Philippine Economic Zone Authority

PEZA

MEMORANDUM CIRCULAR NO. 2015-008

FOR	:	**Economic Zone Locator Enterprises** **Economic Zone Administrators and Managers**
FROM	:	**Director General LILIA B. DE LIMA**
SUBJECT	:	**Chemical Importation Advisory – Revision of the Dangerous Drugs Board (DDB) guidelines on the importation, sale and manufacture of controlled precursor and essential chemicals**
DATE	:	**23 February 2015**

We wish to inform that the Dangerous Drugs Board (DDB) and the Philippine Drug Enforcement Agency (PDEA) has amended Board Regulation No. 3 series of 2003 also known as "Comprehensive Guidelines on Importation, Distribution, Manufacture, Prescription, Dispensing and Sale of, and Other Lawful Acts in Connection with any Dangerous Drugs, Controlled Precursor and Essential Chemicals (CPECs) and Other Similar or Analogous Substances".

The new policy, which is called DDB Board Regulation No. 1 series of 2014, was published last 22 December 2014, with erratum published on 9 February 2015, by The Philippine STAR.

How to ensure compliance to DDB regulation on importation of CPECs?

1. Check the Material Safety Data Sheet or the Globally Harmonized System - Safety Data Sheet (GHS – SDS) of the chemical or materials to be imported, to ensure that it contains the minimum amount of information required by the DDB (**Table 1**). [Reference: Item (4f) Section 11 and Annex M – Material Safety Data Sheet and/or Globally Harmonized System (GHS) Classification of Controlled Chemicals, DDB BR 2014-01]

2. Submit the MSDS or GHS – SDS containing the minimum prescribed information by the DDB to the PEZA Zone Office or email to esg@peza.gov.ph for evaluation.

3. Lodge the PEZA electronic import permit (e-IP) application and allow supplier to ship the chemical or materials only after:
    a. Goods are cleared by the PEZA Zone Office as unregulated; OR,
    b. Regulated goods are accompanied by appropriate permits and PEZA Zone Office has given clearance to lodge e-IP application.

What are the requirements for importation of chemicals or materials with CPECs content?

4. If CPECs concentration is less than or equal to what is specified in DDB's Table of Concentration Limits (**Table 2**), secure PDEA license prior to importation. [Reference: Items (3), (6), (7) Section 4, Annex D – Table of Concentration Limits, DDB BR 2014-01]

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Example: Importers of lead acid batteries (containing <30% by weight or volume sulphuric acid) for uninterruptible power supply (UPS) may now import the batteries without the need for a PDEA import permit or a DDB Certificate of Exemption. The importer however, needs to present a copy of a valid PDEA license to PEZA Zone Office.

5. If CPECs concentration is more than what is specified in DDB's Table of Concentration Limits (**Table 2**), secure PDEA license and PDEA Import Permit fifteen (15) working days before the arrival of the shipment.
    a. Ensure that the amount of shipment corresponds to the amount specified in the PDEA Import Permit.
    b. In cases where the total quantity of the shipment is more than 30% of the approved quantity in the PDEA import permit, the shipment shall be subject to seizure proceedings of the Bureau of Customs [Reference: Section 10, Section 26 DDB BR 2014-01]

6. PDEA license holders are required to maintain a controlled chemical register and follow the format prescribed by the DDB. Update the register within one hundred twenty (120) hours of any import, export, manufacture, supply, acquisition or disposal of the controlled chemical. [Reference: Section 38, Section 26 DDB BR 2014-01]

What are the new policies affecting the process of securing a PDEA license?

7. PDEA license may be renewed within three (3) months prior to expiration and license holders are required to report discontinuance of license granted. PDEA license holders are advised to renew within the period covered to avoid payment of surcharge, if they will opt not to renew, licensees are advised to notify PDEA Compliance Service in writing at least sixty (60) days prior to expiration to avoid payment of surcharge and to allow PDEA to conduct pre-retirement compliance inspection. [Reference: Item (10) Section 6 and Item (2) Section 18, DDB BR 2014-01]

8. Grounds for denial of registration of license as well as procedure for the suspension and revocation are prescribed in the new guidelines [Reference: Item (2) Section 8 and Annex F – Administrative Procedure in Suspending or Revoking License DDB BR 2014-01]

What are the requirements for storage, labelling, transport and disposal of CPECs?

