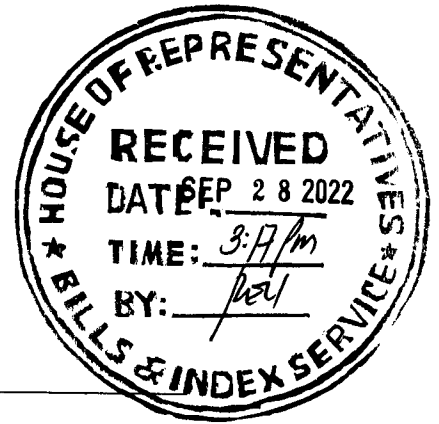


NINETEENTH CONGRESS )  
OF THE REPUBLIC OF THE PHILIPPINES )  
First Regular Session )

HOUSE OF REPRESENTATIVES

House Bill No. 5252



Introduced by Representative CHRISTIAN TELL A. YAP

EXPLANATORY NOTE

It is the policy of the State to protect and promote the right to health, instill health consciousness, establish and maintain an effective food and drug regulatory system and undertake appropriate health research and development responsive to the country's needs. Towards this end, the State is duty-bound to craft and enact measures in response and to prevent the proliferation of counterfeit pharmaceutical products which threatens the life and health of our people.

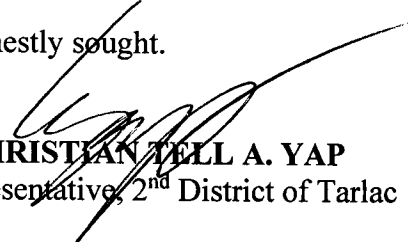
Counterfeit pharmaceutical products refers to those products which do not contain the amount it claims, having reduced safety, efficacy, quality, strength or purity. It refers also to products that are deliberately and fraudulently misrepresented with respect to their identity, composition and source. Counterfeit pharmaceutical products pose serious threat to public health and safety because their effectivity is unverified and questionable. The distribution of these bogus products may worsen illnesses and diseases that may cause serious adverse health consequences, drug resistance, or worst, death.

Republic Act No. 8203 or the Special Law on Counterfeit Drugs prohibits the manufacture, sale, distribution, possession, and similar acts that spread counterfeit pharmaceutical products. However, the law does not contemplate and penalize massive-scale counterfeiting practices which not only multiplies health-related risks to our people but also undermine and weaken the local pharmaceutical industry.

The Counterfeit Pharmaceutical Products Prevention Act seeks to strengthen the regulatory system on pharmaceutical products by defining counterfeit pharmaceutical products and the prohibited acts associated with it, delineating further the administrative proceedings on the search, seizure and prosecution of found counterfeit products and the persons liable, and providing stricter penalties for violations of this act.

This proposal was originally filed by Senator Risa Hontiveros in the present 19<sup>th</sup> Congress of the Philippine Senate. This bill is likewise filed for consideration as its counterpart in the House of Representatives.

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

  
CHRISTIAN TELL A. YAP  
Representative, 2<sup>nd</sup> District of Tarlac

HOUSE OF REPRESENTATIVES

House Bill No. **5252**

Introduced by Representative CHRISTIAN TELL A. YAP

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 in Congress assembled:*

1       **SECTION 1. *Short Title.*** - This Act shall be known as the "Counterfeit Pharmaceutical  
2 Products Prevention Act".

3  
4       **SEC.2. *Declaration of Policy.*** -It is the policy of the State, under Article II, Section 15 of  
5 the 1987 Constitution, to protect and promote the right to health of the people and instill health  
6 consciousness among them.

