



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



Eighteenth Congress  
Third Regular Session

HOUSE BILL NO. 9582

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**Introduced by Representative Jocelyn Sy Limkaichong**

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#### **EXPLANATORY NOTE**

This bill seeks to improve the access to and delivery of safe and effective biologicals and vaccines to the Filipino people and support the creation of a local biologicals and vaccines development and manufacturing ecosystem in the country.

Section 15, Article II of the 1987 Constitution provides:

*“Section 15. The State shall protect and promote the right to health of the people and instill health consciousness among them.”*

Vaccines underpin prevention and control of major infectious diseases across the world. Vaccines are biological medicines that prevent disease by showing the body how the disease-causing agent looks like and train the immune system to create antibodies. Over the past hundred years, together with antibiotics, vaccines have extended human lifespans and have led to eradication of disease like smallpox. Generations of children have been spared from lifetime disability due to polio, disfigurement from measles, and death from rabies, because of vaccination.

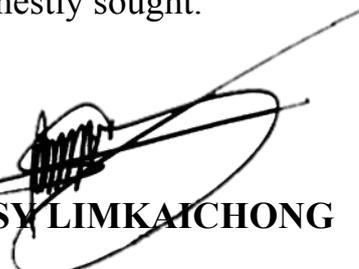
Biologicals, including vaccines, antibodies, anti-toxins, anti-venoms, and sera, are highly sophisticated and resource-intensive products that can sustain entire economic sectors. Programs like the Expanded Program on Immunization (EPI) of the Department of Health have already influenced human development on a massive scale by ensuring survival of Filipino children to adulthood. By

these reasons alone, domestic biological research and production in the Philippines should have been initiated. A more recent and still evolving reason pushes further why local biological manufacturing is imperative to control pandemics. Biological products against the “severe acute respiratory syndrome coronavirus 2” or SARS-CoV 2 will help the restoration of social and economic activities disrupted by the pandemic. However, countries with local capacity to produce vaccines and other biologicals are expected to prioritize domestic demand over exporting to other countries like the Philippines. COVID-19 is upon us but this scourge will not be the last nor will it be the worst. It is thus vital that a domestic biological and vaccine production ecosystem is established in the Philippines not only for the current pandemic response but more importantly, to prepare for the next one.

Yet for all the necessity of making biologicals for our own use here in the country, headwinds in the form of regulatory policy, market competition, and an anti-science culture have derailed past efforts and continue to pose risk to initiatives. Making biologicals here in the Philippines for Filipinos requires a community of researchers, engineers, health professionals, managers, and decision-makers. Great patience and persistence are needed through the long planning and execution period. Deep pockets are needed to finance the billions of pesos necessary to build just one manufacturing facility. The partnership of the public and private sectors is needed to make products that require complex technology, significant resources, and specialized safety and security measures.

A State policy supporting biological manufacturing and research needs not only to provide incentives to innovation but also streamline regulations to ensure access by Filipinos to safe and effective goods. By encouraging the industrial ecosystem and aligning public sector demand, biological and vaccine manufacturing can finally be established in the Philippines, thus, provide another pillar of economic activity. This helps assure national security, and more importantly, provides Filipinos a better quality of life by protecting them from disease.

In accordance with the State policy of protecting and promoting the right to health of the people, the approval of this measure is earnestly sought.



**JOCELYN SY LIMKAICHONG**



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**AN ACT**  
**PROVIDING FOR THE DEVELOPMENT OF LOCAL BIOLOGICALS**  
**MANUFACTURING CAPABILITY, ESTABLISHING FOR THE**  
**PURPOSE THE PHILIPPINE BIOLOGICALS AUTHORITY,**  
**DEFINING ITS POWERS AND FUNCTIONS, AND APPROPRIATING**  
**FUNDS THEREFOR**

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

SECTION 1. **Short Title.** – This Act shall be known as the “*Biologicals Development Act.*”

SEC. 2. **Declaration of Policy.** – It is the policy of the State to improve the access to and delivery of safe and effective biologicals and vaccines to the Filipino people. Towards this end, the State shall adopt measures to support the development of a local biologicals and vaccines manufacturing ecosystem, streamline regulations, and ensure compliance with international safety standards of biologicals and vaccines.

SEC. 3. **Objectives.** – This Act has the following objectives:

- a) Support human resource development for biologicals and vaccines technology and related fields;
- b) Encourage and support local research on biologicals and vaccines; and
- c) Provide incentives for the local manufacture of biologicals and vaccines by Filipino companies.