9. PDEA license holders are responsible for the safe and secure storage and handling of CPECS, this shall follow the specifications in the MSDS or GHS-SDS. [Reference: Item (4) Section 41, Section 42, Annex L – Safe keeping, storage and transport, DDB BR 2014-01]

10. Notify PDEA Regional Office or Compliance Service in writing if damaged, expired or contaminated CPECs will be disposed. Chemicals for disposal or treatment are considered as hazardous wastes, thus, locators should only deal with DENR-registered hazardous waste treatment, storage and disposal (HW TSD) facility for the proper management of wastes. [Reference: Item (2) Section 42 DDB BR 2014-01]

What are the penalties imposed by DDB for importation without a PDEA Import Permit?

11. Penalty for violation of the DDB regulation has been revised
    a. First violation – fine of P 50,000 or 15% of the total value of the shipment (whichever is higher).

b. Second violation – fine of P 50,000 or 30% of the total value of the shipment (whichever is higher) and a recommendation from PDEA that the shipment be subjected to forfeiture proceedings.
c. Third violation - fine of P 50,000 or 50% of the total value of the shipment (whichever is higher) with a recommendation from PDEA that the shipment be subjected to forfeiture proceedings and responsible officials shall be criminally liable. [Reference: Section 51 DDB BR 2014-01]

For your information and strict compliance.

TABLE 1 - Minimum amount of information in the MSDS or GHS – SDS

Source: Annex M, DDB Board Regulation 2014-01

Item	Heading	Information
1	Identification of the substance or mixture and of the supplier	• GHS product identifier. • Other means of identification. • Recommended use of the chemical and restrictions on use. • Supplier's details (including name, address, phone number etc). • Emergency phone number
2	Hazards identification	• GHS classification of the substance/mixture and any national or regional information. • GHS label elements, including precautionary statements. (Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol e.g. flame, skull and crossbones.) • Other hazards which do not result in classification (e.g. dust explosion)
3.	Composition/information on ingredients	**Substance** • Chemical identity. • Common name, synonyms, etc. • CAS number, EC number, etc. • Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance. **Mixture** • The chemical identity and concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cut-off levels. ***NOTE**: For information on ingredients, the competent authority rules for CBI take priority over the rules for product identification.*
4.	First aid measures	• Description of necessary measures, subdivided according to the different routes of exposure, i.e. inhalation, skin and eye contact and ingestion. • Most important symptoms/effects, acute and delayed. • Indication of immediate medical attention and special treatment needed, if necessary
5.	Firefighting measures	• Suitable (and unsuitable) extinguishing media. • Specific hazards arising from the chemical (e.g. nature of any hazardous combustion products). • Special protective equipment and precautions for firefighters.
6.	Accidental release measures	• Personal precautions, protective equipment and emergency procedures. • Environmental precautions. • Methods and materials for containment and cleaning up.
7.	Handling and Storage	• Precautions for safe handling. • Conditions for safe storage, including any incompatibilities.
8.	Exposure controls/personal protection.	• Control parameters e.g. occupational exposure limit values or biological limit values. • Appropriate engineering controls. • Individual protection measures, such as personal protective equipment.
9.	Physical and chemical properties	• Appearance (physical state, color etc). • Odor.

Item	Heading	Information
		• Odor threshold. • PH. • Melting point/freezing point. • Initial boiling point and boiling range. • Flash point. • Evaporation rate. • Flammability (solid, gas). • Upper/lower flammability or explosive limits. • Vapor pressure. • Vapor density. • Relative density. • Solubility(ies). • Partition coefficient: n-octanol/water. • Auto-ignition temperature. • Decomposition temperature.
10.	Stability and reactivity	• Chemical stability. • Possibility of hazardous reactions. • Conditions to avoid (e.g. static discharge, shock or vibration). • Incompatible materials. • Hazardous decomposition products.
11.	Toxicological information	Concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects, including: • information on the likely routes of exposure (inhalation, ingestion, skin and eye contact); • Symptoms related to the physical, chemical and toxicological characteristics; • Delayed and immediate effects and also chronic effects from short- and long-term exposure; • Numerical measures of toxicity (such as acute toxicity estimates).
12.	Ecological information	• Ecotoxicity (aquatic and terrestrial, where available). • Persistence and degradability. • Bioaccumulative potential. • Mobility in soil. • Other adverse effects.
13.	Disposal considerations	• Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.
14.	Transport information	• UN number. • UN Proper shipping name. • Transport Hazard class(es). • Packing group, if applicable. • Marine pollutant (Yes/No). • Special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises.
15.	Regulatory information	• Safety, health and environmental regulations specific for the product in question. *NOTE: indicate whether controlled substance (Controlled Precursor and Essential Chemical or Dangerous Drug)*
16.	Other information including information on preparation and revision of the SDS	

