the Philippines;

(h) **Good Manufacturing Practices or GMP** refer to the standards, systems, and procedures for pharmaceutical manufacturing, quality assurance, quality control, sanitation, personnel qualification, facility management, documentation, validation, storage, and distribution, as adopted, recognized, or required to ensure that medicines are consistently produced and controlled according to applicable quality standards;

(i) **Green Lanes** refer to risk-based priority processing, regulatory facilitation, or expedited coordination mechanisms established under this Act for eligible FDA-licensed and GMP-compliant local pharmaceutical manufacturers, subject to a standardized eligibility criteria, continuing compliance, and applicable laws, rules, and regulations;

(j) **Imported Pharmaceutical Product** refers to any medicine or pharmaceutical product manufactured, processed, formulated, filled, finished, packaged, tested, released, or otherwise produced in whole or in substantial part outside Philippine territory and brought into the Philippines for registration, distribution, sale, dispensing, procurement, donation, or use;

(k) **License to Operate or LTO** refers to the authorization issued by the Food and Drug Administration to an establishment or entity to engage in the manufacture, importation, exportation, distribution, sale, offer for sale, dispensing, or other regulated activity involving medicines or pharmaceutical products;

(l) **Local Pharmaceutical Manufacturer** refers to an entity duly organized or authorized to do business in the Philippines, licensed by the FDA, and engaged in local pharmaceutical manufacturing in an FDA-licensed facility compliant with Good Manufacturing Practices;

(m) **Local Pharmaceutical Manufacturing** refers to the manufacture, formulation, processing, compounding, filling, finishing, packaging, testing, release, or other substantial production-related activity involving medicines or pharmaceutical products within Philippine territory in facilities duly licensed by the FDA and compliant with GMP. For purposes of this Act, local pharmaceutical manufacturing shall require actual, verifiable pharmaceutical manufacturing operations in the Philippines. Mere importation, warehousing, distribution, marketing, relabeling, or repacking of finished imported products shall not, by itself, constitute local pharmaceutical manufacturing for purposes of this Act, unless such activity forms part of a substantial manufacturing process recognized by the FDA under other applicable laws, rules, and regulations;

(n) **Locally Manufactured Medicine** refers to a medicine or pharmaceutical product whose finished dosage form, or such other substantial stage of manufacture as may be determined under the implementing rules and regulations, is manufactured in the Philippines by a local pharmaceutical manufacturer in an FDA-licensed facility compliant with GMP;

(o) **Medicine Security** refers to the ability of the State to ensure the sustained availability, accessibility, affordability, quality, safety, efficacy, and rational use of medicines through

resilient, transparent, competitive, and well-regulated pharmaceutical supply chains, including sufficient domestic pharmaceutical manufacturing capacity and effective safeguards against supply disruptions, public health emergencies, and the entry or circulation of counterfeit, substandard, falsified, unregistered, or non-compliant medicines;

(p) **Medicines or Pharmaceutical Products** refer to drugs, medicines, biologicals, vaccines, herbal medicines, and other pharmaceutical products intended for human use, whether branded or generic, and whether locally manufactured or imported, which are subject to regulation by the FDA;

(q) **Parallel Importation** refers to the importation of patented or off-patent medicines without the authorization of the patent holder, subject to applicable quality, safety, efficacy, registration, customs, legal and regulatory requirements;

(r) **Post-Market Surveillance** refers to the activities undertaken after a medicine or pharmaceutical product has been authorized, registered, distributed, sold, dispensed, or used in the Philippines to monitor and verify its continued quality, safety, efficacy, performance, compliance, and proper use, including sampling, testing, market audits, inspection, adverse event monitoring, recall monitoring, pharmacovigilance, and other regulatory actions;

(s) **Pre-Clearance** refers to the verification, coordination, risk-profiling, or other regulatory process undertaken by the FDA, BOC, or other competent authorities prior to customs release or market entry of imported medicines or pharmaceutical products, for purposes of confirming the validity of relevant authorizations, including the LTO, CPR, and, where applicable, GMP status;

(t) **Priority Medicines** refer to medicines identified under the National Pharmaceutical Manufacturing and Resilience Strategy as having high public health impact, significant government procurement volume, vulnerability to shortage or supply disruption, strategic importance during public health emergencies;

(u) **Public Health Emergency** refers to a state of public health emergency, calamity, national emergency, epidemic, pandemic, outbreak, or other public health exigency declared, recognized, or determined by competent government authority under applicable law;

