ISSUANCE OF DANGEROUS DRUGS LICENSE (S2-LICENSE MEDICAL PRACTITIONER)

Schedule: Monday to Friday – 8AM to 5:00PM NO NOON BREAK

WHO IS QUALIFIED TO APPLY FOR S2-LICENSE? A PRC- registered Physician, Dentist and Veterinarian who will prescribe [a] Dangerous Drugs Preparations (DDPs) or [b] Drug Preparations containing Table 1 controlled chemical except drug preparation/s containing PPA at doses of 25 mg or below [OTC drugs, per BFAD AO 163, S. 2000].

WHO IS QUALIFIED TO APPLY FOR S2-LICENSE ONLINE? Renewal S2 licensed applicant, i.e.Physician, Dentist, and Veterinarian who initially applied in person at PDEA office and whose information were entered into the PDEA Permits and Licensing System (PPLS).

WHAT ARE THE REQUIREMENTS?

1. DULY ACCOMPLISHED S2 LICENSE APPLICATION FORM FM-CSVlrd-O1
2. ORIGINAL AND PHOTOCOPY OF VALID PRC ID CARD
3. ORIGINAL AND PHOTOCOPY OF VALID PROFESSIONAL TAX RECEIPT (PTR). FOR GOVERNMENT EMPLOYED, CERTIFICATE OF EMPLOYMENT AND NOTARIZED AFFIDAVIT FOR THE USE OF S2 LICENSE FOR GOVERNMENT PRACTICE ONLY.
4. ONE-TIME SUBMISSION OF TAX IDENTIFICATION NUMBER OR LATEST INCOME TAX RETURN
5. VALID DRUG TEST RESULT (DOH-DDB IDTOMIS-GENERATED REPORT)
6. ONE PIECE 2" X 2" ID PICTURE WITH WHITE BACKGROUND TAKEN AT LEAST 6 MONTHS FROM APPLICATION. NO EYEGLASSES.

INSTRUCTIONS FOR THE S-2 LICENSE APPLICATION

1. COMPLETELY FILL-OUT APPLICATION FORM FM-CSVlrd-01 WITH THE DATA REQUIRED, AND SIGNED WITH ATTACHED COMPLETE REQUIREMENTS. ONLY APPLICATIONS WITH COMPLETE REQUIREMENTS WILL BE PROCESSED.
2. ORIGINAL COPIES OF PRC ID CARD, PTR, AND TIN WILL BE RETURNED AFTER VALIDATION. SUBMIT CLEAR PHOTOCOPIES.
3. NEW APPLICANT IS REQUIRED TO APPLY IN PERSON AT THE PDEA COMPLIANCE SERVICE/REGIONAL UNIT. RENEWAL APPLICATION MAY BE APPLIED ONLINE.
   FOR RENEWAL APPLICATION, A REPRESENTATIVE IS ALLOWED UPON PRESENTATION OF AN AUTHORIZATION LETTER, ORIGINAL COPY OF REPRESENTATIVE'S VALID ID AND SUBMISSION OF PHOTOCOPY THEREOF.
4. IN LIEU OF PTR, FOR GOVERNMENT EMPLOYED MEDICAL PRACTITIONER, SUBMIT CERTIFICATE OF GOVERNMENT EMPLOYMENT AND ORIGINAL COPY OF A DULY-NOTARIZED AFFIDAVIT ATTESTING THAT THE S2 LICENSE GRANTED SHALL BE USED EXCLUSIVELY FOR HIS/HER GOVERNMENT PRACTICE ONLY. A GOVERNMENT MEDICAL PRACTITIONER IS EXEMPTED FROM PAYMENT OF LICENSE FEES BUT NOT REGISTRATION OF LICENSE.
5. FOR ONLINE APPLICATION, UPLOAD RECENT PICTURE. IF UNABLE, SUBMIT 2" X 2" ID PICTURE.
6. S2 LICENSE VALIDITY CONFORMS WITH PROFESSIONAL REGULATION COMMISSION (PRC) ID CARD VALIDITY. A 3-YEAR RENEWAL IS ALLOWED.
7. WRITTEN NOTIFICATION ON LOSS OF LICENSE WITHIN 48 HOURS FROM OCCURRENCE TO PDEA COMPLIANCE SERVICE. ADDITIONALLY, SUBMIT NOTARIZED AFFIDAVIT OF LOSS AND POLICE BLOTTER. RE-APPLICATION FOR A NEW LICENSE AND PAYMENT OF LICENSE FEES.
8. UNLESS SURRENDERED, SUSPENDED OR REVOKED SUCH SHALL BE RENEWED AFTER RENEWAL FROM PRC OTHERWISE A PHP 500 PER YEAR PENALTY SHALL BE IMPOSED FOR FAILURE TO RENEW.NOTIFY PDEA IN WRITING AT LEAST 60 DAYS IN ADVANCE FOR AN INTENTION TO DISCONTINUE/RETIRE THE S-2 LICENSE AUTHORITY GRANTED.

HOW TO APPLY FOR S-2 LICENSE?

STEP	APPLICANT / CLIENT	ACTIVITY	DURATION	PERSON IN CHARGE	FEES	FORM
1	Submit completely filled- out and signed application form. Submit photocopy of requirements. Present original for validation	Receive and check application form and requirements. Encode information to database. Capture photo of applicant and attach in file. Print/issue assessment slip for payment of license (2copies)	10 minutes	DDRO I	-	FM-CSVlrd-01
2	Pay S2-license fee	Issue Official Receipt (O.R.)	-	DDB Cashier	Php 500.00 / yr Php 1500/3yrs	-
3	Submit duly noted assessment (2nd copy) and present DDB Official Receipt.	Attach noted assessment to file. Encode OR# to database.	10 minutes	DDRO I	-	-
		Verify and print S2 License Certificate		DDRO III		
4	Receive S-2 License Certificate *S2 applications filed at PDEA Regional Offices to claim license at respective regional office within 60 days from date of application.*	Release S2- License Certificate. Require applicant or representative to acknowledge receipt in corresponding logbook.		RO I	-	-
END TRANSACTION						
A DANGEROUS DRUG PREPARATION IS PRESCRIBED IN A SPECIAL PRESCRIPTION FORM FOR DANGEROUS DRUGS WITH S2 LICENSE INDICATED THEREIN UNLESS OTHERWISE EXEMPTED BY A REGULATION.						

HOW TO APPLY ONLINE FOR S2-LICENSE?

