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OFFICE OF THE S.P. SECRETARIAT TUGUEGARAO CITY, CAGAYAN

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"A DRAFT ORDINANCE PROHIBITING THE UNAUTHORIZED DISPENSING, SELLING, AND RESELLING OF PHARMACEUTICAL PRODUCTS IN NEIGHBORHOOD RETAIL OUTLETS AND PRESCRIBING PENALTIES THEREOF"

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WHEREAS, Section 15, Article II of the 1987 Philippine Constitution mandates the State to protect and promote the right to health of the people and instill health consciousness among them;

**WHEREAS**, Section 30 of Republic Act No. 10918, otherwise known as the *Philippine Pharmacy Act*, prohibits the compounding, dispensing, selling, or reselling of pharmaceutical products through retail drug outlets not duly licensed by the Food and Drug Administration (FDA), to ensure the safety, efficacy, and quality of medicines;

**WHEREAS**, Republic Act No. 8203, otherwise known as the *Special Law on Counterfeit Drugs*, strictly prohibits the manufacture, sale, offering for sale, donation, distribution, trafficking, brokering, exportation, importation, or processing of counterfeit drugs, considering the serious danger they pose to public health and safety;

**WHEREAS**, Section 16 of Republic Act No. 7160, otherwise known as the *Local Government Code of 1991*, provides that every local government unit shall exercise the powers necessary for its efficient and effective governance, and shall promote the general welfare of its constituents, which includes preserving the health and well-being of its citizens;

WHEREAS, the Sangguniang Panlungsod of Tuguegarao City, as the legislative body of the local government unit, is mandated to enact measures that protect public health, uphold national laws, and support local enforcement initiatives to ensure the safety of all pharmaceutical products circulating within the city;

WHEREAS, the presence of unlicensed drug outlets and counterfeit medicines within local jurisdictions poses a direct threat to the health, safety, and welfare of the citizens of Tuguegarao City, and undermines the integrity of the public health system;

WHEREAS, it is the duty of the Sangguniang Panlungsod to actively support and reinforce the implementation of national health and safety laws, and to work in coordination with concerned government agencies and stakeholders in eradicating the sale and distribution of unlicensed and counterfeit pharmaceutical products;

**NOW, THEREFORE**, be it **ORDAINED**, as it is hereby **ORDAINED**, by the Tenth City Council of Tuguegarao City, in session duly assembled, to enact the following:

SECTION 1. TITLE. This Ordinance shall be known as "An Ordinance Prohibiting the Unauthorized Dispensing, Selling, and Reselling of Pharmaceutical Products in Neighborhood Retail Drug Outlets."

**SECTION 2. OBJECTIVES.** This Ordinance is enacted to establish clear regulations governing the sale and dispensation of pharmaceutical products within Tuguegarao City. Specifically, it seeks to achieve the following objectives:

a. To regulate and restrict the unauthorized dispensing, selling, and reselling of pharmaceutical products—including both prescription and over-the-counter (OTC)

medicines—in sari-sari stores and similar informal or unlicensed retail outlets, in recognition of the public health risks these practices pose.

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b. To safeguard the health, safety, and well-being of residents by ensuring that all pharmaceutical products available in the city are: Authentic and free from tampering or contamination, properly registered and approved by the Food and Drug Administration (FDA), and dispensed only by licensed pharmacists or authorized outlets in accordance with existing laws, particularly Republic Act No. 10918.

c. To prevent the circulation and use of counterfeit, substandard, or unregistered pharmaceutical products, which may lead to adverse drug reactions, treatment failure, drug resistance, or even fatal health outcomes, especially when used without proper medical supervision.

d. To promote awareness, accountability, and compliance among local business owners and retailers regarding their role in upholding national and local health regulations.

## **SECTION 3. DEFINITION OF TERMS.** As used in this ordinance, the following terms shall mean:

- a. **Botika Ng Barangay** refers to a drug outlet managed by a legitimate Community Organization (CO) / Non-Government Organization (NGO) and/or the Local Government Unit (LGU), with a trained operator and a supervising pharmacist.
- b. Counterfeit pharmaceutical products refer to pharmaceutical products, which do not contain the amount as claimed; with wrong ingredients; without active ingredients; or with insufficient quantity of active ingredients, which result in the reduction of the products' safety, efficacy, quality, strength, or purity. These also refer to products that are deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products.
- c. Household remedies refer to any preparation containing pharmaceutical substances of common or ordinary use to relieve common physical ailments and which may be dispensed without a medical prescription in original packages, bottles, or containers, of which the nomenclature has been duly approved by the FDA.
- d. **Neighborhood Retail Outlets** Refer to small-scale retail businesses such as sari-sari stores, convenience stores, and mini markets that serve the immediate needs of a local residential area or community.
- e. **Over-the-counter (OTC) medicines** refer to medicines used for symptomatic relief of minor ailments and which may be dispensed without prescription.
- f. **Pharmaceutical products** refer to drugs, medicines, biological, pharmaceutical and bio-pharmaceutical products/specialties, veterinary products, veterinary biologics, and veterinary medicinal products.
- g. **Pharmacist** refers to a health professional who has been registered and issued a valid Certificate of Registration (COR) and Professional Identification Card (PIC) by the PRC and the Professional Regulatory Board of Pharmacy.
- h. **Pharmacist-only OTC medicines** refer to over-the-counter medicines classified by appropriate government agencies to be obtained only from a licensed pharmacist, with mandatory pharmacist's advice on their selection and proper use.
- i. **Prescription medicines** refer to medicines that can only be dispensed by a pharmacist to a patient upon the presentation of a valid prescription from a physician, dentist, or veterinarian, and for which a pharmacist's advice is necessary.
- j. **Retail Outlet for Non-Prescription Drugs** refers to a licensed establishment authorized by the Philippine FDA to sell over-the-counter (OTC) medications without requiring a prescription.

