

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

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'22 SEP 14 P5:09

SENATE

S.B. No. 1314

RECEIVED BY: _____

INTRODUCED BY SENATOR RISA HONTIVEROS

**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

Republic Act 8203 or the Special Law on Counterfeit Drugs defines counterfeit medicines, declares prohibited acts, identifies liable parties, and imposes administrative sanctions and penalties involved. The law was enacted in September 1996 and is in force for more than 24 years. In spite of this, counterfeit drugs still proliferate in the country¹.

The implementation of R.A. 8203 has been affected by several counterfeit drug-related cases where the Supreme Court ruling favored the accused². On one case, the court stated that "Republic Act No. 9502 or the Universally Accessible Cheaper and Quality Medicines Act of 2008 nullifies the reason or purpose of R.A. 8203 so the latter loses all meaning and function³". Several laws enacted by Congress also significantly affected the provisions of RA 8203. Alongside R.A. 9502, Republic Act 9711 or the FDA Act of 2009, and Republic Act 10918 or the Philippine Pharmacy Law, all have inconsistent definition of "drugs".

Pharmaceutical crimes and the proliferation of falsified medicines are becoming more complex and compounded. The Philippines, being an archipelago, is vulnerable to illegal entry of smuggled goods, including medicines. Additionally, internet sales of pharmaceutical products grow coming from the increasing cases of counterfeit

¹ Medicines Transparency Alliance Report, Addressing the Barriers to Effective Monitoring, Reporting and Containment of spurious/substandard/falsely-labelled/ falsified/counterfeit medical products through Sustainable Multi-stakeholder Collaboration and Community/Consumer-based interventions, 2015. Available at: http://www.who.int/medicines/areas/coordination/SSFFC_Report.pdf

² Ibid.

³ G.R. No. 149907, Roma Drug, et al. v. Glaxo SmithKline, et al

pharmaceutical products entering and moving through countries worldwide.

This bill seeks to strengthen the prohibitions against counterfeit pharmaceutical products, declare the manufacture, importation, distribution, sale, offering for sale, donation, trafficking, brokering, exportation, or possession counterfeit pharmaceutical products as offenses involving economic sabotage, and provide stricter penalties for violations of this Act. This is to address the continuing real threat that counterfeit pharmaceutical products presents to Filipinos.

Our medicines must conform to national and international standards of quality, efficacy and safety. Otherwise, it may potentially harm and even create additional health risks. This bill will also complement Republic Act No. 11223 or the Universal Health Care Act which implements a comprehensive outpatient drug benefit and ensures that quality health care goods are accessible to all Filipinos.

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


RISA HONTIVEROS
Senator


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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:

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

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

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

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

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

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

- 2 a) "Brokering" shall refer to any act of facilitating the disposal or sale of
3 counterfeit pharmaceutical products, including acts of agency.
- 4 b) "Biopharmaceuticals" shall refer to pharmaceutical products that are used
5 for therapeutic or for in vivo diagnostic purposes, such as vaccines, sera,
6 and drugs derived from life forms using biotechnology. These include
7 proteins, nucleic acids, or living microorganisms where the virulence is
8 reduced and are used for therapeutic or for in vivo diagnostic purposes.
- 9 c) "CDRR" shall refer to the Center for Drug Regulation and Research of the
10 FDA.
- 11 d) "Counterfeit pharmaceutical products" shall refer to pharmaceutical
12 products which fall under any of the following conditions, which results in
13 the reduction of the pharmaceutical products' safety, efficacy, quality,
14 strength or purity:
- 15 1. do not contain the amounts as claimed;
 - 16 2. with wrong ingredients;
 - 17 3. without active ingredients; or
 - 18 4. with less than eighty percent (80%) of the active ingredient it
19 purports to possess as distinguished from an adulterated
20 pharmaceutical products including reduction or loss of efficacy due
21 to expiration.

22 It shall also refer to products that are deliberately and fraudulently
23 misrepresented with respect to their identify, composition and/or source.

24 For this purpose, the terms:

- 25 5. "Identity" shall refer to the name, labelling or packaging or to
26 documents that support the authenticity of an authorized
27 pharmaceutical product.
- 28 6. "Composition" shall refer to any ingredient or component of the
29 pharmaceutical product in accordance with applicable
30 specifications authorized/recognized by the FDA.
- 31 7. "Source" shall refer to the identification, including name and
32 address, of the marketing authorization holder, manufacturer,
33 importer, exporter, distributor or retailer, as applicable.

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

- 36 e) "Director General" shall refer to the Director General of the FDA.

