REPUBLIC OF THE PHILIPPINES
OFFICE OF THE PRESIDENT
DANGEROUS DRUGS BOARD

BOARD REGULATION NO. 1
SERIES OF 2021

SUBJECT: PROVISIONAL REMOVAL OF LIANHUA QINGWEN FROM THE LIST OF DANGEROUS DRUGS FOR A PERIOD OF ONE (1) YEAR

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 in China;

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

WHEREAS, on 7 August 2020, the Food and Drug Administration issued a Certificate of Product Registration (Registration No. THPR-50) for *Lianhua Qingwen* capsules with Philippine Archipelago International Trading Corporation as Importer/Distributor;

WHEREAS, *Lianhua Qingwen* capsules contain *Ephedra*, a plant-based substance used in traditional Chinese medicine, which is classified as a dangerous drug pursuant to Board Regulation No. 3, Series of 2019[1] in relation to Section 93[2] of RA No. 9165 or the Comprehensive Dangerous Drugs Act of 2002, as amended (the "Act");

WHEREAS, as a dangerous drug, importers and distributors of *Lianhua Qingwen* capsules shall comply with all relevant regulatory requirements set forth in Board Regulation No. 1, Series of 2014[3];

WHEREAS, in a letter addressed to President Rodrigo Roa Duterte dated 19 November 2020, the Philippine Archipelago International Trading Corporation proposed the reclassification of *Lianhua Qingwen* capsules to make the same more accessible to the people in light of the COVID-19 pandemic;

---

[1] Subject: Classification of Plants Containing Substances Listed in or Thereafter Added to the 1961 Single Convention on Narcotic Drugs, the 1971 Single Convention on Psychotropic Substances, and Those Classified by the Dangerous Drugs Board as Dangerous Drugs, or are Sources Thereof, as Dangerous Drugs

[2] Reclassification, Addition or Removal of Any Drug from the List of Dangerous Drugs

[3] Comprehensive Guidelines on Importation, Distribution, Manufacture, Prescription, Dispensing, and Sale of, and other Lawful Acts in Connection with Any Dangerous Drugs, Controlled Precursors and Essential Chemicals, and Other Similar or Analogous Substances

WHEREAS, the matter was referred to the Committee on Reclassification for the conduct of public hearing and evaluation, and consider the criteria set forth in Section 93 of the Act relative to reclassification of any drug in the list of dangerous drugs.

WHEREAS, a public hearing on the proposed delisting of *Lianhua Qingwen* capsules was conducted on 20 January 2021 and attended by representatives of national government agencies, medical societies, pharmaceutical associations, and various stakeholders.

WHEREAS, after discussion and evaluation of the presentations made by the resource persons vis-à-vis the criteria set forth in Section 93 of the Act and pertinent Regulations of the Board during the public hearing, the following conclusions were realized:

a. There are no reports from the Department of Health ("DOH") and various stakeholders relative to abuse of *Lianhua Qingwen* capsules
b. The ephedra and ephedrine content are minimal and cannot be readily extracted from *Lianhua Qingwen* capsules;
c. *Lianhua Qingwen* capsules contain non-narcotic ingredients sufficient to prevent enhancement, potentiation, or synergism of the abuse liability of ephedra and ephedrine; and,
d. There is no other ingredient of *Lianhua Qingwen* capsules that is listed under the 1971 Convention on Psychotropic Substances.
e. The preparation is not in injectable form

WHEREAS, the Committee recommends the provisional delisting of *Lianhua Qingwen* capsules from the list of dangerous drugs for a period of one (1) year, provided that the Board shall conduct a review prior to the expiration of said period should issues on public safety arise relative to the use of such capsules.

WHEREAS, the Committee also recommends that the importer and/or distributor of *Lianhua Qingwen* capsules comply with the prescription and dosing requirements of the Food and Drug Administration ("FDA"), analogous to similarly-situated medicines.

WHEREFORE, be it **RESOLVED,** as it is hereby **RESOLVED,** that the Board adopt the recommendation of the Committee on Reclassification to remove *Lianhua Qingwen* capsules from list of dangerous drugs for a period of one (1) year pursuant to Section 93 of the Act: *Provided,* that the 1-year period shall start from the date of publication of this Regulation in a newspaper of general circulation and registration with the Office of the National Administrative Register.

RESOLVED FURTHER, that prior to the expiration of the 1-year period, the Committee on Reclassification shall evaluate whether to shorten or extend said period given the prevailing circumstances at such time and provide recommendation/s to the Board on the matter.

RESOLVED FURTHERMORE, that the DOH, through the FDA, continue to evaluate the dosage ceiling per day for *Lianhua Qingwen* capsules and the recommended ceiling be reflected in the pamphlet/insert of said medicine;

RESOLVED FURTHERMORE, that DOH, through the FDA, study alleged toxicity concerns on the abuse of *Lianhua Qingwen* capsules together with stakeholders such as the University of the Philippines National Poison Management and Control Center, National Institute on Health and Philippine Medical Association;

RESOLVED FINALLY, that the importer/s and distributor/s of *Lianhua Qingwen* capsules shall continue to comply with appropriate prescription and dosing requirements set forth by the FDA notwithstanding the delisting of said preparation.

APPROVED and ADOPTED this 4th day of February in the year of Our Lord, 2021 in Quezon City.

Secretary CATALINO S. CUY, CEO VI
Chairman

Attested:

Undersecretary EARL P. SAAVEDRA, CESE
Secretary of the Board