(v) **Risk-Based Assessment** refers to a regulatory, customs, procurement, surveillance, or enforcement approach that with the purpose of conducting review, verification, inspection, testing, monitoring, or, if applicable, enforcement, in accordance with the level of risk posed by a product, facility, entity, transaction, supply chain activity, or market behavior, taking into account public health impact, product characteristics, dosage form, compliance history, source, manufacturing site, vulnerability to counterfeiting or falsification, history of quality defects, and other relevant factors;

(w) **Strategic Pharmaceutical Investment** refers to pharmaceutical manufacturing projects and related activities that qualify under the Strategic Investment Priority Plan and are eligible for incentives or other support under applicable tax and investment laws, rules and regulations, subject to the applicable qualifications, performance-based conditions, time-bound requirements, and approval processes administered by the appropriate government agencies;

(x) **Strategic Procurement Measures** refer to procurement policies, tools, or arrangements adopted to support stable, reliable, quality-assured, and value-for-money access to medicines; and

(y) **Supply Resilience** refers to the capacity of the Philippine pharmaceutical supply chain to anticipate, withstand, absorb, respond to, and recover from disruptions affecting the availability, affordability, quality, safety, or timely delivery of medicines and critical pharmaceutical inputs.

SECTION 5. Establishment of the Inter-Agency Committee on Medicine Security – There is hereby established an Inter-Agency Committee on Medicine Security, which shall be the primary coordinating body for the formulation, implementation, monitoring, and periodic review of policies, programs, and measures under this Act.

The Committee shall coordinate national government efforts relating to medicine security, domestic pharmaceutical manufacturing capacity, supply resilience, quality assurance, procurement alignment, investment facilitation, research and innovation, and regulatory coordination. It shall ensure that the implementation of this Act is guided by a coherent, evidence-based, and whole-of-government framework for strengthening domestic pharmaceutical capability and ensuring continuous access to safe, effective, affordable, and quality medicines.

SECTION 6. Composition of the Committee. – The Committee shall be composed of the following:

- (a) Secretary of the Department of Health, as Chairperson;
- (b) Secretary of the Department of Trade and Industry, as Co-Chairperson;
- (c) Director General of the Food and Drug Administration, as Vice Chairperson;
- (d) Office of the President, through the Executive Secretary;
- (e) Secretary of the Department of Science and Technology;
- (f) Secretary of the Department of Finance;
- (g) Secretary of the Department of Economy, Planning and Development;
- (h) Secretary of the Department of Budget and Management;
- (i) Commissioner of the Bureau of Customs;
- (j) Commissioner of Internal Revenue;
- (k) President and Chief Executive Officer of the Philippine Health Insurance Corporation;
- (l) Secretary of the Department of Information and Communications Technology;
- (m) Director General of the Intellectual Property Office of the Philippines; and
- (n) Chairperson of the Philippine Competition Commission.

The members of the Committee may designate permanent representatives with a rank not lower than Assistant Secretary or any official of equivalent rank with sufficient authority to bind the agency or office concerned.

The Committee may invite representatives from the domestic pharmaceutical manufacturing sector, importers, distributors, healthcare professionals, patient groups, academic and research institutions, development partners, and other relevant stakeholders as resource persons, as may be necessary.

SECTION 7. Mandatory Subcommittees. – Within sixty (60) days from its first organizational meeting, the Committee shall constitute and maintain the following standing subcommittees:

(a) Subcommittee on Domestic Pharmaceutical Manufacturing and Supply Resilience, which shall focus on the identification of essential and priority medicines suitable for domestic manufacture, the assessment of domestic manufacturing capacity, the identification of critical pharmaceutical inputs, and the development of measures to reduce vulnerability to external supply disruptions;

(b) Subcommittee on Regulatory Quality Assurance, which shall focus on regulatory facilitation for compliant manufacturers, risk-based green lanes, GMP compliance, product registration and renewal processes, quality verification for imported medicines, FDA-BOC pre-clearance and border control, traceability, post-market surveillance, and enforcement against counterfeit, substandard, falsified, unregistered, or non-compliant medicines, including those sold through online or digital platforms;

(c) Subcommittee on Strategic Procurement and Market Access, which shall focus on strategic procurement measures for locally manufactured medicines, price benchmarking, supply reliability, and other lawful measures to support stable access to essential and priority medicines, especially for government hospitals and healthcare institutions; and

(d) Subcommittee on Investments, Research and Innovation, which shall focus on investment facilitation, fiscal and non-fiscal incentives, alignment with the Strategic Investment Priority Plan, pharmaceutical research and development, technology transfer, advanced manufacturing, including vaccines and biologics manufacturing, and pharmaceutical testing facilities.

