FEE FOR REGULATORY FUNCTIONS OF DRUG REGULATORY AUTHORITY OF PAKISTAN

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Drug Regulatory Authority of Pakistan
Islamabad-Pakistan

1. HISTORY

This is the first edition of this document.

2. APPLICATION

This document is applicable on the Therapeutic Goods Industry and the officers / officials of DRAP, who are involved in processing of various applications from the Therapeutic Goods Industry.

3. PURPOSE

3.1. The purpose of this guideline is to:-

3.1.1. Provide complete fee structure which is payable by the therapeutic goods industry for various regulatory operations performed by the Drug Regulatory Authority of Pakistan.

3.1.2. Ensure the availability of a consolidated document and clarity of fees for various regulatory operations.

3.1.3. Ensure smooth and efficient functioning of DRAP.

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4. INTRODUCTION

The DRAP under Section 7(n) of DRAP Act, 2012 is empowered for levy of charges or fees for services and facilities provided by it and its offices. The fee is determined by the Policy Board of DRAP under Section 11(1)(d) of DRAP Act, 2012. The purpose of fee collection is the cost recovery to ensure financial autonomy and efficient functioning.

5. DEFINITIONS AND ACRONYMS

Fee	Charges collected by DRAP to recover the costs of regulated functions under the DRAP Act, 2012.
SRO	Statutory Regulatory Orders
Therapeutic Goods	Includes drugs or alternative medicine or medical devices or biological or other related products as may be notified by the Authority.
New drug / molecule	A drug that has not been commonly sold or distributed to the public in Pakistan and is introduced for the first time.

6. ONLINE FEE CHALLAN SYSTEM

DRAP has introduced an online fee challan system to facilitate the therapeutic goods industry. The system can be accessed at https://fee.dra.gov.pk/login. The applicant is required to first register in the system using DML / DSL / Establishment License / Establishment Enlistment number and other details. Once the account is created, the applicant can generate the fee challan(s) for any required purpose. The applicant must ensure that the correct fee challan is generated because fee once deposited cannot be refunded. Further guideline for applicants is available in the user guide on official website of DRAP i.e. www.dra.gov.pk.

7. APPLICABLE FEE STRUCTURE

7.1. Drug Licensing

Detail	Fee (Rs.)
Site Verification and Layout	
Site Verification	7,500
Lay out Plan per section	7,500
Revision or extension of lay out plan per section	7,500
Drug Manufacturing License Fee	
Basic	45,000
Semi Basic	45,000
Formulation	150,000
Repacking	90,000
Repacking of Drugs	
Repacking of drugs (per drug specified in Schedule-D of the Drugs (Licensing, Registering & Advertising) Rules, 1976).	7,500
Renewal of License /Change of Management / Company Name / Title	
Basic	22,500
Semi Basic	22,500
Formulation	75,000
Repacking	45,000
If the application for renewal is made after the expiry of the period of validity of license but within sixty days of its expiry.	7,500 per day surcharge in addition to renewal fee.
Miscellaneous (Please Specify)	
Duplicate Copy	7,500
Miscellaneous Fee	7,500

7.2. Pharmaceutical Evaluation & Registration & Biological Evaluation & Research Divisions

Detail	Fee (Rs.)
Drugs Registration Fee	
New Drug / Molecule (local manufacture / import)	75,000
Any other Drug for Import	150,000
Locally manufactured drug with imported source of Half Finished Products (Ready to Fill Bulk i.e. Pellets, Granules, etc)	
Generic Drugs (local manufacture)	30,000

Drugs for Export Purpose	
Drugs for export purpose on contract manufacturing basis.	
Drugs for Export Purpose; where no generic product is available.	75,000
Grant / extension of contract manufacturing permission (per product)	75,000
Grant / extension of contract manufacturing permission for export purpose only (per product)	30,000
Renewal of Drugs Registration Fee (if the application for renewal is made before the expiry of the period of validity of registration)	
Drugs for Import	30,000
Locally manufactured drug with imported source of Half Finished Products (Ready to Fill Bulk i.e. Pellets, Granules, etc)	
Drug for local manufacture	15,000
Renewal of Drugs Registration Fee (If the application for renewal is made after the expiry of the period of validity of certificate of registration and but within 60 days after the expiry of the period of validity)	
Drugs for Import	60,000
Locally manufactured drug with imported source of Half Finished Products (Ready to Fill Bulk i.e. Pellets, Granules, etc)	
Drug for local manufacture	30,000
Renewal of Drugs Registration Fee (If the application for renewal is made after 60 Days of Expiry of validity of Registration but Within 01 Year)	
Drugs for Import	Applicable renewal fee for each month till one year of the expiry of registration.
Locally manufactured drug with imported source of Half Finished Products (Ready to Fill Bulk i.e. Pellets, Granules, etc)	
Drug for local manufacture	
Pre-Registration Variation	
Variation in registration application i.e. changes in in-active raw materials, method of manufacture, testing methods or quality specifications, product specification, packing material including change of labelling etc.	7,500 (in case of more than one variation, one fee will be charged)
Correction / standardization of composition as per reference regulatory authority / innovator's product	Full fee of registration as applicable for that particular category
Change of source	
Change of manufacturer	
Post-Registration Variation	
Change of Brand Name except cases of resemblance	Full fee of registration as applicable for that particular category
Change of title / name of manufacturer / Marketing Authorization holder	
Change in contract manufacturing permission (per product)	
Change of registration from one manufacturer / Marketing Authorization holder to another manufacturer / Marketing Authorization holder /	