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

- a) *Biological* refers to a substance that is produced by or extracted from a biological source that needs for its characterization and the determination of its quality a combination of physical-chemical-biological testing together with the production process and its control; also refers to products or preparations containing the said substance as an active ingredient;
- b) *Biosafety* refers to containment principles, technologies, and practices that are implemented to prevent unintentional exposure to pathogens and toxins or their accidental release from a laboratory or similar facility;
- c) *Biosecurity* refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens and toxins from a laboratory or similar facility;
- d) *Biotechnology* refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

e) *Vaccine* refers to a biological preparation that improves immunity to a particular disease that contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins, its surface proteins, or its genetic material; and

f) *Vaccine technology* refers to any technological application to make vaccines including genetic engineering, cell and tissue culture, chemical engineering, and packaging and materials technology.

**SEC. 5. *Philippine Biologicals Authority.*** – There is hereby established a body to be known as the Philippine Biological Authority, hereinafter referred to as the Authority, that shall oversee an ecosystem conducive to the development of the Philippine biologicals industry. The Authority shall be attached to the Department of Science and Technology (DOST) for policy and program coordination. Its principal office shall be in Metro Manila, but it may establish other branches or offices elsewhere in the Philippines as may be necessary or proper for the accomplishment of its purposes and objectives.

**SEC. 6. *Powers and Functions.*** – In furtherance of the objectives of this Act, the Authority shall exercise the following powers and functions:

a) Create a long-term Philippine Biologicals Development Plan and update it accordingly;

b) Create a research agenda for biologicals and vaccines;

c) Develop and prescribe policies and standards for biologicals and vaccines research and manufacturing including biosecurity and biosafety, for recommendation to appropriate government implementing agencies;

d) Coordinate and facilitate technology transfer from technology owners and research institutions to local institutions and manufacturers;

e) Enter into, make and execute contracts and agreements of any kind or nature related to the implementation of this Act;

f) Acquire or obtain from any governmental authority whether national or local, foreign or domestic, or from any person, corporation, partnership, association or other entity, such charters, franchises, licenses, rights, privileges, assistance, financial or otherwise, and concessions as are conducive to, and necessary or proper for the attainment of its purposes and objectives;

g) Outsource services, activities, projects, and programs to capable third-party providers; and

h) Exercise all the powers necessary to attain the objectives of this Act.

**SEC. 7. Board of Administrators.** – The powers of the Authority shall be exercised, and all its activities and properties shall be controlled by a Board of Administrators, hereinafter referred to as the Board.

The Board is composed of the following:

a) Secretary of Science and Technology, as *ex-officio* chairperson;

- b) Secretary of Health, as *ex-officio* co-chairperson;
- c) Permanent representatives of the following government offices:
  - 1) Department of Trade and Industry; and
  - 2) Department of National Defense.
- d) Permanent representatives of the following industries or sectors:
  - 1) One (1) researcher from an academic or research institution engaged in biotechnology, vaccine technology, virology, or related fields;
  - 2) One (1) licensed clinician providing vaccination services; and
  - 3) One (1) members from the pharmaceutical industry belonging to Filipino companies.

The members representing the sectors or industries shall be appointed by the President of the Philippines upon recommendation of the Secretary of Science and Technology.

The appointive members of the Board shall have a term of four (4) years. The Board shall meet regularly at least once a month or more often as the exigencies of the service demand. The presence of at least four (4) members shall constitute a quorum, and the majority vote of the members present, there being a quorum, shall be necessary for the adoption of any resolution, decision, or any other act of the Board. For expediency, virtual meetings may be held in lieu of face-to-face meetings.

The members of the Board are entitled to receive a per diem for every meeting actually attended subject to the pertinent laws, rules and regulations on compensation, honoraria and allowances.

SEC. 8. ***Powers and Functions of the Board.*** – The Board shall exercise the following powers and functions:

a) Define and approve the policies, plans, strategies, programs, procedures and guidelines for the Authority in accordance with its purposes and objectives, and to control the management, operation and administration of the Authority;

b) Approve the Authority's organizational structure, staffing pattern, operating and capital expenditure, and financial budgets in accordance with pertinent laws;

c) Appoint, transfer, promote, suspend, remove or otherwise discipline any subordinate officer or employee of the Authority, upon recommendation of the Director General;

d) Create such committee or committees and appoint the members thereof, as may be necessary or proper for the management of the Authority or the attainment of its purposes and objectives;

e) Determine the research priorities of the Authority consistent with the framework of its purposes and objectives and in coordination with other government agencies; and

f) Exercise other powers and functions and perform other acts as may be necessary or proper for the attainment of the purposes and objectives of the Authority.

SEC. 9. ***Director General and Other Officers.*** – The Authority is headed by a Director General who shall be appointed by the President of the Philippines upon recommendation of the Secretary of Science and Technology. The Director General shall have a term of six (6) years.