The Committee shall determine the lead agency, composition, internal rules, work plan, deliverables, and reporting arrangements of each subcommittee, taking into account the respective mandates and technical competencies of the member agencies. The Committee may assign member agencies, attached agencies, bureaus, offices, and invited resource persons to participate in any subcommittee as may be necessary for the effective implementation of this Act.

The subcommittees shall be mandatory and continuing under this Act. Each subcommittee shall submit periodic reports and recommendations to the Committee in accordance with the schedule and format prescribed by the Committee.

SECTION 8. Technical Secretariat. – There is hereby established a Technical Secretariat under the supervision of the Committee, and the Secretariat shall provide technical, administrative, research, and coordination support to the Committee. It shall assist in the preparation of the National Pharmaceutical Manufacturing and Resilience Strategy, progress

reports, policy recommendations, inter-agency work plans, and other documents necessary for the implementation of this Act.

The Secretariat shall be directly supported by the DOH as the Chairperson of the Committee.

The member agencies of the Committee shall designate focal persons to support the Technical Secretariat and the relevant subcommittees. The operations of the Technical Secretariat shall be supported from the existing appropriations of the concerned agencies, subject to applicable budgeting, accounting, and auditing rules.

SECTION 9. Powers and Functions of the Committee. — The Committee shall have the following powers and functions:

- (a) Formulate, approve, implement, monitor, and periodically update the National Pharmaceutical Manufacturing and Resilience Strategy;
- (b) Coordinate the implementation of this Act among member agencies and ensure the alignment of agency programs, regulatory pathways, procurement policies, investment facilitation measures, research initiatives, and enforcement activities with the National Pharmaceutical Manufacturing and Resilience Strategy;
- (c) Establish implementation milestones, performance indicators, reporting mechanisms, and monitoring tools for programs and measures under this Act;
- (d) Recommend policy, regulatory, administrative, budgetary, procurement, investment, and legislative measures necessary to strengthen domestic pharmaceutical manufacturing capacity, medicines security, and pharmaceutical supply resilience;
- (e) Facilitate inter-agency data sharing, subject to applicable data privacy, confidentiality, and competition laws, for purposes of pharmaceutical supply planning, regulatory coordination, procurement alignment, market monitoring, and emergency preparedness;
- (f) Coordinate with relevant agencies to support the effective implementation of green lanes, strategic procurement measures, risk-based quality verification, pre-clearance and post-market surveillance, and enforcement against counterfeit, substandard, falsified, unregistered, or non-compliant medicines;
- (g) Consult relevant stakeholders, including domestic pharmaceutical manufacturers, importers, distributors, healthcare professionals, patient groups, academic and research institutions, and development partners, as may be necessary;
- (h) Submit annual progress reports to the President and to Congress; and
- (i) Perform such other functions as may be necessary to carry out the purposes of this Act.

All relevant government agencies shall cooperate with the Committee and align their programs and implementation activities with the National Pharmaceutical Manufacturing and Resilience Strategy, consistent with their respective mandates and applicable laws.

SECTION 10. National Pharmaceutical Manufacturing and Resilience Strategy. — Within twelve (12) months from the effectivity of this Act, the Inter-agency Committee on Medicine

Security shall formulate and approve a ten-year National Pharmaceutical Manufacturing and Resilience Strategy.

In the formulation of the Strategy, the Committee shall ensure coordination among its member agencies and alignment with national public health and economic development objectives.

The Strategy shall:

- (a) Identify essential and priority medicines suitable for domestic manufacture;
- (b) Identify critical pharmaceutical inputs, including active pharmaceutical ingredients, requiring strategic supply security;
- (c) Establish phased development targets for formulation capacity, input security, and advanced manufacturing;
- (d) Prescribe measurable performance indicators and annual reporting requirements;
- (e) Integrate pharmaceutical supply resilience into public health and procurement planning; and
- (f) Be subject to review and updating every three (3) years.

The Committee shall submit the Strategy for the approval of the President and all subsequent updates shall be submitted to the President and to Congress.

