Republic of the Philippines
House of Representatives
Quezon City, Metro Manila

Twentieth Congress
First Regular Session

House Bill No. **8896**

HOUSE OF REPRESENTATIVES
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Introduced by Representatives Ferdinand Martin G. Romualdez, Yedda Marie K. Romualdez, Andrew Julian K. Romualdez and Jude A. Acidre

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AN ACT

STRENGTHENING THE REGULATORY SYSTEM IN THE COUNTRY TO COMBAT COUNTERFEIT PHARMACEUTICAL PRODUCTS, DECLARING THE MANUFACTURE, IMPORTATION, DISTRIBUTION, SALE OR OFFER FOR SALE, OR POSSESSION OF COUNTERFEIT PHARMACEUTICAL PRODUCTS AS AN OFFENSE INVOLVING ECONOMIC SABOTAGE, PROVIDING PENALTIES FOR VIOLATIONS THEREOF, REPEALING FOR THE PURPOSE REPUBLIC ACT NO. 8203, OTHERWISE KNOWN AS THE "SPECIAL LAW ON COUNTERFEIT DRUGS"

EXPLANATORY NOTE

The bill seeks to strengthen the State's capacity to prevent, detect, investigate, suppress, and respond to counterfeiting activities in the pharmaceutical sector by repealing, modernizing, and broadening the scope of Republic Act No. 8203 otherwise known as the Special Law on Counterfeit Drugs. Furthermore, the bill declares the manufacture, importation, distribution, sale, offering for sale, or possession of counterfeit pharmaceutical products as acts constituting economic sabotage and imposes stiffer administrative and criminal penalties for violations of the Act. It likewise establishes a rapid alert system and pharmacovigilance unit within the Food and Drug Administration (FDA) to strengthen its capacities in addressing the proliferation of counterfeit pharmaceutical products.

Counterfeit pharmaceutical products pose a grave threat to public health and safety. These fraudulent products not only endanger the lives of patients and consumers by depriving them of the intended therapeutic effect, but also erode trust in the country's health system, weaken legitimate pharmaceutical industries,

and compromise national development.

In a 2019 study of the UN Office on Drugs and Crime (UNODC), the Philippines recorded the highest incidence of falsified medicines in the region, accounting for 193 out of 460 reported cases of counterfeit and illegally distributed pharmaceutical products between 2013 and 2017. As of September 2024, the government, through the FDA, seized PhP 28 million worth of counterfeit medicines and health products under its *Oplan Katharos* campaign.

Yet, such counterfeiting activities in the health sector continue to persist despite the existence and implementation of the Republic Act No. 8203, otherwise known as the "Special Law on Counterfeit Drugs." Furthermore, the implementation of Republic Act No. 8203 has also been weakened by Supreme Court rulings on drug-related cases. In one ruling, the Court held that Republic Act No. 9502, or the Universally Accessible Cheaper and Quality Medicines Act of 2008, effectively nullified the purpose of R.A. 8203, rendering it "meaningless and without function."

Thus, this proposed measure seeks to address the continuing rise and increasing complexity of pharmaceutical crimes and the widespread proliferation of falsified medicines, which have grown more sophisticated over time. It likewise aims to repeal Republic Act No. 8203 to effectively remedy the gaps, limitations, and enforcement challenges that have hindered its full implementation.

This bill affirms the primacy of public health and embodies a stronger, more deterrent, and health-centered approach to eradicate counterfeit pharmaceutical products towards the protection of the lives of the Filipino people. It aligns with the State's constitutional obligation to promote the people's right to health while building upon the State's policy to maintain an effective regulatory framework responsive to present and future challenges in public health.

In view of the foregoing, the immediate passage of this bill is earnestly sought.

