NINETEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Third Regular Session)

24 SEP 18 P5 :43

SENATE

S. No. 2833

Introduced by Senator Joseph Victor G. Ejercito

AN ACT
TO ACCELERATE THE DISCOVERY AND DEVELOPMENT OF INNOVATIVE MEDICINES BY STRENGTHENING CLINICAL TRIALS, AND FOR OTHER PURPOSES

EXPLANATORY NOTE

Enacted in 2018, the Republic Act No. 11223, otherwise known as the *"Universal Health Care Act"*, is driven to improve the health care system of the country through strengthening health literacy, a progressive health care model, and a systematic framework of policies and programs rooted from the needs of the people. To ensure that quality and cost-effective services are delivered within these healthcare structures, it is by mitigating pharmaceutical innovations through clinical trials that the industry can provide timely medicines that are accessible to people.

The Philippines' principal health agency, the Department of Health (DOH), and the Food and Drug Administration (FDA), as the regulatory agency under the former, maintain the ethical regulations of clinical trials in the country. The positive progression of clinical trials in the Philippines has been recognized throughout the years,[1] however, recent data shows that there are existing areas for improvement in terms of availability and affordability,[2] with the need for policy reviews, adequate resources, and improved monitoring, among others.[3]

[1] FDA Circular 2012-007.
[2] Chang, J., et al. (2020). Prices, availability and affordability of medicines with value-added tax exemption: A cross-sectional survey in the Philippines. *International Journal of Environmental Research and Public Health.*
[3] Reyes, C. & Tabuga, A. (2020). A Profile of the Philippine Pharmaceutical Industry. *Philippine Competition Commission.*

There have been reputable health research and technologies in the country[4] that reflect the potential of local healthcare professionals, but the pharmaceutical market is still led by multi-national drug companies.[3] Alongside this status are a decrease in drug manufacturers, a decline in employment in the industry, and variations in the prices of medicines.

Further, as the Philippines currently ranks fourth out of 10 countries in Southeast Asia with the number of clinical trials.[5] The proposed measure seeks for a progressive support for clinical trials through instituting an Experimental Drug Development and Discovery Center that fosters pharmaceutical innovations, training professionals, and set standards for ethical conduct established by its governing council.

Regional Clinical Trial Hubs are also key to pushing forward these objectives and aligning clinical studies with the health needs of the population, while also providing easy access to an online enrollment system that serves as a platform for patients to find sponsors and studies appropriate for their condition.

Immediate passage of this measure is eagerly sought.

JOSEPH VICTOR G. EJERCITO

[4] 5 health technologies that will make you proud as a Filipino. *Department of Science and Technology - Philippine Council for Health Research and Development (DOST-PCHRD).*
[5] ClinicalTrails.gov. National Library of Medicine (Accessed September 1, 2024).

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TO ACCELERATE THE DISCOVERY AND DEVELOPMENT OF INNOVATIVE MEDICINES BY STRENGTHENING CLINICAL TRIALS, AND FOR OTHER PURPOSES

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

CHAPTER 1
GENERAL PROVISIONS

Section 1. *Short Title.* – This Act shall be known as the "Pharmaceutical Innovation Act."

Sec 2. *Declaration of Policy.* – It is recognized that well-designed and well-implemented clinical trials are indispensable for the discovery and development of innovative medicines and for assessing the safety and efficacy of health interventions and in informing associated comparative cost-effectiveness evaluations vis-à-vis existing interventions with a view to promoting the affordability of health products. Accordingly, it is hereby declared a policy of the State to accelerate the discovery and development of innovative medicines by strengthening clinical trials in a manner that addresses public health priorities and the health needs of Filipinos. For this purpose, the Government shall establish a national experimental drug discovery and development center, which shall aim to develop innovative medicines, and that will work collaboratively with the public sector and industry partners.

Sec. 3. *Definition of Terms.* – For purposes of this Act, the following terms shall have the meanings provided below:

(a) "Access to innovative medicines and investigational products" refers to the capability of the patient to timely and equitably receive innovative and/or investigational medicines that deliver the intended and sustainable outcomes.

(b) "Clinical Research Organization" refers to a person or an organization (commercial, academic or others) contracted by a sponsor to perform one or more of the sponsor's trial-related duties and functions.