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

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

16       It shall likewise provide for the strengthening of prohibitions against counterfeit  
17 pharmaceutical products; declare the manufacture, importation, distribution, sale or offer for sale,  
18 or possession of counterfeit pharmaceutical products as offenses involving economic sabotage;  
19 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:
  - 1. do not contain the amounts as claimed;
  - 2. with wrong ingredients;
  - 3. without active ingredients; or
  - 4. with less than eighty percent (80%) of the active ingredient it purports to possess as distinguished from an adulterated pharmaceutical products 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:

- 5. "Identity" shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized pharmaceutical product.
- 6. "Composition" shall refer to any ingredient or component of the pharmaceutical product in accordance with applicable specifications authorized/recognized by the FDA.
- 7. "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:
  - 1. any article recognized in the Philippine Pharmacopoeia, Philippine National Drug Formulary, or in any foreign official pharmacopoeias and formularies which are adopted by the FDA or any documentary supplement to any of them;

2. any article, other than food, intended to affect the structure or any function of the human body or animals;
3. any article intended for use as a component of any chemical compound or biological substance or articles specified above, not including devices or their components, parts, or accessories; or
4. 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 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) "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

1 with the use of information and communication technology system. The term shall also  
2 cover Online Selling or Online Pharmacy Services.

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

7 q) Pharmaceutical Products" shall refer to drugs, medicines, biologicals, pharmaceutical  
8 and biopharmaceutical products/specialties, veterinary products, veterinary biologics and  
9 veterinary medicinal products.

10 r) "Residence" shall refer to a private dwelling or abode where a person lives, either as  
11 owner or lessee, or usufructuary including, for purposes of this Act, its yard, garage,  
12 storage rooms or premises; provided that where the yard, garage, storage rooms or premises  
13 are used to manufacture, process, pack, or hold pharmaceutical products for introduction  
14 into domestic commerce, the same shall not fall as residence but be considered as  
15 establishment  
16

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

19 a) The manufacture, importation, distribution, sale, offering for sale, donation,  
20 trafficking, brokering, exportation, or possession of counterfeit pharmaceutical  
21 products as defined in Section 3 hereof.  
22

23 The presence or availability of such counterfeit pharmaceutical product within the  
24 premises of any entity engaged in the manufacture, importation, distribution, sale,  
25 offering for sale, donation, trafficking, brokering, exportation, of pharmaceutical  
26 products or in a private residence, or in public or private vehicle, shall constitute a  
27 prima facie evidence of violation of this Act.  
28

29 The above presumption shall not apply to the legitimate owners of trademarks, trade  
30 names or other identifying marks, or the legitimate or authorized representatives or  
31 agents of such owners, who have in their possession counterfeit pharmaceutical  
32 products which bear the trademarks, trade names or marks if they can show the sales  
33 invoices or official receipts evidencing their purchase from a drugstore, manufacturer  
34 or distributor suspected by them of dealing in counterfeit pharmaceutical products  
35 involving the trademarks, trade names and other similar identifying marks registered  
36 in their names: Provided, that such material information and counterfeit  
37 pharmaceutical products shall be reported and immediately turned over to the FDA  
38 within a period of ten (10) days from the date of purchase of such counterfeit

1 pharmaceutical product as indicated in the sales invoice, official receipt, or other  
2 similar documents abovementioned to the time the counterfeit pharmaceutical product  
3 are reported and turned over to the FDA.  
4

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

8 1. Presentation of sales invoices, official receipt or other legally acceptable documents  
9 evidencing his purchase thereof from a drugstore, hospital pharmacy or dispensary, or  
10 any other person or place duly licensed to sell and/or dispense pharmaceutical product,  
11 or

12 2. Presentation of certificates and other documents evidencing the importation or  
13 exportation of the counterfeit pharmaceutical product found in his possession as  
14 required by existing laws, including those documents required in the preceding  
15 paragraph covering the commercial transactions involving counterfeit pharmaceutical  
16 products;

17 In both cases, the subject counterfeit pharmaceutical product must not on its face  
18 appear to be as such, or do not bear any marking or any patently unusual characteristic  
19 sufficient to arouse the suspicion of a reasonable and prudent person that such  
20 pharmaceutical product is counterfeit. Furthermore, the amount or volume of  
21 counterfeit pharmaceutical product held is such that it does not negate or is inconsistent  
22 with the averment that the same are for personal use, notwithstanding the presentation  
23 by the possessor of medical records and other similar documents accompanying and  
24 justifying the use of such pharmaceutical product.  
25

