

A. Issuance of Dangerous Drugs License (S-License for Non-Practitioner)

(Decentralized processing and payment of fees at PDEA Regional Offices.
Centralized database entry and issuance of License Certificate at PDEA Main Office)

S-License refers to the authority issued to qualified entities to procure for sale/retail, wholesale /distribute, manufacture, export, import, make use for research, training and/or laboratory analysis of dangerous drugs (DD) and/or its preparations.

Office or Division	Compliance Service (CS)
Classification	Highly Technical
Type of Transaction	G2C – Government to Client G2B – Government to Business G2G – Government to Government
Who May Avail	Non-medical practitioner who are engaged in procuring, selling, manufacturing, importing, exporting and/or using DD / DDP in research, training and laboratory analysis.
Checklist of Requirements	Where to Secure
<p><u>CLEAR/FULL SCANNED COPIES OF THE FOLLOWING REQUIREMENTS:</u></p> <ol style="list-style-type: none"> Duly filled-up Application for S-License form (FM-CSVlrd-02). Valid National Bureau of Investigation (NBI) clearance of the following (One-time submission): <ol style="list-style-type: none"> Head of Office; and Authorized pharmacist. Valid Professional Regulation Commission (PRC) ID card of authorized pharmacist. Notarized & originally signed affidavit or joint affidavit of undertaking of head of office and authorized pharmacist (FM-csvlrd-06). Submit whichever is appropriate: (For Private entities only) <p><u>For Corporation:</u></p> <ol style="list-style-type: none"> Securities & Exchange Commission (SEC) Certificate of Registration (first page only) (One-time submission); Current General Information Sheet (GIS) duly received by SEC (cover and list of officer/directors’ page only) <p><u>For Partnership:</u></p> <ol style="list-style-type: none"> Securities & Exchange Commission (SEC) Certificate of Partnership. 	<p>Download application form at PDEA website: https://pdea.gov.ph/downloads/file/12-s-license</p> <p>NBI</p> <p>PRC</p> <p>Download prescribed format at PDEA website: https://pdea.gov.ph/downloads/file/59-j-o-i-n-t-a-f-f-i-d-a-v-i-t</p> <p>SEC</p> <p>SEC</p>

<p><u>For Cooperative:</u> a. Cooperative Development Authority Registration Certificate.</p>	<p>CDA</p>
<p><u>For Single Proprietorship</u> a. Valid Department of Trade and Industry Certificate of Registration of Business Name (CRBN).</p>	<p>DTI</p>
<p>6. Valid Mayor's Permit of office and plant/warehouse, if there's any: <u>(For Private entities only)</u> a. Certificate; and/or b. Official Receipt. (If payment is on a quarterly basis, submit the OR of the present quarter/s).</p>	<p>LGU</p>
<p>7. Valid Department of Health (DOH) or Food & Drug Administration (FDA): a. License to Operate Certificate, as appropriate; or b. Expired License to Operate Certificate with Official Receipt on renewal payment, if the new License to Operate Certificate is not yet available. (for private entities only)</p>	<p>DOH/FDA</p>
<p>8. <u>For importers & Exporters:</u> a. Valid Bureau of Customs (BOC) Certificate of Accreditation or Registration.</p>	<p>BOC</p>
<p>9. <u>For Importers, Exporters & Manufacturers:</u> a. Valid FDA Certificate of Product Registration (CPR) of dangerous drug preparation/s; and b. Picture of controlled finished dangerous drugs preparations, a copy of each product's insert/literature and box label. (One-time submission)</p>	<p>FDA SUPPLIER</p>
<p>10. Company profile. (One-time submission)</p>	
<p>11. Latest Organizational structure with pictures (head of office and authorized signatory), complete name and designation of all personnel. (One-time submission)</p>	
<p>12. Front view picture of company/ pharmacy (office and/or plant/warehouse) with signage. (One-time submission)</p>	
<p>13. Location / vicinity map (Simple sketch with landmarks) of office and/or plant/warehouse addresses. (One-time submission)</p>	
<p>14. One-time submission of pictures of <u>immovable sturdy locked facility</u> (see below requirements) for storage <u>exclusively</u> of dangerous drugs and or drug preparations containing controlled substances,</p>	

in accordance with Annex L - Safe keeping, storage, and transportation of Controlled Substances:

