

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

NINETEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 8554



Introduced by: **REP. FERJENEL G. BIRON, M.D.**

**AN ACT REGULATING THE ESTABLISHMENT AND USE OF ONLINE
PHARMACIES IN THE PHILIPPINES**

EXPLANATORY NOTE

This bill seeks to regulate the establishment and use of online pharmacies or as dubbed in this proposed measure - “*eBotika*” - in the sale and distribution of various pharmaceutical products including, among others, drugs, medicines, and medical devices in the Philippines.

Online ordering of various drugs and medicines has been a savior during the COVID-19 pandemic, giving at-risk individuals such as Persons with Disability (PWDs), people with compromised immune systems, people who do not live in close proximity to a pharmacy or unavailability of the same in their locality, and senior citizens, the alternative of not having to go out and get exposed to the virus while buying their prescribed or maintenance medications. On the other hand, with the proliferation of e-commerce, the number of reputable pharmacies offering online ordering and delivery of drugs and medicines is dwarfed by those that operate illegally and inappropriately, putting the public health at risk for unsafe and counterfeit drugs and medicines. As we gradually ease out of restrictions, there are still many who opt for the convenience of buying consumer products online rather than going to a physical outlet.

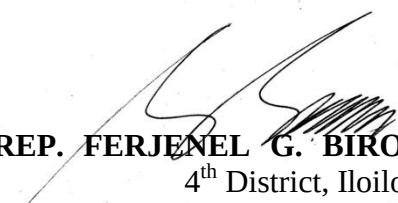
The Philippine Pharmacy Act (Republic Act No. 10918) governs the practice of pharmacy in the Philippines but the regulatory provisions thereof relate more to the traditional pharmacies, the licensing of which, require a physical outlet. Last 11 June 2019, cognizant of the growing number of drugs and medicines being unlawfully sold through online platforms, the Philippine Food and Drug Administration issued FDA Advisory No. 2019-154 warning the public that “online selling of medicines is NOT permitted pursuant to existing laws, rules and regulations”. Further it stated that the FDA only allows online ordering services by a seller who has an existing FDA-licensed pharmacy or *botika* with a physical address, and who has applied for prior approval for online ordering services. On 20 March 2020, the FDA also issued Circular No. 2020-010 reminding all concerned establishments that online selling of medical devices and supplies without the corresponding authorizations issued by the FDA is strictly prohibited. However, despite the advisory, many

unauthorized online sales of drugs and medicines as well as medical devices directly to consumers still operate.

Our lack of a dedicated legislation in the country gives rise to the ambiguity in the regulation of online pharmacy services thereby posing increased perils on public health. To this end, this bill aims to achieve the following purposes:

- (1) deter the proliferation of illegal online sale of drugs and medicines and drug trafficking activities;
- (2) deter the proliferation of the online sale of unregistered products such as medical devices, cosmetics and food supplements;
- (3) develop a streamlined licensing process and regular monitoring of online pharmacy services;
- (4) ensure efficiency in delivery of services and capability of online pharmacies to cater several regions nationwide by requiring presence at a minimum number of regions in the country as well as minimum capitalization, which shall be used to develop and maintain a secure online platform, adequate inventory of pharmaceutical products and implementation of quality control measures in the delivery of pharmaceutical services;
- (5) direct patients to legitimate and authorized online pharmacies by the provision of mechanisms by which the consumer can easily verify that the online pharmacy is duly authorized or licensed;
- (6) develop and enforce policies and procedures for online pharmacies to ensure reasonable verification of identity of the patient, prescriber, and caregiver if applicable, to detect forged prescriptions and to verify electronic prescriptions and prevent drug orders from being submitted and filled by multiple pharmacies;
- (7) require from online pharmacies a safe and secure mechanism to obtain and maintain patient medication profiles, ensure confidentiality of personal and sensitive information of patients when such information is transmitted over the internet;
- (8) ensure that online pharmacies adhere to a system for shipping drugs and medicines safely, securely and appropriately to patients; and
- (9) provide stiffer sanctions for violation thereof.

For these legitimate objectives, with the ultimate goal of protecting public health, the approval of this bill is earnestly sought.


REP. FERJENEL G. BIRON, M.D.
4th District, Iloilo

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

SECTION 1. This Act shall be known as the “*eBotika Act*”.