STEP	APPLICANT / CLIENT	ACTIVITY	DURATION	PERSON IN CHARGE	FEES	FORM
1	Visit PDEA website: pdea.gov.ph Click 'S2 Application' Click 'Apply Now' button Login, i.e. enter username and password. If unable to recall, email pdea_cs@yahoo.com.ph				-	-
2	Enter complete data in the 'Online Application' Upload picture Click 'Print' button at the bottom of the Application after completing all the required fields. A successful printing of the form bears the Application Number at the upper right portion of the form. Sign on the space provided in the application form.				-	S2-Online Application Form with Assessment
3	Log-out of the system				-	-
4	Send the following to PDEA Compliance Service, 2nd Floor, PDEA Building, NIA Northside Road, National Government Center, Brgy. Pinyahan, Quezon City through courier or authorized representative: (a) Duly-signed printed Application Form (b) Required documents (c) Fee, in cash. For the fees, please refer to the printed form. (d) Pre-paid self addressed return envelope (if through courier) If application sent thru authorized representative, please refer to steps above on "How to Apply at the PDEA Office."				S2 License Fee: Php 500.00 / yr Php 1500/3yrs PVC ID fee: Php 100.00	-

5	Email PDEA if no feedback received within 30 days	Receive document from courier. Check contents of envelope. Forward document to DDRO on duty		RO I	-	-
		If application and requirements adequate, retrieve application in the system. Process and pay to the DDB cashier. If otherwise, inform applicant of the deficiency. Application withheld / pending.		DDRO I		
		Verify and print license certificate		DDRO III		
6	Receive S2-license Certificate through return envelope provided. If no return envelope submitted, license shall be claimed at the PDEA Office. (If application sent through authorized representative, license may be claimed immediately after payment of the S2 license fee)	Send S2 license certificate (thru return envelope).		DDRO III	-	-
END TRANSACTION						
UNLESS EXEMPTED, GENERALLY DANGEROUS DRUGS PREPARATION IS PRESCRIBED IN A SPECIAL PRESCRIPTION FORM FOR DANGEROUS DRUGS WITH S2 LICENSE INDICATED THEREIN.						

ISSUANCE OF DANGEROUS DRUGS LICENSE (S-LICENSE FOR NON-PRACTITIONER)

Schedule: Monday to Friday – 8AM to 5:00PM NO NOON BREAK

License Type	Category	Annual Fee
S-1 (Retailer)	License to sell, procure, acquire, deal in or with specified drug preparations,containing controlled chemical for retail, except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000].	P 500.00
S-3 (Retailer)	License to sell, procure, acquire, deal in or with specified (a) dangerous drugs preparations in any form; or, (b) drug preparations containing controlled chemical for retail, except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000]. Covers activities granted to S-1 License Holders including compounding and filling of prescription.	P 1,000.00
S-4 (Wholesaler)	License to sell, procure, acquire, deal in or with specified (a) dangerous drugs and their preparations in any form; (b) drug preparations, containing controlled chemicals for wholesale distribution to license holders, except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000]; and (c) controlled chemicals used in the manufacture of drugs preparations The license holder need not obtain another license of the same nature of activity for such controlled chemicals.	P 3,000.00
S-5C (Manufacturer)	License to manufacture specified (a) dangerous drugs and their preparations in any form; and (b) drug preparations containing controlled chemicals provided, that the license shall not apply to the compounding and filling of prescription in drugstores, clinics and hospitals. The license holder need not obtain another license of the same nature of activity for such controlled chemicals. May engage in wholesale distribution of that substance or class for which license was issued; may not distribute any substance or class for which it is not licensed. May conduct chemical analysis and quality control analysis with those substances for which license as a manufacturer was issued. May procure, acquire scientific apparatus or controlled laboratory equipment for manufacture of drugs. A controlled substances trader shall be categorized as a manufacturer.	P 5,000.00
S-5D (Bulk Depot / Storage)	License for bulk depot/storage of specified dangerous drugs and their preparations in any form; (b) drug preparations containing controlled chemicals except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000].; (c) controlled chemicals used in the manufacture of drug preparations; and when such address is separate and distinct from the office address of the license holder.	P 5,000.00
S-5E (Exporter)	License to export specified (a) dangerous drugs and their preparations in any form; and/or (b) drug preparation containing controlled chemicals : to foreign license holders.	P 5,000.00
S-5I (Importer)	License to import specified (a) dangerous drugs and their preparations in any form; (b) drug preparations containing controlled chemicals, except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000]; (c) controlled chemicals used in the manufacture of drugs preparations; and, (d) in vitro diagnostic reagents, buffers and analytical standards, test kits containing dangerous drug. The license holder need not obtain another license of the same nature of activity for such controlled chemicals. May engage in wholesale distribution of that substance or class for which license was issued; may not distribute any substance or class for which not licensed].	P 5,000.00
S-6 (Research/Analysis/ Instructional program)	License to conduct laboratory analysis or technical research or instructional / training program, using controlled substances or drugs containing controlled chemicals or plant sources of controlled substances. May procure, acquire syringe, scientific apparatus or laboratory equipment	P 500.00

WHAT ARE THE REQUIREMENTS FOR S-LICENSE APPLICATION? (*Original current document required. For the rest of the requirements, submit clear photocopy and present original for validation)