Room/Mesh Wire Enclosure: OR

- ✓ Entrance with double-keyed locks
- ✓ Firefighting equipment such as:
 - Fire extinguisher and/or
 - Fire hydrant

Cabinet / Drawers / Vault (not visible to customers and not near entrance or exit)

- ✓ Fixed on wall or floor
- ✓ Double-keyed locks
- ✓ Firefighting equipment such as:
 - Fire extinguisher and/or
 - Fire hydrant

Post the following inside or near the storage area of dangerous drugs and /or preparations containing controlled substances.

- Emergency Hotline numbers

Optional:

CCTV cameras

15. Floor plan / lay-out, highlighting the storage area of dangerous drugs and /or preparations containing controlled substances.

16. Proof of ownership of property (office and/or warehouse). Any of the following will do (One-time submission) :

- Land title
- Contract of lease
- Contract of Agreement

17. Previously issued PDEA S-License Certificate. (Renewal only)

18. *Notarized Corporate Secretary Certificate for the Head **only if the company designation of the appointed Head is NOT the Chairman of the Board, President, Principal Executive Officer, General/ Resident/ Country/ Plant/ Area/ Branch Manager, Partner, Owner/Proprietor, Medical Director, Hospital Administrator, Chief of Hospital*

Note:

Documents with “**One-time submission**” need not to be submitted if renewal application. Unless, there are material changes / variations.

Visit the link provided to view Annex L - Safe keeping, storage, and transportation of Controlled Substances at DDB website:

https://www.ddb.gov.ph/images/Board_Regulation/2014/BD.REG1/Annex_L_-_Safekeeping_storage_and_transportation.pdf

Download the PDEA format of Corporate Secretary Certificate through this link:

<https://pdea.gov.ph/downloads/file/73-sample-secretary-certificate>

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
--------------	---------------	-----------------	-----------------	--------------------

<p>1. Download S-license Application form.</p> <p>Email duly accomplished application form with complete and valid requirements at cs.spapplication@pdea.gov.ph using the authorized pharmacist/entity's official email address.</p> <p>Recommended email format:</p> <p>Subject: New/Renewal S License application</p> <p>Dear Sir/Madam: Attached herewith is the application with complete requirements for S license.</p> <p>Very truly yours, Name of Authorized Pharmacist Designation Name of Establishment</p> <p>NOTE: IF ENTITY IS LOCATED OUTSIDE NCR PLEASE COORDINATE AND SUBMIT YOUR APPLICATION DIRECTLY TO THE PDEA REGIONAL OFFICE CONCERNED. KINDLY CHECK PDEA COMPLIANCE SERVICE FACEBOOK PAGE "DIRECTORY OF EMAIL ADDRESS".</p>	<p>Log, monitor in S/P NCR google monitoring sheet all S applications received through email. Forward to RCO for evaluation of subject application.</p> <p>Evaluate received applications. Endorse to Supervisor RCO if requirements are lacking or complied with.</p> <p>Email applicant on noted lacking requirement/s and/or clarification/s. Otherwise, send assessment of fees for online payment</p> <p>For new applicants: Endorse to C, LRD to assign inspector, once the application passed the initial stage.</p>	<p>None</p>	<p>Within 7 working days</p> <p>1 day</p>	<p>Supervisor RCO</p> <p>RCO</p> <p>Supervisor RCO</p> <p>Supervisor RCO</p>
<p><u>FOR NEW APPLICANTS:</u></p> <p>❖ Submit to PDEA Main Office, Quezon City via any courier service or you may drop at the PDEA Guardhouse the applicable duly-accomplished application form/s and complete requirements (hard copy) in one (1) color-coded long folder.</p> <ul style="list-style-type: none"> • Green Folder - Application for S-License • Yellow Folder 	<p>Assign Inspector and forward application to inspector.</p> <p>Review emailed requirements</p> <p>Coordinate / notify client on scheduled date of inspection Notify C, LRD on preferred date of inspection</p>			<p>C, LRD</p> <p>Assigned inspector</p> <p>Assigned inspector</p>