SEC. 2. *Statement of Policy.* - It is the declared policy of the State to protect and promote the right to health of the people and instill health consciousness among them. The State shall likewise adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable costs. To this end, the State shall adopt, establish and maintain an effective regulatory system and viable mechanism responsive to the country's health needs and problems. In so doing, the State shall ensure safe, reliable, and convenient access to quality pharmaceutical products and medical devices through online pharmacies nationwide.

SEC.3. *Definition of Terms.* -

- (a) *Accredited professional organization (APO)* refers to the duly integrated and accredited professional organization of registered and licensed pharmacists, of which there shall be only one (1), as prescribed under Section 41, Article V of R.A. No. 10918, or the “Philippine Pharmacy Act”;
- (b) *Antimicrobials or Antimicrobial Agents* refer to medicines which kill or inhibit the growth of germs and are used in treating infectious diseases. These include antibiotics, antivirals, antifungals, antiparasitics and disinfectants.
- (c) *Cold Chain Management Requirements* refers to the standards set by the FDA for all establishments engaged in the manufacture, importation, distribution, and outlets

involved in the selling of pharmaceutical products for the safe storage and distribution of time- and temperature- sensitive pharmaceutical products.

- (d) *Dangerous drugs* refer to those listed in the (1) Schedules annexed to the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol; (2) Schedules annexed to the 1971 Single Convention on Psychotropic Substances; and (3) Annex of Republic Act No. 9165, otherwise known as the “Comprehensive Dangerous Drugs Act of 2002”, and its amendments;
- (e) *Drugs* refer to pharmaceutical products that pertain to chemical compounds or biological substances, other than food, intended for use in treatment, prevention, or diagnosis of disease in humans or animals, including the following:
 - (1) Any article recognized in the official *United States Pharmacopeia/ National Formulary, Homeopathic Pharmacopeia of the United States of America, Philippine Pharmacopeia, Philippine National Drug Formulary, British Pharmacopoeia, Japanese Pharmacopoeia*, and any official compendium or any supplement to them;
 - (2) Any article intended for use in diagnosis, cure, mitigation, treatment, or presentation of disease of man or animals;
 - (3) Any article other than food, intended to affect the structure or any function of the human body or animals;
 - (4) Any article intended for use, as a component of articles, specified in clauses (1), (2), and (3), not including devices or their components, parts and accessories; and
 - (5) Herbal or traditional drugs as defined in Republic Act No. 9502;
- (f) *eBotika* refers to a pharmaceutical outlet providing pharmaceutical services over the internet. The term shall be synonymous with and can be used interchangeably with the words “*epharmacy*” or “*online pharmacy*”.
- (g) *eBotika warehouse* refers to a place where ebotika merchandise is stored, whether owned by the business owner or by a third-party provider, suitably designed and well-maintained to carry out online pharmacy activities;
- (h) *eCommerce platform* refers to digital platforms and marketplaces operated by a natural or juridical person whose business is to connect consumers and online merchants, facilitating sales of products, goods or services through the internet with the presence and use of monetary transactions. These include social media websites, mobile apps and any other similar platforms in so far as it is used for business;
- (i) *ePrescription* refers to a written, printed, or typed order for the preparation and administration of a drug or medicine for a patient, issued by or made by a licensed physician, which is received, recorded, transmitted, stored, processed, retrieved or produced electronically. The term may be used synonymously with *electronic prescription*.
- (j) *Generic name* refers to the scientifically and internationally recognized name of the active ingredients, as approved by the FDA pursuant to Republic Act No. 6675, otherwise known as the “Generics Act of 1988”;

