



GUIDELINES ON POST LICENSE VARIATIONS

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Drug Regulatory Authority of Pakistan
Islamabad-Pakistan

TABLE OF CONTENT

1. HISTORY	3
2. APPLICATION.....	3
3. PURPOSE	3
4. INTRODUCTION.....	3
5. BACKGROUND:	4
6. DEFINITIONS& ACRONYMS:	4
7. RISK-BASED CLASSIFICATION OF POST LICENSE VARIATIONS:	5
7.1 Type I – Low Risk Variations :.....	5
7.2 Type II – Moderate Risk Variations :	5
7.3 Type III – High Risk Variations :	5
8. SUBMISSION OF APPLICATION FOR A POST LICENSE VARIATION.....	5
9. TYPES OF POST LICENCE VARIATIONS AND DOCUMENTS REQUIRED	6
10. SUBMISSTION OF REGULATORY FEE:	13
11. REFERENCES:.....	13

1. HISTORY

This is the first edition of the document.

2. APPLICATION

This guidance document is applicable to all pharmaceutical manufacturing units holding a Drug Manufacturing License and intends to make any post-license variation in their approved premises, facilities, manufacturing activities, technical staff, or other license particulars.

3. PURPOSE

This guidance document is intended to provide a clear, transparent regulatory framework for the management of post-licence variations to Drug Manufacturing License, including their classification, submission, assessment, approval and inspection, where applicable.

4. INTRODUCTION

Drug Manufacturing License holders are responsible for ensuring that their licensed manufacturing premises, facilities, equipment, utilities, manufacturing activities and qualified technical personnel remain in compliance with the applicable legal requirements and Good Manufacturing Practices throughout the validity of the licence.

During the lifecycle of a pharmaceutical manufacturing facility, changes are being made due to technological advancements, expansion or modification of manufacturing operations, replacement or addition of equipment, changes in premises or utilities, changes in manufacturing activities, or changes in qualified technical personnel. Such changes, regardless of their nature, are referred to as post-licence variations and may require prior approval, notification or regulatory assessment, depending upon their nature and potential impact on the compliance and GMP status of the licensed facility.

These guidelines establish a systematic and risk-based framework for the classification, submission, assessment, approval and, where applicable, inspection of post-licence variations to Drug Manufacturing Licences. The guidelines retain the relevant requirements and procedures applicable to post-licence changes under the existing regulatory framework and introduce a risk-based classification and assessment approach, including defined documentation requirements and criteria for regulatory inspection, where applicable.

5. BACKGROUND

The pharmaceutical manufacturing environment continuously evolves due to technological advancement, expansion of facilities, improvement of processes and changes in

organizational arrangements. Therefore, an effective regulatory mechanism is required to ensure that post license changes are appropriately evaluated while maintaining GMP compliance. The existing Licensing Division framework covers post licensure activities including changes of qualified staff, grant of APIs, additional/revised sections, issuance of inspection books and changes of management/title of firms etc.

6. DEFINITIONS& ACRONYMS

- 6.1. **Active Pharmaceutical Ingredient (API):** A substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a pharmacologically active compound (ingredient).
- 6.2. **Drug Manufacturing License:** Drug Manufacturing License is a permission from the competent Authority to manufacture drugs following the conditions required for such manufacturing. Five types of the Drug Manufacturing Licenses are as follow:
- Manufacture by way of Formulation
 - Manufacture by way of Basic Manufacturing
 - Manufacture by way of Semi-Basic Manufacturing
 - Manufacture by way of Re-packing
 - Manufacture for Experimental purpose.
- 6.3. **Basic Manufacture:** Manufacture of an intermediate from basic raw materials to a product which is used as a starting material for the manufacture of an active pharmaceutical or biopharmaceutical ingredient, used in the manufacturing of a final pharmaceutical or biopharmaceutical product as a pharmacologically active compound (ingredient).
- 6.4. **Semi-basic manufacture:** Manufacture of active pharmaceutical or biopharmaceutical ingredient from an intermediate substance, to be used in the manufacturing of a final pharmaceutical or biopharmaceutical product as a pharmacologically active compound (ingredient).
- 6.5. **Formulation:** All operations involved in converting a drug into a final pharmaceutical dosage form ready for use, including compounding, processing, filling, packing, finishing and labelling.
- 6.6. **Technical staff:** The production activities in any pharmaceutical unit are carried out in the presence of approved Production Incharge & Quality Control Incharge.
- 6.7. **Inspection Book:** The official document-book issued at the time of grant of Drug Manufacturing License and used for recording regulatory inspections.
- 6.8. **Repacking Products/Drugs:** The products/drugs which are enlisted in Schedule-D of Drugs (Licensing, Registration &Advertising) Rules, 1976.