I. NEW APPLICATION

1. DULY ACCOMPLISHED S- LICENSE APPLICATION FORM FM-CSVlrd-O2
2. ORIGINAL & PHOTOCOPIES OF VALID MAYOR'S PERMIT & OFFICIAL RECEIPT (PRIVATE ENTITIES ONLY)
3. a. ONE TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF TAX IDENTIFICATION NUMBER (TIN) OF ENTITY OR LATEST ITR OF THE DRUG ESTABLISHMENT
   b. ONE-TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF TIN OF HEAD OF ESTABLISHMENT. FOR FOREIGN NATIONAL, PASSPORT OR ALIEN CERTIFICATE OF REGISTRY (ACR) OR ALIEN EMPLOYMENT PERMIT (AEP)
   c. ONE-TIME SUBMISSION OF ORIGINAL AND PHOTOCOPY OF TIN OF AUTHORIZED PHARMACIST
4. A.FOR CORPORATIONS/PARTNERSHIP AS APPROPRIATE
   a. ONE-TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF SECURITIES & EXCHANGE COMMISSION (SEC) CERTIFICATE OF REGISTRATION AND ARTICLES OF INCORPORATION OR CERTIFICATE OF PARTNERSHIP
   b.ORIGINAL & PHOTOCOPY OF VALID SEC GENERAL INFORMATION SHEET (GIS)-CORPORATION
   B.FOR SINGLE PROPRIETORSHIP/COOPERATIVE AS APPROPRIATE
   a. ORIGINAL & PHOTOCOPY OF VALID DEPARTMENT OF TRADE AND INDUSTRY- CERTIFICATE OF REGISTRATION OF BUSINESS NAME (CRBN)
   b. ORIGINAL & PHOTOCOPY OF VALID COOPERATIVE DEVELOPMENT AUTHORITY REGISTRATION CERTIFICATE
5. ORIGINAL & PHOTOCOPY OF VALID DEPARTMENT OF HEALTH (DOH) OR FOOD & DRUG ADMINISTRATION (FDA) LICENSE TO OPERATE CERTIFICATE AND OFFICIAL RECEIPT, AS APPROPRIATE
6. a. ONE-TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF VALID NBI CLEARANCE OF HEAD OF THE DRUG ESTABLISHMENT
   B. ORIGINAL & PHOTOCOPY OF VALID NBI CLEARANCE OF AUTHORIZED PHARMACIST
7. ONE-TIME SUBMISSION OF ORIGINAL LETTER OF AUTHORIZATION IN FAVOR OF THE PHARMACIST WHO WILL HANDLE TRANSACTIONS ON DANGEROUS DRUGS BY HEAD OF ESTABLISHMENT (PDEA FORMAT)- FM-CSVLRD-05
8. ORIGINAL & PHOTOCOPY OF VALID PRC ID CARD OF AUTHORIZED PHARMACIST
9. ORIGINAL & PHOTOCOPY OF VALID PTR OF AUTHORIZED PHARMACIST. IN LIEU OF PTR FOR GOVERNMENT EMPLOYED, CERTIFICATE OF EMPLOYMENT
7. DULY NOTARIZED & SIGNED ORIGINAL COPY OF JOINT AFFIDAVIT OF UNDERTAKING OF HEAD AND AUTHORIZED PHARMACIST (PDEA FORMAT)- FM-CSVlrd-O6
10. ONE –TIME SUBMISSION OF DULY AUTHENTICATED COMPANY PROFILE
11. ONE-TIME SUBMISSION OF DULY AUTHENTICATED ORGANIZATIONAL STRUCTURE WITH NAMES/PICTURES OF OFFICERS AND POSITIONS
12. ONE-TIME SUBMISSION OF DULY AUTHETICATED LOCATION / VICINITY MAP & PICTURE OF ESTABLISHMENT'S FACADE WITH SIGNAGE
13. ONE-TIME SUBMISSION OF DULY AUTHENTICATED FLOOR PLAN / LAY-OUT HIGHLIGHTING THE STORAGE AREA & PICTURE OF CONTROLLED DRUG STORAGE AREA (WITH DOUBLE LOCKS)
14. ONE-TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF PROOF OF OWNERSHIP OF ESTABLISHMENT'S LOCATION OR CONTRACT OF LEASE AS APPLICABLE
15. FOR IMPORTERS & EXPORTERS-ORIGINAL & PHOTOCOPY OF VALID BUREAU OF CUSTOMS' CERTIFICATE OFACCREDITATION OR REGISTRATION
16. FOR IMPORTERS, EXPORTERS & MANUFACTURERS- PROJECTED IMPORTATION / EXPORTATION/ MANUFACTURE FOR THE FORTHCOMING YEAR
17. FOR IMPORTERS, EXPORTERS & MANUFACTURERS VALID FDA CERTIFICATE OF PRODUCT REGISTRATION-CPR OF DANGEROUS DRUG PREPARATIONS
18. FOR IMPORTERS, EXPORTERS & MANUFACTURERS- ONE-TIME SUBMISSION OF PICTURE OF CONTROLLED FINISHED DANGEROUS DRUGS PREPARATIONS, A COPY OF EACH PRODUCT'S INSERT/LITERATURE AND BOX LABEL

II. RENEWAL APPLICATION

1. DULY ACCOMPLISHED S- LICENSE APPLICATION FORM FM-CSVlrd-O2
2. ORIGINAL& PHOTOCOPIES OF VALID MAYOR'S PERMIT & OFFICIAL RECEIPT (PRIVATE ENTITIES ONLY)
3. FOR CORPORATIONS/PARTNERSHIP AS APPROPRIATE- ORIGINAL & PHOTOCOPIES OF VALID SECURITIES & EXCHANGE COMMISSION (SEC) GENERAL INFORMATION SHEET (GIS) OR CERTIFICATE OF PARTNERSHIP
   FOR SINGLE PROPRIETORSHIP/COOPERATIVE, AS APPROPRIATE
   a. ORIGINAL & PHOTOCOPY OF VALID DEPARTMENT OF TRADE AND INDUSTRY- CERTIFICATE REGISTRATION OF BUSINESS NAME (CRBN)
   b. ORIGINAL & PHOTOCOPY OF VALID COOPERATIVE DEVELOPMENT AUTHORITY REGISTRATION CERTIFICATE
4. ORIGINAL & PHOTOCOPY OF VALID DEPARTMENT OF HEALTH(DOH) OR FOOD & DRUG ADMINISTRATION (FDA) LICENSE TO OPERATE CERTIFICATE AND OFFICIAL RECEIPT
5. ORIGINAL & PHOTOCOPY OF VALID NBI CLEARANCE OF AUTHORIZED PHARMACIST
6. ORIGINAL & PHOTOCOPY OF VALID PRC ID CARD OF AUTHORIZED PHARMACIST
7. ORIGINAL & PHOTOCOPY OF VALID PTR OF AUTHORIZED PHARMACIST. IN LIEU OF PTR FOR GOVERNMENT EMPLOYED, CERTIFICATE OF EMPLOYMENT
8. DULY NOTARIZED & SIGNED ORIGINAL COPY OF JOINT AFFIDAVIT OF UNDERTAKING OF HEAD AND AUTHORIZED PHARMACIST (PDEA FORMAT) FM-CSVlrd-O6
9. LATEST SUBMITTED SEMI-ANNUAL REPORT AND AUTOMATED REGISTER OR RECORD BOOK OF DANGEROUS DRUG TRANSACTIONS
10. PHOTOCOPY OF EXPIRED PDEA LICENSE TO HANDLE
11. FOR IMPORTER/EXPORTER/ MANUFACTURER- PROJECTION FOR FORTHCOMING YEAR
12. IF WITH CHANGES, ORIGINAL & PHOTOCOPY OF VALID NBI CLEARANCE OF HEAD OF DRUG ESTABLISHMENT
13. IF WITH CHANGES,ORIGINAL LETTER OF AUTHORIZATION IN FAVOR OF THE PHARMACIST WHO WILL HANDLE TRANSACTIONS ON DANGEROUS DRUGS BY HEAD OF ESTABLISHMENT (PDEA FORMAT) FM-CSVlrd-O5
14. FOR IMPORTER/EXPORTER- ORIGINAL & PHOTOCOPY SUBMISSION DEPENDING ON VALIDITY OF BUREAU OF CUSTOMS' CERTIFICATE OF ACCREDITATION OR REGISTRATION
15. IF WITH CHANGES, DULY AUTHENTICATED COMPANY PROFILE
16. IF WITH CHANGES, DULY AUTHENTICATED ORGANIZATIONAL STRUCTURE WITH NAMES/PICTURES OF OFFICERS & POSITIONS
17. IF WITH CHANGES, DULY AUTHENTICATED LOCATION/VICINITY MAP& PICTURE OF ESTABLISHMENT'S FAÇADE WITH SIGNAGE
18. IF WITH CHANGES, DULY AUTHENTICATED FLOOR PLAN/LAYOUT HIGHLIGHTING STORAGE AREA & PICTURE OF CONTROLLED DRUG STORAGE AREA (WITH DOUBLE LOCKS)
19. IF WITH CHANGES, ORIGINAL & PHOTOCOPY OF PROOF OF OWNERSHIP OF ESTABLISHMENT'S LOCATION OR CONTRACT OF LEASE AS APPLICABLE
20. FOR IMPORTERS, EXPORTERS & MANUFACTURERS- IF WITH CHANGES, SUBMIT PICTURE OF CONTROLLED FINISHED DANGEROUS DRUGS PREPARATIONS, A COPY OF EACH PRODUCT'S INSERT/LITERATURE AND BOX LABEL

