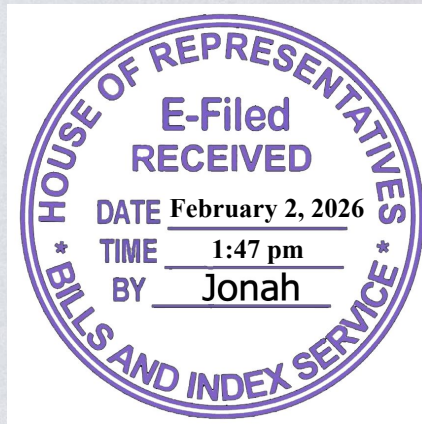




Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City, Metro Manila

Twentieth Congress
First Regular Session

HOUSE BILL NO. 7538



Introduced by **Representatives JOCELYN P. TULFO and RALPH WENDEL P. TULFO**

**AN ACT STRENGTHENING THE NATIONAL REGULATORY FRAMEWORK TO
PREVENT AND ELIMINATE COUNTERFEIT PHARMACEUTICAL PRODUCTS,
DECLARING LARGE-SCALE COUNTERFEITING AS AN ACT OF ECONOMIC
SABOTAGE, MANDATING STIFFER PENALTIES, AND REPEALING REPUBLIC ACT
NO. 8203.**

EXPLANATORY NOTE

The right to health is a fundamental constitutional mandate. However, for nearly thirty years, the primary shield against substandard and fake medicines—Republic Act No. 8203, or the "Special Law on Counterfeit Drugs"—has been rendered increasingly ineffective. Since its enactment in 1996, the pharmaceutical landscape has undergone a digital and global revolution, leaving our existing laws ill-equipped to handle modern threats.

The urgency of this measure is underscored by recent Supreme Court jurisprudence which has highlighted inconsistencies between R.A. 8203 and subsequent laws like the "Universally Accessible Cheaper and Quality Medicines Act of 2008" (R.A. 9502) and the "Food and Drug Administration (FDA) Act of 2009" (R.A. 9711). These legal ambiguities have, in several instances, allowed the perpetrators of drug counterfeiting to evade justice, effectively rendering the old law "meaningless and without function."

Furthermore, the rise of e-commerce has birthed a new frontier for "online pharmacies" that operate outside the traditional reach of regulatory inspections. Counterfeiters now utilize sophisticated digital marketing and anonymous logistics chains to distribute fake life-saving medicines to unsuspecting Filipinos.

This House Bill addresses these critical gaps through the following reforms:

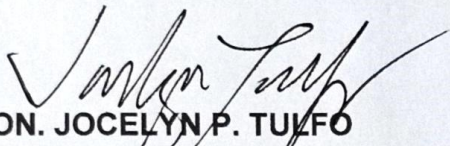
1. **Defining "Economic Sabotage":** By classifying large-scale counterfeiting (involving ₱1,000,000.00 or more) as an act of economic sabotage, the State recognizes that these crimes do not just harm individuals, they threaten the stability of the national health system and the economy.
2. **Objective Standards for Enforcement:** It introduces the definition of "**Patently Unusual Characteristics**," providing a clear, objective checklist—such as packaging irregularities, missing FDA registration, and physical

product defects—to ensure that law enforcement and the FDA can act swiftly while protecting innocent consumers.

3. **Mandatory Imprisonment:** Moving away from mere administrative fines, this bill mandates **imprisonment for all levels of counterfeiting**. By setting the minimum penalty for even small-scale offenses at six years and one day, the bill ensures that these crimes are non-probationable, serving as a powerful deterrent.
4. **Modernizing Regulatory Scope:** It explicitly grants the FDA authority over digital evidence and online transactions, ensuring that "online pharmacies" are held to the same rigorous standards as brick-and-mortar drugstores.

Counterfeit medicines are silent killers. They do not just fail to cure; they cause disability, antibiotic resistance, and death.

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



HON. JOCELYN P. TULFO
Representative, ACT-CIS PARTYLIST



HON. RALPH WENDEL P. TULFO
Representative, 2ND DISTRICT OF
QUEZON CITY



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NO. 8203**

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

SECTION 1. Short Title. — This Act shall be known as the ***"Anti-Counterfeit
Pharmaceutical Products Act of 2026."***

SECTION 2. Declaration of Policy. — It is the policy of the State to protect the people's
right to health and ensure a robust regulatory system. To achieve this, the State shall
implement aggressive measures to detect, investigate, and suppress counterfeiting
activities that compromise the safety and efficacy of medicines.