(c) "Clinical Trial" refers to any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

(d) "Innovative medicine" refers to any novel drug, active pharmaceutical ingredient or molecule that does not contain or include indication, product, or brand name of existing pharmaceutical ingredient or molecule (*e.g.,* generic equivalent, biosimilars) registered with the Food and Drug Administration.

(e) "Investigational product" refers to a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

(f) "Managed entry agreements" refers to arrangements or patient access schemes that enable access to innovative medicines and investigational products.

(g) "Medicine" refers to any chemical compound or biological substance, other than food, intended for use in the treatment, mitigation, prevention, or diagnosis of disease in humans or animals, including but not limited to:

1. any article recognized in the Philippine Pharmacopoeia, Philippine National Drug Formulary, or in any foreign official pharmacopoeias and formularies which are adopted by the Food and Drug Administration or any document supplementary to any of them;
2. any article, other than food, intended to affect the structure or any function of the human body or animals;
3. any article intended for use as a component of any chemical compound or biological substance or articles specified above, not including devices or their components, parts, or accessories; and,
4. herbal and/or traditional drugs, and the components thereof, which are articles of plant or animal origin used in folk medicine, which are:
    i. recognized in the Philippine National Formulary;
    ii. intended for use in the treatment, cure, mitigation, prevention, or diagnosis 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; or
    v. intended for use as a component of any of the articles specified in clauses (i), (ii), (iii) and (iv) above.

(h) "Sponsor" refers to a natural or juridical person that is responsible for the initiation, management and/or financing of a clinical trial.

(i) "Philippine National Health Research System (PNHRS)" refers to the framework anchored on the principles of Essential National Health Research on inclusiveness, participation, quality, equity, efficiency and effectiveness, institutionalized within the mandate of the Philippine Council for Health

Research and Development (PCHRD) of the Department of Science and Technology (DOST) under Republic Act No. 10532, otherwise known as the Philippine National Health Research System Act of 2013.

CHAPTER 2
EXPERIMENTAL DRUG DEVELOPMENT AND DISCOVERY CENTER

Sec. 4. ***Experimental Drug Development and Discovery Center.*** – To improve access to innovative medicines and investigational products by strengthening clinical trials and to carry out the provisions of this Act, an Experimental Drug Development and Discovery Center is hereby established which shall serve as the collaborating hub on all matters regarding pharmaceutical research and development in the Philippines.

The Experimental Drug Development and Discovery Center shall have the following purposes and objectives:

a) Ensure strategic alignment with national plans and programs to strengthen clinical trials with a view of improving access to innovative medicines and investigational products;
b) Promote, encourage, and engage in pharmaceutical research and clinical trials on investigational products;
c) Stimulate and underwrite scientific research and clinical studies on the safety and efficacy of health interventions in the prevention and treatment of diseases; and
d) Encourage and undertake the training of physicians, nurses, medical and laboratory technicians, pharmacists, clinical trial investigators, clinical research coordinators and associates, data officers, health officers, and social workers on the practical, scientific, and ethical conduct and implementation of clinical trials.

Sec. 5. ***The Governing Council.*** – The Experimental Drug Development and Discovery Center shall be governed by a Council composed of the following:

(a) Chair, Secretary of the Department of Science and Technology;

(b) Co-chair, Secretary of the Department of Health;

(c) Members:

i. Director-General of the Food and Drug Administration;

ii. Secretary of the Department of Finance;

iii. A representative from the Pharmaceutical & Healthcare Association of the Philippines;

iv. A representative from the Philippine Hospital Association; and

v. A representative from the Philippine Clinical Research Professionals.

The representatives from the Pharmaceutical & Healthcare Association of the Philippines, Philippine Hospital Association, and the Philippine Clinical Research Professionals shall have the following qualifications:

(a) must be of good moral character;

(b) must be of recognized probity and independence;

(c) must have distinguished themselves professionally in the public, private, civic or academic service in the field of pharmacology; and

(d) must have been in the active practice of their professions for at least five (5) years.

The representatives must be chosen from at least five (5) persons for each position, to be recommended by the Secretary of Health, and to be appointed by the President for a term of three (3) years.

The non *ex officio* members may receive honoraria in accordance with existing laws, rules and regulations.

The Experimental Drug Development and Discovery Center and the Council shall be established within ninety (90) days from the enactment of this Act.