INSTRUCTIONS FOR S-LICENSE APPLICATION

1. COMPLETELY FILL-OUT APPLICATION FORM FM-CSVlrd-02 WITH THE DATA REQUIRED, AND SIGNED WITH ATTACHED COMPLETE REQUIREMENTS. ONLY APPLICATIONS WITH COMPLETE REQUIREMENTS WILL BE PROCESSED.
2. REQUIREMENTS (LEGAL SIZE) ARRANGED CONSECUTIVELY BASED ON THE SEQUENCE ARRANGEMENT INDICATED IN THE APPLICATION FORM WITH PROPER TABS.
3. APPLICATION DOCUMENTS SUBMITTED IN GREEN FOLDER.
   FOR MULTIPLE LICENSE APPLICATIONS ex. S & P- APPLICATIONS – SUBMIT IN YELLOW FOLDER
4. ORIGINAL COPIES OF DOCUMENTS WILL BE RETURNED AS APPROPRIATE.
5. ONE –TIME SUBMISSION OF DOCUMENTS DEPENDING ON THEIR VALIDITY AND MATERIAL CHANGES FOR REQUIREMENTS.
6. FOR RENEWAL APPLICATION-APPLY 3 MONTHS PRIOR TO EXPIRATION OF LICENSE.
7. A GOVERNMENT INSTITUTION IS EXEMPTED FROM PAYMENT OF LICENSE FEES BUT NOT REGISTRATION OF LICENSE.

8. RENEWAL APPLICATION- A REPRESENTATIVE IS ALLOWED UPON PRESENTATION OF AN AUTHORIZATION LETTER, ORIGINAL COPY OF REPRESENTATIVE'S VALID ID AND SUBMISSION OF PHOTOCOPY THEREOF.
9. WRITTEN NOTIFICATION ON LOSS OF LICENSE WITHIN 48 HOURS FROM OCCURRENCE TO PDEA COMPLIANCE SERVICE/REGIONAL UNIT. ADDITIONALLY SUBMIT NOTARIZED AFFIDAVIT OF LOSS AND POLICE BLOTTER.
10. UNLESS SURRENDERED, SUSPENDED OR REVOKED SUCH SHALL BE RENEWED OTHERWISE A SURCHARGE OF 50% OF THE REQUIRED ANNUAL FEE, CUMULATIVELY BY YEAR NOT PAID SHALL BE IMPOSED ON TOP OF THE CURRENT ANNUAL FEE.NOTIFY PDEA IN WRITING AT LEAST 60 DAYS IN ADVANCE FOR AN INTENTION TO DISCONTINUE/RETIRE THE S-LICENSE AUTHORITY GRANTED.A LICENSE RETIREMENT INSPECTION WILL BE CONDUCTED.

HOW TO APPLY FOR S-LICENSE -NEW APPLICATION?

STEP	APPLICANT/ CLIENT	ACTIVITY	DURATION OF ACTIVITY	PERSON IN CHARGE	FEES
1	Submit completely filled-out and signed application form (FM-CSVlrd-02). Arrange all requirements consecutively and neatly in a color-coded folder: S License Application – **Green** Multiple License Applications – **Yellow**	Receive and check application with requirements. Interview. Encode information in database. Print/issue assessment slip.	30 minutes	DDRO II	-
2	Request preferred date of inspection.	Schedule date of inspection. Assign inspector. Print/issue Inspection Order. Provide copy to client.	5 minutes	DD, CS	-
3	Accompany inspector on scheduled inspection date. Sign in the PSI report to signify concurrence of findings and acknowledgement.	Conduct Physical Security Inspection (PSI) and orientation on scheduled date. Provide client with copy of PSI Report. Submit report to D,CS through C, CID within 3 days from date of inspection.	1 hour exclusive of travel time	DDRO / RCO	-
4	Report to PDEA 3 days after inspection date.	Retrieve application folder with noted report from CS Records Officer. Check if approved or otherwise. Require submission of lacking requirement, if any. Issue assessment slip.	15 minutes	DDRO II	-
5	Pay License fee as appropriate.	Issue Official Receipt	-	DDB Cashier	500.00(S1)/yr 1,000.00(S3)/yr 3,000.00(S4)/yr 5,000.00(S5C)/yr 5,000.00(S5D)/yr 5,000.00(S5E)/yr 5,000.00(S5I)/yr

					500.00(S6)/yr
6	Submit duly noted assessment and present Official Receipt. Receive claim slip/temporary license.	Encode O.R. # in database. Re-orient authorized pharmacist on regulatory control, if necessary. Issue claim slip/temporary license and CS advisory.	10 minutes	DDRO II	-
		Batch print licenses.	Within 15 working days	Admin Asst	-
7	Claim license on specified date. Submit claim slip	Receive and check claim slip. Require submission of lacking requirement, if any. Note released license in designated logbook. File application folder.	10 minutes	RO	-
END TRANSACTION					
A SEPARATE PERMIT APPROVAL IS REQUIRED PRIOR TO IMPORT/EXPORT/MANUFACTURE/LOCAL TRANSFER OF DD/DDPs, UNLESS SPECIFICALLY EXEMPTED.					

HOW TO APPLY FOR S-LICENSE RENEWAL APPLICATION?

Please refer to Steps 1, 5, 6 and 7 above.

ISSUANCE OF CONTROLLED PRECURSORS AND ESSENTIAL CHEMICALS (P-LICENSE)

Schedule: Monday to Friday – 8AM to 5:00PM NO NOON BREAK

License Type	License Holder	Annual Fee
P-1 (Retailer)	License to sell, procure, acquire, dealing in or with specified controlled chemical or their mixtures or preparations, except drugs containing controlled chemicals, for retail sale.	P 500.00
P-3 (End-user)	End-user of specified controlled chemicals. NOT authorize to resell the controlled chemical. Authorized to purchase from local sources only	P 2,500.00
P-4 (Wholesaler)	License to sell, procure, acquire, dealing in or with specified controlled chemical except drugs containing controlled chemicals for wholesale distribution to license holders	P 3,000.00
P-5C (Manufacturer)	License to manufacture or recycle specified controlled chemicals or chemical mixtures excluding drugs containing controlled chemicals. May distribute that substance or class for which license was issued; may not distribute any substance or class for which not licensed. May conduct chemical analysis and quality control analysis with those substances for which license as a manufacturer was issued. May procure and acquire scientific apparatus or laboratory equipment for manufacture or recycling of chemical.	P 5,000.00
P-5D (Bulk depot / Storage)	License for bulk depot/storage the address is separate and distinct from the office address of the license holder.	P 5,000.00
P-5E (Exporter)	License to export specified controlled chemicals excluding drug preparations containing controlled chemicals	P 5,000.00
P-5I (Importer)	License to import specified controlled chemicals. May distribute that substance for which license was issued; may not distribute any substance for which not licensed].	P 5,000.00
P-5IM (Importer/ End-user)	License to import specified controlled chemicals, as End-user. Acquisition of controlled chemical shall be made through importation. The license holder is authorized also to acquire controlled chemical from local sources. Not authorized to resell the chemicals acquired.	P 5,000.00
P-6 (Research/Analysis/ Instructional program)	License to conduct laboratory analysis or technical research or instructional / training program, using controlled chemicals May procure, acquire laboratory equipment	P 500.00