SECTION 3. Definition of Terms. — For purposes of this Act:

- **Counterfeit Pharmaceutical Products** — Refers to products deliberately misrepresented regarding their identity, composition, or source. This includes products with incorrect ingredients, no active ingredients, or less than 80% of the claimed active ingredient.
- **Economic Sabotage** — Any prohibited act under this Act where the total value of counterfeit products involved is One Million Pesos (₱1,000,000.00) or more.
- **Online Service** — Any sale, promotion, or facilitation of pharmaceutical transactions via information and communication technology, including "online pharmacies".
- **"Patently Unusual Characteristics"** — Refers to observable physical discrepancies or irregularities in a pharmaceutical product or its packaging that would lead a reasonable person, or a person with basic knowledge of the product, to suspect its authenticity. These include, but are not limited to:
 - **Packaging Irregularities:** Misspellings of the product name, manufacturer, or active ingredients; blurred or grainy printing; inconsistent font styles or sizes; and the absence of required security features such as holograms, tamper-evident seals, or QR codes.

- **Labeling Discrepancies:** Absence of a valid FDA Registration Number (DR Number), batch/lot number, or expiration date; or the presence of an expiration date that appears altered or superimposed.
- **Physical Product Defects:** Unusual color, texture, odor, or consistency of the tablet, capsule, or liquid; presence of foreign particulates in vials; or crumbling/discoloration not typical of the genuine brand.
- **Price Disparity:** A retail price that is significantly and inexplicably lower (e.g., more than 50% below the prevailing Market Retail Price) than the standard price offered by legitimate and licensed pharmacies.
- **Trafficking** — The act of storing, transporting, trans-shipping, or supplying counterfeit products, whether in transit or within free trade zones.

SECTION 4. Prohibited Acts and Presumptions. — The manufacture, importation, distribution, online sale, and possession of counterfeit pharmaceutical products are prohibited.

- **Prima Facie Evidence:** The presence of counterfeit products within any business establishment, private residence used for storage, or vehicle shall constitute *prima facie* evidence of a violation.
- **Exemption for Personal Use:** Individuals may be exempt from liability if they provide official receipts from licensed drugstores and the product does not have "*patently unusual characteristics*" that would arouse suspicion of it being counterfeit.

SECTION 5. Enhanced Administrative Powers. — The FDA is authorized to:

1. **Routine Inspection:** Conduct unannounced inspections and obtain digital evidence, including video recordings and copies of electronic records.
2. **Preventive Closure:** Issue immediate closure orders for buildings or warehouses where counterfeit products are found, effective for up to 30 days during investigation.

SECTION 6. Penalties. - Any person or entity found to have committed any of the prohibited acts under this Act shall be liable as follows:

A. Administrative Sanctions. The Food and Drug Administration (FDA) shall impose an administrative fine ranging from **One Hundred Thousand Pesos (P100,000.00) to Five Hundred Thousand Pesos (P500,000.00)** and the permanent revocation of all licenses to operate and certificates of product registration.

B. Criminal Penalties (Standard Scale). For violations involving counterfeit pharmaceutical products with a total value of **less than One Million Pesos (P1,000,000.00)**, the penalty shall be:

1. **Imprisonment** for a period of not less than **six (6) years and one (1) day but not more than twelve (12) years**; and
2. A **Fine** ranging from **Two Hundred Fifty Thousand Pesos (P250,000.00) to One Million Pesos (P1,000,000.00)**.

C. Criminal Penalties (Large-Scale / Economic Sabotage). When the violation involves counterfeit pharmaceutical products with a total value of **One Million Pesos (P1,000,000.00) or more**, the offense shall be deemed **Economic Sabotage**, and the penalty shall be:

1. **Life Imprisonment**; and

2. A **Fine** ranging from **Five Million Pesos (₱5,000,000.00)** to **Ten Million Pesos (₱10,000,000.00)**.

D. Aggravated Offenses (Resulting in Physical Injury or Death). If the use or consumption of the counterfeit pharmaceutical product results in:

1. **Physical Injury:** The penalty shall be imprisonment of **twelve (12) years and one (1) day to twenty (20) years**, and a fine of **Two Million Pesos (₱2,000,000.00)**.
2. **Permanent Disability or Death:** The penalty shall be **Life Imprisonment** and a fine of **Ten Million Pesos (₱10,000,000.00)**. This is without prejudice to the filing of separate charges for Homicide or Murder under the Revised Penal Code.

E. Liability of Juridical Persons. If the offender is a corporation, partnership, or association, the penalty of imprisonment shall be imposed upon the **President, Managing Director, and/or the Quality Control Manager** or the officers responsible for the violation. Additionally, the business permit shall be permanently cancelled.

SECTION 7. Separability Clause. — If any provision of this Act is held unconstitutional, other provisions remain in effect.

SECTION 8. Repealing Clause. — Republic Act No. 8203 is hereby repealed.

SECTION 9. Effectivity. — This Act shall take effect fifteen (15) days after its publication in the Official Gazette or a newspaper of general circulation.

Approved,