SECTION 11. Phased Development of Domestic Pharmaceutical Manufacturing Capacity. – Consistent with the National Pharmaceutical Manufacturing and Resilience Strategy, the State shall pursue a phased approach to strengthen domestic pharmaceutical manufacturing capacity, support medicine security, and reduce vulnerability to external supply disruptions.

The phased development framework shall include:

- (a) **Essential Medicines Formulation Capacity** – The State shall prioritize the domestic manufacture of finished dosage forms of essential medicines, particularly those identified by the Inter-agency Committee on Medicine Security as having high public health impact, significant procurement volume, or strategic importance during public health emergencies. Concerned agencies shall, within their respective mandates, support regulatory facilitation, technology transfer, workforce development, shared quality testing facilities, and other measures necessary to strengthen domestic formulation capacity.
- (b) **Strategic Security for Critical Pharmaceutical Inputs** – The State shall identify and support measures to improve the availability and supply security of critical pharmaceutical inputs, including active pharmaceutical ingredients (APIs), intermediates, excipients, and other raw materials necessary for the production of essential medicines. Such measures may include incentives, public-private arrangements, regional cooperation, inventory rotation mechanisms, framework supply contracts, and other lawful supply assurance systems.
- (c) **Research, Innovation, and Advanced Manufacturing** – The State shall support pharmaceutical research, innovation, and advanced manufacturing, including vaccines, biologics, and other strategic pharmaceutical technologies. The Department of Science and

Technology (DOST), in coordination with the DOH, FDA, DTI, BOI, and other relevant agencies, shall promote research and development, manufacturing process innovation, technology transfer, public-private research collaboration, and specialized human capital development in pharmaceutical sciences, biomanufacturing, quality systems, and advanced manufacturing.

Support under this Section shall be implemented in accordance with existing laws, applicable investment and tax rules, government procurement laws, competition laws, and international commitments.

SECTION 12. Local Pharmaceutical Manufacturing as a Strategic Investment. – Local pharmaceutical manufacturing activities, including but not limited to formulation, processing, filling, finishing, packaging, testing, active pharmaceutical ingredient (API) production, vaccine manufacturing, herbal medicines, biologics, and other pharmaceutical or health-related activities shall be recognized as strategic investment activities that support medicine security and shall be covered by the Strategic Investment Priority Plan.

Projects covering the foregoing activities shall be eligible for tax incentives, as well as other fiscal and non-fiscal incentives under Republic Act No. 11534, Republic Act No. 12066, and other applicable laws, rules and regulations, subject to the applicable qualifications, performance-based conditions, and time-bound requirements administered by the appropriate investment promotion agencies and the Fiscal Incentives Review Board.

SECTION 13. Green Lanes for Compliant Local Manufacturers. – In accordance with Executive Order No. 18 (s. 2023), and consistent with the applicable Strategic Investment Priority Plan and Tatak Pinoy initiatives, the FDA, the Bureau of Customs (BOC), and other relevant agencies shall establish risk-based priority processing or green lanes for FDA-licensed, GMP-compliant local pharmaceutical manufacturers, subject to objective eligibility criteria to be prescribed in the implementing rules and regulations.

Green lane privileges may include:

- (a) priority scheduling of GMP inspections;
- (b) expedited processing of initial and renewal applications for licenses and permits, including the License to Operate (LTO);
- (c) expedited processing of applications relating to essential medicines, including Certificate of Product Registration (CPR) and renewal, variations, and post-approval changes;
- (d) facilitated importation and customs clearance of manufacturing inputs, including APIs, excipients, packaging materials, and laboratory supplies, subject to risk-based controls; and
- (e) priority coordination for regulatory clearances required for medicine security investments.

Eligibility for green lane privileges shall be provided to FDA-licensed local pharmaceutical manufacturers with actual, verifiable pharmaceutical manufacturing operations in the Philippines. Mere corporate registration, trading operations, distribution activities, warehousing, relabeling, repacking, rebranding, or other activities that do not constitute local pharmaceutical manufacturing under this Act shall not qualify an entity for green lane privileges. The FDA may require documentary verification, facility inspection, compliance

history review, or such other risk-based validation measures as may be necessary to determine eligibility for green lane privileges.

Green lane privileges may be suspended or revoked for cause, including serious or repeated regulatory violations, falsification of documents, or significant quality failures, after due notice and opportunity to be heard, without prejudice to other administrative, civil, or criminal remedies.

The agencies mandated by this Act to provide green lane privileges shall issue their respective rules and regulations within 180 calendar days from the effectivity of this Act.