6.9. Central Licensing Board: Central Licensing Board (CLB) is a statutory body for licensing of drug manufacturing facilities.

6.10. Post License Variation (PLV): Any change made after issuance of Drug Manufacturing License that affects approved license particulars, facilities, activities or technical arrangements.

6.11. Technical Assessment: Evaluation of submitted technical information to determine the potential impact of a proposed variation.

7. RISK-BASED CLASSIFICATION OF POST LICENCE VARIATIONS

Post license variations are classified according to their potential impact and level of regulatory assessment required, as follows:

7.1. Type I – Low Risk Variations: Changes having negligible or no impact on GMP compliance or manufacturing operations. These may be accepted for record or processed through administrative assessment.

7.2. Type II – Moderate Risk Variations: Changes having limited potential impact requiring documentary or technical assessment and prior approval/recording.

7.3. Type III – High Risk Variations: Changes having significant potential impact on premises, manufacturing capability, GMP controls or licensed activities requiring prior approval and inspection where applicable.

8. SUBMISSION OF APPLICATION FOR A POST LICENSE VARIATION

8.1. General Requirements

- a. The applicant shall submit an application for a post license variation through the DRAP online application portal (eApp) available at: <https://eapp.dra.gov.pk/>
- b. The applicant shall select the relevant licensing module and applicable category of post license variation according to the nature of the proposed change. The application shall be submitted along with all required supporting documents as specified in this guideline and the relevant checklist issued by the Licensing Division.
- c. The applicant shall ensure that:
 - i. The Drug Manufacturing License (DML) is valid at the time of submission of the application.
 - ii. The application shall contain complete and accurate information regarding the proposed change, its justification, impact assessment and supporting evidence.
 - iii. The applicant shall submit the prescribed regulatory fee for the relevant post license variation category as specified in Schedule F of the Drugs (Licensing, Registering and Advertising) Rules, 1976, or as amended from time to time.
 - iv. The applicant shall ensure that the correct fee category is selected and the valid fee challan is attached with the application.

9. TYPES OF POST LICENCE VARIATIONS AND DOCUMENTS REQUIRED

9.1. PLV-01: Change of Management

Type of Variation	Change of Management
Risk Category	Type I – Low Risk
Documents Required	i. Proper application. ii. A Fee as notified by Authority. iii. CNICs of all partner(s)/CEO/Director (s)/owner (s)etc. iv. Detail of previous and new management in tabulated form. v. For limited company: Latest certified true copy of Form-9 or Form-A or any other form issued by S.E.C.P vi. For Partnership firms: Partnership deed, Agreement of Sale and Transfer of Share/ Transfer Deeds, NOC from Previous Owners on Stamp Paper and Form-D from Registrar of firms. vii. For proprietorship firm: Undertaking as sole proprietor on stamp paper, NOC from Previous Owner on Stamp Paper and NTN certificate from FBR. viii. Any other document with the approval of the Director (Lic)
Regulatory Action	Accepted for record and communicated to the firm through e-App.

