Item No.: <u>01</u>

Date: 1 6 2024 DEC





Tacloban City
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# Released Agrid





# 2<sup>nd</sup> INDORSEMENT

December 3, 2024

Respectfully returned to the Sangguniang Panlalawigan of Leyte, through the SP Secretary, the attached Ordinance No. 06, series of 2024 of the Sangguniang Bayan of La Paz, Leyte.

Issues/concerns for review/recommendation/legal opinion is/are as follows:

 Ordinance No. 06, series of 2024 entitled: "An Ordinance regulating the dispensing, selling and reselling of pharmaceutical products in sari-sari stores, etc."

# **REVIEW/RECOMMENDATION/LEGAL OPINION:**

This office is of the opinion that the subject Ordinance is generally in accordance with its power under R.A. No. 10918<sup>1</sup> in relation to Section 447(a)<sup>2</sup> of the Local Government Code of 1991 (R.A 7160). Hence, we recommend for the declaration of its validity.

We hope to have assisted you with this request. Please note that the opinion rendered by this Office are based on the facts available and may vary or change when additional facts and documents are presented or changed. This opinion is likewise without prejudice to the opinions rendered by higher and competent authorities and/or the courts.

ATTY. JOSE RAYMUND A. ACOL Asst. Provincial Legal Officer

<sup>1&</sup>quot; Philippine Pharmacy Act",

<sup>&</sup>lt;sup>2</sup> (a) The sangguniang bayan, as the legislative body of the municipality, shall enact ordinances, approve resolutions and appropriate funds for the general welfare of the municipality and its inhabitants pursuant to Section 16 of this Code and in the proper exercise of the corporate powers of the municipality as provided for under Section 22 of this Code

## Republic of the Philippines PROVINCE OF LEYTE Palo, Leyte



#### OFFICE OF THE SANGGUNIANG PANLALAWIGAN

1<sup>st</sup> INDORSEMENT 21 November 2024

The Provincial Legal Office is respectfully requested to review and submit recommendations on the herein enclosed Municipal Ordinance No. 06, series of 2024 of the Municipality of La Paz, Leyte, entitled: An Ordinance regulating the dispensing, selling and reselling of pharmaceutical products in sari-sari stores and other similar retail outlets in the Municipality of La Paz, Leyte and providing penalties for violations thereof.

FLORINDA JUL S UYVICO Secretary to the Sanggunian









PROVINCE OF LEYTE

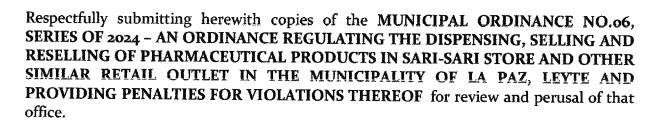
### OFFICE OF THE SANGGUNIANG BAYAN

22 November 2024

FLORINDA JILL S. UYVICO

Secretary to the Sanggunian Sangguniang Panlalawigan Province of Leyte Legislative Bldg., Capitol Complex Palo, Leyte

Madam:



Please acknowledge receipt hereof and requesting the same be given due course and appropriate action.

Early action hereon will be highly appreciated.

Thank you.

Very truly yours,

ERWIN M. CERNAL

Secretary of the Sangguniang Bayan









### OFFICE OF THE SANGGUNIANG BAYAN

22 November 2024

HON. LEONARDO "SANDY" JAVIER, JR.

Vice Governor and Presiding Officer The Honorable Members Sangguniang Panlalawigan Province of Leyte Legislative Bldg., Capitol Complex Palo, Leyte

Dear Honorable Ladies and Gentlemen:

Respectfully submitting herewith copies of MUNICIPAL ORDINANCE NO.06, SERIES OF 2024 – AN ORDINANCE REGULATING THE DISPENSING, SELLING AND RESELLING OF PHARMACEUTICAL PRODUCTS IN SARI-SARI STORE AND OTHER SIMILAR RETAIL OUTLET IN THE MUNICIPALITY OF LA PAZ, LEYTE AND PROVIDING PENALTIES FOR VIOLATIONS THEREOF for review and perusal of that office.

Please acknowledge receipt hereof and requesting the same be given due course and appropriate action.

Early action hereon will be highly appreciated.

Thank you.