WHAT ARE THE REQUIREMENTS FOR P-LICENSE APPLICATION? (*Original current document required. For the rest of the requirements, submit clear photocopies and present original copy for validation)

I. NEW APPLICATION

1. DULY ACCOMPLISHED P- LICENSE APPLICATION FORM FM-CSVlrd-O3
2. ORIGINAL & PHOTOCOPIES OF VALID MAYOR'S PERMIT & OFFICIAL RECEIPT (PRIVATE ENTITIES ONLY)
3. a. ONE TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF TAX IDENTIFICATION NUMBER (TIN) OF ENTITY OR LATEST ITR OF THE ESTABLISHMENT
   b. ONE-TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF TIN OF HEAD OF ENTITY. FOR FOREIGN NATIONAL, PASSPORT OR ALIEN CERTIFICATE OF REGISTRY (ACR) OR ALIEN EMPLOYMENT PERMIT (AEP)
   c. ONE-TIME SUBMISSION OF ORIGINAL AND PHOTOCOPY OF TIN OF AUTHORIZED SIGNATORY-
4. A.FOR CORPORATIONS/PARTNERSHIP AS APPROPRIATE –
   a. ONE-TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF SECURITY & EXCHANGE COMMISSION (SEC) CERTIFICATE OF REGISTRATION AND ARTICLES OF INCORPORATION OR CERTIFICATE OF PARTNERSHIP
   b. ORIGINAL & PHOTOCOPY OF VALID SEC GENERAL INFORMATION SHEET (GIS)-CORPORATION

   B.FOR SINGLE PROPRIETORSHIP/COOPERATIVE AS APPROPRIATE-
   a. ORIGINAL & PHOTOCOPY OF VALID DEPARTMENT OF TRADE AND INDUSTRY- CERTIFICATE OF REGISTRATION OF BUSINESS NAME (CRBN)
   b. ORIGINAL & PHOTOCOPY OF VALID COOPERATIVE DEVELOPMENT AUTHORITY REGISTRATION CERTIFICATE
5. FOR ECOZONE APPLICANT ONLY- DEPENDING ON VALIDITY, ONE-TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF VALID CERTIFICATE OF REGISTRATION/SBMA CERTIFICATE OF REGISTRATION/CLARK CERTIFICATE OF REGISTRATION & TAX EXEMPTION /APPLICABLE ECOZONE CERTIFICATE OF REGISTRATION, AS APPROPRIATE
6. a. ONE-TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF VALID NBI CLEARANCE OF HEAD OF THE ENTITY
   B. ORIGINAL & PHOTOCOPY OF VALID NBI CLEARANCE OF AUTHORIZED SIGNATORY
7. ONE-TIME SUBMISSION OF ORIGINAL LETTER OF AUTHORIZATION IN FAVOR OF THE SIGNATORY WHO WILL HANDLE TRANSACTIONS ON CONTROLLED CHEMICAL BY HEAD OF ENTITY (PDEA FORMAT) FM-CSVlrd-O7
8. DULY NOTARIZED & SIGNED ORIGINAL COPY OF JOINT AFFIDAVIT OF UNDERTAKING OF HEAD AND AUTHORIZED SIGNATORY (PDEA FORMAT) FM-CSVlrd-O8
9. ONE –TIME SUBMISSION OF DULY AUTHENTICATED COMPANY PROFILE
10. ONE-TIME SUBMISSION OF DULY AUTHENTICATED ORGANIZATIONAL STRUCTURE WITH NAMES/PICTURES OF OFFICERS AND POSITIONS
11. ONE-TIME SUBMISSION OF DULY AUTHETICATED LOCATION / VICINITY MAP & PICTURE OF ESTABLISHMENT'S FACADE WITH SIGNAGE
12. ONE-TIME SUBMISSION OF DULY AUTHENTICATED FLOOR PLAN / LAY-OUT HIGHLIGHTING THE STORAGE AREA & PICTURE OF CONTROLLED CHEMICAL STORAGE AREA (WITH DOUBLE LOCKS)
13. ONE-TIME SUBMISSION OF ORIGINAL & PHOTOCOPY OF PROOF OF OWNERSHIP OF ESTABLISHMENT'S LOCATION OR CONTRACT OF LEASE AS APPLICABLE
14. FOR IMPORTERS & EXPORTERS-ORIGINAL & PHOTOCOPY OF VALID BUREAU OF CUSTOMS' CERTIFICATE OF ACCREDITATION OR REGISTRATION
15. FOR IMPORTERS, EXPORTERS & MANUFACTURERS- PROJECTED IMPORTATION / EXPORTATION/MANUFACTURE FOR THE FORTHCOMING YEAR
16. FOR IMPORTERS, EXPORTERS & MANUFACTURERS- ONE-TIME SUBMISSION OF CERTIFIED MATERIAL SAFETY DATA SHEET (MSDS) OF CHEMICAL MIXTURES
17. FOR IMPORTERS, EXPORTERS, & MANUFACTURERS- ONE TIME SUBMISSION OF PICTURE/S OF CPECS/CPECS MIXTURES AND LABELLING MATERIALS HANDLED

II. RENEWAL APPLICATION

1. DULY ACCOMPLISHED P- LICENSE APPLICATION FORM FM-CSVlrd-O3
2. ORIGINAL& PHOTOCOPIES OF VALID MAYOR'S PERMIT & OFFICIAL RECEIPT-(PRIVATE ENTITIES ONLY)