9.2. PLV-02: Change of Title / Name of Firm

Type of Variation	Change of Title / Name of Firm
Risk Category	Type I – Low Risk
Documents Required	i. Proper application. ii. A Fee as notified by Authority. ix. CNICs of all partner(s)/CEO/Director (s)/owner (s)etc. iii. Detail of previous and new title in tabulated form. iv. For limited company: Certificate of change of title/name or any other form issued by S.E.C.P v. For Partnership firms: Form-D from Registrar of firms for change of title. vi. For proprietorship firm: Undertaking as sole proprietor on stamp paper and NTN certificate from FBR. vii. Any other document with the approval of the Director (Lic)
Regulatory Action	Accepted for record and letter issued to the firm through e-App.

9.3. PLV-03: Change of Qualified Staff

Type of Variation	Change of Qualified Staff (Production Incharge/QC Incharge)
Risk Category	Type II – Moderate Risk
Documents Required	i. Proper application ii. Prescribed fee as notified by the Authority. iii. Appointment letter. iv. Job acceptance letter by the appointee. v. CNIC of appointee. vi. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976. vii. Registration certificate from Pharmacy Council (in case of Production Incharge). viii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976. ix. Resignation / retirement of earlier Production Incharge / QC Incharge. x. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm. xi. Approval letter of previous Incharge. xii. Undertaking as whole time employee on stamp paper on following format: LETTER OF UNDERTAKING FOR PRODUCTION/QC INCHARGE I -----, S/O ----- ----- CNIC No. ----- and Managing Director ----- CNIC No. ----- For the management of ----- ----- do here by agree that proposed Production/QC Incharge ----- is whole time employee of the firm and not working anywhere else. We hereby confirm that the information / documents provided for academic qualification and experience as per Rule 16-c of Drugs (Licensing, Registering & Advertising) Rules, 1976 are correct and up-to-date. Management signature / Date Production/QC Incharge signature / date All documents should be attested by gazette officer or Notary Public.
Regulatory Action	Documentary assessment and approval letter issued.

9.4. PLV-04: Grant of Additional Section(s)

Type of Variation	Grant of Additional Section(s)																																										
Risk Category	Type III – High Risk																																										
Documents Required	i. Proper application. ii. Prescribed fee as notified by the Authority for each section/facility. iii. Two (02) copies of proposed layout plan. iv. Highlight the proposed amendments on copy of approved master layout plan. v. Men and material flow maybe intimated in different colored arrows. Area Requirements: <table border="1"> <thead> <tr> <th>S. No</th><th>Section</th><th>Minimum Area</th><th>Remarks</th></tr> </thead> <tbody> <tr> <td>1</td><td>External Appliances or Suspension</td><td>200 Sq. ft</td><td></td></tr> <tr> <td>2</td><td>Syrups, Elixirs & Solutions</td><td>300 Sq. ft</td><td></td></tr> <tr> <td>3</td><td>Compressed Tablets</td><td>900 Sq. ft</td><td>Should be divided into three distinct subsections situated in different rooms (Granulation, Compression, Coating) Hypodermic Tablets in aseptic & separate room</td></tr> <tr> <td>5</td><td>Hard Gelatin Capsules</td><td>200 Sq. ft</td><td></td></tr> <tr> <td>7</td><td>Eye ointments, Eye drops, Eye lotions and other use</td><td>250 Sq. ft</td><td>Manufacture and filling shall be in aseptic conditions</td></tr> <tr> <td>8</td><td>Pessaries and Suppositories</td><td>200 Sq. ft</td><td>If compression is involved, a separate room with min. 300 Sq. ft</td></tr> <tr> <td>9</td><td>Inhaler and Vitralae</td><td>200 Sq. ft</td><td></td></tr> <tr> <td>10</td><td>Repacking</td><td>300 Sq. ft</td><td></td></tr> <tr> <td>11</td><td>Sterilization</td><td>400 ft/ unit of sterilizer</td><td></td></tr> </tbody> </table> Dedicated and self-contained facilities for the production of particular drugs shall be provided in addition to the general facilities such as highly sensitizing materials (e.g. penicillin) or biological preparations (e.g. live microorganisms) or cytotoxic substances or radiopharmaceutical or veterinary immunological preparations or sterile products or for that matter such other highly active pharmaceutical products, antibiotics, hormones, as may be identified by the Central Licensing Board at any stage.			S. No	Section	Minimum Area	Remarks	1	External Appliances or Suspension	200 Sq. ft		2	Syrups, Elixirs & Solutions	300 Sq. ft		3	Compressed Tablets	900 Sq. ft	Should be divided into three distinct subsections situated in different rooms (Granulation, Compression, Coating) Hypodermic Tablets in aseptic & separate room	5	Hard Gelatin Capsules	200 Sq. ft		7	Eye ointments, Eye drops, Eye lotions and other use	250 Sq. ft	Manufacture and filling shall be in aseptic conditions	8	Pessaries and Suppositories	200 Sq. ft	If compression is involved, a separate room with min. 300 Sq. ft	9	Inhaler and Vitralae	200 Sq. ft		10	Repacking	300 Sq. ft		11	Sterilization	400 ft/ unit of sterilizer	
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	vi. After construction, inspection shall be carried out, once applicant inform the Licensing Division.
Regulatory Action	Technical assessment followed by inspection and approval letter.