The Director General shall be assisted by such Deputy Director General(s), program managers, and coordinators as the Board may determine to carry out the purposes and objectives of this Act.

SEC. 10. ***Powers, Functions and Duties of the Director General.*** – The Director General shall exercise the following powers, functions and duties:

- a) Supervise and direct the management, operation and administration of the Authority;
- b) Execute contracts, including the deeds that may incur obligations, acquire and dispose of assets, and deliver documents on behalf of the Authority;
- c) Implement and enforce policies, decisions, orders, rules and regulations adopted by the Board;
- d) Recommend to the Board the Authority's organizational structure, staffing pattern, operating and capital expenditure in accordance with pertinent laws;

e) Submit to the Board a quarterly report on the operations of the Authority;

f) Submit to the Board an annual budget and such supplemental budget as may be necessary for its consideration and approval; and

g) Exercise such other powers and functions and perform [such] other acts as may be necessary or proper for the attainment of the purposes and objectives of the Authority, or as may be delegated by the President of the Philippines.

SEC. 11. ***Government Agency Support and Coordination.*** – The Authority may, for the purpose of its research and development activities, obtain and secure the services of scholars, scientists, and technical personnel of any unit of the DOST, Department of Health (DOH), and other agencies of the government. Such personnel may be paid honoraria as may be fixed and authorized by the Board following the usual government rules and regulations governing honoraria and allowances. The Authority shall also assist, cooperate and coordinate with other government agencies, such as the Food and Drug Administration and Research Institute for Tropical Medicine of the DOH, Philippine Council for Health Research and Development of the DOST, State universities and colleges, National Institutes of Health, and the Philippine Genome Center for the implementation of the purposes and objectives of this Act.

SEC. 12. ***Human Resource Development.*** – The Authority, in pursuit of its objectives, shall:

- a) Provide for human resource development in the following fields: biotechnology and related areas including molecular biology, microbiology, virology, chemistry, biosecurity and biosafety, and vaccine technology;
- b) Provide funds for scholarships, study grants, training programs and short courses, both local and foreign;
- c) Support annual conventions and conferences of professionals in the field of biotechnology and related areas;
- d) Engage *Balik* scientists and foreign experts following the terms of reference and compensation structure of the *Balik* Scientist Program; and
- e) Provide for qualified employees of the Authority and its attached units the benefits of Republic Act No. 8439, also known as the “*Magna Carta for Scientists, Engineers, Researchers and Other S & T Personnel in the Government,*” or Republic Act No. 7305, also known as the “*Magna Carta of Public Health Workers,*” whichever is applicable.

SEC. 13. ***Biologicals and Vaccines Research and Development.*** – The Authority, in pursuit of its objectives, shall:

- a) Provide funding for a spectrum of researches, from basic to clinical, towards the development of safe and effective biologicals and vaccines;
- b) Support research institutions, facilities, and laboratories, in the private or government sector, in terms of funding for operations, maintenance,

research, capacity building, acquisition of equipment, buildings, and other capital assets; and

c) Support venues for publication and dissemination of research output in the field of biotechnology and related areas.

SEC. 14. ***Biotechnology Industrial Parks.*** – In coordination with the Philippine Economic Zone Authority, the Authority shall designate biotechnology industrial parks with applicable economic zone privileges, and with infrastructure adequate for biosafety and biosecurity global standards.

SEC. 15. ***Support for Filipino Biologicals Manufacturers.*** – The following support shall be provided to Filipino biologicals and vaccines manufacturers:

a) ***Financial Incentives*** – In coordination with the Department of Trade and Industry-Board of Investments and the Department of Finance, local biological and vaccine manufacturers shall be granted a tax holiday for the first five (5) years of their operations covering the following:

- 1) Income;
- 2) Import duties on equipment and modular units including bioreactors, related materials including active pharmaceutical ingredients, reagents, excipients, and preservatives, as well as vials, containers and other packaging materials; and
- 3) Export sales of locally-manufactured biologicals and vaccines, whether in bulk or in finished form.

b) *Guaranteed Purchase (Filipino First)* – Notwithstanding any law to the contrary, the DOH and Local Government Units, together with their health facilities, offices, and hospitals, shall preferentially purchase first from Filipino manufacturers all the vaccines and biologicals required for their programs including the Expanded Program on Immunization; *Provided*, That such vaccines and biologicals shall be procured in the most judicious, economical, and expeditious manner, and shall be exempted from the provisions on bidding process required under Republic Act No. 9184 or the “Government Procurement Reform Act” and other relevant laws; *Provided further*, That in case the forecasted demand exceeds the capacity of local production by Filipino manufacturers, the balance may be purchased by the DOH and local government units from foreign producers.

c) *Multi-year Supply Agreement* – The DOH and local government units, together with their health facilities, offices, and hospitals, may procure biologicals and vaccines through negotiated multi-year supply agreements with Filipino manufacturers.

d) *Technology Transfer* – The DOH and the Authority shall undertake initiatives to improve the capacity of Filipino manufacturers including acquiring biologicals and vaccines production know-how, and license these to Filipino manufacturers.

