Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
*****

NOTIFICATION

Islamabad, the 17th April, 2023.

S.R.O.496(I)/2023.-- In exercise of the powers conferred by sub-section (1) of section 20 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with sub-rule (3) of rule 4 of the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022, and in supersession of all such previous Notifications, the Drug Regulatory Authority of Pakistan, with the approval of the Policy Board, is pleased to direct that the fee specified in column (4) of the Table below shall be levied in respect of functions specified in column (2) and (3) thereof, namely:-

TABLE

Sr.	Regulatory function	Description	Fee (Rs.)
(1)	(2)	(3)	(4)
DRUG LICENSING			
1	Grant of drug manufacturing license	By way of basic manufacturing	45,000
2		By way of semi-basic manufacturing	45,000
3		By way of formulation	150,000
4		By way of repacking	90,000
5	Renewal of drug manufacturing license (If the application for renewal is made before the expiry of the period of validity of license).	By way of basic manufacturing	22,500
6		By way of semi-basic manufacturing	22,500
7		By way of formulation	75,000
8		By way of repacking	45,000
9	Renewal of drug manufacturing license (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
10	Site verification and layout	Site inspection and verification	7,500
11		Approval of layout plan	7,500 per section
12		Revision or extension of layout plan	7,500 per section
13	Repacking of drugs	---	7,500 per drug
PHARMACEUTICAL EVALUATION AND REGISTRATION			
14	Grant of drug registration	New drug or molecule / drug not manufactured locally	75,000
15		Any other drug for import	150,000
16		Drug for local manufacture	30,000

17	Renewal of drug registration (If the application for renewal is made before the expiry of the period of validity of registration)	New drug or molecule / drug not manufactured locally	30,000
18		Any other drug for import	30,000
19		Drug for local manufacture	15,000
20	Renewal of drug registration (If the application for renewal is made after the expiry of the period of validity of certificate of registration but within 60 days after the expiry of the period of validity)	New drug or molecule / drug not manufactured locally / any other drug for import	60,000
21		Drug for local manufacture	30,000
22	Grant / extension of contract manufacturing permission	For local use	75,000 per product
23		For export purpose	30,000 per product
24	Pre-registration variation	Variance to registration application i.e. changes in inactive raw materials, method of manufacture, testing methods or quality specifications, product specification, packing materials including change of labeling specification, etc. except those specified in the following entry (No. 25)	7,500 (in case of more than one variation, one fee will be charged)
25		• Correction / standardization of composition as per reference regulatory authority / innovator's product • Change of source • Change of manufacturer	Full fee of registration
26	Post-registration variation	Any variation in registered drug except those specified in the following entry (No. 27)	10,000
27		• Change of brand name except cases of resemblance • Change of title / name of manufacturer / marketing authorization holder • Change / extension in contract manufacturing • Change of source of pellets / bulk drug product / substance • Approval of additional source of pellets / bulk drug product/substance • Change of registration status form one manufacturer / marketing authorization holder to another manufacturer / marketing authorization holder	Full fee of registration

MEDICAL DEVICES AND MEDICATED COSMETICS			
28	Enlistment / registration of medical devices	Enlistment of Class A medical device for local manufacture or importer	5,000
29		Renewal of enlistment of Class A medical device for local manufacture or importer	5,000
30		Registration of Class B, C and D medical device for local manufacture	20,000
31		Renewal of registration of Class B, C and D medical device for local manufacture	10,000
32		Registration of Class B medical device or accessory or component for importer	25,000
33		Renewal of registration of Class B medical device or accessory or component for importer	12,500
34		Registration of Class C and D medical device or accessory or component for importer	50,000
35		Renewal of registration of Class C and D medical device for importer	25,000
36		Enlistment or registration of accessory or component for local manufacture	5,000
37		Renewal of enlistment or registration of accessory or component for local manufacture	5,000
38		Post-enlistment or registration variation	5,000
39		Change in particulars of enlisted or registered medical device	Half of the enlistment or registration fee
40	Establishment licenses	Establishment license to manufacture medical devices	100,000
41		Establishment license to import medical devices	20,000
42		Renewal of establishment license to manufacture medical devices	50,000
43		Renewal of establishment license to import medical devices	10,000
44		Change in particulars of licenses establishment	Half of the licensing fee
45	Outsourcing	Certificate to outsource manufacturing processes of medical devices for each contract acceptor	50,000
46		Renewal of certificate to outsource manufacturing processes of medical devices	25,000

