REPUBLIC OF THE PHILIPPINES
OFFICE OF THE PRESIDENT
DANGEROUS DRUGS BOARD

BOARD REGULATION NO. 5
Series of 2021

SUBJECT: ALLOWING THE USE OF ORDINARY PRESCRIPTION IN TRIPLICATE FORM TO PRESCRIBE ESKETAMINE SINGLE-USE NASAL SPRAY DEVICE FOR TREATMENT-RESISTANT DEPRESSION

WHEREAS, Section 77 of RA No. 9165, or the Comprehensive Dangerous Drugs Act of 2002, as amended (the "Act"), provides that the Dangerous Drugs Board (the "Board") shall be the policy-making and strategy-formulating body in the field of drug prevention and control;

WHEREAS, Section 81(r) of the Act states that the Board shall formulate guidelines relative to transactions involving any dangerous drug, controlled precursors, and essential chemicals according to medical and research needs or requirement of the country;

WHEREAS, RA No. 11036, or the Mental Health Act, provides that the State shall commit itself to promote the well-being of the people by ensuring that mental health conditions are treated and prevented; and timely, affordable, high quality, and culturally-appropriate mental health care is made available to the public;

WHEREAS, Regulation No. 1, Series of 2014[1] provides that the Board may exempt any preparation from specific measures of regulatory control;

WHEREAS, Esketamine, as an isomer of Ketamine, is classified as a dangerous drug pursuant to Regulation No. 3, Series of 2005[2];

WHEREAS, Esketamine, as contained in a single-use nasal spray device, is used in treating Treatment-Resistant Depression, a major depressive disorder in adults who have not responded adequately to at least two (2) different antidepressants of adequate dose and duration to treat the current depressive episode;

WHEREAS, Johnson and Johnson formally requested the use of ordinary prescription in triplicate form in prescribing Esketamine single-use nasal spray device for treatment resistant depression;

WHEREAS, the Committee on Reclassification, after its evaluation recommended the granting of such request with the following observations:

a. that said drug, in intranasal spray form, shall only be administered in a hospital or clinic under the supervision by a health care professional;
b. that the spray is designed to be used only once and difficult to take apart;
c. that there is negligible risk of abuse due to its mechanism of action; and
d. that there is negligible risk of diversion because the Esketamine content cannot be readily recovered in a quantity liable to present such risk.

[1] "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"

[2] "Inclusion of Ketamine in the List of Dangerous Drugs and Amending Section 32-6(b) of Board Regulation No. 3, S. 2003 and in the List of Dangerous Drugs to be Prescribed in a Single Applicable Prescription by a Licensed Practitioner"

WHEREFORE, be it **RESOLVED,** as it is hereby **RESOLVED,** to approve the recommendation of the Committee on Reclassification allowing the use of ordinary prescription in triplicate form to prescribe Esketamine Single-Use Nasal Spray Device for Treatment-Resistant Depression.

RESOLVED FURTHER, that all other regulatory measures set forth in the Regulation shall be complied with by individuals and entities engaged in the prescription, importation, distribution, sale, and trade of such product.

APPROVED and **ADOPTED**, this 29th day of July in the year of our Lord, 2021, in Quezon City.

Secretary CATALINO S. CUY, CEO VI
Chairman

Attested by:

Undersecretary EARL P. SAAVEDRA, CESE
Secretary of the Board