- (k) *Good Distribution Practices or GDP* refers to that part of quality assurance which ensures that the quality of a pharmaceutical product is maintained through adequate control throughout numerous activities which occur during the distribution process.
- (l) *Good Storage Practices or GSP* refers to that part of quality assurance which ensures that the quality of a pharmaceutical product is maintained through adequate control throughout storage.
- (m) *Licensed physician* refers to all individuals licensed or authorized to practice medicine as defined by Republic Act No. 2382 or the Medical Act of 1959, as amended;
- (n) *Medical device* refers to any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings, for one (1) or more of the specific purposes of: diagnosis, prevention, monitoring, treatment, or alleviation of disease; diagnosis, monitoring, treatment, or alleviation of or compensation for an injury; investigation, replacement, modification or support of the anatomy of a physiological process, supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means, as defined under Republic Act No. 9711;
- (o) *Medicines* refer to drugs in their appropriate dosage forms, with assured quality, safety and efficacy for humans or animals, or both;
- (p) *eBotika services* refer to pharmaceutical services of a duly licensed pharmaceutical outlet done over the internet;
- (q) *Over-the-counter (OTC) medicines* refer to medicines used for symptomatic relief of minor ailments and which may be dispensed without a prescription;
- (r) *Pharmaceutical establishment* refers to an entity licensed by appropriate government agencies, involved in the manufacture, importation, exportation, repacking, and distribution of pharmaceutical products to pharmaceutical outlets;
- (s) *Pharmaceutical outlet* refers to an entity licensed by appropriate government agencies, and which are involved in compounding and/or dispensing and selling of pharmaceutical products directly by patients or end-users;
- (t) *Pharmaceutical products* refer to drugs, medicines, biological, pharmaceutical and biopharmaceutical products/specialties, veterinary products, veterinary biological and veterinary medicinal products;

- (u) *Pharmacist* refers to a health professional who has been registered and issued a valid Certificate of Registration (COR) and Professional Identification Card (PIC) by the PRC and the Professional Regulatory Board of Pharmacy;
- (v) *Prescription/ethical drugs/medicines* refer to drugs or medicines which can only be dispensed by a pharmacist to a patient, upon the presentation of a valid prescription from a physician, dentist, or veterinarian and for which a pharmacist's advice is necessary;
- (w) *Pure eBotika* refers to a duly licensed pharmaceutical outlet providing pharmaceutical services over the internet only, without a physical store for dispensing of drugs and medicines;

SEC.4. Online Sale and Distribution of Pharmaceutical Products. The sale and distribution of pharmaceutical products and medical devices, except regulated and dangerous drugs as defined by the Food and Drug Administration (FDA) and regulated by the Philippine Drug Enforcement Agency (PDEA), by means of the internet by a duly licensed ebotika in the Philippines shall be allowed.

SEC. 5. General Requirements for the Establishment and Operation of an eBotika.

(a) The establishment and operation of an ebotika shall be subject to the requirements provided for in this Act and the rules and regulations prescribed by the Food and Drug Administration (FDA).

(b) All pharmaceutical outlets engaged or intending to engage in the selling of all pharmaceutical products and medical devices to consumers and patients over the internet shall be required to secure a License to Operate (LTO) as an ebotika from the Food and Drug Administration (FDA), whether as an additional activity for physical pharmaceutical outlets or as a pure ebotika. The application for the LTO shall not be approved unless applied for by a Filipino registered and licensed pharmacist, either as owner or as pharmacist-in-charge. The FDA shall establish such other rules and regulations prescribing the requirements for the issuance of the LTO.

(c) Only FDA-registered products are allowed to be offered for sale or distribution through the ebotika. The ebotika may use online ecommerce platforms or may create their own website or mobile app in accordance with the minimum requisites provided under Section 8 of this Act.

(d) All pharmaceutical outlets with additional activity as an ebotika or as pure online pharmacy shall appoint a PRC-licensed pharmacist to act as pharmacist-in-charge who shall be responsible and accountable for compliance with FDA laws, rules and regulations pertaining to product safety, efficacy and quality. Such pharmacist-in-charge shall be declared and updated with the FDA.

(e) Pharmaceutical outlets that do not have any physical store for face-to-face dispensing shall be issued a LTO as an ebotika by the FDA, provided it has a warehouse and an office that can hold product inventories or stocks following prescribed standards in handling different types of pharmaceutical products, medical devices and supplies, over-the-counter (OTC) supplies or devices, and milk formula. All additional warehouses operating under the same licensee shall be declared and subject to inspection by the FDA. All existing

pharmaceutical outlets with additional activity as online pharmacy shall declare all warehouses which shall be subject to inspection by the FDA.

(f) The ebotika shall comply with Good Distribution Practices and Good Storage Practices, including Cold Chain Management Requirements as may be applicable, to ensure the integrity and stability of all pharmaceutical products and medical devices supplied. Approval and issuance of the LTO shall require prior FDA inspection to be conducted.