- 1 f) "Drugs" shall refer to pharmaceutical products that pertain to any
2 chemical compound or biological substance, other than food, intended for
3 use in the treatment, cure, mitigation, prevention or diagnosis of disease
4 in humans or animals, including but not limited to:
- 5 1. any article recognized in the Philippine Pharmacopoeia, Philippine
6 National Drug Formulary, or in any foreign official pharmacopoeias
7 and formularies which are adopted by the FDA or any documentary
8 supplement to any of them;
 - 9 2. any article, other than food, intended to affect the structure or any
10 function of the human body or animals;
 - 11 3. any article intended for use as a component of any chemical
12 compound or biological substance or articles specified above, not
13 including devices or their components, parts, or accessories; or
 - 14 4. herbal and/or traditional drug which are articles of plant or animal
15 origin used in folk medicine, which are:
 - 16 i. recognized in the Philippine National Drug Formulary; or
 - 17 ii. intended for use in the treatment, cure, mitigation,
18 prevention or diagnosis of disease symptoms, injury or body
19 defects in humans; or
 - 20 iii. other than food, intended to affect the structure or any
21 function of the human body; and
 - 22 iv. in finished or ready-to-use dosage form; or
 - 23 v. intended for use as a component of any of the articles
24 specified in clauses (i), (ii), (iii), and (iv);
- 25 g) "Department" shall refer to the Department of Health.
- 26 h) "Economic Sabotage" shall refer to any of the acts which are declared
27 unlawful and prohibited under this Act when committed and the amount
28 of the counterfeit pharmaceutical product(s) involve (whether as a single
29 product or totality of different pharmaceutical products) is One Million
30 Pesos (Php1,000,000.00) or more, as valued by the Food and Drug
31 Administration, any provision of law to the contrary notwithstanding.
- 32 i) "Establishment" shall refer to a sole proprietorship, a partnership, a
33 corporation, an institution, an association, or an organization engaged in
34 the manufacture, importation, exportation, sale, offer for sale,
35 distribution, donation, transfer, use, testing, promotion, advertising, or

1 sponsorship of pharmaceutical product, including the facilities and
2 installations needed for its activities.

- 3 j) "FDA" shall refer to the Food and Drug Administration.
- 4 k) "FDRO" shall refer to the Food and Drug Regulation Officer of the FDA.
- 5 l) "LSD" shall refer to the laboratories under the FDA including those private
6 laboratories accredited by the agency to conduct particular scope of
7 analysis.
- 8 m) "LSSC" shall refer to the Legal Services Support Center of the FDA.
- 9 n) "Medicines" shall refer to drugs in their appropriate dosage forms, with
10 assured quality, safety and efficacy for humans or animals, or both.
- 11 o) "Online Service" shall refer to the sale, offering for sale, donation,
12 distribution, trafficking, brokering of pharmaceutical product, or the sale
13 of any punch, dye, plate or any other equipment or instrument designed
14 to print, imprint or reproduce the trademark, trade name or other
15 identifying mark for use to any pharmaceutical product, through and with
16 the use of information and communication technology system. The term
17 shall also cover Online Selling or Online Pharmacy Services.
- 18 p) "Owner" shall refer to a person or group of persons who is the registered
19 owner of a license to operate a business or business undertaking in the
20 Philippines or the branch manager or operator, license, franchise, or any
21 person acting on behalf of the corporate entity.
- 22 q) "Pharmaceutical Products" shall refer to drugs, medicines, biologicals,
23 pharmaceutical and biopharmaceutical products/specialties, veterinary
24 products, veterinary biologics and veterinary medicinal products.
- 25 r) "Residence" shall refer to a private dwelling or abode where a person
26 lives, either as owner or lessee, or usufructuary including, for purposes of
27 this Act, its yard, garage, storage rooms or premises; provided that where
28 the yard, garage, storage rooms or premises are used to manufacture,
29 process, pack, or hold pharmaceutical products for introduction into
30 domestic commerce, the same shall not fall as residence but be
31 considered as establishment

32 **Sec. 4. *Prohibited Acts.*** – The following acts are declared unlawful and therefore
33 prohibited:

- 34 a) The manufacture, importation, distribution, sale, offering for sale, donation,
35 trafficking, brokering, exportation, or possession of counterfeit
36 pharmaceutical products as defined in Section 3 hereof.

