REPUBLIC OF THE PHILIPPINES
OFFICE OF THE PRESIDENT
DANGEROUS DRUGS BOARD

Board Resolution No. 8
Series of 2020

SUBJECT: REITERATION OF REGULATORY CONTROL REQUIREMENTS FOR *LIANHUA QINGWEN* CAPSULES

WHEREAS, on 5 May 2020, the Dangerous Drugs Board (the "Board") issued Resolution No. 1, s 2020 on the product registration of *Lianhua Qingwen* capsules with the Food and Drug Administration ("FDA");

WHEREAS, the Resolution states that should FDA issue a Certificate of Product Registration for *Lianhua Qingwen* capsules, the importer shall comply with all regulatory control requirements set forth in Regulation No. 1, s 2014 and other relevant issuances of the Board;

WHEREAS, Lianhua Qingwen capsules, originally used to treat influenza during the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, is one of the recommended drugs in the Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia by the National Health Commission of China and the State Administration of Traditional Medicine of China;

WHEREAS, Lianhua Qingwen has been registered in Hong Kong, Macau, Thailand, Indonesia, and Brazil as "plant medicine," food supplement, and/or natural health product, and has obtained marketing authorization in said countries;

WHEREAS, on 7 August 2020, the FDA issued a Certificate of Product Registration (Registration Number THPR-50) for *Lianhua Qingwen* capsules containing 9.14mg *Ephedra sinica* per capsule with Philippine Archipelago International Trading Corporation as Importer / Distributor;

WHEREAS, *Ephedra* is a plant-based substance used in traditional Chinese medicine to treat various lung problems. It contains Ephedrine, a Table I Substance in the 1988 United Nations Convention Against Illicit Traffic of Narcotic Drugs and Psychotropic Substances which forms part of the Annex to RA No. 9165 or the Comprehensive Dangerous Drugs Act of 2002, as amended (the "Act");

WHEREAS, Ephedrine is classified as a dangerous drug in the Philippines pursuant to Regulation No. 4, s 2005 in relation to Section 93 of the Act; Regulation No. 3, s 2019 also states that all plants containing substances listed in the 1961 Single Convention on Narcotic Drugs, the 1971 Single Convention on Psychotropic Substance, and *those classified by the Board as dangerous drugs, or are found to be sources thereof,* are classified as dangerous drugs;

WHEREAS, given the aforesaid issuances of the Board, *Ephedra* is considered as a dangerous drug in this jurisdiction;

WHEREAS, Section 2 of the Act provides that the government shall aim to achieve a balance in the national drug control program so that people with legitimate medical needs are not prevented from being treated with adequate amounts of appropriate medications, which include the use of dangerous drugs;

WHEREAS, the minimal *Ephedra* content as reflected in the Certificate of Product Registration of *Lianhua Qingwen* capsules presents low or negligible risk of abuse and cannot be readily extracted in a quantity liable to present such a risk, and can be made available for importation, and distribution and purchase in licensed pharmacies, provided that regulatory control requirements have been complied with;

WHEREAS, the Board, however, also takes cognizance of various reports of unlawful selling and trading of *Lianhua Qingwen* capsules which do not comply with regulatory control requirements mandated by the Act and relevant issuances of the Board, and proposes measures so only people with legitimate medical needs may be able to use such medication.

NOW THEREFORE, be it **RESOLVED**, as it is hereby **RESOLVED,** that in guaranteeing people with legitimate medical needs are able to access medications containing dangerous drugs and at the same time ensure proper monitoring of these medicines, we reiterate the regulatory control requirements and safeguards for the importation, sale, distribution, and prescription of *Lianhua Qingwen* capsules:

a. The importer of *Lianhua Qingwen* capsules shall secure a S-5-I License while retail distributors such as pharmacies and wholesale distributors thereof shall acquire S-3 and S-4 Licenses, respectively, from the Philippine Drug Enforcement Agency ("PDEA")[1];
b. Importation of *Lianhua Qingwen* capsules shall be accompanied by an Import Permit from PDEA[2];
c. *Lianhua Qingwen* capsules are exempted from the local order permit requirement and shall be prescribed through ordinary prescription in triplicate copies[3] by a PDEA S-2 licensed practitioner[4] not to exceed thirty (30) days' supply per prescription, except under extraordinary circumstances[5]; and
d. Entities licensed by PDEA for the importation, sale, distribution, and prescription of *Lianhua Qingwen* capsules shall maintain a Dangerous Drugs Register and ensure proper recording of all transactions and submission of such reports to the Board and PDEA[6], and be subject to monitoring and inspection activities by PDEA Regulatory Compliance Officers[7].

Persons who fail to comply with the requirements shall incur penalties provided in the Act and relevant Board Regulations.

RESOLVED FURTHER, that the Department of Trade and Industry, Philippine Drug Enforcement Agency, Food and Drug Administration, Bureau of Customs, Philippine National Police, and National Bureau of Investigation be furnished copies of this Resolution.

Secretary CATALINO S. CUY, CEO VI
Chairman

Attested by:

Undersecretary EARL P. SAAVEDRA, CESE
Secretary of the Board

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[1] Sec. 6(8), Regulation No. 1, s 2014.
[2] Sec. 11, Regulation No. 1, s 2014.
[3] Sec. 4(4), Regulation No. 1, s 2014.
[4] Sec. 6(3), Regulation No. 1, s 2014.
[5] Sec. 31(6)(a), Regulation No. 1, s 2014.
[6] Sec. 37, Regulation No. 1, s 2014.
[7] Sec. 46, Regulation No. 1, s 2014.