FERDINAND MARTIN G. ROMUALDEZ **YEDDA MARIE K. ROMUALDEZ**

ANDREW JULIAN K. ROMUALDEZ **JUDE A. ACIDRE**

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STRENGTHENING THE REGULATORY SYSTEM IN THE COUNTRY TO COMBAT COUNTERFEIT PHARMACEUTICAL PRODUCTS, DECLARING THE MANUFACTURE, IMPORTATION, DISTRIBUTION, SALE OR OFFER FOR SALE, OR POSSESSION OF COUNTERFEIT PHARMACEUTICAL PRODUCTS AS AN OFFENSE INVOLVING ECONOMIC SABOTAGE, PROVIDING PENALTIES FOR VIOLATIONS THEREOF, REPEALING FOR THE PURPOSE REPUBLIC ACT NO. 8203, OTHERWISE KNOWN AS THE "SPECIAL LAW ON COUNTERFEIT DRUGS"

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 *"Anti-Counterfeit Medicine Act".*

SECTION 2. ***Declaration of Policy.*** – As declared in Article II, Section 15 of the 1987 Philippine Constitution, it is the policy of the State "to protect and promote the right to health of the people and instill health consciousness among them." Additionally, the State shall establish and maintain an effective food and drug regulatory system, and undertake appropriate health human resource

development and research responsive to the country's health needs and problems as stipulated in Article XIII, Section 12.

Towards the fulfillment of these mandates, the State shall adopt, establish, institutionalize, and enhance structures, mechanisms, processes, and initiatives that shall strengthen the State's capacity to prevent, detect, investigate, suppress, and more effectively respond to activities resulting in the manufacture and circulation of counterfeit pharmaceutical products. The State shall likewise reinforce prohibitions against counterfeit pharmaceutical products; declare the manufacture, importation, distribution, sale, offering for sale, or possession thereof as offenses constituting economic sabotage; and impose more stringent penalties for violations of the provisions of this Act.

SECTION 3. ***Definition of Terms.*** **-** For the purposes of this Act, the following definitions shall apply:

a. ***Biopharmaceuticals*** shall refer to pharmaceutical products that are used for therapeutic or for in vivo diagnostic purposes, such as vaccines, sera, and drugs derived from life forms using biotechnology. These include proteins, nucleic acids, or living microorganisms where the virulence is reduced and are used for therapeutic or for in vivo diagnostic purposes.
b. ***Brokering*** shall refer to any act of facilitating the disposal or sale of counterfeit pharmaceutical products, including acts of agency;
c. ***CDRR*** shall refer to the Center for Drug Regulation and Research of the FDA;
d. ***Counterfeit pharmaceutical products*** shall refer to pharmaceutical products which fall under any of the following conditions, resulting in the reduction of the pharmaceutical products' safety, efficacy, quality, strength or purity:

i. Does not contain the amounts as claimed;

ii. With wrong ingredients;

iii. Without active ingredients; or

iv. With less than eighty percent (80%) of the active ingredient it purports to possess as distinguished from an adulterated drug including reduction or loss of efficacy due to expiration.

It shall also refer to products that are deliberately and fraudulently misrepresented with respect to their identity, composition and/or source. For this purpose, the terms:

1. ***"Identity"*** shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized pharmaceutical product;
2. ***"Composition"*** shall refer to any ingredient or component of the pharmaceutical product in accordance with applicable specifications authorized/recognized by the FDA;
3. ***"Source"*** shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.

Any consideration related to intellectual property rights does not fall within this definition.

e. ***Director General*** shall refer to the Director General of the FDA.

f. ***Drugs*** shall refer to pharmaceutical products that pertain to any chemical compound or biological substance, other than food, intended for use in the treatment, cure, mitigation, prevention or diagnosis of disease in humans or animals, including but not limited to:

i. Any article recognized in the Philippine Pharmacopoeia, Philippine National Drug Formulary, or in any foreign official pharmacopoeias and formularies which are adopted by the FDA or any documentary supplement to any of them;

ii. Any article, other than food, intended to affect the structure or any function of the human body or animals;

iii. 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; or

iv. Herbal and/or traditional drug which are articles of plant or animal origin used in folk medicine, which are:

1. recognized in the Philippine National Drug Formulary; or
2. intended for use in the treatment, cure, mitigation, prevention or diagnosis of disease symptoms, injury or body defects in humans; or
3. other than food, intended to affect the structure or any function of the human body; and
4. in finished or ready-to-use dosage form; or
5. intended for use as a component of any of the articles specified in clauses (a), (b), (c), and (d);

g. ***Department*** shall refer to the Department of Health;

h. ***Economic Sabotage*** shall refer to any of the acts declared unlawful and prohibited under this Act when committed, and where the value of the counterfeit pharmaceutical products involved (whether consisting of a single product or the totality of different pharmaceutical products) amounts to at least One Million Pesos (PHP 1,000,000.00), as determined by the Food and Drug Administration, which shall prevail over any inconsistent provisions of law.

i. ***Establishment*** shall refer to a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of

pharmaceutical product, including the facilities and installations needed for its activities.

j. ***FDA*** shall refer to the Food and Drug Administration.

k. ***FDRO*** shall refer to the Food and Drug Regulation Officer of the FDA.

l. ***LSD*** shall refer to the laboratories under the FDA including those private laboratories accredited by the agency to conduct particular scope of analysis.

m. ***LSSC*** shall refer to the Legal Services Support Center of the FDA.

n. ***Medicines*** shall refer to drugs in their appropriate dosage forms, with assured quality, safety and efficacy for humans or animals, or both.

o. ***Residence*** shall refer to a private dwelling or abode where a person lives, either as owner or lessee, or usufructuary including, for purposes of this Act, its yard, garage, storage rooms or premises; provided that where the yard, garage, storage rooms or premises are used to manufacture, process, pack, or hold pharmaceutical products for introduction into domestic commerce, the same shall not fall as residence but be considered as establishment.

p. ***Owner*** shall refer to a person or group of persons who is the registered owner of a license to operate a business or business undertaking in the Philippines or the branch manager or operator, license, franchise, or any person acting on behalf of the corporate entity.

q. ***Pharmaceutical Products*** shall refer to drugs, medicines, biologicals, pharmaceutical and biopharmaceutical products/specialties, veterinary products, veterinary biologics, and veterinary medicinal products.

SECTION 4. ***Prohibited Acts.*** - The following acts are declared unlawful and therefore prohibited:

a. The manufacture, importation, distribution, sale, offering for sale,

donation, trafficking, brokering, exportation, or possession of counterfeit pharmaceutical products as defined in Section 3 hereof.

Any provision of law to the contrary notwithstanding, when any of the acts in the preceding paragraph is committed and the amount of the counterfeit pharmaceutical products) involve (whether as a single product or totality of different pharmaceutical products) is One Million Pesos (PHP 1,000,000.00) or more, as valued by the FDA, they shall be deemed as an offense involving economic sabotage.

The presence or availability of such counterfeit pharmaceutical product within the premises of any entity engaged in the manufacture, importation, distribution, sale, offering for sale, donation, trafficking, brokering, exportation, of pharmaceutical products or in a private residence, or in public or private vehicle, shall constitute a *prima facie* evidence of violation of this Act.

The above presumption shall not apply to the legitimate owners of trademarks, trade names or other identifying marks, or the legitimate or authorized representatives or agents of such owners, who have in their possession counterfeit pharmaceutical products which bear the trademarks, trade names or marks if they can show the sales invoices or official receipts evidencing their purchase from a drugstore, manufacturer or distributor suspected by them of dealing in counterfeit drugs involving the trademarks, trade names and other similar identifying marks registered in their names: *Provided*, that such counterfeit pharmaceutical products shall be reported and immediately turned over to the FDA within a period of ten (10) days from the date of purchase of such counterfeit pharmaceutical product as indicated in the sales invoice, official receipt, or other similar documents

abovementioned to the time the counterfeit pharmaceutical product are reported and turned over to the FDA.

b. Possession of any such counterfeit pharmaceutical product. However, any person found in possession of counterfeit pharmaceutical product, in violation of this subsection, shall be exempted from liability under the provisions of this Act after:

   i. Presentation of sales invoices, official receipt or other legally acceptable documents evidencing his purchase thereof from a drugstore, distributor, manufacturer, hospital pharmacy or dispensary; or any other person or place duly licensed to sell and/or dispense pharmaceutical product, and indicating therein the batch and lot numbers, as well as the expiry dates of such pharmaceutical product; or

   ii. Presentation of certificates and other documents evidencing the importation or exportation of the counterfeit pharmaceutical product found in his possession as required by existing laws, including those documents required in the preceding paragraph covering the commercial transactions involving counterfeit drugs.

