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

Senate
Office of the Secretary

'22 JUL 13 P2 :58

RECEIVED BY:

S E N A T E

S. No. 522

Introduced by **SENATOR CYNTHIA A. VILLAR**

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 FOR THE PROHIBITIONS AND PENALTIES FOR VIOLATIONS AND REVISING FOR THE PURPOSE REPUBLIC ACT NO. 8203 OR THE "SPECIAL LAW ON COUNTERFEIT DRUGS"

EXPLANATORY NOTE

Since the enactment in 1996 of Republic Act (RA) No. 8203, otherwise known as the "Special Law on Counterfeit Drugs", the following subsequent laws were enacted by Congress affecting certain provisions of Ra No. 8203, namely: a.) RA No. 9502 (Cheaper Medicines Law); b.) RA No. 9711 (FDA Act); c.) RA No. 10918 (Philippine Pharmacy Law) on the definition of drugs; d.) RA No. 10175 (Cybercrime Prevention Act of 2012) concerning certain prohibited acts in Section 4 of RA No. 8203 (online selling, online service, online pharmacy); and e.) RA No. 10918 (Philippine Pharmacy Law) on the definition of counterfeit drugs, as well as in declaring registered pharmacists liable under RA No. 10918, apart from liability under RA No. 8203.

Undeniably, in twenty six (26) years since Republic Act No. 8203 was enacted, there have been many changes in the industry and in anti-counterfeiting technologies, but the continuing real threat that counterfeit pharmaceutical products

present to our health, to the security of our family especially our children, and our collective safety cannot be overemphasized. It cannot be denied that we are faced by a rapidly growing flood of illicit and dangerous pharmaceutical products.

This problem is even more compounded as we have witnessed in the last decade a growth in internet sales of pharmaceutical products and this has been associated with the increasing cases of counterfeit pharmaceutical products entering and moving through countries worldwide, including the Philippines. Given the vast, almost limitless possibilities of the internet, and borderless movement of goods, it undeniably becomes even more challenging for the Food and Drug Administration (FDA) to combat the distribution of counterfeit pharmaceutical products.

Thus, there is a need to safeguard the interest of the general public and the government, particularly the Food and Drug Administration under the Department of Health, against the syndicated or highly organized operations of unscrupulous persons engaged in the illegal manufacture, importation, distribution, sale or possession of counterfeit pharmaceutical products.

Undeniably, these illegal operations threaten to undermine the people's confidence in the health regulatory system and have already resulted in the loss of considerable government revenues.

During the previous administration, the Philippine National Police conducted an operation to arrest persons involved in the manufacture, importation, trade, administration, delivery and distribution of counterfeit drugs and charge them with economic sabotage. The acts of those involved in counterfeit pharmaceutical products undermine not only the economy (because of its effect on the law of supply and demand and the prices), but also threaten the security of the nation because it pose danger to the health of the people.[1]

This is the reason behind this proposed bill. The bill incorporates as economic sabotage the illegal manufacture, importation, distribution, sale or offer for sale, or possession of counterfeit pharmaceutical products to a certain extent to emphasize

[1] https://newsinfo.inquirer.net/978785/duterte-fake-medicine-pnp-arrest-fda-counterfeit-drugs

the seriousness of the prohibited acts and their highly deleterious effect on people's lives.

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

CYNTHIA A. VILLAR

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

SENATE
Office of the Secretary
'22 JUL 13 P2 :58
RECEIVED BY:

S E N A T E

S. No. 522

Introduced by **SENATOR CYNTHIA A. VILLAR**

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 FOR THE PROHIBITIONS AND PENALTIES FOR VIOLATIONS AND REVISING FOR THE PURPOSE REPUBLIC ACT NO. 8203 OR THE "SPECIAL LAW ON COUNTERFEIT DRUGS"

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

CHAPTER I
GENERAL PROVISIONS

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

Sec. 2. *Declaration of Policy.* – It is the policy of the State, under Article II, Section 15 of the 1987 Constitution, to protect and promote the right to health of the 38 people and instill health consciousness among them.

The 1987 Constitution also provides, under Article XIII, Section 12, that: The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

Pursuant to the above policies, the State must adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to strengthen its capability to prevent activities that may result, or detect, investigate, suppress, and more effectively respond to actions that result in counterfeit pharmaceutical products.

It shall likewise provide for the strengthening of prohibitions against counterfeit pharmaceutical products; declare the manufacture, importation, distribution, sale or offer for sale, or possession of counterfeit pharmaceutical products as offenses involving economic sabotage; and provide stricter penalties for violations of the Act

Sec. 3. *Definition of Terms.* – As used in this Act:

a) "Brokering" shall refer to any act of facilitating the disposal or sale of counterfeit pharmaceutical products, including acts of agency.

b) "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.

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, which results in the reduction of the pharmaceutical products' safety, efficacy, quality, strength or purity:

i. do 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 identify, composition and/or source. For this purpose, the terms:

i. "Identity" shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized pharmaceutical product.

ii. "Composition" shall refer to any ingredient or component of the pharmaceutical product in accordance with applicable specifications authorized/recognized by the FDA.

iii. "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:

i. recognized in the Philippine National Drug Formulary; or

ii. intended for use in the treatment, cure, mitigation, prevention or diagnosis of disease symptoms, injury or body defects in humans; or

iii. other than food, intended to affect the structure or any function of the human body; and

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);

g) Department shall refer to the Department of Health.

h) "Economic Sabotage" shall refer to any of the acts which are declared unlawful and prohibited under this Act when committed and the amount of the counterfeit pharmaceutical product(s) involve (whether as a single product or totality of different pharmaceutical products) is One Million Pesos (PhP1,000,000.00) or more, as valued by the Food and Drug Administration, any provision of law to the contrary notwithstanding.