SEC. 6: Minimum Capitalization Requirement. In order to ensure the financial stability, accountability, and quality of service provided by online pharmacies, any individual or entity seeking to establish an ebotika as defined by this Act, shall be required to meet a minimum capitalization of One Hundred Million Pesos (PHP 100, 000, 000.00) upon initial application and approval, which shall be further increased to Two Hundred Million Pesos (PHP 200,000,000.00) on its second year of operation. The capitalization requirement shall be in the form of cash or its equivalent, which must be fully paid-up before the issuance of the necessary license to operate an ebotika. Failure to comply with the minimum capitalization requirement shall result in the denial or revocation of the permits and licenses necessary to operate an online pharmacy.

SEC.7. Minimum Regional Presence Requirement. (a) To ensure accessibility and availability of pharmaceutical services across different regions in the country, including those in remote or underserved areas, any individual or entity seeking to establish an ebotika in the country must demonstrate a presence in at least ten (10) regions in the Philippines, distributed in at least four (4) regions in Luzon, three (3) regions in Visayas, and three (3) regions in Mindanao.

(b) Regional presence shall be fulfilled by establishing physical distribution centers, commissaries or strategic partnerships with existing licensed pharmacies or warehouses in the designated regions. The distribution centers, commissaries or partnerships must enable prompt and efficient delivery of pharmaceutical products and medical devices to customers within the specified regions.

(c) Failure to maintain a presence in the required number of regions in Luzon, Visayas and Mindanao shall be a ground for the suspension or revocation of the permits and licenses necessary to operate an online pharmacy.

SEC.8. Requisites of an eBotika Platform, Website or Application. - The ebotika platform, website or app shall comply with the following minimum requisites:

(a) All ebotikas shall render services through digital platforms or websites hosted only in the Philippine domain;

(b) An ebotika shall display in a visible and clear manner on its homepage a statement that it complies with the requirements of this Act with respect to the delivery and sale or offer for sale of pharmaceutical products and medical devices through an ebotika as well as the fact of its registration as an ebotika;

(c) Each online pharmacy shall post in a visible and clear manner on the homepage of each internet platform, site or mobile app it operates, or on a page directly

linked thereto in which a hyperlink is also visible and clear on the homepage, the following information:

- i. The registered name and principal office or warehouse address of the ebotika as it appears on the pharmacy's License to Operate;
- ii. The registered contact number and email address of the ebotika;
- iii. The registered name, professional degree and licensure of the pharmacist-in-charge and the contact number at which the pharmacist-in-charge can be contacted;

(d) All FDA-required information, education, and communication campaign materials shall be displayed in the ebotika page, website, or app;

(e) All pharmaceutical products and medical devices offered for sale must bear illustrations of the product including its primary and secondary packaging, if any, and must provide all information required by existing FDA rules and regulations on labeling; provided further, that all online pharmacies are encouraged to share useful information about medicines and illnesses, provide links to useful information as well as important medical resources and government agencies;

(f) For prescription drugs, the display shall bear a note clearly indicating that the drug or medicine requires a prescription, provided, there shall be a mechanism by which an electronic copy of the valid prescription must be uploaded or attached prior to adding to cart or checkout;

(g) The page or website shall provide a mechanism by which photos of senior citizen/PWD ID and page of last entry of booklet can be uploaded for the application of discounts, subject to verification as to its authenticity;

(h) All consumers who shall purchase pharmaceutical products and medical devices from an ebotika shall be required to sign in an account which shall be used for proper recording of patient medication profiles; provided that all information given shall be used and kept confidential in accordance with the Data Privacy Act (R.A. No. 10173);

SEC. 9. Issuance of ePrescription.- (a) All licensed physicians shall be authorized to issue electronic prescriptions pursuant to this Act by issuing it via email or any other alternative modes considered electronic document acceptable under the Electronic Commerce Act of 2000 (R.A. No. 8792). The electronic prescription shall be deemed an equivalent of a written prescription.

(b) All licensed physicians shall issue a separate electronic prescription for all antimicrobials particularly, antibiotics, anti-infectives, and anti-viral preparations.

(c) All eprescriptions shall contain the name of the individual to whom the medicines or drugs are prescribed, his or her age, complete address, the generic name of the medicines or drugs prescribed, the dosage, the form of medication, the route and timing of administration, the quantity, and the date of prescription.

(d) All eprescriptions shall contain the registered digital signature, name, license number, professional tax receipt (PTR) number, the contact number, and office address of the issuing physician.