In both instances, the counterfeit pharmaceutical product shall not, on its face, appear to be counterfeit, nor shall it bear any marking or patently unusual characteristic sufficient to arouse the suspicion of a reasonable and prudent person as to its authenticity. Moreover, the quantity or volume of the counterfeit pharmaceutical product in possession shall not be inconsistent with, or shall not negate, the claim that the same is intended for personal use, even if accompanied by medical records or similar documents purporting to justify such use.

When the amount of the counterfeit pharmaceutical products) in possession of any person (whether as a single product or totality of different pharmaceutical products) is One Million Pesos (PHP 1,000,000.00) or more, as valued by the FDA, the act of possession shall be deemed as an offense involving economic sabotage.

c. Photocopying, duplicating, altering, printing, transferring, obliterating, or removing an approved label, or any part thereof, lawfully belonging to another person, for the purpose of affixing or using such label, or any part thereof, on a counterfeit pharmaceutical product: Provided, that if the person who performed any of the acts enumerated in this paragraph and the person who subsequently used the labels produced thereby are not one and the same, and the former had knowledge of the intended unlawful use of such labels, the former shall likewise be held liable under this Act, notwithstanding the failure of the latter to achieve the intended purpose; and
d. Making, selling, or concealing any punch, dye, plate or any other equipment or instrument designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark of another registered producer or any likeness thereof, upon any pharmaceutical product or device or its container or label without authority from the legitimate owners of the trademark or trade name.

SECTION 5. ***Parties Liable.*** – The following persons shall be liable for violations) of this act:

a. The manufacturer, importer exporter, distributor, seller, distributor, trafficker, broker or donor of the counterfeit pharmaceutical products and their agents, as the case may be;
b. The possessor of counterfeit pharmaceutical product as provided in Section

4(b) of this Act;

c. The manager, operator or lessee of the laboratory or laboratory facilities used in the manufacture of counterfeit pharmaceutical product;
d. The owner, proprietor, administrator or manager of the drugstore, hospital pharmacy or dispensary, laboratory or other outlets or premises where the counterfeit pharmaceutical product is found who induces, causes or allows the commission of any act herein prohibited; and
e. The licensed and registered pharmacist of the establishment, or the licensed and registered pharmacist of the outlet where the counterfeit pharmaceutical product is sold or found, who sells or dispenses such drug to a third party.

Should the offense be committed by a juridical person, the penalty shall be imposed upon the officer or officers of the corporation, partnership, association, or entity responsible for the violation. If such officer is an alien, he shall, in addition to the penalties herein prescribed be deported without further proceedings.

SECTION 6. ***Liability under Other Laws.*** – Prosecution under this Act shall be without prejudice to any liability for violation of any provisions of other laws.

SECTION 7. ***Administrative Proceedings.*** – The FDA is hereby further authorized to undertake the following administrative actions:

a. Procedure when counterfeit pharmaceutical product is monitored in the market pursuant to a routine inspection of the FDRO. - If the FDRO, in the course of their routine/regular inspection of a factory, warehouse, establishment in which drugs are manufactured, processed, packed, or held, for introduction into domestic commerce, or vehicle, and all pertinent equipment, finished or unfinished materials, containers, and labeling

therein, upon the authority conferred by Section 27 of Republic Act No. 3720 as amended, shall suspect certain stocks as counterfeit pharmaceutical product, the FDRO shall conduct an inventory, segregate and seal the suspected stocks, and collect samples for examination as to the pharmaceutical product's genuineness and authenticity;

b. *Procedure when information is received about the presence of counterfeit pharmaceutical product in the possession of any person or establishment*. - Any information, either referred by the government office or officer or from anonymous sources or person requesting confidentiality of their identities, on the existence of suspected counterfeit pharmaceutical product in the possession of any manufacturer, seller or distributor, shall undergo the verification process by the FDRO, or any officer deputized or authorized by the Director General. The verification process shall follow the existing system and procedure in the conduct of case build-up, investigation or other appropriate interventions adopted by the FDA.