26 c) Photocopying, duplicating, altering, printing, transferring, obliterating or removing the  
27 approved label or any part thereof, lawfully belonging to another person, for the  
28 purpose of using such label or a part thereof on any counterfeit pharmaceutical  
29 product: Provided, that If the person who committed any of the acts enumerated in this  
30 paragraph and the person who used the labels produced thereby are not one and the  
31 same person and the former had knowledge of the purpose for which the labels are  
32 intended, the former shall also be liable under the act notwithstanding the failure of  
33 the latter to achieve the intended purpose; and  
34

35 d) Making, selling, or concealing any punch, dye, plate or any other equipment or  
36 instrument designed to print, imprint or reproduce the trademark, trade name or other  
37 identifying mark of another registered producer or any likeness thereof, upon any

1 pharmaceutical product or device or its container or label without authority from the  
2 legitimate owners of the trademark or trade name.  
3

4 Any provision of law to the contrary notwithstanding, when any of the acts in the  
5 preceding paragraphs (a) or (b) is committed and the amount of the counterfeit  
6 pharmaceutical product(s) involved (whether as a single product or totality of different  
7 pharmaceutical products) is one million pesos (PhP 1,000,000.00) or more, as valued  
8 by the Food and Drug Administration, they shall be deemed as an offensive involving  
9 economic sabotage.  
10

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

12 a) the manufacturer, importer exporter, distributor, seller, trafficker, broker or donor of the  
13 counterfeit pharmaceutical product and their agents, as the case may be;

14 b) the possessor of counterfeit pharmaceutical product as provided in Section 4(b) of this  
15 Act;

16 c) the manager, operator or lessee of the laboratory or laboratory facilities used in the  
17 manufacture of counterfeit pharmaceutical product;

18 d) the owner, proprietor, administrator or manager of the drugstore, hospital pharmacy or  
19 dispensary, laboratory or other outlets or premises where the counterfeit pharmaceutical  
20 product is found who induces, causes or allows the commission of any act herein  
21 prohibited;

22 e) the licensed and registered pharmacist of the establishment, or the licensed and  
23 registered pharmacist of the outlet where the counterfeit pharmaceutical product is sold or  
24 found, who sells or dispenses such pharmaceutical products to a third party; and

25 f) should the offense be committed by a juridical person the penalty shall be imposed upon  
26 the officer or officers of the corporation, partnership, association or entity responsible for  
27 the violation; and if such officer is an alien, he shall, in addition to the penalties herein  
28 prescribed be deported without further proceedings.  
29

30 **SEC.6. Liability under Other Laws.** - A prosecution under this Act shall be without  
31 prejudice to any liability for violation of any provisions of other laws.  
32

33 **SEC.7. Administrative Proceedings.** - The FDA is hereby further authorized to undertake  
34 the following administrative actions.  
35

36 a) Procedure when Counterfeit Pharmaceutical Product is Monitored in the Market  
37 Pursuant to a Routine Inspection of the FDRO.

1 If the FDRO, in the course of his/her routine/regular inspection of a factory,  
2 warehouse, establishment in which pharmaceutical products are manufactured,  
3 processed, packed, or held for introduction into domestic commerce, or vehicle, and  
4 all pertinent equipment, finished or unfinished materials, containers, and labeling  
5 therein, upon the authority conferred by Section 27 of Republic Act No. 3720, as  
6 amended, shall suspect certain stocks as counterfeit pharmaceutical product, the  
7 FDRO shall conduct an inventory, segregate and seal the suspected stocks, and collect  
8 samples for examination as to the pharmaceutical product's genuineness and  
9 authenticity;

10 b) Procedure when Information is Received about the Presence of Counterfeit  
11 Pharmaceutical Product in the Possession of Any Person or Establishment.

12 1. Any information, either referred by the government office or officer or from  
13 anonymous sources or person requesting confidentiality of their identities, on the  
14 existence of suspected counterfeit pharmaceutical product in the possession of any  
15 manufacturer, seller, distributor, or any other person shall undergo the verification  
16 process by the FDRO, or any officer deputized or authorized by the Director  
17 General. Verification process shall follow the existing system and procedure in the  
18 conduct of case build-up. Investigation or other appropriate interventions adopted  
19 by the FDA.