		for each contract acceptor	
47		Certificate to outsource analysis of medical devices for each contract acceptor	50,000
48		Renewal of certificate to outsource analysis of medical devices for each contract acceptor	25,000
49		Change in particulars of certificate	Half of the initial certificate fee
ALTERNATIVE MEDICINES AND HEALTH PRODUCTS			
50	Application for approval of layout plan / revised layout	---	2,500 (whole facility)
51	Application for enlistment as local manufacturer	---	15,000
52	Approval of change in qualified staff	---	2,500
53	Approval of additional section	---	2,500
54	Application for enlistment as importer	---	15,000
55	Enlistment of imported product / new medicine	Alternative medicine	2,500
56		Health product	5,000
57	Enlistment of locally manufactured homeopathic medicine	Mother tincture	2,500
58		Dilutions and potencies	2,500
59		Combination product and dosage form	5,000
60	Enlistment of locally manufactured herbal / *unani* product	---	2,500
61	Enlistment of locally manufactured health product	---	5,000
62	GMP inspection	---	25,000 per annum
63	Firm / company enlistment for contract manufacturing or change in contract giver (manufacturer to manufacturer only)	---	15,000
64	Product fee for contract manufacturing	For each category	5,000
65		If contract manufacturing exceeds 10 products	10,000 per product
76	Enlistment for referral laboratories	---	50,000
77	Variations allowed such as change of brand name and management	---	15,000
78	Miscellaneous variation activities like additional pack, change in specifications, packing material, change in excipient and other activities	---	2,500
79	Change in title of the firm / company or change in the ownership or management of the firm / company	---	15,000
80		Addition or deletion of Director	2,500 per case

81	Transfer of product enlistment from import to local manufacturing	---	5,000
82	Renewal	Manufacturing enlistment after two years	Half of the initial fee
83		Product enlistment after two years	Half of the initial fee
84	Free Sale Certificate	---	2,500
85	CoPP of alternative medicine and health product	---	2,500
86	Grant of approval of product testing from the referral laboratory (not for routine testing)	---	2,500
	CONTROLLED DRUGS		
87	Processing of application of quota allocation and issuance of import authorization (for routine and first time allocation)	---	20,000
88	Processing of enhancement of quota application by the firm	---	10,000
89	Processing of application for destruction of controlled substances received from hospitals, pharmaceutical units, etc.	---	5,000
90	Processing of application for export and issuance of export permit for medicine containing controlled substance and other miscellaneous functions	---	5,000
	PHARMACY SERVICES		
91	Grant of new license for Bio-equivalence / Bio-availability Studies Center	---	300,000
92	Grant of new license for Contract Research Organization	---	300,000
93	Grant of new license for Bio-analytical Laboratory for Clinical Research	---	300,000
94	Grant of new license for Clinical Trial Site	---	100,000
95	Grant for approval and registration of Clinical Trials	---	200,000
96	Grant of approval and registration of Bio-equivalence / Bio-availability Study	---	200,000
97	Grant of renewal of license for Bio-equivalence / Bio-availability Studies Center, Contract Research Organization, Bio-analytical Laboratory for Clinical Research	If applied before expiry of validity of license.	300,000
98		If applied within 60 days of expiry of validity of license	400,000
99	Grant of renewal of license for Clinical Trial Site	If applied before expiry of validity of license.	100,000
100		If applied within 60 days of expiry of validity of license	150,000

101	Approval of amendment in already approved Clinical Trial or Bio-equivalence/ Bio-availability Study	---	25,000
102	Miscellaneous request under the Bio-Study Rules, 2017	---	25,000
103	Advertisement of therapeutic goods	Per advertisement for print media.	15,000
104		Per advertisement for radio / audio.	22,500
105		Per advertisement for television / cinema.	37,500
COSTING AND PRICING			
106	Grant of additional pack (price fixation)	Any drug for local manufacture or import (human).	7,500
107	Price increase (hardship cases)		30,000
108	Price increase (linked with consumer price index)		2,000
QUALITY ASSURANCE AND LABORATORY TESTING			
109	License to import drugs other than finished drugs	---	7,500
110	Addition to the import license of any drug manufactured by the same manufacturer	For each subsequent application by the same importer	7,500
111	License to export drugs / NOC to export drugs	---	7,500
112	Addition to the export license of any drug manufactured by the same manufacturer	For each subsequent application by the same exporter	7,500
113	Certificate of Good Manufacturing Practices (GMP) for all therapeutic goods	For local manufacturing with validity for a period of one year	25,000
		For local manufacturing with validity for a period of two years	50,000
114		For export purposes with validity for a period of three years	75,000
115	Clearance of import requests for all therapeutic goods (active pharmaceutical ingredients, excipients, intermediates, finished products, etc.)	---	2,000 per consignment
CENTRAL DRUGS LABORATORY			
116	Description (General)	Per sample	400
117	Identification (General)	Per sample	400
118	Identification (TLC)	Per sample	1,200
119	Identification (FTIR)	Per sample	1,600
120	Assay (Spectrophotometric)	Per sample	2,000
121	Assay (HPLC)	Per sample	5,000
122	Assay Titration (Simple)	Per sample	1,000
123	Assay Titration (Potentiometeric)	Per sample	2,000
124	Bio Assay	Per sample	3,000