   i. If the counterfeit pharmaceutical product is located in an establishment:
      1. Seize the counterfeit pharmaceutical product and take them into custody; and
      2. Proceed in filing a criminal complaint and/or administrative complaint.

   ii. If the counterfeit pharmaceutical product is located in a private residence:
      1. Secure a valid search warrant from a competent court;
      2. After having obtained the search warrant, inventory and seize such counterfeit pharmaceutical product and take them into custody; and
      3. Proceed in filing a criminal complaint and/or administrative

complaint.

c. *Findings of counterfeit drug/medicine by owners of trademarks, trade names or other identifying marks.* - Owners of trademarks, trade names or other identifying marks, or their authorized agents who have found their pharmaceutical product being counterfeited shall file an administrative case before the FDA following the procedure in the preceding section.

SECTION 8. ***Hearing of Administrative Complaints and Institution of Criminal Action.*** – The FDA shall hear and decide administrative complaints filed before the agency following the rules of procedure provided under Republic Act No. 3720, as amended, and its Implementing Rules and Regulations.

Upon preliminary findings of the conduct of prohibited acts, the Director General shall issue the proper notices or orders to the person or persons concerned and such person or persons shall be given an opportunity to be heard before the FDA.

A summons with preventive closure order shall be issued against the warehouse, building, factory, store, shop or any other structure where the said counterfeit pharmaceutical products are contained or stored within fifteen (15) days upon the filing of administrative complaint. This is for the purpose of preventing the disposition or tampering of evidence, the continuance of acts being complained of, and/or the flight of the Respondent.

After the lapse of the 30-day period, the preventive closure order is deemed lifted without prejudice to the resolution of the case.

Both criminal and administrative actions may be instituted separately and

independent of one another.

SECTION 9. ***Penalties.*** – Any violation of the provisions of this Act shall subject the offender to the following penalties:

a. *Administrative Sanctions and Other Remedies*

Upon finding that the pharmaceutical product examined is counterfeit and the determination of the parties liable thereof, the FDA shall impose any or all of the following administrative penalties and/or pursue other remedies:

i. Minimum Penalty. An administrative fine of not less than One hundred thousand pesos (PHP 100,000.00) but not more than Five hundred thousand pesos (PHP 500,000.00) shall be the minimum administrative penalty.

ii. Medium Penalty. An administrative fine of at least Three hundred thousand pesos (PHP 300,000.00) but less than Five hundred thousand pesos (PHP 500,000.00) and suspension or revocation of its license to do business shall be the medium administrative penalty. When any violation of any provisions of this Act comes to the knowledge of the Director General, of such character that a criminal prosecution ought to be instituted against the offender, he shall certify the facts together with the laboratory report, the findings of the FDA, or other documentary evidence on which the charge is based.

The Director General is hereby authorized to call on the assistance of any Department, Office or Agency for the effective implementation of the provisions of this Act.

iii. Maximum Penalty. An administrative fine of Five hundred thousand

pesos (PHP 500,000.00) and permanent closure of the establishment concerned as well as the revocation of its license to do business shall be the maximum administrative penalty.

Provided, that if any or all of the instances below occur, the maximum imposable fine of Five hundred thousand pesos (PHP 500,000.00), revocation of its license to do business and permanent closure of establishment, and permanent disqualification of the person concerned whether natural or juridical, from owning or operating a drug establishment or outlet, as the case maybe, shall be imposed:

1. If the Respondent or any of his officer or agent shall conceal, substitute, dispose or destroy any pharmaceutical product that may have been segregated and sealed by the; or
2. If the Respondent or any of his officer or agent shall break, alter or tamper any mark or seal used by the FDA to identify those segregated drugs; or
3. As a result of the use of the pharmaceutical product found to be counterfeit, the illness sought to be cured is aggravated or physical injury or suffering results therefrom or be the proximate cause of death or permanent disability of the victim or patient.