20 2. If the counterfeit pharmaceutical product is located in an establishment:

- 21 i. Seize the counterfeit pharmaceutical product and take them into custody; and  
22 ii. Proceed in filing a criminal complaint and/or administrative complaint.

23 3. If the counterfeit pharmaceutical product is located in a private residence as defined:  
24

- 25 i. Secure a valid search warrant from a competent court;  
26 ii. After having obtained the search warrant, inventory and seize such counterfeit  
27 pharmaceutical product and take them into custody; and  
28 iii. Proceed in filing a criminal complaint and/or administrative complaint.

29  
30 c) Findings of Counterfeit Pharmaceutical Product by Owners of Trademarks, Trade  
31 Names or Other Identifying Marks. Owners of trademarks, trade names or other  
32 identifying marks, or their authorized agents who have found their pharmaceutical  
33 product being counterfeited shall file an administrative case before the FDA, without  
34 prejudice to the institutions of a separate action for criminal case, following the  
35 procedure in Section 8.  
36  
37  
38

1       **SEC.8. *Hearing of Administrative Complaints and Other Remedies.* –**

2       a) The FDA shall hear and decide administrative complaints filed before the agency  
3       following the rules of procedure provided under Republic Act No. 3720, as amended, and  
4       its Implementing Rules and Regulations. Upon preliminary findings of the conduct of  
5       prohibited acts, the Director General shall issue the proper notices or orders to the person  
6       or persons concerned and such person or persons shall be given an opportunity to be heard  
7       before the FDA.

8       Preventive Closure Order. If seizure cannot be reasonably effected, a summons with  
9       preventive closure order shall be issued against the warehouse, building, factory, store,  
10      shop or any other structure where the said counterfeit pharmaceutical product is contained  
11      or stored within fifteen (15) days upon the filing of administrative complaint. This is for  
12      the purpose of preventing the disposition or tampering of evidence, the continuance of acts  
13      being complained of, and/or the flight of the Respondent. After the lapse of the 30-day  
14      period, the preventive closure order is deemed lifted without prejudice to the resolution of  
15      the case.

16      b) Filing of an appropriate proceedings against the registered pharmacist with the  
17      Professional Regulations Commission for imposition of the appropriate penalties as  
18      provided under Republic Act No. 10918 or the Philippine Pharmacy Act or its amendment;

19      c) Filing of criminal charges against the violator(s), which can be instituted separately and  
20      independently from the administrative case: Provided, That the dismissal of the criminal  
21      case shall not lift the closure order or dismiss the administrative case: Provided, further,  
22      That the withdrawal of the private criminal complaint shall not be a ground for the  
23      dismissal of the administrative proceedings.

24      d) The Director General is hereby authorized to call on the assistance of any Department,  
25      Office, Agency, Organization, or Body for the effective implementation of the provisions  
26      of this Act.

27  
28      **SEC.9. *Penalties.* –**

29      a) Administrative Penalties

30      1. Upon finding that the pharmaceutical product examined is counterfeit and the  
31      determination of the parties liable thereof, the FDA shall impose any or all of the following  
32      administrative penalties:

33      i. Minimum Penalty. An administrative fine of not less than One hundred thousand pesos  
34      (PHP100,000.00) but not more than Five hundred thousand pesos (PHP500,000.00) shall  
35      be the minimum administrative penalty.