SECTION 4. BOTIKA NG BAYAN AND BOTIKA NG BARANGAY - The City Health Office, in close coordination with the Food and Drug Administration (FDA) and the respective component barangays, shall be responsible for monitoring, supporting, and ensuring the operational functionality of all Botika ng Bayan (BnB) and Botika ng Barangay (BnBgy) outlets within their jurisdiction.

These community-based pharmaceutical outlets shall be:

- A. Properly licensed and compliant with FDA and Department of Health (DOH) regulations,
- B. Regularly stocked with safe, effective, and authentic pharmaceutical products, particularly essential medicines,
- C. Staffed and supervised by qualified personnel, in accordance with RA 10918 and relevant administrative orders.

This guarantees continuous and equitable access to affordable medicines, especially for under-served and geographically isolated populations, and helps prevent the proliferation of counterfeit and unregulated drugs in the community.

**SECTION 5. REQUIREMENTS FOR THE OPENING AND OPERATION OF A RETAIL PHARMACEUTICAL OUTLET OR ESTABLISHMENT** - Stores such as convenience stores, cooperative-run stores, and other small and medium enterprises which intend to sell household remedies and OTC drugs (which are not pharmacist-only) are first required to apply as a retail outlet for non-prescription drugs (RONPD), pursuant to FDA Circular No. 2014-028, and secure the following:

- A. A license to operate (LTO) from the FDA;
- B. The employment of the supervision and oversight of a duly registered and licensed pharmacist, pursuant to Section 31 (b) of RA 10918;
- C. Other requirements imposed by the FDA on its LTO applicants. Section 5. Operation of

## **SECTION 6. PROHIBITED ACTS**

- 1. Pursuant to Section 30 of RA 10918, No pharmaceutical product—regardless of its type, classification, or intended use—shall be compounded, dispensed, sold, resold, or otherwise made available to the public except through a retail drug outlet that is duly licensed by the Food and Drug Administration (FDA).
- 2. Sari-sari stores and other similar retail outlets and micro-enterprises are prohibited from dispensing, selling, or reselling prescription and pharmacist-only OTC medicines, as defined and classified by the FDA, as these medicines may only be dispensed by or obtained from a licensed pharmacist and with said licensed pharmacist's advice, pursuant to RA 10918.
- 3. The manufacture, sale, or offering for sale, donation, distribution, trafficking, brokering, exportation, importation, or possession of counterfeit drugs as defined in Section 3 hereof, not otherwise covered by Republic Act No. 3720, as amended. The presence or availability of such counterfeit drugs within the premises of any entity engaged in the sale, manufacture or distribution of drugs and/or pharmaceutical products or in a private residence, or in public or private vehicle, or in the premises not covered by a valid license to operate from the Bureau are likewise prohibited pursuant to Section 4 of RA 8203;

**SECTION 7. PENALTIES.** Any person found to have committed a violation any of the following acts shall be penalized as follows:

a. First offense – a fine of P1,500.00

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b. Second offense - a fine of P3,000.00 and revocation of Mayor's Permit.

If the violation is committed by a group, organization, or entity, may it be a corporation, partnership, or single proprietorship, the Head, President, General Manager, or Owner, or person acting on behalf of such responsible officers, shall be held liable for the violation.

In addition to the foregoing penalties, revocation of the business permit or license of stores determined by the LGU, the FDA, or the PNP to be dispensing, selling, or reselling pharmaceutical products without proper authorization upon the commission of the second offense.

**SECTION 8. ENFORCEMENT.** The Local Chief Executive or their duly authorized representative in coordination with the Punong Barangays, the Philippine National Police (PNP) and the Food and Drugs Administration (FDA) shall be primarily responsible for the enforcement of this Ordinance which shall include the crackdown of counterfeit drugs and the illegal distribution of pharmaceutical products.

**SECTION 9. INFORMATION, EDUCATION AND CAMPAIGN**. It shall be the obligation of the local government unit of Tuguegarao to conduct massive information, education, and communication efforts on the regulations for the benefit of sari-sari store owners within the city through the Office of the City Health Officer in partnership with the Punong Barangays.

**SECTION 10. REPEALING CLAUSE** - All ordinances, rules and regulations, other issuances or parts thereof which are inconsistent with this Ordinance is hereby repealed.

**SECTION 11. SEPARABILITY CLAUSE** - If any part of this Ordinance is declared invalid, unconstitutional or unlawful, section or parts thereof which are not affected shall remain or continue to be in full force and effect.

**SECTION 12. EFFECTIVITY** - This Ordinance shall take effect fifteen (15) days after its publication in a newspaper of local or general circulation and posting in at least two (2) conspicuous places in the city.