TABLE 2 – Table of Concentration Limits

Source: Annex D, DDB Board Regulation 2014-01

Table I CPECs	Concentration	Special conditions
Acetic Anhydride CAS Registry number: 108-24-7 Harmonized System (HS) code 2915.24	20% by Weight or Volume	
N-Acetylanthranilic acid, its salts and esters CAS number: 89-52-1 HS code: 2924.23	20% by Weight	Concentration based on any combination of N-acetylanthranilic acid and its salts and esters.
Ergometrine CAS number: 60-79-7 HS code: 2939.61	0	
Ergotamine CAS number: 113-15-5 HS code: 2939.62	0	
Isosafrole CAS number. 120-58-1 HS code: 2932.91	20% by Weight or Volume	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with safrole.
Lysergic Acid CAS number: 82-58-6 HS code: 2939.63	0	
3, 4-methylenedioxyphenyl-2-propanone CAS number. 4676-39-5 HS code: 2932.92	0	
Norephedrine, its salts, optical isomers, and salts of optical isomers CAS number: 14838-15-4 HS code: 2939.492939.44	0.6% by Weight	Concentration based on any combination of phenylpropanolamine and their salts, optical isomers and salts of optical isomers.
Phenylacetic acid, and its salts and esters CAS number: 103-82-2 HS code: 2933.32	40% by Weight	Concentration is based on any combination of phenylacetic acid and its salts and esters.
1-phenyl-2-propanone CAS number: 103-79-7 HS code: 2914.31	0	
Piperonal CAS number: 120-57-0 HS code: 2932.93	20% by Weight or Volume	
Potassium permanganate CAS number: 7722-64-7 HS code: 2841.61	15% by Weight	
Safrole CAS number: 94-59-7 HS code: 2932.94	20% by Volume	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with isosafrole.

Table II CPECs	Concentration	Special Conditions
Acetone CAS number: 67-64-1 HS code: 2914.11	35% by Weight or Volume	Limit applies to acetone or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Anthranilic acid, and its salts and esters CAS number: 118-92-3 HS code: 2922.43	50% by Weight	Concentration is based on any combination of anthranilic acid and its salts and esters.
Ethyl ether CAS number: 60-29-7 HS code: 2909.11	35% by Weight or Volume	Limit applies to ethyl ether or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Hydrochloric acid CAS number: 7647-01-0 HS code: 2806.10	30% by Weight or Volume	Weight is based on hydrogen chloride in the mixture and not the combined weight of the carrier solvent, if any.
Methyl ethyl ketone CAS number:: 78-93-3 HS code: 2914.12	35% by Weight or Volume	Limit applies to methyl ethyl ketone or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Piperidine, and its salts CAS number: 110-89-4 HS code: 2933.32	35% by Weight or Volume	Concentration based on any combination of piperidine and its salts. Concentration based on weight if a solid, weight or volume if a liquid.
Sulfuric acid CAS number: 7664-93-9 HS code: 2807.00	30% by Weight or Volume	Weight is based on sulfuric acid in the mixture and not the combined weight of the carrier solvent, if any.
Toluene CAS number: 108-88-3 HS code: 2902.30	35% by Weight or Volume	Limit applies to toluene or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Classified under Sec 93 Article XI, RA 9165	**Concentration**	**Special Condition**
Thionyl Chloride CAS number: 7719-09-7 HS Code: 2812.10	0	

THE PHILIPPINE STAR
TRUTH SHALL PREVAIL

Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

ERRATUM on the Dangerous Drugs Board (DDB) Board Regulation entitled "BOARD REGULATION No 3, Series 2013" or the "Comprehensive Amendments to Board Regulation No. 3, Series 2003....." published in The Philippine Star last December 22, 2014.

Title of the Regulation should be "**BOARD REGULATION No. 1, Series of 2014**" and not BOARD REGULATION No. 3, Series of 2013

Section 1 (m) to read –

m) "Controlled substance trader" means any establishment which is a registered owner of a health product that may procure raw materials and packing components and provide production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products. A controlled substance trader shall be categorized as a manufacturer under this Regulation.

Section 4: Preparations

Sec. 4(2)(b) to read-

Patches of Buprenorphine which is listed under Philippine Schedule 3 are automatically exempted from the Special Prescription Form for Dangerous Drugs but shall be prescribed using an ordinary prescription form in triplicate copies, bearing the current s-2 License of the prescribing medical practitioner.

First paragraph of Sec. 4(6) to read:

In application of Section 4(2)(d) the following categories of chemical mixtures in concentration equal to or less than those specified in the "Table of Concentration Limits" or unless otherwise specified, that are contained in articles or finished products intended for sale to the general public, except as otherwise banned by the Food and Drug Administration in case of food and cosmetics or the Department of Health in case of household hazardous substance or by the Department of Environment and Natural Resources and the Department of Trade and Industry are exempted from all regulatory requirements under this Regulation, excluding registration of license of manufacturer, and recording and reporting of acquisition and usage of raw material by the manufacturer.