125	Weight variation / Mass variation	Per sample	600
126	Content Uniformity	Per sample	10,000
127	Dissolution Test (Spectrophotometric)	Per sample	5,000
128	Dissolution Test (Chromatographic)	Per sample	7,000
129	Disintegration Test (Uncoated / film coated / sugar coated Tablets and Capsules)	Per sample	800
130	Disintegration Test (Enteric coated Tablets and Capsules)	Per sample	1,200
131	Disintegration Test (Sustained release Tablets and Capsules)	Per sample	3,200
132	pH Test	Per sample	800
133	Melting Point	Per sample	800
134	Loss on drying	Per sample	1,000
135	Sulphated Ash	Per sample	800
136	Sterility Test (Direct)	Per sample	2,500
137	Sterility Test (Filter)	Per sample	3,000
138	Endotoxin Test (Gel clot method)	Per sample	3,000
139	Endotoxin Test (Chromogenic method)	Per sample	4,000
140	Gravimetric Assay	Per sample	2,000
141	Appearance of solution (syringes)	Per sample	400
142	Acidity or Alkalinity	Per sample	800
143	Absorbance (Syringes)	Per sample	1,000
144	Reducing Substances	Per sample	1,200
145	Fiber Identification Test	Per sample	500
146	Absorbency (Cotton)	Per sample	500
147	Color of Aqueous extract	Per sample	1,000
148	Fluorescence Test	Per sample	800
149	Water Soluble Substance	Per sample	2,000
150	Warp Thread and Weft Thread Test (Bandage)	Per sample	500
151	Weight Per Unit Area (Bandage)	Per sample	500
152	Elasticity Test (Crepe Bandage)	Per sample	1,000
153	Clarity Test (Parenterals)	Per sample	600
154	Optical Rotation	Per sample	2,000
155	Specific Gravity	Per sample	1,500
156	Refractive Index	Per sample	1,200
157	Limit Test (Trace Elements)	Per sample	2,500
158	Acid Value	Per sample	2,000
159	Iodine Value	Per sample	2,000
160	Sponification Value	Per sample	2,000
161	Acetyl Value	Per sample	2,000
162	Hydroxyl Value	Per sample	2,000
163	Viscosity Test	Per sample	1,500
164	Friability Test	Per sample	1,500
165	Alcohol Determination Test	Per sample	3,000
166	Others	Per sample	1,000

NATIONAL CONTROL LABORATORY FOR BIOLOGICALS			
167	Tetanus Toxoid (Locally Manufactured)	Per sample	30,000
168	Anti-Tetanus Sera (Locally Manufactured)	Per sample	30,000
169	Oral Polio Vaccine (Locally Manufactured)	Per sample	20,000
170	Measles Vaccine (Locally Manufactured)	Per sample	20,000
171	Rabies Vaccine (Locally Manufactured)	Per sample	30,000
172	Hepatitis-B Vaccine (Locally Manufactured)	Per sample	20,000
173	Snake Venom Anti-Sera (Locally Manufactured)	Per sample	30,000
174	Interferon (Locally Manufactured)	Per sample	20,000
175	All other imported vaccines, sera and interferon	Per sample	20,000
APPELLATE BOARD			
176	Filing of an appeal before the Appellate Board	Per appeal	50,000
MISCELLANEOUS			
177	Miscellaneous applications	Any other application having commercial significance	7,500

[No. F.11-1/2023-DD(LA)]

AAMAR LATIF,
Deputy Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
Islamabad.