Approval of New manufacturing Site or Change in Address of Manufacturing Site for Imported drug	
Change of source / approval of Additional Source of pellets / liquid / bulk drug product [If Half Finished Products (Ready to Fill Bulk i.e. Pellets, Granules, etc) are from imported source]	150,000
Change of source / approval of Additional Source of pellets / liquid / bulk drug product [If Half Finished Products (Ready to Fill Bulk i.e. Pellets, Granules, etc) are from local source]	30,000
Any other post registration variation e.g. extension / reduction in shelf life of product, Change in labelled storage conditions, Change in Prescribing Information (PI), Change in Primary packaging material / container closure system, Change in the shape or dimensions of the container closure system, Change of secondary packaging materials, Change in shape of tablet / color and size of capsule, Standardization of formulation in accordance with the Innovator's Product / Reference Regulatory Authorities and pharmacopeias, Change of finished product specifications, Grant of additional pack size for locally manufactured veterinary products (excluding injectable), Grant of additional pack size for export purpose only, Change in address of local storage facility of importer for imported drugs etc. (per variation)	10,000
Miscellaneous (Please Specify)	
Duplicate Copy of Registration Certificate	7,500
Any other application of commercial significance.	

7.3. Medical Devices & Medicated Cosmetics

Detail	Fee (Rs.)
Establishment License	
Fee for establishment licence to manufacture medical devices.	100,000
Fee for establishment licence to import medical devices.	20,000
Fee for renewal of establishment licence to manufacture medical devices.	50,000
Fee for renewal of establishment licence to import medical devices.	10,000
Fee for change in particulars of licensed establishment (Manufacturing)	Fifty percent of the licensing fee.
Fee for change in particulars of licensed establishment (Import)	
Enlistment / Registration of Medical Devices	
Fee for enlistment of Class A medical device for local manufacture or importer.	5,000
Fee for renewal of enlistment of Class A medical device for local manufacture or importer.	
Fee for registration of Class B, C & D medical device for local manufacture.	20,000

Fee for renewal of registration of Class B, C & D medical device for local manufacture.	10,000
Fee for registration of Class B medical device or accessory or component for importer.	25,000
Fee for renewal of registration of Class B medical for importer.	12,500
Fee for registration of Class C & D medical device or accessory or component for importer.	50,000
Fee for renewal of registration of Class C & D medical device for importer.	25,000
Fee for enlistment or registration of accessory or component for local manufacture.	5,000
Fee for renewal enlistment or registration of accessory or component for local manufacture.	
Fee for post enlistment or registration variation	5,000
Fee for change in particulars of enlisted or registered medical device.	fifty percent of the registration fee
Advertisement	
Advertisement for print media (Per product per advertisement)	15,000
Advertisement for Radio / Audio (Per product per advertisement)	22,500
Advertisement for T.V / Cinema (Per product per advertisement)	37,500
Import Permits of medical devices	
Import permit or its renewal.	5,000
Miscellaneous (Please Specify)	
Fee for any other activity having commercial significance.	5,000

7.4. Health & OTC

Detail	Fee (Rs.)
Enlistment of Firm / Company	
Approval of layout plan/revised layout (Whole Facility)	2,500
Enlistment as local manufacturer	15,000
Additional section	2,500
Enlistment as Importer	15,000
Firm/Company Enlistment for contract manufacturing or change in contract giver. (Manufacturer to Manufacturer only)	15,000
Renewal of establishment enlistment after 02 years	Half of the initial fee
Enlistment of Alternative Medicines and Health & OTC Products	
Enlistment of imported product / new medicine (Alternative medicine)	2,500