Very truly yours,

ERWIN M. CERNAL

Secretary of the Sangguniang Bayan







#### OFFICE OF THE SANGGUNIANG BAYAN

Municipal Ordinance No. o6
Series of 2024

NOV 2 2 2024 PROVINCE OF LEYTE

AN ORDINANCE REGULATING THE DISPENSING, SELLING AND RESELLING OF PHARMACULTICAL PRODUCTS IN SARI-SARI STORES AND OTHER SIMILAR RETAIL OUTLETS IN THE MUNICIPALITY OF LA PAZ, LEYTE AND PROVIDING PENALTIES FOR VIOLATIONS THEREOF

Author: Hon. Araceli P. Go - Chairperson on Health and Sanitation

Section 16 of the Republic Act No. 7160, otherwise known as the Local Government Code of 1991, states that every local government unit shall exercise the powers expressly granted, those necessarily implied therefrom, as well as powers necessary, appropriate, or incidental of its efficient and effective governance, and those which are essential to the promotion of the general welfare;

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

Section 30 of the Republic Act No. 10918, otherwise known as the Philippine Pharmacy Act prohibits the compounding, dispensing, selling, or reselling of pharmaceutical products through retail drug store outlets not licensed by the Food and Drug Administration (FDA);

Republic Act No. 8203, otherwise known as the Special Law on Counterfeit Drugs, prohibits any person from manufacturing, selling, offering for sale, donating, distributing, trafficking, brokering, exporting, importing, or processing counterfeit drugs;

The FDA, through its Advisory No. 2020-1348 has issued a public health warning against the purchase and use of several counterfeit drug products that proliferated in the market, including commonly known medicines such as phenylephrine HCI/ Chlorphenamine Maleate/ Paracetamol (Neozep® Forte), Loperamide (Diabtabs®), Ibuprofen/ Paracetamol (Alaxan® FR), Carbocisteine (Solmux®), and others;

The proliferation of the counterfeit pharmaceutical products and the sale of medicines by sari-sari stores, without authorization from the FDA, are potential cause of serious harm and safety of the general public, thus the passage of this Ordinance.

BE IT ORDAINED by the Sangguniang Bayan of La Paz, Leyte, in session duly assembled that:

Section 1. Title – This Ordinance shall be known as "An Ordinance Regulating the Dispensing, Selling, and Reselling of Pharmaceutical Products in Sari-Sari Stores and Othe Similar Retail Outlets in the Municipality of La Paz, Leyte, and Providing Penalties for Violations Thereof".

Section 2. Objectives - This Ordinance aims to:

- a. regulate the dispensing, selling, and reselling of pharmaceutical products in sari-sari stores and other similar retail outlets in the municipality of La Paz, Leyte, as it poses health risks to the public;
- b. to safeguard the health of the people and protect them from counterfeit drugs;

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Page 1 of 4 Ordinance No. 06. s, 2024.

c. avoid potentially fatal side effects resulting from irresponsible use of counterfeit drugs and other similar products not registered or licensed by the Food and Drug Administration (FDA).

**Section 3. Definition of Terms** – As used in this Ordinance the following terms shall mean:

- a. Botika ng Bayan/Botika ng Baranggay 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 supervising pharmacist.
- b. Brokering shall refer to any acts of facilitating the disposal or sale of counterfeit drugs, including acts of agency.
- c. 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.
- d. Dispensing refers to the sum of processes performed by a pharmacist from reading, validating and interpreting prescriptions; preparing; packaging; labelling; record keeping; dose calculations; and counseling or giving information, in relation to the sale or transfer of pharmaceutical or medication order.
- e. 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.
- f. Over-the-counter (OTC) medicines refer to medicines used for symptomatic relief of minor ailments and which may be dispensed without prescription.
- g. Pharmaceutical products refer to drugs, medicines, biologicals, pharmaceutical and biopharmaceutical products/specialties, veterinary products, veterinary biologics, and veterinary medicinal products.
- h. Pharmacist refers to ha 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.
- i. Pharmacists-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.
- j. Prescription medicines refer to medicines which can be dispensed by a pharmacist to a patient, upon the presentation of valid prescription from a physician, dentist, or veterinarian and for which a pharmacist's advice is necessary.
- k. Sari-sari stores refer to retailing stores selling a general line of merchandise, classified as micro-enterprise.