Sec. 6 (4)(a) (ii) to read:

(ii) An approved Local Order Permit shall bear, among others, the PDEA Permit number, date of issue and validity of the PDEA Permit, name, address and current PDEA license numbers (with validity) of applicant and seller, full name of the applicant's authorized pharmacist , particulars of the dangerous drug preparation to be purchased, i.e., brand and generic name, dosage strength and form, packaging presentation, quantity ordered, and the signatures of the authorized processing and approving PDEA-CS Officer. Once approved, no request for alteration will be allowed.

Sec.6 (4)(bii)(5) – to read:

(5) "Agreement Contract of contracting parties which shall include among others the provision of the security measures that will be undertaken to prevent diversion, loss, theft, pilferage and other analogous circumstances during transport of controlled substance;"

Sec. 7 To read additionally:

3. An original application for an S2 License shall be completely filled –out, signed, and filed with the PDEA for the grant of a license by the applicant. The application shall be accompanied by the following:

a. Current Professional Regulation Commission (PRC) ID Card/ Registration;
b. Current Professional Tax Receipt. For government employed, Certificate of Employment;
c. Tax Identification Number (TIN) or latest ITR;
d. Valid DOH-DDB-IDTOMIS Drug Test generated report ;
e. 2" X 2" ID picture with white background, no eyeglasses and taken not later than 6 months from application
g. Others as PDEA may prescribe from time to time; and
h. the prescribed fee.

Section 8 (a) should read as follows:

Section 8. Grant of license

Where an appropriate application has been made accordingly, PDEA may grant a license if satisfied that:

(a). the applicant and, if a company, each director and the company secretary:

i. has never been convicted in the Philippines or elsewhere for any serious offense, or any offense however described relating to a dangerous drug or controlled chemical; and

ii. is otherwise a fit and proper person to hold a license;

Section 9 (1) (c) To read :

(c) the controlled substance to which the license relates;

Annex D should read as follows:

Annex D – Table of Concentration Limits

Table I CPECs	*Concentration Weight / Volume (whichever is applicable)*	*Special Conditions*
Acetic Anhydride CAS Registry number: 108-24-7 Harmonized System (HS) code 2915.24	20% by Weight or Volume	
N-Acetylanthranilic acid, its salts and esters CAS number: 89-52-1 HS code: 2924.23	20% by Weight	Concentration based on any combination of N-acetylanthranilic acid and its salts and esters.
Ergometrine CAS number: 60-79-7 HS code: 2939.61	0	
Ergotamine CAS number: 113-15-5 HS code: 2939.62	0	

Isosafrole CAS number. 120-58-1	20% by Weight or Volume	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with safrole.
Lysergic Acid CAS number: 82-58-6 HS code: 2939.63	0	
3,4-methylenedioxyphenyl -2-propanone CAS number. 4676-39-5 HS code: 2932.92	0	
Norephedrine, its salts, optical isomers, and salts of optical isomers CAS number: 14838-15-4 HS code: 2939.492939.44	0.6% by Weight	Concentration based on any combination of phenylpropanolamine and their salts, optical isomers and salts of optical isomers.
Phenylacetic acid, and its salts and esters CAS number: 103-82-2 HS code: 2933.32	40% by Weight	Concentration is based on any combination of phenylacetic acid and its salts and esters.
1-phenyl-2-propanone CAS number: 103-79-7 HS code: 2914.31	0	
Piperonal CAS number: 120-57-0 HS code: 2932.93	20% by Weight or Volume	
Potassium permanganate CAS number: 7722-64-7 HS code: 2841.61	15% by Weight	
Safrole CAS number: 94-59-7 HS code: 2932.94	20% by Volume	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with isosafrole.