36      ii. Medium Penalty. An administrative fine of at least Three hundred thousand pesos  
37      (PHP300,000.00) but not more than Five hundred thousand pesos (PHP500,000.00) 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 (PHP500,000.00) 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 (PHP500,000.00) 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:

iv. 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 FDRO or any officer deputized or authorized by the Director General; or

v. 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 pharmaceutical products; or

vi. 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 sub-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, vehicles, and other articles used in violation of this Act or its implementing rules and regulations,

b) Criminal Penalties. The commission of any of the acts prohibited under Section 4 of this Act shall be punished by:

1. 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

2. 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 (PHP100,000.00) but not more than Five hundred thousand pesos (PHP500,000.00) or both such imprisonment and fine at the discretion of the court in any other case mentioned in Section 4 of the Act; or

3. 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

4. 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

1 destroy any pharmaceutical product as may have been segregated and sealed by the FDA,  
2 or who shall break, alter or tamper any mark or seal used by the FDA to identify those  
3 segregated pharmaceutical products as provided for under Section 6(A) of this Act. Any  
4 other person who breaks, alters or tampers any mark or seal used by the FDA to identify  
5 the segregated pharmaceutical product shall suffer the penalty of not less than six (6)  
6 months and one (1) day, but not more than six (6) years imprisonment; or  
7 5. if, as a result of the use of the pharmaceutical product found to be counterfeit, the illness  
8 sought to be cured is aggravated or physical injury or suffering results therefrom, a  
9 punishment of imprisonment from twelve (12) years to fifteen (15) years and a fine ranging  
10 from One hundred thousand pesos (P100,000.00) to Five hundred thousand pesos  
11 (PHP500,000.00) shall be meted out; or  
12 6. should a counterfeit pharmaceutical product be the proximate cause of death of a victim,  
13 who unknowingly purchased and took a counterfeit pharmaceutical product, the penalty of  
14 life imprisonment and a fine of Five hundred thousand pesos (PHP500,000.00) to Five  
15 million pesos (PHP5,000,000.00) shall be imposed.  
16 Provided that, any provision of law to the contrary notwithstanding, when any of the acts  
17 declared unlawful and prohibited under Section 4 above is committed and the amount of  
18 the counterfeit pharmaceutical product(s) involve (whether as a single product or totality  
19 of different pharmaceutical products) is One Million Pesos (Php1,000,000.00) or more, as  
20 valued by the Food and Drug Administration, it shall be deemed as an offense involving  
21 economic sabotage and punishable by life Imprisonment and a fine of Five Million Pesos  
22 (Php5,000,000.00) to Ten Million Pesos (Php10,000,000.00).  
23 In case any Act prohibited in Section 4 of this Act is also punishable under other laws, the  
24 offender shall, if warranted by the evidence, be prosecuted under the law prescribing the  
25 highest penalty. When the sale, offering for sale, donation, distribution, trafficking, or  
26 brokering of counterfeit pharmaceutical product, or the sale of any punch, dye, plate or any  
27 other equipment or instrument designed to print, imprint or reproduce the trademark, trade  
28 name or other identifying mark of another registered producer or any likeness thereof, upon  
29 any pharmaceutical product or device or its container or label without authority from the  
30 legitimate owners of the trademark or trade name, as prohibited in Section 4 of this Act, is  
31 committed by, through and with the use of online service, the same shall also be covered  
32 by the relevant provisions of Republic Act No. 10175 or the "Cybercrime Prevention Act  
33 of 2012". Provided, that the penalty to be imposed shall be one (1) degree higher than that  
34 provided under this Act.

35  
36 **SEC.10. *Inter-agency, Stakeholders and International Cooperation.*** - All relevant inter  
37 agency, other stakeholders and international instruments, programs, cooperation, and  
38 arrangements agreed, whether in regulatory or criminal matters, to the widest extent possible for

1 the purposes of detection, investigation, suppression, proceedings or effective response concerning  
2 administrative or criminal offenses related to counterfeit pharmaceutical products, or for the  
3 collection of evidence, shall be given full force and effect.

4  
5 **SEC.11. *Establishments' Responsibilities.*** - All pharmaceutical product establishments,  
6 including the licensed and registered pharmacist under their employ, shall ensure at all times that  
7 pharmaceutical products satisfy the requirements of pharmaceutical products' laws and standards  
8 relevant to their activities in the pharmaceutical product supply chain and that control systems are  
9 in place to prevent or eliminate counterfeit pharmaceutical products and counterfeiting activities.