<p>- Application for both S and P-Licenses</p> <p><u>FOR NEW APPLICANTS AND RENEWAL APPLICANTS APPLYING FOR THREE (3) YEARS VALIDTY OR WITH CHANGES ON:</u></p> <ul style="list-style-type: none"> ➤ <u>STORAGE AREA</u> ➤ <u>OFFICE/ WAREHOUSE ADDRESS</u> <ul style="list-style-type: none"> ❖ Wait for notification if application passed the assessment stage and the scheduled date of Physical Security Inspection (PSI). ❖ Attended Virtual Inspection or On-site Inspection. (case to case basis) 	<p>Prepare and print CS Letter Order. Forward to assigned inspector.</p> <p>Conduct inspection. Orient the Authorized Pharmacist and provide corresponding summary guidelines.</p> <p>Submit After Activity Report with recommendation to C, CID w/in three (3) working days from date of PSI.</p> <p>Evaluate After Activity Report and Submit to D, CS for Approval.</p> <p>Approve/Disapprove the application.</p> <p>Message Center to forward the application to the assigned inspector.</p> <p>Notify Supervisor RCO to schedule appointment for payment of fees.</p> <p>Log, email / notify applicant assessment of fees for online payment</p> <p>Print the application form,</p>			<p>C, LRD</p> <p>Assigned Inspector</p> <p>Assigned Inspector</p> <p>C, CID</p> <p>D, CS / DD, CS</p> <p>Admin Assistant</p> <p>Assigned inspector</p> <p>Supervisor RCO</p>
--	---	--	--	--

	Affidavit and previous License Certificate. Entry data in PPLS			RCO
<p>2. Online Payment of License Fee through Landbank Link.BizPortal.</p> <p>Go to Landbank – Link.BizPortal : https://www.lbp-eservices.com/egps/portal/index.jsp</p> <p>Click “PAY NOW” button. Select DANGEROUS DRUGS BOARD as Merchant. Input Payment Details. Choose Mode of Payment.</p> <p>NOTE: FOR GOVERNMENT APPLICANTS, NO LICENSE FEE REQUIRED NO NEED TO REPORT TO PDEA. APPLICANTS SHALL BE NOTIFIED OF THE PROCESSING DATE AND ELECTRONIC COPY OF S/ P CERTIFICATE WILL BE EMAILED WITHIN TEN (10) WORKING DAYS AND SEND THE CLIENT FEEDBACK FORM LINK.</p>	<p>Generate DDB Online payment report of confirmed payments and send copy to PDEA CS</p>	<p>S1- ₱ 500/yr S3- ₱1,000/yr S4- ₱3,000/yr S5C- ₱5,000/yr S5I- ₱5,000/yr S5E- ₱5,000/yr S5D- ₱5,000/yr S6- ₱ 500/yr</p> <p>Surcharge for late renewal = 50% of the required annual fee, cumulative by year not paid</p>	1 day	DDB Cashier
<p>3. FOR NEW / RENEWAL APPLICANTS (Private Entities)</p> <p>Email clear copy or photo of the proof of payment and/or Screenshot of the email confirmation receipt of payment by Landbank or chosen payment gateway on the same date and email thread at cs.spapplication@pdea.gov.ph, once license fee is paid.</p>	<p>Email client to acknowledge receipt of the proof of payment and/or Screenshot of the email confirmation receipt of payment by Landbank or chosen payment gateway and send Client Feedback Form Link.</p> <p>Enter the O.R. number from the submitted DDB Online Payment</p>	None	1 day	RCO
				RCO