3. A.FOR CORPORATIONS/PARTNERSHIP AS APPROPRIATE – ORIGINAL & PHOTOCOPIES OF VALID SECURITIES & EXCHANGE COMMISSION (SEC)GENERAL INFORMATION SHEET (GIS)-CORPORATION OR CERTIFICATE OF PARTNERSHIP
   B.FOR SINGLE PROPRIETORSHIP/ COOPERATIVE, AS APPROPRIATE
   a. ORIGINAL & PHOTOCOPY SUBMISSION DEPENDING ON VALIDITY OF A VALID DEPARTMENT OF TRADE AND INDUSTRY- CERTIFICATE REGISTRATION OF BUSINESS NAME (CRBN)
   b. ORIGINAL & PHOTOCOPY SUBMISSION DEPENDING ON VALIDITY OF A VALID COOPERATIVE DEVELOPMENT AUTHORITY REGISTRATION CERTIFICATE
4. ORIGINAL & PHOTOCOPY OF VALID NBI CLEARANCE OF AUTHORIZED SIGNATORY
5. DULY NOTARIZED & SIGNED ORIGINAL COPY OF JOINT AFFIDAVIT OF UNDERTAKING OF HEAD AND AUTHORIZED SIGNATORY (PDEA FORMAT) FM-CSVlrd-O8
6. PHOTOCOPY OF EXPIRED PDEA LICENSE TO HANDLE
7. LATEST SUBMITTED SEMI-ANNUAL REPORT AND AUTOMATED REGISTER OR RECORD BOOK OF CONTROLLED PRECURSORS & ESSENTIAL CHEMICALS TRANSACTIONS
8. FOR IMPORTER/EXPORTER/ MANUFACTURER- PROJECTION FOR FORTHCOMING YEAR
9. FOR IMPORTER/EXPORTER- ORIGINAL & PHOTOCOPY SUBMISSION DEPENDING ON VALIDITY OF BUREAU OF CUSTOMS' CERTIFICATE OF ACCREDITATION OR REGISTRATION
10. IF WITH CHANGES, ORIGINAL & PHOTOCOPY OF VALID NBI CLEARANCE /TIN OR PASSPORT/ACR/AEP OF HEAD OF DRUG ENTITY
11. IF WITH CHANGES, ORIGINAL LETTER OF AUTHORIZATION IN FAVOR OF THE AUTHORIZED SIGNATORY WHO WILL HANDLE TRANSACTIONS ON CONTROLLED CHEMICALS BY HEAD OF ESTABLISHMENT (PDEA FORMAT) FM-CSVlrd-O7
12. FOR IMPORTER/EXPORTER- ORIGINAL & PHOTOCOPY SUBMISSION DEPENDING ON VALIDITY OF A VALID BUREAU OF CUSTOMS' CERTIFICATE OF ACCREDITATION OR REGISTRATION
13. IF WITH CHANGES, DULY AUTHENTICATED COMPANY PROFILE
14. IF WITH CHANGES, DULY AUTHENTICATED ORGANIZATIONAL STRUCTURE WITH NAMES/PICTURES OF OFFICERS & POSITIONS
15. IF WITH CHANGES, DULY AUTHENTICATED LOCATION/VICINITY MAP & PICTURE OF ESTABLISHMENT'S FAÇADE WITH SIGNAGE
16. IF WITH CHANGES, DULY AUTHENTICATED FLOOR PLAN/LAYOUT HIGHLIGHTING STORAGE AREA & PICTURE OF CONTROLLED CHEMICAL STORAGE AREA (WITH DOUBLE LOCKS)
17. IF WITH CHANGES, ORIGINAL & PHOTOCOPY OF PROOF OF OWNERSHIP OF ESTABLISHMENT'S LOCATION OR CONTRACT OF LEASE AS APPLICABLE
18. IF WITH CHANGES- FOR IMPORTERS, EXPORTERS & MANUFACTURERS- CERTIFIED MATERIAL SAFETY DATA SHEET (MSDS) OF CHEMICAL MIXTURES
19. IF WITH CHANGES-FOR IMPORTERS, EXPORTERS, & MANUFACTURERS- PICTURE/S OF CPECS/CPECS MIXTURES AND LABELLING MATERIALS HANDLED

INSTRUCTIONS FOR P-LICENSE APPLICATION

1. COMPLETELY FILL-OUT APPLICATION FORM FM-CSVlrd-03 WITH THE DATA REQUIRED, AND SIGNED WITH ATTACHED COMPLETE REQUIREMENTS. ONLY APPLICATIONS WITH COMPLETE REQUIREMENTS WILL BE PROCESSED.
2. REQUIREMENTS (LEGAL SIZE) ARRANGED CONSECUTIVELY BASED ON THE SEQUENCE ARRANGEMENT INDICATED IN THE APPLICATION FORM
3. APPLICATION DOCUMENTS SUBMITTED IN RED FOLDER.
   FOR MULTIPLE LICENSE APPLICATIONS ex. S & P- APPLICATIONS – SUBMIT IN YELLOW FOLDER
4. ORIGINAL COPIES OF DOCUMENTS WILL BE RETURNED AS APPROPRIATE.
5. ONE –TIME SUBMISSION OF DOCUMENTS DEPENDING ON THEIR VALIDITY AND MATERIAL CHANGES FOR REQUIREMENTS.
6. FOR RENEWAL APPLICATION-APPLY 3 MONTHS PRIOR TO EXPIRATION OF LICENSE.
7. A GOVERNMENT INSTITUTION IS EXEMPTED FROM PAYMENT OF LICENSE FEES BUT NOT REGISTRATION OF LICENSE.
8. RENEWAL APPLICATION- A REPRESENTATIVE IS ALLOWED UPON PRESENTATION OF AN AUTHORIZATION LETTER, ORIGINAL COPY OF REPRESENTATIVE'S VALID ID AND SUBMISSION OF PHOTOCOPY THEREOF.
9. WRITTEN NOTIFICATION ON LOSS OF LICENSE WITHIN 48 HOURS FROM OCCURRENCE TO PDEA COMPLIANCE SERVICE. ADDITIONALLY SUBMIT NOTARIZED AFFIDAVIT OF LOSS AND POLICE BLOTTER.

10. UNLESS SURRENDERED, SUSPENDED OR REVOKED SUCH SHALL BE RENEWED OTHERWISE A SURCHARGE OF 50% OF THE REQUIRED ANNUAL FEE, CUMULATIVELY BY YEAR NOT PAID SHALL BE IMPOSED ON TOP OF THE CURRENT ANNUAL FEE.NOTIFY PDEA IN WRITING AT LEAST 60 DAYS IN ADVANCE FOR AN INTENTION TO DISCONTINUE/RETIRE THE P-LICENSE AUTHORITY GRANTED.

HOW TO APPLY FOR P-LICENSE -NEW APPLICATION?

STEP	APPLICANT/ CLIENT	ACTIVITY	DURATION OF ACTIVITY	PERSON IN CHARGE	FEES
1	Submit completely filled-out and signed application form (FM-CSVIrd-03) and arrange all requirements consecutively and neatly in a long color-coded folder: P License Application – **Red** Multiple License Application – **Yellow**	Receive and check application with requirements. Interview. Encode information in database. Print/issue assessment slip.	30 minutes	DDRO II	-
2	Signify preferred date of inspection.	Schedule date of inspection. Assign inspector. Print/issue Inspection Order. Provide copy to client.	5 minutes	DD, CS	
3	Accompany inspector on scheduled inspection date. Sign in the PSI report to signify concurrence of findings and acknowledgement.	Conduct Physical Security Inspection (PSI) and orientation on scheduled date. Provide client with copy of PSI Report. Submit report to D,CS through C, CID within 3 days from date of inspection.	1 hour exclusive of travel time	DDRO / RCO	
4	Report to PDEA 3 days after inspection date	Retrieve application folder with noted report from CS Records Officer. Check if approved or otherwise. Require submission of lacking requirement, if any. Issue assessment slip.	15 minutes	DDRO II	
5	Pay License fee	Issue Official Receipt	-	DDB Cashier	500.00(P1)/yr 2,500.00(P3)/yr 3,000.00(P4)/yr 5,000.00(P5C)/yr 5,000.00(P5D)/yr 5,000.00(P5E)/yr 5,000.00(P5I)/yr 500.00(P6)/yr
6	Submit duly noted assessment and present Official Receipt. Receive claim slip/temporary license.	Encode O.R. # in database. Re-orient authorized signatory on regulatory control, if necessary. Issue claim slip/temporary license and CS advisory.	10 minutes	DDRO II	-

		Batch print licenses	Within 15 working days	Admin Asst	
7	Claim license on specified date. Submit claim slip	Receive and check claim slip. Require submission of lacking requirement, if any. Note released license in designated logbook. File application folder.	10 minutes	RO	
END TRANSACTION					
A SEPARATE PERMIT APPROVAL IS NECESSARY PRIOR TO IMPORT/EXPORT of CPECs, UNLESS SPECIFICALLY EXEMPTED					

HOW TO APPLY FOR P-LICENSE- RENEWAL APPLICATION?