Any of the imposable penalties in Paragraphs i, ii, and iii above shall be accompanied by forfeiture, confiscation and destruction of the pharmaceutical products) found to be counterfeit and the equipment, instrument and other articles used in violation of this Act or these implementing rules and regulations.

The other remedies are as follows:

iv. Filing of an appropriate proceeding against the registered pharmacist with the Professional Regulations Commission for imposition of the appropriate penalties as provided under Republic Act No. 10918 or the Philippine Pharmacy Act or its amendment;

v. Filing of criminal charges against the violator(s), which can be instituted independently from the administrative case: Provided, That the dismissal of the criminal case shall not lift the closure order, except when it is a dismissal on the merits or for lack of basis: Provided, further, That the withdrawal of the private criminal complaint shall not be a ground for the dismissal of the administrative proceedings; and

b. Criminal Sanctions

The commission of any of the acts prohibited under Section 4 of this Act shall be punished by:

i. Imprisonment of no less than six (6) months and one (1) day but not more than six (6) years for mere possession of counterfeit pharmaceutical product as provided for in Section 4 (b) of this Act; or

ii. Imprisonment of six (6) years and one (1) day, but not more than ten (10) years or a fine of not less than One Hundred Thousand Pesos (PHP 100,000.00) but not more than Five Hundred Thousand Pesos (PHP 500,000.00) or both such imprisonment and fine at the discretion of the court in any other case mentioned in Section 4 of the Act; or

iii. Imprisonment of not less than six (6) months and one (1) day, but not more than two (2) years and four (4) months if the counterfeit

pharmaceutical product is intended for animals; or

iv. Imprisonment of no less than six (6) years and one (1) day but not more than ten (10) years for any manufacturer, seller, or distributor who shall conceal, substitute, dispose or destroy any pharmaceutical product as may have been segregated and sealed by the FDA, or who shall break, alter or tamper any mark or seal used by the FDA to identify those segregated drugs as provided for under Section 6(A) of this Act. Any other person who breaks, alters or tampers any mark or seal used by the FDA to identify the segregated pharmaceutical product shall suffer the penalty of no less than six (6) months and one (1) day, but not more than six (6) years imprisonment; or

v. Imprisonment from twelve (12) years to fifteen (15) years and a fine ranging from One Hundred Thousand Pesos (PHP 100,000.00) to Five Hundred Thousand Pesos (PHP 500,000.00) if, as a result of the use of the pharmaceutical product found to be counterfeit, the illness sought to be cured is aggravated or physical injury or suffering results therefrom; or

vi. Life imprisonment and a fine of Five Hundred Thousand Pesos (PHP 500,000.00) to Five Million Pesos (PHP 5,000,000.00) should a counterfeit pharmaceutical product be the proximate cause of death of a victim, who unknowingly purchased and took a counterfeit pharmaceutical product.

Provided: That, any provision of law to the contrary notwithstanding, when any of the acts declared unlawful and prohibited under Section 4 above is committed and the amount of the counterfeit pharmaceutical products) involve (whether as a single product or totality of different pharmaceutical products) is One Million Pesos (PHP 1,000,000.00) or more, as valued by the Food and Drug Administration, it shall be deemed as an offense

involving economic sabotage and punishable by life imprisonment and a fine of Five Million Pesos (PHP 5,000,000.00) to Ten Million Pesos (PHP 10,000,000.00).

In case any Act prohibited in Section 4 of this Act is also punishable under other laws, the offender shall, if warranted by the evidence, be prosecuted under the law prescribing the highest penalty.

When the sale, offering for sale, donation, distribution, trafficking, or brokering of counterfeit pharmaceutical product, or the sale of any punch, dye, plate or any other equipment or instrument designed to print, imprint or reproduce the trademark, trade name or other identifying mark of another registered producer or any likeness thereof, upon any pharmaceutical product or device or its container or label without authority from the legitimate owners of the trademark or trade name, as prohibited in Section 4 of this Act is committed by, through and with the use of online service, the same shall also be covered by the relevant provisions of Republic Act No. 10175 or the "Cybercrime Prevention Act of 2012". Provided that the penalty to be imposed shall be one degree higher than that provided under this Act.