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

7 The above presumption shall not apply to the legitimate owners of
8 trademarks, trade names or other identifying marks, or the legitimate or
9 authorized representatives or agents of such owners, who have in their
10 possession counterfeit pharmaceutical products which bear the trademarks,
11 trade names or marks if they can show the sales invoices or official receipts
12 evidencing their purchase from a drugstore, manufacturer or distributor
13 suspected by them of dealing in counterfeit pharmaceutical products
14 involving the trademarks, trade names and other similar identifying marks
15 registered in their names: Provided, that such material information and
16 counterfeit pharmaceutical products shall be reported and immediately
17 turned over to the FDA within a period of ten (10) days from the date of
18 purchase of such counterfeit pharmaceutical product as indicated in the
19 sales invoice, official receipt, or other similar documents abovementioned
20 to the time the counterfeit pharmaceutical product are reported and turned
21 over to the FDA.

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

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

31 2. Presentation of certificates and other documents evidencing the
32 importation or exportation of the counterfeit pharmaceutical product
33 found in his possession as required by existing laws, including those
34 documents required in the preceding paragraph covering the
35 commercial transactions involving counterfeit pharmaceutical
36 products;

1 In both cases, the subject counterfeit pharmaceutical product must not on
2 its face appear to be as such, or do not bear any marking or any patently
3 unusual characteristic sufficient to arouse the suspicion of a reasonable and
4 prudent person that such pharmaceutical product is counterfeit.
5 Furthermore, the amount or volume of counterfeit pharmaceutical product
6 held is such that it does not negate or is inconsistent with the averment that
7 the same are for personal use, notwithstanding the presentation by the
8 possessor of medical records and other similar documents accompanying
9 and justifying the use of such pharmaceutical product.

10 c) Photocopying, duplicating, altering, printing, transferring, obliterating or
11 removing the approved label or any part thereof, lawfully belonging to
12 another person, for the purpose of using such label or a part thereof on any
13 counterfeit pharmaceutical product: Provided, that if the person who
14 committed any of the acts enumerated in this paragraph and the person
15 who used the labels produced thereby are not one and the same person
16 and the former had knowledge of the purpose for which the labels are
17 intended, the former shall also be liable under the act notwithstanding the
18 failure of the latter to achieve the intended purpose; and

19 d) Making, selling, or concealing any punch, dye, plate or any other equipment
20 or instrument designed to print, imprint or reproduce the trademark, trade
21 name or other identifying mark of another registered producer or any
22 likeness thereof, upon any pharmaceutical product or device or its container
23 or label without authority from the legitimate owners of the trademark or
24 trade name.

25 Any provision of law to the contrary notwithstanding, when any of the acts
26 in the preceding paragraphs (a) or (b) is committed and the amount of the
27 counterfeit pharmaceutical product(s) involved (whether as a single product
28 or totality of different pharmaceutical products) is one million pesos (PhP
29 1,000,000.00) or more, as valued by the Food and Drug Administration,
30 they shall be deemed as an offensive involving economic sabotage.

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

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

- 1 b) the possessor of counterfeit pharmaceutical product as provided in Section
2 4(b) of this Act;
- 3 c) the manager, operator or lessee of the laboratory or laboratory facilities
4 used in the manufacture of counterfeit pharmaceutical product;
- 5 d) the owner, proprietor, administrator or manager of the drugstore, hospital
6 pharmacy or dispensary, laboratory or other outlets or premises where the
7 counterfeit pharmaceutical product is found who induces, causes or allows
8 the commission of any act herein prohibited;
- 9 e) the licensed and registered pharmacist of the establishment, or the licensed
10 and registered pharmacist of the outlet where the counterfeit
11 pharmaceutical product is sold or found, who sells or dispenses such
12 pharmaceutical products to a third party; and
- 13 f) should the offense be committed by a juridical person the penalty shall be
14 imposed upon the officer or officers of the corporation, partnership,
15 association or entity responsible for the violation; and if such officer is an
16 alien, he shall, in addition to the penalties herein prescribed be deported
17 without further proceedings.

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

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

- 22 a) Procedure when Counterfeit Pharmaceutical Product is Monitored in the
23 Market Pursuant to a Routine Inspection of the FDRO.

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

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

1 1. Any information, either referred by the government office or officer
2 or from anonymous sources or person requesting confidentiality of
3 their identities, on the existence of suspected counterfeit
4 pharmaceutical product in the possession of any manufacturer,
5 seller, distributor, or any other person shall undergo the verification
6 process by the FDRO, or any officer deputized or authorized by the
7 Director General. Verification process shall follow the existing
8 system and procedure in the conduct of case build-up, investigation
9 or other appropriate interventions adopted by the FDA.

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

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

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

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

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

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

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

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

30 *Sec. 8. Hearing of Administrative Complaints and Other Remedies. –*

31 a) The FDA shall hear and decide administrative complaints filed before the
32 agency following the rules of procedure provided under Republic Act No.
33 3720, as amended, and its Implementing Rules and Regulations.