(e) Every licensed physician who shall make use of the electronic prescription shall keep records of all eprescriptions he or she issues pursuant to this Act.

SEC.10. Recognition, Verification and Recording of Electronic Prescription.- (a) All ebotikas shall recognize the validity and effectivity of eprescriptions issued by a licensed medical practitioner subject to reasonable verification. An optical electronic copy, a scanned or captured image in *pdf*, *jpeg*, or other photo file format of the traditional written prescription uploaded on the platform, website or app shall likewise be recognized. Prescriptions containing anti-biotic, anti-infective, and anti-viral preparations shall only be valid for one (1) week after its issuance.

(b) The ebotika shall strictly dispense drugs as prescribed by the licensed physician in the eprescription and the latter shall be deemed equivalent to a written prescription for all intents and purposes.

(c) The ebotika shall dispense drugs only if the eprescription is complete and complies with the requirements of a valid eprescription as provided in Section 9 hereof.

(d) All eprescriptions shall be verified from the licensed physician through his/her official contact information indicated in the eprescription before dispensing. The epharmacy shall further verify the identity of the licensed physician issuing the eprescription and the validity of his or her license with the Philippine Regulation Commission (PRC).

(e) The ebotika shall ensure an accurate and secure record of all eprescriptions it receives and for which prescription drugs and medicines have been dispensed and sold.

SEC.11. Dispensation and Delivery of Drugs and Medicines Sold Online.- (a) All ebotikas shall ensure the safe and proper transport and delivery of all drugs and medicines sold online to the patient for which the drug or medicine was bought or to his or her authorized representative.

(b) The ebotika shall declare in its registration whether it shall establish its own courier services for the delivery of pharmaceutical products sold online or contract with a third-party provider. In the latter case, the name of the third-party courier service shall be declared upon registration and kept updated.

(c) All prescription drugs dispensed shall be properly sealed and delivered only to the patient or his or her authorized representative upon presentation of competent proof of identification. The hard copy of the traditional written prescription, if any, that is completely dispensed, shall be handed over to the courier, which in turn shall secure the document and ensure a return service of the same to the pharmacist-in-charge.

(d) Upon complete delivery of the prescription drug, and upon receipt of the hard-copy of the prescription, the pharmacist-in charge shall ensure that the prescribing physician is immediately notified thereof in writing.

SEC.12. Penal Provisions. - Any person who shall commit any of the acts penalized under Article VII of R.A. No. 10918, or the Philippine Pharmacy Law, by means of the internet shall upon conviction, be adjudged the maximum of the penalty imposed under said Republic Act.

SEC. 13. Enforcement. - It shall be the primary duty of the Professional Regulatory Board of Pharmacy (hereinafter the “Board”) and the Professional Regulation Commission (PRC), in coordination with the Food and Drug Administration and other relevant government agencies to effectively enforce the provisions of this Act. All duly constituted law enforcement agencies and officers of the national, provincial, city or municipal government or of any political subdivision thereof shall ensure the effective enforcement and implementation of the provisions of this Act.

SEC. 14. Suppletory Application of the “Philippine Pharmacy Act”. The provisions of Republic Act No. 10918, otherwise known as the “Philippine Pharmacy Act” shall apply suppletorily to the provisions of this Act.

SEC.15. Appropriations. – The Chairperson of the PRC shall immediately include in its programs the implementation of this Act, the funding of which shall be charged against their current year’s appropriations and thereafter, in the annual General Appropriations Act.

SEC.16. Implementing Rules and Regulations. - Within one hundred and fifty (150) days after the approval of this Act, the Board, subject to the approval of the PRC, and in consultation with the APO, the FDA, and the Department of Trade and Industry (DTI) shall formulate and issue the rules and regulations to implement the provisions of this Act.

SEC.17. Separability Clause. – If any clause, provision, paragraph or part hereof shall be declared unconstitutional or invalid, such declaration shall not effect, invalidate, or impair the other provisions otherwise valid and effective.

SEC.18. Repealing Clause. - All other laws, presidential decrees, executive orders and other administrative issuances or parts thereof which are contrary to or inconsistent with the provisions of this Act are hereby repealed, amended or modified accordingly.

SEC. 19. Effectivity. – This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in a newspaper of general circulation.

Approved,