SECTION 14. Government Procurement Preference and Strategic Procurement Measures for Locally Manufactured Medicines. – Consistent with Republic Act No. 12009, otherwise known as the New Government Procurement Act, and other applicable procurement, competition, and trade laws, government procuring entities shall, in the procurement of medicines for public health programs, government hospitals, local government health facilities, and other public healthcare institutions, give preference to locally manufactured medicines where equivalent locally manufactured medicines are available, subject to the following conditions:

- (a) The locally manufactured medicine is duly registered with the Food and Drug Administration and manufactured in an FDA-licensed facility compliant with Good Manufacturing Practices;
- (b) The locally manufactured medicine meets the required quality, safety, efficacy, therapeutic, technical, and delivery specifications of the procuring entity;
- (c) The locally manufactured medicine is available in sufficient commercial quantities and within the required delivery period; and
- (d) The procurement remains consistent with value-for-money principles, applicable procurement rules, competition laws, and the Philippines' obligations under international agreements.

For purposes of this Section, procurement evaluation shall not be based solely on the lowest price, but may consider quality, clinical effectiveness, supply reliability, compliance history, manufacturing track record, post-market performance, delivery reliability, and other relevant criteria consistent with law.

To support medicine security, domestic manufacturing capacity, and supply stability, the DOH, PhilHealth, local government units, government hospitals, and other procuring entities may adopt strategic procurement and market stabilization measures for essential medicines and other priority medicines identified under the National Pharmaceutical Manufacturing and Resilience Strategy, including:

- (a) Consolidated or pooled procurement to generate predictable demand and improve supply planning;
- (b) Multi-year or framework supply agreements, subject to appropriations law and applicable procurement rules;

(c) Volume commitments or indicative demand forecasts for priority medicines where domestic manufacturing capacity is available;

(d) Transparent price benchmarking and reference pricing mechanisms that consider quality, clinical effectiveness, supply reliability, and total value to the health system;

(e) Direct delivery, regional delivery, cold chain, inventory management, and logistics requirements that may be considered in bid evaluation where relevant to medicine availability, shelf-life protection, and timely delivery to public health facilities;

(f) Risk-based post-delivery quality verification, including random sampling, independent laboratory testing, batch verification, market audits, and other quality assurance measures for medicines procured for public health programs, government hospitals, local government health facilities, and other public healthcare institutions; and

(g) Other lawful procurement arrangements that support stable supply, competitive pricing, and the development of domestic pharmaceutical manufacturing capacity.

The DOH, in coordination with the Government Procurement Policy Board (GPPB), PhilHealth, DTI, BOI, FDA, and other relevant agencies, shall issue guidelines to operationalize this Section, including the standards for determining equivalence, availability, quality, supply reliability, and value-for-money in the procurement of medicines.

Nothing in this Section shall prohibit the procurement of imported medicines where no locally manufactured equivalent is available, where the locally manufactured product fails to meet the required quality, safety, efficacy, therapeutic, technical, delivery, or quantity requirements, or where the application of domestic preference would be inconsistent with applicable law or international obligations.

SECTION 15. Quality Assurance and GMP Linkage for Imported Medicines. – As a condition for the approval or renewal of a CPR for an imported pharmaceutical product, the applicant shall submit evidence, in form and substance acceptable to the FDA, that the foreign manufacturing site complies with internationally recognized GMP standards, including documentation capable of verification.

The FDA shall implement a risk-based and proportionate assessment framework for imported products, taking into account the dosage form, public health risk, history of quality defects or recalls, compliance record of the applicant, and the reliability of the regulatory authority having oversight over the manufacturing site. The FDA may require such additional documentary submissions and verification measures as may be warranted by risk, in accordance with internationally accepted practices.

The FDA shall, through the implementing rules and regulations, identify categories of pharmaceutical products that warrant heightened quality assurance review based on public health risk, vulnerability to counterfeiting, history of quality defects, or other relevant factors, and may prescribe additional documentary and verification requirements for such categories consistent with internationally accepted practices.

Nothing in this Section shall prohibit or restrict lawful parallel importation under Republic Act No. 9502, provided that products introduced through parallel importation shall remain subject to equivalent quality, safety, and efficacy requirements under this Act and other applicable laws.