Enlistment of imported product / new medicine (Health product)	5,000
Enlistment of locally manufactured homeopathic medicine (Mother tincture)	2,500
Enlistment of locally manufactured homeopathic medicine (Dilutions and potencies)	2,500
Enlistment of locally manufactured homeopathic medicine (Combination product and dosage form)	5,000
Enlistment of locally manufactured herbal / unani product	2,500
Enlistment of locally manufactured health product	5,000
Product Fee for contract manufacturing (For each category) (per product)	5,000
Product Fee for contract manufacturing (If contract manufacturing exceeds 10 products) (For each category) (Per Product)	10,000
Transfer of product enlistment from import to local manufacturing	5,000
Renewal of Product Enlistment after 02 Years - Imported product/ new medicine (Alternative medicine)	1,250
Renewal of Product Enlistment after 02 Years - Imported product/ new medicine (Health product)	2,500
Renewal of Product Enlistment after 02 Years - Locally manufactured homeopathic medicine (Mother tincture)	1,250
Renewal of Product Enlistment after 02 Years - Locally manufactured homeopathic medicine (Dilutions and potencies)	1,250
Renewal of Product Enlistment after 02 Years - Locally manufactured homeopathic medicine (Combination product and dosage form)	2,500
Renewal of Product Enlistment after 02 Years - Locally manufactured herbal / unani product	1,250
Renewal of Product Enlistment after 02 Years - Locally manufactured health product	2,500
GMP	
GMP Inspection (per annum)	25,000
Laboratories Fee	
Enlistment for referral laboratories	50,000
Grant of approval of product testing from the referral laboratory (not for routine testing).	2,500
Post Product Enlistment Variation	
Variations allowed such as change of brand name and management change.	15,000
Miscellaneous variation activities like additional pack, change in specifications, packing material / change in excipient and other activities.	2,500

Miscellaneous (Please Specify)	
Approval of change in qualified staff.	2,500
Change in title of the firm/ company or change in the ownership / management of the firm / company.	15,000
Addition or deletion of Director (Per Case)	2,500
Free Sale Certificate	2,500
CoPP of alternative medicine & health product	2,500

7.5. Pharmacy Services

Detail	Fee (Rs.)
For Advertisement of drugs / alternative medicines & Health products	
Advertisement for print media (Per product per advertisement)	15,000
Advertisement for Radio / Audio (Per product per advertisement)	22,500
Advertisement for T.V / Cinema (Per product per advertisement)	37,500
Clinical Trials (For all therapeutic goods)	
Grant of new license for Bio-analytical Laboratory for Clinical Research.	300,000
Grant of new license for Bioequivalence / Bio-availability Studies center.	
Grant of new license for Contract Research Organization.	
Grant of New License for Clinical Trial site	100,000
Grant of Approval and Registration of Clinical Trial	200,000
Grant of Approval and Registration of Bioequivalence / Bioavailability Study	
Grant of Renewal of License for BA/BE studies center, Contract Research Organization, Bio-analytical lab for Clinical Research (If applied before Expiry of validity of license)	300,000
Grant of Renewal of License for BA/BE studies center, Contract Research Organization, Bio-analytical lab for Clinical Research (If applied within 60 days of expiry of validity of license)	400,000
Grant of Renewal of License for clinical trial site (If applied before Expiry of validity of license)	100,000
Grant of Renewal of License for clinical trial site (If applied within 60 days of expiry of validity of license)	150,000
Approval of amendment in already approved clinical trials OR Bio-Equivalence / Bio-Availability study	25,000
Miscellaneous requests	25,000

7.6. Controlled Drug

Detail	Fee (Rs.)

Fee for Control Drugs Division	
Quota Allocation and Issuance of Import Authorization (for routine and first time allocation)	20,000
Enhancement of Quota Application	10,000
Destruction of Controlled Substances Received from Hospitals, Pharma Units etc.	5,000
Export and Issuance of Export Permit & Misc Functions	5,000

7.7. Quality Assurance & Laboratory Testing

Detail	Fee (Rs.)
Drug Import License	
Drug Import License - Form 5	7,500
Drug Import License - Form 6	7,500
Import License for alternative medicines & health products	7,500
cGMP Certificate for drugs and biologicals	
Certificate of Good Manufacturing Practices (GMP) for local manufacturing with validity for a period of Two (02) Years	50,000 (25,000 per year)
Certificate of Good Manufacturing Practices (GMP) for export purposes with validity for a period of three (03) years	75,000 (25,000 per year)
GMP Certificate for medical devices	
Certificate of Good Manufacturing Practices (GMP) for local manufacturing with validity for a period of One (01) Year	25,000
Certificate of Good Manufacturing Practices (GMP) for export purposes with validity for a period of three (03) years	75,000 (25,000 per year)
Export Permits of medical devices	
Export permit or its renewal.	1,000
Miscellaneous (Please Specify)	
Issuance of NOC for export of drugs	7,500
Free Sale Certificate / COPP	7,500
Any other application of commercial significance	7,500
Consignment Clearance	
Per consignment clearance of import requests for all therapeutic goods (API, excipients, intermediates, finished products etc.)	2,000

7.8. Legal Affairs

Detail	Fee (Rs.)
Application for Drugs Appellate Board	
Filing of an appeal before the Appellate Board regarding therapeutic goods.	50,000

