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

Islamabad, the 30th August, 2024.

S.R.O. 1324(I)/2024.– 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 partial modification of Notification No. S.R.O. 496(I)/2023 dated the 17th April, 2023, 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)
	Costing and Pricing		
1.	Hardship	- - -	37,000
2.	Additional Pack	- - -	9000
3.	Consumer Price Index (CPI)	- - -	2500
	Controlled Drugs		
4.	Processing of application of quota allocation and issuance of import authorization (for routine and first time allocation) and NOC for combined Ground Check	- - -	25,000
5.	Processing of enhancement/ supplementary allocation of quota application by the firm	- - -	12,000
6.	Processing of application for destruction of controlled substances received from hospitals, pharmaceutical units, etc.	- - -	6000
7.	Processing of application for export and issuance of export permit for medicine containing controlled substance and other miscellaneous function	- - -	5,000
8.	Processing of application of quota allocation and issuance of import authorization exclusively for tender supply to Government hospital institutions	- - -	25,000
9.	Processing of application of quota allocation of narcotic products for hospital use to private institution in Islamabad	- - -	4,000

	Pharmacy Services		
10.	Grant of new license for Bio-equivalence / Bio-availability Studies center	- - -	370,000
11.	Grant of new license for Contract Research Organization	- - -	370,000
12.	Grant of new license for Bio-analytical Laboratory for Clinical Research	- - -	370,000
13.	Grant of new license for Clinical Trial Site	- - -	125,000
14.	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	370,000
15.		If applied within 60 days of expiry of validity of license	495,000
16.	Grant of renewal of license for Clinical Trial Site	If applied before expiry of validity of license	125,000
17.		If applied within 60 days for expiry of validity of license	185,000
18.	Grant for approval and registration of Clinical Trials	- - -	245,000
19.	Grant of approval and registration of Bio-equivalence / Bio-availability Study	- - -	245,000
20.	Approval of amendment in already approved Clinical Trial or Bio-equivalence / Bio-availability Study	- - -	50% fee of relevant registration/approval
21.	Miscellaneous request related to clinical trials	- - -	31,000
22.	Approval of amendment in already approved License for Bio-equivalence / Bio-availability Studies Center, Contract Research Organization, Bio-analytical Laboratory for Clinical Research and Clinical Trial Site	- - -	50% fee of relevant license
23.	Per advertisement for print media	- - -	19,000
24.	Per advertisement for radio / audio	- - -	28,000
25.	Per advertisement for television / cinema	- - -	46,000
26.	Per advertisement for Display *(banner, flyers, billboards, product placement / dispensers etc.)*	- - -	46,000
	Health and OTC Products		
27.	Processing fee for application of Site Verification for establishment of locally manufacturing facility	- - -	10,000
28.	Application for approval of layout plan / revised layout	- - -	3000 per section
29.	Application for enlistment as local manufacturer	- - -	19,000
30.	Approval of change in qualified staff	- - -	3000
31.	Approval/Enlistment of additional section	- - -	3000
32.	Application for enlistment as importer	- - -	19,000

33.	Enlistment of imported product / new medicine	Alternative medicine (Herbal Unani)	3000
34.		Health product	6000
35.	Enlistment of locally manufactured homeopathic medicine	Mother tincture	3000
36.		Dilutions and potencies	3000
37.		Combination product and dosage form	6000
38.	Enlistment of locally manufactured herbal / *Unani* product	- - -	3000
39.	Enlistment of locally manufactured health product	- - -	6000
40.	Firm / company enlistment for contract manufacturing or change in contract giver (manufacturer to manufacturer only)	- - -	19,000
41.	Product fee for contract manufacturing	For each category	6000
42.		If contract manufacturing exceeds 10 products	12,000
43.	Variations allowed such as change of brand name and management	- - -	19,000
44.	Miscellaneous variation activities like additional pack, change in specifications, packing material, change in excipient and other activities	- - -	3000
45.	Change in title of the firm / company or change in the ownership or management of the firm / company	- - -	19,000
46.	Addition or deletion of Director	- - -	3000
47.	Change of product enlistment from import to local manufacturing	- - -	6000
48.	Renewal	Manufacturing enlistment	Half of the initial fee
49.		Product enlistment	Half of the initial fee
Management Information Services			
50.	Processing fee for adjustment of online submitted challans	- - -	15,000
Quality Assurance and Laboratory Testing			
51.	Clearance of import requests for therapeutic goods	- - -	Rs.2500 per consignment
52.	Issuance of GMP certificate for all therapeutic goods requiring panel inspection	- - -	25,000 per annum
53.	Issuance of a subsequent GMP certificate for any other country on the basis of already conducted inspection for GMP certificate	- - -	12,500
54.	Issuance of Free Sale Certificate for all therapeutic goods	- - -	7,500
55.	Issuance of CoPP of all therapeutic goods	- - -	7,500