SECTION 16. Statutory FDA-BOC Pre-Clearance and Border Control. – The FDA and BOC shall institutionalize an integrated pre-clearance and risk-profiling system for pharmaceutical imports, consistent with their respective mandates under existing laws. The system shall verify the validity of the importer’s License to Operate (LTO), the product’s CPR, and, where applicable, the GMP status of the manufacturing site prior to customs release, and shall authorize the holding, examination, and referral of shipments that fail verification or are flagged as high-risk, in accordance with law.

This Section shall be implemented in a manner that facilitates legitimate trade while preventing the entry of counterfeit, substandard, falsified, or unregistered pharmaceutical products.

SECTION 17. Traceability and Post-Market Surveillance. – The FDA shall develop and implement a risk-based traceability or serialization system for designated essential and priority medicines, prioritizing products with high public health impact or high risk of counterfeiting.

Post-market surveillance activities shall be institutionalized, including random sampling, adverse event monitoring, and market audits.

The FDA may prioritize post-market surveillance for medicines and pharmaceutical products that are high-risk, widely procured or dispensed, subject to repeated quality complaints, sourced from manufacturers or importers with adverse compliance history, or otherwise identified under the National Pharmaceutical Manufacturing and Resilience Strategy.

SECTION 18. Regulation of Online and Digital Sale of Medicines. – The online sale or distribution of medicines without proper FDA authorization is hereby prohibited. The FDA, in coordination with the DTI and the Department of Information and Communications Technology (DICT), shall establish a takedown mechanism requiring digital platforms and online marketplaces to remove or disable access to listings of unregistered, counterfeit, or non-compliant pharmaceutical products upon notice. Digital platforms shall be required to cooperate in enforcement actions, without being deemed sellers of the regulated products.

The FDA shall maintain, or cause to be maintained, an updated and electronically accessible registry or verification system of authorized medicines and pharmaceutical products, including relevant CPR information, for use by consumers, procuring entities, healthcare institutions, digital platforms, online marketplaces, and other stakeholders. The registry or verification system may be made available through the FDA website, electronic verification tool, or other digital mechanism, subject to data privacy, cybersecurity, confidentiality, and operational safeguards.

Digital platforms and online marketplaces that allow the listing, sale, offer for sale, advertising, facilitation, or distribution of medicines shall adopt reasonable verification, notice-and-takedown, and cooperation mechanisms, consistent with guidelines to be issued by the FDA, DTI, and DICT. Such mechanisms may include seller verification, product authorization checks, removal or disabling of non-compliant listings upon notice, preservation of relevant transaction information, and cooperation with lawful enforcement actions.

Digital platforms and online marketplaces shall not be deemed manufacturers, importers, distributors, sellers, or dispensers of medicines solely by reason of hosting, indexing, advertising, facilitating, or processing listings or transactions involving regulated products: Provided, that this shall not exempt any platform, marketplace, seller, or other person from liability under applicable laws where it has actual knowledge of unlawful activity and fails to

act in accordance with lawful notice, or where it directly engages in the unauthorized sale, distribution, importation, dispensing, or promotion of medicines.

SECTION 19. Transparency and Consumer Right to Choose. – All pharmaceutical products shall clearly indicate the country of manufacture and the name of the importer or manufacturer on labels, packaging, and online listings. The DTI and FDA may issue joint regulations to promote fair substitution practices and ensure that consumers are informed whether a product is locally manufactured or imported.

Nothing in this Section shall mandate price controls or violate competition laws.

SECTION 20. Competition and Market Oversight. – The Philippine Competition Commission (PCC) is encouraged to monitor market concentration, pricing behavior, and potential abuse of dominance in the pharmaceutical retail and distribution sector, consistent with existing competition laws.

SECTION 21. Implementing Rules and Regulations. – Within one hundred eighty (180) days from the effectivity of this Act, the constituted Inter-Agency Committee on Medicine Security, with the assistance of other implementing agencies under this Act, shall promulgate the necessary implementing rules and regulations (IRR) to carry out the provisions of this Act.

The IRR shall ensure effective, coordinated, and consistent implementation of this Act, and shall be issued in accordance with existing laws, rules and regulations, and applicable international commitments.

SECTION 22. Separability Clause. – If any part or provision of this Act is held unconstitutional or invalid, the remaining provisions shall not be affected and shall continue in full force and effect.

SECTION 23. Repealing Clause. – All laws, executive orders, administrative rules, or regulations inconsistent with this Act are hereby repealed, amended, or modified accordingly.

SECTION 24. Effectivity. – This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in at least two (2) newspapers of general circulation.

Approved,


HON. EMIGDIO P. TANJUATCO III