	<p>report in the payment details in PPLS.</p> <p>Consolidate all processed applications within the day and prepare Daily/ Weekly Transmittal for all S & P License issued.</p> <p>Check all processed applications per batch. Forward to C, LRD.</p> <p>Approve all processed applications per batch in the PPLS. Forward to Admin Officer/ Admin Assistant for printing.</p> <p>Print S/P License Certificates per batch. Forward to D, CS.</p> <p>Countersign the printed S/P- License Certificates</p>			<p>RCO</p> <p>DDRO IV / Supervisor RCO</p> <p>C, LRD/ DDRO IV</p> <p>Admin Officer/ Admin Assistant</p> <p>D, CS / DD, CS</p>
<p>4. Acknowledge receipt of Electronic copy of License Certificate.</p> <p><i>(Due to centralized database, the issuance of License Certificates of applications processed at PDEA Regional Offices shall be claimed therein within 60 days from its date of processing.)</i></p>	<p>Send Electronic copy of License Certificates to Clients within Ten (10) working days after receipt of the DDB Online Payment Report.</p> <p>Forward to Records officer for file.</p>	<p>None</p>	<p>Within 10 working days</p>	<p>Admin Officer/ Admin Assistant</p> <p>Records Officer</p>

	File printed S license Certificates			
	TOTAL	<i>*pursuant to Section 6 (8 a, c and 10 b, c) of DDB Reg 1 S. 2014</i>	Within 20 working s days	

END TRANSACTION

IMPORTANT REMINDERS

- UNLESS SURRENDERED, SUSPENDED OR REVOKED, LICENSE SHALL BE RENEWED ON OR BEFORE THREE (3) MONTHS PRIOR TO EXPIRATION TO AVOID VIOLATION OF REGULATIONS AND PAYMENT OF SURCHARGES.
- NOTIFY PDEA IN WRITING AT LEAST 60 DAYS IN ADVANCE IF YOU INTEND NOT TO RENEW YOUR S- LICENSE.
- A SURCHARGE OF 50% OF THE REQUIRED ANNUAL FEE, CUMULATIVELY BY YEAR NOT PAID, SHALL BE IMPOSED ON TOP OF THE CURRENT ANNUAL FEE FOR FAILURE TO RENEW OR RETIRE YOUR S-LICENSE WITHIN THE COVERED PERIOD.
- NOTIFY MATERIAL CHANGES WITHIN FIVE (5) WORKING DAYS UPON OCCURRENCE OF CHANGES TO AVOID VIOLATION OF REGULATIONS AND PAYMENT OF PENALTY.
- WRITTEN NOTIFICATION ON LOSS OF LICENSE/PERMIT WITHIN 48 HOURS FROM OCCURRENCE TO PDEA COMPLIANCE SERVICE/REGIONAL COMPLIANCE SECTION, ADDITIONALLY SUBMIT NOTARIZED AFFIDAVIT OF LOSS AND POLICE BLOTTER.
- A SEPARATE PERMIT APPROVAL IS REQUIRED PRIOR TO IMPORT/EXPORT/MANUFACTURE/LOCAL TRANSFER OF DD/DDPs, UNLESS SPECIFICALLY EXEMPTED.

GENTLE REMINDERS

- Make sure that the Authorized Pharmacist is present during inspection for the interview and orientation.
- The storage area must be available for inspection and in accordance with the security and safety requirements set by the Board.
- Do not forget to email the clear copy of the proof of payment and/or Screenshot of the email confirmation receipt of payment by Landbank or chosen payment gateway to the same email thread at cs.spapplication@pdea.gov.ph, once payment was made.
- **The Dangerous Drug Board is the collecting Agency for the PDEA License and Regulatory fees. All online payment inquiries and issuances of Official Receipt should be coordinated through email with the Dangerous Drugs Board Cashier Division at cashier@ddb.gov.ph, 89294544 local 111 or 112 or at their Facebook page: Dangerous Drugs Board**