SECTION 10. ***Inter-agency, Stakeholders and International Cooperation.*** – All relevant inter-agency, other stakeholders and international instruments, programs, cooperation, and arrangements agreed, whether in regulatory or criminal matters, to the widest extent possible for the purposes of detection, investigation, suppression, proceedings or effective response concerning administrative or criminal offenses related to counterfeit pharmaceutical products, or for the collection of evidence, shall be given full force and effect.

SECTION 11. ***Establishments' Responsibilities.*** **–** All pharmaceutical product establishments, including the licensed and registered pharmacist under their employ, shall ensure at all times that pharmaceutical products satisfy the requirements of pharmaceutical products' laws and standards relevant to their activities in the pharmaceutical product supply chain and that control systems are in place to prevent or eliminate counterfeit pharmaceutical products.

Pharmaceutical product establishments shall be knowledgeable of the specific requirements and standards of pharmaceutical product laws and regulations relevant to their activities in the pharmaceutical product supply chain and the procedures adopted by the regulatory authority.

If a pharmaceutical product establishment considers or has reason to believe that a pharmaceutical product which it produced, processed, imported, distributed, sold, offered for sale is counterfeit, it shall immediately initiate procedures to withdraw the pharmaceutical product in question form the market and inform the regulatory authority.

Pharmaceutical product establishments shall allow inspection of their business and collaborate with the regulatory authority on actions taken to avoid risks posed by the counterfeit pharmaceutical product they have supplied.

SECTION 12. ***Rapid Alert System.*** **–** The rapid alert system in place for the notification of direct or indirect risk to human health due to counterfeit pharmaceutical products shall be strengthened by the FDA.

SECTION 13. ***Strengthening the Pharmacovigilance System.*** **–** The FDA, in coordination with the DOH or other stakeholders shall strengthen the existing Pharmacovigilance System.

Within one hundred twenty (120) days from effectivity of this Act, the FDA shall establish a pharmacovigilance unit within its CDRR with appropriate staffing of officers and personnel and experts and be regularly allocated with appropriate budget.

SECTION 14. ***Training and Consumer Advocacy and Education.*** **–** Training, orientation, education, and other advocacy activities shall be regularly provided by the FDA to pharmaceutical product establishments, communities, and other sectors of the community.

A consumer advocacy and education program shall be developed and implemented by the FDA in partnership with relevant NGOs, private organizations, coalitions, academic institutions, or other relevant government agencies. The FDA shall allocate and provide funds for the development and implementation of training and consumer advocacy and education programs.

SECTION 15. ***Enforcement and Implementation.*** **–** The FDA of the Department of Health is hereby authorized to administer and supervise the implementation of this Act subject to the applicable provisions of Republic Act No. 10175 or the "Cybercrime Prevention Act of 2012".

SECTION 16. ***Implementing Rules and Regulations.*** **–** The FDA, in consultation with the stakeholders, shall promulgate the implementing rules and regulations within One Hundred Twenty (120) days from the effectivity of this Act.

SECTION 17. ***Interpretation and Construction in Favor of Protection of Public Health.*** **–** All doubts in the implementation and interpretation of the provisions of this Act, including its implementing rules and regulations, shall be

resolved in favor of protecting public health against counterfeit pharmaceutical products.

SECTION 18. ***Appropriations.*** **–** The amount necessary to carry out the provisions of this Act shall be included in the General Appropriations Act for the year following its enactment and every year thereafter.

SECTION 19. ***Separability Clause.*** **–** If any provision of this Act is held invalid or unconstitutional, the same shall not affect the validity and effectivity of the other provisions hereof.

SECTION 20. ***Repealing Clause.*** **–** Republic Act No. 8203 is hereby repealed. All other laws, decrees, executive orders and rules and regulations contrary to or inconsistent with the provisions of this Act are hereby repealed, amended or modified accordingly.

SECTION 21. ***Effectivity.*** **–** This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in a newspaper of general circulation.

Approved,