34 Upon preliminary findings of the conduct of prohibited acts, the Director
35 General shall issue the proper notices or orders to the person or persons

1 concerned and such person or persons shall be given an opportunity to be
2 heard before the FDA.

3 Preventive Closure Order. If seizure cannot be reasonably effected, a
4 summons with preventive closure order shall be issued against the
5 warehouse, building, factory, store, shop or any other structure where the
6 said counterfeit pharmaceutical product is contained or stored within fifteen
7 (15) days upon the filing of administrative complaint. This is for the purpose
8 of preventing the disposition or tampering of evidence, the continuance of
9 acts being complained of, and/or the flight of the Respondent.

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

- 12 b) Filing of an appropriate proceedings against the registered pharmacist with
13 the Professional Regulations Commission for imposition of the appropriate
14 penalties as provided under Republic Act No. 10918 or the Philippine
15 Pharmacy Act or its amendment;
- 16 c) Filing of criminal charges against the violator(s), which can be instituted
17 separately and independently from the administrative case: Provided, That
18 the dismissal of the criminal case shall not lift the closure order or dismiss
19 the administrative case: Provided, further, That the withdrawal of the
20 private criminal complaint shall not be a ground for the dismissal of the
21 administrative proceedings.
- 22 d) The Director General is hereby authorized to call on the assistance of any
23 Department, Office, Agency, Organization, or Body for the effective
24 implementation of the provisions of this Act.

25 *Sec. 9. Penalties. –*

26 a) Administrative Penalties

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

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

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

1 suspension or revocation of its license to do business shall be
2 the medium administrative penalty.

3 iii. Maximum Penalty. An administrative fine of Five hundred
4 thousand pesos (PHP500,000.00) and permanent closure of
5 the establishment concerned as well as the revocation of its
6 license to do business shall be the maximum administrative
7 penalty.

8 Provided, that if any or all of the instances below occur, the
9 maximum imposable fine of Five hundred thousand pesos
10 (PHP500,000.00), revocation of its license to do business and
11 permanent closure of establishment, and permanent disqualification
12 of the person concerned whether natural or juridical, from owning or
13 operating a drug establishment or outlet, as the case maybe, shall
14 be imposed:

15 iv. If the Respondent or any of his officer or agent shall conceal,
16 substitute, dispose or destroy any pharmaceutical product
17 that may have been segregated and sealed by the FDRO or
18 any officer deputized or authorized by the Director General;
19 or

20 v. If the Respondent or any of his officer or agent shall break,
21 alter or tamper any mark or seal used by the FDA to identify
22 those segregated pharmaceutical products; or

23 vi. As a result of the use of the pharmaceutical product found to
24 be counterfeit, the illness sought to be cured is aggravated or
25 physical injury or suffering results therefrom, or be the
26 proximate cause of death or permanent disability of the victim
27 or patient.

28 Any of the imposable penalties in sub-paragraphs (i), (ii) and (iii)
29 above shall be accompanied by forfeiture, confiscation and
30 destruction of the pharmaceutical product(s) found to be counterfeit
31 and the equipment, instrument, vehicles, and other articles used in
32 violation of this Act or its implementing rules and regulations.

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

35 1. imprisonment of not less than six (6) months and one (1) day but
36 not more than six (6) years for mere possession of counterfeit

1 pharmaceutical product as provided for in Section 4 (b) of this Act;
2 or

3 2. imprisonment of six (6) years and one (1) day, but not more than
4 ten (10) years or a fine of not less than One hundred thousand pesos
5 (PHP100,000.00) but not more than Five hundred thousand pesos
6 (PHP500,000.00) or both such imprisonment and fine at the
7 discretion of the court in any other case mentioned in Section 4 of
8 the Act; or

9 3. imprisonment of not less than six (6) months and one (1) day, but
10 not more than two (2) years and four (4) months if the counterfeit
11 pharmaceutical product is intended for animals; or

12 4. imprisonment of not less than six (6) years and one (1) day but not
13 more than ten (10) years for any manufacturer, seller or distributor
14 who shall conceal, substitute, dispose or destroy any pharmaceutical
15 product as may have been segregated and sealed by the FDA, or
16 who shall break, alter or tamper any mark or seal used by the FDA
17 to identify those segregated pharmaceutical products as provided for
18 under Section 6(A) of this Act. Any other person who breaks, alters
19 or tampers any mark or seal used by the FDA to identify the
20 segregated pharmaceutical product shall suffer the penalty of not
21 less than six (6) months and one (1) day, but not more than six (6)
22 years imprisonment; or