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

14 If a pharmaceutical product establishment considers or has reason to believe that a  
15 pharmaceutical product which it produced, processed, imported, distributed, sold, offered for sale  
16 is counterfeit, it shall immediately initiate procedures to withdraw the pharmaceutical product in  
17 question from the market and inform the regulatory authority. Pharmaceutical product  
18 establishments shall allow inspection of their business and collaborate with the regulatory  
19 authority on actions taken to avoid risks posed by the counterfeit pharmaceutical product they have  
20 supplied.

21  
22 **SEC.12. *Rapid Alert System.*** - The rapid alert system in place for the notification of direct  
23 or indirect risk to human health due to counterfeit pharmaceutical product shall be strengthened  
24 by the FDA.

25 Emphasis shall be made on the strengthening and full implementation of science-based  
26 risk analysis, emergency measures, crisis management, and stakeholders involvement and  
27 participation.

28  
29 **SEC.13. *Strengthening the Pharmacovigilance System.*** - In addition to Sections 10,11,  
30 and 12 of this Act, the FDA, in coordination with the DOH or other stakeholders, shall strengthen  
31 the existing National Policy and Program on Pharmacovigilance, underscoring the adoption,  
32 support, establishment, institutionalization, improvement and maintenance of structures,  
33 processes, mechanisms and initiatives that are aimed, directed and designed to strengthen the  
34 government and other stakeholders' capability to prevent activities that may result, or detect,  
35 investigate, suppress, and more effectively respond to actions that result in counterfeit  
36 pharmaceutical products.

1        Within one hundred twenty (120) days from effectivity of this Act, the FDA shall establish  
2 a pharmacovigilance unit within its CDERR with appropriate staffing of officers and personnel and  
3 experts and be regularly allocated with appropriate budget.  
4

5        **SEC.14. *Training and Consumer Advocacy and Education*** -Training, orientation,  
6 education, and other advocacy activities shall be regularly provided by the FDA to pharmaceutical  
7 product establishments, communities, and other sectors of the community. As such Proclamation  
8 No. 2082 which proclaims that every third week or November of every year shall be the National  
9 Consciousness Week against counterfeit medicines, including all directives therein are hereby  
10 adopted.

11        A consumer advocacy and education program shall be developed and implemented by the  
12 FDA in partnership with relevant NGOs, private organizations, coalitions, academic institutions,  
13 or other relevant government agencies. The FDA shall allocate and provide funds for the  
14 development and implementation of training and consumer advocacy and education programs.  
15

16        **SEC.15. *Appropriations*** - The amount necessary to carry out the provisions of this Act  
17 shall be included in the General Appropriations Act for the year following its enactment and every  
18 year thereafter.  
19

20        **SEC.16. *Enforcement and Implementation.*** - The FDA of the Department of Health is  
21 hereby authorized to administer and supervise the implementation of this Act subject to the  
22 applicable provisions of Republic Act No. 10175 or the "Cybercrime Prevention Act of 2012".  
23

24        **SEC.17. *Implementing Rules and Regulations.*** - The FDA, in consultation with the  
25 stakeholders, shall promulgate the implementing rules and regulations within One Hundred  
26 Twenty (120) days from the effectivity of this Act.  
27

28        **SEC.18. *Interpretation and Construction in Favor of Protection of Public Health.*** - All  
29 doubts in the implementation and interpretation of the provisions of this Act, including its  
30 implementing rules and regulations, shall be resolved in favor of protecting public health against  
31 counterfeit pharmaceutical products.  
32

33        **SEC.19. *Separability Cause.*** - If any provision of this Act is held unconstitutional or  
34 invalid, the same shall not affect the validity and effectivity of the other provisions hereof.  
35

36        **SEC.20. *Repealing Cause.*** - Republic Act No. 8203 is hereby revised. All other laws,  
37 decrees, executive orders and rules and regulations contrary to or inconsistent with the provisions  
38 of this Act are hereby repealed, amended or modified accordingly.

1  
2           **SEC.21. *Effectivity.*** -This Act shall take effect fifteen (15) days after its publication in the  
3 Official Gazette or in a newspaper of general circulation  
4

5           *Approved,*