Sec. 6. ***Duties and Functions of the Center and Council.*** – The Experimental Drug Development and Discovery Center and its Council shall:

(a) Establish and resource regional clinical trial hubs;

(b) Provide support for the conduct of clinical trials, including capacity building, technical support, funding support, and intellectual property support;

(c) Establish incentives for the conduct of local clinical trials and the introduction of innovative medicines, including but not limited to expeditious regulatory review and approval, fiscal incentives, as may be applicable, priority review vouchers, and exemption from pricing intervention for innovative medicines and investigational products notwithstanding any prior or existing law or regulation to the contrary;

(d) Ensure patient protection and benefits for participating in clinical trials;

(e) Establish early access mechanisms for qualified patients, including online enrollment facilities for ongoing clinical trials and early access through managed entry agreements; and

(f) Reinforce provisions on intellectual property protection, including technology transfers.

Sec. 7. *Regional Clinical Trial Hubs.* – The Council shall develop standards to classify, accredit, and designate regional clinical trial hubs under the control and supervision of the DOST through the PCHRD.

In accordance with Section 15 of this Act, the Council shall provide in the implementing rules and regulations of this Act for the minimum required investigational, research capacities and facilities, technical, operational and personnel standards of these hubs, as well as the appropriate licensing and accreditation requirements and procedure for licensing in a timely manner. The use of Public-Private Partnership shall be allowed on the procurement of clinical trial infrastructure and delivery of services to improve access to and accelerate the discovery and development of innovative medicines. Private institutions may also be accredited as regional clinical trial hubs, provided they comply with the requirements for such accreditation.

The objectives and functions of a regional clinical trial hub shall be as follows:

a) Conduct clinical trials to discover and develop innovative medicines and assess the safety and efficacy of investigational products and/or health interventions;
b) Match clinical trials and innovative medicines with patients and align clinical study selections and initiatives with the health needs of the population;
c) Undertake and support the training of physicians, nurses, medical and laboratory technicians, pharmacists, clinical trial investigators, clinical research coordinators and associates, data officers, health officers, and social workers on evidence-based and good practice models for the delivery of clinical trials in a safe and ethical manner;
d) Establish, as necessary, networks with both public and private facilities to promote patients' access to innovative medicines and investigational products at reduced costs;
e) Adopt and promote evidence-based innovations, good practice models, ethical, equitable, sustainable strategies and actions across the conduct of clinical trials and discovery and development of innovative medicines;
f) Engage and collaborate with local government units, private sector, philanthropic institutions, advocacy organizations and civil society organizations to facilitate the procurement of clinical trial infrastructure and the conduct of clinical trials;
g) Promote and assist in ethical scientific research and clinical trial; and
h) Raise awareness on the benefits of clinical trials among the local community.

Sec. 8. ***Experimental Drug Development Research Fund.*** – There is hereby created an Experimental Drug Development Fund to be used exclusively for the implementation of this Act, which shall be administered by the Experimental Drug Development and Discovery Center following existing government budgeting, accounting, and auditing rules and regulations, with a quarterly report to the Office of the President and Congress on the disbursement of such fund.

The Experimental Drug Development and Discovery Center may solicit and receive donations which shall form part of the Experimental Drug Development Fund.

Notwithstanding any prior or existing law or regulations to the contrary, such donations whether from local or foreign donors shall be exempt from income tax, donor's tax, and all other taxes, fees, and charges imposed by the national government or local government. Likewise, fund-raising activities may be conducted by the Experimental Drug Development and Discovery Center, and the proceeds of which shall accrue to the Experimental Drug Development Fund and shall be exempt from any and all taxes, fees, and charges imposed by the national government or local government notwithstanding any prior or existing law or regulations to the contrary.

Without prejudice to the appropriation allotted to the implementation of this Act as mentioned in Section 16 hereof, the Experimental Drug Development Fund may be used to implement the provisions and policies introduced by or pursuant to this Act.

Sec. 9. ***Fiscal Incentives.*** – Clinical Research Organizations and Sponsors of local clinical trials shall be eligible to register their business activities in relation to the conduct of local clinical trials and/or the introduction of innovative medicines under the Strategic Investment Priority Plan with the Fiscal Incentives Review Board, or the Investment Promotion Agencies, under a delegated authority from the Fiscal Incentives Review Board.

For the purpose of this Act, local clinical trials shall be regarded as research and development resulting in demonstrably significant breakthroughs in science and health which falls under Tier III of the Strategic Investment Priority Plan.