23 5. if, as a result of the use of the pharmaceutical product found to be
24 counterfeit, the illness sought to be cured is aggravated or physical
25 injury or suffering results therefrom, a punishment of imprisonment
26 from twelve (12) years to fifteen (15) years and a fine ranging from
27 One hundred thousand pesos (P100,000.00) to Five hundred
28 thousand pesos (PHP500,000.00) shall be meted out; or

29 6. should a counterfeit pharmaceutical product be the proximate cause
30 of death of a victim, who unknowingly purchased and took a
31 counterfeit pharmaceutical product, the penalty of life imprisonment
32 and a fine of Five hundred thousand pesos (PHP500,000.00) to Five
33 million pesos (PHP5,000,000.00) shall be imposed.

34 Provided that, any provision of law to the contrary notwithstanding, when
35 any of the acts declared unlawful and prohibited under Section 4 above is
36 committed and the amount of the counterfeit pharmaceutical product(s)

1 involve (whether as a single product or totality of different pharmaceutical
2 products) is One Million Pesos (Php1,000,000.00) or more, as valued by the
3 Food and Drug Administration, it shall be deemed as an offense involving
4 economic sabotage and punishable by life imprisonment and a fine of Five
5 Million Pesos (Php5,000,000.00) to Ten Million Pesos (Php10,000,000.00).
6 In case any Act prohibited in Section 4 of this Act is also punishable under
7 other laws, the offender shall, if warranted by the evidence, be prosecuted
8 under the law prescribing the highest penalty.

9 When the sale, offering for sale, donation, distribution, trafficking, or
10 brokering of counterfeit pharmaceutical product, or the sale of any punch,
11 dye, plate or any other equipment or instrument designed to print, imprint
12 or reproduce the trademark, trade name or other identifying mark of
13 another registered producer or any likeness thereof, upon any
14 pharmaceutical product or device or its container or label without authority
15 from the legitimate owners of the trademark or trade name, as prohibited
16 in Section 4 of this Act, is committed by, through and with the use of online
17 service, the same shall also be covered by the relevant provisions of
18 Republic Act No. 10175 or the "Cybercrime Prevention Act of 2012".
19 Provided, that the penalty to be imposed shall be one (1) degree higher
20 than that provided under this Act.

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

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

34 Pharmaceutical product establishments shall be knowledgeable of the specific
35 requirements and standards of pharmaceutical product laws and regulations relevant to

1 their activities in the pharmaceutical product supply chain and the procedures adopted
2 by the regulatory authority.

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

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

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

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

16 Sec. 13. *Strengthening the Pharmacovigilance System.* – In addition to Sections
17 10, 11, and 12 of this Act, the FDA, in coordination with the DOH or other stakeholders,
18 shall strengthen the existing National Policy and Program on Pharmacovigilance,
19 underscoring the adoption, support, establishment, institutionalization, improvement and
20 maintenance of structures, processes, mechanisms and initiatives that are aimed,
21 directed and designed to strengthen the government and other stakeholders' capability
22 to prevent activities that may result, or detect, investigate, suppress, and more effectively
23 respond to actions that result in counterfeit pharmaceutical products.

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

27 Sec. 14. *Training and Consumer Advocacy and Education* – Training, orientation,
28 education, and other advocacy activities shall be regularly provided by the FDA to
29 pharmaceutical product establishments, communities, and other sectors of the
30 community. As such Proclamation No. 2082 which proclaims that every third week or

1 November of every year shall be the National Consciousness Week against counterfeit
2 medicines, including all directives therein are hereby adopted.

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

8 *Sec. 15. Appropriations* – The amount necessary to carry out the provisions of this
9 Act shall be included in the General Appropriations Act for the year following its enactment
10 and every year thereafter.

11 *Sec. 16. Enforcement and Implementation* – The FDA of the Department of Health
12 is hereby authorized to administer and supervise the implementation of this Act subject
13 to the applicable provisions of Republic Act No. 10175 or the “Cybercrime Prevention Act
14 of 2012”.

15 *Sec. 17. Implementing Rules and Regulations.* – The FDA, in consultation with the
16 stakeholders, shall promulgate the implementing rules and regulations within One
17 Hundred Twenty (120) days from the effectivity of this Act.

18 *Sec. 18. Interpretation and Construction in Favor of Protection of Public Health.* -
19 All doubts in the implementation and interpretation of the provisions of this Act, including
20 its implementing rules and regulations, shall be resolved in favor of protecting public
21 health against counterfeit pharmaceutical products.

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

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

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

Approved,