Please refer to Steps 1, 5, 6 and 7 above.

ISSUANCE OF LOCAL ORDER PERMIT (LOP)

Schedule: Monday to Friday - 8AM to 5PM NO NOON BREAK

WHO IS QUALIFIED TO APPLY LOP FOR THE TRANSFER OF STOCK OF DANGEROUS DRUGS (DD) AND/OR DANGEROUS DRUG PREPARATIONS (DDPs)? A PDEA- registered entity who intends to purchase / acquire / surrender to PDEA specified [a] DD / DDPs with the exception of drugs per Board Regulation No.1, Series 2014 [b] Table 1 controlled chemicals used in the manufacture of drugs.

WHO IS QUALIFIED TO APPLY LOP FOR THE MANUFACTURE OF DDP? A PDEA- registered S5C-licensed entity who intends to manufacture specified [a] DD / DDPs and [b] drug preparations containing Table 1 controlled chemical as the only active medicinal ingredient or contains Table 1 controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient.

WHAT ARE THE REQUIREMENTS?

1. Duly filled-out and signed LOP application
2. Current S-License
3. Current PRC ID card and PTR of authorized Pharmacist

HOW TO APPLY FOR LOCAL ORDER PERMIT (LOP)?

STEP	APPLICANT / CLIENT	ACTIVITY	DURATION	PERSON IN CHARGE	FEES	FORM
1	Submit completely filled-out and signed LOP application FM-CSV-lrd-09 (2 copies)	Receive and check form for appropriateness and content. Process/encode information in database.	15 minutes	DDRO I	-	FM-CSV-lrd-09
2	Claim and receive approved LOP.	Print approved permit (Seller and Purchaser copies) To be checked by Supervisor prior to release to client			-	Approved LOP
END TRANSACTION						

INSTRUCTIONS FOR LOCAL ORDER PERMIT (LOP) APPLICATION:

1. ACCOMPLISH 2 COPIES OF APPLICATION FORM - FM-CSVlrd-O9.
2. ONLY PROPERLY FILLED-OUT WITH CORRECT DATA AS REQUIRED WILL BE PROCESSED. ANY CORRECTIONS PRIOR TO APPROVAL SHALL BE SIGNED BY THE AUTHORIZED PHARMACIST.
3. COMPLETELY FILL-OUT DATA REQUIRED AND SIGN i.e. DATE OF APPLICATION, SUPLLIER'S COMPLETE NAME, ADDRESS AND VALID S-LICENSE, DANGEROUS DRUG (DD) PREPARATION INCLUDING BRAND AND GENERIC NAME, DOSAGE STRENGTH AND FORM, PACKAGING PRESENTATION, QUANTITY ORDERED, COMPLETE NAME OF AUTHORIZED PHARMACIST AND DRUG ESTABLISHMENT, VALID S-LICENSE INDICATING VALIDITY.
4. A MAXIMUM OF FIVE ITEMS PER LOP FOR A SINGLE SUPPLIER MAY BE APPLIED.
5. PRESENT VALID PRC ID AND PTR OF AUTHORIZED PHARMACIST FOR THE FIRST APPLICATION DURING THE CURRENT YEAR.
6. EVERY TRANSFER OF DANGEROUS DRUGS (DD) SHALL BE COVERED WITH AN APPROVED PDEA PERMIT EXCEPT WHEN DISPENSING TO A PATIENT WHICH WILL REQUIRE AN APPROPRIATE PRESCRIPTION.

7. VALIDITY OF AN APPROVED PERMIT IS ONE MONTH.
8. NO ALTERATION ALLOWED AFTER APPROVAL. LOP WILL BE CANCELLED.
9. A REPRESENTATIVE IS ALLOWED UPON PRESENTATION OF AN AUTHORIZATION LETTER, ORIGINAL COPY OF REPRESENTATIVE'S VALID ID AND SUBMISSION OF PHOTOCOPY THEREOF.
10. IF TRANSACTION WAS NOT EFFECTED WITHIN PERIOD OF VALIDITY OF LOP, SURRENDER APPROVED LOP (PURCHASER & SUPPLIER COPY) TO PDEA-CS IMMEDIATELY FOR CANCELLATION.
11. WRITTEN NOTIFICATION ON LOSS OF LOCAL ORDER WITHIN 48 HOURS FROM OCCURRENCE TO PDEA COMPLIANCE SERVICE. ADDITIONALLY ,SUBMIT NOTARIZED AFFIDAVIT OF LOSS AND POLICE BLOTTER.

ISSUANCE OF IMPORT PERMIT (IP), SPECIAL PERMIT (SP), AND EXPORT PERMIT (EP)

Schedule: Monday to Friday – 8AM to 5PM NO NOON BREAK

WHO IS QUALIFIED TO APPLY AN IP? A PDEA-registered importer of Dangerous Drugs (DD) and/or their preparations. Such is applied for every specific importation of the controlled substance.

WHO IS QUALIFIED TO APPLY A SP? A PDEA-registered importer of [a] Controlled Precursors and Essential Chemicals (CPECs) and their mixtures and [b] Drug preparations containing Table 1 controlled chemical. Such is applied for every specific importation of the controlled substance.

WHO IS QUALIFIED TO APPLY AN EP? A PDEA-registered exporter of [a] DD and/or their preparations, [b] Drug preparations containing Table 1 controlled chemical, [c] CPECs. Such is applied for every specific exportation of the controlled substance.

WHAT ARE THE REQUIREMENTS FOR IMPORTATION/EXPORTATION OF A CONTROLLED SUBSTANCE?