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 theFDA.

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) "SSC" 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) "Online Service" shall refer to the sale, offering for sale, donation, distribution, trafficking, brokering of 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 for use to any pharmaceutical product, through and with the use of information and communication technology system. The term shall also cover Online Selling or Online Pharmacy Services.

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.

r) "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.

Sec. 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 product(s) involve (whether as a single product or totality of different pharmaceutical products) is One Million Pesos (PhP1,000,000.00) or more, as valued by the Food and Drug Administration, 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 products 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:

a. 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

b. 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 cases, the subject counterfeit pharmaceutical product must not on its face appear to be as such, or do not bear any marking or any patently unusual characteristic sufficient to arouse the suspicion of a reasonable and prudent person that such pharmaceutical product is counterfeit. Furthermore, the amount or volume

of counterfeit pharmaceutical product held is such that it does not negate or is inconsistent with the averment that the same are for personal use, notwithstanding the presentation by the possessor of medical records and other similar documents accompanying and justifying the use of such pharmaceutical product.

When the amount of the counterfeit pharmaceutical product(s) in possession of any person (whether as a single product or totality of different pharmaceutical products) is One Million Pesos (P1,000,000.00) or more, as valued by the Food and Drug Administration, the act of possession shall be deemed as an offense involving economic sabotage.

c) Photocopying, duplicating, altering, printing, transferring, obliterating or removing the approved label or any part thereof, lawfully belonging to another person, for the purpose of using such label or a part thereof on any counterfeit pharmaceutical product: Provided, that if the person who committed any of the acts enumerated in this paragraph and the person who used the labels produced thereby are not one and the same person and the former had knowledge of the purpose for which the labels are intended, the former shall also be liable under the 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.

Sec. 5. *Parties Liable.* – The following persons shall be liable for violation(s) of the act:

a) the manufacturer, importer exporter, distributor, seller, distributor, trafficker, broker or donor of the counterfeit pharmaceutical product 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;

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; and

f) 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; and if such officer is an alien, he shall, in addition to the penalties herein prescribed be deported without further proceedings.

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

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

I. 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 his/her 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 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;

II. Procedure When Information is Received About the Presence of Counterfeit pharmaceutical product in the Possession of Any person or Establishment.

a) 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. 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.

b) If the counterfeit pharmaceutical product is located in an establishment:

i. Seize the counterfeit pharmaceutical product and take them into custody; and

ii. Proceed in filing a criminal complaint and/or administrative complaint.

c) If the counterfeit pharmaceutical product is located in a private residence:

i. Secure a valid search warrant from a competent court;

ii. After having obtained the search warrant, inventory and seize such counterfeit pharmaceutical product and take them into custody; and

iii. Proceed in filing a criminal complaint and/or administrative complaint.

III. 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.

Sec. 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 he given an opportunity to he heard before the FDA.

Preventive Closure Order. 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 product 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.

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.

Both criminal and administrative actions may be instituted separately and independent of one another.

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.

Sec. 9. *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 (₱100,000.00) but not more than Three hundred thousand pesos (₱300,000.00) shall be the minimum administrative penalty.

ii. *Medium Penalty*. An administrative fine of at least Three hundred thousand pesos (₱300,000.00) but less than Five hundred thousand pesos (₱ 500,000.00) and suspension or revocation of its license to do business shall be the medium administrative penalty.

iii. *Maximum Penalty*. An administrative fine of Five hundred thousand pesos (₱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 least five hundred thousand pesos (₱ 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:

a) 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

b) 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

c) 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 product(s) found to be counterfeit and the equipment, instrument and other articles used in violation of this Act or this implementing rules and regulations.

A. *Other Remedies*

a. filing of an appropriate proceedings 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;

b. 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:

a) imprisonment of not 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

b) 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 (₱100,000.00) but not more than Five hundred thousand pesos (₱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

c) 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

d) imprisonment of not 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 not less than six (6) months and one (1) day, but not more than six (6) years imprisonment; or

e) 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, a punishment of imprisonment from twelve (12) years to fifteen (15) years and a fine ranging from One hundred thousand pesos (₱100,000.00) to Five hundred thousand pesos (₱500,000.00) shall be meted out; or

f) should a counterfeit pharmaceutical product be the proximate cause of death of a victim, who unknowingly purchased and took a counterfeit pharmaceutical product, the penalty of life imprisonment and a fine of Five hundred thousand pesos (₱500,000.00) to Five million pesos (₱5,000,000.00) shall be imposed.

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 product(s) involve (whether as a single product or totality of different pharmaceutical products) is One Million Pesos (₱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 (₱5,000,000.00) to Ten Million Pesos (₱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 (1) degree higher than that provided under this Act.

Sec. 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

Sec. 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.

Sec. 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 product shall be strengthened by the FDA.

Sec. 13. *Strengthening the Pharmacovigilance System.* -- Strengthening the 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.

Sec. 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.

Sec. 15. *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

Sec. 16. *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".

Sec. 17. *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.

Sec. 18. *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.

Sec. 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.

Sec. 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

Sec. 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,