9.5. PLV-05: Grant of Revised Section(s)

Type of Variation	Grant of Revised Section(s)			
Risk Category	Type III – High Risk			
Documents Required	vii. Proper application. viii. Prescribed fee as notified by the Authority for each section/facility. ix. Two (02) copies of proposed layout plan. x. Highlight the proposed amendments on copy of approved master layout plan. xi. Men and material flow maybe intimated in different colored arrows. Area Requirements:			
	S. No	Section	Minimum Area	Remarks
	1	External Appliances or Suspension	200 Sq. ft	
	2	Syrups, Elixirs & Solutions	300 Sq. ft	
	3	Compressed Tablets	900 Sq. ft	Should be divided into three distinct subsections situated in different rooms (Granulation, Compression, Coating) Hypodermic Tablets in aseptic & separate room
	5	Hard Gelatin Capsules	200 Sq. ft	
	7	Eye ointments, Eye drops, Eye lotions and other use	250 Sq. ft	Manufacture and filling shall be in aseptic conditions
	8	Pessaries and Suppositories	200 Sq. ft	If compression is involved, a separate room with min. 300 Sq. ft
	9	Inhaler and Vitallae	200 Sq. ft	
	10	Repacking	300 Sq. ft	
	11	Sterilization	401 ft/ unit of sterilizer	
	Dedicated and self-contained facilities for the production of particular drugs shall be provided in addition to the general facilities such as highly sensitizing materials (e.g. penicillin) or biological preparations (e.g. live			

	microorganisms) or cytotoxic substances or radiopharmaceutical or veterinary immunological preparations or sterile products or for that matter such other highly active pharmaceutical products, antibiotics, hormones, as may be identified by the Central Licensing Board at any stage. xii. After construction, inspection shall be carried out, once applicant inform the Licensing Division.
Regulatory Action	Technical assessment followed by inspection and approval letter.

9.6 PLV-06: Enlistment of Active Pharmaceutical Ingredient(s) (API)

Type of Variation	Grant of Active Pharmaceutical Ingredient(s) (API)
Risk Category	Type III – High Risk
Documents Required	i. Proper application on covering letter on letter head. ii. Prescribed fee as notified by the Authority per API. iii. Names and quantities of chemicals to be used in manufacturing. iv. Names and quantities of chemicals to recycled in manufacturing. v. Manufacturing process steps and flow chart. vi. Theoretical yield of manufacturing process. vii. Trial batches record and stability data along with validation (if available). viii. Reference monograph and Testing method ix. List of Testing equipments. x. Shelf life of API xi. Material safety data sheet All documents should be duly attested/verified by approved technical staff along with Company stamp.
Regulatory Action	Technical assessment followed by inspection and approval letter for enlistment.