Pharmaceutical Evaluations and Registration			
56.	Grant of registration	Any drug product for import including pellets, granules, bulk concentrate / ready to fill bulk	300,000
57.		Drugs for local manufacture	37,000
58.	Renewal of drugs registration (if the application for renewal is made before the expiry of the period of validity or registration)	Any drug for import	Half fee of registration
59.		Drug for local manufacture	Half fee of registration
60.	Renewal of drugs registration (if the application for renewal is made after the expiry of the period of validity but within 60 days after the expiry of the period of validity)	Any drug for import	Full fee of registration
61.		Drug for local manufacture	Full fee of registration
62.	Renewal of drugs registration (if the application for renewal is made after the expiry of the period of validity but within one year after the expiry of the period of validity under S.R.O. 1005(I)/2017)	Any drug for import	Applicable renewal fee as per S.R.O. 1005(I)/2017
63.		Drug for local manufacture	
64.	Grant/extension of contract manufacturing permission	For local manufacture	93,000 per product
65.		For export purpose only	30,000
66.	Pre-registration variation (Before issuance of registration certificate)	Variance to registration application except those specified in the below entry.	9,000 (in case of more than one variation, single fee will be charged)
67.		Change of source of drug substance	Half fee of registration (in case of more than one variation, single fee will be charged)
68.		Change of manufacturer	
69.		Change of MAH in case of import	
70.		Submission of afresh stability data of drug product	
71.	Post-registration variation (After issuance of registration certificate)	Any variation in registered drug except those specified in the following entry	12,000
72.		Change of brand name expect cases of resemblance	37,000
73.		Change of title/name of manufacturer/marketing authorization holder	37,000
74.		Change of source of pellets/substance	65,000
75.		Approval of additional source of pellets/ bulk drugs product/ substance	37,000
76.		Change of registration status from one manufacturer / marketing	65,000

		authorization holder to another manufacturer / marketing authorization holder	
Drug Licensing			
77.	Grant of drug manufacturing License	By way of basic manufacturing	56,000
78.		By way of semi-basic manufacturing	56,000
79.		By way of formulation	185,000
80.		By way of repacking	110,000
81.	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	28,000
82.		By way of semi-basic manufacturing	28,000
83.		By way of formulation	93,000
84.		By way of repacking	56,000
85.	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)	By way of basic manufacturing	9000 per day surcharge, in addition to renewal fee
86.		By way of semi-basic manufacturing	
87.		By way of formulation	
88.		By way of repacking	
89.	Site verification and layout	Site inspection and verification	9000 per section
90.		Approval of layout plan / Revision or extension of layout plan	9000 per section
91.	Repacking of Drugs	- - -	9000 per product
92.	Approval of technical person	- - -	9000
93.	Attestation of DML	- - -	9000
94.	Issuance of NOC for equipment	- - -	9000
95.	Issuance of Inspection Book	- - -	9000
96.	Grant of DML by way of Experimental Purpose	- - -	9000
97.	Change of management/title of DML	By way of basic manufacturing.	28,000
98.		By way of semi-basic manufacturing	28,000
99.		By way of formulation.	93,000
100.		By way of repacking	56,000
101.	API enlistment	- - -	9000
102.	Miscellaneous application	Any other application having commercial significance	9000
Medical Devices and Medicated Cosmetics			
103.	Enlistment / registration of medical devices and renewal of enlistment / registration thereof	Enlistment of Class A medical device for local manufacture or import and renewal thereof	6000

104.		Registration of Class B, C & D medical device for local manufacture	25,000
105.		Renewal of registration of Class B, C & D medical device for local manufacture	12,000
106.		Registration of Class B medical device or accessory or component for import	31,000
107.		Renewal of registration of Class B medical for import	15,000
108.		Registration of Class C & D medical device or accessory or component for import	62,000
109.		Renewal of registration of Class C & D medical for import	31,000
110.		Enlistment or registration of accessory or component for local manufacture and renewal thereof	6000
111.		Post enlistment or registration variation	6000
112.		Any change in particulars of enlisted or registered medical device	Fifty percent of the registration / enlistment fee
113.	Establishment Licenses	Establishment license to manufacture medical devices	123,000
114.		Establishment license to import medical devices	25,000
115.		Renewal of establishment license to manufacture medical devices	62,000
116.		Renewal of establishment license to import medical devices	12,000
117.		Any change in particulars of licensed establishment	Fifty percent of the establishment license fee
118.	Import Permits	Import permit or its renewal for medical devices.	6000
119.	Miscellaneous	Any other application having commercial significance	9000
120.	Outsourcing	Certificate to outsource manufacturing processes of medical devices for each	62,000

		contract acceptor	
121.		Certificate to outsource analysis of medical devices for each contract acceptor.	62,000
122.		Renewal of certificate to outsource manufacturing processes of medical devices for each contract acceptor	31,000
123.		Renewal of certificate to outsource analysis of medical devices for each contract acceptor	31,000
124.		Any change in particulars of certificate of outsourcing	Fifty percent of the initial fee of certificate
125.	Enlistment / registration of medical devices applying as an in-vitro cluster	Class A medical device for local manufacture or import	25,000 (for 20 articles / reagents) & 5000 for each extra reagent / article incluster application
126.		Class B medical device for local manufacture or import	50,000 (for 20 articles / reagents) & 5000 foreach extra reagent / article in cluster application
127.	Renewal of enlistment / registration of medical devices as in-vitro cluster	Class A & B medical device for local manufacture or import as an in-vitro cluster	Fifty percent of the registration / enlistment fee
128.	Enlistment / registration of medical devices as system / family having more than one medical device	Class A medicaldevice for local manufacture or import	25,000 (for up to 20 medical devices / accessory / article) & 2500 for each extra medical device / accessory / article
129.		Class B medicaldevice for local manufacture or import	50,000 (for up to 20 medical devices / accessory / article) & 5000 for each extra medical device / accessory / article
130.		Class C & D medicaldevice for local manufacture or import	100,000 (for up to 20 medical devices / accessory / article) & 5000 for eachextra medical device
131.	Renewal of enlistment / registration of medical devices as system / family having more than one medical device	Class A, B, C & D medical device for local manufacture or import as system / family having more than one medical device	Fifty percent of the registration / enlistment fee

Appellate Board			
132.	Application for appeal	- - -	62,000

2. The fee deposited for any regulatory service shall in no case be refunded.

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AAMAR LATIF,
Additional Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
Islamabad.