Table II CPECs	***Concentration Weight / Volume (whichever is applicable)***	***Special Conditions***
Acetone CAS number: 67-64-1 HS code: 2914.11	35% by Weight or Volume	Limit applies to the aggregate sum of acetone or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone, and toluene if present in the mixture.
Anthranilic acid, and its salts and esters CAS number: 118-92-3 HS code: 2922.43	50% by Weight	Concentration is based on any combination of anthranilic acid and its salts and esters.
Ethyl ether CAS number: 60-29-7 HS code: 2909.11	35% by Weight or Volume	Limit applies to the aggregate sum of ethyl ether or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone, and toluene if present in the mixture.
Hydrochloric acid CAS number: 7647-01-0 HS code: 2806.10	30% by Weight or Volume	Weight is based on hydrogen chloride in the mixture and not the combined weight of the carrier solvent, if any.
Methyl ethyl ketone CAS number:: 78-93-3 HS code: 2914.12	35% by Weight or Volume	Limit applies to the aggregate sum of methyl ethyl ketone or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone, and toluene if present in the mixture.
Piperidine, and its salts CAS number: 110-89-4 HSN: 2933.32	35% by Weight or Volume	Concentration based on any combination of piperidine and its salts. Concentration based on weight if a solid, weight or volume if a liquid.
Sulfuric acid CAS number: 7664-93-9 HS code: 2807.00	30% by Weight or Volume	Weight is based on sulfuric acid in the mixture and not the combined weight of the carrier solvent, if any.
Toluene CAS number: 108-88-3 HS code: 2902.30	35% by Weight or Volume	Limit applies to the aggregate sum of toluene or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone, and toluene if present in the mixture.

***The phrase "aggregate sum" shall be understood as the total percentage content of each of the controlled chemical present in the chemical mixture.**

Classified under Sec 93 Article XI, RA 9165	Concentration Weight / Volume (whichever is applicable)	Special Conditions
Thionyl Chloride CAS number: 7719-09-7 HS Code: 2812.10	0	

***Corrections of ANNEX E- Pharmaceutical Drugs in Airplanes and Vessels**

(b) (iv) should read as follows...

(iv) The quantity of dangerous drugs or drug preparations containing controlled chemicals that PDEA may authorize are considered sufficient to provide treatment for a crew of ten (10) persons on either a Category A or B vessel as defined in each of the sub columns. "Category A ships" are seagoing ships with no limitation on length of trips; "Category B ships" are seagoing ships making trips of less than two hundred (200) nautical miles (370 kilometers) from the nearest port with adequate medical equipment and includes RO-RO passenger ships, fishing vessels on extended voyages of more than seven (7) days), and yachts on voyages of more than sixty (60) miles (111 kilometers) from safe harbor "Category C ships" are harbor vessels, boats and craft staying very close to shore or with no cabin accommodation other than a wheelhouse, or staying not more than thirty (30) nautical miles (56 kilometers) from shore and does not go to sea for more than twenty four (24) hours.

Corrections on ANNEX J pertaining to Report Forms

1) PDEA Report Form 1-13 should be labeled "PDEA Report Form 1-14"
2) PDEA Report Form 2-13 should be labeled "PDEA Report Form 2-14"
3) PDEA Report Form 3-13 should be labeled "PDEA Report Form 3-14"

Corrections on ANNEX I on S-Registers

1) PDEA S Register 1-13 should be labeled "PDEA S Register 1-14"
2) PDEA S Register 2-13 should be labeled "PDEA S Register 2-14"
3) PDEA S Register 3-13 should be labeled "PDEA S Register 3-14"
4) PDEA S Register 4-13 should be labeled "PDEA S Register 4-14"
5) PDEA S Register 5-13 should be labeled "PDEA S Register 5-14"
6) PDEA S Register 6A-13 should be labeled "PDEA S Register 6A-14"
7) PDEA S Register 6B-13 should be labeled "PDEA S Register 6B-14"
8) PDEA S Register 7-13 should be labeled "PDEA S Register 7-14"
9) PDEA S Register 8-13 should be labeled "PDEA S Register 8-14"
10) PDEA S Register 9-13 should be labeled "PDEA S Register 9-14"
11) PDEA S Register 10A-13 should be labeled "PDEA S Register 10A-14 (Records required of a S2 licensed physician or dentist acquiring dangerous drug stocks in accordance with Section 30(1)(c) (ii) or other special case/s)"
12) PDEA S Register 10B-13 should be labeled "PDEA S Register 10B-14"

Corrections on ANNEX K on P-Registers

1) PDEA P Register 1-13 should be labeled "PDEA P Register 1-14"
2) PDEA P Register 2-13 should be labeled "PDEA P Register 2-14"
3) PDEA P Register 3-13 should be labeled "PDEA P Register 3-14"
4) PDEA P Register 4-13 should be labeled "PDEA P Register 4-14"
5) PDEA P Register 5-13 should be labeled "PDEA P Register 5-14"
6) PDEA P Register 5A-13 should be labeled "PDEA P Register 5A-14"
7) PDEA P Register 5B-13 should be labeled "PDEA P Register 5B-14"
8) PDEA P Register 5C-13 should be labeled "PDEA P Register 5C-14"
9) PDEA P Register 5D-13 should be labeled "PDEA P Register 5D-14"

P.S. Feb. 9, 2015