Section 4. Requirements for the Opening and Operation of a Retail Pharmaceutical Outlets or Establishments – Stores such as convenience store, 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-

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Page 2 of 4 Ordinance No. 06. s, 2024.

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; and
- c. Other requirements imposed by the FDA on its LTO applicants.

Section 5. Operation of Botika ng Bayan and Botika ng Barangay – The Municipal Health Office and in coordination with the FDA and component barangays shall ensure the functionality of Botika ng Bayan and Botika ng Baranagay outlets within their locality to secure unhampered access to authentic pharmaceutical products. The operation of said "Botikas" shall be supervised by a registered pharmacist. The LGU and/or any barangays that will establish a Botika in their community shall ensure the hiring of qualified personnel and must secure all necessary documents required by all concerned government offices and agencies.

#### Section 6. Prohibited Acts

- 1. Pursuant to Section 30 of RA 10918, no pharmaceutical product of whatever nature and kind, shall be compounded, dispensed, sold or resold, or otherwise be made available to the consuming public, except through a retail drug outlet duly licensed by the FDA;
- 2. The manufacture, sale, or offering for sale, donation, distribution, trafficking, brokering, exportation, or 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 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 premised not covered by a valid license to operate from the Bureau are likewise prohibited pursuant to Section 4 of RA 8203;
- 3. 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;
- 4. The possession, dispensing, selling, or reselling of counterfeit pharmaceutical products are prohibited and shall be governed by the provisions of RA 8203.

**Section 7. Penalties** – Any Person found to have committed violation of any of the acts stated in Section 6 hereof shall be penalized as follows:

First offense - a fine of ₱1,500.00 or warning

**Second offense** – a fine of ₱2,000.00 or imprisonment of not more than three (3) months or both fine and imprisonment at the discretion of the Court

Third offense – a fine of ₱2,500.00 or imprisonment of not more than six (6) months or both fine and imprisonment at the discretion of the Court

If the violation is committed by a group, organization, or entity, may it be a corporation, partnership or single proprietorship, the Head, President or General Manager or Owner, or person acting on behalf of such responsible officers shall be held liable for 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 of pharmaceutical products without proper authorization upon the commission of the third offense.

Page 3 of 4 Ordinance No. 06. s, 2024.

**Section 8. Enforcement** - The Local Chief Executive or his duly authorized representative on coordination with the Punong Barangay, the Philippine National Police (PNP) and the Food and Drug 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 La Paz, Leyte to conduct massive information, education, and communication efforts on the regulations for the benefit of sari-sari store owners within the municipality through the Office of the Municipal Health Officer in partnership with the Punong Barangays.

**Section 10. Repeating Clause** – All ordinances, rules and regulations, other issuances, or parts thereof which are inconsistent with this Ordinance are 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 municipality.

ENACTED this 28th day of October, 2024.

I HEREBY CERTIFY to the correctness of the foregoing ordinance which was duly enacted by the Sangguniang Bayan during its regular session held on October 28, 2024.

ERWIN M. CERNAL ecretary to the Sanggunian

ATTESTED:

LYNDO A. QUIÑA

APPROVED

Municipal Vice Mayor/Presiding Officer

NGEL A. SIA, JR. Mynicipal Mayor









#### OFFICE OF THE SANGGUNIANG BAYAN

#### **CERTIFICATION OF POSTING**

### TO WHOM THIS MAY CONCERN:

THIS IS TO CERTIFY that POSTING in prominent places in the Municipal Hall and other conspicuous places in the locality was undertaken and copies of said ordinances was remain posted for three (3) consecutive weeks pursuant to Section 59 (b) of Republic Act 7190, in relation on the ordinance - MUNICIPAL ORDINANCE NO.06, SERIES OF 2024 - AN ORDINANCE REGULATING THE DISPENSING, SELLING AND RESELLING OF PHARMACEUTICAL PRODUCTS IN SARI-SARI STORE AND OTHER SIMILAR RETAIL OUTLET IN THE MUNICIPALITY OF LA PAZ, LEYTE AND PROVIDING PENALTIES FOR VIOLATIONS THEREOF

Subject ordinance is being forwarded to that Body for review in compliance with Section 56 of Republic Act 7160.

ISSUED this  $22^{\rm nd}$  day of November 2024 at the office of Sangguniang Bayan, La Paz, Leyte.

Very truly yours,

ERWIN M. CERNAL

Secretary of the Sangguniang Bayan