		IP	SP	EP-DD	EP-CPECs
1.	Lodged appropriate permit application and requirements through the Phil. National Single Window (PNSW) site. Please visit nsw.gov.ph for details.	✓	✓	✓	✓
2.	Invoice /Proforma Invoice / Purchase Order	✓	✓	-	✓
3.	Certificate of Product Registration (CPR)-DD/IF NO CPR-APPLICATION OF CPR TO FDA	✓	-	✓	-
4.	Material Safety Data Sheet (MSDS)-CPECs	-	✓	-	✓
5.	Import Permit issued by the Government (Competent Authority) of importing country	-	-	✓	
6.	End-User Declaration (EUD)-Importing country				✓

INSTRUCTIONS FOR IMPORT/EXPORT TRANSACTIONS OF CONTROLLED SUBSTANCES

1. REGISTER AT THE PNSW SITE (NSW.GOV.PH) TO LODGE APPLICATION.
2. UPLOAD/ATTACH REQUIREMENTS (PDF FILE).
3. APPLICATIONS SHALL BE MADE AT LEAST FIFTEEN (15) DAYS BEFORE TRANSACTION IS TO TAKE PLACE.
4. AN APROVED PERMIT IS VALID FOR SINGLE SHIPMENT ONLY.
5. AN APPROVED PERMIT WILL REQUIRE PAYMENT OF REGULATORY FEE DEPENDING ON THE VOLUME OF SHIPMENT.
6. VALIDITY OF AN APPROVED IMPORT/SPECIAL PERMIT IS 6 MONTHS FROM APPROVAL DATE.
7. VALIDITY OF AN APPROVED EXPORT PERMIT IS 3 MONTHS FROM APPROVAL DATE.
8. WRITTEN NOTIFICATION FOR MATERIAL CHANGES ARE REQUIRED TO BE SUBMITTED TO PDEA-COMPLIANCE SERVICE WITHIN 5 WORKING DAYS FROM OCCURRENCE.
9. A PERMIT IS NOT VALID FOR ARTICLES ARRIVING BEFORE DATE OF APPROVAL.
10. SUBMIT NOTICE OF ARRIVAL OF SHIPMENT AT THE PORT OF ENTRY AND WAREHOUSE AT LEAST 5 WORKING DAYS TO PDEA-COMPLIANCE SERVICE. VERIFICATION INSPECTION WILL BE CONDUCTED.
11. ALL SHIPMENTS TO BE TRANSPORTED THROUGH THE BUREAU OF CUSTOMS.

12. WRITTEN NOTIFICATION ON LOSS OF IMPORT/EXPORT PERMIT AND SHIPMENT WITHIN 48 HOURS FROM OCCURRENCE. ADDITIONALLY SUBMIT NOTARIZED AFFIDAVIT OF LOSS AND POLICE BLOTTER.

HOW TO APPLY FOR AN IMPORT/EXPORT PERMIT FOR CONTROLLED SUBSTANCES?

STEP	APPLICANT/ CLIENT	ACTIVITY	DURATION OF ACTIVITY	PERSON IN CHARGE	FORM
1	Register at the Philippine National Single Window (PNSW) to lodge appropriate application online and upload corresponding requirements (PDF File) to the PNSW site nsw.gov.ph. In cases when PNSW is not accessible, submit application and corresponding requirements (hard copy) to PDEA-Compliance Service.	Retrieve application and check documents for completeness and content.	10-30 minutes	IMPEX DDRO II	Import Permit/Special Permit/Export Permit
2	View status of application at PNSW site and receives email for the payment of regulatory fee.	Update regulatory fee. Generate and send email for the payment of regulatory fee.	within 15 working days	IMPEX DDRO II PNSW	Regulatory Fee PhP500(≤1000kg/l) Php1000(>1000-<5000kg/l) Php1500(≥5000kg/l)
3	Present PNSW generated application. Pay regulatory fee.	Issue Official Receipt. Encode O.R. # in the PNSW.		DDB Secretariat Cashier	
5	Present Official Receipt.	Indicate/Note O.R. # and date to the approved permit.	5 minutes	IMPEX DDRO II	
6	Claim approved permit and sign in the release portion.	Release approved permit.	10 minutes	IMPEX DDRO II	
END OF TRANSACTION					

HOW TO APPLY FOR AN IMPORT PERMIT FOR DANGEROUS DRUGS PREPARATIONS INTENDED FOR MEDICAL MISSION?

STEP	APPLICANT/ BENEFICIARY	ACTIVITY	DURATION OF ACTIVITY	PERSON IN CHARGE	FORM
1	Register at the Philippine National Single Window (PNSW) to lodge appropriate application online and upload corresponding requirements (PDF File) to the PNSW site nsw.gov.ph. In cases when PNSW is not accessible, submit application and corresponding requirements (hard copy) to PDEA-Compliance Service. Note: Requirements : a) Legal document/s establishing bona fide of company/entity (beneficiary) b) Acknowledgement letter from partner S3 licensed registered pharmacist or S2 licensed physician to handle safekeeping, dispensing, recording of donated controlled substances and reporting of the same to PDEA immediately upon culmination of the activity c) Endorsement from respective Local Government Unit d) Deed of Donation with complete list of medicines / substances donated e) Export Authorization from competent authority where DDPs originated No regulatory fee required.	Retrieve application and check documents for completeness and content. Verifies and receives application. Process Import Permit ASAP.	10-30 minutes	IMPEX DDRO II	Import Permit

2	Claim approved permit and sign in the release portion.	Release approved permit.	5- 10 minutes	Impex DDRO II	
3	Send copy to foreign partner/benefactor.			Applicant beneficiary	
END OF TRANSACTION					

CONDUCT OF VERIFICATION OF ARRIVAL OF A DANGEROUS DRUG AND/OR THEIR PREPARATIONS

Schedule of verification: Thursday or Friday

WHO MAY REQUEST FOR VERIFICATION OF ARRIVAL OF DANGEROUS DRUG SHIPMENT? A PDEA- registered Importer whose shipment of specified Dangerous Drug, and/or their preparation or a Table 1 controlled chemical used in the manufacture of a pharmaceutical product covered with an approved Import Permit arrives at the Philippine Port of entry and subsequently released by Bureau of Customs and the specified shipment is already at the entity's warehouse/storage area.

WHAT ARE THE REQUIREMENTS FOR VERIFICATION?

1. First Notice of Arrival of (a) Dangerous Drug and/or their preparation, (b) drug preparation containing Table 1 controlled chemical, (c) Table 1 controlled chemical used in the manufacture of drugs with proof of arrival at port of entry.
2. Second Notice of Arrival of above with proof of arrival at entity's warehouse.

HOW TO APPLY?

STEP	APPLICANT/ CLIENT	ACTIVITY	DURATION OF ACTIVITY	PERSON IN CHARGE	FEES	FORM
1	Submit duly filled out 1st Notice Form with attached proof of arrival at port of entry.	Check documents for completeness and content. Receive document and record in designated log book.	10 minutes	DDRO II	-	1ST Notice
2	Submit duly filled-out 2nd Notice Form with attached proof of arrival at company warehouse.	Check documents for completeness and content. Retrieve 1st Notice Form and attach to file.	10 minutes	DDRO II	-	2nd Notice
3	Request verification inspection schedule.	Schedule and assign inspector.	5 minutes	DD, CS	-	-
4	Accompany inspector on scheduled date. Sign in the verification report to signify concurrence and acknowledgement. Submit affidavit, if quantity is inconsistent with the approved quantity.	Verify arrival of imported goods. Check/Inventory shipment based from the notice submitted and corresponding approved Import Permit. Inform client of discrepancies, if any. Accomplish verification report for subsequent submission to D, CS on the following working day.		DDRO I	-	-
END TRANSACTION.						