9.7. PLV-07: Issuance of New/Duplicate Inspection Book

Type of Variation	Issuance of New/Duplicate Inspection Book
Risk Category	Type II – Moderate Risk
Documents Required	i. Proper application ii. Prescribed fee as notified by the Authority. iii. Notarized copy of last three pages of previous inspection book. iv. Notarized copy of FIR and Advertisement in National News Paper (in case of lost / damaged inspection book).
Regulatory Action	Inspection book issued after completion of checklist requirements.

9.8. PLV-08: Grant of Repacking Item (s)

Type of Variation	Grant of Repacking Item(s)
Risk Category	Type II- Moderate Risk
Documents Required	i. Proper application ii. Prescribed fee as notified by the Authority. iii. Repacking section approval letter.
Regulatory Action	Documentary assessment and approval letter issued.

9.9. PLV-09: Change of Title of Section (s)

Type of Variation	Change of Title of Section (s), if there is no structural change.
Risk Category	Type II- Moderate Risk
Documents Required	i. Proper application ii. Prescribed fee as notified by the Authority. iii. Section approval letter. iv. Justification for change of title of section
Regulatory Action	Documentary assessment and approval letter issued.

9.10. Miscellaneous**9.9.1 NOC for import of Plant, Machinery & Equipment at reduced Customs Duty**

Type of Variation	Issuance of NOC for import of reduced customs duty (5%) plant, machinery & equipment for registered pharmaceutical manufacturers
Documents Required	i. Proper application ii. Prescribed fee as notified by the Authority. iii. Section approval letter approved by CLB along with Approval letter of layout plan of the section where machinery to be installed. iv. Invoice of Machine/Equipment being imported. v. Picture of imported Machine/Equipment. vi. Previous installation report of the machine imported by the firm verified by the Area Federal inspector of Drugs.

	vii. The scientific reason / justification for import of the machine. viii. Due diligence & recommendations by the field office. ix. Notarized Undertaking on Stamp Paper issued in the name of the firm/company or signatory & signed by the MD/CEO) of the firm/company containing following contents: i. Name, Model, Quantity of Machine/Equipment to be imported. ii. Name of section in which imported machinery/equipment is to be installed. iii. Total Cost of machinery as on Invoice of the machine / equipment to be imported. iv. Fulfilment of following Clauses in the light of the decision of DRAP (Authority); v. The machine(s) will be imported for their own use as per spirit of heading of 38 of the amended 5th schedule of the Customs Act 1969. vi. The conditions specified in amended 5th schedule of the Customs Act 1969 shall be abide by. vii. In case of any violation, firm will be responsible.
Regulatory Action	Documentary assessment and forwarding of recommendations of the field office to the M/o NHSRC

9.9.2 Attestation of DML Certificate (Form-2)

Type of Variation	Attestation of DML Certificate (Form-2)
Documents Required	i. Proper application ii. Prescribed fee as notified by the Authority. iii. Notarized copy of valid Drug Manufacturing License Certificate on Form-2
Regulatory Action	Documentary assessment and attestation of Form-2.

10. SUBMISSION OF REGULATORY FEE

DRAP has introduced an online fee challan system, available on the [link](#) provided at the official website of DRAP. This system will help user (s) in the selection of applicable regulatory fee for the required service(s) under the respective regulatory function. The applicant can generate the fee challan(s) for any required purpose. The Regulatory fees of DRAP can be submitted on any branch of the banks listed on the fee challan.

11. REFERENCE:



- 11.1. The Drugs Act, 1976.
- 11.2. The DRAP Act, 2012.
- 11.3. The Drugs (Licensing, Registering & Advertising) Rules, 1976.
- 11.4. Decision of the Central Licensing Board on post License variations
- 11.5. SRO 1582(I)/2025 dated 25-08-2025 for Implementation of PIC/S Guide to Good Manufacturing practice for Medicinal Products Part-I (PE 009).
- 11.6. Circular letter No.F.6-1/2026-Lic(M-314) dated 24-02-2026 (Annexure A and B/Compliance Framework Document No. I,II,III &IV)