SEC. 16. *Biologicals Statistics Database.* – In coordination with the DOH, the Authority shall:

a) Regularly collect and publish domestic vaccination information including prevalence of vaccination, volume of vaccines purchased and sold, and volume of imported and exported vaccines;

b) Establish and regularly update a registry of biologicals and vaccines research institutions, biologicals and vaccines manufacturers, and biotechnology industrial parks in the country, including production capacity and current status; and

c) Establish and regularly update a registry of individuals trained in biotechnology and related fields including molecular biology, microbiology, virology, chemistry, biosecurity and biosafety, and vaccine technology.

**SEC. 17. *International Cooperation.*** – The Authority may enter into a memorandum of agreement or memorandum of understanding with international partners, upon the approval of the Board.

**SEC. 18. *Biologicals Development Fund.*** – The Biologicals Development Fund, hereinafter referred to as the Fund, is created and shall be used exclusively to finance activities to achieve the objectives of this Act. The Authority shall administer the Fund following existing government budgeting, accounting, and auditing rules and regulations.

The Fund shall be sourced from the following:

a) The amount of Two billion pesos (P 2,000,000,000.00) shall be appropriated from available funds of the National Treasury not otherwise appropriated;

b) Grants, license fees, bequests, and donations consisting of such properties, real or personal, including funds and valuable effects or things, as may be useful, whether from local or foreign sources: *Provided*, That acceptance of grants, license fees, bequests, and donations from foreign governments shall be subject to the approval of the President of the Philippines upon the recommendation of the Secretary of Science and Technology;

c) Sub-allotments from other government entities; and

d) A portion of the revenues from excise tax on alcohol, heated tobacco products, and vapor products as provided under Subsections B (3) and D(3), Section 288-A of Presidential Decree No. 1158, as amended by, among others, Republic Act No. 11346 and Republic Act No. 11467, otherwise known as the “*National Internal Revenue Code of 1997*,” as determined by the Secretary of Health upon consultation with the Board. This allocation is in furtherance of the attainment of one of the Sustainable Development Goals, specifically ensuring healthy lives and promoting well-being for all at all ages by supporting the research and development of vaccines and medicines for the communicable and non-communicable diseases.

SEC. 19. ***Appropriations.*** – The amount necessary for the initial implementation of this Act shall be charged to the current year’s appropriations for the Department of Science and Technology and the Department of Health. Thereafter, such amount as may be necessary to fund the continued

implementation of this Act shall be included in the annual General Appropriations Act.

SEC. 20. ***Appointment of Board Members.*** – Within thirty (30) days from the approval of this Act, the President of the Philippines shall appoint the members of the Board as well as the Director General and Deputy Director General(s) of the Authority.

SEC. 21. ***Annual Report.*** – The Authority shall submit to Congress an annual accomplishment report which shall include the status of its priority researches and operations, including the disbursements from the Fund. In the exercise of its oversight functions, Congress may inquire into the programs of the Authority and the disbursements from the Fund.

SEC. 22. ***Implementing Rules and Regulations.*** – Within thirty (30) days from the completion of their appointments, the Board shall convene and, in collaboration with the Secretary of Science and Technology, formulate the rules and regulations necessary for the implementation of this Act. The implementing rules and regulations shall be issued within one hundred twenty (120) days from the date of the Board's initial meeting and shall take effect fifteen (15) days after its publication in a newspaper of general circulation.

SEC. 23. ***Separability Clause.*** – If any provision or part of this Act is declared unconstitutional or invalid, the remaining parts or provisions not affected shall remain in full force and effect.

SEC. 24. **Repealing Clause.** – Subsections B(3) and D(3), Section 288-A of the National Internal Revenue Code of 1997, as amended by, among others, Republic Act No. 11346 and Republic Act No. 11467, are amended accordingly insofar as the Biologicals Development Fund shall be allocated a portion of the revenues from excise tax on alcohol, heated tobacco products, and vapor products.

All other laws, decrees, executive orders, rules and regulations, and other issuances inconsistent with or contrary to the provisions of this Act are repealed, amended or modified accordingly.

SEC. 25. **Effectivity.** – This Act shall take effect fifteen (15) days following its publication in the *Official Gazette* or in a newspaper of general circulation.

Approved,