The qualified Clinical Research Organizations and Sponsors of local clinical trials shall be entitled to tax incentives under Chapter II of the National Internal Revenue Code of 1997, as amended by Republic Act No. 10963 or the "Tax Reform for Acceleration and Inclusion" (TRAIN), Republic Act No. 11256, Republic Act No. 11346, Republic Act No. 11467 and Republic Act No. 11534 or the "Corporate Recovery and Tax Incentives for Enterprises Act" (CREATE), subject to the conditions of availment provided therein.

Sec. 10. ***Priority Review.*** – Subject to rules and regulations to be promulgated by the Department of Health, the Experimental Drug Development and Discovery Center may award priority review vouchers to Sponsors of a local clinical trial that shall entitle the holders of such vouchers to priority review of their medicines with the Health Technology Assessment Council and the Food and Drug Administration.

Sec. 11. ***Exemption from Pricing Interventions.*** – An innovative medicine or investigational product that underwent local clinical trial shall be exempt from the imposition of maximum retail prices under Section 17 of Republic Act No. 9502 for a period of ten (10) years from the date it is issued a marketing authorization or certificate of product registration by the Food and Drug Administration.

Sec. 12. ***Online Enrollment System.*** – The DOST, in coordination with the Council, shall create, manage, and control an online enrollment system that shall be accessible through the existing PNHRS website.

The online enrollment system shall facilitate the engagement of patients afflicted with life threatening, seriously debilitating, or serious and chronic illnesses or diseases with the appropriate Sponsor for purposes of being enrolled in ongoing clinical trials in whatever stage, and to facilitate access of such patients to the relevant investigational products: *Provided,* that the Sponsor shall be responsible for the funding of the clinical trial.

For purposes of this Section, the Sponsor shall be responsible for formulating the appropriate criteria to be used as basis to determine the qualification of the prospective participants, subject to the approval of the Council, and taking into consideration the following, among others:

a) the purpose of the study;
b) the nature of the medicine or investigational product subject of the study, including its side-effects and risks;
c) the age and sex of the prospective participant;
d) the type and stage of the illness or disease that he or she is afflicted with;

e) his or her previous medical and treatment history; and

f) other existing medical conditions.

Section 13. ***Managed Entry Agreements.*** – For the purposes of this Act, the Department of Health and/or the Philippine Health Insurance Corporation, in consultation with the Council, shall promote and enter into managed entry agreements with the appropriate Sponsors with a view to enable early access to investigational products and innovative medicines that have yet to be listed in the Philippine National Formulary; *Provided,* that said managed entry agreements shall be available to qualified beneficiaries whether or not they are enrolled in any clinical trial: *Provided, further,* that the managed entry agreements shall have as its main objective the expedited procurement, coverage, or reimbursement by the government of innovative medicines and investigational products under a criteria to be formulated by the Department of Health.

It shall be the duty of the Experimental Drug Development and Discovery Center to keep a record of all managed entry agreements entered pursuant to this Section, and to monitor the progress and implementation thereof. Such records shall be available for perusal by the general public in accordance with existing laws, rules, and regulations.

Section 14. ***Philippine Biopharmaceutical Patent Pool.*** – The Experimental Drug Development and Discovery Center shall also establish a Philippine Biopharmaceuticai Patent Pool that will coordinate with innovative pharmaceutical companies and interested local manufacturers towards increasing local production of patented medicines. Incentives for participating in the Biopharmaceuticai Patent Pool shall also be established.

Section 15. ***Implementing Rules and Regulations.*** – The Council, in consultation with other appropriate agencies, shall, within one hundred twenty (120) days from the effectivity of this Act, promulgate the rules and regulations necessary to effectively implement its provisions.

CHAPTER 3
MISCELLANEOUS PROVISIONS

Section 16. ***Appropriations.*** – The amount necessary for the initial implementation of this Act shall be charged against the current fiscal year's appropriations for the Department of Science and Technology. Thereafter, such amount as may be necessary for the continued implementation of this Act must be included in the annual General Appropriations Act.

Section 17. ***Separabillty Clause.*** – Any portion or provision of this Act that may be declared unconstitutional or invalid shall not have the effect of nullifying other portions and provisions hereof as long as such remaining portion or provision can still subsist and be given effect in their entirety.

Section 18. ***Repealing Clause.*** – All other laws, decrees, executive orders, or rules and regulations contrary to or inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

Section 19. ***Effectivlty.*** – This Act shall take effect fifteen (15) days after its publication in the Official Gazette or at least two (2) newspapers of general circulation.

Approved,