7.9. Budget & Accounts

Detail	Fee (Rs.)
CRF	
Central Research Fund	One percent of gross profit before tax
TA/DA Paid by Companies for Panel Inspection	
TA/DA paid by Companies for Panel Inspections	As per estimated cost
Manual Slip Adjustment (Pink Color)	
Manual Slip Adjustment (Pink Color) (Differential Fee)	As per actual

7.10. Costing & Pricing

Detail	Fee (Rs.)
Fee For the Grant of Additional Pack	
Grant of Additional Pack (Per Pack)	7,500
Price Increase	
Any drug for Local Manufacture or Import (Human) under hardship cases	30,000
Price increase (linked with CPI) per product	2,000

7.11. Central Drug Laboratory

Detail	Fee (Rs.)
Central Drug Testing Laboratory	
Description (General)	400
Identification (General)	400
Identification (TLC)	1,200
Identification (FTIR)	1,600
Assay (Spectrophotometric)	2,000
Assay (HPLC)	5,000
Assay Titration (Simple)	1,000
Assay Titration (Potentiometric)	2,000
Bio Assay	3,000

Weight variation / Mass variation	600
Content Uniformity	10,000
Dissolution Test (spectrophotometric)	5,000
Dissolution Test (Chromatographic)	7,000
Disintegration Test (uncoated /film coated /sugar coated tablet and capsule)	800
Disintegration Test (Enteric coated tablet / capsule)	1,200
Disintegration Test (Sustained Release tablet / capsule)	3,200
pH Test	800
Melting Point	800
Loss on drying	1,000
Sulphated Ash	800
Sterility Test (direct)	2,500
Sterility Test (Filter)	3,000
Endotoxin Test (Gel Clot method)	3,000
Endotxin Test (Chromogenic method)	4,000
Gravimetric Assay	2,000
Appearance of solution (syringes)	400
Acidity or Alkalinity	800
Absorbance (Syringes)	1,000
Reducing Substances	1,200
Fiber Identification Test	500
Absorbency (cotton)	500
Color of aqueous extract	1,000
Fluorescence Test	800
Water soluble substance	2,000
Warp thread and weft thread test (Bandage)	500
Weight per unit area (bandage)	500
Elasticity Test (crepe bandage)	1,000
Clarity Test (parenterals)	600
Optical Rotation	2,000
Specific Gravity	1,500
Refractive Index	1,200
Limit Test (Trace elements)	2,500
Acid Value	2,000
Iodine Value	2,000
Sponification Value	2,000
Acetyl Value	2,000
Hydroxyl Value	2,000

Viscosity Test	1,500
Friability Test	1,500
Alcohol determination Test	3,000
Others	1,000

7.12. National Control Laboratory for Biologicals

Detail	Fee (Rs.)
Fee for Lot Release by NCLB	
Tetanus Toxoid (Locally Manufactured)	30,000
Anti Tetanus Sera (Locally Manufactured)	30,000
Oral Polio Vaccine (Locally Manufactured)	20,000
Measles Vaccine (Locally Manufactured)	20,000
Rabies Vaccine (Locally Manufactured)	30,000
Hepatitis-B Vaccine (Locally Manufactured)	20,000
Snake Venom Anti Sera (Locally Manufactured)	30,000
Interferon (Locally Manufactured)	20,000
Any other Biological Drug (Imported or Locally Manufactured)	20,000

8. REFERENCES

8.1. DRAP Act, 2012.
8.2. The Drugs (Licensing, Registering & Advertising) Rules, 1976.
8.3. Notification No.F.8-4/2018-H&OTC/DRAP dated 13th July, 2021.
8.4. Notification No.F.7-11/2012-B&A/DRAP dated 13th July, 2021.
8.5. S.R.O. No.F.7-11/2012-B&A/DRAP dated 7th May, 2021.
8.6. S.R.O. No.6-18/2020-QA/DRAP dated 16th April, 2020.
8.7. S.R.O. No.1047(I)/2019 dated 12th September, 2019.
8.8. Schedule C of S.R.O.32(I)/2018 dated 16th January, 2018.
8.9. S.R.O. No.412 (I)/2014 dated 27th May, 2014.
8.10. S.R.O. No.461 (I)/2013 dated 30th May, 2013.
8.11. S.R.O. No.463 (I)/2013 dated 29th May, 2013.
8.12. S.R.O. 765(I)/2018 dated 14th June, 2018.
8.13. Notification No. F.5-14/2019-B&A/DRAP dated 30th April, 2020.

DRUG REGULATORY AUTHORITY OF PAKISTAN
Telecom Foundation Complex, G-9/4, Islamabad, Pakistan
Email: feedback.qms@dra.gov.pk Phone:92-51-9107416
www.dra.gov.pk